COVID-19 Vaccine Introduction

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Disclosures

There is no commercial support for today’s webinar

Neither the speakers nor planners for today’s webinar have disclosed any financial interests related to the content of the meeting

This webinar is meant for healthcare facilities and is off the record and reporters should log off now.
Disclaimer

• This is a rapidly evolving situation so the information being presented is current as of today (12/07/20) so we highly recommend that if you have questions after today you utilize the resources that we will review at the end of this presentation.
Objectives

1. Understand the biology and development of COVID-19 vaccines

2. Understand the importance of COVID-19 vaccination, particularly for healthcare workers

3. Discuss updates on COVID-19 vaccine roll-out for LA County
1. COVID-19 Vaccine: Development, mechanism, safety
COVID-19 vaccine results

• A scientific, collaborative triumph with better and faster results than expected: **94% efficacious**

• Endpoint was symptomatic disease. Also prevented severe disease

• Reassuringly similar results from two largely similar vaccines

• Extensively studied with 43,000+ (Pfizer) and 30,000+ (Moderna) phase 3 participants

• 42% and 37% respectively from diverse racial and ethnic groups
COVID-19 vaccine development

• Jump started thanks to lessons from vaccine development since 2003 with SARS-CoV then MERS coronaviruses

• No skipped steps: phases 1, 2, 3 completed

• Timeline shortened by overlapping certain phases including manufacturing

• 2 months of full safety data will be assessed prior to EUA

Demming et al. NEJM, 2020
Mechanism of action

- mRNA codes for the viral spike (S) protein which is used to enter human cells through the ACE2 receptor

- Encapsulated in lipid nano-particles that stabilize and allow cell entry

- Translated by ribosomes with the spike protein then anchored on the cell wall

- Recognized by antigen presenting cells leading to the development of humoral (antibody) and cellular immunity

- Similar process to natural infection
## Comparison of the two leading vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Preparation</th>
<th>Route</th>
<th>Dosing</th>
<th>Storage</th>
<th>Ages*</th>
<th>Exclusions**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer/BioNTech</td>
<td>30µg in 0.3mL 5 dose vial</td>
<td>IM</td>
<td>2 doses 21d apart</td>
<td>-80°C</td>
<td>6m</td>
<td>12-85 Immunocompromised Pregnancy Prior SARS-COV-2+</td>
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<tr>
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<td>4°C</td>
<td>5d</td>
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<td></td>
<td>Room</td>
<td>6h</td>
<td></td>
</tr>
<tr>
<td>Moderna</td>
<td>100µg in 0.5mL 10 dose vial</td>
<td>IM</td>
<td>2 doses 28d apart</td>
<td>-20°C</td>
<td>6m</td>
<td>&gt;18 Immunocompromised Pregnancy Prior SARS-COV-2+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>4°C</td>
<td>28d</td>
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<td></td>
<td>Room</td>
<td>12h</td>
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</tbody>
</table>

*Ages in phase 3 trials

**Excluded in phase 3 trials

Final indications based on EUA
Safety data: Pfizer

- In >43,000 phase 3 participants:
  - No serious adverse events reported
  - No evidence of antibody-dependent enhancement

Phase 2 detailed data
- Local events:
  - Mostly mild, pain at site of injection was common
- Systemic events:
  - Mostly mild, fatigue was common

- Summary:
  - Mild reactions, more after the 2\textsuperscript{nd} dose

Walsh et al. NEJM, 2020
Safety data: Moderna

- In >30,000 phase 3 participants:
  - No serious adverse events reported
  - No evidence of antibody-dependent enhancement

Phase 2 detailed data

- Local events:
  - Mostly mild, pain at site of injection was common

- Systemic events:
  - Mostly mild, fatigue and headache were common with chills, fever, and myalgia presenting after the 2\textsuperscript{nd} dose

- Summary:
  - Mild to moderate reactions, more after the 2\textsuperscript{nd} dose

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Dose Group</th>
<th>Vaccination 1</th>
<th>Vaccination 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any systemic symptom</td>
<td>25 µg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 µg</td>
<td></td>
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<tr>
<td></td>
<td>250 µg</td>
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<td>Arthralgia</td>
<td>25 µg</td>
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<td></td>
<td>100 µg</td>
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<td>250 µg</td>
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<tr>
<td>Fatigue</td>
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<td>25 µg</td>
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<td>250 µg</td>
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<td>Fever</td>
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<td></td>
<td>250 µg</td>
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<tr>
<td>Chills</td>
<td>25 µg</td>
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<td></td>
<td>100 µg</td>
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<td></td>
<td>250 µg</td>
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<tr>
<td>Headache</td>
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<td></td>
<td>25 µg</td>
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<td>250 µg</td>
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<td>Myalgia</td>
<td>25 µg</td>
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<td></td>
<td>100 µg</td>
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<td></td>
<td>250 µg</td>
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<td>Nausea</td>
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<td>100 µg</td>
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<td></td>
<td>250 µg</td>
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<tr>
<td>Any local symptom</td>
<td>25 µg</td>
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<td></td>
<td>100 µg</td>
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<td></td>
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<tr>
<td></td>
<td>250 µg</td>
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<td></td>
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<tr>
<td>Size of erythema or redness</td>
<td>25 µg</td>
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<td></td>
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<tr>
<td></td>
<td>100 µg</td>
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<td></td>
<td>250 µg</td>
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<tr>
<td>Size of induration or swelling</td>
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<td>Pain</td>
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<td></td>
<td>250 µg</td>
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</tbody>
</table>
Immune response data

Phase 2 immune correlates studied:

- Antibody titers
- Virus neutralization
- T-cell responses (Moderna)
- Compared against convalescent serum (natural infection)

Summary:

- Robust responses in all three measures
- Notably, higher than achieved by natural infection in plasma donors

- Corresponds with phase 3 clinical correlation, but unclear implications for duration of protection, and benefit to those with prior infection
Recommendation development

- Led by the Advisory Committee on Immunization Practices. ACIP consists of independent medical experts who develop recommendations through regular public meetings.

- After FDA EUA approval, ACIP will quickly hold a public meeting to review all available data and review all available clinical trial information, including descriptions of
  - Who is receiving each candidate vaccine (age, race, ethnicity, underlying medical conditions)
  - How different groups respond to the vaccine
  - Side effects experienced

- From these data, ACIP will then vote on whether to recommend the vaccine and, if so, who should receive it.
2. COVID-19 Vaccine: Importance of COVID-19 vaccination
Individual benefits to vaccination

• Protect yourself COVID-19 disease

• Decrease the risk of severe disease in case of infection

• Prevent spread to loved ones
Social benefits to vaccination

- Protect others in your community, masking and physical distancing are important but not perfect
- Help maintain essential services and allow economic activity restrictions lifting
- End the pandemic

Source: CDC
Healthcare workers and vaccination

• Priority group number 1 for the limited supplies of the new vaccine because:
  – At higher-risk due to frequent, close exposure
  – Essential workers whose protection is necessary to maintain the functioning of our health system and society

• Healthcare workers are the most trusted source of information on COVID-19 and vaccination for the public.

• Heroes in the eyes of the public for their dedication, and commitment during the pandemic.

• Professional obligation to get vaccinated and continue to lead by example
Improving healthcare worker vaccination

- Use best practices from your experience with flu

- Offer onsite vaccination

- Encourage documentation of refusal to receive including medical and other exemptions

- Mask use required as present for those who decline. Vaccinees also need to mask until data on infection transmission available

- Goals should be the same or higher rate as your previous highest influenza vaccine coverage
3. COVID-19 Vaccine: LA County roll-out
Sources of COVID-19 vaccine supply

• Pre-positioned vaccine:
  – Shipped before EUA so it's ready to go once FDA and ACIP approvals made

• Pharmacy partnership for Long-Term Care facilities

• Direct orders
  – Health facilities enrolled in VTrckS through CDPH

• Retail pharmacy program
  – 19 chains and independent as of now
  – 38,000 retail pharmacies covering 60% of the US population
Phased approach to vaccine availability

### Work Group Proposed Interim Phase 1 Sequence

<table>
<thead>
<tr>
<th>Time</th>
<th>Phase 1a</th>
<th>Phase 1b</th>
<th>Phase 1c</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HCP, LTCF residents</td>
<td>Essential workers (examples: Education Sector, Food &amp; Agriculture, Utilities, Police, Firefighters, Corrections Officers, Transportation)</td>
<td>Adults with high-risk medical conditions, Adults 65+</td>
</tr>
</tbody>
</table>
Consensus values guiding the phases

• Goals for vaccination while supply is limited
  – Decrease death and serious disease as much as possible
  – Preserve functioning of society
  – Reduce the extra burden the disease is having on people already facing disparities
  – Increase the chance for everyone to enjoy health and well-being

• Ethical principles while supply is limited
  – Maximize benefits and minimize harms — Respect and care for people using the best available data to promote public health and minimize death and severe illness
  – Mitigate health inequities — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible
  – Promote justice — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination
  – Promote transparency — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes

LA County specifics

• Need for further triaging of the 1A and 1B groups until large vaccine supplies available

• Planning in process for specifics within facility and between facility

• Informed by data including social vulnerability, healthcare worker surveillance, and will be finalized after inputs from diverse sources

• More to follow
Vaccine information systems and documentation

- Multiple information needs currently across multiple different systems:
  - Scheduling
  - Ordering
  - Inventory
  - Reporting

- Local and federal reporting requirements
  - Record all individual level vaccine administration in EMR within 24 hours
  - Report all EMR data within 72 hours

- Goal is for an integrated end-to-end system without the need for duplication. May be fragmented initially with progressive improvement.
Adverse event monitoring and reporting

- New voluntary, self-reporting system V-SAFE
  - Linked to VAERS

- VAERS online reporting as usual

- Reporting responsibility is with the facility where the AE presents, not facility where vaccinated

- AE reporting list finalization pending
  - Mandatory (expected): SARS-CoV-2 infection, hospitalization, death, Guillan-Barre syndrome, etc
  - Recommended: all serious events, i.e. result in a staying home from work or seeking healthcare
  - Suggested: all others
Infection prevention and control reminder

- Vaccination for COVID-19 will be critical

- At the same time, for both COVID-19 control, and for other infectious diseases continue public health fundamentals:
  - PPE
  - Staff screening
  - Hand hygiene
  - Precautions
  - Environmental cleaning
  - AMR
  - Routine vaccinations
Take home points

- Well developed, safe, efficacious vaccines
- Health facility and healthcare worker responsibility
- Patience and understanding with gradual phased roll out

More info:
CDPH COVID-19 Vaccine Plan