

# COVID-19 Vaccine Basics: The Why, What, Where & When

March 1<sup>st</sup>, 2021

**UCI** School of Pharmacy &  
Pharmaceutical Sciences

# Panelists



*Jan Hirsch – Moderator  
Founding Dean*



*Rob Spitale – Panelist  
Founding Associate Dean of Research*



*Alex Chan – Panelist  
Founding Chair*



*Keri Hurley Kim – Panelist  
Health Sciences Assistant Clinical Professor*

# What will be covered?

- Why are Vaccines Important
- Basics about how vaccines work
- Safety & Efficacy of vaccinations
- Distribution of vaccinations

As of 2/26/2021

## Orange County's tier rating

Positive cases per 100K	11.9
Testing positivity rate:	5.4%
State threshold:	>7%

	Rate /100K	Test positivity
 Widespread	>7	>8%
 Substantial	4-7	5-8%
 Moderate	1-3.9	2-4.9%
 Minimal	<1	<2%

California assigns each county to a tier, based on the prevalence of the coronavirus in the community, that determines how tightly businesses will be restricted. Details at: [covid19.ca.gov/safer-economy](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Community-Tiering.aspx)

Source: Orange County Health Care Agency

Rates are 7 day average with 7 day lag

Source: <https://www.ocregister.com/2021/02/26/coronavirus-orange-county-reported-349-new-cases-and-3-new-deaths-as-of-feb-26/>







As of 2/26/2021

# Orange County's tier rating

Positive cases per 100K	11.9
Testing positivity rate:	5.4%
State threshold:	>7%

2 ½ weeks earlier: 2/7/2021

39.0  
10.9%

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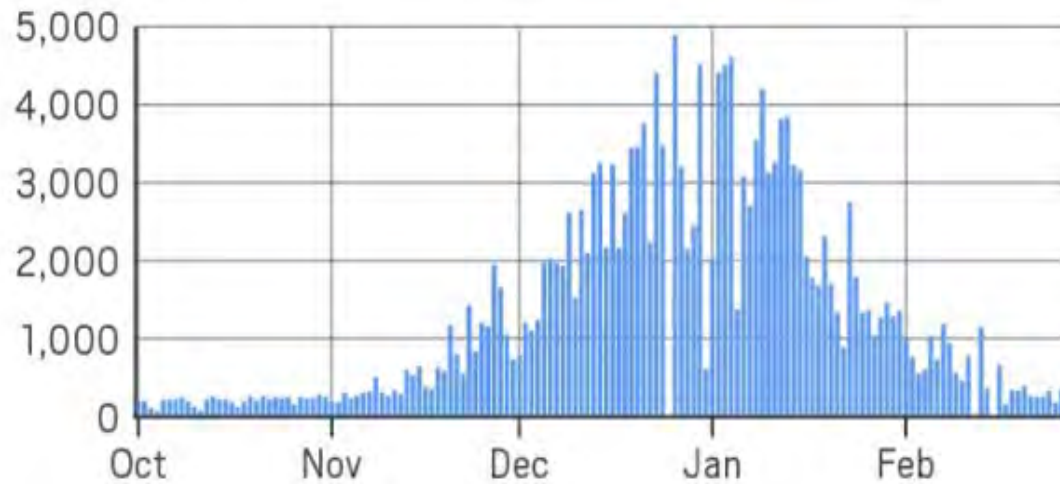
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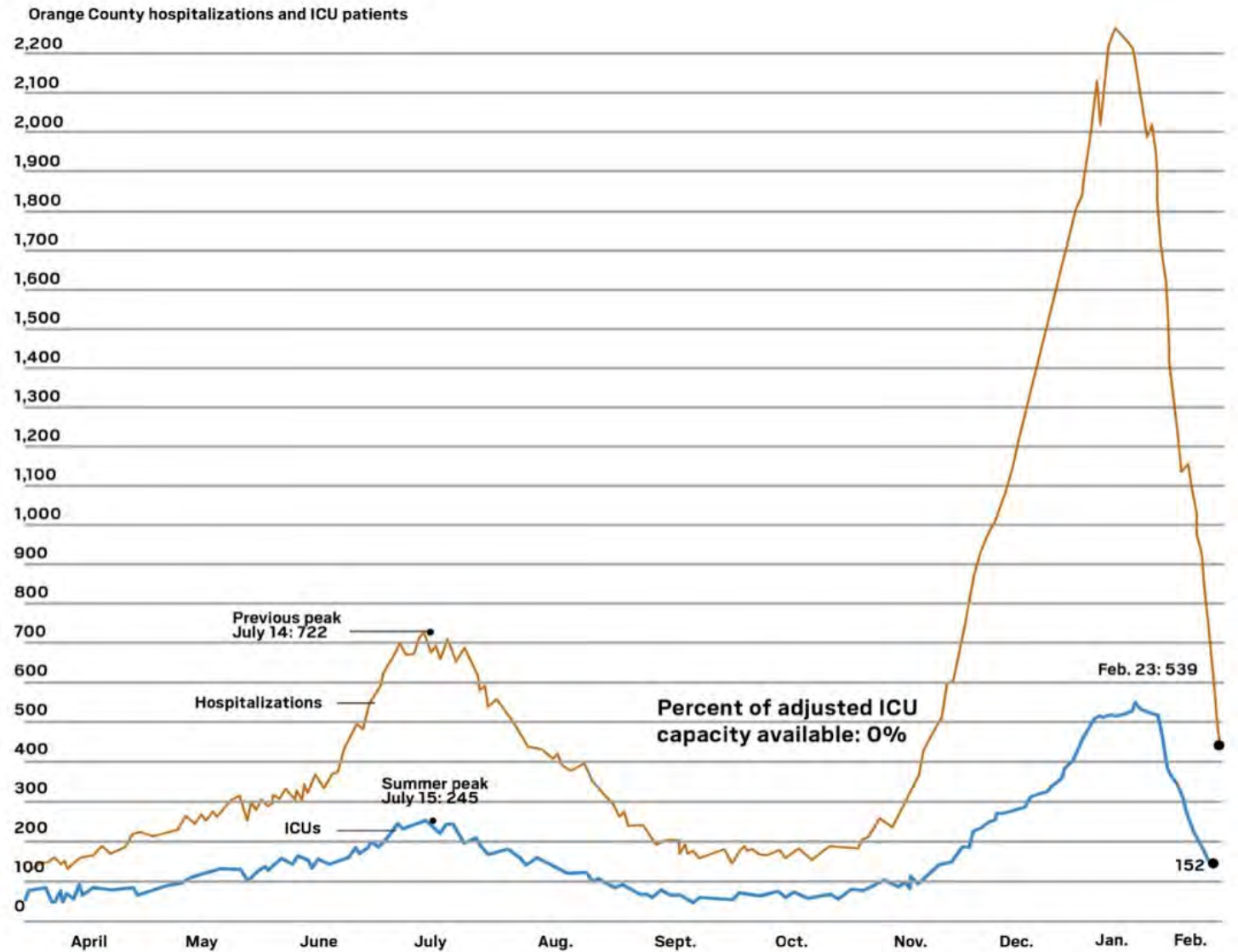
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As of 2/26/2021

### Daily cases

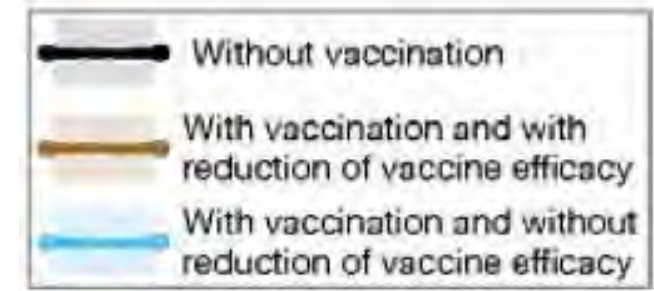
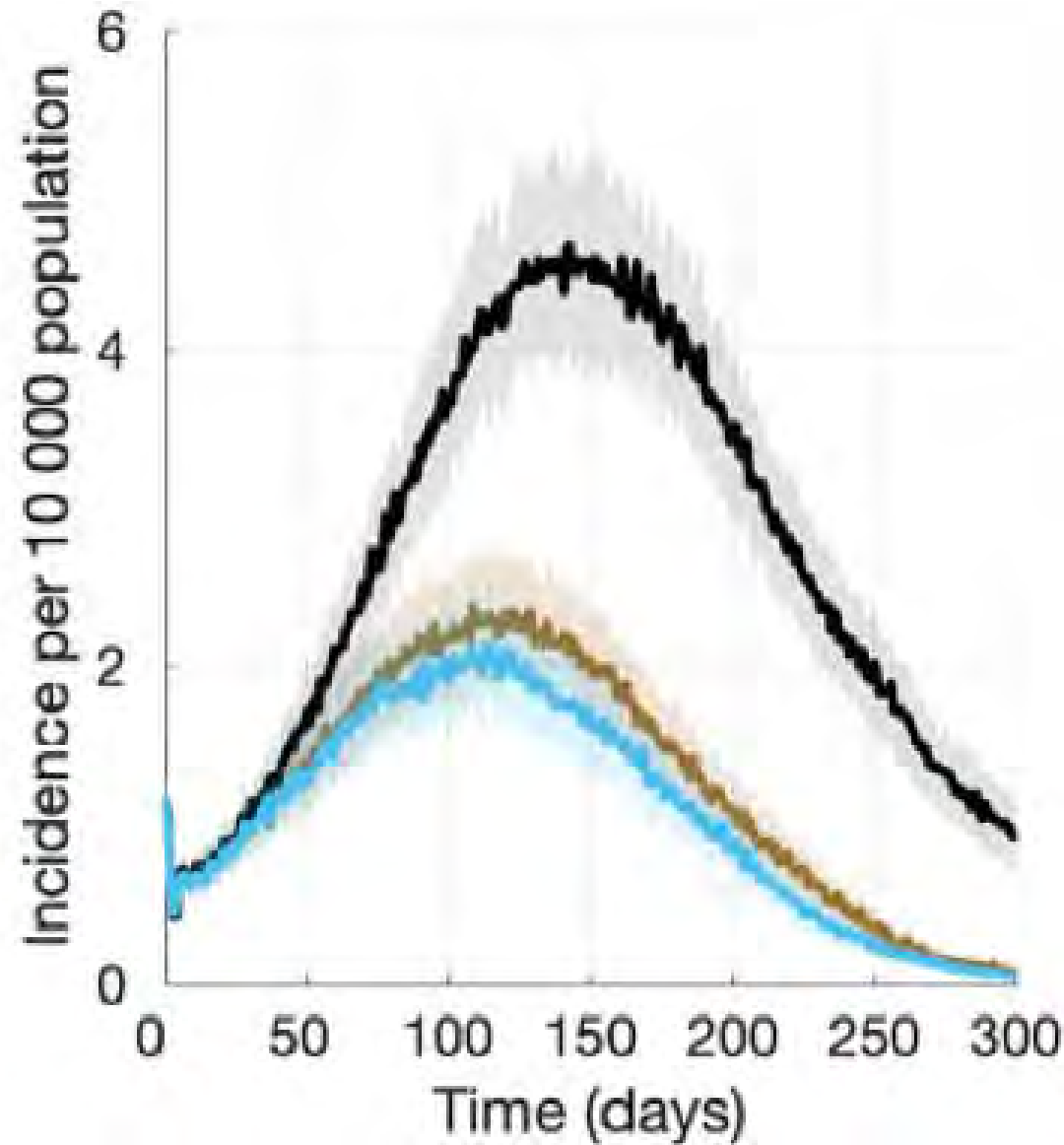


### Orange County hospitalizations and ICU patients



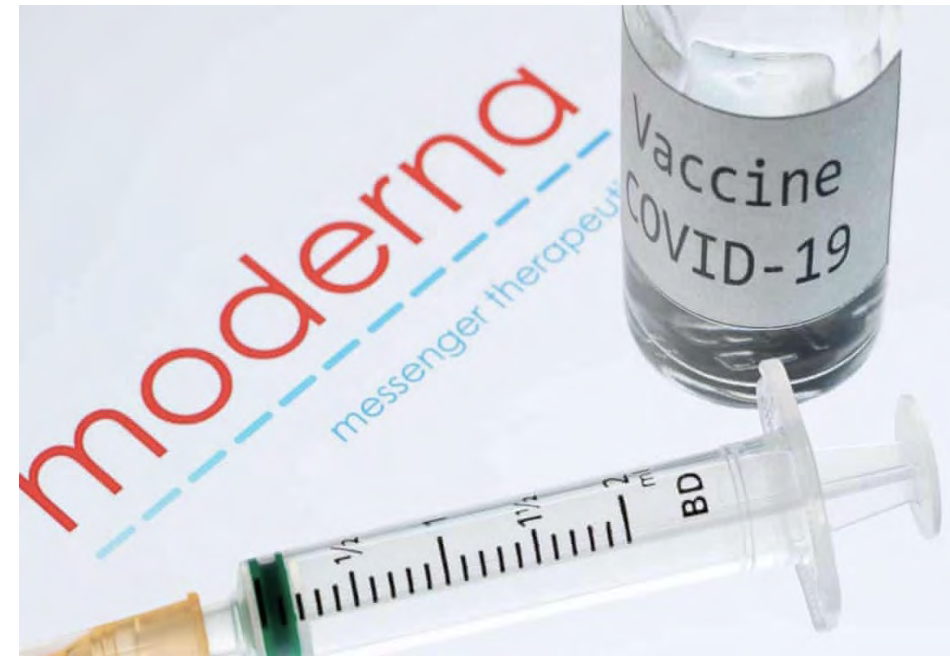
Source: <https://www.ocregister.com/2021/02/26/coronavirus-orange-county-reported-349-new-cases-and-3-new-deaths-as-of-feb-26/>

# Projected daily incidence of COVID-19 per 10,000 population



- Assuming 95% vaccine efficacy
- Reference point OC 2/7/21 = 3.9/10K





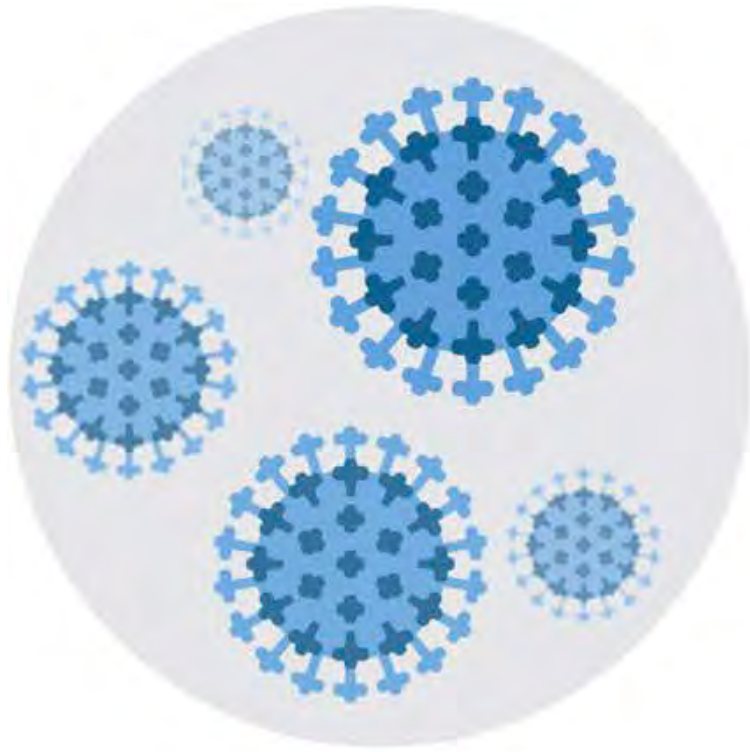


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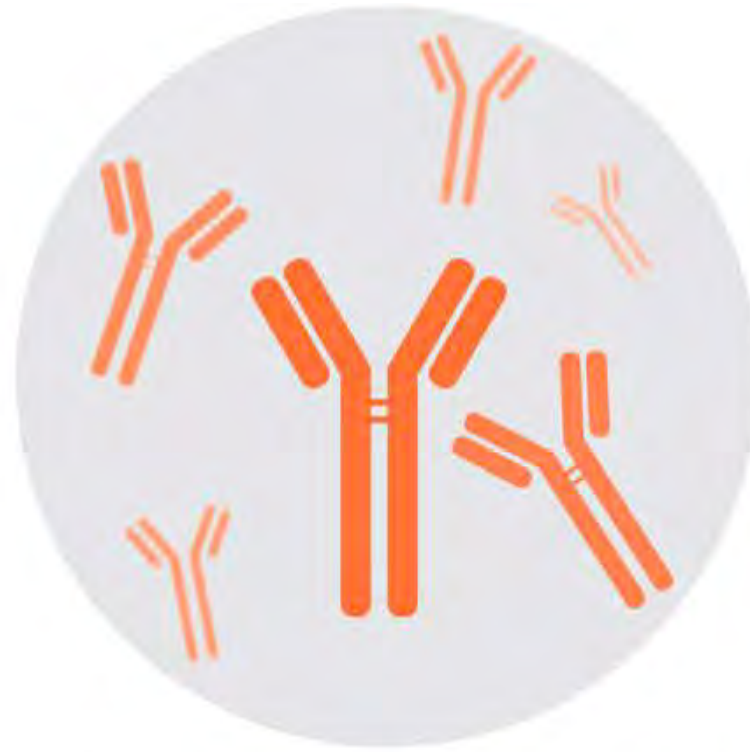
# COVID-19 Vaccines: Vaccine Basics

*Robert Spitale, Ph.D.  
Founding Associate Dean of Research and Professor  
Department of Pharmaceutical Sciences  
School of Pharmacy & Pharmaceutical Sciences*

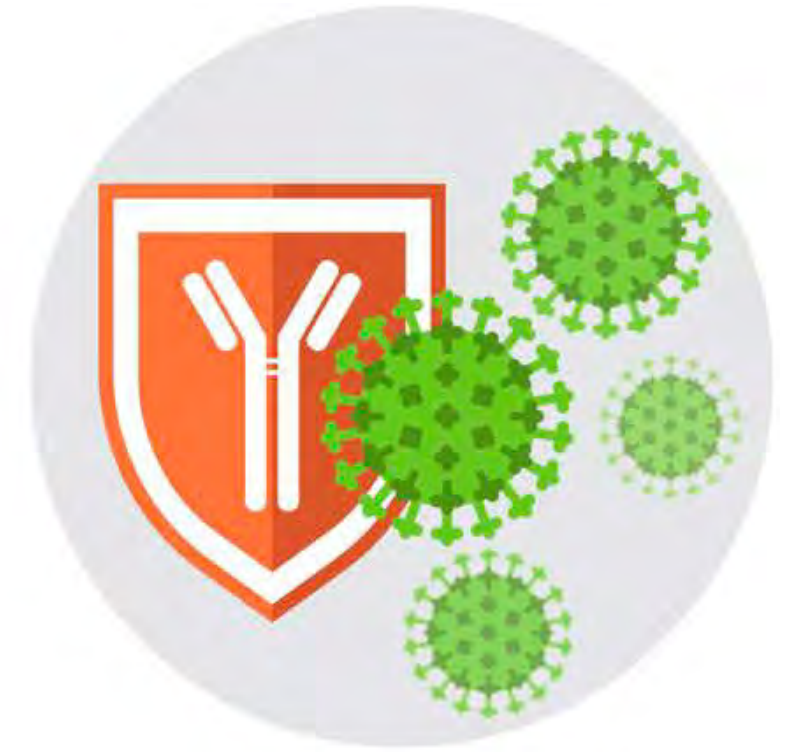
# How do vaccines work?



Vaccines introduce a weak or inactive form of the disease to the body.



The body reacts by stimulating the immune system and creating antibodies.



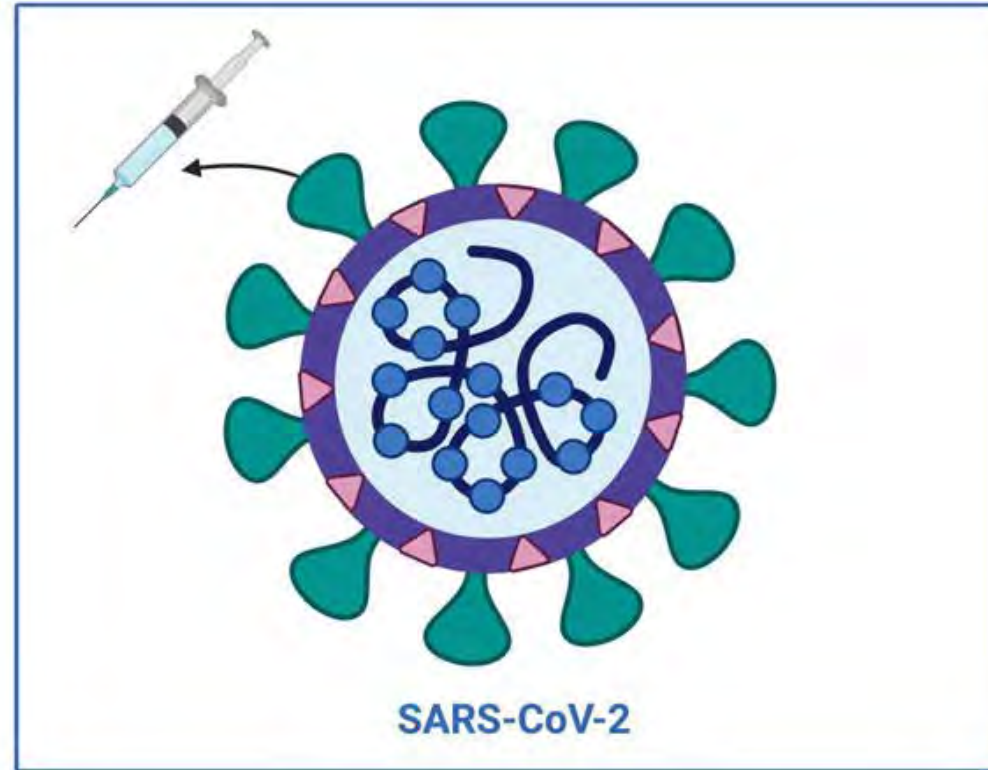
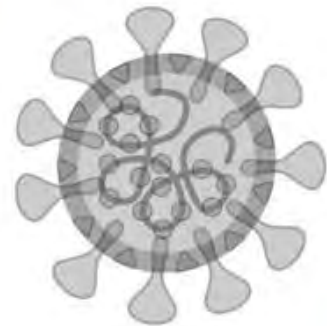
The antibodies remember the disease and can defend against it if a person becomes exposed to it.

# Types of vaccines under development for SARS-CoV2

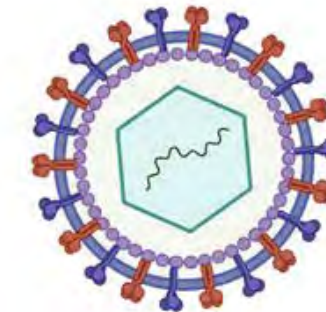
a. Live attenuated



b. Whole inactivated



f. Recombinant viral vectors



c. RNA



d. DNA



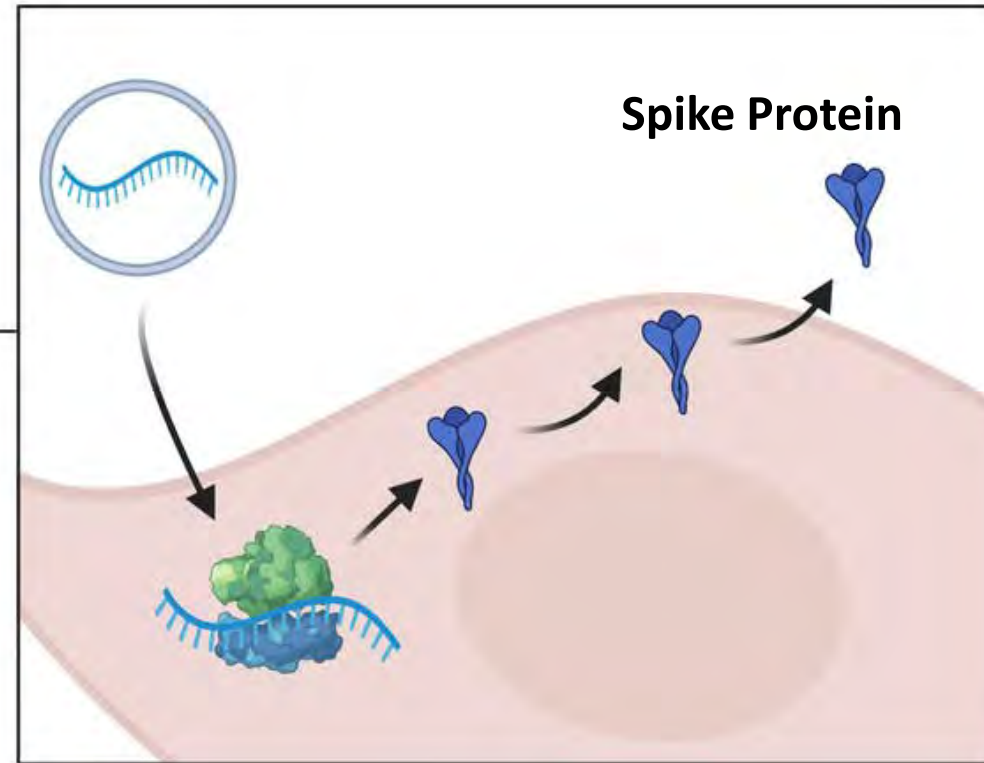
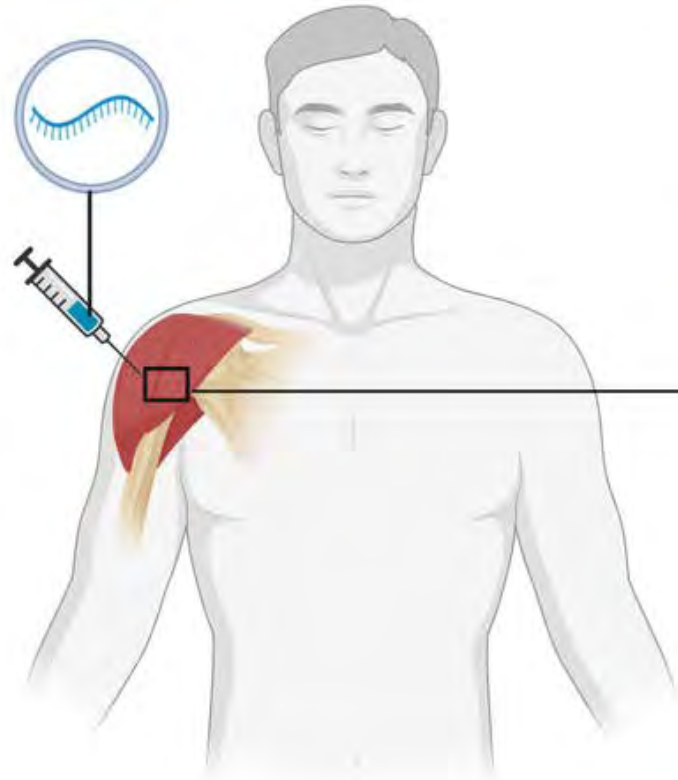
e. Recombinant subunits





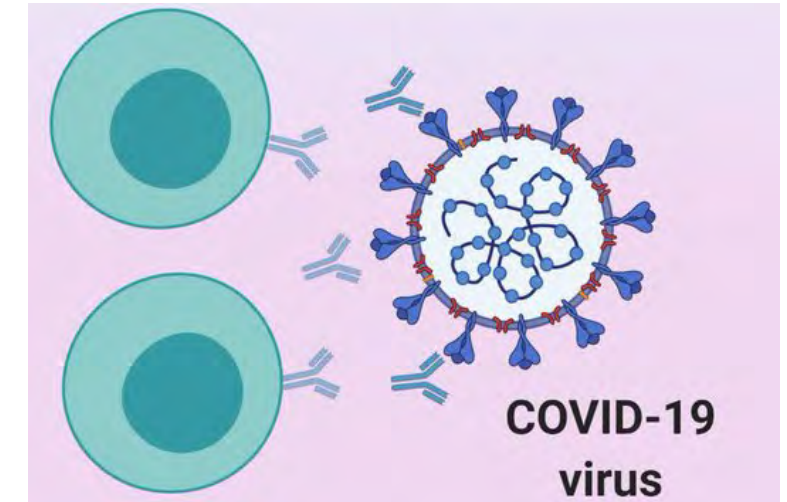
# How does the mRNA vaccine work?

mRNA  
in Capsule



mRNA  
Translation

FUTURE INFECTIONS



Your body will now recognize the spike protein if you are infected. Your immune system will fight off virus now.



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# Current COVID Vaccines: Efficacy and Safety

*Alexandre Chan, Pharm.D., MPH, FCCP, FISOPP, BCPS, BCOP, APh  
Founding Chair and Professor of Clinical Pharmacy  
Department of Clinical Pharmacy Practice  
School of Pharmacy & Pharmaceutical Sciences*

# Who participated in the COVID-19 vaccine trials?

	<u>Pfizer-BioNTech</u>	<u>Moderna</u>	<u>Janssen</u>
<b>Targeted Participants</b>	16+ years old	18+ years old	18+ years old
<b># of Participants</b>	43,448	30,351	39,321
<b>U.S. Participation (%)</b>	76.7%	100%	46.7%
<b>Racial/Ethnic Distribution</b>			
Hispanic or Latinx (%)	28%	20%	45.1%
Black or African American (%)	9%	10%	17.2%
Asian (%)	4%	4%	3.5%
All others (%)	1%	3%	11.8%
<b>Age 65+ (years)</b>	21.4%	25%	20.4%



Polack FP, et al. *N Engl J Med* 2020; 383:2603-2615; Barden LR, et al. *N Engl J Med* 2020; 384:403-416; FDA Briefing Document: Janssen Ad26.COV2.S Vaccine. Last Accessed: 25 February 2021

# How effective are the vaccines?

Pfizer-BioNTech Vaccine (n=43,448)

Efficacy against symptomatic infection: **95%**

Subgroup Analysis - Age 16-55: **95.6%**; Age >56: **93.7%**

Moderna Vaccine (n=30,420)

Efficacy against symptomatic infection: **94%**

Subgroup Analysis - Age 18-<65: **95.6%**; Age >65: **86.4%**

Janssen Vaccine (n=39,058)

Efficacy against symptomatic infection : **66.9%**

Efficacy against symptomatic infection within the US : **74.4%**

Efficacy against severe disease: **85%** @ 28 days after vaccination

Subgroup Analysis – Age 18-59: **63.7%**; Age >60: **76.3%**

# Vaccine ingredients

Pfizer-BioNTech & Moderna	Janssen
mRNA	Adenovirus 26
Polyethylene glycol (PEG2000)	Polysorbate 80 (Tween 80)
Salts	Salts
Sucrose	Ethanol
Buffers	Buffers
Diluent	Diluent



*None of the vaccines contain eggs, gelatin, latex, preservatives, or adjuvants*



# Safety profiles of COVID-19 vaccines

	<u>Pfizer-BioNTech</u>	<u>Moderna</u>	<u>Janssen</u>
Injection-site reactions	84%	92%	49%
Fatigue (all grades)	63%	60%	38%
Headache (all grades)	55%	63%	39%
Muscle ache	38%	60%	33%
Fever	14%	15%	9%

- Very likely to cause side effects after vaccination
- After vaccination, you can use over-the-counter medications such as acetaminophen (e.g., Tylenol) and ibuprofen (e.g., Motrin, Advil) to manage symptoms



Polack FP, et al. *N Engl J Med* 2020; 383:2603-2615; Barden LR, et al. *N Engl J Med* 2020; 384:403-416; FDA Briefing Document: Janssen Ad26.COVID.S Vaccine. Last Accessed: 25 February 2021

# Severe reactions associated with COVID-19 mRNA vaccines

(through VAERS, December 14, 2020 to January 18, 2021)

	<u>Pfizer-BioNTech</u>	<u>Moderna</u>
<b>Doses given</b>	9,943,247 doses	7,581,429 doses
<b>Anaphylaxis reporting rate</b>	4.7 per million doses	2.5 per million doses
<b>Onset</b>		
@ First dose (n)	37	17
@ Second dose (n)	4	1
Unknown	6	1
<b>Age (years)</b>	39 (27-63)	41 (24-63)
<b>Female (%)</b>	94%	100%
<b>Symptom onset</b>		
≤15 min	76%	84%
≤ 30 min	89%	89%
<b>Reported history</b>		
Allergies or allergic reactions	77%	84%
Prior anaphylaxis	34%	26%



Shimabukuro TT, et al. *JAMA* 2021 doi: 10.1001/jama.2021.1967.

# Monitoring Post Approval

## Filed for Emergency Use

## Current Status

## Full Approval

- National- and state-level reviews, focus on efficacy and safety

- All three COVID-19 vaccines (Pfizer-BioNTech, Moderna and Janssen) have received EUA

- Six months of post-vaccine safety data must be provided

**VAERS** Vaccine Adverse Event Reporting System  
[www.vaers.hhs.gov](http://www.vaers.hhs.gov)



# Lingering Concerns

- Vaccine variants and efficacy
- Conception and breastfeeding
- Immunocompromised hosts (cancer and autoimmune disorders)





# COVID-19 Vaccine Logistics: Administration, Distribution & Allocation

Keri Hurley-Kim, PharmD, MPH, BCACP, APh

*Health Sciences Assistant Clinical Professor*

*Department of Clinical Pharmacy Practice, School of Pharmacy & Pharmaceutical Sciences*

*Vice Chair, Immunization Coalition of LA County*

# COVID-19 Vaccines

## Administration

### Pfizer-BioNTech

- Two doses
- At least 21 days apart



### Moderna

- Two doses
- At least 28 days apart



### Janssen- J&J

- One dose



# COVID-19 Vaccines

## Storage & distribution

### Pfizer-BioNTech

- Must be stored at ultra-cold temperatures
- **UPDATE:** can be stored short term at standard freezer temperatures
- **Many/some** logistical challenges

### Moderna

- Can be stored at standard freezer temperatures
- **Some** logistical challenges

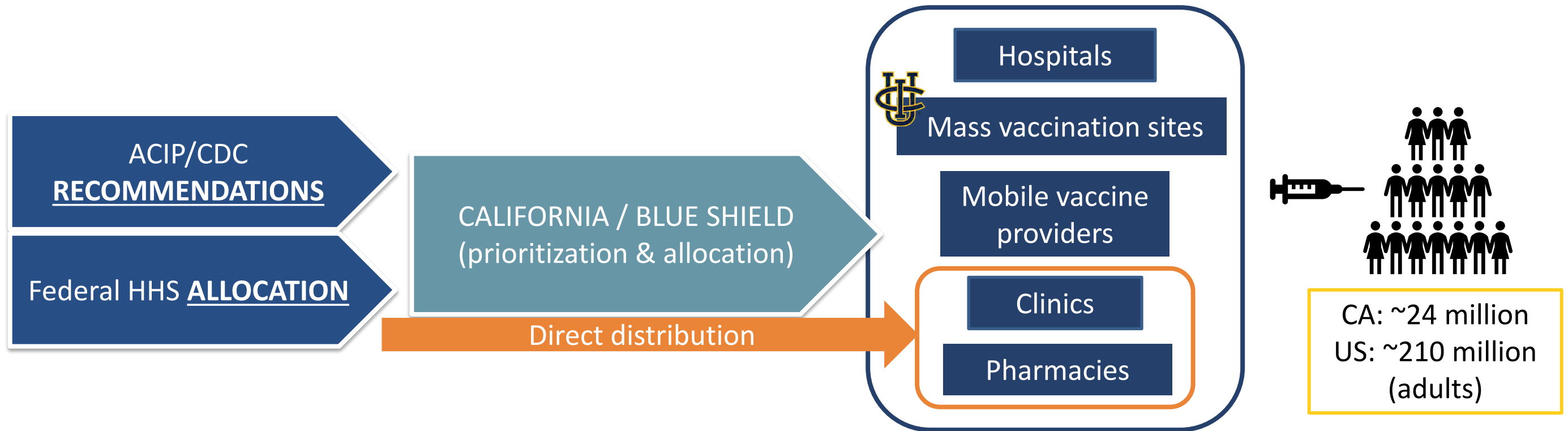
### Janssen-J&J

- Can be stored under simple refrigeration
- Minimal logistical challenges



# COVID-19 Vaccines

## Distribution process





# COVID-19 Vaccines

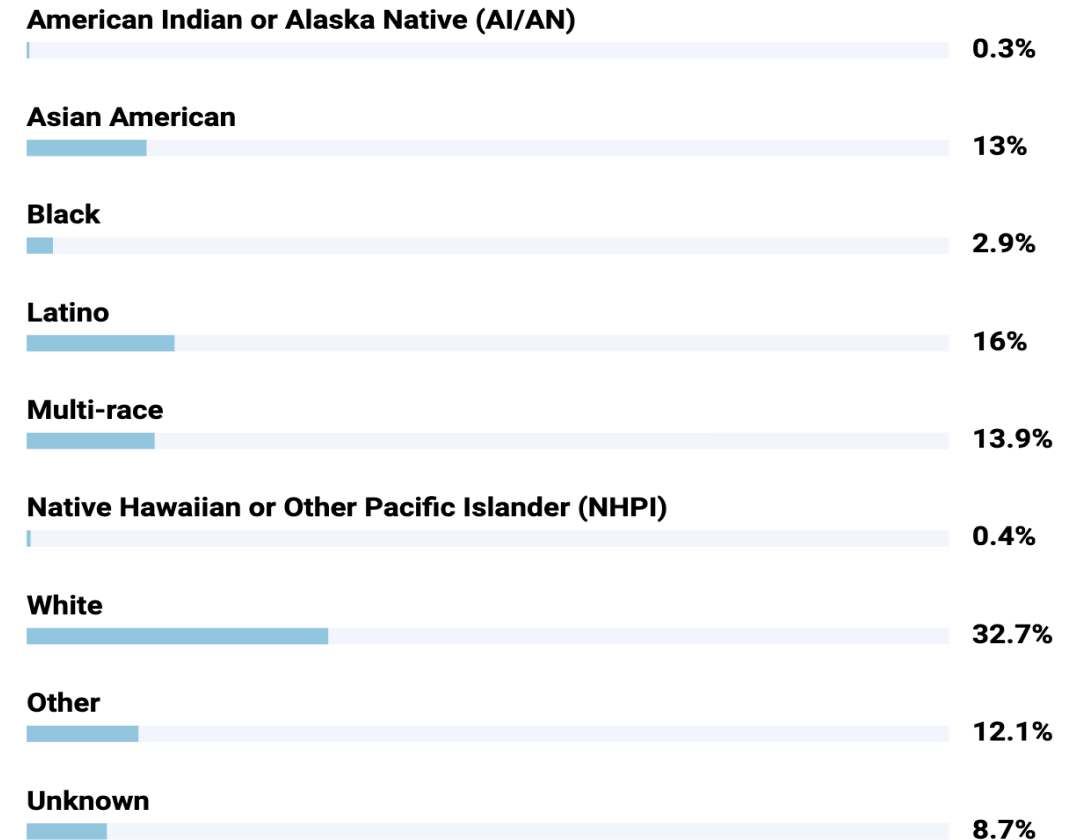
## Equity

### CDC Factors in allocation & prioritization

1. Maximizing benefit, minimizing harm
2. **Equity**
3. Efficiency, minimizing disuse

People with at least one dose of vaccine administered by race and ethnicity in California

■ % of vaccines administered



**Health equity** "...is defined as the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically".  
- WHO. *Social determinants of health*. 2020.

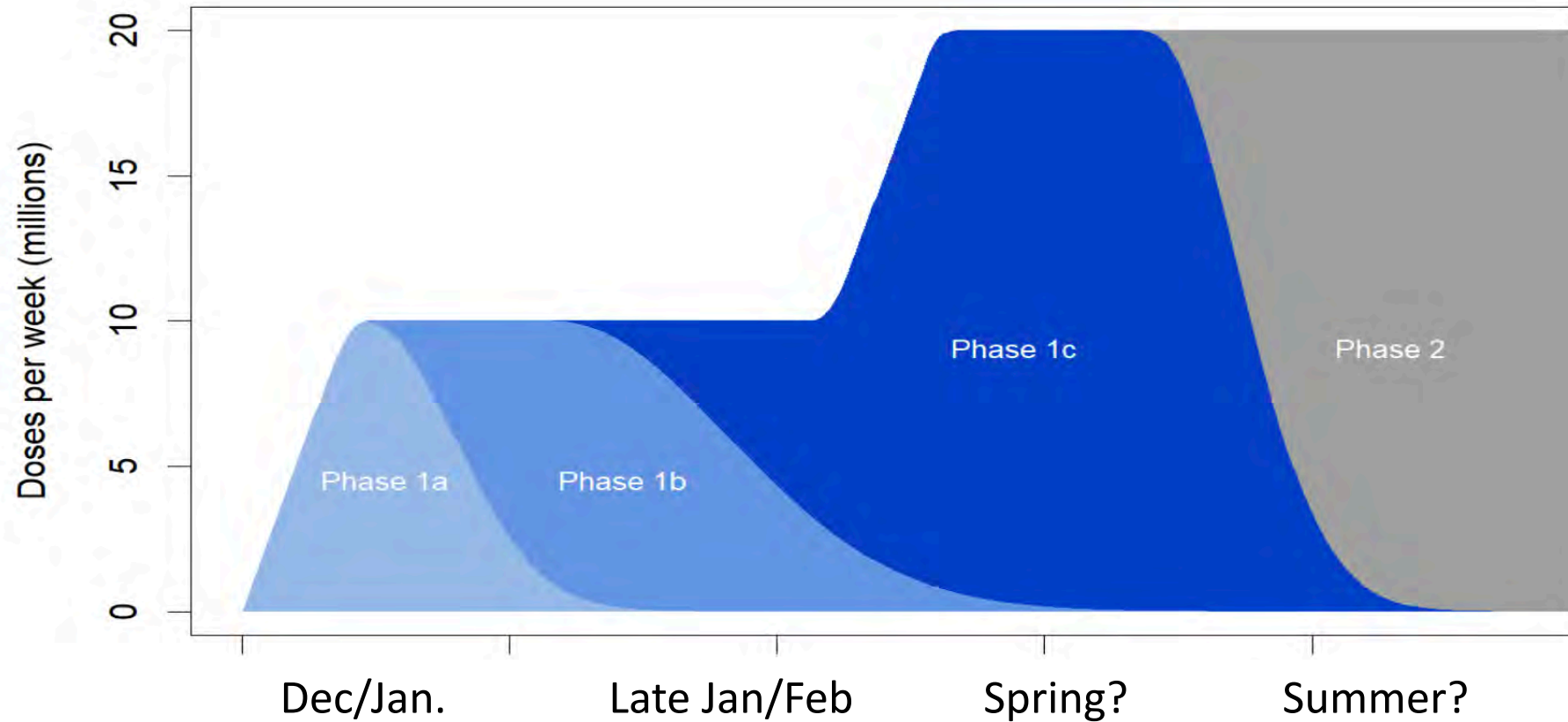
# COVID-19 Vaccines

## Tiered roll-out

PHASE	CDC/ACIP recommendations as of Dec 20, 2020	Additional federal guidance on Jan. 12, 2021	California As of Feb. 22, 2021
1A	Health care workers & long-term care	-	Health care workers & long-term care
1B	Age 75+ & frontline essential workers	Age 65+	Age 65+ & tier 1 frontline essential workers
1C	Age 65-74 & high risk conditions & other essential workers	-	Starting March 15: individuals with high risk medical conditions / disabilities
2	Healthy younger adults		Likely age-based

# COVID-19 Vaccines

## Estimated timing



## Factors in timing for groups/individuals

- Doses available
- Prioritization
- Uptake
- Efficiency and process
- Location

*Adapted from CDC ACIP meeting materials 12/20/20*

# COVID-19 Vaccines

## Where to find more information

### Centers for Disease Control and Prevention (CDC)

- COVID-19 Vaccine website
  - FAQs and “8 Things to Know”

### State and county public health

- Information about eligible groups
- How to schedule appointments

Los Angeles, San Diego and select other CA counties: [MyTurn.ca.gov](https://myturn.ca.gov)



Orange County: [Othena.com](https://othena.com)





# Questions?

# Closing & Next Steps

- Thank you for attending and for your questions!
- Future additional webinar updates as significant changes occur

## Next Steps

- Stay safe, don't let your guard down.
- Continue to wear your mask, wash your hands and avoid large gatherings.
- Stay informed
  - CDC, UCI Health FAQ <https://www.ucihealth.org/covid-19/covid-vaccine-faq>
  - Othena.com, myturn.ca.gov for vaccine availability updates.