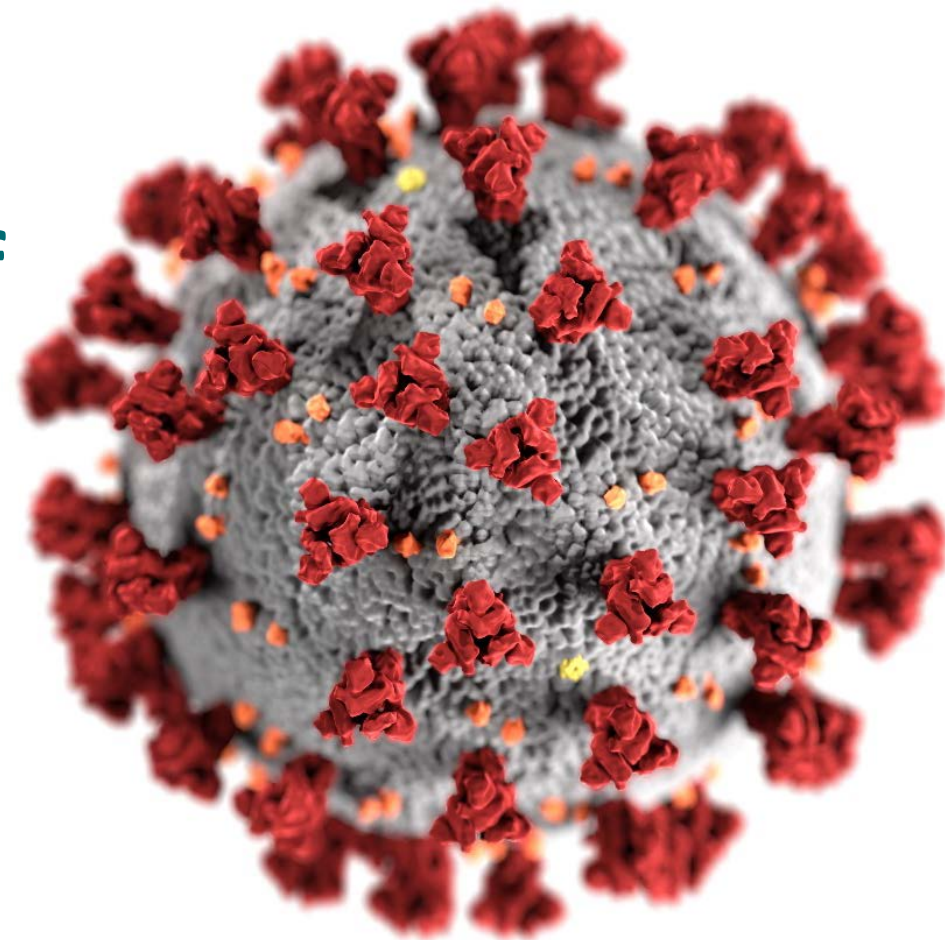


# Considerations for booster doses of COVID-19 vaccines

Sara Oliver MD, MSPH  
ACIP Meeting  
August 13, 2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

## Policy questions:

### Recommendations for booster doses of COVID-19 vaccines

- **Main policy question**: Are booster doses of COVID-19 vaccines needed for those previously vaccinated with a primary series?
- Policy on booster doses coordinated with **FDA** for regulatory allowance, and **ACIP** for recommendations around use in specific populations

# Roles of an Additional Dose

There are two distinct potential uses for an additional dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
- **Booster dose**: a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

# Roles of an Additional Dose

There are two distinct potential uses for an additional dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
- **Booster dose**: a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

# COVID-19 vaccines administered

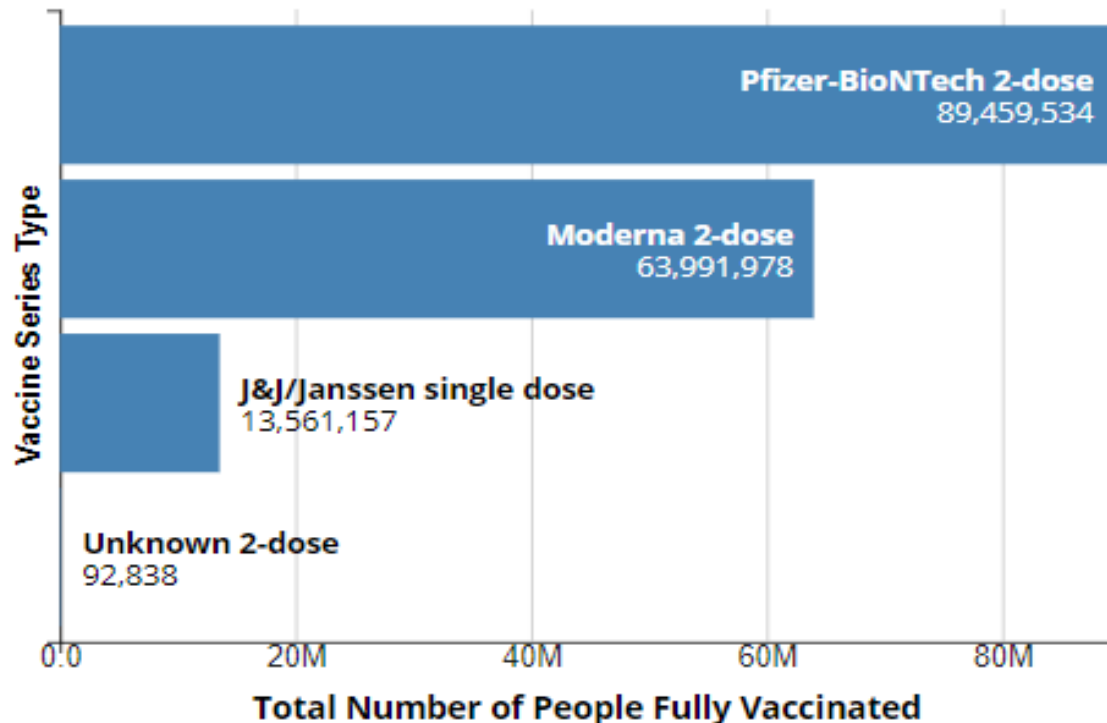
As of August 11, 2021

**Total Vaccine Doses Administered:**

**353,205,544**

**% of Population Fully Vaccinated:**

Number of People Fully Vaccinated in the U.S. by COVID-19 Vaccine Series Type



**≥12 years of age:**

**58.9%**



**≥18 years of age:**

**61.3%**



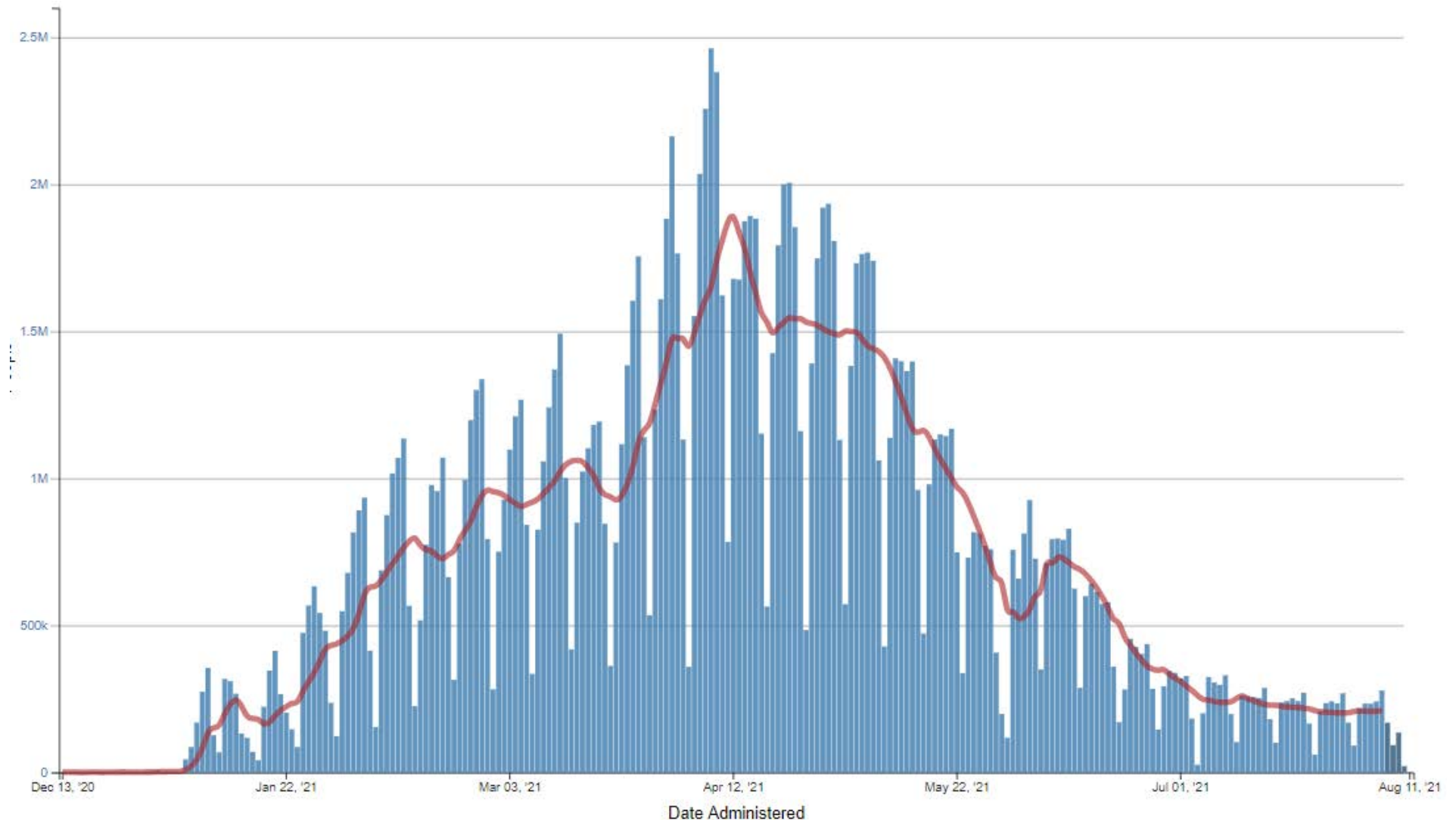
**≥65 years of age:**

**80.5%**

# COVID-19 vaccines administered

As of August 11, 2021

**Daily Count  
of Fully  
Vaccinated  
People**

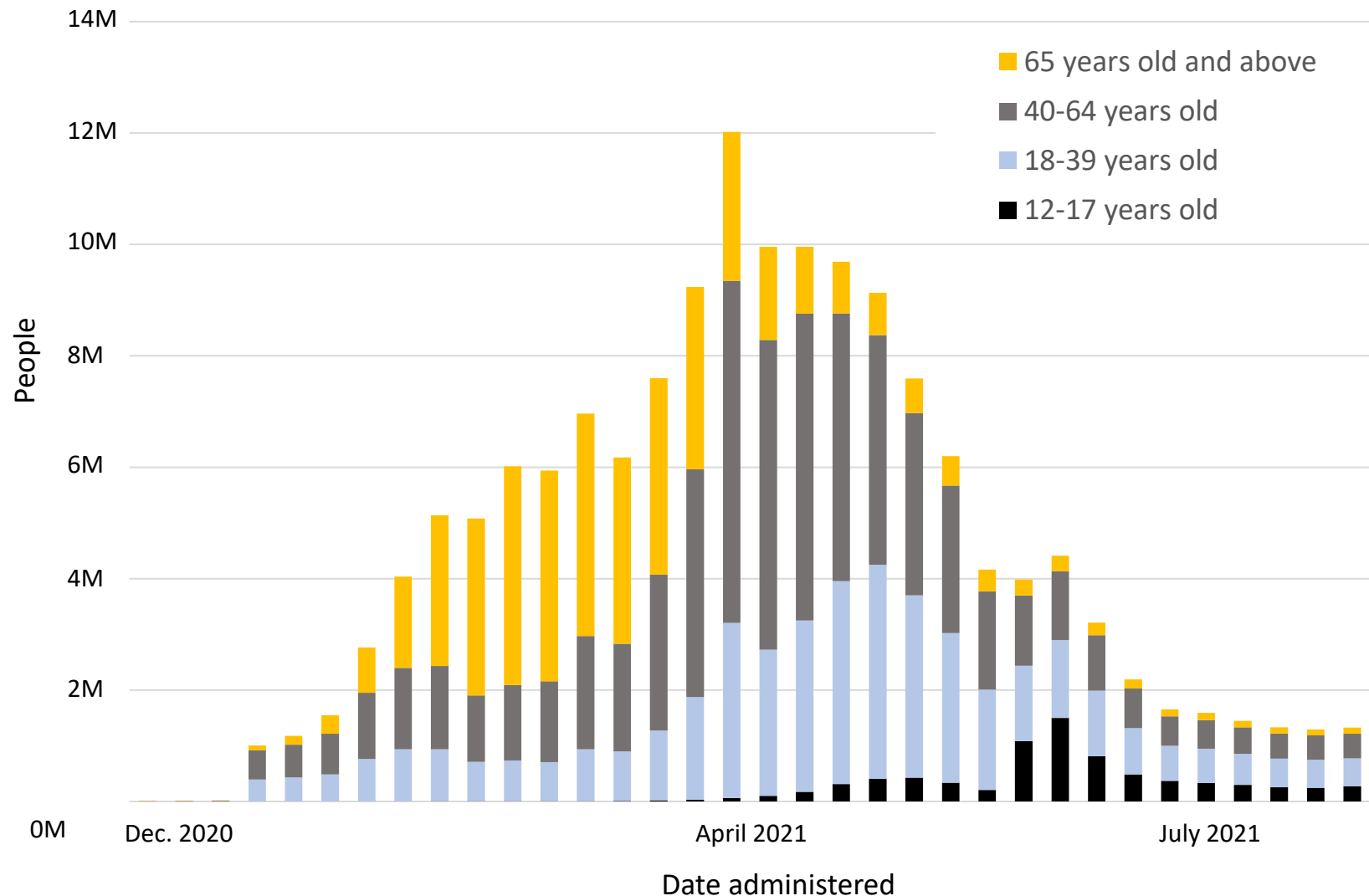


A person is considered fully vaccinated against COVID-19  $\geq 2$  weeks after receipt of the second dose in a two-dose series (Pfizer-BioNTech and Moderna) or  $\geq 2$  weeks after receipt of the single dose of the Janssen vaccine; CDC. <https://covid.cdc.gov/covid-data-tracker>

# COVID-19 vaccines administered

As of August 11, 2021

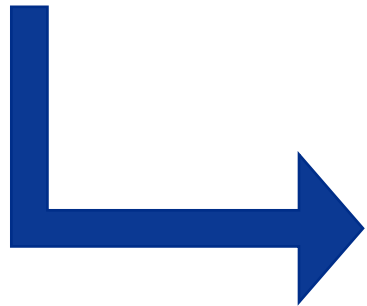
## Weekly Count of Fully Vaccinated People in US, by age group



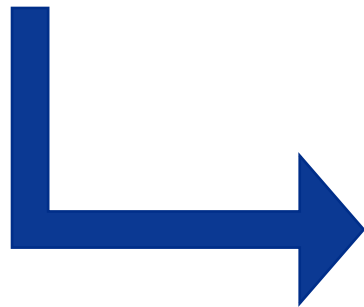
A person is considered fully vaccinated against COVID-19  $\geq 2$  weeks after receipt of the second dose in a two-dose series (Pfizer-BioNTech and Moderna) or  $\geq 2$  weeks after receipt of the single dose of the Janssen vaccine; CDC. <https://covid.cdc.gov/covid-data-tracker>

# Booster doses of COVID-19 vaccines

What are the **key considerations** for decision making?



What **data** are available for decision making?



Does ACIP **recommend** booster doses of COVID-19 vaccines in any populations?



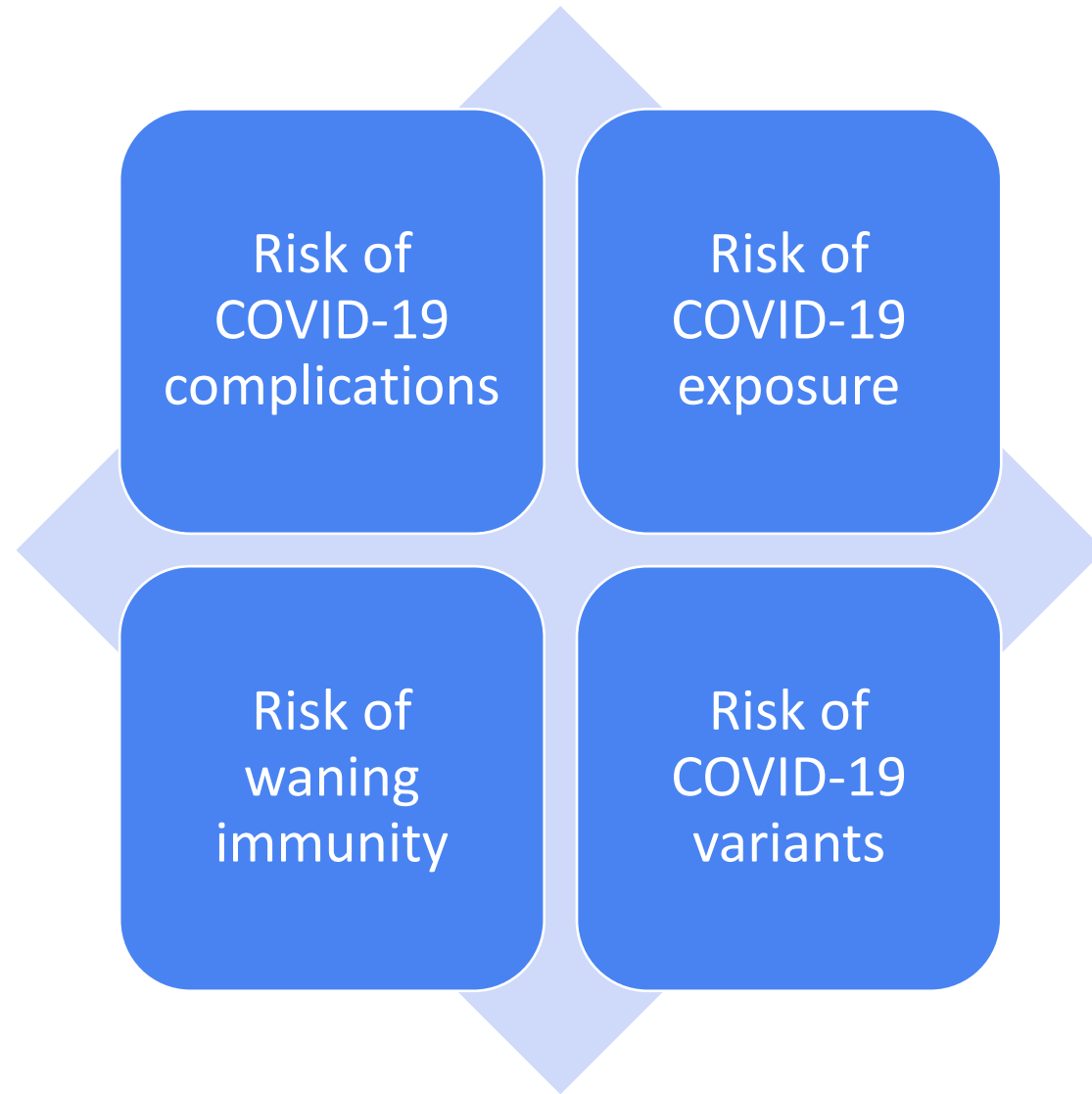
# Booster doses of COVID-19 vaccines

What are the **key considerations** for decision making?

What **data** are available for decision making?

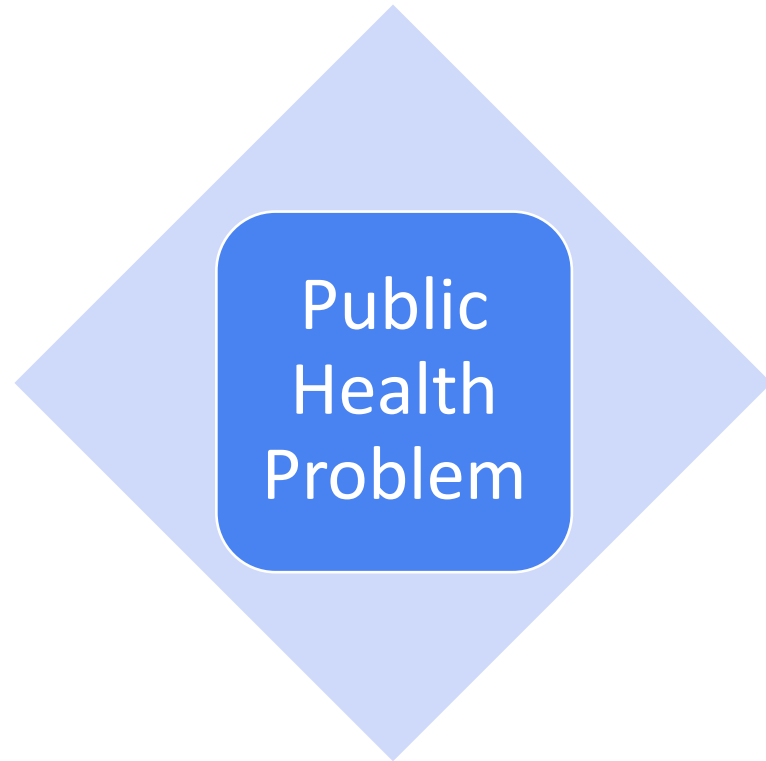
Does ACIP **recommend** booster doses of COVID-19 vaccines in any populations?

# Booster doses of COVID-19 vaccines: Data to inform recommendations



# Booster doses of COVID-19 vaccines

Do we need them?



Do they work?



# Booster doses of COVID-19 vaccines

Public  
Health  
Problem

Is vaccine effectiveness (VE) **waning** over time?

Is VE **reduced** for the **Delta variant**?

Does the data vary by **sub-population**?

Benefits  
and  
Harms

Are booster doses of COVID-19 vaccines **safe** and **immunogenic**?

Will booster doses of COVID-19 vaccines reduce COVID-19 **incidence, hospitalization** and/or **mortality**?

Do booster doses **improve VE** against the Delta variant?

# Booster doses of COVID-19 vaccines: Data to inform recommendations



Public  
Health  
Problem

Is vaccine effectiveness (VE) waning over time?

Is VE at **6-8 months** similar to what was noted at **2 months** after vaccination?

How does this data vary by **severity** of disease?

What data on **waning VE** would identify a need for **booster dose** of COVID-19 vaccines?

# Booster doses of COVID-19 vaccines: Data to inform recommendations



Public  
Health  
Problem

Is VE **reduced** for the **Delta variant**?

How does this vary by **severity** of disease?

How would this information impact VE  
for **future variants**?

# Booster doses of COVID-19 vaccines: Data to inform recommendations

Public  
Health  
Problem

Does the data vary by **sub-population**?

Residents of  
long-term care  
facilities

Adults  $\geq 65$   
years of age

Healthcare  
personnel

# Booster doses of COVID-19 vaccines: Data to inform recommendations



Public  
Health  
Problem

Does the data vary by **sub-population**?

## LTCF residents, adults $\geq 65$ years of age

- Vaccinated in early phase of COVID-19 vaccine roll-out
- Needed special considerations for other vaccines (boosters, higher-dose vaccines)

## Healthcare personnel

- Vaccinated in early phase of COVID-19 vaccine roll-out
- Continued exposure to SARS-CoV-2
- Additional considerations include continuity of healthcare systems
  - May have need to prevent asymptomatic or mild infections in healthcare personnel



# Booster doses of COVID-19 vaccines: Data to inform recommendations

Are booster doses of COVID-19 vaccines **safe** and **immunogenic**?

Do COVID-19 vaccines provide a **boost** in neutralizing antibody response?

How do neutralizing antibodies correlate to **clinical protection** from COVID-19?



Benefits  
and  
Harms

# Booster doses of COVID-19 vaccines: Data to inform recommendations

Will booster doses of COVID-19 vaccines reduce COVID-19 **incidence**, **hospitalization** and/or **mortality**?



Benefits  
and  
Harms

# Booster doses of COVID-19 vaccines: Data to inform recommendations

Do boosters **improve VE** against the Delta variant and other variants of concern?

How can we use this data to inform VE for **future variants**?



Benefits  
and  
Harms

# Booster doses of COVID-19 vaccines:

## Work Group interpretation

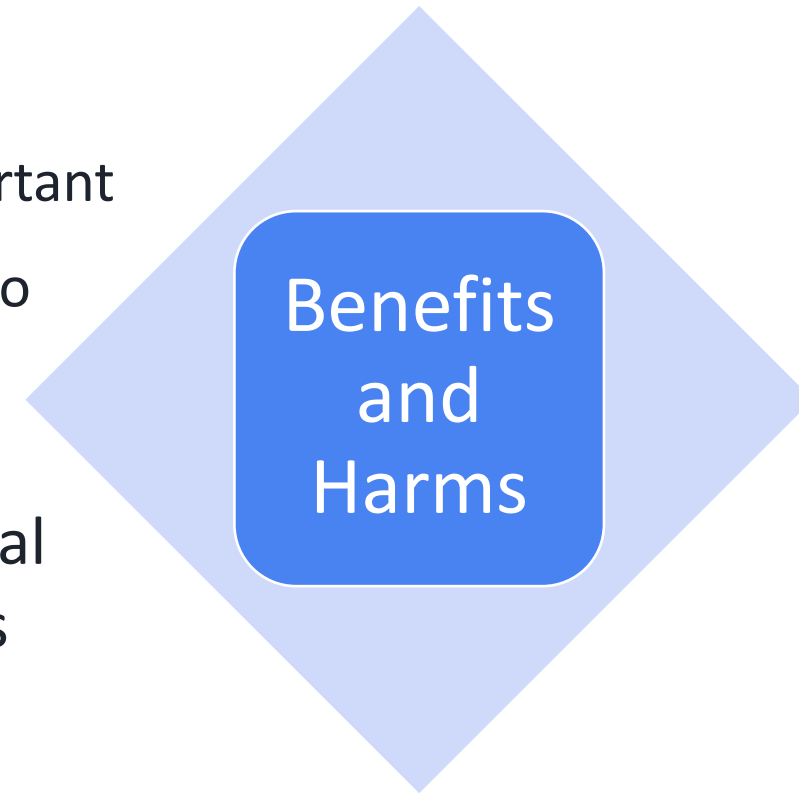


Public  
Health  
Problem

- Receipt of **COVID-19 vaccine primary series** will continue to have the largest public health impact
- Decisions for boosters need to focus on prevention of **severe disease, hospitalization and death**
- Important to ensure **global vaccine availability**: new variants could emerge from regions with **low** vaccine coverage and **high** community transmission

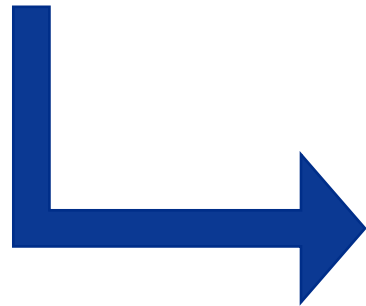
# Booster doses of COVID-19 vaccines: Work Group interpretation

- **Neutralizing antibody** data will be important for booster dose discussions, but may not represent the entire immune response to COVID-19 vaccines
  - Cellular immune response can be difficult to measure, but important
  - Commercial antibody testing **not authorized** or **recommended** to evaluate post-vaccination immune response
- Based on available data and timing of vaccine roll-out, initial booster vaccine policy focused on at-risk **adult** populations
  - At-risk populations could include:  
Adults  $\geq 65$  years of age, LTCF residents, healthcare personnel

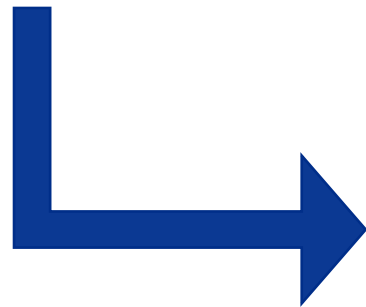


# Booster doses of COVID-19 vaccines

What are the **key considerations** for decision making?



What **data** are available for decision making?



Does ACIP **recommend** booster doses of COVID-19 vaccines in any populations?

# Booster doses of COVID-19 vaccines

What are the **key considerations** for decision making?

```
graph TD; A[What data are available for decision making?] --> B[Does ACIP recommend booster doses of COVID-19 vaccines in any populations?];
```

What **data** are available for decision making?

Does ACIP **recommend** booster doses of COVID-19 vaccines in any populations?

# Booster doses of COVID-19 vaccines:

## Remaining questions

- How does VE vary by specific COVID-19 vaccine in each sub-population?
- What is the VE for booster doses of COVID-19 vaccines, and how does it vary by sub-population?
- How will the need for booster doses of COVID-19 vaccines evolve as the pandemic evolves?



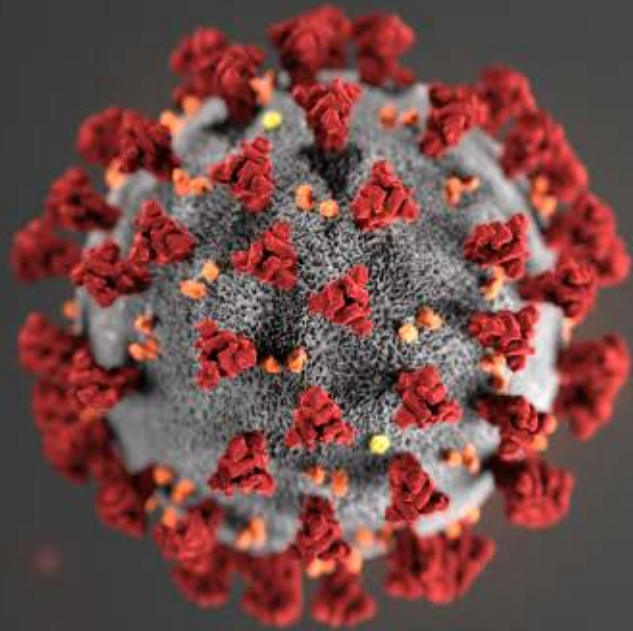


# Acknowledgements

- Kathleen Dooling
- Amy Blain
- Mary Chamberland
- Julia Gargano
- Jack Gersten
- Monica Godfrey
- Stephen Hadler
- Danielle Moulia
- Heidi Moline
- Ian Plumb
- Nicole Reisman
- Hannah Rosenblum
- Heather Scobie
- Eddie Shanley
- Megan Wallace
- Neela Goswami
- Kristine Schmidt
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

# Questions for ACIP

1. Does ACIP agree with the framework laid out to address COVID-19 booster dose recommendations?
2. What other questions would be important for ACIP to address?



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



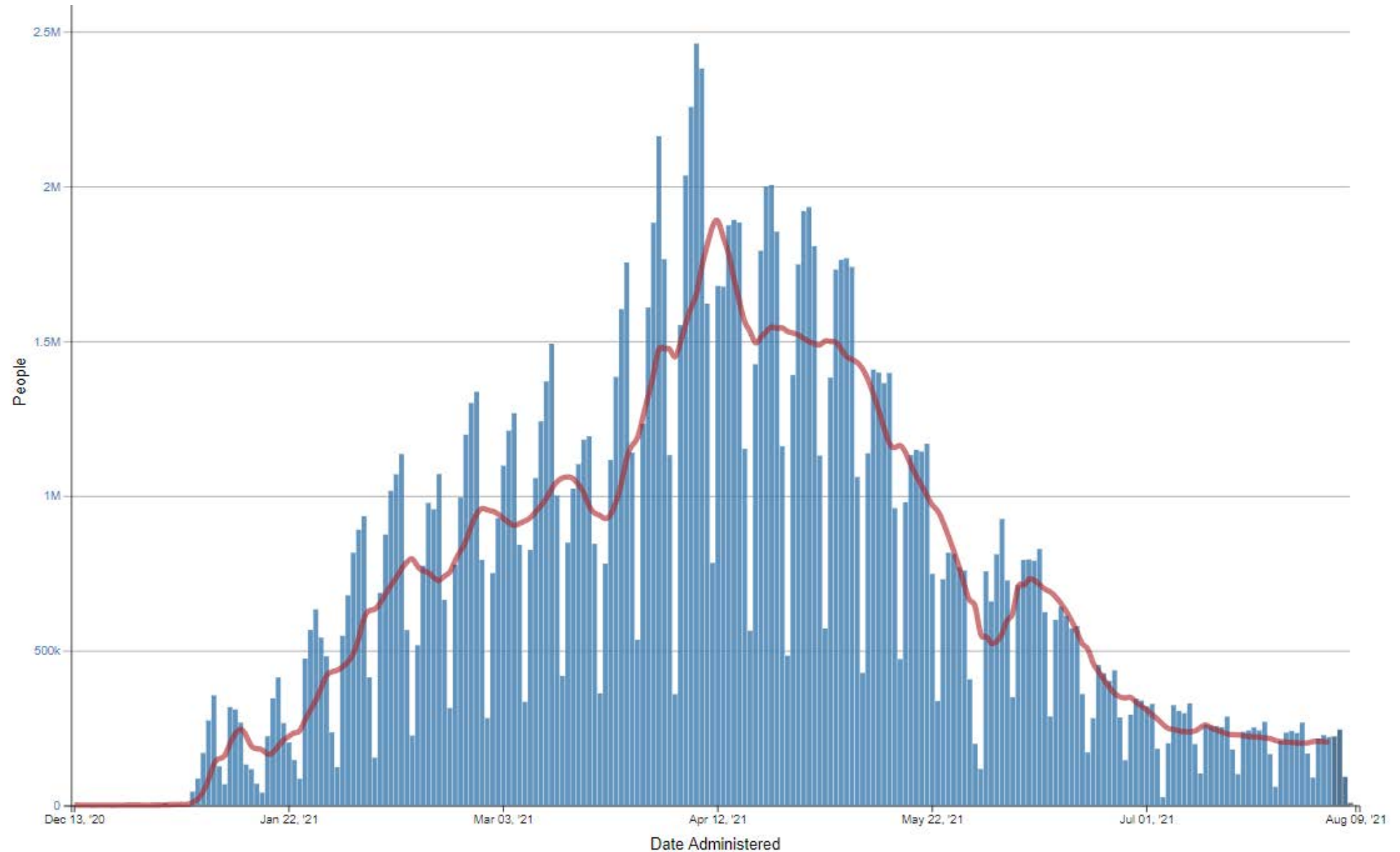
# Additional Slides



# COVID-19 vaccines administered

As of August 10, 2021

## Daily Count of Fully Vaccinated People



# Upcoming studies:

## NIH or manufacturer studies

### Data from Phase I/II/III trials

- Monitor kinetics of antibody response, efficacy from early phase clinical trials
- BLA submission: Include efficacy for ~6 months

### Heterologous boost

- Primary series followed by different boost vaccine
- NIH-sponsored study: 150 individuals, 12-20 weeks following initial series (any series)  
Results expected late summer 2021

### Booster studies

- Moderna: Preliminary results for mRNA-1273 (50µg) published May 2021;  
Additional data on mRNA-1273 and other variants as boosters expected July-Sept 2021
- Pfizer: Data on BNT162b2 (30µg) and variant booster studies expected July-Sept 2021

# Upcoming studies:

## CDC studies

### Vaccine breakthrough cases

- Track breakthrough infections
- Monitor severity of disease and genomic sequence (specifically for variants of concern)

### Vaccine effectiveness studies

- Continue to monitor VE studies over time:  
Stratify by **age, time since vaccination, setting** and **medical condition**
- Ability to track any waning VE could be impacted by declining incidence, changes in variant prevalence
- Over time, individuals who are vaccinated may become increasingly less comparable to the unvaccinated population

# Vaccine effectiveness: Select upcoming studies

## **HEROES-RECOVER Cohort**

- Following ~5,000 essential workers with weekly SARS-CoV-2 testing and quarterly serology
- To date, fully vaccinated populations followed for ~130 days (~4 months) post-vaccination
- Assess neutralizing antibodies 6-months post-vaccination

## **VISION VE Network**

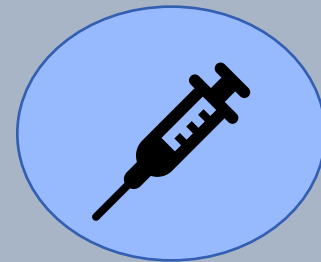
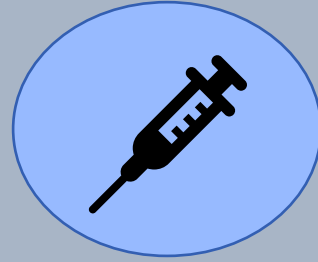
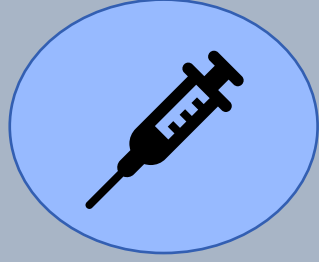
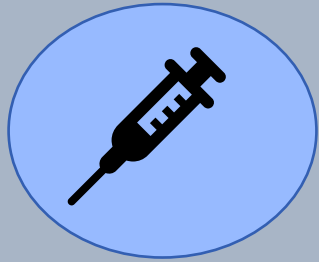
- Multi-state network of 8 integrated care systems and research centers; assess COVID-19 confirmed by molecular assays and vaccination documented by EHR and registries
- Network assesses waning effectiveness using test-negative VE design

## **IVY VE Network**

- Collaborative of hospital-based investigators, through 18 tertiary academic medical centers in 16 states
- Plans to assess duration of protection by adapting prior methods used for influenza



# Timeline for additional data



**Summer:**  
July-September

**Manufacturer data**  
Safety and Immunogenicity of booster doses

**Manufacturer data**  
Phase I/II/III follow-up

**Mix-and-match studies**  
Heterologous prime-boost

**Early Fall:**  
September-October

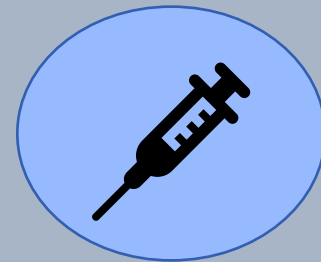
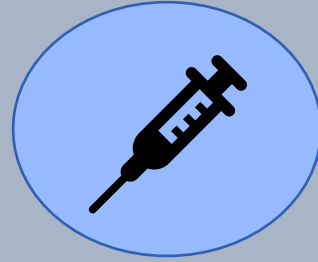
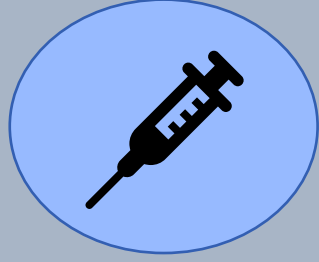
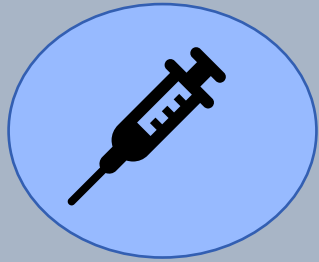
**COVID-19 epi**  
Incidence of cases, hospitalizations, deaths

**COVID-19 variants**  
Variant proportions, VE by variant

**VE studies**  
VE by age, setting, time since vaccination

**Breakthrough cases**  
Comparison of variants and clinical outcomes

# Timeline for additional data



## Summer:

July-September

### Manufacturer data

Safety and Immunogenicity of booster doses

### Manufacturer data

Phase I/II/III follow-up

### Mix-and-match studies

Heterologous prime-boost

## Early Fall:

September-October

### COVID-19 epi

Incidence of cases, hospitalizations, deaths

### COVID-19 variants

Variant proportions, VE by variant

### VE studies

VE by age, setting, time since vaccination

### Breakthrough cases

Comparison of variants and clinical outcomes

## ACIP meetings

Continue to provide updates. Vote could occur whenever data support updating policy