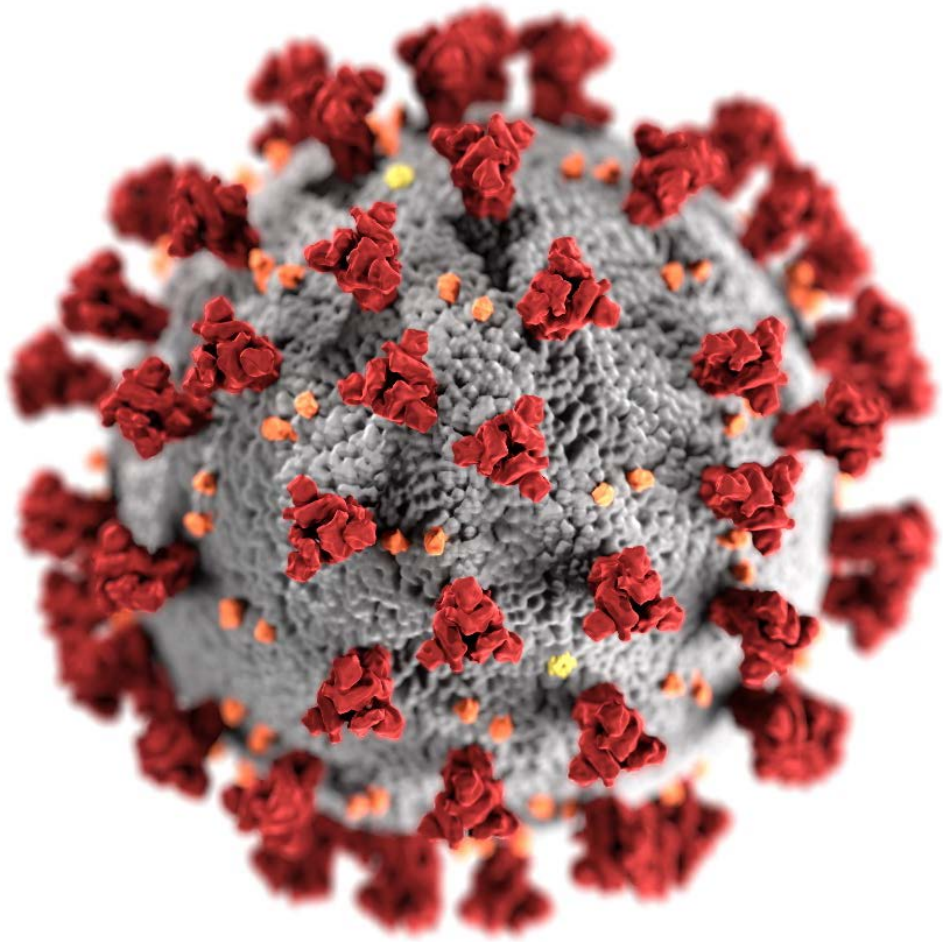
Considerations for booster doses of COVID-19 vaccines



Sara Oliver MD, MSPH
ACIP Meeting
August 13, 2021

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

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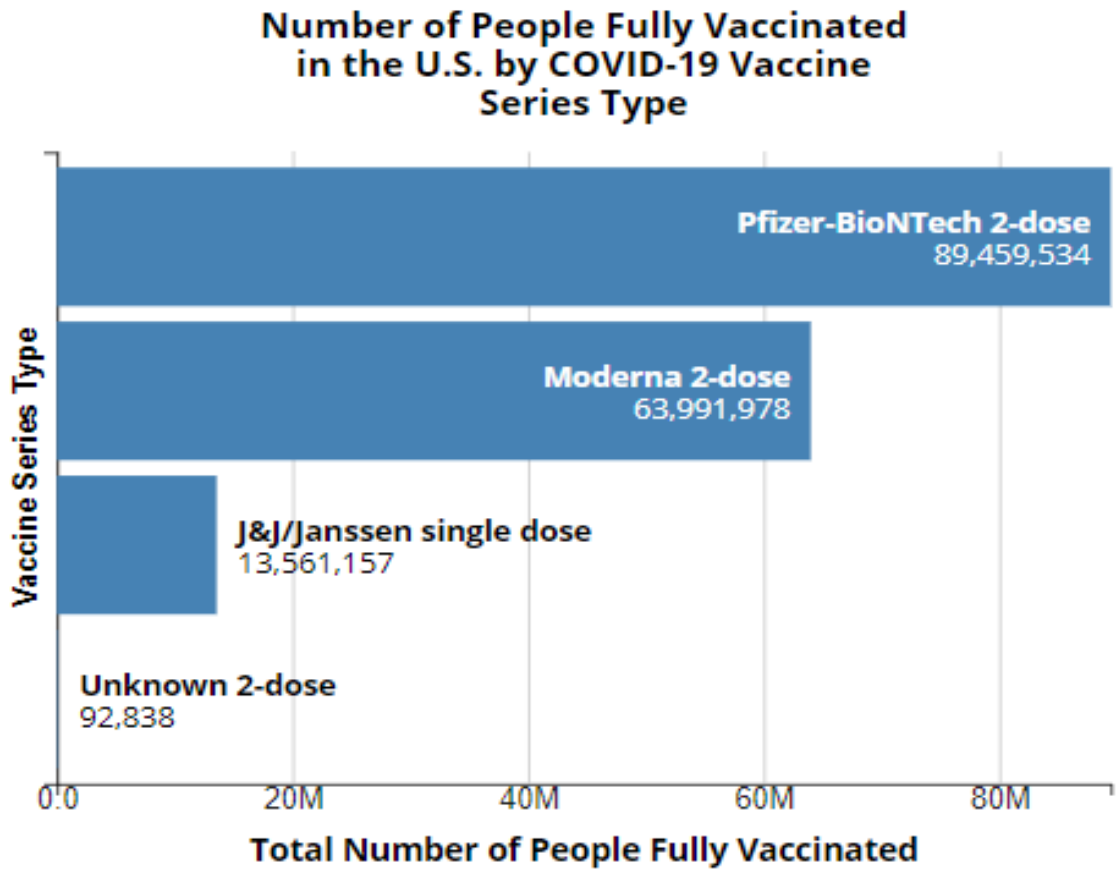
COVID-19 vaccines administered

As of August 11, 2021

Total Vaccine Doses Administered:

353,205,544



% of Population Fully Vaccinated:

≥12 years of age:
58.9%

≥18 years of age:
61.3%

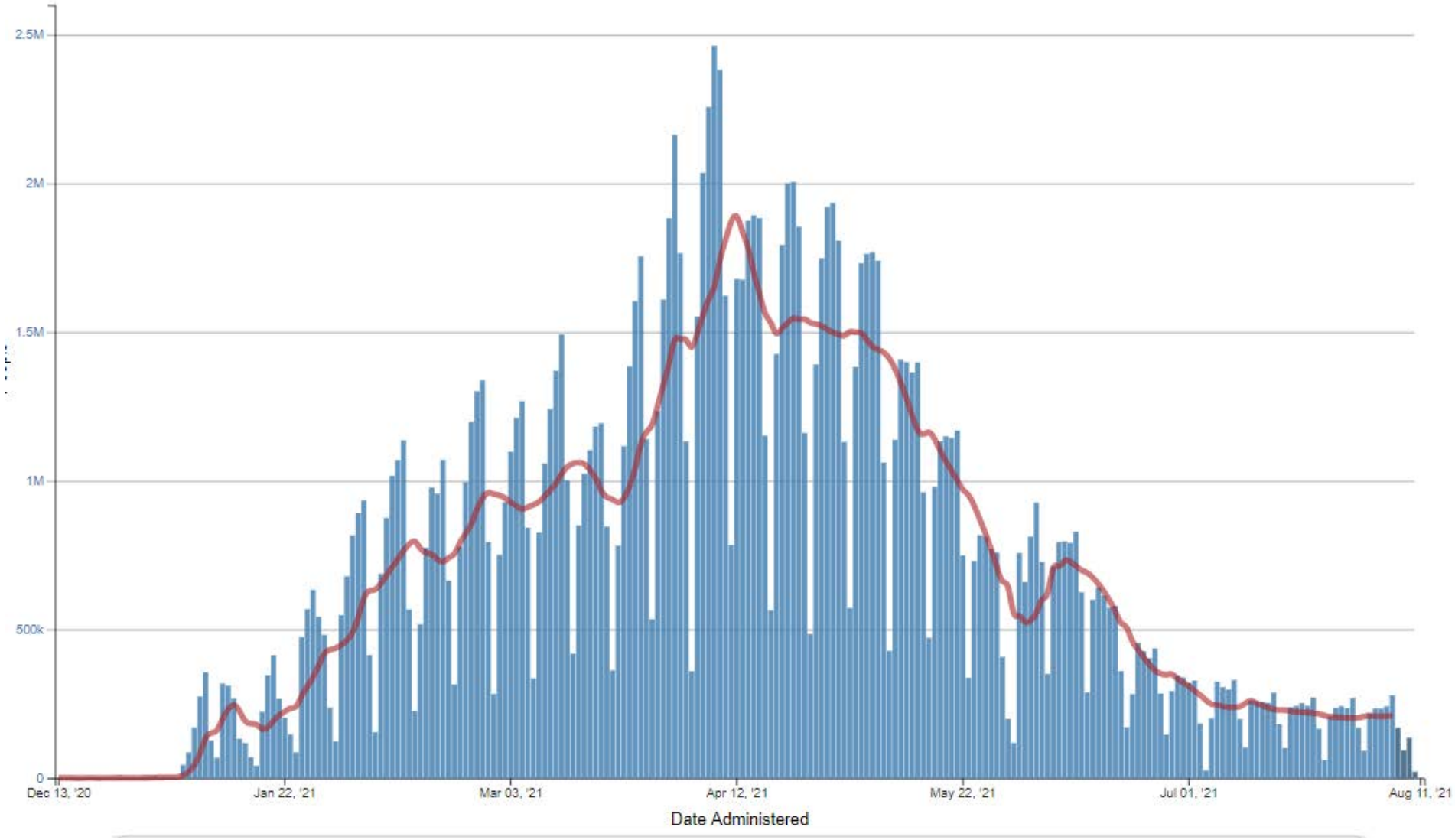
≥65 years of age:
80.5%

CDC. https://covid.cdc.gov/covid-data-tracker

COVID-19 vaccines administered

As of August 11, 2021

Daily Count of Fully Vaccinated People

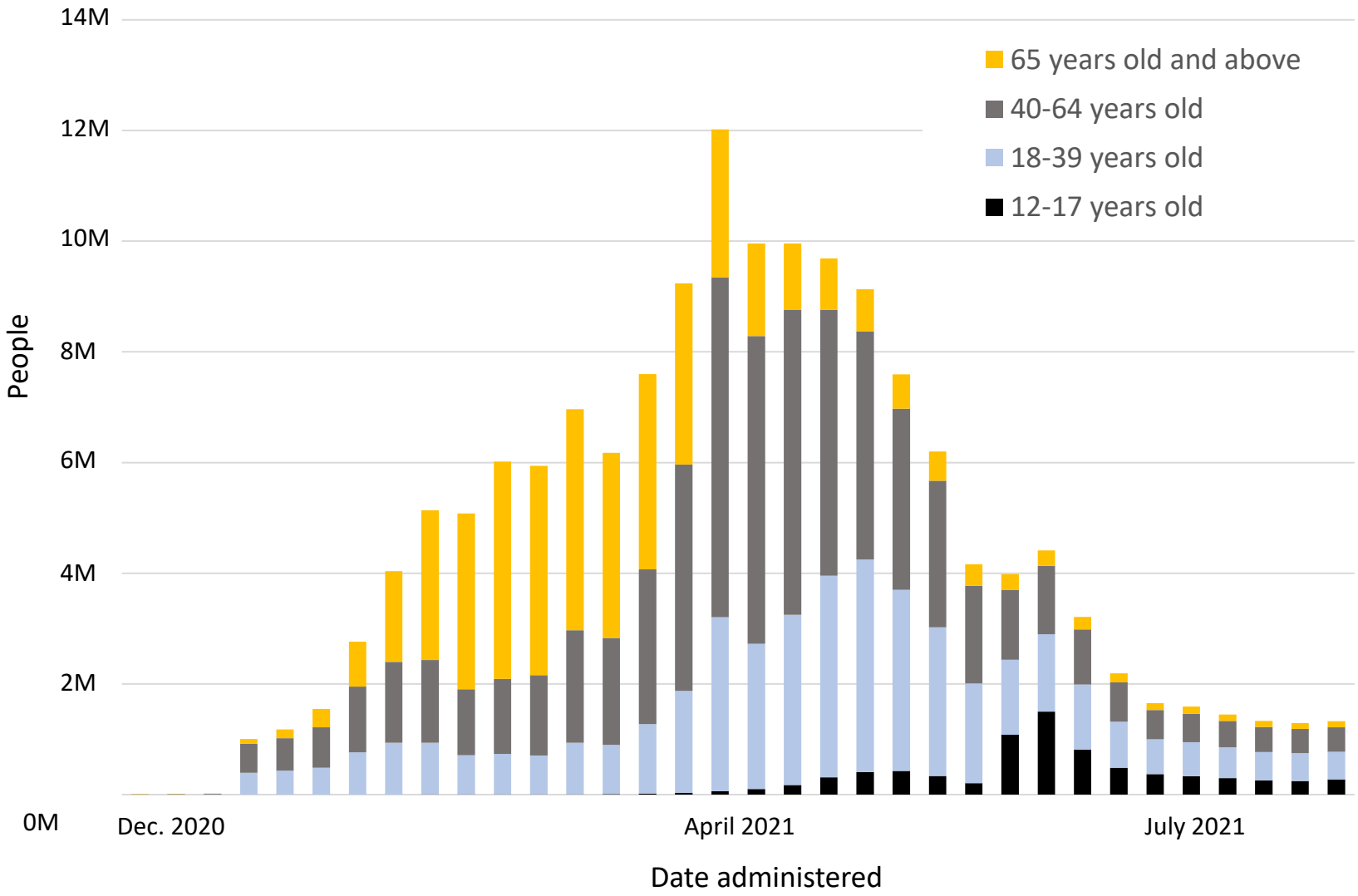


A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a two-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen vaccine; CDC. https://covid.cdc.gov/covid-data-tracker

COVID-19 vaccines administered

As of August 11, 2021

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



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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?

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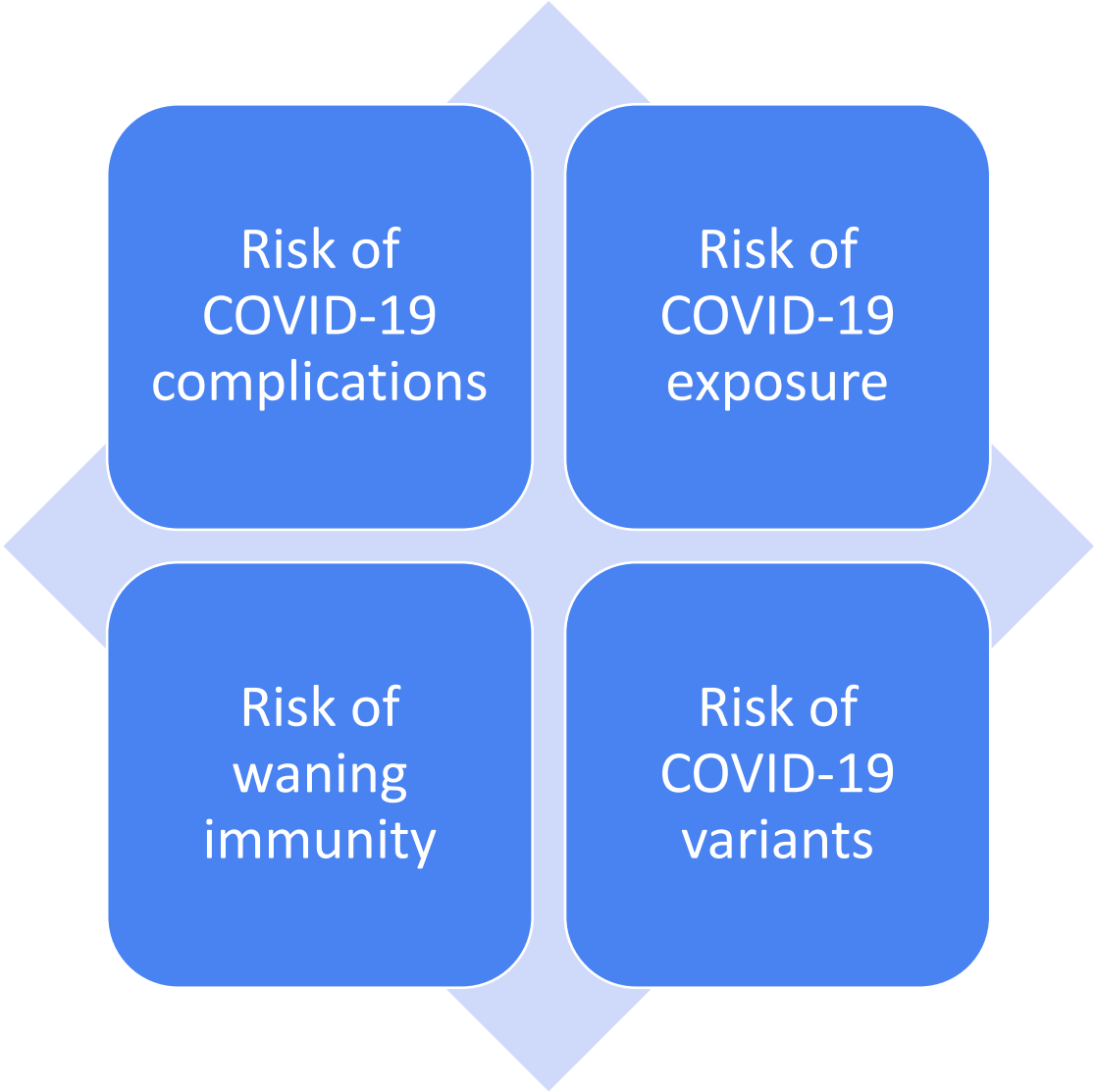
Booster doses of COVID-19 vaccines:
Data to inform recommendations



Booster doses of COVID-19 vaccines

Do we need them?

Public Health Problem

Do they work?

Benefits and Harms

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 ≥65 years of age
- Healthcare personnel

Public Health Problem

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

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

LTCF residents, adults ≥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?

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**?

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**?

Booster doses of COVID-19 vaccines:
Work Group interpretation

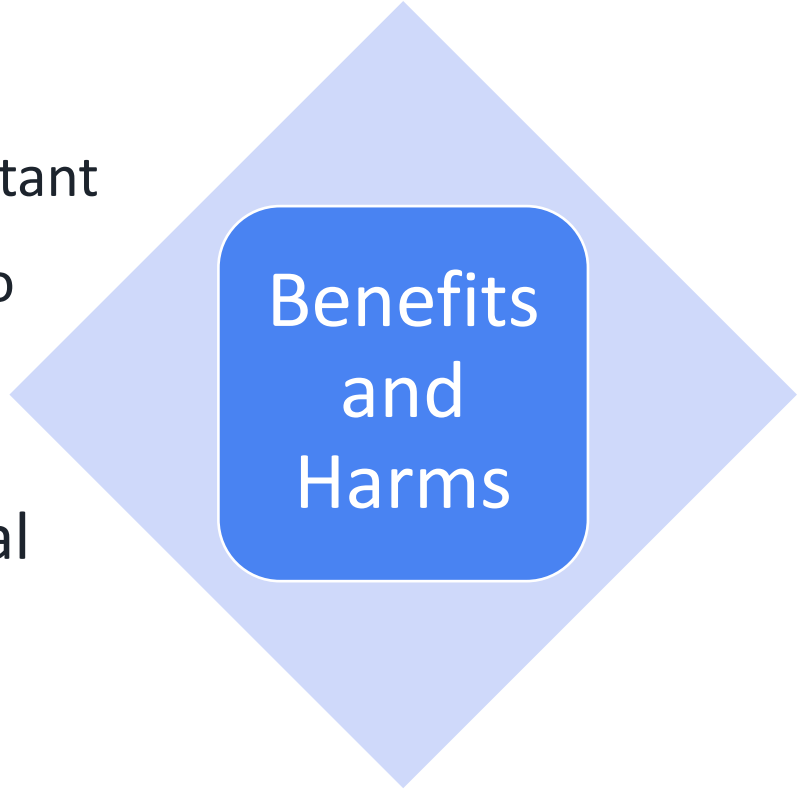
Public Health Problem

- 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 ≥65 years of age, LTCF residents, healthcare personnel



Booster doses of COVID-19 vaccines

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

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

Booster doses of COVID-19 vaccines

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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

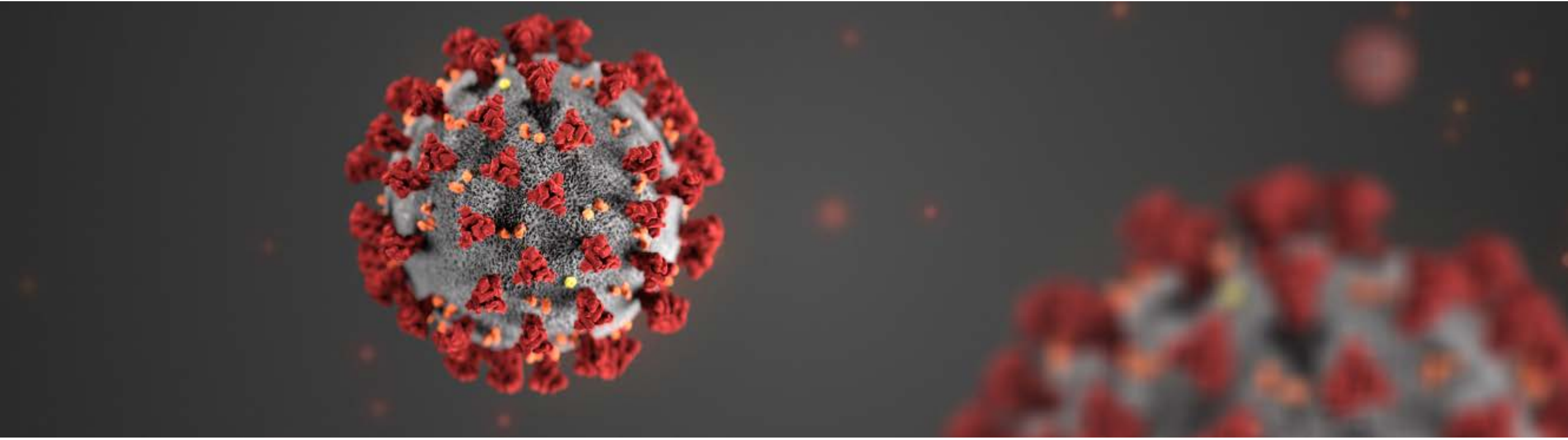
- Kathleen Dooling
- Amy Blain
- Mary Chamberland
- Julia Gargano
- Jack Gersten
- Monica Godfrey
- Stephen Hadler
- Danielle Moulia
- Heidi Moline
- Ian Plumb
- Nicole Reisman
- Hannah Rosenblum
- Heather Scobie
- Eddie Shanley
- Megan Wallace
- Neela Goswami
- Kristine Schmidt

- 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?



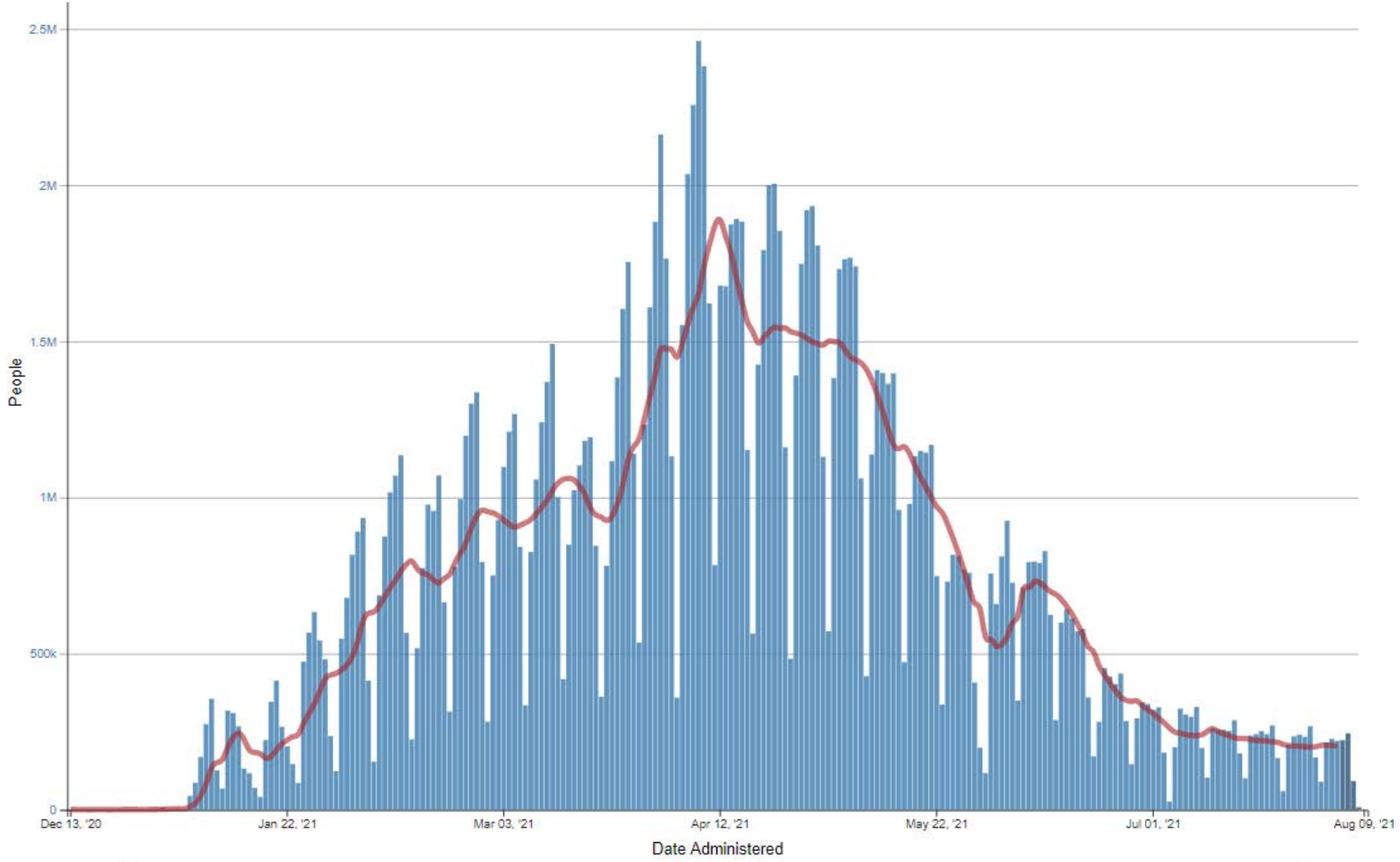
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Additional Slides

COVID-19 vaccines administered

As of August 10, 2021

Daily Count of Fully Vaccinated People



CDC. https://covid.cdc.gov/covid-data-tracker

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

https://www.nih.gov/news-events/news-releases/nih-clinical-trial-evaluating-mixed-covid-19-vaccine-schedules-begins

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

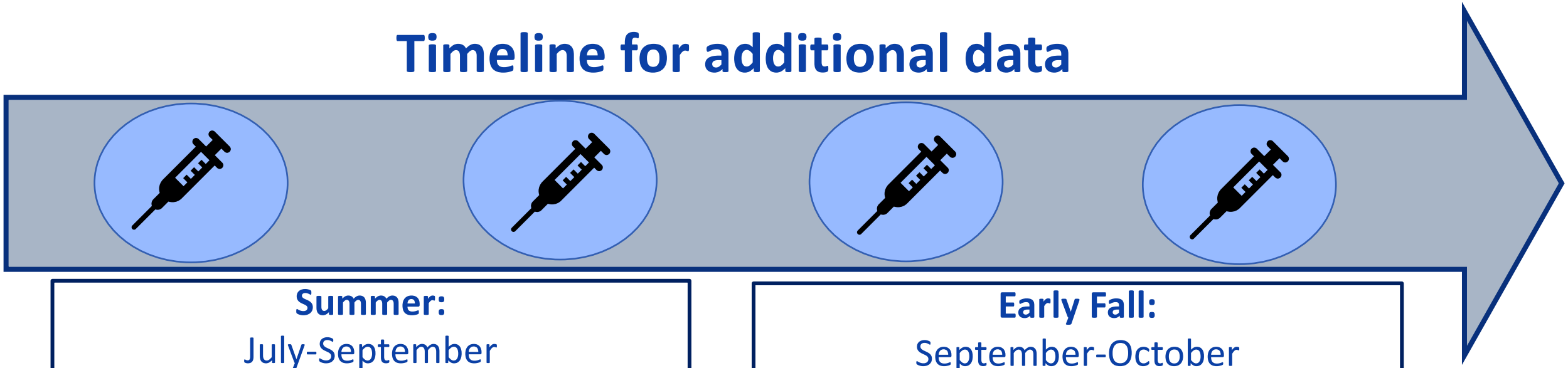
- Multi-state network of 8 integrated care systems and research centers; assess COVID-19 confirmed by molecular assays and vaccination documented by EHR and registries
- Network assesses waning effectiveness using test-negative VE design

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

EHR=Electronic Health Registries

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

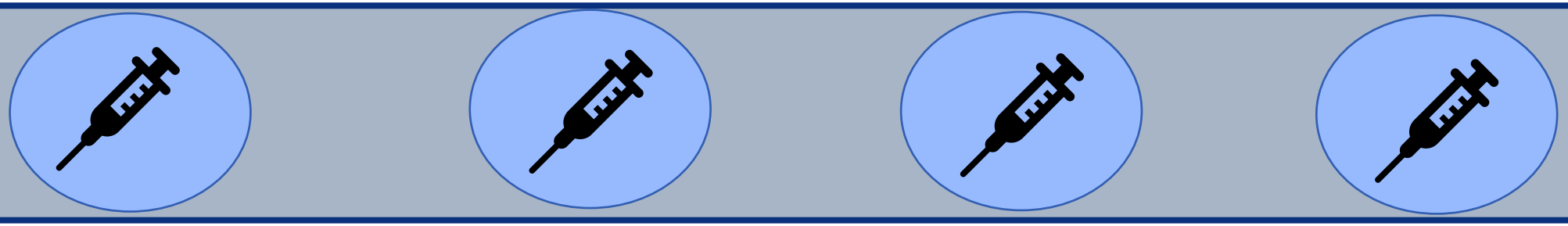
COVID-19 epi
Incidence of cases, hospitalizations, deaths

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



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