Considerations for booster doses of COVID-19 vaccines

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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.
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%

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

- Pfizer-BioNTech 2-dose: 89,459,534
- Moderna 2-dose: 63,991,978
- J&J/Janssen single dose: 13,561,157
- Unknown 2-dose: 92,838

CDC. https://covid.cdc.gov/covid-data-tracker
COVID-19 vaccines administered

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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
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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

- Risk of COVID-19 complications
- Risk of COVID-19 exposure
- Risk of waning immunity
- Risk of COVID-19 variants
Booster doses of COVID-19 vaccines

- Do we need them?
- Do they work?

Public Health Problem

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?
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

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

Does the data vary by sub-population?

- Residents of long-term care facilities
- Adults ≥65 years of age
- Healthcare personnel
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

- 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

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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?
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- 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)

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.