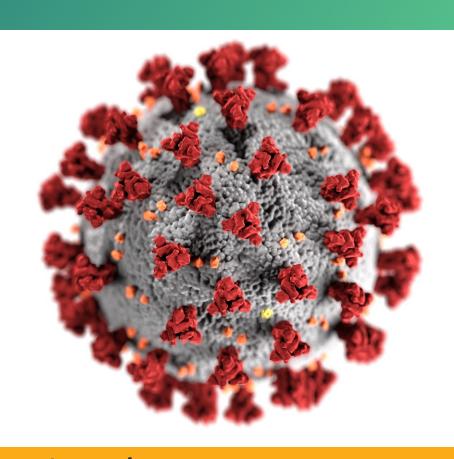
# Framework for booster doses of COVID-19 vaccines

Sara Oliver MD, MSPH ACIP Meeting August 30, 2021





cdc.gov/coronavirus

## **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

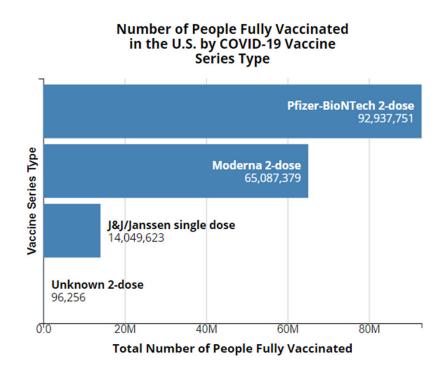
- Are booster doses of COVID-19 vaccines needed for those previously vaccinated with a primary series?
- Policy on booster doses will be coordinated with FDA for regulatory allowance, and ACIP for recommendations for use



## **COVID-19 vaccines administered**

As of August 26, 2021

## Total Vaccine Doses Administered: 365,767,674



% of Population Fully Vaccinated:



≥**12** years of age:

60.7%



≥**18** years of age:

62.8%



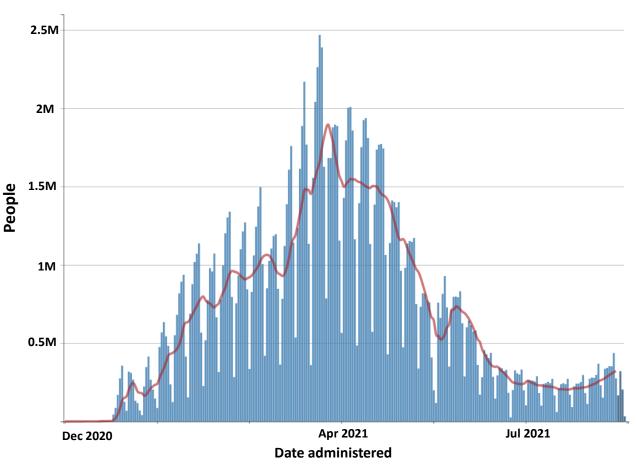
≥**65** years of age:

81.4%

## **COVID-19 vaccines**

As of August 26, 2021

Daily Count of Newly Fully Vaccinated People

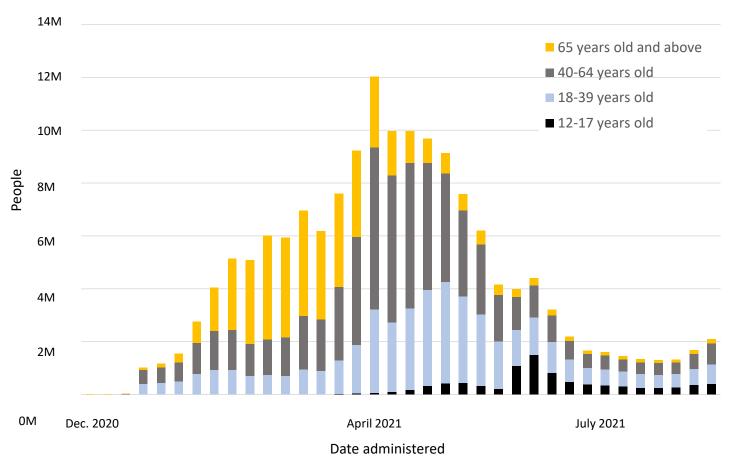


A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a two-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen vaccine; CDC. <a href="https://covid.cdc.gov/covid-data-tracker">https://covid.cdc.gov/covid-data-tracker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

## **COVID-19 vaccines**

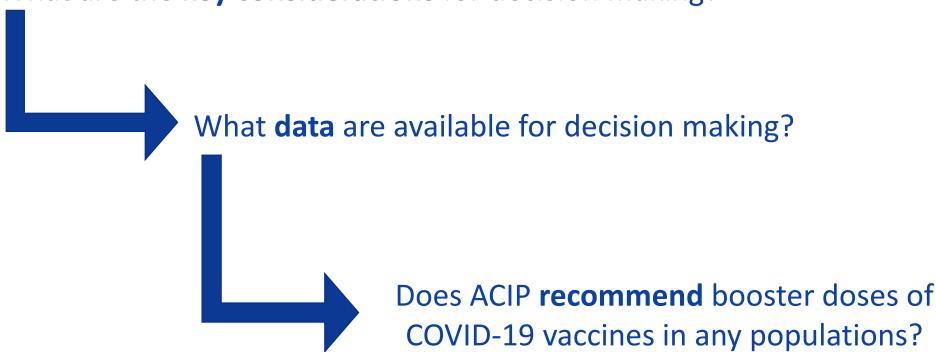
As of August 11, 2021

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



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 6 receipt of the single dose of the Janssen vaccine; CDC. https://covid.cdc.gov/covid-data-tracker

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



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

ACIP Meeting Aug 13: Framework for COVID-19 booster doses presented



What data are available for decision making?

ACIP Meeting Aug 30: Begin to provide data to inform booster dose policy



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

Do we need them?

Do they work?

Public Health Problem

Is vaccine effectiveness (VE) waning over time?

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

Does the need vary by sub-population?

Benefits and Harms

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

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

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

### Data to inform recommendations

Public Health Problem Is vaccine effectiveness (VE) waning over time?

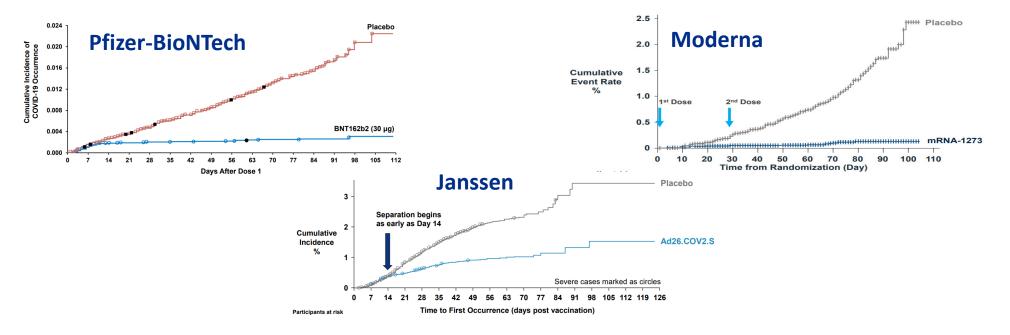
Is VE **recently** similar to what was noted at **2 months** after vaccination?

How do these data vary by **severity** of disease?

How do these data vary by **vaccine**?

## Is vaccine effectiveness waning over time?

Initial VE reviewed during EUA application



Will work with manufacturers to review longer-term follow up from clinical trials

## **Recent U.S. Publications**



Author	Publication (Date)	Population	Outcomes	Time Assessed
Tenforde et al.	MMWR (8/18/21)	Multi-state network of hospitalized adults	Hospitalization	March – July 2021
Rosenberg et al.	MMWR (8/18/21)	Adult residents of NY	Documented infection Hospitalization	May – July 2021
Nanduri et al.	MMWR (8/18/21)	Nursing home residents	Documented infection	March – July 2021
Fowlkes et al.	MMWR (8/25/21)	Healthcare workers and first responders in six states	Documented infection	Dec 2020 – July 2021
Puranik et al.	Preprint (8/9/21)	Adults within the Mayo Clinic health system	Documented infection Hospitalization	February – July 2021

Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March—July 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

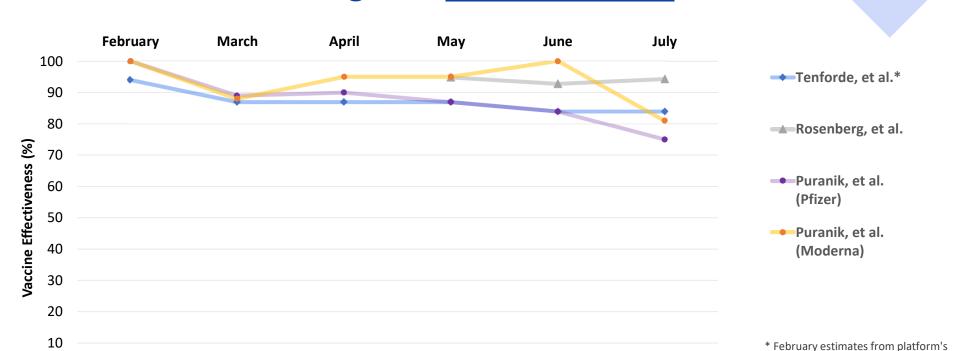
Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021 2021;70.

Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020—August 2021. MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021.

Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv 2021.08.06.21261707.

0

## Vaccine effectiveness against hospitalization



Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March—July 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021. MMWR Morb Mortal Wkly Rep 2021;70:674–679.

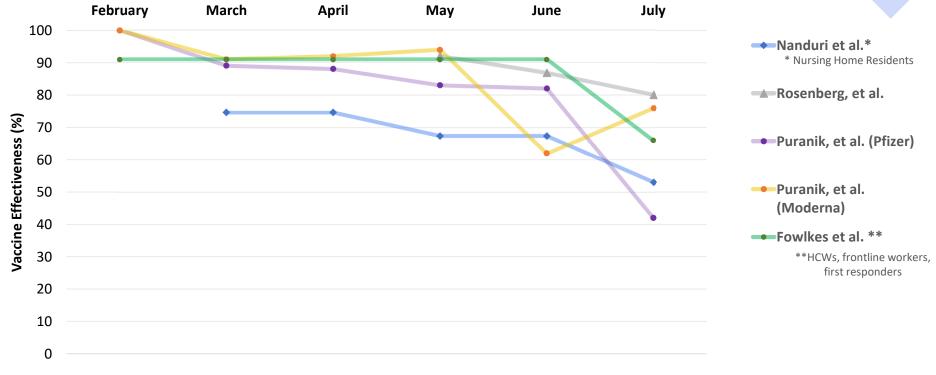
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3—July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv 2021.08.06.21261707.

Public Health

**Problem** 

May 2021 MMWR

## Vaccine effectiveness against infection



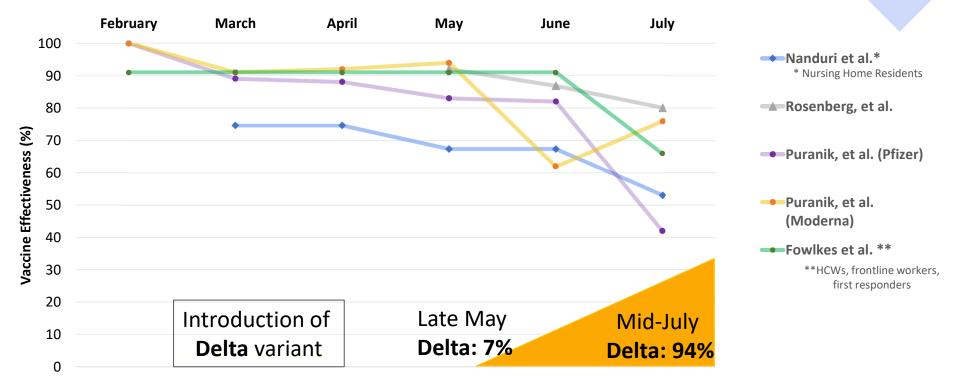
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3—July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1—August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021 2021;70.

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## Vaccine effectiveness against infection



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Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv 2021.08.06.21261707.

15

Public Health

**Problem** 

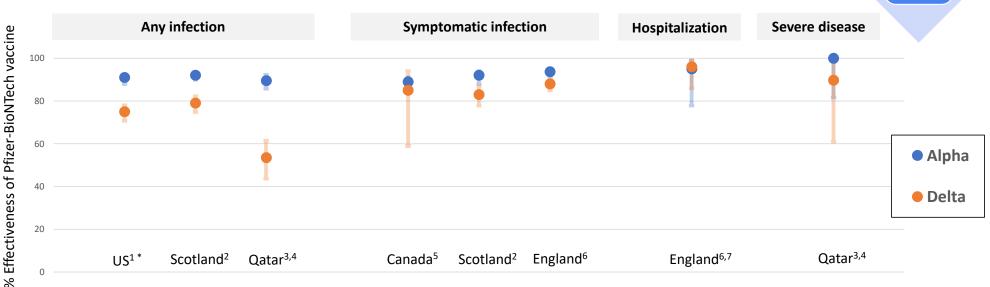
### Data to inform recommendations

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: Is effectiveness reduced because of the Delta variant?



Public Health

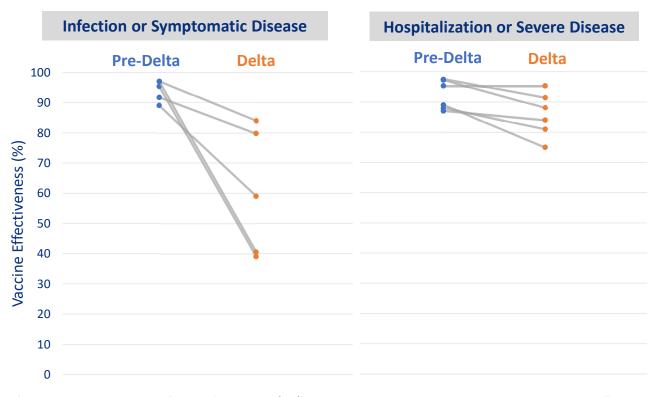
**Problem** 

17

- Globally, among studies assessing infections with Alpha vs Delta: mild decrease in Delta VE<sup>1-7</sup>
- Other factors may include study methods, interval between doses, and timing with vaccination and variant increases

References: 1. Tartof et al. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3909743 2. Sheikh A, et al. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01358-1/fulltext 3. Tang et al. https://www.medrxiv.org/content/10.1101/2021.08.11.21261885v1 4. Abu-Raddad et al. https://www.nejm.org/doi/full/10.1056/NEJMc2104974 5. Nasreen S, et al. https://www.medrxiv.org/content/10.1101/2021.06.28.21259420v2 6. Bernal Lopez et al. https://www.medrxiv.org/content/10.1101/2021.05.22.21257658v1 7. Stowe et al. https://khub.net/web/phenational/public-library/-/document\_library/v2WsRK3ZlEig/view/479607266 \*Included other variants

### Vaccine effectiveness in the Pre-Delta and Delta Periods

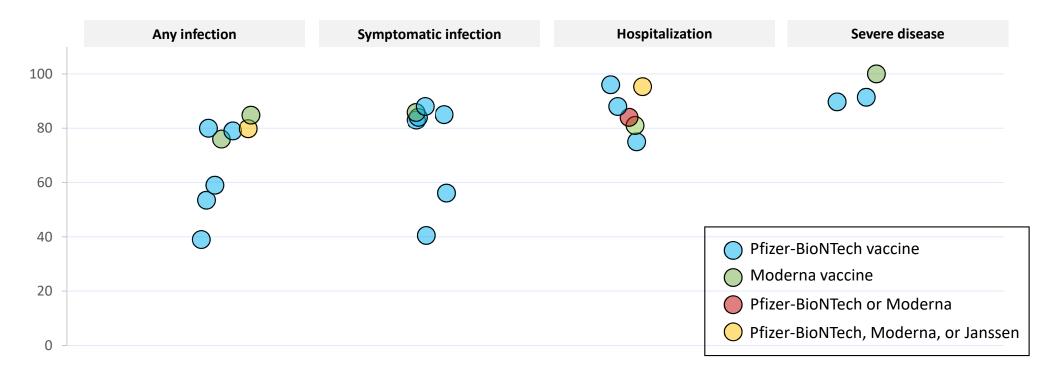


In studies comparing the 'Pre-Delta' and 'Delta' periods:

- Pre-Delta vaccine effectiveness estimates high (87% or higher)
- Since the introduction of the Delta variant (varies by region)
  - VE against **infection** ranges from **39–84%**
  - VE against hospitalization ranges from 75–95%

References: 1. Israel Ministry of Health (committee/he/files\_publications\_corona\_two-dose-vaccination-data.pdf) 2. Haas et al. (Israel) https://doi.org/10.1016/S0140-6736(21)00947-8 3. Pouwels et al. (UK) survey/finalfinalcombinedve20210816.pdf 4. Puranik https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v2 5. Rosenberg (US) https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm 6. Tenforde (US) https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm

### Summary of vaccine effectiveness estimates since introduction of the Delta variant



- Vaccines remain effective in preventing hospitalization and severe disease but might be less effective in preventing infection or milder symptomatic illness
- Reasons for lower effectiveness likely include both waning over time and Delta variant

19

### Data to inform recommendations

Public Health Problem Does the need vary by **sub-population**?

Adults ≥65 years of age

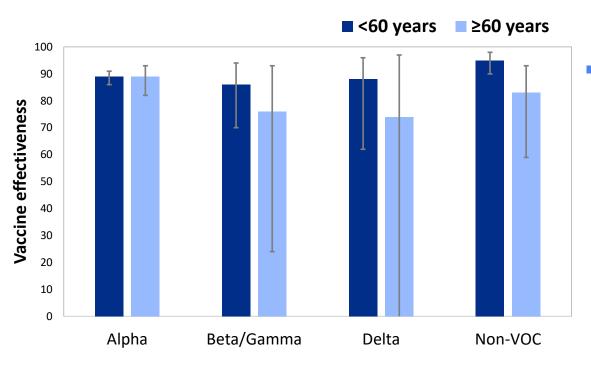
Residents of long-term care facilities

Healthcare personnel

## Adults ≥60 years of age

#### VE for **symptomatic infection**

≥7 days after dose 2, Pfizer-BioNTech vaccine





some decreases noted against VoC

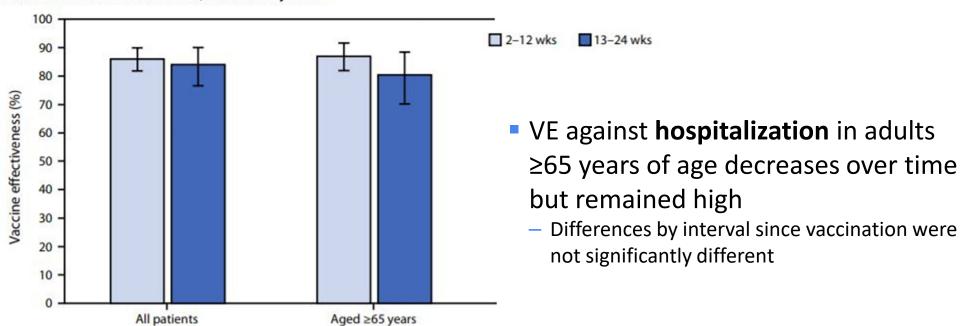
 Differences were not significantly different: small numbers and wide confidence intervals



# **Booster doses of COVID-19 vaccines:** Adults ≥65 years of age

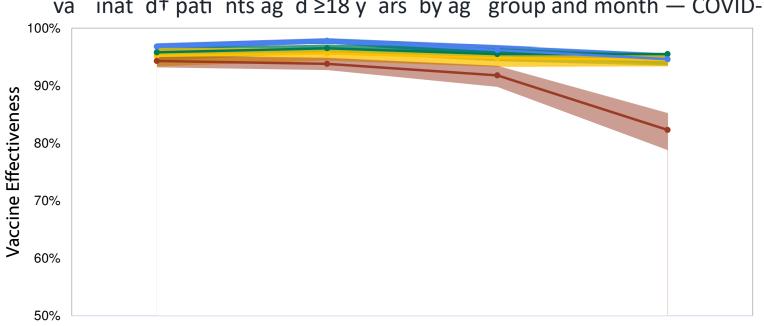


FIGURE 2. Sustained vaccine effectiveness\* against COVID-19 among hospitalized adults, by patient status<sup>†,§</sup> and interval since vaccination — 21 medical centers in 18 states, ¶ March–July 2021



## Adults ≥65 years of age

Preliminary VE against COVID-19—associated **hospitalization** among fully inat d<sup>†</sup> pati nts ag d ≥18 y ars by ag group and month — COVID-NET



May

Preliminary VE against hospitalization in adults ≥75 years of age decreased in July, but remains >80%

Sour : Unpublish d COVID-NET data

**April** 

--- 18-49 years

†Fully va inat d patints riv d both dos s of od rna or fiz r-BioNT h va in with sond dos riv d ≥14 days b for hospitalization or a singledos of Janssen (Johnson & Johnson)

→ 50-64 years → 65-74 years → 75 years and up

June

July

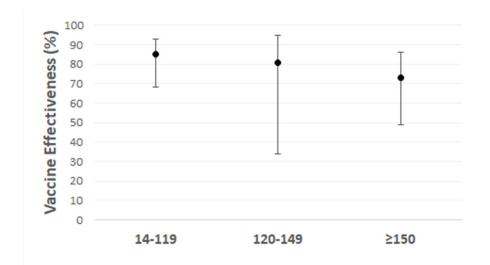
va in ≥14 days b for hospitalization

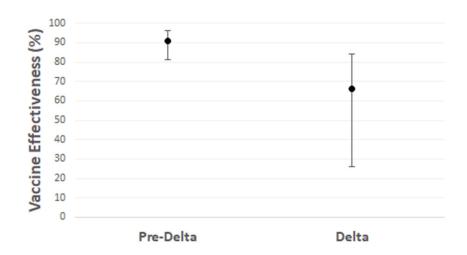


## Healthcare personnel



- VE against infection among frontline workers (including healthcare personnel) declined somewhat over time and from the pre-Delta period to Delta period
  - VEs were not significantly different



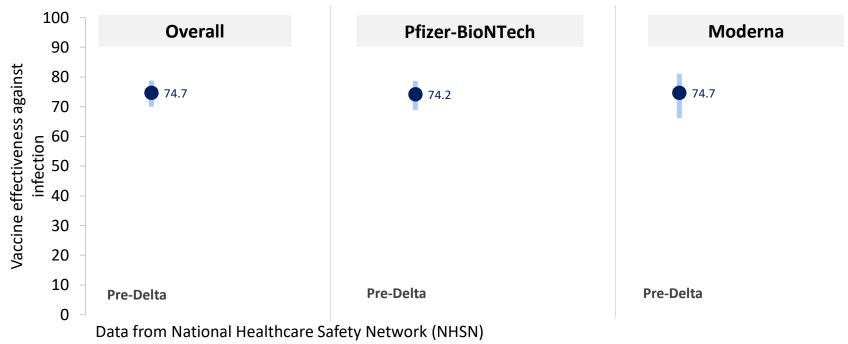


#### Data from HEROES-RECOVER Cohort

## Long-term care facility residents



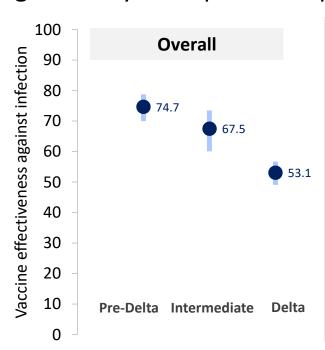
Initially, VE against infection among long-term care facility residents was high

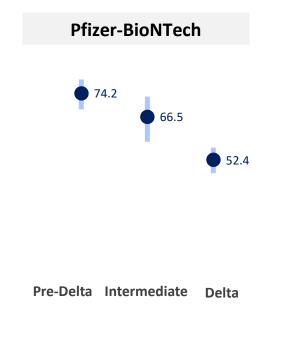


Adapted from: Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021;70. Slide courtesy of Ian Plumb.

## Long-term care facility residents

 VE against infection among long-term care facility residents differed significantly from pre-Delta period to Delta period

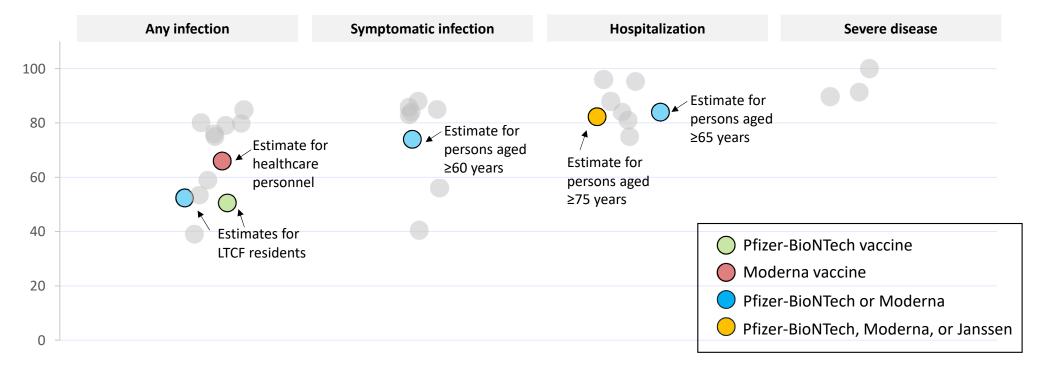






Adapted from: Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021;70. Slide courtesy of lan Plumb.

#### Summary of vaccine effectiveness estimates since introduction of the Delta variant



- Lower vaccine effectiveness estimated against infection for long term care facility resident
- Vaccine effectiveness among older age groups and healthcare personnel comparable with other subgroups; follow up needed to monitor VE estimates over time

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### 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: Are booster doses safe and immunogenic?



- Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) conducting studies to evaluate safety and immunogenicity of COVID-19 vaccine booster doses
- Important to include sufficient safety data for booster doses

### Data to inform recommendations

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

Benefits and Harms

Will booster doses reduce COVID-19 morbidity and mortality?

Benefits and Harms

 Evaluating data available to assess the potential impact of COVID-19 booster doses in a variety of populations and settings

### Data to inform recommendations

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

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

Benefits and Harms

## Do booster doses improve VE against Delta and other VoC?



- Immunogenicity data (including sera from study participants who received a booster dose) can evaluate neutralizing antibody data for variants of concern (including Delta)
- No correlate of protection available, but growing understanding around impact of neutralizing antibodies
  - Can infer impact of booster doses on neutralizing antibodies to clinical protection (VE) against Delta and other VoC

## Data to inform recommendations



Are booster doses of COVID-19 feasible to implement?

## Are booster doses feasible to implement?



- Some aspects of implementation will be more feasible than primary series roll-out:
  - Supply and number of vaccination sites not a serious limitation
- Some aspects of implementation will be more complex:
  - Different primary series
    - Individuals received a variety of primary series
    - Upcoming data will evaluate booster response for same (homologous) and different (heterologous) series
    - Booster dose policy will need to address individuals who received all primary series
  - Different doses
    - Some COVID-19 vaccine booster studies have evaluated various doses for booster vaccines for the same product

## **Summary and Work Group Considerations**



# **Booster doses of COVID-19 vaccines:** Summary

- Not uncommon for a vaccine series to require several doses
- Vaccines that require >1 dose do not necessarily mean annual boosters needed
  - For many vaccines, the final dose is given at least 6 months after the initial dose

Sample of adult vaccines requiring >1 dose	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose
Herpes zoster (shingles)	Initial	2-6 months	
Hepatitis A	Initial	6 months	
Hepatitis B	Initial	1-2 months	6-18 months
Human papillomavirus (HPV) (Age ≥15 at initial vaccination)	Initial	1-2 months	6 months

# **Summary**



Initial dose(s) of vaccine: **Prime** 



**B-cells** 

**Antibodies** 



T-cells





**Time** between the doses can allow for a 'boosting' effect with the immune system



Subsequent doses of vaccine:

**'Boost' Effect** 



A

**B-cells** 











# Summary

- COVID-19 vaccines continue to maintain high protection against severe disease, hospitalization, and death
- Protection against infection (including asymptomatic or mild infections) appears lower in recent months
  - Difficult to distinguish role of time since primary series and Delta variant
- Reported data through July; data through August shown at future ACIP meetings
  - Important to monitor **trends** of effectiveness by severity of disease over time
- Policy around booster doses requires <u>continued evaluation</u> of effectiveness, monitoring impact of both time and variants, and ability of booster doses to improve protection

# Recommendations for Allocation of Initial Doses of COVID-19 Vaccines December 2020–Early 2021

#### Phase 1a

LTCF Residents
Healthcare Personnel

#### Phase 1b

Adults ≥75 years of age Frontline Essential Workers

#### Phase 1c

Adults ≥65 years of age
All Essential Workers
Adults 16-64 years of age with
high-risk medical conditions

Highest Risk Individuals

- Early in vaccine roll-out, ACIP voted for arisk-based approach to allocation of COVID-19 vaccines
- Variation in implementation across states/jurisdictions

# Work Group considerations

- Top priority should be continued vaccination of unvaccinated individuals
  - Planning for delivery of booster doses to vaccinated individuals should not deter outreach for delivery of <u>primary series</u> to <u>unvaccinated individuals</u>
- Priority for booster dose policy:
   Prevention of severe disease in at-risk populations
- Simplicity and flexibility will be important to support equitable and efficient delivery of booster doses

# Work Group considerations

- Important to ensure global vaccine availability
  - Uncontrolled spread globally that could result in new variants threaten control
    of the pandemic everywhere
- Policy around booster doses should also consider equity in the U.S. population
  - Access to booster doses may vary by population and setting
  - Lessons learned around equitable access in early primary series roll-out

# Work Group considerations

- In addition to immunogenicity data, need to review available safety data for booster doses
- Balance of benefits and risks for booster doses may vary by age
  - Policy for booster doses needs to take this benefit/risk balance into account
- Critical to wait for additional safety data and regulatory allowance for booster doses

# Work Group considerations

- At this time, the Work Group discussed a risk-based approach for booster dose recommendations
  - Prevent severe disease in the most at-risk populations:

LTCF residents

Older adults (≥65 or ≥75 years of age)

— Support strained healthcare infrastructure:

Healthcare personnel with mild disease cannot work, so prevention of mild disease takes on greater importance as a public health goal in this population

- Time since vaccination with primary series also important
  - For many vaccines, a minimum interval beneficial for full 'boosting effect'
  - Ability to benefit from 'boosting effect' extends well beyond the minimum interval

Recommendations for Allocation of Initial Doses of COVID-19 Vaccines

Phase 1a

LTCF Residents
Healthcare Personnel

**Highest Risk Individuals** 

Phase 1b

Adults ≥75 years of age Frontline Essential Workers

Phase 1c

Adults ≥65 years of age
All Essential Workers
Adults 16-64 years of age with
high-risk medical conditions

Time since recommendation

Recommendations for Allocation of Initial Doses of COVID-19 Vaccines

#### Phase 1a

LTCF Residents
Healthcare Personnel

Phase 1b

Adults ≥75 years of age Frontline Essential Workers

Phase 1c

Adults ≥65 years of age
All Essential Workers
Adults 16-64 years of age with
high-risk medical conditions

**Highest Risk Individuals** 

Time since recommendation

<u>Possible</u> Recommendations for <u>Initial</u> Booster Doses

**Highest Risk Individuals** 

LTCF Residents
Healthcare Personnel
Adults ≥65/75 years of age

Time interval since receipt of last dose

ACIP will continue to review additional data:

Manufacturer data on safety + immunogenicity of booster doses

Effectiveness, breakthrough infections and epi data through August

 Further discussions around feasibility, implementation, and balance of benefit and risks by age group and population

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

ACIP Meeting Aug 13: Framework for COVID-19 booster doses presented



What data are available for decision making?

ACIP Meeting Aug 30: Begin to provide data to inform booster dose policy



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

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

ACIP Meeting Aug 13: Framework for COVID-19 booster doses presented



# What data are available for decision making?

ACIP Meeting Aug 30: Begin to provide data to inform booster dose policy

**ACIP Meeting mid-September:** Additional data to inform policy



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

**ACIP Meeting after FDA authorization:** Possible vote

# **Acknowledgements**

- Kathleen Dooling
- Heidi Moline
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- Heather Scobie

- Eddie Shanley
- Megan Wallace
- Neela Goswami
- Kristine Schmidt

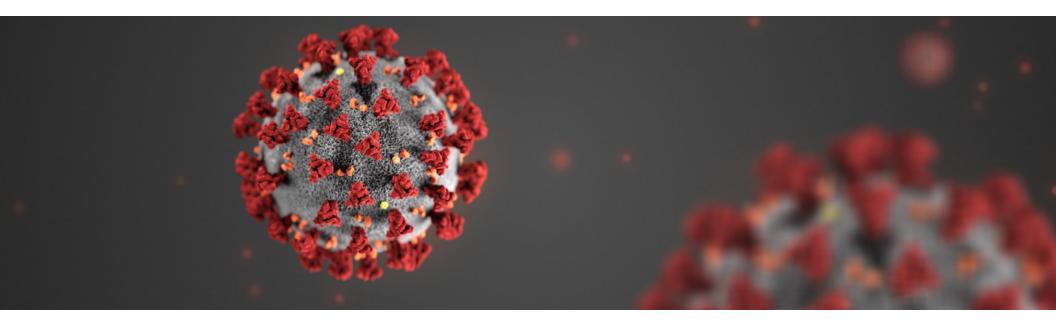
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

## **Questions for ACIP**

- 1. Does ACIP agree with the proposed risk-based approach for COVID-19 booster dose recommendations?
- 2. What other questions would be important for ACIP to address?

# Reference list for recent estimates of vaccine effectiveness against the Delta variant

- 1. Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance Eight U.S. Locations, December 2020–August 2021. MMWR Morb Mortal Wkly Rep 2021;70:1167-1169.
- 2. Bernal JL, Andrews N, Gower C, Gallagher E, Simmons R, Thelwall S, et al. Effectiveness of COVID-19 vaccines against the B.1.617.2 variant. medRxiv. 2021:2021.05.22.21257658
- 3. Israel Ministry of Health. COVID-19 Weekly Data (8/11/21). https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files\_publications\_corona\_two-dose-vaccination-data.pdf
- 4. Lopez Bernal J, Andrews N, Gower C, Gallagher E, Simmons R, Thelwall S, et al. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. New England Journal of Medicine. 2021 2021/08/12;385(7):585-94.
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