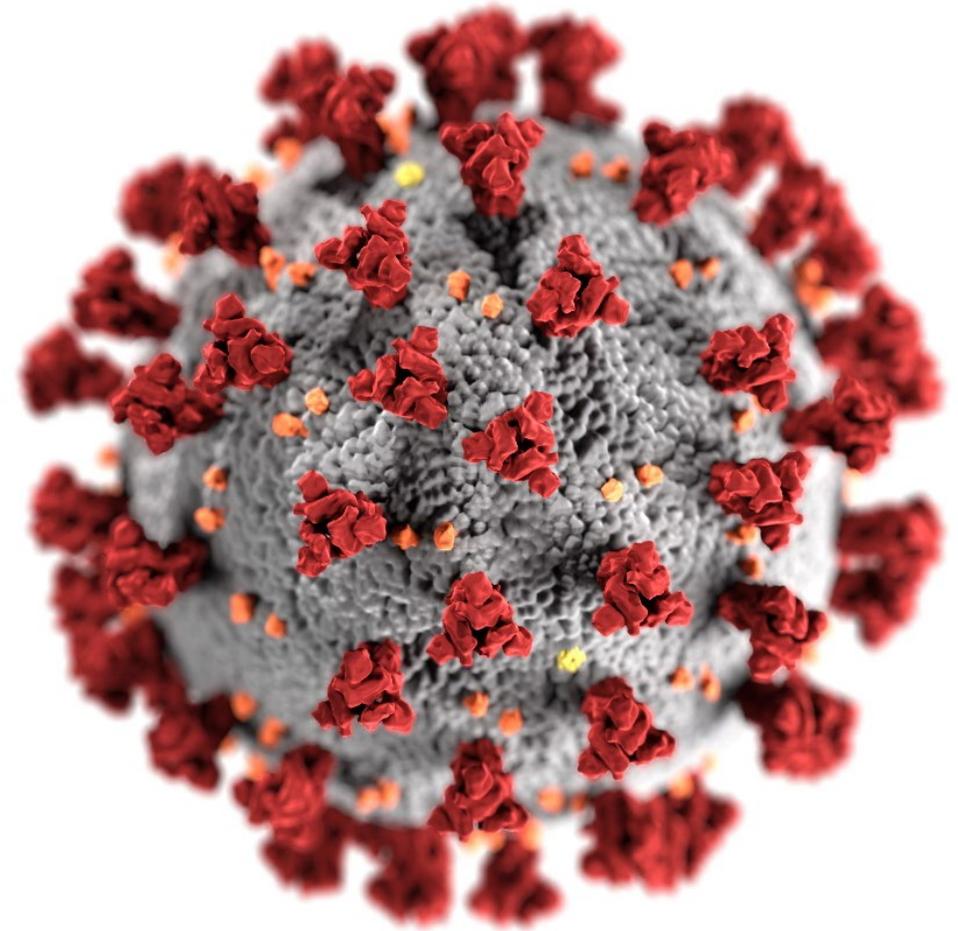


**Vaccines and Related Biological Products
Advisory Committee September 17, 2021
Meeting Presentation**

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

Updates to COVID-19 Epidemiology and COVID-19 Vaccines

Sara Oliver MD, MSPH
VRBPAC Meeting
September 17, 2021



cdc.gov/coronavirus

COVID-19 Epidemiology and COVID-19 Vaccines

- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

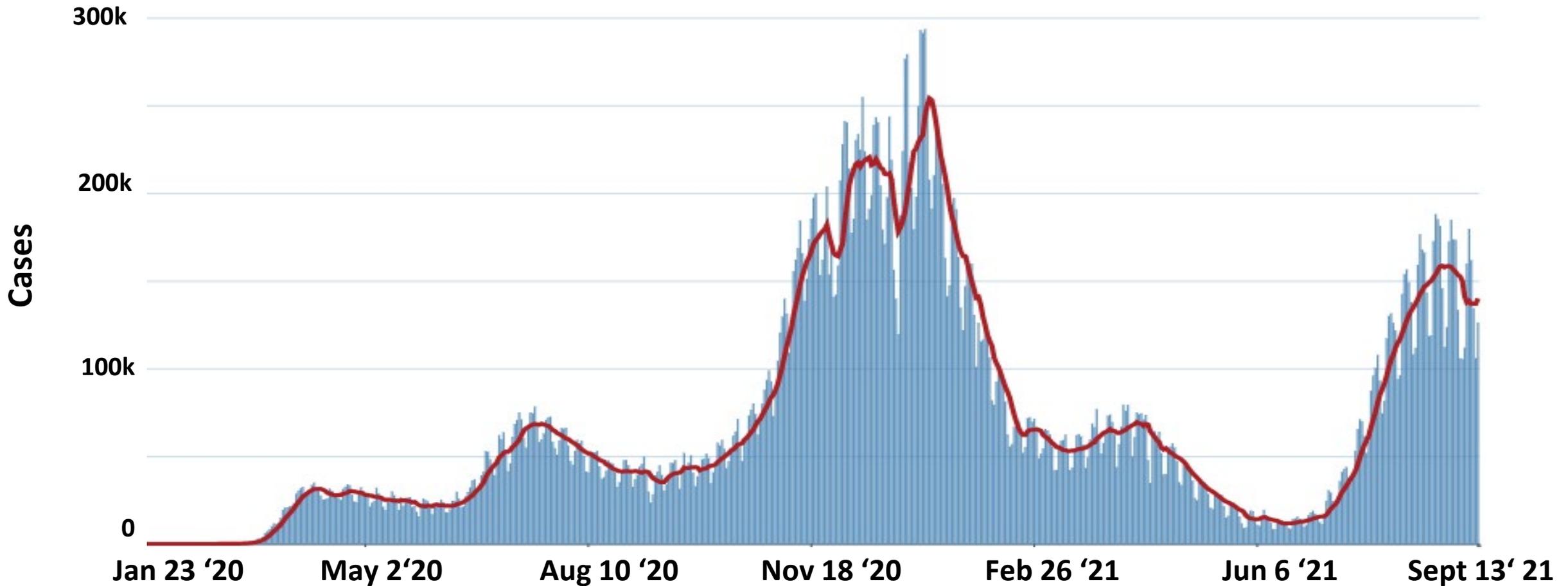
COVID-19 Epidemiology and COVID-19 Vaccines

- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

Daily Trends in Number of COVID-19 Cases in the U.S.

January 23, 2020 – Sept 13, 2021

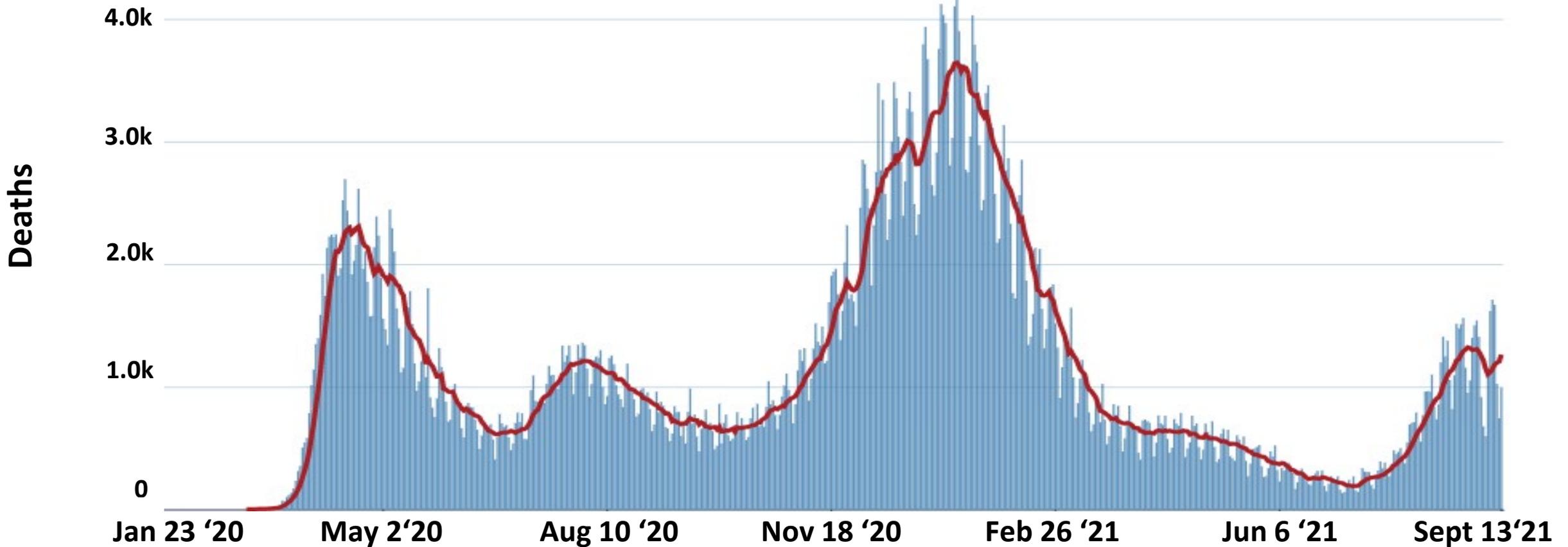
Cases Total **41,262,574**



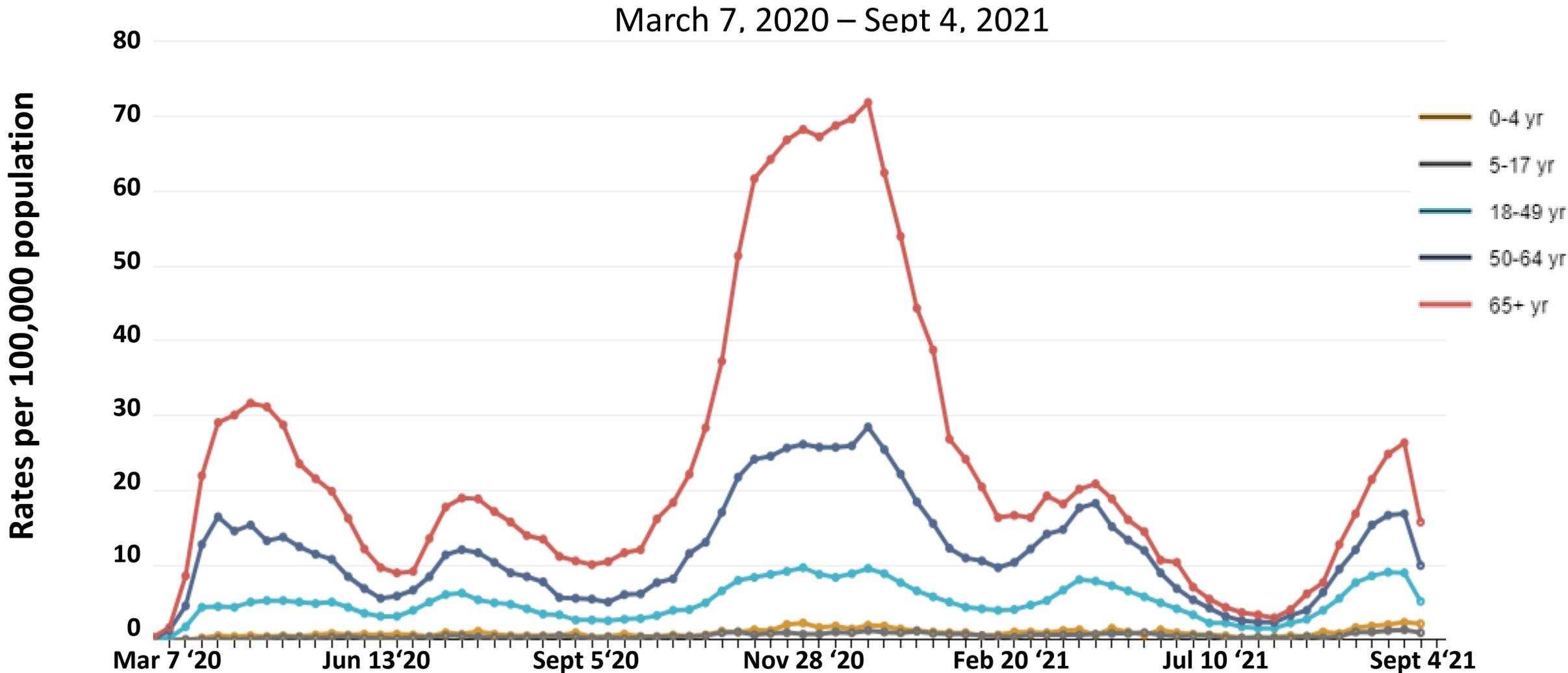
Daily Trends in Number of COVID-19 Deaths in the U.S.

January 23, 2020 – Sept 13, 2021

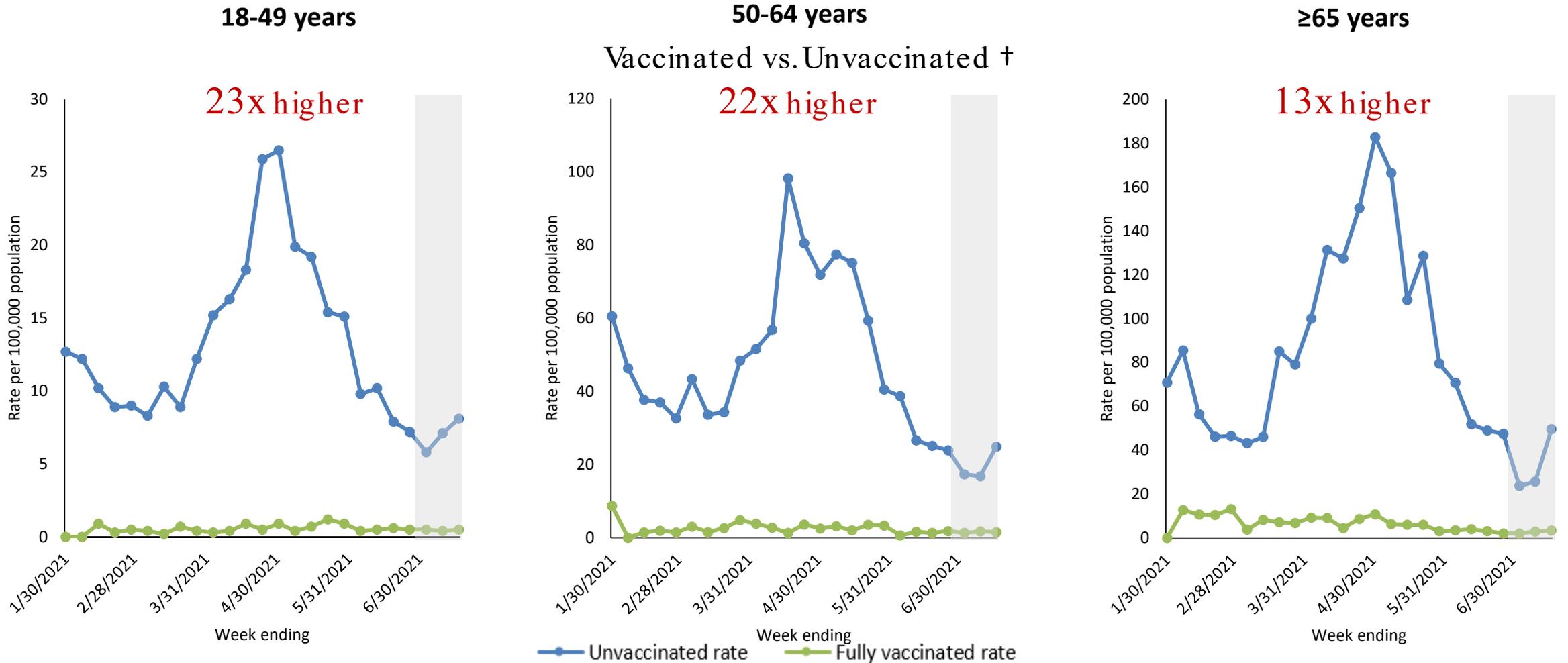
Deaths Total 660,380



Weekly Trends in COVID-19 Associated Hospitalization Rates in the U.S.



Age-adjusted weekly COVID-19-associated hospitalization rates among adults by week of admission and age group*—COVID-NET, January 24–July 17, 2021

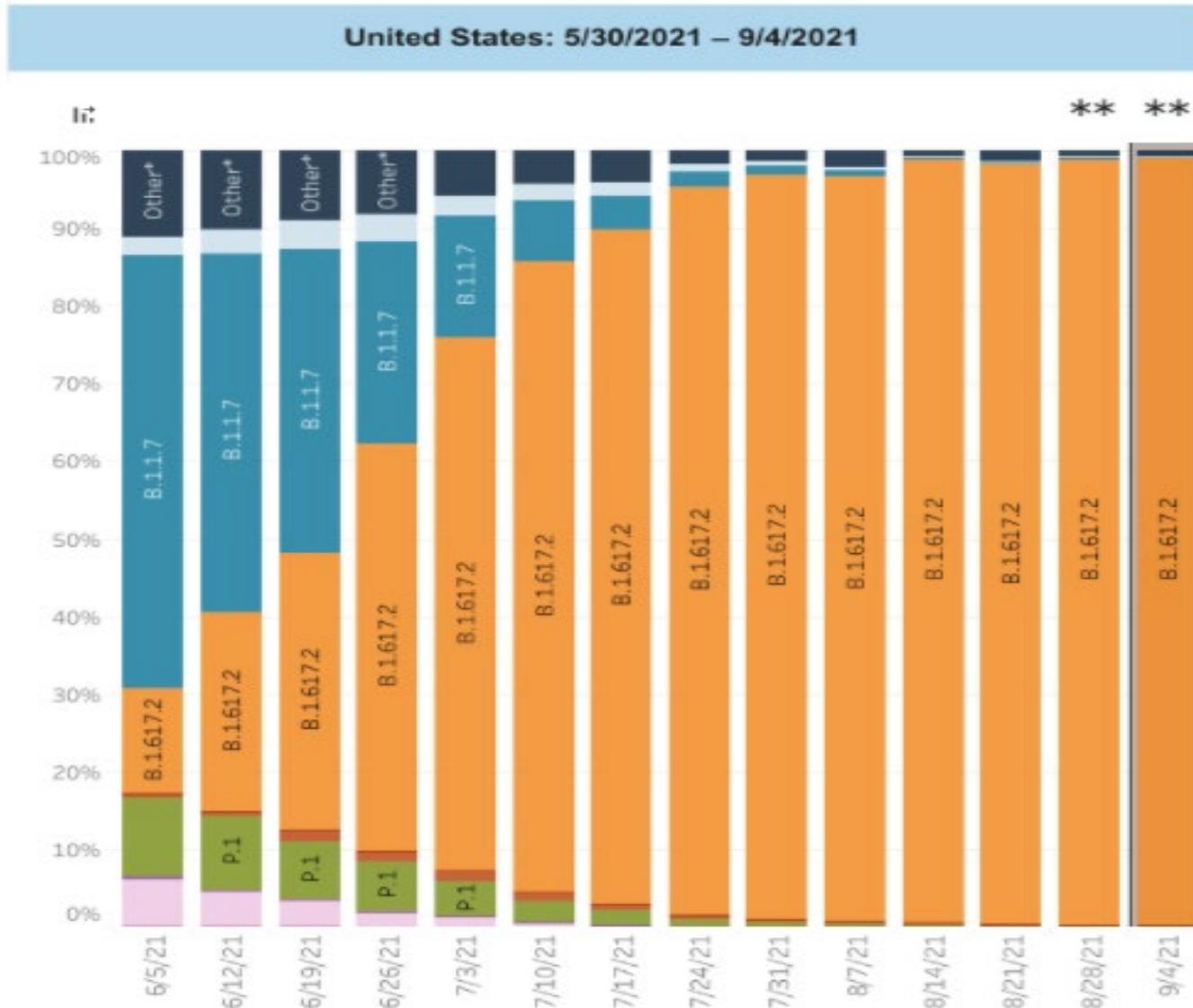


*Data are preliminary and case counts and rates for recent hospital admissions are subject to lag. As data are received each week, prior case counts and rates are updated accordingly.

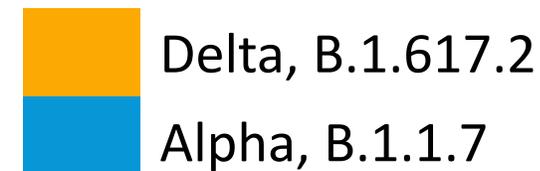
†Cumulative rate ratio from January 24 – July 17, 2021. Shaded area indicates preliminary July data that does not include one site.

Havers et al. <https://medrxiv.org/cgi/content/short/2021.08.27.21262356v1>. COVID-19-associated hospitalizations among vaccinated and unvaccinated adults ≥18 years - COVID-NET, 13 states, January 1-July 24, 2021

Delta Is the dominant circulating SARS-CoV-2 variant



- Delta represents **99%** of recently sequenced lineages
- Delta is more than 2x as contagious than previous variants



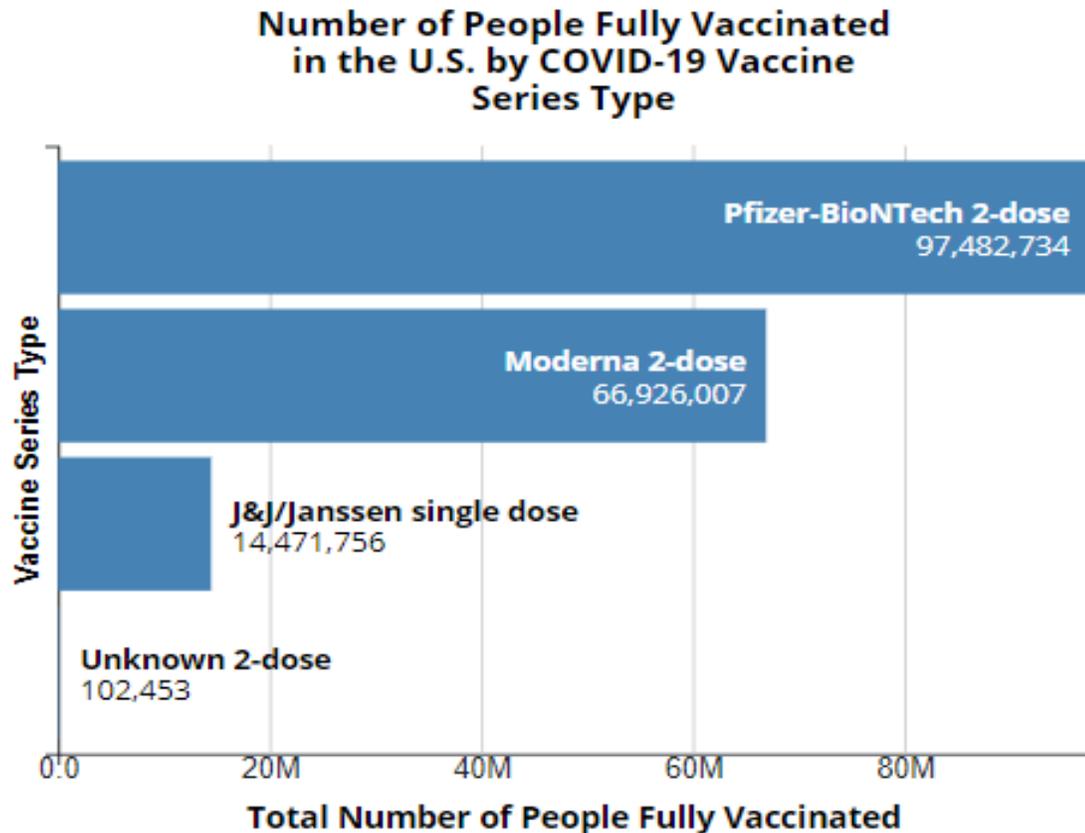
COVID-19 Epidemiology and COVID-19 Vaccines

- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

COVID-19 vaccines administered

**Total Vaccine Doses Administered:
380,831,725**

% of Population Fully Vaccinated:



**≥12 years of age:
63.1%**



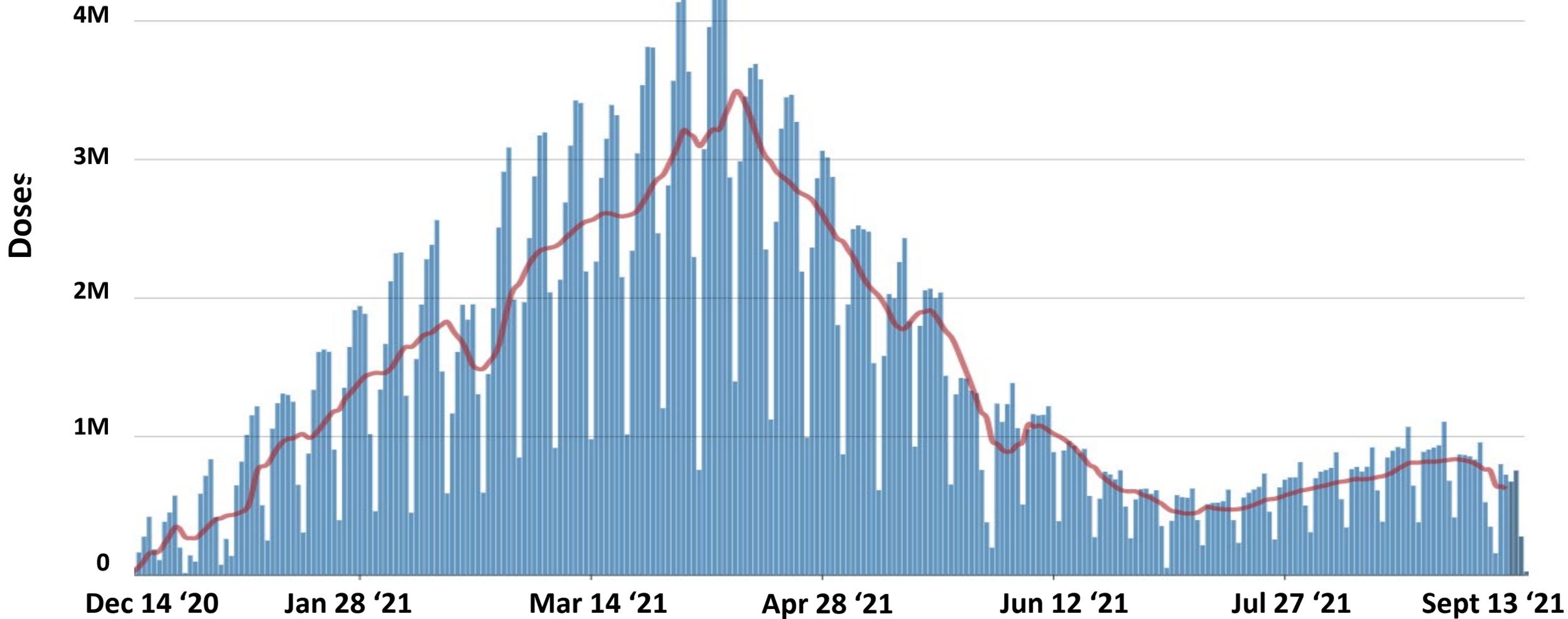
**≥18 years of age:
65.0%**



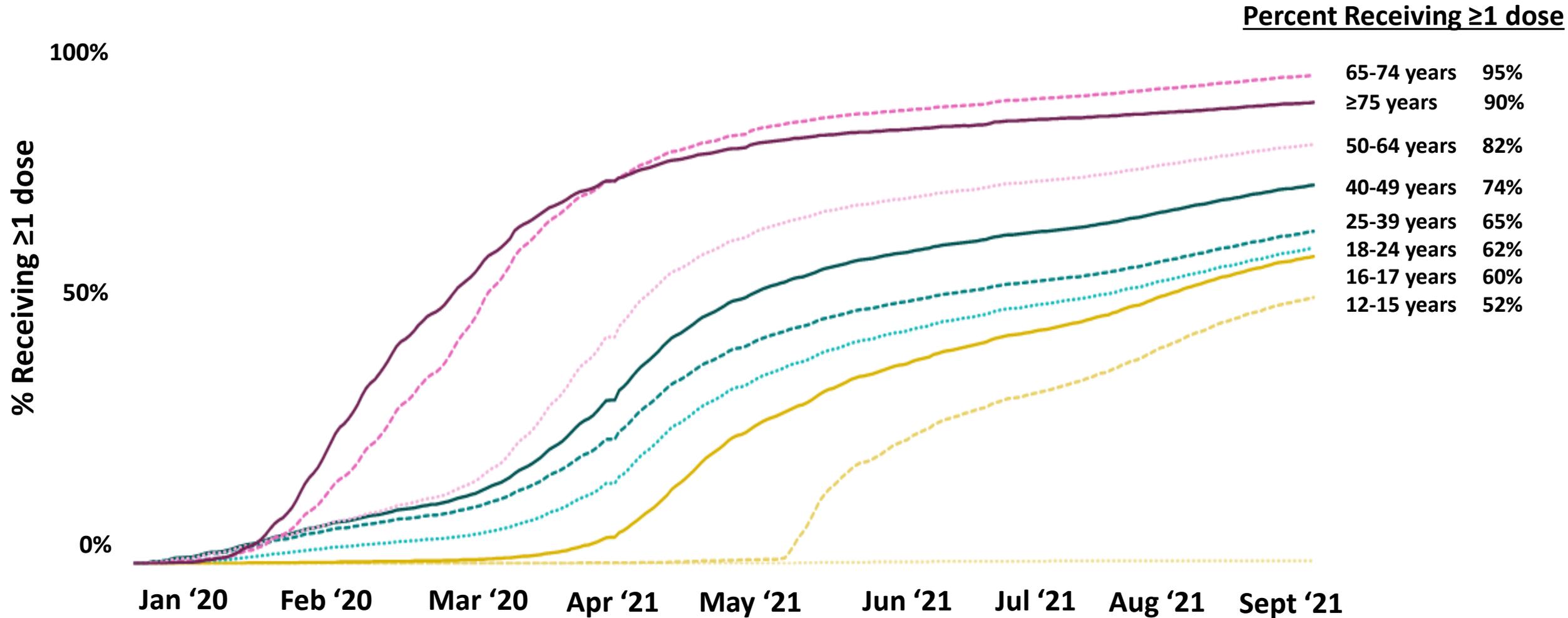
**≥65 years of age:
82.5%**

Daily Trends in Doses of COVID-19 Vaccine Administered

December 23, 2020 – Sept 13, 2021



COVID-19 Vaccination Coverage by Age



COVID-19 Epidemiology and COVID-19 Vaccines

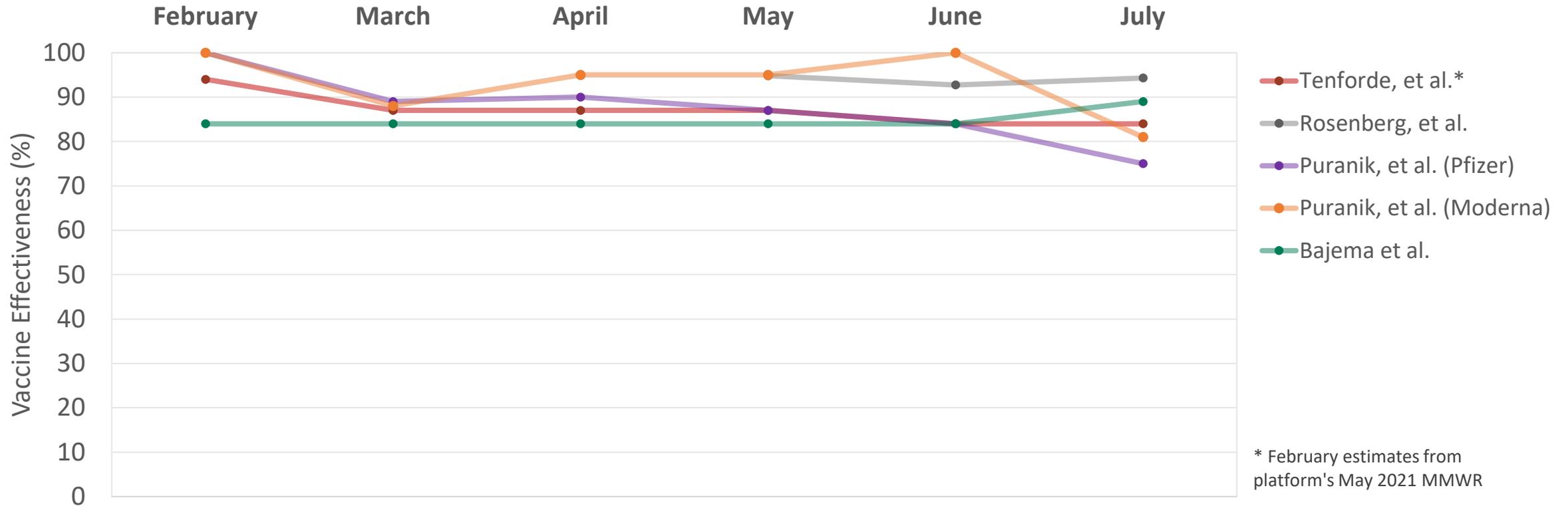
- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

Recent U.S. publications evaluating VE after primary series

Author	Publication	Population	Outcomes	Time Assessed
Puranik et al.	Preprint (8/9/21)	Adults within the Mayo Clinic health system	Documented infection Hospitalization	February – July 2021
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
Keehner et al.	NEJM (9/1/21)	UCSDH Healthcare workers	Documented infection	March – July 2020
Puranik et al.	Preprint (9/7/21)	Adults within the Mayo Clinic health system	Documented infection Hospitalization	Feb- August 2021
Thompson et al.	NEJM (9/8/21)	Ambulatory and hospitalized adults 50+	Hospitalization ICU admission	January – June 2021
Bruxvoort al.	Preprint (9/8/21)	Adults 18+ in Kaiser Permanente health system	Documented infection Hospitalization/Death	Dec 2020 – June 2021
Bajema et al.	MMWR (9/10/21)	Adults 65+ in VA system	Hospitalization	Feb – August 2021
Grannis et al.	MMWR (9/10/21)	Ambulatory and hospitalized adults 18+	Hospitalization Urgent care/ED visits	June – August 2021
Scobie et al.	MMWR (9/10/21)	Adults 18+	Documented infection Hospitalization, Death	April – July 2021

Vaccine effectiveness against hospitalization over time

Adults ≥ 18 years of age



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.

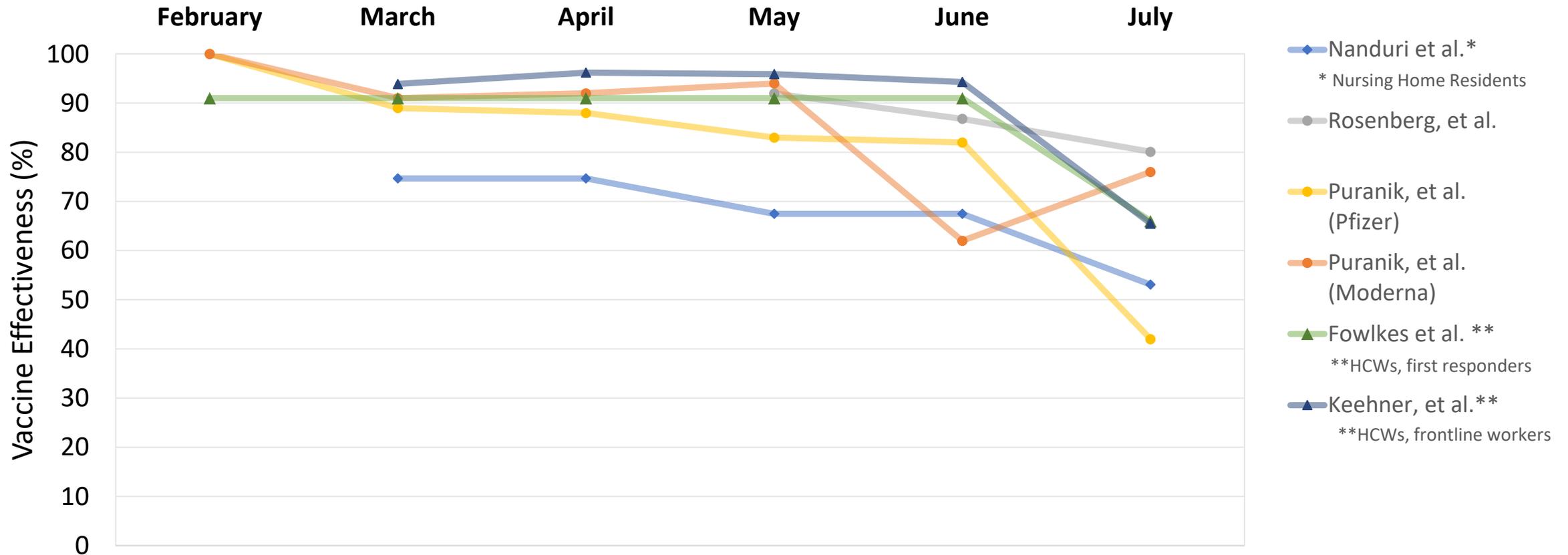
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

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.

Bajema KL, Dahl RM, Prill MM, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1–August 6, 2021. MMWR Morb Mortal Wkly Rep.

Vaccine effectiveness against infection over time

Adults ≥18 years of age



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.

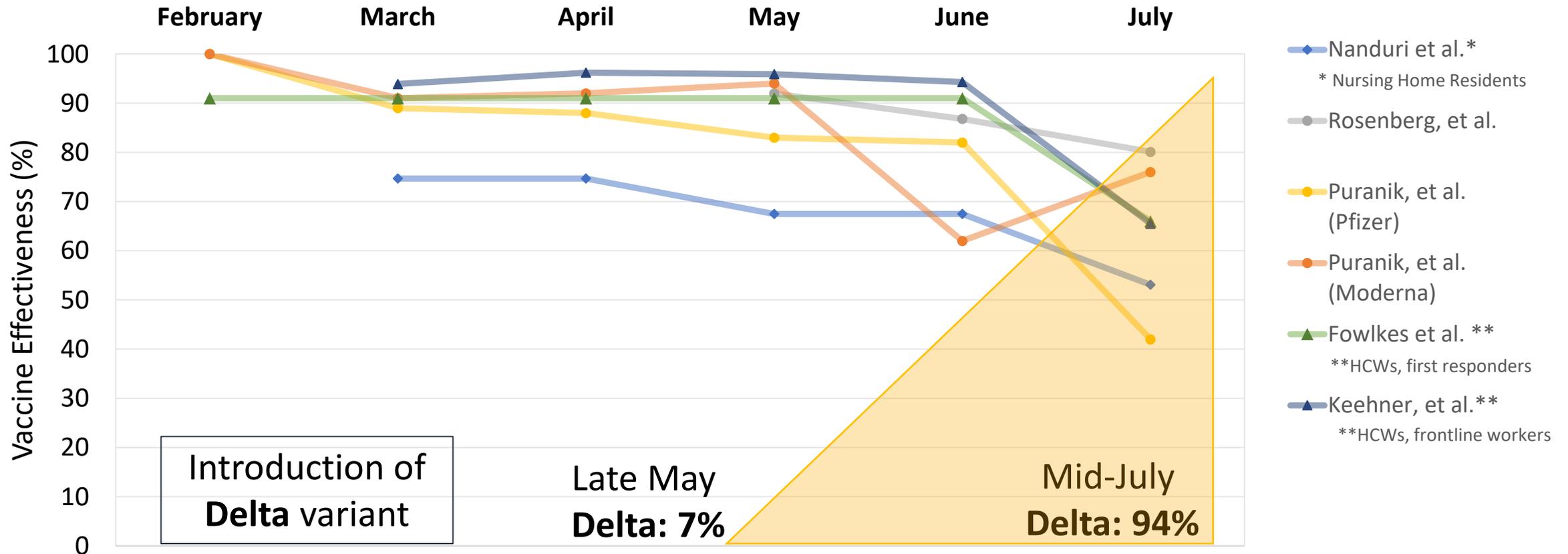
Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021.

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.

Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. NEJM, September 1, 2021. DOI: 10.1056/NEJMc2112981

Vaccine effectiveness against infection over time

Adults ≥ 18 years of age



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.

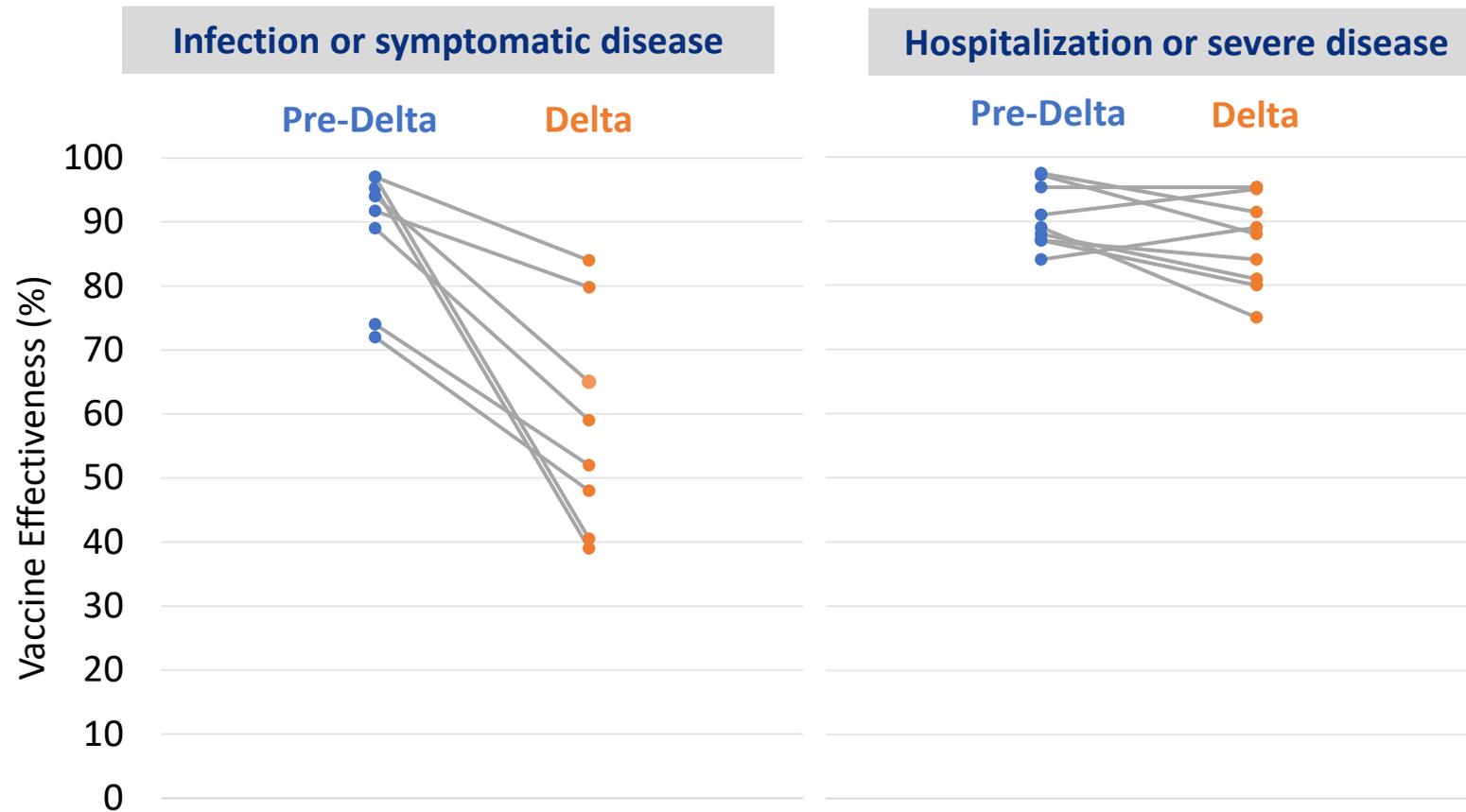
Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. NEJM, September 1, 2021. DOI: 10.1056/NEJMc2112981

COVID-19 Epidemiology and COVID-19 Vaccines

- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

Vaccine effectiveness, comparing **pre-Delta** to **Delta** time points

Adults ≥ 18 years of age



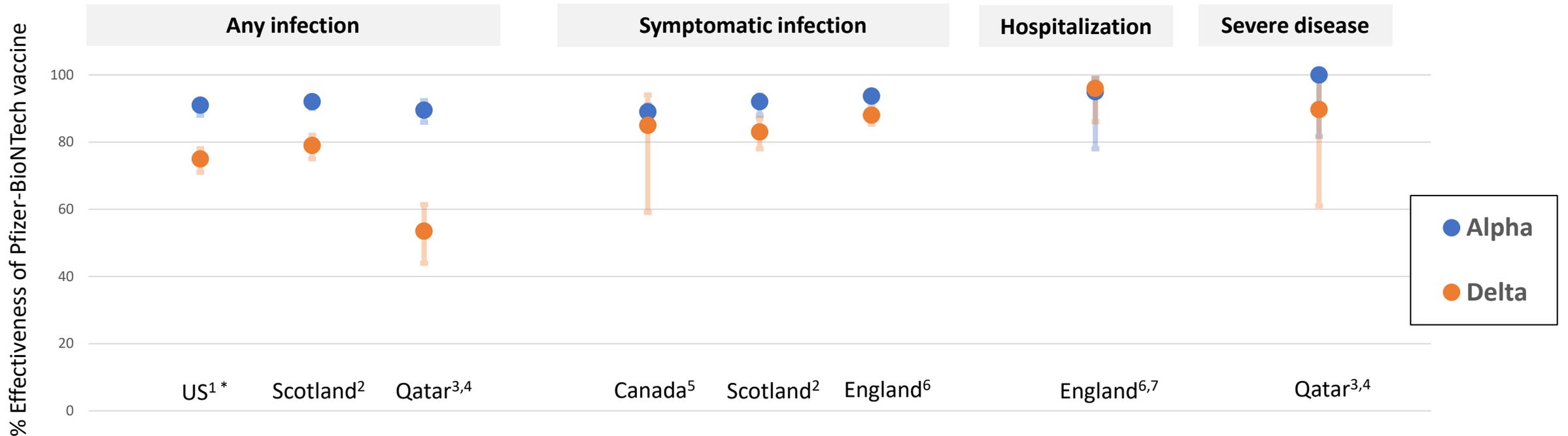
In studies comparing the pre-Delta and Delta periods:

- Pre-Delta estimates **high**
 - VE against **infection** ranges from **72–97%**
 - VE against **hospitalization** ranges from **84–97%**
- 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](https://doi.org/10.1016/S0140-6736(21)00947-8) 3. Pouwels et al. (UK) [survey/finalfinalcombinedve20210816.pdf](https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v2) 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> 7. Bajema (US) <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e3.htm> 8. Nanduri (US) <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm> 9. Keehner (US) <https://www.nejm.org/doi/full/10.1056/NEJMc2112981> 10. Thompson (US) <https://www.nejm.org/doi/full/10.1056> 11. Grannis (US) <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm>

Vaccine effectiveness, comparing **pre-Delta** to **Delta** time points

Adults ≥ 18 years of age, Pfizer-BioNTech COVID-19 vaccine



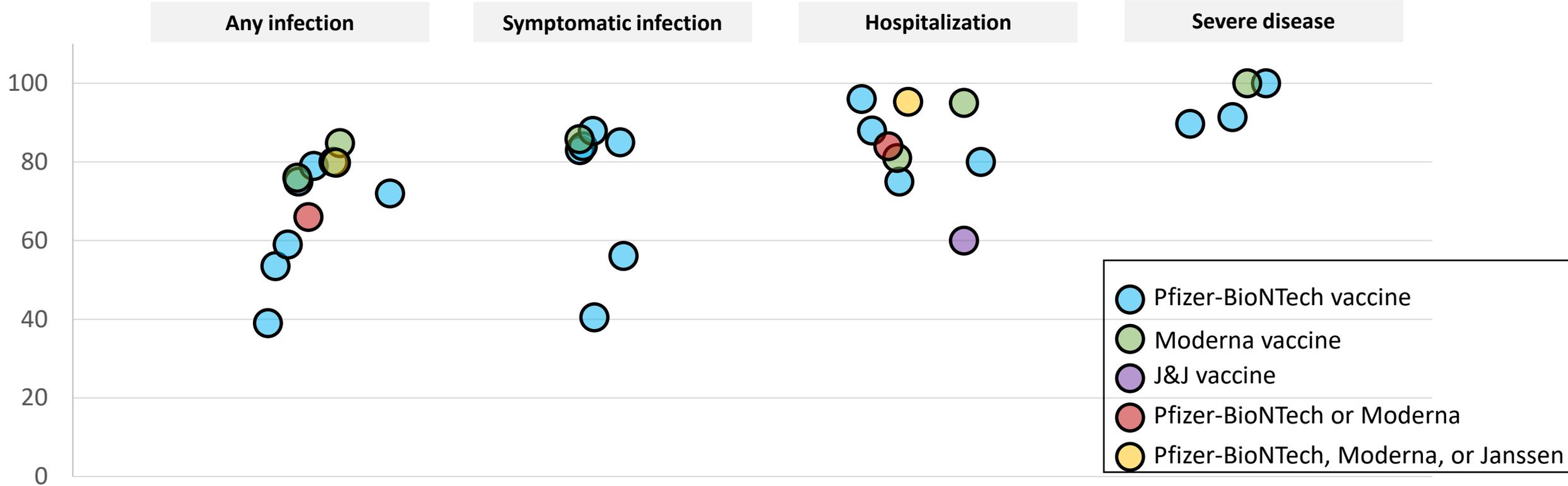
- Globally, among studies assessing infections with Alpha vs Delta: mild decrease in Delta VE¹⁻⁷
- Other factors may include study methods, **interval** between doses, and **timing** with vaccination and variant increases

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](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/v2WsRK3ZIEig/view/479607266 *Included other variants

Severe COVID-19 disease defined per WHO classification

Summary of **VE estimates** since introduction of the Delta variant

Adults ≥ 18 years of age



- 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**

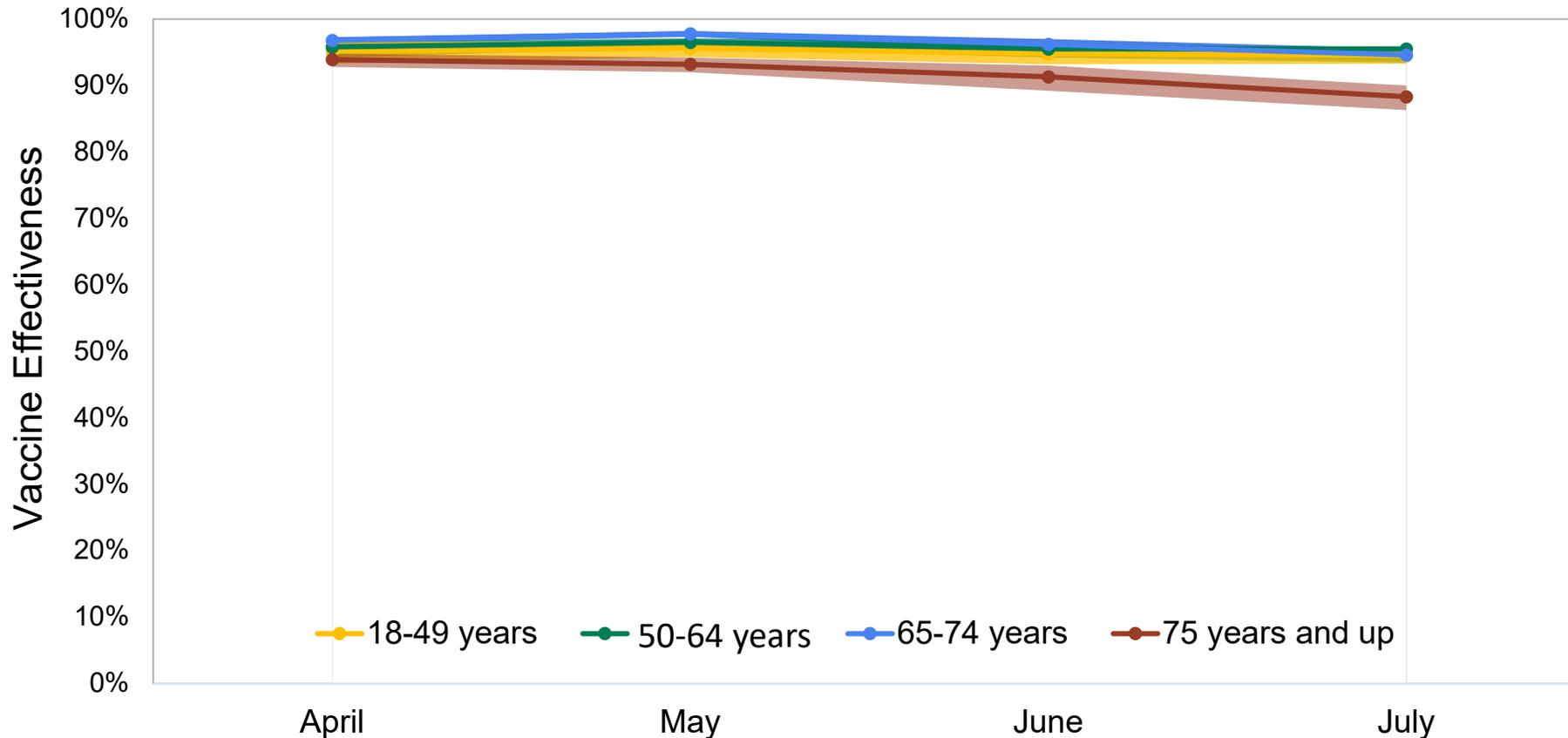
See reference list in later slides

COVID-19 Epidemiology and COVID-19 Vaccines

- COVID-19 cases and hospitalizations
- COVID-19 vaccines administered
- COVID-19 vaccine effectiveness (VE)
 - VE over time
 - VE for Delta variant
 - VE for older adults

Vaccine effectiveness against hospitalization, by month and age

Adults ≥ 18 years, U.S. (COVID-NET)



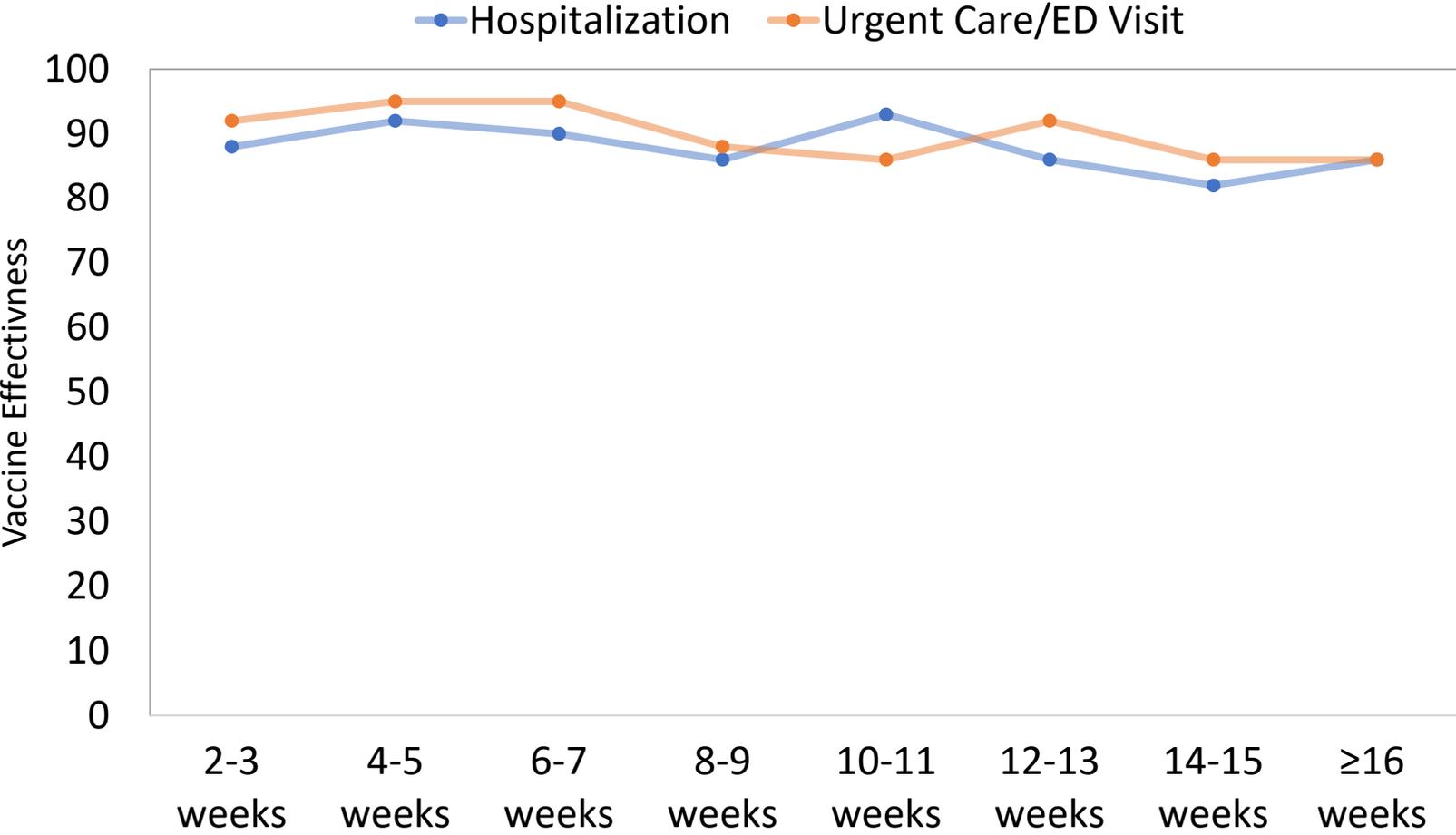
Updated COVID-NET data suggest VE against **hospitalization** in adults ≥ 75 years of age remains $>88\%$

Among **fully vaccinated patients**, defined as receipt of both doses of Moderna or Pfizer-BioNTech vaccine, with second dose received ≥ 14 days before hospitalization, or a single dose of Janssen (Johnson & Johnson) vaccine ≥ 14 days before hospitalization

Source: Unpublished COVID-NET data

Vaccine effectiveness against hospitalization by time since vaccination

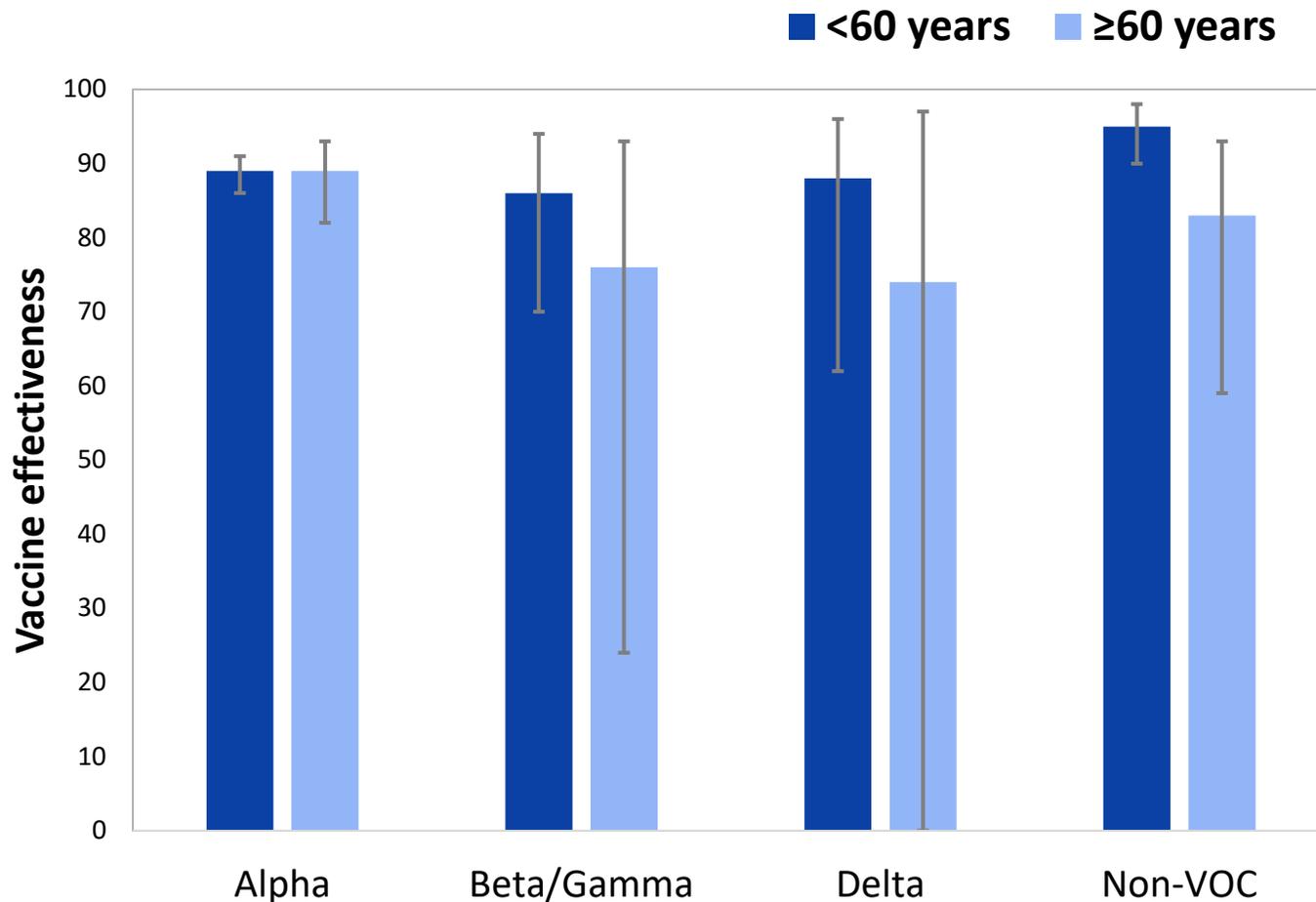
Adults ≥50 years, U.S.



VE against both **hospitalization** and **urgent care/ED visits** remained consistently high ($\geq 82\%$) through at least 16 weeks after the second dose

Hospitalizations occurred from January 1 to June 22, 2021

Vaccine effectiveness against symptomatic infection, by VoC and age Adults ≥ 18 years, Canada



VE against **symptomatic infection** in adults ≥ 60 years of age is high, but some decreases noted against VoC

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

Time period: December 14, 2020 to May 30, 2021

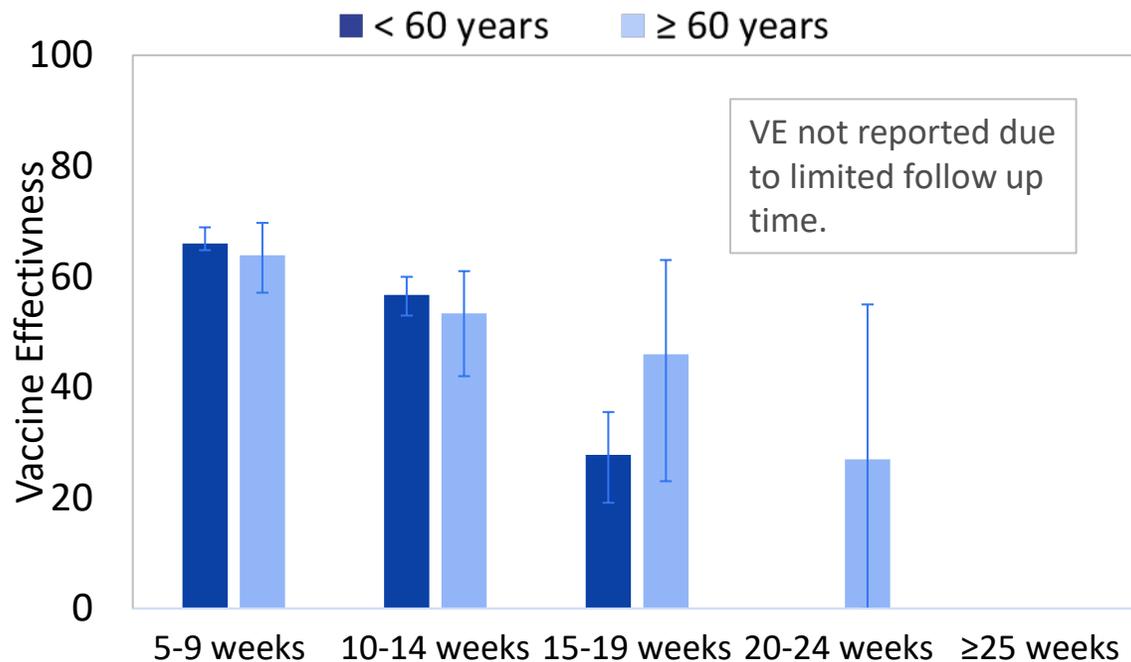
≥ 7 days after dose 2, Pfizer-BioNTech vaccine VoC= Variants of Concern

Nasreen et al. <https://www.medrxiv.org/content/10.1101/2021.06.28.21259420v2.supplementary-material>

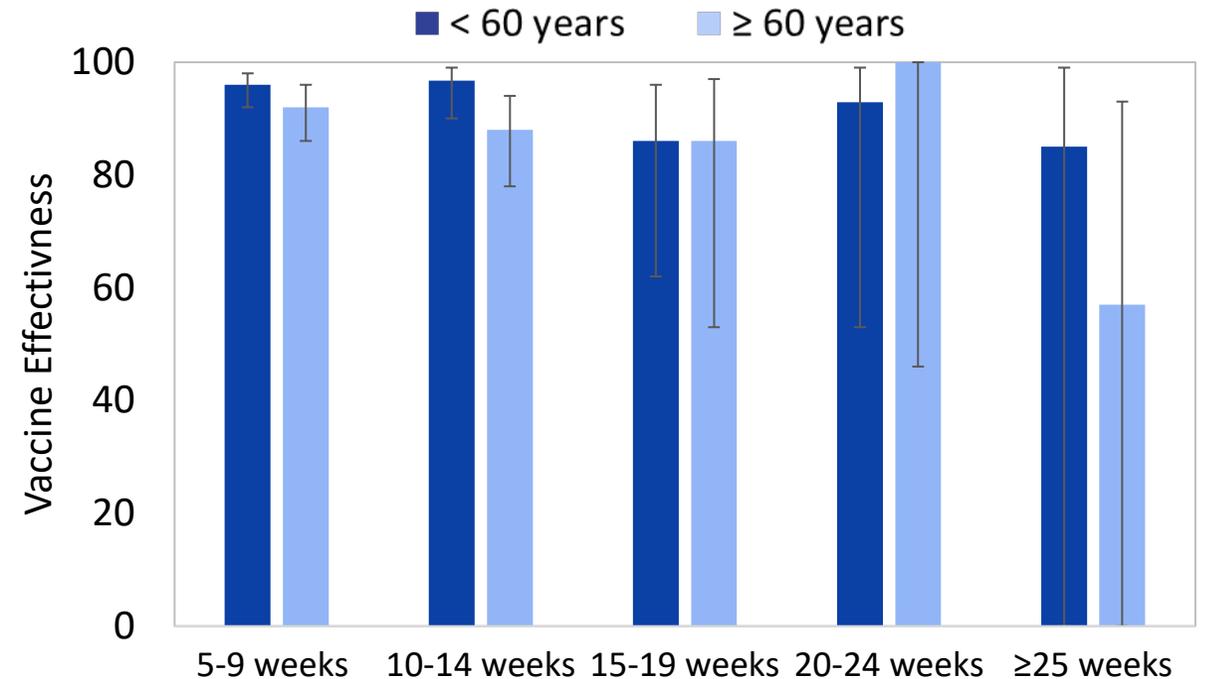
Vaccine effectiveness by age and time since vaccination

Adults ≥ 18 years, Qatar

Documented Infection

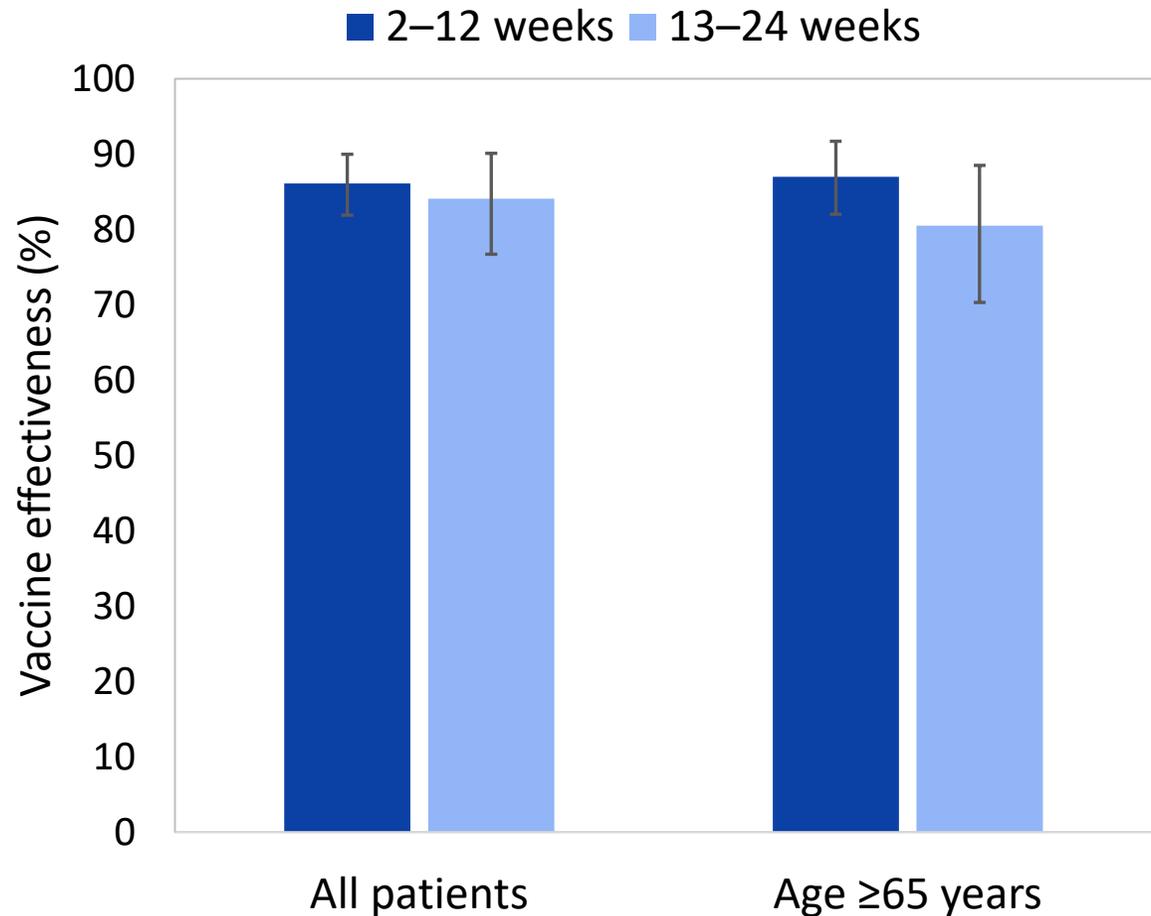


Severe Disease



Effectiveness against **infection** peaked in the first five weeks with a gradual decline. Protection against **severe disease** remained **stable**, with a decline noted in those ≥ 60 years after 25 weeks. Beta and Delta were the dominant variants during study period (January 1 to August 15, 2021).

Vaccine effectiveness against hospitalization by time since vaccination Adults ≥ 65 years, U.S.



VE against **hospitalization** in adults ≥ 65 years of age decreased over time but remained high

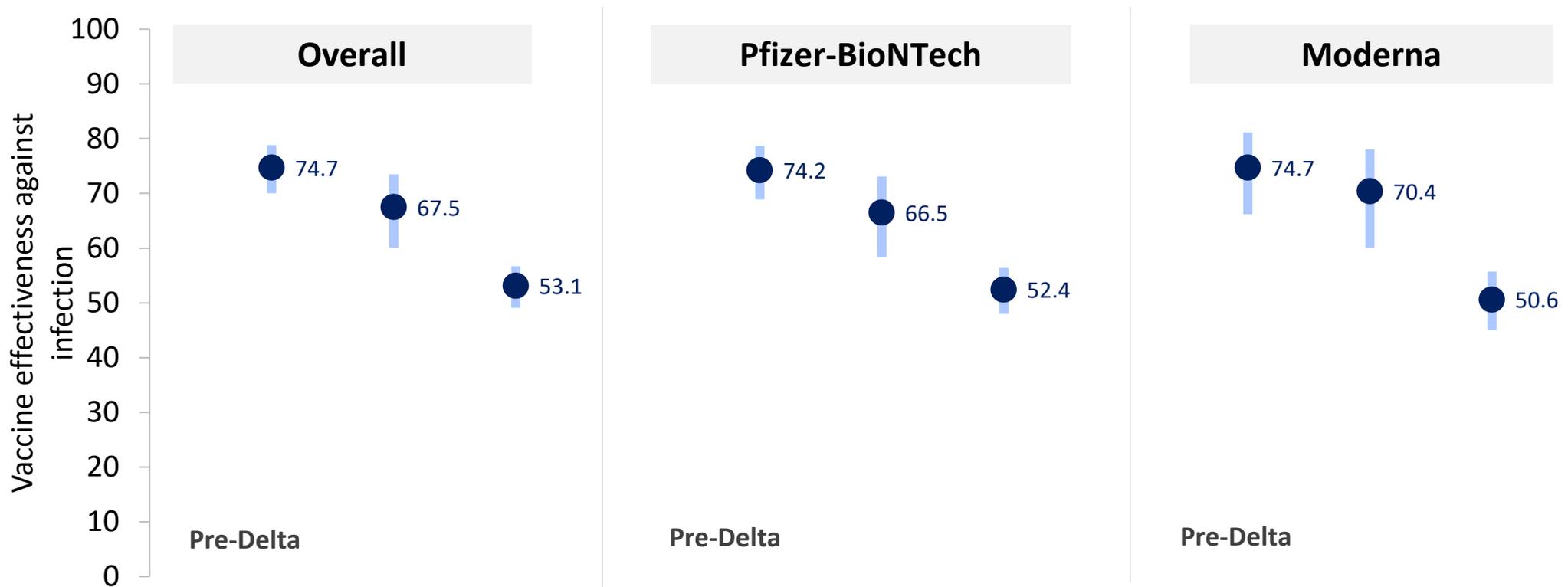
- Differences by interval since vaccination were not significantly different

Time period: March 11 to July 14, 2021

Vaccine effectiveness against infection by time period

Long-term care facility residents, U.S.

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

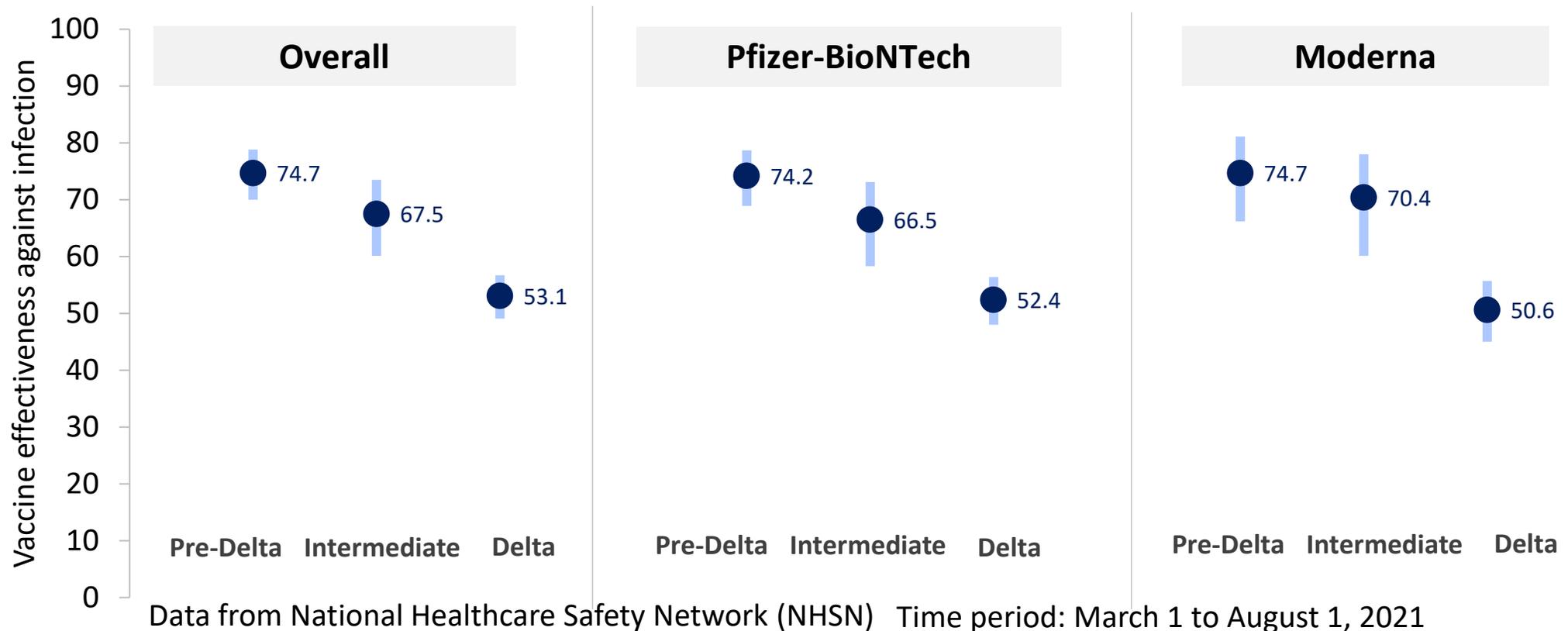


Data from National Healthcare Safety Network (NHSN) Time period: March 1 to August 1, 2021

Vaccine effectiveness against infection by time period

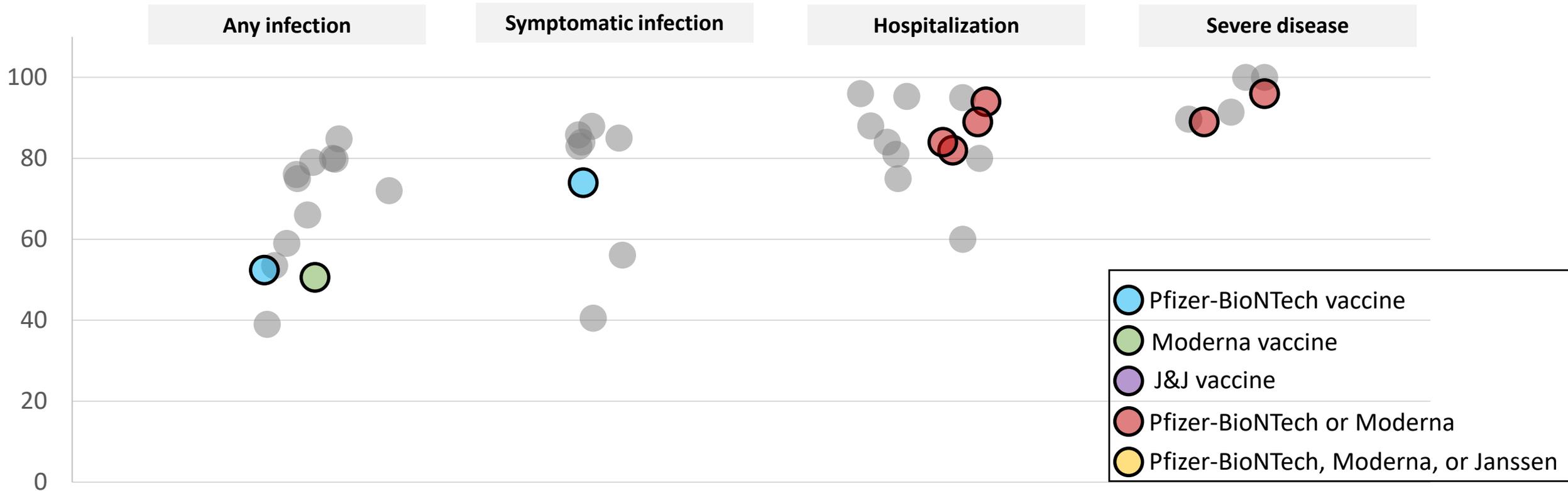
Long-term care facility residents, U.S.

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



Summary of **VE estimates** since introduction of the Delta variant

Adults ≥ 60 years of age



- Vaccine effectiveness of Pfizer-BioNTech COVID-19 vaccine against symptomatic illness with Delta is similar among those aged ≥ 60 years compared with younger age groups
- Persistence of vaccine effectiveness against hospitalization remains high

See reference list in later slides

Vaccine Effectiveness of COVID-19 vaccines

Summary

- COVID-19 vaccines continue to maintain **high protection** against severe disease, hospitalization, and death
- Protection against infection (including asymptomatic or mild infections) lower in recent months
 - Difficult to distinguish effects of increased **time** since primary series versus **Delta variant**
- Important to monitor **trends** of effectiveness by severity of disease over time

Acknowledgements

- Heidi Moline
- Jefferson Jones
- Kathleen Dooling

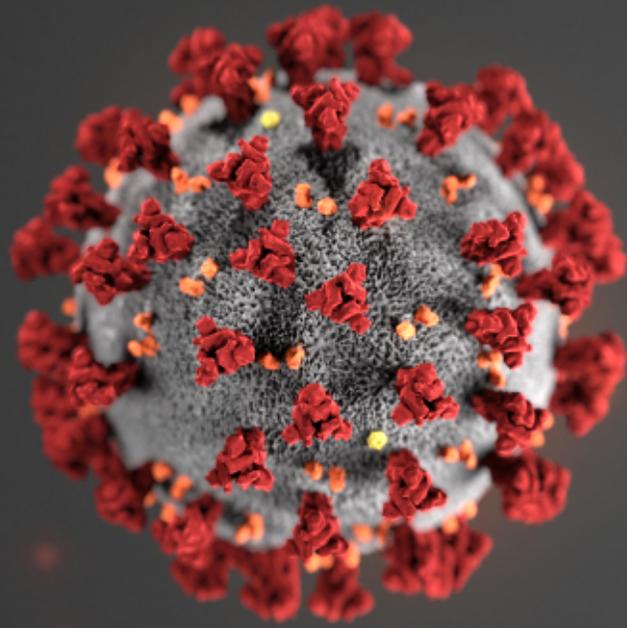
- ACIP Team
- COVID-NET Team
- Vaccine Effectiveness Team
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

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.
5. Nanduri S, Pilishvili T, Derado G, et al. 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 Morb Mortal Wkly Rep* 2021;70:1163-1166.
6. Nasreen S, Chung H, He S, Brown KA, Gubbay JB, Buchan SA, et al. Effectiveness of COVID-19 vaccines against variants of concern in Ontario, Canada. *medRxiv*. 2021:2021.06.28.21259420.
7. Pouwels KB, Pritchard E, Matthews P, Stoesser N, Eyre D, Vihta K-D, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. Preprint. 2021. <https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf>
8. Puranik A, Lenehan PJ, Silvert E, Niesen MJM, Corchado-Garcia J, O'Horo JC, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv*. 2021:2021.08.06.21261707.
9. 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* 2021;70:1150-1155.
10. Sheikh A, McMenamin J, Taylor B, Robertson C. SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness. *The Lancet*. 2021 2021/06/26;397(10293):2461-2.
11. Stowe J, Andrews N, Gower C, Gallagher E, Utsi L, Simmons R, et al. Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant. 2021. https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view/479607266
12. Tang P, Hasan MR, Chemaitelly H, Yassine HM, Benslimane FM, Khatib HAA, et al. BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the Delta (B.1.617.2) variant in Qatar. *medRxiv*. 2021:2021.08.11.21261885.
13. Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, et al. Six-month effectiveness of BNT162b2 mRNA COVID-19 vaccine in a large US integrated health system: a retrospective cohort study. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3909743
14. 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* 2021;70:1156-1162.

Reference list for recent estimates of vaccine effectiveness against the Delta variant (cont'd)

14. Thompson MG, Burgess JL, Naleway AL, et al. Prevention and attenuation of Covid-19 with the BNT162b2 and mRNA-1273 vaccines. *N Engl J Med* 2021;385:320–9.
15. Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021. *MMWR Morb Mortal Wkly Rep*.
16. Grannis SJ, Rowley EA, Ong TC, et al. Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021. *MMWR Morb Mortal Wkly Rep*. ePub: 10 September 2021.
17. Bajema KL, Dahl RM, Prill MM, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1–August 6, 2021. *MMWR Morb Mortal Wkly Rep*.
18. Keehner et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. *N Engl J Med* 2021;385(2):e8.
19. Nunes et al. mRNA vaccines effectiveness against COVID-19 hospitalizations and deaths in older adults: a cohort study based on data-linkage of national health registries in Portugal
20. Chemaitelly et al. Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. medRxiv preprint. August 27, 2021. doi: <https://doi.org/10.1101/2021.08.25.21262584>



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

