COVID-19 vaccine coverage & effectiveness during Omicron for children and adolescents

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VRBPAC
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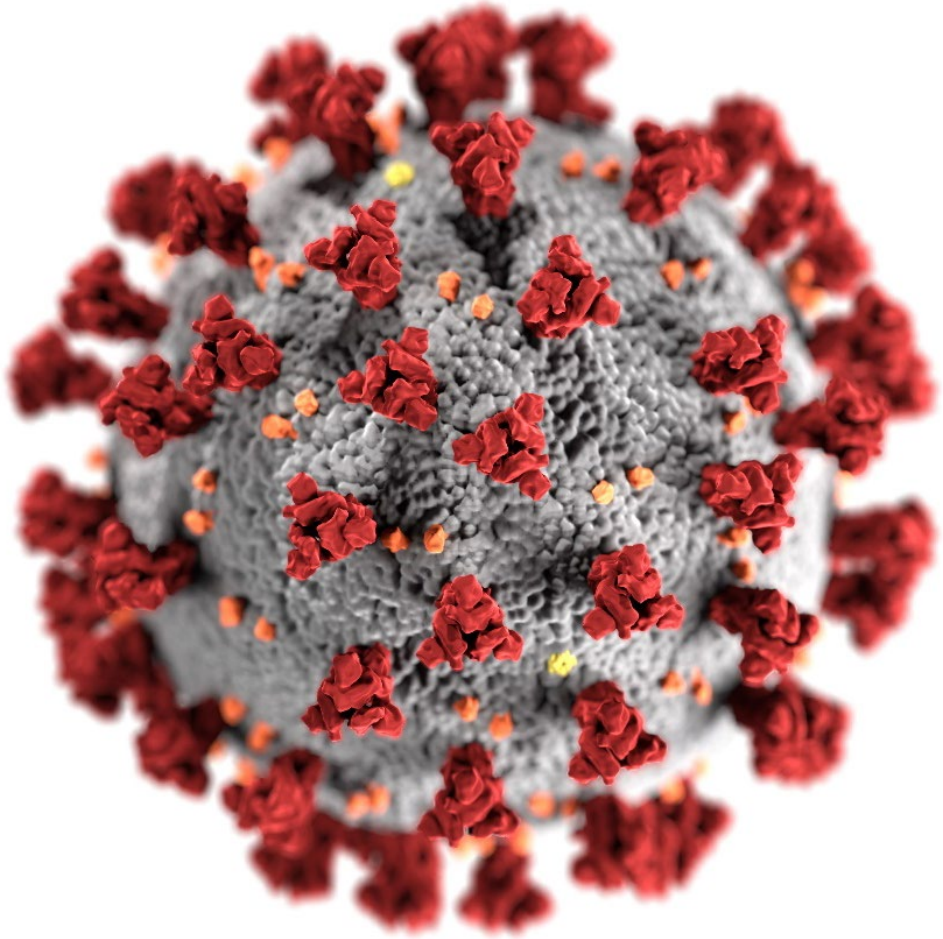


cdc.gov/coronavirus

Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT)

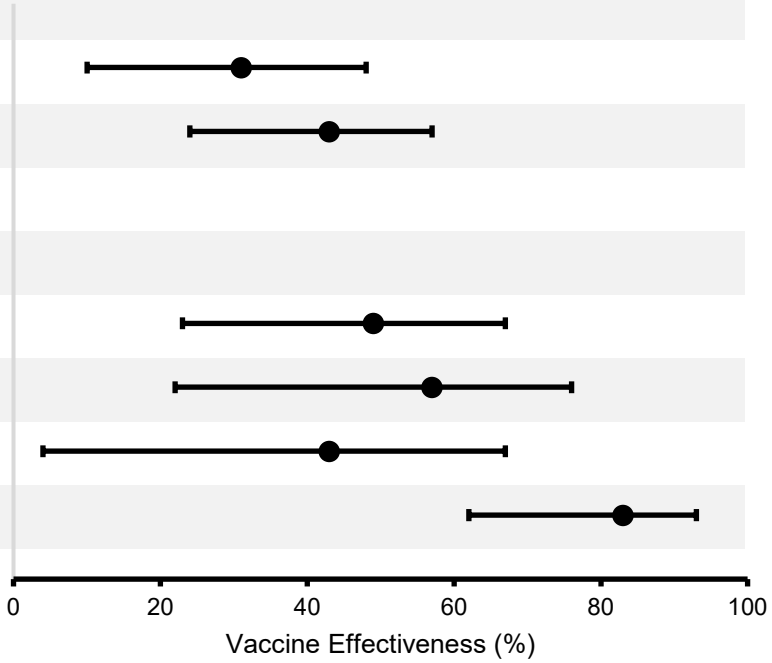
- **Design**: Prospective cohort study
- **Population**: Children ages 4 months – 17 years
- **Methods**: Weekly surveillance and self-swab
  - SARS-CoV-2 testing by RT-PCR and whole genome sequencing
  - Electronic surveys during and after SARS-CoV-2 infection
  - Multi-method vaccination documentation
- **Analysis:** Cox proportional hazards model adjusted by propensity to be vaccinated, site, SARS-CoV-2 circulation, and community mask use
  - Timeframe for analysis during local Omicron predominance
    - December 14, 2021 – April 23, 2022

Recruitment includes children of adult participants in a similar study (HEROES-RECOVER) of frontline workers and from the local community

Update to: Fowlkes AL, Yoon SK, Lutrick K, et al. Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5–11 Years and Adolescents Aged 12–15 Years — PROTECT Cohort, July 2021–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:422–428. DOI: http://dx.doi.org/10.15585/mmwr.mm7111e1

PROTECT: VE against SARS-CoV-2 infection by age group during Omicron variant predominance, mid-Dec 2021-Apr 2022

	Person-days	SARS-CoV-2 positive	Median (IQR) time from last dose end of observation	Adjusted VE % (95% CI)
5 – 11 years				
2 doses (≥14 days)	60,290	212	130 (59-142)	31 (10-48)
2 doses (14-59 days)	26,411	156	59 (59-59)	43 (24-57)
12 – 17 years				
2 doses (≥14 days)	14,501	59	218 (184-252)	49 (23-67)
2 doses (14-149 days)	4,022	20	141 (119-149)	57 (22-76)
2 doses (≥150 days)	13,716	39	218 (185-252)	43 (4-67)
3 doses (≥7 days)	8,340	8	101 (92-107)	83 (62-93)

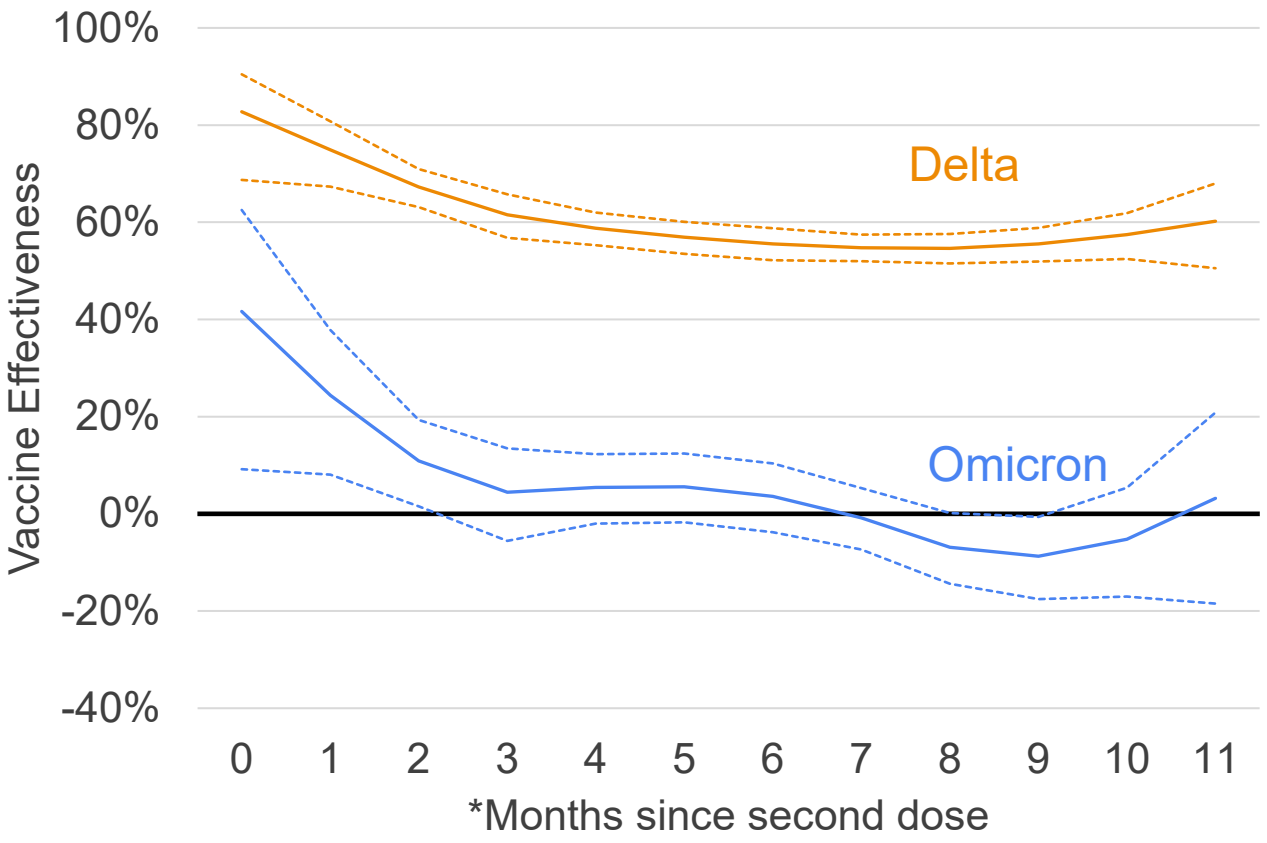


CDC preliminary unpublished. Based on methods in: Fowlkes AL, Yoon SK, Lutrick K, et al. Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5–11 Years and Adolescents Aged 12–15 Years — PROTECT Cohort, July 2021–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:422–428. DOI: http://dx.doi.org/10.15585/mmwr.mm7111e1

Increasing Community Access to Testing (ICATT) Partnership: VE analysis for symptomatic infection

- Nationwide community-based drive-through COVID-19 testing via pharmacies
- Self-reported vaccine history at time of registration for COVID-19 testing; excluded those who did not report vaccination status
- **Design**: Test-negative, case-control analysis
- **Population**: Persons with ≥1 COVID-like symptom and nucleic acid amplification testing (NAAT)
- **Adjusted for**:
  - Calendar day, race, ethnicity, gender, site's HHS region, site census tract's social vulnerability index (SVI)
- **Period for Omicron analysis:**
  - **Adults**: Tested December 10, 2021 – January 1, 2022, also adjusted for number of underlying conditions and tests, excluded if prior positive test within 90 days (Omicron defined by s-gene target failure)
  - **Children**: Tested March 11-May 31, 2022 (mix of BA1, BA2, and BA2.12.2)

ICATT: Pfizer-BioNTech 2-dose VE against symptomatic infection by variant and time since 2nd dose receipt, adults ages ≥18 years, Dec 10, 2021–Jan 1, 2022

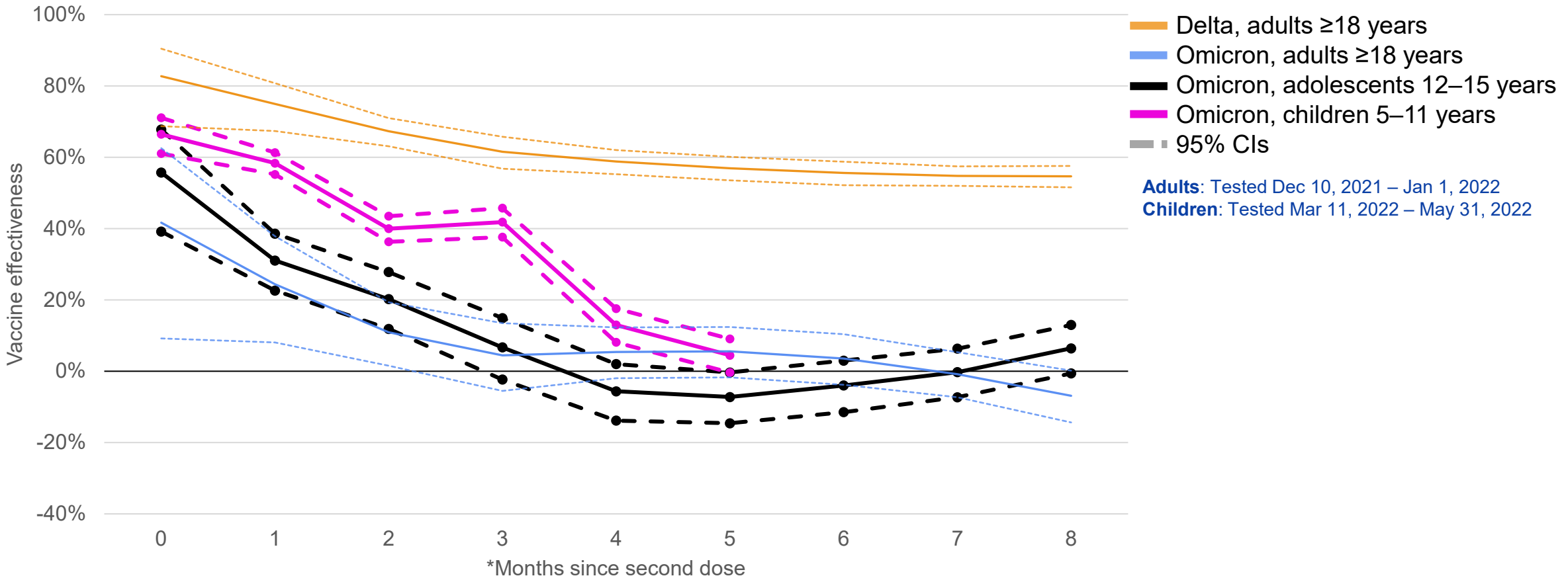


- VE against symptomatic Omicron compared to Delta variant over time since 2nd dose:
  - Baseline is lower
  - No longer significant by 3 months

*Vaccination dose dates are collected as month and year. Month 0 represents tests in the same month as 2nd dose (at least 2 weeks after 2nd dose). For all months greater than or equal to 1 the value represents the difference between calendar month of test and calendar month of 2nd dose receipt (at least 2 weeks after 2nd dose).

Accorsi EK, Britton A, Fleming-Dutra KE, et al. Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants. JAMA. 2022;327(7):639–651. doi:10.1001/jama.2022.0470

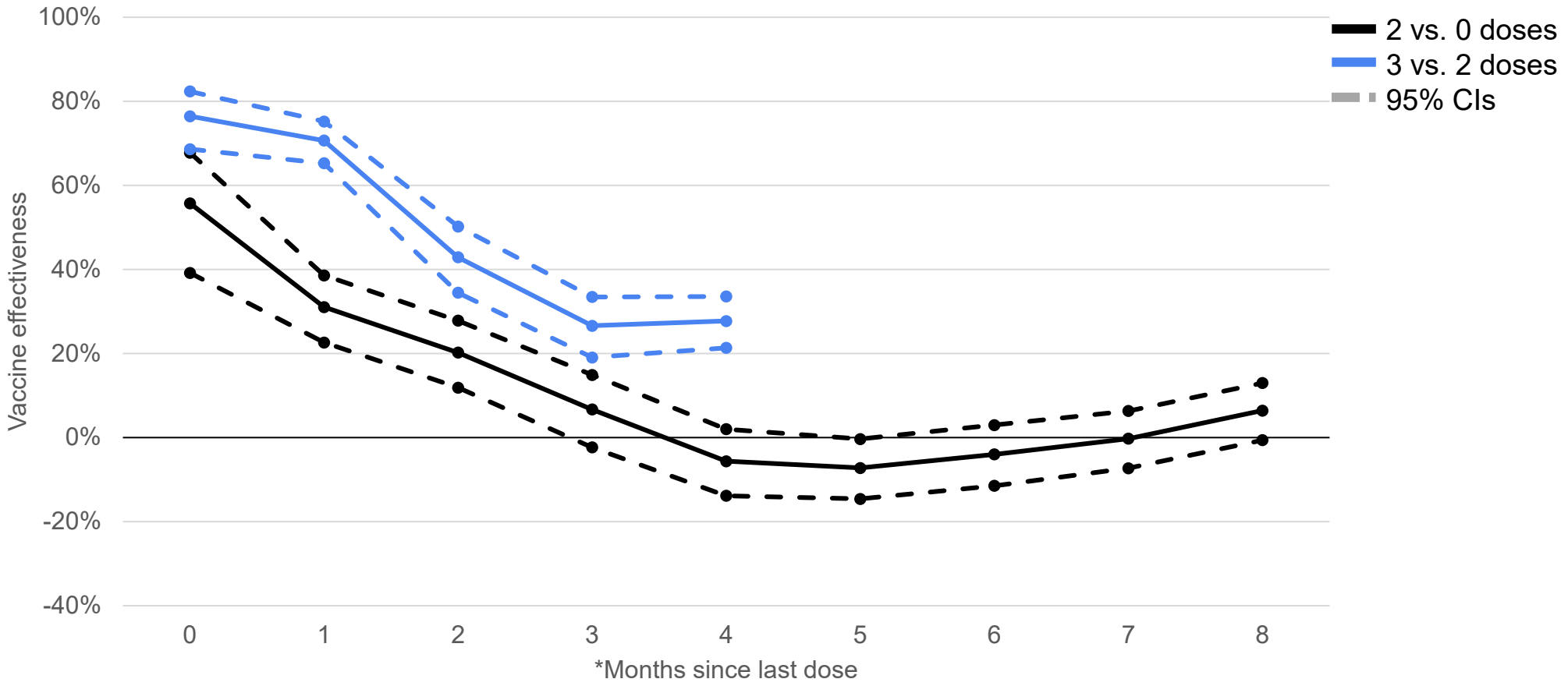
ICATT: Pfizer-BioNTech 2-dose VE against symptomatic infection, by age group and variant



*Vaccination dose dates are collected as month and year. Month 0 represents tests in the same month as 2nd dose (at least 2 weeks after 2nd dose). For all months greater than or equal to 1 the value represents the difference between calendar month of test and calendar month of 2nd dose receipt (at least 2 weeks after 2nd dose).

CDC preliminary unpublished data. Prior infection excluded, other methods based on: Fleming-Dutra KE, Britton A, Shang N, et al. Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance. *JAMA.* Published online May 13, 2022. doi:10.1001/jama.2022.7493

ICATT: Pfizer-BioNTech 3 vs. 2-dose relative VE against symptomatic infection, age 12-15 years



*Vaccination dose dates are collected as month and year. Month 0 represents tests in the same month as 2nd dose (at least 2 weeks after 2nd dose). For all months greater than or equal to 1 the value represents the difference between calendar month of test and calendar month of 2nd dose receipt (at least 2 weeks after 2nd dose).

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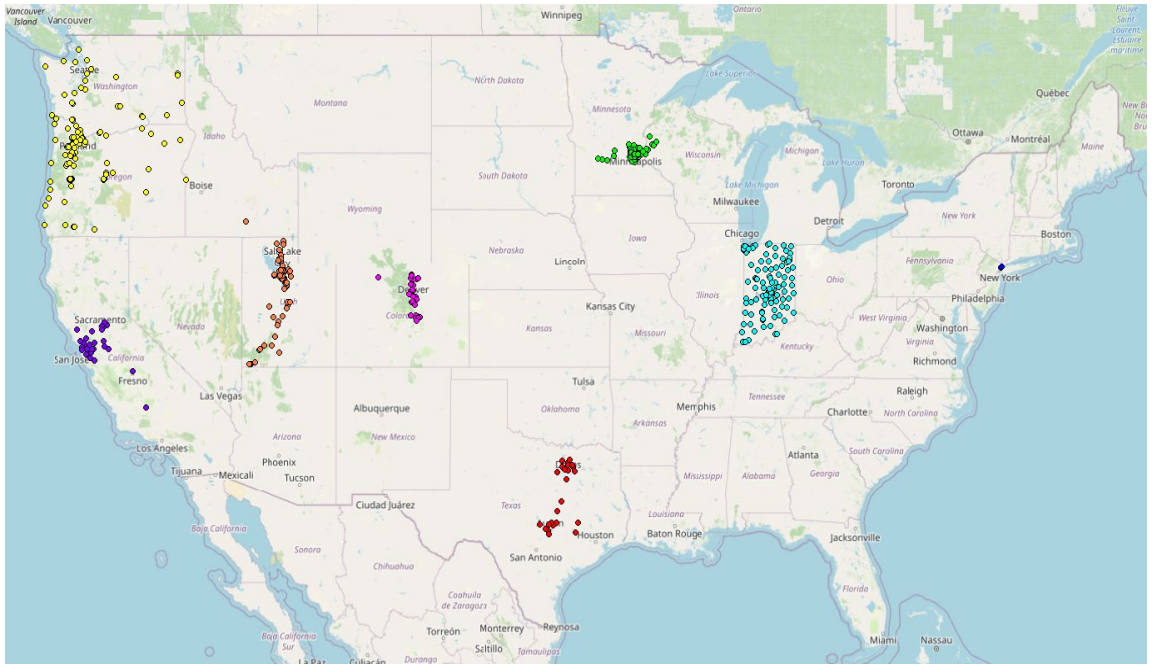
VISION Multi-State Network of Electronic Health Records

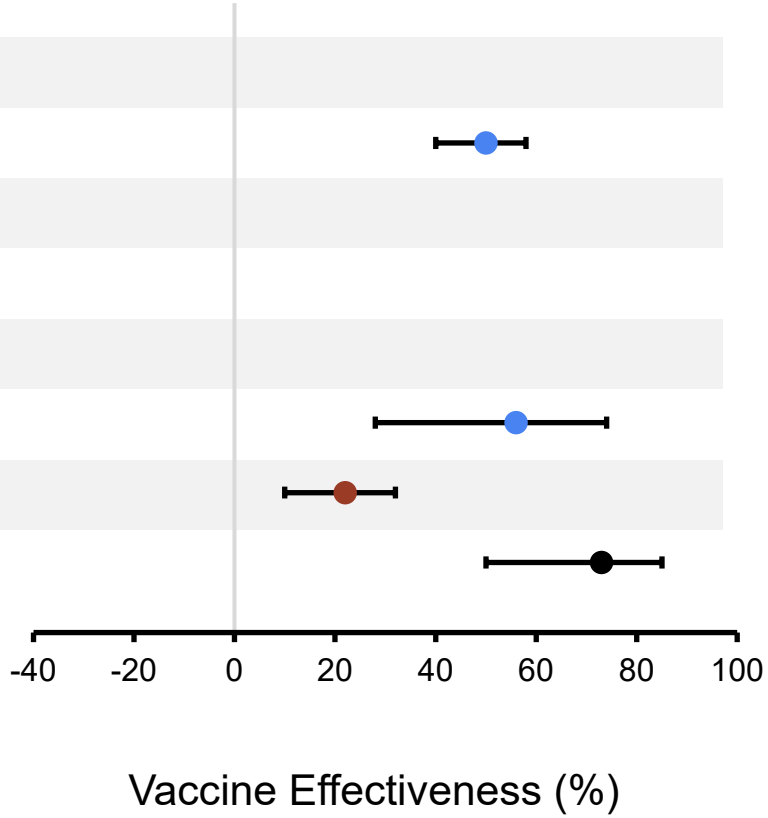


- **Cases**: COVID-like illness (CLI) with positive PCR for SARS-CoV-2 within 14 days before or 72 hours after the admission or encounter
- **Controls**: CLI with negative PCR for SARS-CoV-2

- Delta vs. Omicron determined by time when Omicron predominated in study site (mid-December 2021)
- VE adjusted by propensity to be vaccinated weights, calendar time, region, local virus circulation, and age
- Vaccination documented by electronic health records and state and city registries

VISION: mRNA VE for ED/UC visits by number of doses and time since last dose receipt for children and adolescents during Omicron, mid-Dec 2021–mid-May 2022

	Total	Median day from last dose to ED/UC encounter (IQR)	SARS-CoV-2 positive, N (%)	Adjusted VE (95% CI)
5-11 years				
Unvaccinated	18,223		2719 (14.9)	Ref
2 doses 14-59 days	1,705	36 (26-46)	239 (14.0)	50 (40-58)
12-15 years				
Unvaccinated	5,242		1182 (22.6)	Ref
2 doses 14-59 days	196	40 (28-52)	24 (12.2)	56 (28-74)
2 doses ≥60 days	3,132	195 (143-226)	635 (20.3)	22 (10-32)
3 doses ≥7 days	554	58 (35-79)	16 (2.9)	73 (50-85)

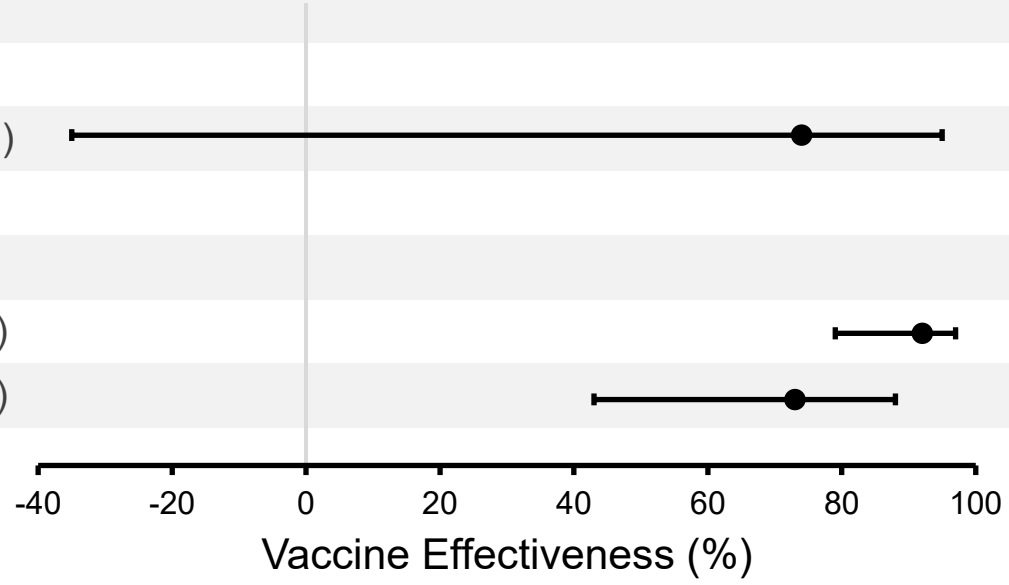


CDC, preliminary unpublished data. Individuals with prior infections excluded. Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated

COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea)

VISION: mRNA VE against hospitalization, all variants, ages 5-15 years, Apr 9, 2021-Jan 29, 2022

	Total	SARS-CoV-2 positive, no. (%)	Adjusted VE % (95% CI)
5–11 years			
Unvaccinated	262	59 (22.5)	Ref
2 doses, 14–59 days earlier	23	2 (8.7)	74 (-35–95)
12–15 years			
Unvaccinated	496	149 (30)	Ref
2 doses, 14–149 days earlier	182	7 (3.8)	92 (79–97)
2 doses, ≥150 days earlier	63	13 (20.6)	73 (43–88)



Note: estimates include all variants.
- 5–11 years: 190 (67%) due to Omicron
- 12–15 years: 111 (15%) due to Omicron

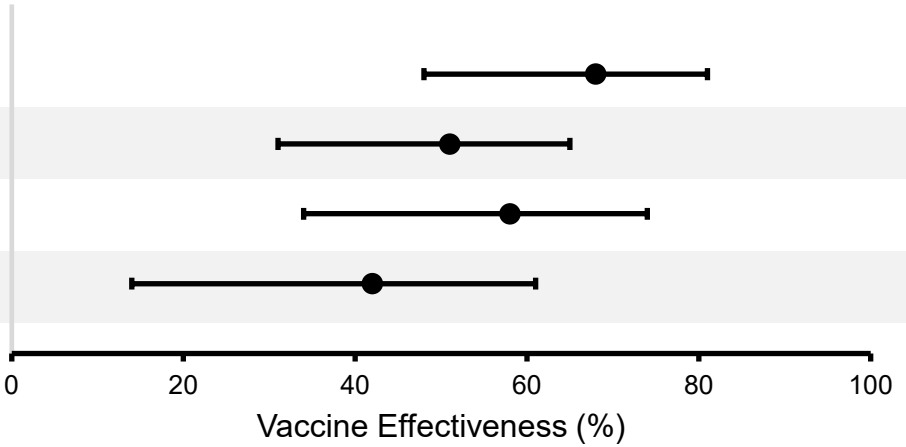
Klein NP, Stockwell MS, Demarco M, et al. Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5–17 Years — VISION Network, 10 States, April 2021–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:352–358. DOI: http://dx.doi.org/10.15585/mmwr.mm7109e3

Overcoming COVID-19 Methods

- **Design:** Case-control test-negative design
- **Population:** Children and adolescents hospitalized at 31 pediatric medical centers in 23 U.S. states
- **Case status (RT-PCR or antigen)**
  - Cases tested SARS-CoV-2 positive
  - Controls tested SARS-CoV-2 negative
- **Vaccination status (documented or plausible self-report)**
  - Fully vaccinated with Pfizer-BioNTech vaccine (dose 2 is ≥14 days prior to illness onset)
  - Or unvaccinated by illness onset
- **Logistic regression to estimate VE against hospitalization (VE_s)**
  - Comparing odds of being fully vaccinated vs unvaccinated in COVID-19 cases and controls
  - VE_s = 100 × (1 – adjusted odds ratio)
    - Adjusting for admission date, hospital region, age, sex, race/ethnicity

Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against hospitalization, Dec 19, 2021-Apr 27, 2022

	No. vaccinated COVID-19 patients/Total no. COVID-19 patients (%)	Adjusted VE % (95% CI)
5–11 years*	25/325 (8)	68 (48-81)
12–18 years	109/286 (38)	51 (31-65)
2–22 weeks since vaccination	42/219 (19)	58 (34-74)
23–45 weeks since vaccination	67/244 (27)	42 (14-61)

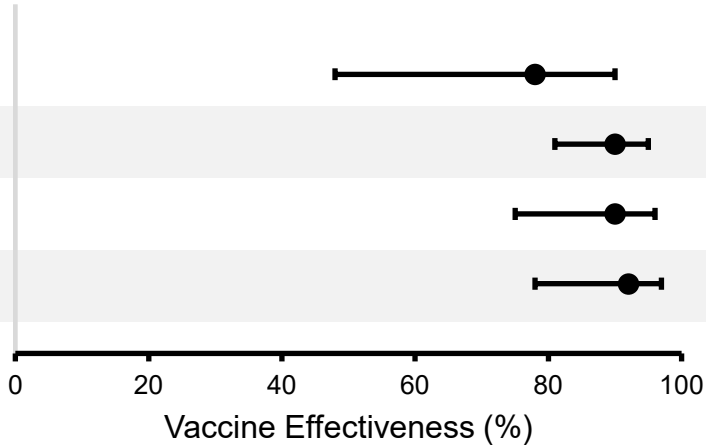


*median time from vaccination to hospitalization is 37 days

CDC preliminary unpublished data. Methods from: Price AM, Olson SM, Newhams MM, Halasa NB, Boom JA, Sahni LC, Pannaraj PS, Irby K, Bline KE, Maddux AB, Nofziger RA, Cameron MA, Walker TC, Schwartz SP, Mack EH, Smallcomb L, Schuster JE, Hobbs CV, Kamidani S, Tarquinio KM, Bradford TT, Levy ER, Chiotos K, Bhumbra SS, Cvijanovich NZ, Heidemann SM, Cullimore ML, Gertz SJ, Coates BM, Staat MA, Zinter MS, Kong M, Chatani BM, Hume JR, Typpo KV, Maamari M, Flori HR, Tenforde MW, Zambrano LD, Campbell AP, Patel MM, Randolph AG; Overcoming Covid-19 Investigators. BNT162b2 Protection against the Omicron Variant in Children and Adolescents. N Engl J Med. 2022 Mar 30. doi: 10.1056/NEJMoa2202826. Epub ahead of print. PMID: 35353976.

Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against MIS-C, Jul 1, 2021-Apr 7, 2022

	No. vaccinated MIS-C patients/Total no. MIS-C patients (%)	Median (IQR) days from 2nd dose to MIS-C	Adjusted VE (95% CI)
5–11 years	10/144 (7)	44 (32-56)	78 (48-90)
12–18 years	14/160 (9)	120 (57-169)	90 (81-95)
28-120 days since vaccination	7/153 (5)	60 (42-89)	90 (75-96)
≥121 days since vaccination	7/131 (5)	172 (138-215)	92 (78-97)



CDC preliminary unpublished data

Summary

- Infection
  - 2-dose VE declines quickly in children and adolescents, following similar pattern to adults during Omicron predominance
  - A booster dose in adolescents significantly improved VE initially, although there was waning

- Emergency department/urgent care visits
  - 2-dose VE was higher for ED/UC visits compared to infection.
    - Declined ≥60 days after the 2nd dose for adolescents
  - A booster dose in ages 12-15 years significantly improved VE

- Severe disease: hospitalization and MIS-C
  - 2-doses provided protection for both age groups, with some waning for hospitalization in adolescents
  - High VE in both age groups against MIS-C
  - Not enough data to assess waning in 5-11 or impact of booster dose in 12-15

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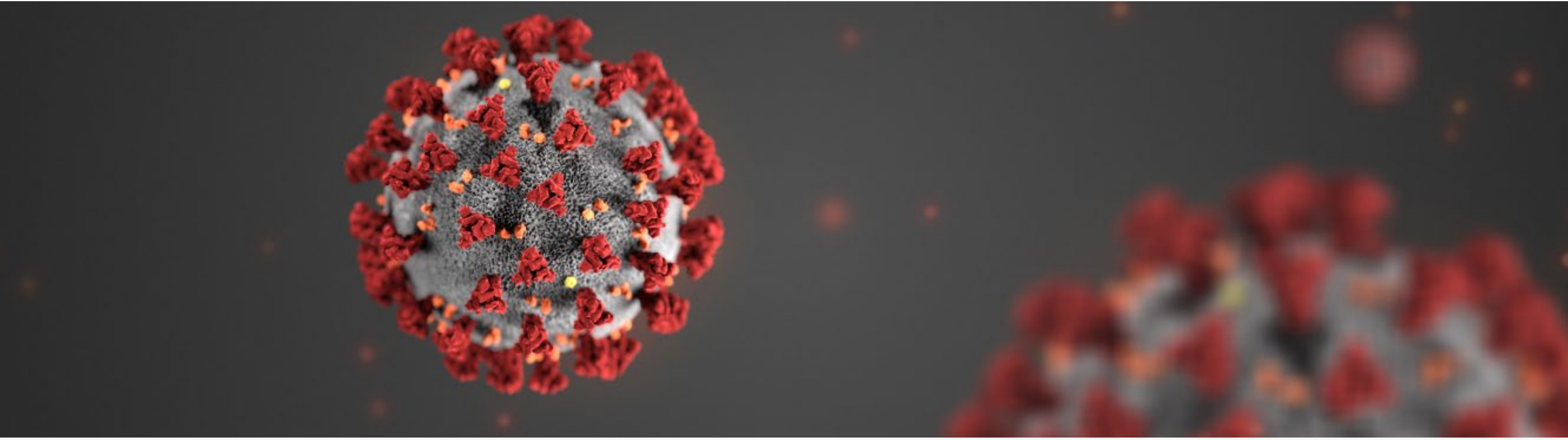

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