Effectiveness of COVID-19 (2023-2024 Formula) vaccines

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Agenda: effectiveness of COVID-19 (2023-2024 Formula) vaccines

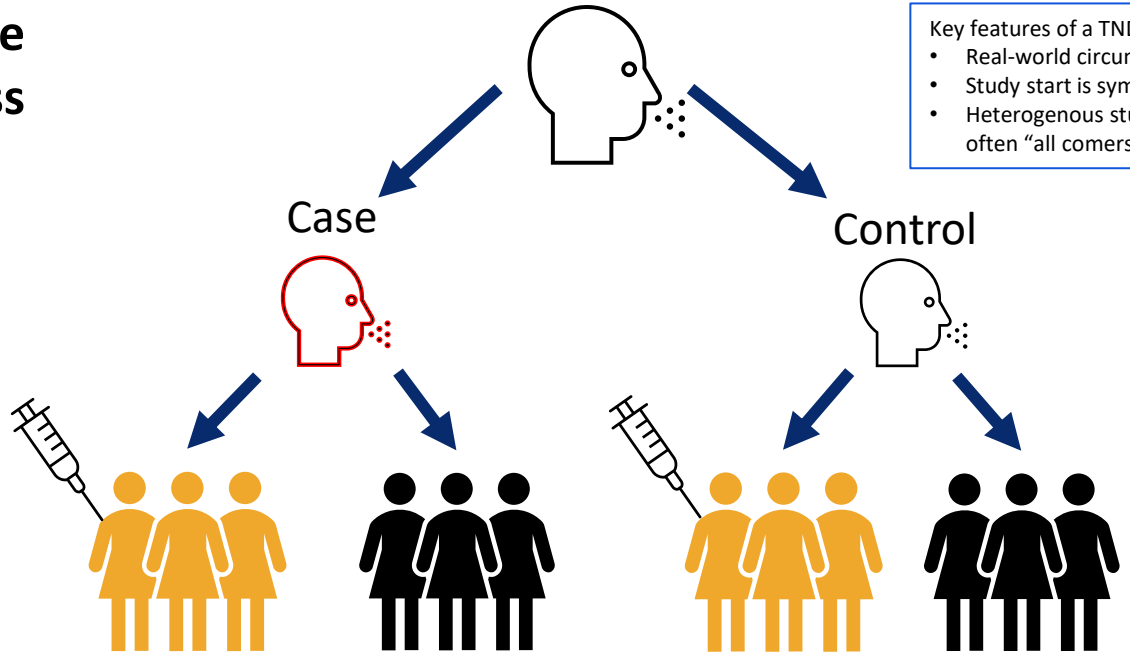
- **Vaccine effectiveness (VE) methods refresher**
- **Context for interpretation of COVID-19 VE**
- **COVID-19 VE in adults, by outcome and variant:**
  - Symptomatic SARS-CoV-2
  - COVID-19-associated emergency department/urgent care (ED/UC) encounters
  - COVID-19-associated hospitalizations, by immunocompromise status
  - COVID-19-associated critical outcomes
- **COVID-19 VE in young children and by age group**

Observational effectiveness measured in a test-negative design (TND) study

Person with acute respiratory illness

Pathogen test
(e.g., SARS-CoV-2, RSV, etc.)

Immunization status



Key features of a TND
- Real-world circumstances
- Study start is symptomatic medical encounter
- Heterogenous study population, often “all comers”

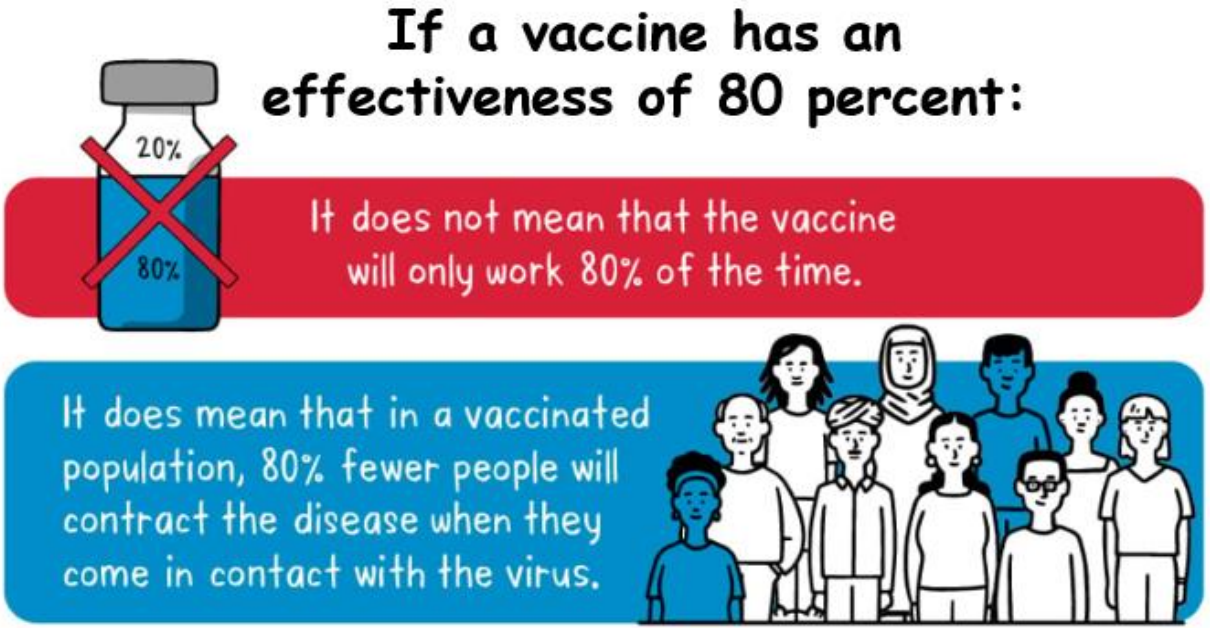
Effectiveness = 1 – (odds ratio) x 100% Odds ratio = $\frac{Odds\ of\ immunization_{cases}}{Odds\ of\ immunization_{controls}}$

Test-negative design methods

- **Benefits**
  - Reduces bias from health-care seeking behavior by including cases and controls who presented to care and received testing (usually at the same facility).
  - Efficient use of resources → allows controls to be selected from same healthcare system or testing location as cases.

- **Considerations**
  - Dependent on sensitivity and specificity of diagnostic testing.
  - Controls positive for another vaccine preventable disease can bias results. Sensitivity analyses excluding influenza positive controls can be helpful in assessing COVID-19 VE.

Vaccine effectiveness is a population level estimate.



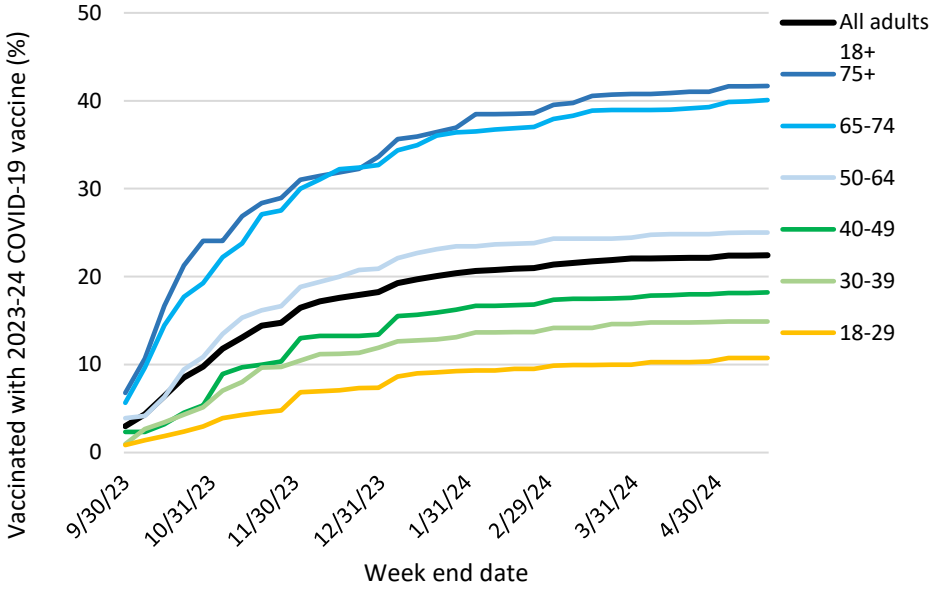
Adapted from: https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection

Percent of adults and children who received 2023-24 COVID-19 vaccine

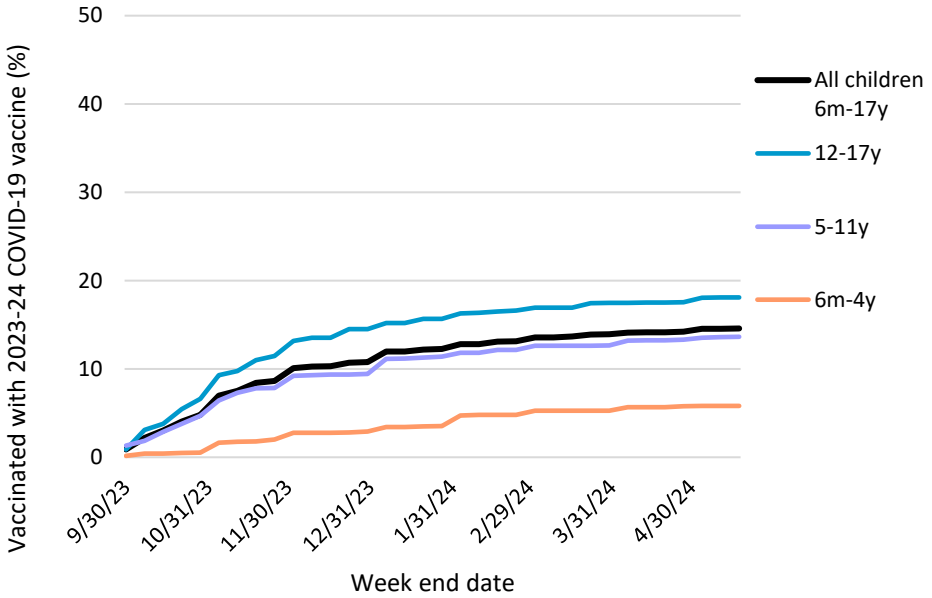
National Immunization Survey-Adult COVID Module (NIS-ACM) and -Child COVID Module (NIS-CCM)

September 2023-April 2024

COVID-19 Vaccination Coverage with 2023-24 Vaccine Among Adults ≥18 Years, NIS-ACM



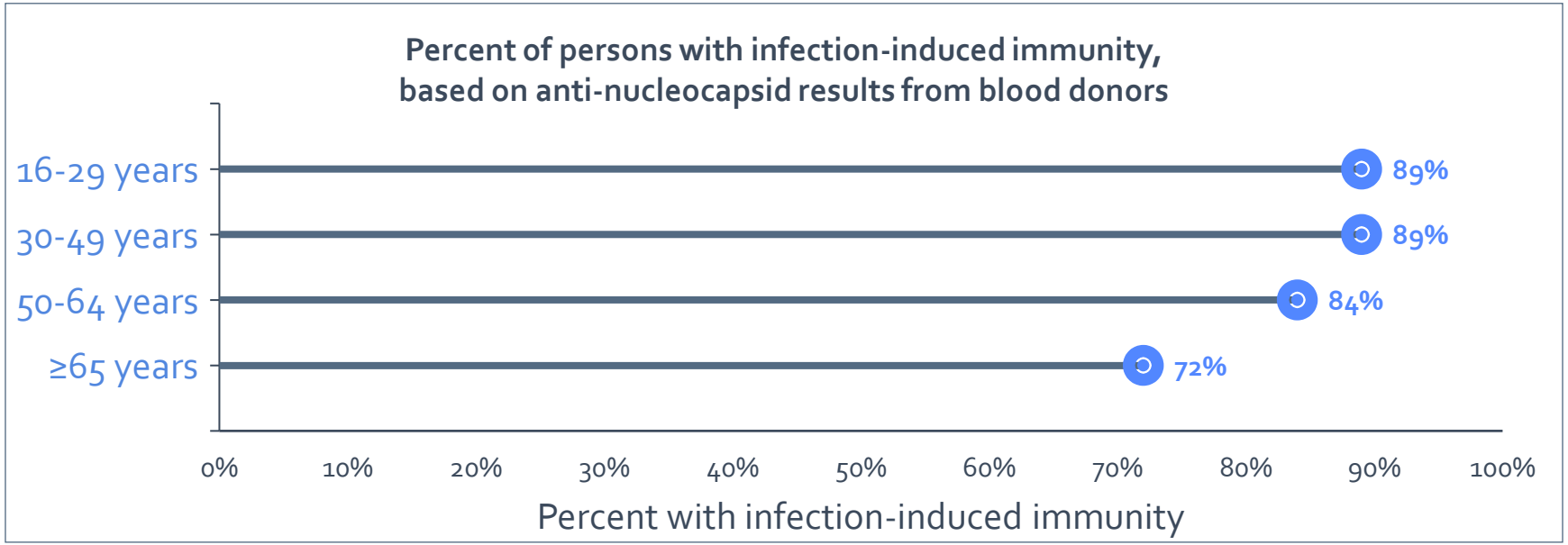
COVID-19 Vaccination Coverage with 2023-24 Vaccine Among Children 6 Months-17 Years, NIS-CCM



https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/index.html

Context for interpreting COVID-19 VE across age groups

- High rates of SARS-CoV-2 infection-induced immunity by July – August 2023.*



VE findings should be interpreted as the incremental benefit provided by COVID-19 vaccination in a population with a high prevalence of vaccine- and infection-induced immunity.

* Internal CDC data. Data on persons aged ≥16 years is from a longitudinal, national cohort of >35,000 blood donors.
Methods and prior data available at: https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022

Measuring 2023-2024 COVID-19 VE

Measure	Definition	Vaccinated group	Comparison group
Absolute VE	Compares frequency of health outcomes in vaccinated and unvaccinated people	Received **updated (2023-24) dose**	Received no COVID-19 vaccines ever
Relative VE	Compares frequency of health outcomes in people who received one type of vaccine to people who received a different vaccine	Received **updated (2023-24) dose**	Eligible for, but did not receive, an **updated (2023-24) dose**, but received previous doses of COVID-19 vaccine
VE presented today	Compares people who received 2023-2024 COVID-19 vaccine to people who did not, regardless of past vaccination	Received **updated (2023-24) dose**	Eligible for, but did not receive, an **updated (2023-24) dose**, regardless of past vaccination history

Early Estimates of Updated 2023–2024 (Monovalent XBB.1.5) COVID-19 Vaccine Effectiveness Against Symptomatic SARS-CoV-2 Infection Attributable to Co-Circulating Omicron Variants Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, September 2023–January 2024

Ruth Link-Gelles, PhD[1]; Allison Avrich Ciesla, PhD[1,2]; Josephine Mak, MPH[1]; Joseph D. Miller, PhD[3]; Benjamin J. Silk, PhD[1]; Anastasia S. Lambrou, PhD[1]; Clinton R. Paden, PhD[1]; Philip Shirk, PhD[1]; Amadea Britton, MD[1]; Zachary R. Smith, PhD[3]; Katherine E. Fleming-Dutra, MD[1]

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Updates to COVID-19 VE against symptomatic infection:

Increasing Community Access to Testing (ICATT) program

Increasing Community Access to Testing (ICATT): COVID-19 VE from national pharmacy testing data

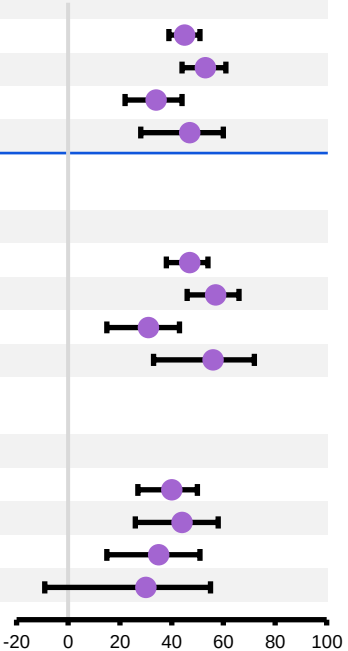
- Nationwide community-based pharmacy SARS-CoV-2 testing
- Self-reported COVID-19 vaccination history at time of registration for SARS-CoV-2 testing*
- **Design:** Test-negative analysis**
- **Population:** Adults ≥18 years with ≥1 COVID-like symptom and nucleic acid amplification testing (NAAT) for SARS-CoV-2
- **Exclusion criteria:** Individuals with self-reported immunocompromising conditions, reported a positive SARS-CoV-2 test in preceding 90 days***
- **Periods for analysis:**
  - Full analysis included tests from September 21, 2023 – May 22, 2024
  - Sub-analysis using S-gene target failure**** included tests from October 27, 2023 – April 3, 2024

*At 5% of testing encounters, COVID-19 vaccination status is collected by clinician interview. Receipt of 2023-2024 COVID-19 vaccine formulation determined by date of most recent dose (i.e., after Sept 12, 2023).
**Odds ratios were calculated using multivariable logistic regression, adjusting for single year of age, gender, race/ethnicity, SVI of the testing location (<0.5 versus ≥0.5), pharmacy contractor, underlying conditions (presence versus absence), U.S. Department of Health and Human Services region of testing location, and date of testing
***Additional exclusion criteria: 1) reported receiving Novavax as their most recent dose and reported receiving <2 total COVID-19 vaccine doses; 2) reported receiving a Janssen (Johnson & Johnson) COVID-19 vaccine dose after May 12, 2023; 3) received most recent COVID-19 dose <7 days prior to the date of testing or during September 1-12, 2023; or 4) registered for testing with a version of the questionnaire that only reported month and year of the most recent vaccine dose rather than calendar date.
**** Results of spike gene (S-gene) amplification in real-time reverse transcription–polymerase chain reaction (RT-PCR) can be used to distinguish certain SARS-CoV-2 lineages over time (2). S-gene target presence (SGTP) was detected in most lineages that circulated in 2023, including XBB lineages, whereas S-gene target failure (SGTF) is detected in JN.1 and other BA.2.86 lineages
Link-Gelles, et al. MMWR 2024: http://dx.doi.org/10.15585/mmwr.mm7304a2 (Results updated with additional data since publication.)

ICATT: VE of *2023-2024 COVID-19 vaccine* against *symptomatic infection* among adults aged ≥18 years, by age group and time since dose

September 2023 – May 2024

Age group/2023-2024 COVID-19 vaccination status/days since dose	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	12,965	4,661 (36)	687 (436 to 879)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	1,895	483 (25)	70 (38 to 102)	**45 (39 to 51)**
2023-2024 COVID-19 dose, 7-59 days earlier	772	181 (23)	32 (20 to 46)	**53 (44 to 61)**
2023-2024 COVID-19 dose, 60-119 days earlier	809	237 (29)	84 (71 to 97)	**34 (22 to 44)**
2023-2024 COVID-19 dose, 120-179 days earlier	262	60 (23)	140 (128 to 152)	**47 (28 to 60)**
18-49 years				
No 2023-2024 COVID-19 dose (ref)	10,395	3,609 (35)	702 (451 to 887)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	1,167	272 (23)	69 (39 to 101)	**47 (38 to 54)**
2023-2024 COVID-19 dose, 7-59 days earlier	474	96 (20)	32 (19 to 46)	**57 (46 to 66)**
2023-2024 COVID-19 dose, 60-119 days earlier	507	144 (28)	82 (71 to 95)	**31 (15 to 43)**
2023-2024 COVID-19 dose, 120-179 days earlier	147	27 (18)	139 (128 to 154)	**56 (33 to 72)**
≥50 years				
No 2023-2024 COVID-19 dose (ref)	2,570	1,052 (41)	610 (407 to 821)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	728	211 (29)	71 (36 to 103)	**40 (27 to 50)**
2023-2024 COVID-19 dose, 7-59 days earlier	298	85 (29)	32 (21 to 44)	**44 (26 to 58)**
2023-2024 COVID-19 dose, 60-119 days earlier	302	93 (31)	85 (73 to 98)	**35 (15 to 51)**
2023-2024 COVID-19 dose, 120-179 days earlier	115	33 (29)	142 (128 to 152)	**30 (-9 to 55)***



Link-Gelles, et al. MMWR 2024: http://dx.doi.org/10.15585/mmwr.mm7304a2 (Results updated with additional data since publication.)

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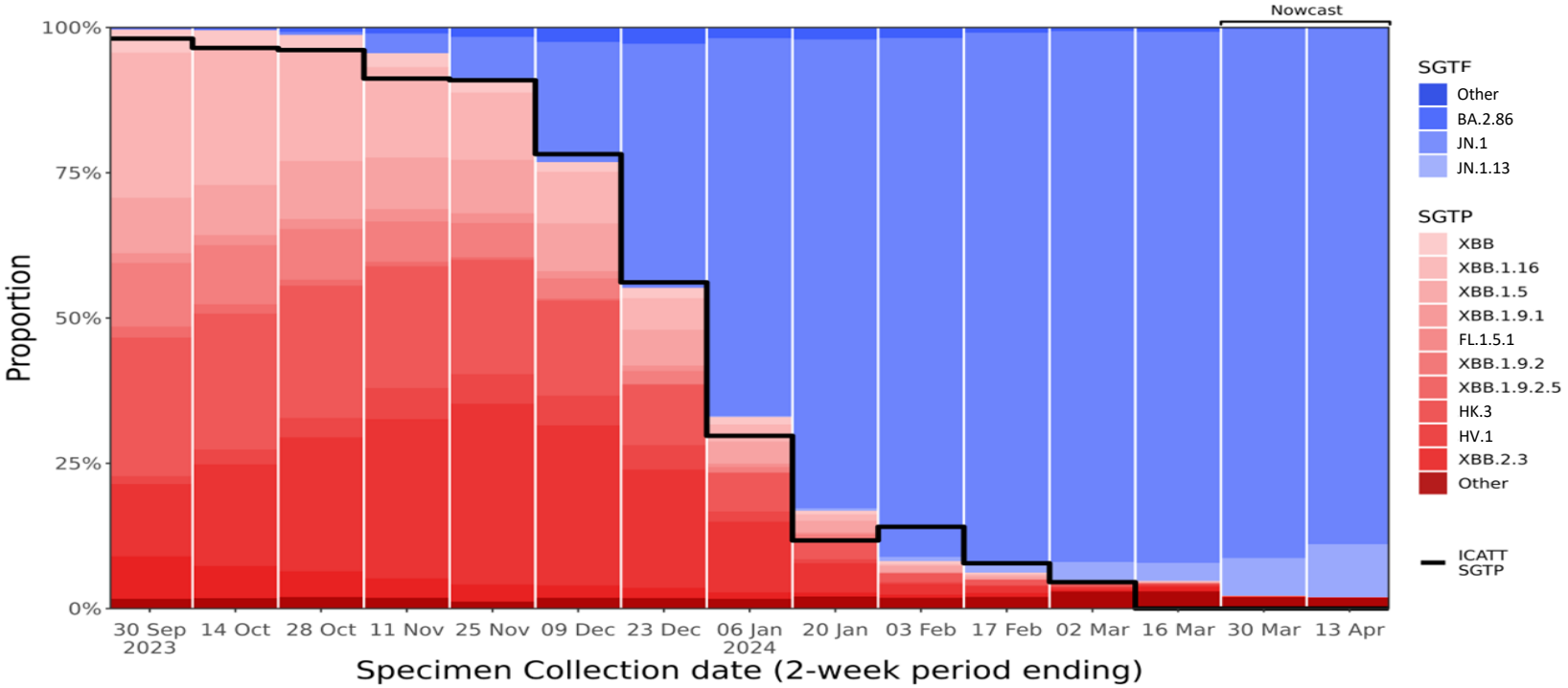
Trends in estimated proportions of SARS-CoV-2 S-gene target presence and variant proportions in ICATT and Nowcast projections from national genomic surveillance

September 2023-April 2024



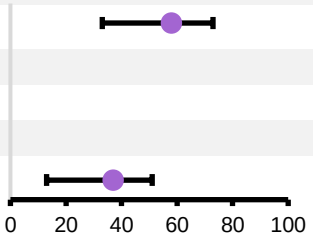
S-gene = spike gene; SGTF = S-gene target failure; SGTP = S-gene target presence

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

ICATT: VE of *2023-2024 COVID-19 vaccine* against *symptomatic infection* among adults aged ≥18 years, by S-gene target (SGT) presence or failure and time since dose

October 2023 – April 2024

SGT status/2023-2024 COVID-19 vaccination status/days since dose	Total tests	SARS-CoV-2 negative		SARS-CoV-2 positive		Adjusted VE (95% CI)
		N (row %)	Median interval since last dose among vaccinated, days (IQR)	N (row %)	Median interval since last dose among vaccinated, days (IQR)	
SGT presence (likely non-JN.1)						
No 2023-2024 COVID-19 dose (ref)	2,357	1,934 (69)	668 (410 to 827)	423 (15)	670 (405 to 800)	**Ref**
2023-2024 COVID-19 dose, 60-119 days earlier	307	282 (77)	85 (72 to 101)	25 (7)	73 (69 to 83)	**58 (33 to 73)**
SGT failure (likely JN.1)						
No 2023-2024 COVID-19 dose (ref)	2,366	1,934 (69)	668 (410 to 827)	432 (15)	686 (426 to 829)	**Ref**
2023-2024 COVID-19 dose, 60-119 days earlier	343	282 (77)	85 (72 to 101)	61 (17)	89 (75 to 101)	**37 (13 to 51)**



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Interim Effectiveness of Updated 2023–2024 (Monovalent XBB.1.5) COVID-19 Vaccines Against COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalization Among Immunocompetent Adults Aged ≥18 Years — VISION and IVY Networks, September 2023–January 2024

Jennifer DeCuir, MD, PhD[1]; Amanda B. Payne, PhD[1]; Wesley H. Self, MD[2]; Elizabeth A.K. Rowley, DrPH[3]; Kristin Dascomb, MD, PhD[4]; Malini B. DeSilva, MD[5]; Stephanie A. Irving, MHS[6]; Shaun J. Grannis, MD[7,8]; Toan C. Ong, PhD[9]; Nicola P. Klein, MD, PhD[10]; Zachary A. Weber, PhD[3]; Sarah E. Reese, PhD[3]; Sarah W. Ball, ScD[3]; Michelle A. Barron[9]; Allison L. Naleway, PhD[6]; Brian E. Dixon, PhD[7,8]; Inih Essien, OD[5]; Daniel Bride, MS[4]; Karthik Natarajan, PhD[11,12]; Bruce Fireman[10]; Ami B. Shah, MPH[1,13]; Erica Okwuazi, MSc[1,13]; Ryan Wiegand, PhD[1]; Yuwei Zhu, MD[2]; Adam S. Lauring, MD, PhD[14]; Emily T. Martin, PhD[14]; Manjusha Gaglani, MBBS[15,16]; Ithan D. Peltan, MD[17,18]; Samuel M. Brown, MD[17,18]; Adit A. Ginde, MD[9]; Nicholas M. Mohr, MD[19]; Kevin W. Gibbs, MD[20]; David N. Hager, MD, PhD[21]; Matthew Prekker, MD[22]; Amira Mohamed, MD[23]; Vasisht Srinivasan, MD[24]; Jay S. Steingrub, MD[25]; Akram Khan, MD[26]; Laurence W. Busse, MD[27]; Abhijit Duggal, MD[28]; Jennifer G. Wilson, MD[29]; Steven Y. Chang, MD, PhD[30]; Christopher Mallow, MD[31]; Jennie H. Kwon, DO[32]; Matthew C. Exline, MD[33]; Cristie Columbus, MD[15,34]; Ivana A. Vaughn, PhD[35]; Basmah Safdar, MD[36]; Jarrod M. Mosier, MD[37]; Estelle S. Harris, MD[18]; Jonathan D. Casey, MD[2]; James D. Chappell, MD, PhD[2]; Carlos G. Grijalva, MD[2]; Sydney A. Swan[2]; Cassandra Johnson, MS[2]; Nathaniel M. Lewis, PhD[38]; Sascha Ellington, PhD[38]; Katherine Adams, MPH[38]; Mark W. Tenforde, MD, PhD[38]; Clinton R. Paden, PhD[1]; Fatimah S. Dawood, MD[1]; Katherine E. Fleming-Dutra, MD[1]; Diya Surie, MD[1]; Ruth Link-Gelles, PhD[1]; CDC COVID-19 Vaccine Effectiveness Collaborators

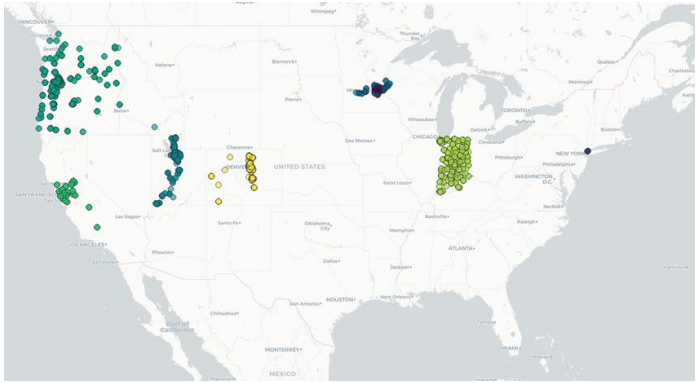
MMWR Morb Mortal Wkly Rep 2024;73:180–188. DOI: http://dx.doi.org/10.15585/mmwr.mm7308a5

Updates to COVID-19 VE against COVID-19-associated ED/UC encounters:

VISION and IVY Networks

VISION Multi-Site Network of Electronic Health Records

369 emergency rooms and urgent cares/229 hospitals

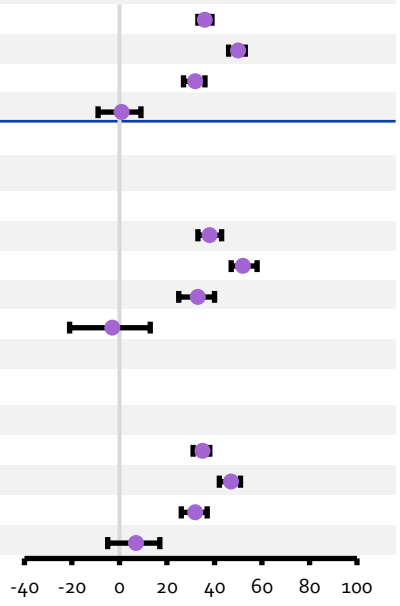


- **Design:** Test-negative analysis
- **Population:** Adults visiting a participating emergency department or urgent care (ED/UC) or hospitalized with COVID-19-like illness (CLI) with a SARS-CoV-2 NAAT test result within 10 days before or 72 hours after encounter
  - **Cases**: CLI with *positive* NAAT for SARS-CoV-2 and no positive NAAT for RSV or influenza
  - **Controls**: CLI with *negative* NAAT for SARS-CoV-2 and no positive NAAT for influenza
- **Vaccination data:** Documented by electronic health records and state and city registries

VISION: VE of *2023-2024 COVID-19 vaccine* against *ED/UC encounters* among immunocompetent adults aged ≥18 years, by age group

September 2023 – May 2024

Age group/2023-2024 COVID-19 vaccination status/days since dose	Total encounters	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among vaccinated among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	207,695	22,530 (11)	720 (481-865)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	37,809	2,720 (7)	82 (46-123)	**36 (33-39)**
2023-2024 COVID-19 dose, 7-59 days earlier	13,144	982 (7)	34 (21-47)	**50 (46-53)**
2023-2024 COVID-19 dose, 60-119 days earlier	14,434	1,171 (8)	87 (73-103)	**32 (27-36)**
2023-2024 COVID-19 dose, 120-179 days earlier	10,231	567 (6)	146 (132-161)	**1 (-9-9)**
18-64 years				
No 2023-2024 COVID-19 dose (ref)	148,273	15,100 (10)	751 (573-887)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	13,696	819 (6)	78 (42-119)	**38 (33-43)**
2023-2024 COVID-19 dose, 7-59 days earlier	5,137	313 (6)	34 (20-47)	**53 (47-58)**
2023-2024 COVID-19 dose, 60-119 days earlier	5,186	345 (7)	87 (73-103)	**33 (25-40)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,373	161 (5)	144 (131-159)	**-3 (-21-13)**
≥65 years				
No 2023-2024 COVID-19 dose (ref)	59,422	7,430 (13)	609 (399-803)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	24,113	1,901 (8)	84 (47-126)	**35 (31-38)**
2023-2024 COVID-19 dose, 7-59 days earlier	8,007	669 (8)	35 (21-47)	**47 (42-51)**
2023-2024 COVID-19 dose, 60-119 days earlier	9,248	826 (9)	88 (73-103)	**32 (26-37)**
2023-2024 COVID-19 dose, 120-179 days earlier	6,858	406 (6)	146 (133-162)	**7 (-5-17)**



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https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a5.htm (Results updated with additional data since publication.) VE was calculated as (1 – odds ratio) x 100%, estimated using a test-negative case-control design, with the odds ratio adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

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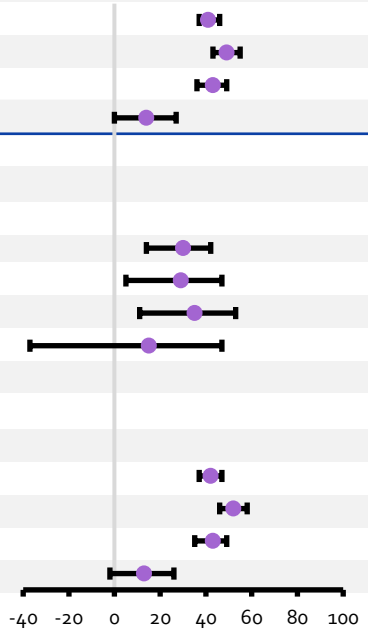
Updates to COVID-19 VE against COVID-19-associated hospitalization and critical illness:

VISION and IVY Networks

VISION: VE of *2023-2024 COVID-19 vaccine* against *hospitalization* among immunocompetent adults aged ≥18 years, by age group

September 2023 – May 2024

Age group/2023-2024 COVID-19 vaccination status/days since dose	Total encounters	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	63,908	6,484 (10)	693 (448-852)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	13,195	912 (7)	84 (46-127)	**41 (37-46)**
2023-2024 COVID-19 dose, 7-59 days earlier	4,458	345 (8)	34 (20-47)	**49 (43-55)**
2023-2024 COVID-19 dose, 60-119 days earlier	4,928	362 (7)	88 (73-104)	**43 (36-49)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,809	205 (5)	146 (133-162)	**14 (0-27)**
18-64 years				
No 2023-2024 COVID-19 dose (ref)	25,209	1,644 (7)	743 (544-888)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	2,363	114 (5)	80 (42-121)	**30 (14-42)**
2023-2024 COVID-19 dose, 7-59 days earlier	870	52 (6)	33 (20-45)	**29 (5-47)**
2023-2024 COVID-19 dose, 60-119 days earlier	887	43 (5)	88 (74-103)	**35 (11-53)**
2023-2024 COVID-19 dose, 120-179 days earlier	606	19 (3)	146 (134-160)	**15 (-37-47)***
≥65 years				
No 2023-2024 COVID-19 dose (ref)	38,699	4,840 (13)	651 (419-827)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	10,832	798 (7)	85 (47-128)	**42 (37-47)**
2023-2024 COVID-19 dose, 7-59 days earlier	3,588	293 (8)	34 (20-47)	**52 (46-58)**
2023-2024 COVID-19 dose, 60-119 days earlier	4,041	319 (8)	88 (73-104)	**43 (35-49)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,203	186 (6)	147 (133-162)	**13 (-2-26)**



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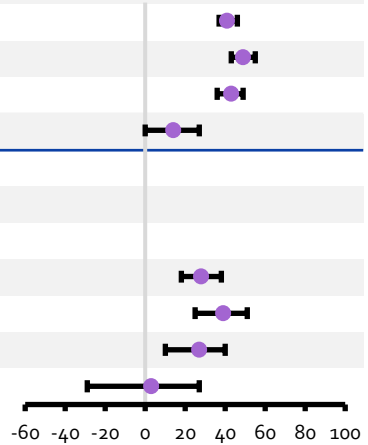
https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a5.htm (Results updated with additional data since publication.) VE was calculated as (1 − odds ratio) x 100%, estimated using a test-negative case-control design, adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

VISION: VE of *2023-2024 COVID-19 vaccine* against *hospitalization* among adults aged ≥18 years, by immunocompromise status

September 2023 – May 2024

Immunocompromise status/2023-2024 COVID-19 vaccination status/days since dose	Total encounters	SARS-CoV-2-test-positive N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years, non-immunocompromised				
No 2023-2024 COVID-19 dose (ref)	63,908	6,484 (10)	693 (448-852)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	13,195	912 (7)	84 (46-127)	**41 (37-46)**
2023-2024 COVID-19 dose, 7-59 days earlier	4,458	345 (8)	34 (20-47)	**49 (43-55)**
2023-2024 COVID-19 dose, 60-119 days earlier	4,928	362 (7)	88 (73-104)	**43 (36-49)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,809	205 (5)	146 (133-162)	**14 (0-27)**
≥18 years, immunocompromised				
No 2023-2024 COVID-19 dose (ref)	17,574	1,463 (8)	644 (414-826)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	4,673	289 (6)	84 (46-127)	**28 (18-38)**
2023-2024 COVID-19 dose, 7-59 days earlier	1,573	104 (7)	34 (21-46)	**39 (25-51)**
2023-2024 COVID-19 dose, 60-119 days earlier	1,753	123 (7)	88 (74-105)	**27 (10-40)**
2023-2024 COVID-19 dose, 120-179 days earlier	1,347	62 (5)	146 (133-162)	**3 (-29-27)***



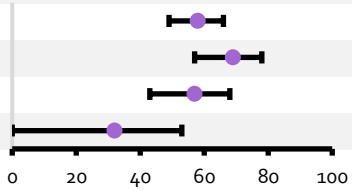
Additional methods, including definition of immunocompromised available: https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a5.htm (Results updated with additional data since publication.) VE was calculated as (1 – odds ratio) x 100%, estimated using a test-negative case-control design, adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

* Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual could increase precision and allow more precise interpretation.

VISION: VE of *2023-2024 COVID-19 vaccine* against *critical illness* among immunocompetent adults aged ≥18 years, by age group

September 2023 – May 2024

Age group/2023-2024 COVID-19 vaccination status/days since dose	Total encounters	SARS-CoV-2-test-positive N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	58,576	1,152 (2)	694 (452-855)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	12,402	119 (1)	85 (46-128)	**58 (49-66)**
2023-2024 COVID-19 dose, 7-59 days earlier	4,151	38 (1)	34 (21-47)	**69 (57-78)**
2023-2024 COVID-19 dose, 60-119 days earlier	4,616	50 (1)	88 (74-104)	**57 (43-68)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,635	31 (1)	147 (133-162)	**32 (0-53)***



CDC unpublished data. Critical illness defined as admission to an intensive care unit (ICU) or death while hospitalized or ≤28 days after hospital admission. VE was calculated as (1 − odds ratio) x 100%, estimated using a test-negative case-control design, adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

*Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual could increase precision and allow more precise interpretation.

IVY Network — 26 hospitals, 20 U.S. States

- **Design**: Test-negative, case-control design
- **Population**: Adults aged ≥18 years hospitalized with COVID-like illness (CLI)* and SARS-CoV-2 test results within 10 days of illness onset and 3 days of admission
  - **Cases:** CLI and test *positive* for SARS-CoV-2 by NAAT or antigen
    - Co-infections with influenza and RSV are excluded
  - **Controls**: CLI and test *negative* for SARS-CoV-2 and influenza by RT-PCR
- **Vaccination data:** Electronic medical records (EMR), state and city registries, and plausible self-report
- **Specimens:** Nasal swabs obtained on all patients for central RT-PCR testing and whole genome sequencing

IVY

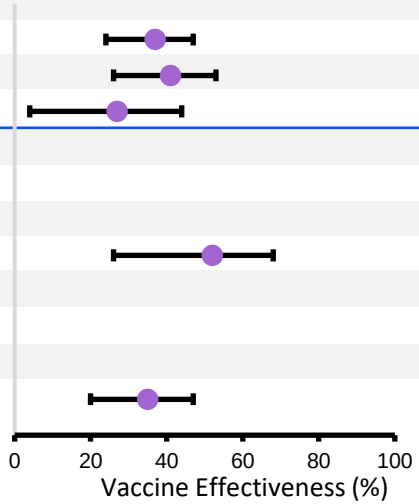
INVESTIGATING RESPIRATORY VIRUSES IN THE ACUTELY ILL

*CLI is defined as presence of any one of the following: fever, cough, shortness of breath, chest imaging consistent with pneumonia, or hypoxemia

IVY: VE of *2023–2024 vaccine* against *hospitalization* among immuno*competent* adults aged ≥18 years, by age group and time since dose

September 21, 2023 – April 30, 2024

COVID-19 dosage pattern/age group	COVID-19 case-patients N (Col %)	COVID-19 control-patients N (Col %)	Median interval since last dose among those vaccinated, days (IQR)	VE* % (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	1538 (89)	4149 (84)	681 (430–840)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	191 (11)	786 (16)	81 (43–121)	**37 (24–47)**
2023-2024 COVID-19 dose, 7–89 days earlier	110 (6)	441 (9)	48 (26-69)	**41 (26–53)**
2023-2024 COVID-19 dose, 90–179 days earlier	81 (5)	345 (7)	127 (107–148)	**27 (4–44)**
18–64 years				
No 2023-2024 COVID-19 dose (ref)	530 (95)	2084 (90)	733 (485–879)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	27 (5)	236 (10)	73 (34–112)	**52 (26–68)**
≥65 years				
No 2023-2024 COVID-19 dose (ref)	1008 (86)	2065 (79)	643 (406–802)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	164 (14)	550 (21)	82 (45–123)	**35 (20–47)**



*Logistic regression models were adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

IVY*: VE of *2023–2024 vaccine* against *hospitalization* among adults aged ≥18 years *by SARS-CoV-2 lineage* using viral whole-genome sequencing

- **Population**
  - **Cases:** COVID-like illness (CLI) and test *positive* for SARS-CoV-2[†]; **restricted to patients with sequence-confirmed[§] JN lineage (BA.2.86 and its descendants) infection or XBB lineage (all other co-circulating lineages) infections**
  - **Controls:** CLI and test *negative* for SARS-CoV-2 and influenza viruses by RT-PCR

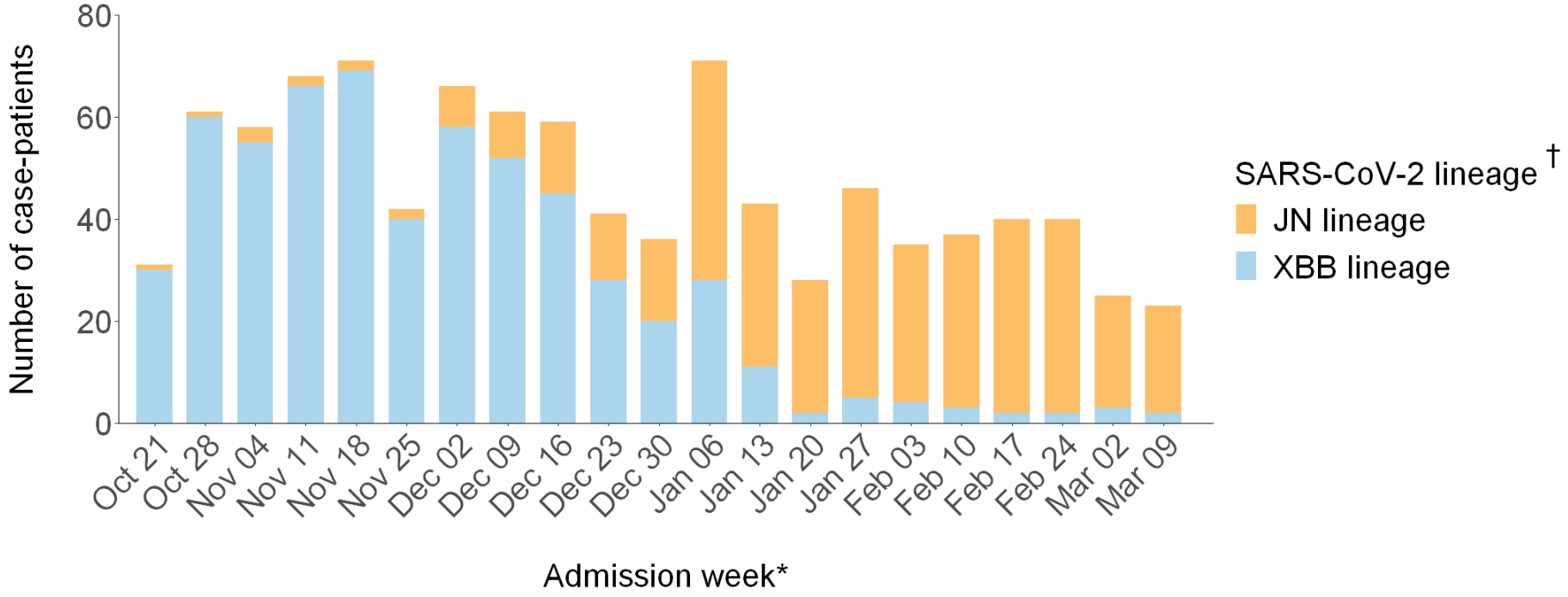
- **Analytic Period:** October 18, 2023–March 9, 2024
  - First date on which a patient was admitted with sequence-confirmed JN lineage infection
  - Last week during which a patient was admitted with sequence-confirmed XBB lineage infection

- VE[¶] against hospitalization was calculated separately using case-patients with sequence-confirmed SARS-CoV-2 JN and XBB lineage infections

* Investigating Respiratory Viruses in the Acutely Ill (IVY) Network. https://www.cdc.gov/flu/vaccines-work/ivy.htm
† Case patients who tested positive for influenza viruses or RSV were excluded.
§ Identification of a SARS-CoV-2 lineage through viral whole-genome sequencing was successful for 63% of case-patients during the analysis period.
¶ Odds ratios were adjusted for age, sex, race and ethnicity, geographic region, calendar time, and Charlson comorbidity index.

IVY: Number of COVID-19 case-patients by hospital admission week and SARS-CoV-2 lineage

October 18, 2023 – March 9, 2024



* Dates are for the end of the admission week.

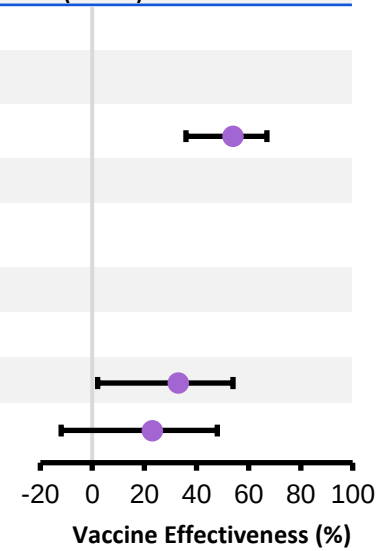
† JN lineages comprised BA.2.86 and its descendants. XBB lineages comprised all other co-circulating lineages.

Identification of a SARS-CoV-2 lineage through viral whole-genome sequencing was successful for 63% of case-patients during the analysis period.

IVY: VE of *2023–2024 COVID-19 vaccine* against *hospitalization* among adults aged ≥18 years*, by SARS-CoV-2 lineage and time since dose

October 18, 2023 – March 9, 2024

COVID-19 dosage pattern	COVID-19 control-patients		COVID-19 case-patients		VE** (95% CI)
	N (Col %)	Median interval since last dose among vaccinated, days (IQR)	N (Col %)	Median interval since last dose among vaccinated, days (IQR)	
XBB lineages†					
No 2023-2024 COVID-19 dose (ref)	3736 (82)	688 (429–834)	532 (91)	557 (385–751)	**Ref**
2023-2024 COVID-19 dose, 7–89 days earlier	568 (12)	47 (26–68)	47 (8)	44 (22–67)	**54 (36–67)**
2023-2024 COVID-19 dose, 90–179 days earlier	276 (6)	118 (106–131)	6 (1)	92 (91–105)	**§**
JN lineages†					
No 2023-2024 COVID-19 dose (ref)	3736 (82)	688 (429–834)	319 (80)	746 (479–855)	**Ref**
2023-2024 COVID-19 dose, 7–89 days earlier	568 (12)	47 (26–68)	38 (10)	56 (31–74)	**33 (2–54)¶**
2023-2024 COVID-19 dose, 90–179 days earlier	276 (6)	118 (106–131)	40 (10)	118 (107–130)	**23 (-12 to 48)¶**



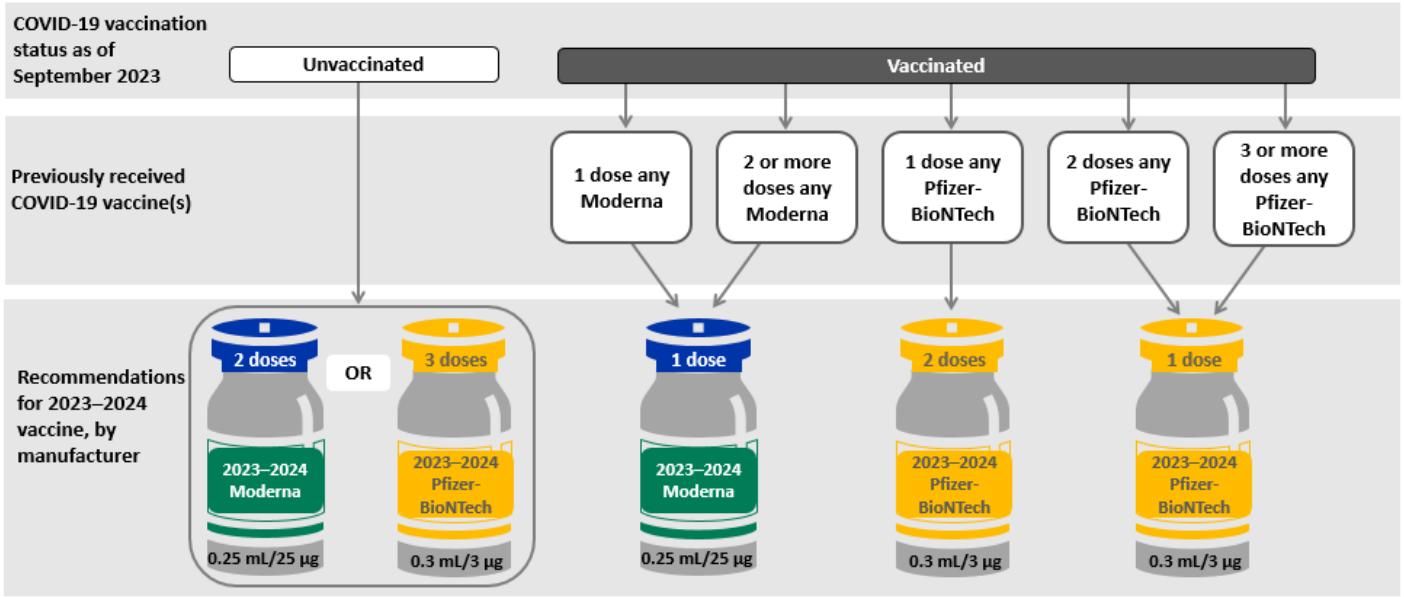
* These results include both immunocompetent and immunocompromised persons.
† JN lineages comprised BA.2.86 and its descendants. XBB lineages comprised all other co-circulating lineages.
§ Based on timing of recommendations to receive 2023–2024 COVID-19 vaccines and JN lineage emergence, limited numbers of individuals with XBB infection were 90–179 days from their updated dose, precluding estimation of VE within this stratum.
¶ Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution.
** VE estimates adjusted for age, sex, race and ethnicity, geographic region, calendar time, and Charlson comorbidity index.

CDC unpublished data.

COVID-19 VE in young children and by age group

Reminder: children aged 6 months-4 years continue to be recommended for a complete initial series

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months–4 years*

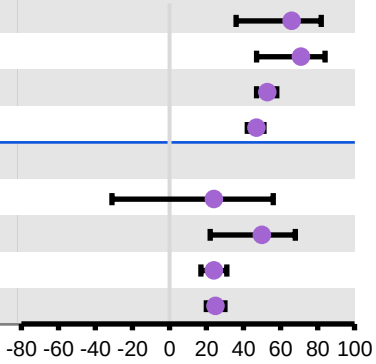


*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

VISION: VE of *2023–2024 COVID-19 vaccine doses* against *ED/UC encounters* was similar across age groups

September 2023 – May 2024

Age group | COVID-19 vaccination status	Total encounters	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
No updated 2023-2024 COVID-19 vaccine dose*				
9 months-4 years	30,286	1,180 (4)	349 (236-443)	**Ref**
5-17 years	37,203	1,449 (4)	650 (449-769)	**Ref**
18-64 years	148,273	15,100 (10)	751 (573-887)	**Ref**
≥65 years	59,422	7,430 (13)	609 (399-803)	**Ref**
2023-2024 COVID-19 dose received 7-59 days earlier				
9 months-4 years	613	10 (2)	33 (19-46)	**66 (36-82)**
5-17 years	805	11 (1)	33 (19-47)	**71 (47-84)**
18-64 years	5,137	313 (6)	34 (20-47)	**53 (47-58)**
≥65 years	8,007	669 (8)	35 (21-47)	**47 (42-51)**
2023-2024 COVID-19 dose received 60-179 days earlier				
9 months-4 years	706	14 (2)	104 (80-137)	24 (-31-56)**
5-17 years	1,343	22 (2)	111 (86-138)	50 (22-68)
18-64 years	8,559	506 (6)	108 (82-137)	24 (17-31)
≥65 years	16,106	1,232 (8)	111 (84-142)	25 (20-30)



* Includes all individuals who did not receive a 2023-2024 COVID-19 vaccine. For those aged ≥5 years, this includes unvaccinated persons and persons who were vaccinated with ≥1 original monovalent or bivalent COVID-19 doses. For those aged <5 years, both those in the referent group and those in the vaccinated group were required to have completed an initial series. The 2023-2024 dose could have been part of the initial series or in addition to the initial series.

** Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual could increase precision and allow more precise interpretation.

Conclusions

- 2023-2024 COVID-19 vaccination provided increased protection against symptomatic SARS-CoV-2 infection and COVID-19-associated ED/UC visits and hospitalizations compared to no 2023-2024 vaccine dose.
- Waning patterns appeared similar to previous COVID-19 vaccine formulations; most durable protection appeared to be for critical illness, though statistical power was lacking in the longest time period since vaccination
- As with previous COVID-19 vaccine formulations, effectiveness was similar across age groups
- Receipt of 2023-2024 COVID-19 vaccine provided protection against JN.1 and other circulating variants, though may be lower than protection provided against XBB sublineage variants

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