Effectiveness of Monovalent mRNA COVID-19 Vaccination in Preventing COVID-19–Associated Invasive Mechanical Ventilation and Death Among Immunocompetent Adults During the Omicron Variant Period — IVY Network, 19 U.S. States, February 1, 2022–January 31, 2023

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As of April 2023, the COVID-19 pandemic has resulted in 1.1 million deaths in the United States, with approximately 75% of deaths occurring among adults aged ≥65 years (*1*). Data on the durability of protection provided by monovalent mRNA COVID-19 vaccination against critical outcomes of COVID-19 are limited beyond the Omicron BA.1 lineage period (December 26, 2021–March 26, 2022). In this case-control analysis, the effectiveness of 2–4 monovalent mRNA COVID-19 vaccine doses was evaluated against COVID-19–associated invasive mechanical ventilation (IMV) and in-hospital death among immunocompetent adults aged ≥18 years during February 1, 2022–January 31, 2023. Vaccine effectiveness (VE) against IMV and in-hospital death was 62% among adults aged ≥18 years and 69% among those aged ≥65 years. When stratified by time since last dose, VE was 76% at 7–179 days, 54% at 180–364 days, and 56% at ≥365 days. Monovalent mRNA COVID-19 vaccination provided substantial, durable protection against IMV and in-hospital death among adults during the Omicron variant period. All adults should remain up to date with recommended COVID-19 vaccination to prevent critical COVID-19–associated outcomes.

Monovalent mRNA COVID-19 vaccination has been shown to prevent hospitalization and critical outcomes, including IMV and death, during SARS-CoV-2 Alpha, Delta, and early Omicron variant periods (*2*,*3*). However, rapid waning of COVID-19 VE against infection, outpatient illness, and hospitalization has been observed during Omicron variant predominance (*4*). Understanding the durability of protection provided by monovalent mRNA vaccination against critical outcomes is vital. Although a bivalent mRNA dose was recommended on September 1, 2022, for all persons who had completed a primary COVID-19 vaccination series, bivalent vaccination coverage among adults aged ≥18 years is 20%, and most adults have only received monovalent mRNA vaccines (*1*,*5*). In addition, COVID-19 VE against hospitalization might be artificially reduced by routine testing for SARS-CoV-2 at admission, which can detect SARS-CoV-2 infection in patients admitted for reasons other than COVID-19 (*4*,*6*,*7*). VE against critical outcomes might be less susceptible to this bias and is therefore needed to help guide COVID-19 vaccination policy regarding revaccination intervals.

Data from the Investigating Respiratory Viruses in the Acutely Ill (IVY) Network[§] were used to conduct a case-control analysis measuring the effectiveness of monovalent mRNA COVID-19 vaccination against COVID-19–associated IMV and in-hospital death. During February 1, 2022–January 31, 2023, adults aged ≥18 years admitted to 24 hospitals in 19 U.S. states who met a COVID-19–like illness case definition[¶] and received SARS-CoV-2 testing were enrolled. IVY Network methods have been described previously (*2*,*3*). Briefly, case-patients were defined as those who received a positive SARS-CoV-2 reverse transcription–polymerase chain reaction (RT-PCR) or antigen test result within 10 days of illness onset and within 3 days of hospital admission, and either received IMV or died in the hospital within 28 days of admission. Control patients were defined as those who received negative SARS-CoV-2 and influenza test results by RT-PCR within 10 days of illness onset and within 3 days of hospital admission. Patients who received positive influenza test results were excluded from the analysis because of potential correlation between COVID-19 and influenza vaccination behaviors (*8*).

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[§] https://www.cdc.gov/flu/vaccines-work/ivy.htm
[¶] COVID-19–like illness was defined as including any one of the following signs and symptoms: fever, cough, shortness of breath, new or worsening findings on chest imaging consistent with pneumonia, or hypoxemia defined as SpO2 <92% on room air or supplemental oxygen to maintain SpO2 ≥92%. For patients on chronic oxygen therapy, hypoxemia was defined as SpO2 below baseline or an escalation of supplemental oxygen to maintain a baseline SpO2.

Demographic and clinical data, including receipt of IMV and in-hospital death within 28 days of admission, were collected through electronic medical record (EMR) review and patient or proxy interview. COVID-19 vaccination history was ascertained from state or jurisdictional registries, EMRs, vaccination cards, and self-report. Patients were included in the analysis if they 1) received zero COVID-19 vaccines doses (unvaccinated) or 2) received 2, 3, or 4 monovalent mRNA COVID-19 vaccine doses (monovalent-vaccinated), with the last dose received ≥14 days before illness onset for a primary series dose or ≥7 days before illness onset for a booster dose. Patients were excluded from the analysis if they were immunocompromised,** received a non-mRNA COVID-19 vaccine dose, received only 1 monovalent mRNA COVID-19 vaccine dose, received a bivalent mRNA COVID-19 vaccine dose, or for other reasons†† that made the patient ineligible.

VE against IMV and in-hospital death was calculated using logistic regression, in which the odds of monovalent mRNA vaccination (versus being unvaccinated) were compared between COVID-19 case-patients and control patients. Logistic regression models were adjusted for U.S. Department of Health and Human Services region, calendar time in biweekly intervals, age, sex, and self-reported race and Hispanic ethnicity. VE was calculated as (1 – adjusted odds ratio) x 100%. Results were stratified by age group, time since receipt of last monovalent mRNA vaccine dose, and number of monovalent mRNA vaccine doses received.§§ Differences between VE point estimates with nonoverlapping 95% CIs were considered statistically significant. Analyses were conducted using SAS (version 9.4; SAS Institute). This activity was determined to be public health surveillance by each participating site and CDC and was conducted in a manner consistent with all applicable federal laws and CDC policy.¶¶

During February 1, 2022–January 31, 2023, a total of 6,354 immunocompetent control patients and COVID-19 case-patients with IMV or in-hospital death were enrolled in the IVY Network. After exclusion of 1,933 patients,*** 4,421 (70%) were included in the analysis (362 case-patients and 4,059 control patients). Patients were most commonly excluded because of receipt of a bivalent mRNA COVID-19 vaccine dose (446 [23% of excluded patients]), receipt of a non-mRNA COVID-19 vaccine (392 [20%]), or receipt of only 1 monovalent mRNA COVID-19 vaccine dose (260 [13%]). Among included patients, the median age was 64 years (IQR = 53–75 years) (Table 1). Ninety-one percent of patients had one or more chronic condition, and 20% had a previous self-reported or documented SARS-CoV-2 infection. Among 362 case-patients with IMV or in-hospital death, 146 (40%) were unvaccinated, 216 (60%) were monovalent-vaccinated, 293 (81%) received IMV, and 156 (43%) died in the hospital within 28 days of admission. Among 4,059 control patients, 979 (24%) were unvaccinated, and 3,080 (76%) were monovalent-vaccinated.

Among monovalent-vaccinated patients, the median interval from receipt of last dose to illness onset was 248 days (IQR = 138–378 days) (Table 2). When compared with unvaccinated patients, the VE of 2–4 monovalent mRNA vaccine doses against IMV and in-hospital death was 62%. VE was 57% among patients aged 18–64 years and 69% among patients aged ≥65 years. When stratified by interval since receipt of last monovalent dose, VE against IMV and in-hospital death was 76% at 7–179 days, 54% at 180–364 days, and 56% at ≥365 days. Within each interval since receipt of last monovalent dose, VE estimates did not differ significantly by number of doses received. VE point estimates were higher 7–179 days since last dose compared with ≥180 days since last dose, although 95% CIs overlapped.

Discussion

Among immunocompetent adults aged ≥18 years admitted to 24 hospitals in the IVY Network in 19 U.S. states, receipt of 2–4 monovalent mRNA COVID-19 vaccine doses provided substantial protection against COVID-19–associated IMV and in-hospital death during the Omicron variant period.

** Immunocompromising conditions were defined as active solid tumor or hematologic cancer (i.e., newly diagnosed cancer or cancer treatment within the previous 6 months), solid organ transplant, bone marrow/stem cell transplant, HIV infection, congenital immunodeficiency syndrome, use of an immunosuppressive medication within the previous 30 days, splenectomy, or another condition that causes moderate or severe immunosuppression.

†† Other reasons for exclusion: 1) illness onset after hospital admission, 2) enrollment >7 days after hospital admission, 3) receipt of a SARS-CoV-2–positive test result >3 days after hospital admission, 4) case-patient with co-infection with influenza or respiratory syncytial virus, 5) control patient with receipt of a positive influenza test result, and 6) participant withdrawal.

§§ VE estimates comparing recipients of 4 monovalent mRNA vaccine doses with unvaccinated patients were restricted to adults aged ≥50 years admitted during April 5, 2022–January 31, 2023, consistent with CDC recommendations regarding eligibility for a second monovalent mRNA booster dose. https://www.cdc.gov/media/releases/2022/s0328-covid-19-boosters.html (Accessed March 26, 2023).

¶¶ 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

*** A total of 1,933 immunocompetent patients were excluded from the analysis for the following reasons (not mutually exclusive): illness onset occurred after hospital admission (82), patient enrolled >7 days after hospital admission (239), inability to obtain an upper respiratory sample for central laboratory testing among controls (149), SARS-CoV-2 test >3 days after hospital admission (33), SARS-CoV-2 testing indeterminate (65), case-patient received a positive influenza test result (21), control patient received a positive influenza test result (29), influenza testing indeterminate or not done (83), case-patient received a positive respiratory syncytial virus test result (27), verified and self-reported vaccination history missing so that vaccination status could not be assigned (57), non-mRNA vaccine received (392), partial vaccination (260), bivalent vaccination (446), received COVID-19 vaccines outside of CDC guidelines (144), last monovalent dose received <14 days before illness onset if primary series or <7 days before illness onset if booster (55), and withdrew (12).

TABLE 1. Characteristics of COVID-19 case-patients who received invasive mechanical ventilation or died in the hospital and COVID-19 test-negative control patients among immunocompetent adults aged ≥18 years — IVY Network, 24 hospitals,* 19 U.S. states, February 1, 2022–January 31, 2023

Characteristic	No. (%) Total (N = 4,421)	COVID-19 case-patients with IMV or death (n = 362)	COVID-19 test-negative control patients (n = 4,059)
Vaccination status			
Unvaccinated	**1,125 (25)**	146 (40)	979 (24)
2–4 Monovalent mRNA doses	**3,296 (75)**	216 (60)	3,080 (76)
2 Monovalent mRNA doses	**1,148 (26)**	87 (24)	1,061 (26)
3 Monovalent mRNA doses	**1,642 (37)**	108 (30)	1,534 (38)
4 Monovalent mRNA doses	**506 (11)**	21 (6)	485 (12)
Female sex	**2,202 (50)**	141 (39)	2,061 (51)
Median age, yrs (IQR)	**64 (53–75)**	66 (55–79)	64 (52–75)
Age group, yrs			
18–64	**2,258 (51)**	163 (45)	2,095 (52)
≥65	**2,163 (49)**	199 (55)	1,964 (48)
Race and ethnicity			
Black or African American, non-Hispanic	**938 (21)**	40 (11)	898 (22)
White, non-Hispanic	**2,616 (59)**	238 (66)	2,378 (59)
Hispanic or Latino, any race	**535 (12)**	48 (13)	487 (12)
Other race, non-Hispanic†	**155 (4)**	18 (5)	137 (3)
Other§	**177 (4)**	18 (5)	159 (4)
HHS region*			
1	**783 (18)**	74 (20)	709 (17)
2	**284 (6)**	18 (5)	266 (7)
3	**150 (3)**	5 (1)	145 (4)
4	**775 (18)**	76 (21)	699 (17)
5	**608 (14)**	45 (12)	563 (14)
6	**473 (11)**	18 (5)	455 (11)
7	**297 (7)**	19 (5)	278 (7)
8	**674 (15)**	53 (15)	621 (15)
9	**153 (3)**	14 (4)	139 (3)
10	**224 (5)**	40 (11)	184 (5)

TABLE 1. (*Continued*) Characteristics of COVID-19 case-patients who received invasive mechanical ventilation or died in the hospital and COVID-19 test-negative control patients among immunocompetent adults aged ≥18 years — IVY Network, 24 hospitals,* 19 U.S. states, February 1, 2022–January 31, 2023

Characteristic	No. (%) Total (N = 4,421)	COVID-19 case-patients with IMV or death (n = 362)	COVID-19 test-negative control patients (n = 4,059)
No. of chronic medical condition categories¶			
0	**423 (10)**	36 (10)	387 (10)
1	**1,095 (25)**	113 (31)	982 (24)
2	**1,304 (30)**	95 (26)	1,209 (30)
≥3	**1,599 (36)**	118 (33)	1,481 (36)
Previous SARS-CoV-2 infection**			
Any previous SARS-CoV-2 infection	**868 (20)**	31 (9)	837 (21)
Previous Omicron variant infection	**471 (11)**	21 (6)	450 (11)

Abbreviations: HHS = U.S. Department of Health and Human Services; IMV = invasive mechanical ventilation.

* Hospitals by HHS region included *Region 1*: Baystate Medical Center (Springfield, Massachusetts), Beth Israel Deaconess Medical Center (Boston, Massachusetts), and Yale University (New Haven, Connecticut); *Region 2*: Montefiore Medical Center (New York, New York); *Region 3*: Johns Hopkins Hospital (Baltimore, Maryland); *Region 4*: Emory University Medical Center (Atlanta, Georgia), University of Miami Medical Center (Miami, Florida), Vanderbilt University Medical Center (Nashville, Tennessee), and Wake Forest University Baptist Medical Center (Winston-Salem, North Carolina); *Region 5*: Cleveland Clinic (Cleveland, Ohio), Hennepin County Medical Center (Minneapolis, Minnesota), Henry Ford Health (Detroit, Michigan), The Ohio State University Wexner Medical Center (Columbus, Ohio), and University of Michigan Hospital (Ann Arbor, Michigan); *Region 6*: Baylor Scott & White Medical Center (Temple, Texas) and Baylor University Medical Center (Dallas, Texas); *Region 7*: Barnes-Jewish Hospital (St. Louis, Missouri) and University of Iowa Hospitals (Iowa City, Iowa); *Region 8*: Intermountain Medical Center (Murray, Utah) and UCHealth University of Colorado Hospital (Aurora, Colorado); *Region 9*: Stanford University Medical Center (Stanford, California) and Ronald Reagan UCLA Medical Center (Los Angeles, California); and *Region 10*: Oregon Health & Science University Hospital (Portland, Oregon) and University of Washington (Seattle, Washington).

† Other race, non-Hispanic includes American Indian or Alaska Native, Asian, and Native Hawaiian or other Pacific Islander categories, which were combined because of small counts.

§ Other includes patients who self-reported their race and ethnicity as "Other" and those for whom race and ethnicity were unknown.

¶ Chronic medical condition categories include autoimmune, cardiovascular, endocrine, gastrointestinal, hematologic, neurologic, pulmonary, and renal diseases.

** Previous SARS-CoV-2 infection was defined as any self-reported or documented previous SARS-CoV-2 infection. Previous Omicron infection was defined as any self-reported or documented previous SARS-CoV-2 infection that occurred during December 26, 2021–January 31, 2023.

Protection was highest during the first 6 months after the last monovalent dose, with persistent residual protection remaining after 6 months and sustained at 1–2 years. Monovalent mRNA vaccination also provided substantial protection against COVID-19–associated IMV and death among adults aged ≥65 years, the age group that remains at highest risk of severe COVID-19 (*1*). These findings underscore the importance of staying up to date with COVID-19 vaccination to prevent critical outcomes of COVID-19, including optional, additional bivalent mRNA booster doses for persons at highest risk of severe disease.†††

A previous analysis from the IVY Network showed high effectiveness of monovalent mRNA COVID-19 vaccination against COVID-19–associated IMV and death during the Delta and early Omicron variant periods (*2*). The current analysis expands on these findings by reporting monovalent mRNA COVID-19

††† https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html?ACSTrackingID=USCDC_2120-DM104004&ACSTrackingLabel=Updated%20Guidance%3A%20Interim%20Clinical%20Considerations%20for%20Use%20of%20COVID-19%20Vaccines&deliveryName=USCDC_2120-DM104004 (Accessed April 24, 2023).

TABLE 2. Effectiveness of monovalent mRNA COVID-19 vaccination against COVID-19–associated invasive mechanical ventilation or in-hospital death among immunocompetent adults aged ≥18 years — IVY Network, 24 hospitals,* 19 U.S. states, February 1, 2022–January 31, 2023

Group	Case-patients who received IMV or died, no. of monovalent-vaccinated†/total no. (%)	Control patients, no. of monovalent-vaccinated†/ total no. (%)	Median interval from last monovalent mRNA vaccine dose to illness onset (IQR), days	Adjusted VE against IMV and death % (95% CI)§
Overall	**216/362 (60)**	**3,080/4,059 (76)**	**248 (138–378)**	**62 (52–70)**
Age group, yrs				
18–64	85/163 (52)	1,421/2,095 (68)	263 (144–380)	57 (39–70)
≥65	131/199 (66)	1,659/1,964 (84)	238 (133–375)	69 (57–78)
Interval from last monovalent mRNA vaccine dose to illness onset, days				
7–179	63/209 (30)	1,112/2,091 (53)	109 (68–145)	76 (66–83)
180–364	95/241 (39)	1,110/2,089 (53)	269 (220–317)	54 (37–66)
≥365	58/204 (28)	858/1,837 (47)	455 (402–549)	56 (36–69)
Interval from last monovalent mRNA vaccine dose to illness onset, by no. of doses received				
≥7 days before illness onset				
2 doses	87/233 (37)	1,061/2,040 (52)	395 (292–512)	53 (37–65)
3 doses	108/254 (43)	1,534/2,513 (61)	210 (129–313)	65 (54–74)
4 doses¶	19/95 (20)	461/968 (48)	118 (66–169)	83 (70–91)
7–179 days before illness onset				
2 doses	6/152 (4)	108/1,087 (10)	114 (72–153)	—**
3 doses	42/188 (22)	633/1,612 (39)	116 (75–147)	70 (55–81)
4 doses¶	15/91 (16)	353/860 (41)	94 (55–135)	84 (69–92)
≥180 days before illness onset				
2 doses	81/227 (36)	953/1,932 (49)	418 (326–531)	50 (32–64)
3 doses	66/212 (31)	901/1,880 (48)	292 (235–366)	59 (42–72)
4 doses¶	4/80 (5)	108/615 (18)	223 (197–258)	—**

Abbreviations: IMV = invasive mechanical ventilation; VE = vaccine effectiveness.

* https://www.cdc.gov/flu/vaccines-work/ivy.htm

† Monovalent-vaccinated patients received 2–4 monovalent mRNA COVID-19 vaccine doses and zero bivalent mRNA COVID-19 vaccine doses.

§ VE was estimated by comparing the odds of monovalent mRNA vaccination among case-patients and control patients, calculated as VE = 100 × (1 − odds ratio). Logistic regression models were adjusted for date of hospital admission (biweekly intervals), U.S. Department of Health and Human Services region (10 regions), categorical age (18–49, 50–64, and ≥65 years), sex, and race and ethnicity (Black or African American, non-Hispanic; White, non-Hispanic; Hispanic or Latino, any race; Other race, non-Hispanic; and Other, unknown) unless otherwise noted. Logistic regression models for age group–specific VE estimates were adjusted for continuous age.

¶ Logistic regression models for VE of 4 monovalent doses were restricted to patients aged ≥50 years admitted during April 5, 2022–January 31, 2023, and were adjusted for continuous age.

** VE estimate was not reported because of insufficient sample size.

VE against IMV and in-hospital death for a full year during the Omicron variant period. These results suggest some waning of protection against IMV and death after 6 months from receipt of the last dose but demonstrate clinically meaningful levels of protection for ≥1 year (median = 455 days). In stratified analyses, VE appeared to correlate more closely with time since last dose than with total number of doses received. These findings are consistent with evidence from the United Kingdom showing that among adults aged ≥65 years, VE of monovalent COVID-19 vaccination against COVID-19–associated mortality during the Omicron variant period was 49.7% for 2 doses and 56.9% for 3 doses after 40 weeks (280 days) from vaccination (*9*). Together, these results suggest maximal benefit of COVID-19 vaccination during the first 6 months after receipt, which should be considered along with trends in COVID-19 incidence and risk factors for severe disease when planning COVID-19 revaccination schedules.

The findings in this report are subject to at least four limitations. First, the sample size was insufficient to generate VE estimates for each Omicron lineage period separately or to calculate some VE estimates stratified by both time since last monovalent mRNA dose and number of doses received. Second, although case-patients had evidence of acute respiratory illness and received a positive SARS-CoV-2 test result, inclusion of case-patients who died or required IMV for reasons other than COVID-19 could have reduced VE because of misclassification. Third, previous SARS-CoV-2 infection was infrequently reported or documented among patients in this analysis, which prevented evaluation of the impact of previous infection on VE against critical outcomes. Finally, although VE estimates were adjusted for patient-level demographic characteristics, calendar time, and geographic region, residual confounding, including from COVID-19 antiviral treatment, cannot be excluded.

Since the start of the COVID-19 pandemic, approximately 1.1 million COVID-19–associated deaths have occurred in the United States, with the majority occurring among patients aged ≥65 years. Monovalent mRNA COVID-19 vaccination provided substantial, durable protection against COVID-19–associated IMV and death during the Omicron variant period,

Summary

What is already known about this topic?

Waning of monovalent mRNA COVID-19 vaccine effectiveness against COVID-19–associated hospitalization among adults is recognized; however, little is known about the durability of protection provided by these vaccines against COVID-19–associated invasive mechanical ventilation (IMV) and in-hospital death during the Omicron variant period.

What is added by this report?

Monovalent mRNA vaccination was 76% effective in preventing COVID-19–associated IMV and death <6 months after the last dose and remained 56% effective at 1–2 years.

What are the implications for public health practice?

Monovalent mRNA COVID-19 vaccines provided substantial, durable protection against COVID-19–associated IMV and death. All adults should remain up to date with recommended COVID-19 vaccination to prevent critical outcomes of COVID-19.

including among older adults. Protection against these critical outcomes appeared to correlate more closely with time since last dose than with total number of doses received. On April 18, 2023, bivalent mRNA vaccines became the only mRNA COVID-19 vaccines authorized for use in the United States.[§§§] Only 42% of adults aged ≥65 years have received a bivalent mRNA COVID-19 vaccine dose and are up to date with COVID-19 vaccination (*1*). CDC recommends that all adults remain up to date with COVID-19 vaccination, including the updated bivalent vaccine, to prevent critical outcomes of COVID-19.

[§§§] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines (Accessed April 25, 2023).

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