2024-2025 BNT162b2 COVID-19 vaccine effectiveness in non-immunocompromised adults: mid-season estimates from vaccine registries in two states linked to administrative claims

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ABSTRACT

Background: Data are limited on 2024-2025 BNT162b2 COVID-19 vaccine effectiveness (VE).

Methods: Retrospective cohort study among non-immunocompromised adults from August 22, 2024 ("index") to December 31, 2024, among residents of California or Louisiana continuously enrolled in health insurance plans reporting to HealthVerity for ≥1 year prior to index. Receipt of 2024-2025 BNT162b2 COVID-19 vaccine was defined using state vaccine registries with health insurance claims, using a time-varying exposure definition. VE against COVID-19-associated hospital admissions was estimated as (1-hazard ratio), using adjusted Cox proportional hazards models with 95% confidence intervals (CI).

Results: Overall, 6,900,361 individuals met selection criteria for the study. By the end of follow-up (median 4.4 months), 325,362 (4.7%) had received a BNT162b2 2024-2025 COVID-19 vaccine dose. VE against COVID-19-associated hospital admission was 41% (95% CI 2-64).

Discussion: The 2024-2025 formulation of BNT162b2 COVID-19 vaccine provided significant protection, particularly for older adults, in mid-season estimates.

This study is registered on clinicaltrials.gov as NCT06923137.

KEYWORDS SARS-CoV-2; COVID-19; mRNA vaccines

INTRODUCTION

On June 27, 2024, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommended 2024–2025 COVID-19 vaccination with an FDA–authorized or approved vaccine for all persons aged ≥6 months.[1] This recommendation aligns with past regulatory decisions to update formulation based on the antigenic divergence of the SARS-CoV-2 virus in an effort to help prevent severe outcomes of infection including COVID-19-associated hospitalization and death.[2] On August 22, 2024, the United States (US) Food and Drug Administration (FDA) approved an updated monovalent messenger RNA (mRNA) COVID-19 vaccine formulation targeting the Omicron KP.2 strain for individuals 12 years and older and authorized for individuals ≥6 months to 12 years.[3]

While prior studies have described the vaccine effectiveness (VE) of mRNA COVID-19 vaccines, there are limited temporal data on 2024-2025 COVID-19 vaccines and estimates by age groups.[4,5] These data are critical to inform public health policy regarding future COVID-19 vaccine recommendations and guide clinicians and public stakeholders. This study uses a novel approach to maximize the reliability of vaccination reporting by combining state vaccine registries with mandatory reporting and linking administrative claims data. We estimated mid-season 2024-2025 BNT162b2 COVID-19 VE against COVID-19-associated hospital admission by various age groups in two heterogenous states in the US.

METHODS

Design, Setting, and Participants

We conducted a retrospective cohort study among non-immunocompromised adults
aged 18 years and older beginning August 22, 2024 ("index date", date of FDA approval
of BNT162b2 2024-2025 season formulation targeting the SARS-COV-2 Omicron KP.2
sub-variant).[3] Individuals were followed from index date until the outcome of interest
(described below), or were censored at the first of December 31, 2024, disenrollment
from medical and/or pharmacy plans, receipt of a non-BNT162b2 vaccine, or receipt of
a second 2024-2025 dose of any kind after receiving a first 2024-2025 BNT162b2 dose.
Details on the methodology of the study design have been previously described.[6–8] In
brief, the study was limited to individuals without pharmacologic or diagnostic evidence
of immunocompromised status who were residents of California or Louisiana and
continuously enrolled in health insurance plans reporting to HealthVerity for at least one
year prior to index.[9] Individuals with missing information for age and/or sex were
excluded, as were people who had a documented case of COVID-19 and/or a COVID-
19 vaccine in the 0-90 days prior to index. This study utilized deidentified data, was
reviewed by the Sterling Institutional Review Board (ID #13433), and deemed exempt
from further ethical oversight. The study protocol was posted on clinicaltrials.gov
(NCT06923137) prior to initiation of all analyses.

Exposure

Non-immunocompromised adults who received the BNT162b2 2024-2025 formulation
were compared to non-immunocompromised adults who had not received any 2024-
2025 season COVID-19 vaccine. Vaccination was treated as a time-varying exposure,

with individuals censored from unvaccinated person-time on the date of vaccination and

considered vaccinated 14 days after receiving a 2024-2025 BNT162b2 COVID-19

vaccine to reflect sufficient time to develop antibody protection.[6,8]

As previously described, any record of COVID-19 vaccine in state vaccine registries via

Clinical Vaccines Administered (CVX) code, pharmacy claims using National Drug

Codes (NDC), and/or medical claims using Current Procedural Terminology (CPT)

codes were considered.[6–8] Person-time in which individuals did not have a record of

receiving any brand of a 2024-2025 COVID-19 vaccine in both the state registry and

claims data was categorized as unvaccinated.

Outcomes

COVID-19-associated hospitalization was defined using International Classification of

Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code U07.1 "COVID-19"

for inpatient admission. Hospitalizations were excluded if there were any additional ICD-

10-CM codes for the same admission indicating that COVID-19 was an incidental

finding concomitant to unintentional injury, physical trauma, poisoning, short-stay

childbirth, or severe and persistent mental illness.[6,10] Hospitalization was modeled

separately for vaccinated and unvaccinated periods at risk and by age (≥18 years, ≥50

years and ≥ 65 years.

Statistical Analyses

Categorical variables are reported as counts with percentages (%), and continuous variables are reported as mean with standard deviation (SD) or median with first and third quartiles (Q1, Q3). Standardized mean differences (SMD) were used to compare descriptive statistics in a sample size independent manner, with >0.1 indicating imbalance between vaccinated and unvaccinated groups. Incidence rates are shown as the number of events per 100,000 person-months, separately for vaccinated and unvaccinated time. Cox proportional hazards models were used to estimate hazard ratios (HR), sex (male, female), state of residence (California or Louisiana), insurance payor (Medicaid, Medicare, commercial), at least one CDC-defined high-risk condition for severe COVID-19 (presence, absence), wellness visit in year prior to index (presence, absence), influenza vaccination in year prior to index (presence, absence), outpatient encounter in 180 days prior to index (presence, absence), ED encounter in 180 days prior to index (presence, absence), and medically- attended COVID-19 in the 91 to 365 days prior to index (presence, absence).[6,11–13] In the models not stratified by age, we additionally adjusted for age (18-64, ≥65 years of age). We calculated 95% confidence intervals using the sandwich estimator, given individuals who were vaccinated had non-independent repeated measures in the time-varying exposure framework, and with the Efron method to address ties in times-to-event, given the compressed follow-up time.[14]

Vaccine effectiveness (VE) was calculated as (1 – adjusted HR), multiplied by 100 to create a percentage, and can be interpreted as the incremental benefit of receiving the 2024-2025 BNT162b2 vaccine in a population with a high level of pre-existing immunity

from prior infection, vaccination or a combination of the two.[5] Analyses were conducted

with one programmer using SAS, version 9.4 (SAS Institute Inc.) and a second

programmer using R, version 4.5.0 (R Foundation for Statistical Computing) to assure

reliability of results.

RESULTS

Cohort descriptives

A total of 6,900,361 persons met selection criteria for the study (6,402,993 [93%] from

California and 497,368 [7%] from Louisiana; 2,801,573 [41%] were aged ≥50 years and

1,128,493 [16%] ≥65 years). The median follow-up time was 4.4 months (Q1: 4.4, Q3:

4.4) and did not differ substantially by state or age. By the end of the study, 325,362

(4.7%) received the BNT162b2 2024-2025 COVID-19 vaccine; 316,693 (4.9%) in

California and 8,669 (1.7%) in Louisiana.

Compared to those who had not received a 2024-2025 season COVID-19 vaccine of

any brand, the 2024-2025 BNT162b2 vaccinated group tended to be older (mean age

54 vs 45 years, SMD: 0.52) **(Table 1)**. Vaccinated individuals were more likely to have

commercial insurance (59% vs 41%, SMD: 0.65), a wellness visit (46% vs 33%, SMD:

0.29), influenza vaccination (62% vs 17%, SMD = 1.05) in the prior year, ever received

a pneumococcal (21% vs 7%, SMD = 0.39) or herpes zoster (30% vs 9%, SMD = 0.56)

vaccine, and an outpatient encounter in the prior 180 days (70% vs 53%, SMD = 0.35).

Additionally, vaccinated individuals were more likely to have received any brand of the

2023-2024 XBB.1.5-adapted COVID-19 vaccine (65% vs 9%, SMD: 1.44).

Prevalence of high-risk conditions

CDC-defined high-risk conditions were common in all individuals but were more prevalent in the vaccinated group (70% vs 61%, SMD: 0.2) for the twenty comorbidities evaluated, compared to the unvaccinated (**Table 2).** The most common comorbid conditions overall were obesity, mental health conditions, heart conditions, cancer and type 2 diabetes mellitus.

COVID-19-associated hospitalization, age ≥18 years old

The incidence rate according to time-varying exposure status is shown in Table 3. There was a total of 16 individuals with COVID-19-associated hospitalizations among those who received the 2024-2025 BNT162b2 COVID-19 vaccine and 1,120 among those who did not receive any 2024-2025 COVID-19 vaccine, corresponding to rates of COVID-19-associated hospitalization of 2.2 per 100,000 person-months (95% CI: 1.3-3.6) in the vaccinated group and 4.1 per 100,000 person-months (95% CI: 3.9-4.4) in the unvaccinated group. In adjusted models, overall BNT162b2 KP.2 VE (compared to not receiving a 2024-2025 COVID-19 vaccine of any kind regardless of prior vaccination history) was 41% (95% CI: 2-64%) against COVID-19-associated hospitalization **(Table 3)**.

COVID-19-associated hospitalization, age ≥50 years old

Similar results were observed in the group of those aged ≥50 years old **(Table 3)**. Among those who had received a 2024-2025 COVID-19 vaccine in this group, there

were 14 people with COVID-19-associated hospitalizations, corresponding to a rate of 3.0 hospitalizations per 100,000 person-months (95% CI: 1.7-5.1). Among those in this age group who had not received a 2024-2025 COVID-19 vaccine, there were 933 people with COVID-19-associated hospitalizations, corresponding to a rate of 8.6 per 100,000 person-months (95% CI: 8.1-9.2). In the adjusted model, BNT162b2 KP.2 VE for those aged ≥50 years old was 45% (95% CI: 6-68%) against COVID-19-associated hospitalization **(Table 3)**.

COVID-19-associated outcomes, age ≥65 years old

This pattern held in the group of those aged ≥65 years old as well **(Table 3)**. Among those who had received a 2024-2025 COVID-19 vaccine in this group, there were 12 people with COVID-19-associated hospitalizations, corresponding to a rate of 5.2 hospitalizations per 100,000 person-months (95% CI: 2.7-9.1). Among those in this age group who had not received a 2024-2025 COVID-19 vaccine, there were 705 people with COVID-19-associated hospitalizations, corresponding to a rate of 16.3 per 100,000 person-months (95% CI: 15.1-17.5). Adjusted BNT162b2 KP.2 VE for those aged ≥65 years old was 46% (95% CI: 3-70%) against COVID-19-associated hospitalization **(Table 3)**.

DISCUSSION

In this retrospective cohort study conducted between August 22, 2024, and December 31, 2024, among nearly 7 million non-immunocompromised adults in California and Louisiana, receipt of the BNT162b2 2024-2025 COVID-19 vaccine provided significant

protection against serious COVID-19-associated hospitalization compared to those who did not receive a 2024-2025 season COVID-19 vaccine of any brand in this period. These results parallel the roughly 40% VE against COVID-19-associated hospitalization reported in other studies, most of which follow a test-negative rather than cohort design, underscoring the convergence of these findings.[4,15]

Of note, the majority of the people in both groups were at high risk of progression to severe disease (70% in the vaccinated group and 61% in the unvaccinated group) based on CDC high risk criteria.[11] The outcome incidence rate as well as VE estimates in this study continue to demonstrate the value of an updated COVID-19 vaccines formulation that is well-matched to target the dominant circulating SARS-CoV-2 variant even in the context of high seropositive rates in the US population. Despite prior vaccination and/or natural infection, individuals are susceptible to subsequent infection due to waning immunity. Our findings underscore the need for universal revaccination as recommended by ACIP, as well as additional doses every six month for individuals ≥65 years of age.[16] In addition, the findings support the June 5, 2024 FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) decision to update the 2024-2025 season COVID-19 vaccine formulation.[17]

Despite recommendations that all individuals age ≥6 months of age in the US receive a 2024-2025 COVID-19 vaccine, mid-season uptake of the BNT162b2 product among non-immunocompromised adults in California and Louisiana was only 4.7%. If adult 2024-2025 mid-season COVID-19 vaccine uptake were instead similar to mid-2024-

2025 season influenza vaccine uptake (41.6% in adults as of December 28, 2024),[18]

and calculating the number needed to vaccinate as the reciprocal of the absolute risk

difference, findings from this study suggest over 12,000 COVID-19-associated adult

hospitalizations could have been avoided from August 22 – December 31, 2024

nationally. Those hospitalized incur significant medical costs, may experience critical

illness, and, if discharged, are at higher risk of post-COVID conditions ("Long

COVID").[19]

There are various limitations associated with this analysis. In terms of generalizability,

the individuals from California and Louisiana can be seen to represent a wide swath of

the US population culturally and demographically. However, the two states alone may

not truly represent the entire country in other important factors. This study utilizes claims

data which limits us to relying on ICD-10 codes rather than laboratory-confirmed

infection. Finally, these results describe the first four months of the 2024-2025

respiratory season and may not be representative of the entire season.[20]

CONCLUSION

BNT162b2 2024-2025 COVID-19 vaccine provided significant protection against

COVID-19-associated hospitalization for non-immunocompromised adults and was

consistent among varying age strata. The findings support the utility of updated COVID-

19 vaccine formulations that target contemporary circulating variants and the

maintenance of routine vaccination recommendations.

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All authors attest they meet the ICMJE criteria for authorship.

Data Sharing Statement

Pfizer's data use agreement with HealthVerity prohibits sharing individual-level data.

Additional Contributions

Data Access and Cleaning Methods

Several authors (KMA, JSM, TY, AZ) had access to the entire database population used to create the study population. Data cleaning methods and results were independently programmed by two programmers, with all discrepancies resolved. All authors had access to all summary data presented in this manuscript.

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Table 1: Cohort Descriptives

	Received 2024-2025 season BNT162b2 COVID-19 vaccine N = 325,362		Never received 2024-2025 COVID-19 vaccine of any kind N = 6,574,999		SMD
	N	(%)	N	(%)	
Age group					0.36
18-64	225,721	69%	5,546,147	84%	
≥65	99,641	31%	1,028,852	16%	
Sex					0.04
Female	178,785	55%	3,480,100	53%	
Male	146,577	45%	3,094,899	47%	
Insurance type					0.65
Commercial/private	190,588	59%	2,675,660	41%	
Medicaid	68,322	21%	3,315,735	50%	
Medicare	66,448	20%	583,511	9%	
Unknown	4	< 0.1%	93	< 0.1%	
Wellness visit in prior year					0.29
At least one	150,909	46%	2,139,696	33%	
None	174,453	54%	4,435,303	67%	
Influenza vaccination in prior year					1.05
Documented receipt	201,712	62%	1,084,436	17%	
No documented receipt	123,650	38%	5,490,563	83%	
Pneumococcal vaccination, ever					0.39
Documented receipt	67,017	21%	479,803	7%	
No documented receipt	258,345	79%	6,095,196	93%	
Herpes Zoster vaccination, ever					0.56
Documented receipt	98,707	30%	594,803	9%	
No documented receipt	226,655	70%	5,980,196	91%	
Outpatient visit in prior 180 days					0.35
At least one	227,261	70%	3,075,600	47%	
None	98,101	30%	3,499,399	53%	
ED visit in prior 180 days					0.09
At least one	24,797	8%	660,106	10%	
None	300,565	92%	5,914,893	90%	
COVID-19 diagnosis in prior 91-365 days	12,087	4%	138,276	2%	0.10
Received 2023-2024 COVID-19 vaccine	212,291	65%	576,216	9%	1.44

The above table represents 2024-2025 season BNT162b2 COVID-19 vaccination status at the time of COVID-19-associated hospitalization or end of follow-up. ED: emergency department; SMD: standardized mean difference, shown as the absolute value, with >0.1 considered imbalance.

Table 2: Prevalence of High-Risk Conditions Conferring Increased Risk of Severe COVID-19

| | Received 2024-2025 season BNT162b2 COVID-19 vaccine | | Never received 2024-2025 COVID-19 vaccine of any kind | | SMD |
	N = 325,362		N = 6,574,999		
	N	%	N	%	
At least one of the following conditions	228,430	70%	3,991,261	61%	0.20
Obesity	88,152	27%	1,765,281	27%	0.01
Mental health conditions	84,424	26%	1,437,939	22%	0.10
Heart conditions	80,908	25%	1,045,852	16%	0.22
Cancer	77,506	24%	834,719	13%	0.29
Diabetes mellitus, type 2	70,508	22%	1,012,410	15%	0.16
Disabilities, including Down syndrome	50,924	16%	862,668	13%	0.07
Cerebrovascular disease	43,478	13%	509,428	8%	0.18
Smoking, current and former	40,234	12%	792,925	12%	0.01
Chronic kidney disease	34,071	10%	373,615	6%	0.18
Chronic lung diseases	32,757	10%	432,100	7%	0.13
Chronic liver diseases	27,967	9%	474,658	7%	0.05
Primary immunodeficiencies	8,961	3%	85,984	1%	0.10
Asthma	7,301	2%	103,494	2%	0.05
Use of corticosteroids or other immunosuppressives	6,361	2%	82,505	1%	0.06
Diabetes mellitus, type 1	5,020	2%	75,623	1%	0.03
Tuberculosis	4,742	1%	89,117	1%	0.01
Neurologic conditions	2,537	1%	32,106	0.5%	0.04
HIV	1,080	0.3%	16,904	0.3%	0.01
Solid organ or blood stem transplantation	466	0.1%	6,318	0.1%	0.01
Cystic fibrosis	121	< 0.1%	3,170	< 0.1%	0.01

Table 3: Rates of and Adjusted BNT162b2 COVID-19 Vaccine Effectiveness against COVID-19-Associated Hospital Admission Among Non-Immunocompromised Adults.

Outcome and exposure status	Events (person-months at risk)	Incidence rate per 100,000 person-months (95% CI)	Adjusted VE (95% CI)
COVID-19-associated hospital admission, age ≥18 years			
Received 2024-2025 season BNT162b2 COVID-19 vaccine	16 (719,540)	2.2 (1.3 – 3.6)	41% (2 – 64)
Did not receive 2024-2025 COVID-19 vaccine of any kind	1,120 (27,288,381)	4.1 (3.9 – 4.4)	ref
COVID-19-associated hospital admission, age ≥50 years			
Received 2024-2025 season BNT162b2 COVID-19 vaccine	14 (459,439)	3.0 (1.7 – 5.1)	45% (6 – 68)
Did not receive 2024-2025 COVID-19 vaccine of any kind	933 (10,830,028)	8.6 (8.1 – 9.2)	ref
COVID-19-associated hospital admission, age ≥65 years			
Received 2024-2025 season BNT162b2 COVID-19 vaccine	12 (230,842)	5.2 (2.7 – 9.1)	46% (3 – 70)
Did not receive 2024-2025 COVID-19 vaccine of any kind	705 (4,333,219)	16.3 (15.1 – 17.5)	ref

CI = confidence interval. Incidence rates are shown per 100,000 person-months at risk. Person-time at risk differ because outcomes were modelled independently, such that the occurrence of one did not interrupt time at risk for others.