Brief Report

Vaccine Effectiveness of mRNA-1345 Against RSV-Associated Hospitalization and Medically Attended Acute Respiratory Illness Among US Veterans, 2025–2026

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Posted Date: 17 April 2026

doi: 10.20944/preprints202604.1261.v1

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Vaccine Effectiveness of mRNA-1345 Against RSV-Associated Hospitalization and Medically Attended Acute Respiratory Illness Among US Veterans, 2025–2026

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Highlights

- mRNA-1345 was associated with substantial protection against severe RSV outcomes.
- Findings are consistent with and extend existing RSV vaccine evidence to an mRNA platform.
- Preventing severe RSV is an unmet need in older adults with comorbidities.
- This study provides important real-world evidence in a medically complex population.

Abstract

Background: Clinical trials showed mRNA-1345 (mRESVIA) was highly efficacious against RSV-associated lower respiratory tract disease in adults; real-world studies are critical to confirm vaccine impact on RSV-related healthcare usage. **Methods:** A retrospective matched test-negative case-control study used Veterans Health Administration electronic health records from the 2025–2026 respiratory season. Veterans aged ≥50 years with acute respiratory illness (ARI) who underwent RSV testing were included. Vaccine effectiveness (VE) of mRNA-1345 was estimated against RSV-positive ARI-associated hospitalization, urgent care/emergency department, and/or outpatient visits using multivariable conditional logistic regression. **Results**: The matched analysis included 2,500 RSV cases and 9,907 controls with balanced baseline characteristics. Among RSV-positive ARI-associated hospitalizations, <3 of 448 cases and 59 of 1,770 controls were vaccinated (VE of 87% (95%CI: 47%-97%)). Protection was consistent across settings. **Conclusions:** mRNA-1345 is associated with high protection against RSV-positive ARI-associated hospitalization that was generally consistent across medically-attended outcomes in the US Veteran population.

Keywords: respiratory syncytial virus; mRNA-1345; vaccine effectiveness

Introduction

Respiratory syncytial virus (RSV) is an important cause of morbidity and hospitalization among older adults and individuals with underlying chronic conditions. In the United States (US), RSV accounts for tens of thousands of hospitalizations annually among adults aged ≥65 years, with risk concentrated in those with cardiopulmonary disease, diabetes, frailty, and immunocompromising

 doi:10.20944/preprints202604.1261.v1

conditions[1,2]. Despite this burden, adult RSV vaccines have only recently become available, and real-world vaccine effectiveness (VE) data are still emerging[3,4].

Randomized clinical trials of RSV vaccines demonstrated high efficacy against lower respiratory tract disease, despite the differences between the study designs and settings in which the trials were conducted. Of public health importance, these trials were not powered to evaluate severe outcomes such as hospitalization and underrepresented high-risk populations[5–7]. The two protein-based RSV vaccines (RSVPreF (Abrysvo) and RSVPref3 (Arexvy)) were first licensed in 2023, followed by the mRNA-based vaccine mRNA-1345 (mRESVIA) in 2024. US Centers for Disease Control and Prevention guidance currently recommends a single dose of RSV vaccine for all adults aged ≥75 years and for adults aged 50–74 years at increased risk of severe RSV disease[8] .

Early real-world studies of protein-based RSV vaccines suggest substantial protection against RSV-related hospitalizations in older adults, with estimated VE of approximately 70-90%[4,9,10]. However, considering the more recent regulatory approval, post-authorization effectiveness data for mRNA-1345 are limited. During the 2025–2026 season, mRNA-1345 was the predominant RSV vaccine utilized in the Veterans Health Administration (VHA), allowing for evaluation of its effectiveness against severe outcomes such as RSV-positive acute respiratory illness (ARI)-related hospitalization in a real-world setting.

We evaluated the effectiveness of mRNA-1345 against RSV-positive ARI-associated hospitalizations and RSV-associated medically attended ARI during the 2025–2026 respiratory season using a test-negative design (TND) among Veterans aged ≥50 years within the VHA system.

Methods

Study Design and Data Source

This study is a retrospective non-interventional study using a matched TND within the VHA electronic health record (EHR) system. This design compares odds of prior vaccination between RSV-positive cases and RSV-negative controls among patients seeking care and undergoing testing for similar illness, thereby reducing bias related to healthcare-seeking behavior. This study was approved by the VA Providence Institutional Review Board (Protocol #:1896275-4).

Study Population

The study population included Veterans who were alive and enrolled in VHA as of October 1, 2025. Eligible individuals were aged ≥50 years, underwent RSV testing between September 1, 2025, and March 31, 2026, and met a standardized ARI definition within −3 to +14 days of testing. ARI was defined using prespecified International Classification of Diseases Tenth Revision (ICD-10-CM) diagnosis codes recorded during inpatient, Emergency Department/Urgent Care (ED/UC), or outpatient encounters (Supplementary Appendix Table 1). Individuals were excluded if they had a positive RSV test within the prior 90 days, resided in a VHA community living center at time of testing, or had disqualifying vaccine history (receipt of RSV vaccine other than mRNA-1345, missing vaccination date for mRNA-1345, or received mRNA-1345 within 14 days prior to the date of testing). If there was more than one ARI episode per individual within the window of a RSV test, preference order was hospitalization, ED/UC, outpatient. If a veteran had multiple RSV tests with linked ARI episodes across the study period their first positive, or if no positive tests one randomly selected negative test, was selected per person.

Exposure

The exposure of interest was receipt of a single dose of mRNA-1345, administered in accordance with the manufacturer's prescribing information[11] , at least 14 days prior to the RSV test date. Vaccination status was ascertained from VHA administrations records, immunization history records, and linked data sources capturing vaccines received outside the VHA but reimbursed by the

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Department of Veterans Affairs (VA). Individuals were classified as vaccinated if they received mRNA-1345 ≥14 days prior to the testing date; those with no record of any RSV vaccination prior to testing were classified as unvaccinated. Vaccination status was evaluated among both RSV-positive cases and RSV-negative controls.

Outcome Definition

Among Veterans with a medically-attended ARI encounter, cases were defined as RSV test-positive versus test-negative as controls. The primary analysis was restricted to ARI-associated hospitalizations, defined as inpatient encounters with an admission occurring within -3 to +14 days of the testing date. Secondary analyses evaluated ARI encounters in ED/UC and outpatient settings, and all three combined as medically attended ARI. Multiplex Polymerase Chain Reaction (PCR) results also include influenza and SARS-CoV-2 results and are reported as covariates.

Covariates

VHA EHR, linked vital status, and non-VA claims were used to describe the baseline characteristics of RSV-positive cases and negative controls indexed to date of test with one year lookback. Covariates included age, sex, race/ethnicity, smoking status, rural setting, driving distance to nearest VA medical center, region of residence, concomitant influenza and SARS-CoV-2 viral testing results, VA Frailty Index score[12] (non-frail [VA-FI<=.1], pre-frail [VA-FI>.1-.2], mildly frail [VA-FI>.2-.3], moderately frail [VA-FI>.3-.4], severely frail [VA-FI>.4]), chronic conditions classified using the Chronic Conditions Warehouse 30 conditions ICD-10-CM codes[13] , immunocompromised status (Supplementary Appendix Table 2), and prior vaccination history (influenza and COVID-19).

Matching and Statistical Analysis

Baseline characteristics were compared using absolute standardized mean differences or absolute mean differences for binary variables, with values <0.1 indicating adequate balance. Cases and controls were matched using a two-stage algorithm, exact match on calendar week of test, ARI episode setting (inpatient hospitalization, outpatient, ED/UC), and geographic region, and then nearest neighbor propensity-score matched using a variable 1:4 ratio with a maximum caliper width of 0.2 on calendar date of test, age, sex, race/ethnicity, rural status, receipt of seasonal influenza vaccine, concomitant SARS-CoV-2 and influenza test result, and chronic conditions including acute myocardial infarction, asthma, chronic obstructive pulmonary disease (COPD), heart failure, and pneumonia. Multivariable conditional logistic regression was used to estimate adjusted odds ratios (aORs), and VE was calculated as (1 − aOR) × 100%. Variables in the nearest neighbor algorithm were also adjusted for in the logistic model except for date of test. Sensitivity analyses included an unadjusted and unmatched analysis, restriction to individuals aged ≥60 years, restriction to tests from October 1, 2025 onward, and an analysis using multivariable logistic regression without matching.

Results

Among 5,366,787 Veterans, 191,408 underwent at least one RSV test from September 1, 2025 to March 31, 2026. Over 97% of the RSV viral tests were part of a multiplex PCR assay. The analytical cohort included 70,909 Veterans, meeting all inclusion and exclusion criteria, with primary reasons for exclusion being age <50 years (n=24,677) and receipt of non-mRNA-1345 RSV vaccinations (n=23,192). Figure 1 describes full inclusion and exclusion details.

Table 1 presents the baseline characteristics of RSV-positive cases and RSV-negative controls in the matched analytic sample. The study population included 12,407 individuals, comprising 2,500 cases matched to 9,907 controls; 97.5% of cases were successfully matched to four controls (Supplementary Appendix Table 3). After matching, baseline characteristics were well balanced between cases and controls, with all absolute standardized mean differences <0.1. In the unmatched cohort, controls had a higher prevalence of concomitant influenza or SARS-CoV-2 positivity, greater

 doi:10.20944/preprints202604.1261.v1

frailty, and more respiratory-related chronic conditions (Supplementary Appendix Table 4). Among vaccinated individuals in the matched sample, time since mRNA-1345 vaccination was similar between cases and controls (median 57 [IQR: 45–63] vs 54 days [IQR: 31–78]).

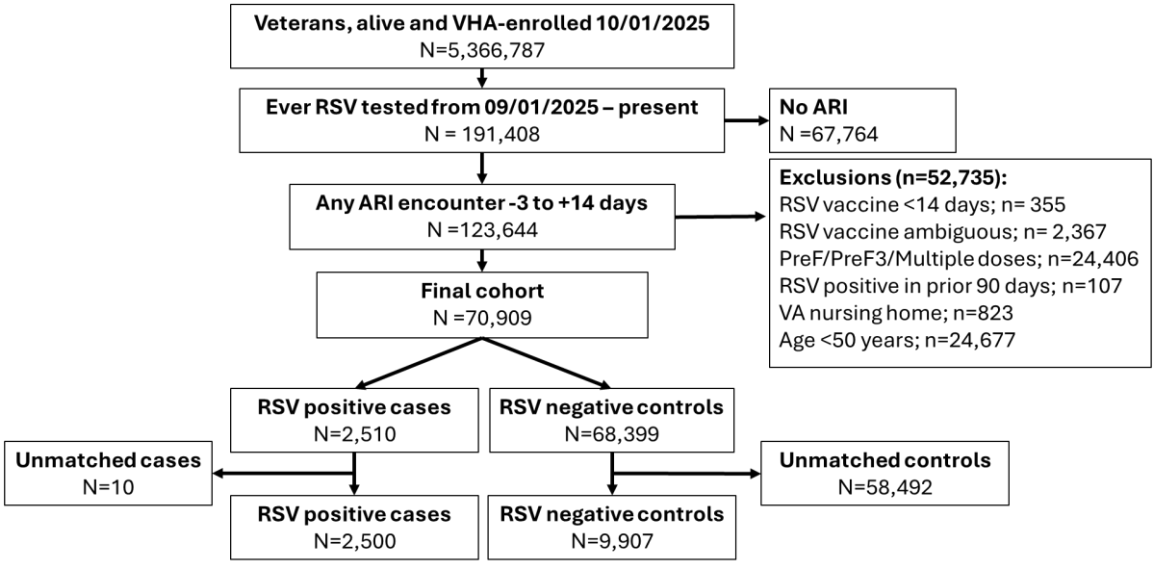

Figure 1. Cohort Workflow Diagram. Full cohort workflow from initial testing criteria until the final analytical cohort, which is limited to those with acute respiratory infections (ARI), and after applying exclusions based on RSV indications and vaccine histories. RSV, Respiratory Syncytial Virus. PreF/PreF3, non-mRNA protein subunit vaccines.

Table 2 presents cases and control counts with VE estimates. Among RSV-positive ARI-associated hospitalizations, <3 of 448 cases and 59 of 1,770 controls were vaccinated, corresponding to an adjusted VE of 87% (95% Confidence Interval [CI]: 47%, 97%). VE estimates were 59% (95% CI: 31%, 76%) against RSV-associated ARI ED/UC visits, 67% (95% CI: −9%, 90%) for outpatient visits, and 68% (95% CI: 50%, 80%) for medically attended RSV-ARI. Alternative analyses yielded broadly consistent findings (Supplementary Table 5). Unmatched estimates were attenuated and less precise, whereas restriction and regression-based analyses were similar to the primary results.

Table 1. Baseline clinical and demographic characteristics of matched cases and controls among veterans with an acute respiratory infection episode and RSV test from September 1, 2025 – March 31, 2026.

	RSV-Positive Cases (n=2,500)	RSV-Negative Controls (n=9,907)	D[1]
Demographics			
Age			
Mean (SD)	69.07 (10.48)	68.80 (10.58)	0.03
65+	1,575 (63.0%)	6,211 (62.7%)	0.01
Male	2,212 (88.5%)	8,736 (88.2%)	0.01
Race/ethnicity			
White, non-Hispanic	1,558 (62.3%)	6,108 (61.7%)	0.01
Black	653 (26.1%)	2,681 (27.1%)	0.02
Other	289 (11.6%)	1,117 (11.3%)	0.01

 doi:10.20944/preprints202604.1261.v1

	RSV-Positive Cases (n=2,500)	RSV-Negative Controls (n=9,907)	D[1]
Hispanic/Latino	235 (9.4%)	840 (8.5%)	0.03
Former/current smoker	459 (18.4%)	1,829 (18.5%)	0.00
Rural	552 (22.1%)	2,191 (22.1%)	0.00
Driving distance, mean minutes (SD)	13.22 (12.87)	13.18 (12.79)	0.00
Region [2]			
Southeast	603 (24.1%)	2,407 (24.3%)	0.00
North Atlantic	566 (22.6%)	2,238 (22.6%)	0.00
Continental	367 (14.7%)	1,462 (14.8%)	0.00
Pacific	367 (14.7%)	1,455 (14.7%)	0.00
Mid-west	448 (17.9%)	1,775 (17.9%)	0.00
Infection History			
PCR (+) COVID-19	20 (0.8%)	75 (0.8%)	0.00
PCR (+) Influenza	28 (1.1%)	117 (1.2%)	0.01
ARI Hospitalization	448 (17.9%)	1,770 (17.9%)	0.00
ARI ED/UC	1,579 (63.2%)	6,269 (63.3%)	0.00
ARI Outpatient	473 (18.9%)	1,868 (18.9%)	0.00
Clinical History[3]			
VA Frailty Index			
Mean score (SD)	0.26 (0.15)	0.26 (0.15)	0.02
Non-frail	385 (15.4%)	1,663 (16.8%)	0.04
Pre-frail	726 (29.0%)	2,762 (27.9%)	0.03
Mildly frail	586 (23.4%)	2,285 (23.1%)	0.01
Moderately frail	369 (14.8%)	1,509 (15.2%)	0.01
Severely frail	434 (17.4%)	1,687 (17.0%)	0.01
1+ Chronic condition	2,450 (98.0%)	9,657 (97.5%)	0.04
AMI	110 (4.4%)	451 (4.6%)	0.01
ADRD	162 (6.5%)	674 (6.8%)	0.01
Anemia	605 (24.2%)	2,452 (24.8%)	0.01
Asthma	337 (13.5%)	1,160 (11.7%)	0.05
AF	444 (17.8%)	1,598 (16.1%)	0.04
BPH	666 (26.6%)	2,681 (27.1%)	0.01
Cancer	145 (5.8%)	661 (6.7%)	0.04
CKD	598 (23.9%)	2,291 (23.1%)	0.02
COPD	654 (26.2%)	2,484 (25.1%)	0.02
Diabetes	1,021 (40.8%)	3,855 (38.9%)	0.04

 doi:10.20944/preprints202604.1261.v1

	RSV-Positive Cases (n=2,500)	RSV-Negative Controls (n=9,907)	D[1]
HF/NIHD	442 (17.7%)	1,771 (17.9%)	0.01
HTN	1,894 (75.8%)	7,292 (73.6%)	0.05
Hypothyroidism	276 (11.0%)	1,068 (10.8%)	0.01
IHD	662 (26.5%)	2,629 (26.5%)	0.00
Immunocompromised	700 (28.0%)	2,742 (27.7%)	0.01
Pneumonia	450 (18.0%)	1,767 (17.8%)	0.00
Stroke	181 (7.2%)	812 (8.2%)	0.04
Vaccine History			
mRNA-1345	21 (0.8%)	252 (2.5%)	0.13
Days since RSV[4] Vaccination, median [IQR] / mean (SD)	57 [45,63] / 56.0 (23.4)	54 [31,78] / 61.0 (51.6)	0.15
Days since Covid Vaccination, median [IQR] / mean (SD)	1340 [708,1564] / 1168 (505)	1333 [665,1565] / 1158 (506)	0.02
Flu Vaccine: 2025-2026 Season	1,031 (41.2%)	4,083 (41.2%)	0.00
COVID-19 LP.8.1 Updated Vaccine, 2025-2026	193 (7.7%)	827 (8.3%)	0.02

Description. Characteristics of RSV (+) cases and RSV (-) controls after matching.

AMI, Acute Myocardial Infarction; ADRD, Alzheimer's Disease and Related Dementia; AF, Atrial Fibrillation or Flutter; BPH, Benign Prostate Hyperplasia; CKD, Chronic Kidney Disease; COPD, Chronic Obstructive Pulmonary Disease; HF/NIHD, Heart Failure and Non-Ischemic Heart Disease; HTN, Hypertension; IHD, Ischemic Heart Disease; IQR, 25%/75% Interquartile; PCR, Polymerase Chain Reaction; SD, Standard-Deviation.

[1]D = standardized mean difference for continuous and count variables and absolute mean difference for binary variables.

[2]VA Regions; SE = {KY, TN, AL, GA, SC, FL, PR}, NA = {ME, NH, VT, MA, RI, CT, NY, PA, DE,NJ, DC, WV, VA, NC}, C = {MT, WY, UT, CO, OK, TX, AR, LA, MS}, PA = {WA, OR, ID, CA, NV, AZ, NM, HI, AK, PH}, MW = {OH, MI, IN, WI, IL, MN, IA, MO, ND, SD, NE, KS}

[3]All other CCW conditions had observed differences <0.03 in the matched and unmatched samples

[4]Median IQR only among those with RSV vaccine

Table 2. Estimated mRNA-1345 vaccine effectiveness against RSV-positive ARI-associated hospitalizations and medically attended visits, from September 1, 2025 – March 31, 2026.

 doi:10.20944/preprints202604.1261.v1

	Matched set, adjusted results		
	Cases (n=2,500) Vaccinated | Unvaccinated	Controls (n=9,907) Vaccinated | Unvaccinated	VE (95% CI)
RSV-associated ARI hospitalizations	<3[1] | 446	59 | 1,711	87% (47%, 97%)
RSV-associated ARI ED / UC encounters	16 | 1,563	145 | 6,124	59% (31%, 76%)
RSV-associated ARI outpatient visits	3 | 470	42 | 1,826	67% (-9%, 90%)
Medically-attended RSV-ARI	21 | 2,479	246 | 9,661	68% (50%, 80%)

Description. mRNA-1345 vaccination among RSV (+) and RSV (-) in the adjusted set, with VE. Abbreviations: RSV, Respiratory Syncytial Virus; ARI, Acute Respiratory Illness; CI, Confidence Interval, ED, Emergency Department; UC, Urgent Care; VE, Vaccine Effectiveness.

[1]Cell counts <3 suppressed in accordance with VA data policy

Discussion

In this large, national study of US Veterans, mRNA-1345 vaccination was associated with substantial protection against RSV-positive ARI-associated hospitalization during the 2025–2026 respiratory season. The estimated VE of approximately 87% in the first season post-vaccination is within the range reported in clinical trials[5–7] and early real-world studies of protein-based RSV vaccines in older adults. TND studies in the US have estimated VE against RSV-associated hospitalization of approximately 70–90% during the first season, while a target trial emulation in the VHA reported VE of approximately 80% [3,4,9,14] . Despite differences in design and populations, these findings indicate that the VE observed in our study is in a similar range with prior real-world estimates for protein-based RSV vaccines. Lower odds of mRNA-1345 vaccination in RSV-positive cases was also observed in ED/UC and outpatient ARI visits, medically-attended RSV-ARI overall. The VHA provides a unique opportunity to evaluate RSV VE in a setting where a substantial proportion of the population has comorbidities that increase the risk of severe outcomes from RSV infection. Compared with the general US population, Veterans are older, predominantly male, and have a higher burden of chronic disease as demonstrated in national epidemiologic analyses [15,16] . VHA's comprehensive EHR system enables detailed capture of vaccination, laboratory testing, and clinical outcomes across care settings.

This study extends real world evidence on RSV VE in several important ways. First, it provides initial real-world effectiveness data for an mRNA-based RSV vaccine, addressing a key evidence gap. Second, it demonstrates mRNA-1345 effectiveness in a population with a high proportion of comorbidities that increase the risk of severe RSV outcomes[17]. Third, the use of a TND within an integrated healthcare system reduces bias related to healthcare-seeking behavior and enables robust outcome ascertainment. In addition, the observed reductions in RSV-positive ARI-associated hospitalizations, ED/UC visits, and outpatient encounters may translate to a potential reduction in healthcare resource utilization in this population[18].

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Several limitations should be considered. First, with few RSV vaccinated RSV-positive ARI-associated hospitalized cases, these VE estimates provide evidence of substantial protection but not precise estimation of effect size. As an observational study, residual confounding may persist despite adjustment for demographic and clinical characteristics, although matching was utilized to minimize confounding. Misclassification of vaccination status is possible if vaccines received outside the VHA were not fully captured, although multiple data sources were used to enhance vaccine capture. The TND conditions on testing and ARI diagnosis may introduce bias if vaccination is not independent of testing behavior given the measured confounders. Finally, the VHA population is predominantly male with a history of military service, which may limit generalizability.

Despite these limitations, the consistency of findings across analyses and alignment with prior evidence from the pivotal efficacy trial[5] support the conclusion that mRNA-1345 provides meaningful protection against severe RSV outcomes. Continued data accrual and evaluation across additional seasons will be important to improve precision and assess durability of protection.

Conclusions

In a national cohort of US Veterans, mRNA-1345 vaccination was associated with approximately 87% effectiveness against RSV-positive ARI-associated hospitalization. These findings highlight the public health importance of RSV vaccination programs in populations at risk of severe outcomes.

Author Contributions: Conceptualization – AA, CC, ECN, EP, EW, KWM, PG, SG, TS, YA Data curation – BS, FD, KWM Formal analysis – FD, KWM Methodology – AA, ECN, EP, EW, KWM, PG, SG, TS, YA Writing – original draft – EW, JT, KWM, SG Writing – review and editing – AA, CC, ECN, EP, EW, FD, JT, KWM, PG, SG, TS.

Funding Statement: This study was supported through a research award from Moderna LLC. Drs. McConeghy, Gravenstein, Skov and Mr. DeVone are supported by the THRIVE COIN (CIN-13-419).

Data Sharing Statement: The data used in these analyses contained potentially identifiable health information on US Veterans, only aggregate, de-identified reports can be shared outside the secure VHA environment. No identifiable or VA-sensitive data was shared with non-federal collaborators.

Conflicts of Interest Statements: KWM and SG have received funding for investigator-initiated research on vaccine products from Genentech, Sanofi-Pasteur, Seqirus, GlaxoSmithKline and Pfizer. EW, TS, EP, ECN, AA, PG, CC and JT are employees of Moderna and may hold stock in the company.

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