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Adjuvanted RSVPreF3 vaccine effectiveness against RSV-related hospitalization among US adults aged 60 years and older

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Adjuvanted RSVPreF3 vaccination was effective against RSV-related hospitalization in adults aged ≥60 years overall and in high-risk subgroups

Background

- RSV is a common respiratory infection that can result in **severe disease, including hospitalization**, among adults aged ≥60 years and those with certain risk factors.¹
- The first vaccines for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged ≥60 years were approved in the US in 2023.²
- Previous observational studies have reported the effectiveness of adjuvanted RSVPreF3 vaccination against RSV-related hospitalizations among older adults,^{3–5} however, evidence gaps remain in vaccine effectiveness (VE) among subgroups at increased risk for severe RSV disease.

The objective of this study was to evaluate the real-world effectiveness of adjuvanted RSVPreF3 vaccination for the prevention of RSV-related hospitalization among adults aged ≥60 years in the US, overall and in key high-risk subgroups over a single RSV season.

Conclusions



Adjuvanted RSVPreF3 vaccination is effective in reducing the risk of RSV-related hospitalization in US adults aged ≥60 years, overall and in subgroups of individuals with comorbidities placing them at increased risk for severe RSV disease.



These findings highlight the value of adjuvanted RSVPreF3 vaccination for individuals at increased risk for severe RSV disease and the importance of improving implementation of existing vaccine recommendations.

Methods



Overview: CLEAR-VE RSV (CLaims-BasEd Assessment of Real-world Vaccine Effectiveness of Adjuvanted RSVPreF3 Vaccination) was a retrospective cohort study using administrative claims data from the Optum Research Database.



Study population:

- Adults aged ≥60 years were identified between August 1, 2023–May 31, 2024 with continuous enrollment ≥12 months before and ≥14 days after the index date (i.e., first date of adjuvanted RSVPreF3 vaccination for vaccinated individuals).
- Vaccinated and unvaccinated patients were exact matched 1:4 by age in years, sex, insurance type, and state of residence (index date for unvaccinated individuals was the same as for their matched vaccinated individual).
- Baseline characteristics were measured in the 12 months before index date to account for differences in the vaccinated and unvaccinated groups.



Variable definitions:

- Vaccination was defined as a medical or pharmacy claim for adjuvanted RSVPreF3 vaccination during the observation period (August 1, 2023–May 31, 2024).
- Primary outcome was VE of adjuvanted RSVPreF3 vaccination against RSV-related hospitalization (≥1 medical claim with RSV diagnosis in the acute inpatient setting).
- Additional outcomes:
 - VE against severe RSV-related hospitalization (≥1 medical claim indicating mechanical ventilation, ECMO, ICU admission, or death during the inpatient stay)
 - VE against a composite measure of RSV-related hospitalization or ED visit
 - VE against mortality during RSV-related hospitalization
- Outcomes were defined using ICD-10-CM, ICD-10-PCS, CPT, provider specialty, and revenue codes.



Analysis:

- Outcomes were assessed from 14 days post-index date to the earliest of the following: disenrollment, death, RSV vaccination, or end of the analysis period (May 31, 2024).
- Propensity score-based weighting was used to balance baseline covariates between vaccinated and unvaccinated groups, and HRs were estimated using Cox proportional hazards regression modeling in the weighted population.
- VE was calculated as $(1 - HR) \times 100\%$.

Results

Table 1: Baseline characteristics of the weighted population

	Vaccinated (N=520,440)	Unvaccinated (N=2,081,760)	SMD ^a (%)
Demographics			
Age, mean ± SD (years)	74.26 ± 6.73	74.27 ± 6.71	0.09
Female, n (%)	296,170 (56.91)	1,185,031 (56.92)	-0.03
Insurance type, n (%)			
Commercial	38,729 (7.44)	155,790 (7.48)	-0.16
Medicare Advantage	481,711 (92.56)	1,925,970 (92.52)	0.16
Baseline clinical characteristics			
Charlson comorbidity score, mean (SD) ^b	1.44 (1.81)	1.45 (1.83)	-0.30
Immunocompromised status, n (%) ^c	51,250 (9.85)	204,920 (9.84)	0.01
Conditions associated with severe RSV disease, n (%)			
≥1 condition ^d	374,256 (71.91)	1,497,529 (71.94)	-0.05
≥2 conditions ^d	234,360 (45.03)	936,411 (44.98)	0.10
Cardiopulmonary disease^e			
Pulmonary disease	121,141 (23.28)	452,052 (21.71)	3.74
COPD	76,209 (14.64)	286,406 (13.76)	2.54
Asthma	53,636 (10.31)	190,590 (9.16)	3.88
Cardiovascular disease			
Heart failure	54,234 (10.42)	224,238 (10.77)	-1.14
Coronary artery disease	123,316 (23.69)	499,774 (24.01)	-0.73
Chronic kidney disease	125,272 (24.07)	510,223 (24.51)	-1.02

Median follow-up was 5.6 months, with a maximum of 9.7 months

^aAn absolute value < 10% indicated balance across groups. ^bDefined based on criteria by Quan et al., 2011.⁶ Immunocompromised status included immunocompromising conditions (HIV/AIDS, hematologic malignancy or other immune condition defined by ≥1 inpatient medical claim with a diagnosis code or ≥2 ambulatory [non-inpatient] claims with a diagnosis code on separate dates within 365 days), ≥1 medical or pharmacy claim with immunotherapy or chemotherapy fill/administration within 120 days prior to index date, or ≥1 pharmacy claim with a fill/administration within 120 days prior to index date with a dose ≥20 mg/day, of prednisone equivalents of a systemic corticosteroid, day supply ≥14 days. ^dIncluded the following: COPD, asthma, interstitial lung disease, cystic fibrosis, heart failure, coronary artery disease, cerebrovascular disease, chronic kidney disease, chronic liver disease, neurological/musculoskeletal disorder, severe obesity, and diabetes mellitus. ^ePulmonary or cardiovascular disease.

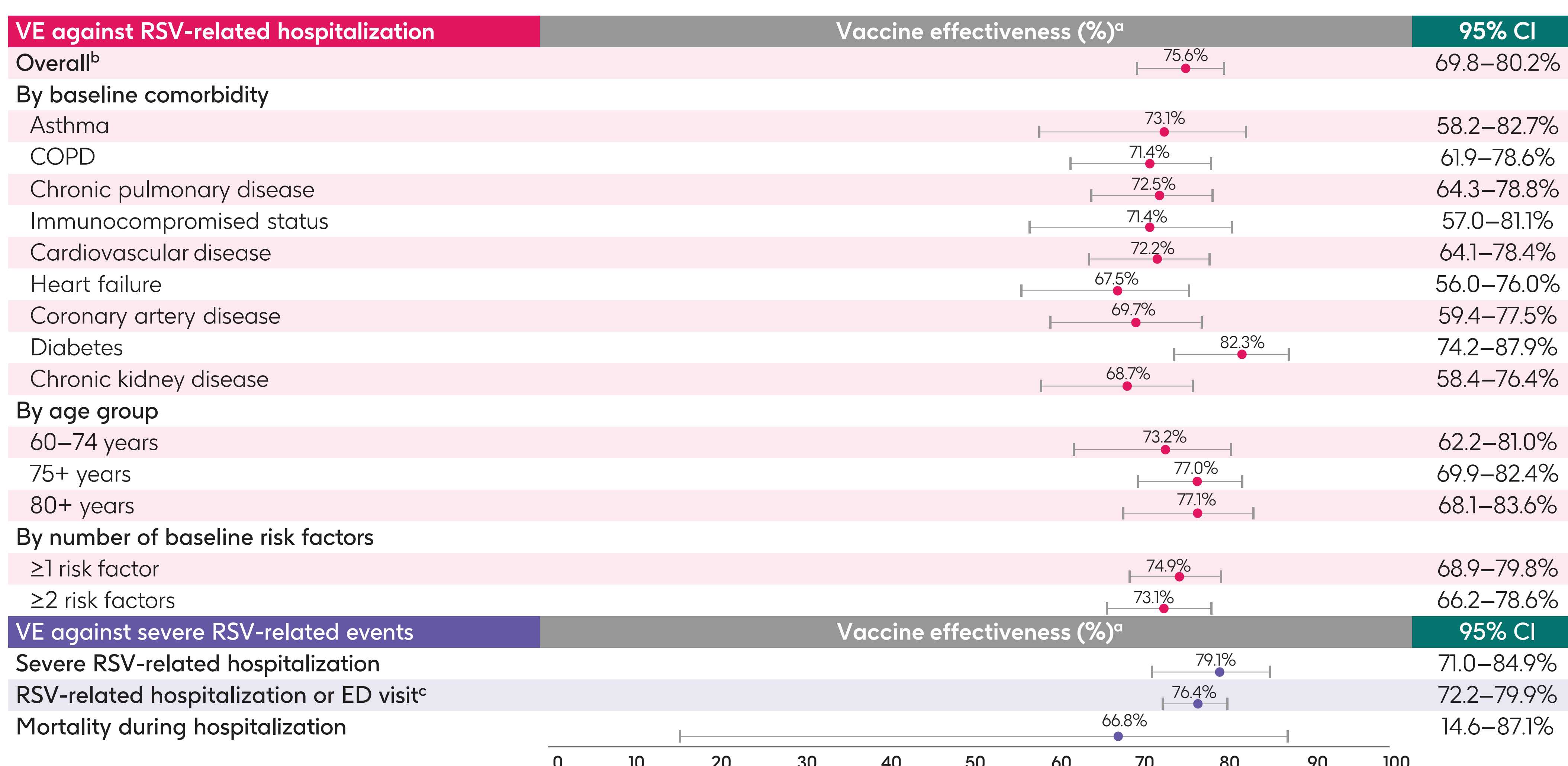


Figure 1: Vaccine effectiveness of adjuvanted RSVPreF3 against RSV-related hospitalization and other RSV-related outcomes

Adjuvanted RSVPreF3 vaccination had > 75% VE overall and > 70% VE across most high-risk subgroups

VE was generally consistent across age groups and number of baseline risk factors

Adjuvanted RSVPreF3 vaccination reduced the risk of RSV-related inpatient mortality with a VE of 67%

^aPropensity score-based weighting was used to balance age, sex, insurance, HHS region, baseline Quan-Charlson comorbidity score, baseline top 20 AHRQ conditions (overall sample), frailty score, baseline immunocompromised status (including systemic corticosteroids), baseline immunocompromising conditions (HIV, malignancy, other immune conditions), baseline conditions associated with severe RSV disease, baseline tobacco use (any type), baseline vaccination (influenza vaccination, COVID-19 vaccination), baseline healthcare resource utilization, and baseline all-cause costs. These variables were included as individual covariates, plus as interaction terms with baseline cardiopulmonary disease (pulmonary or cardiovascular), baseline influenza vaccination, baseline immunocompromised status (including systemic corticosteroids), and baseline diabetes. Balance was assessed after weighting in each subgroup to ensure that subgroups remained similar in their baseline characteristics. ^bWeighted RSV-related hospitalization event counts were 1,419 for unvaccinated individuals (n=2,081,760) and 95 for vaccinated individuals (n=520,440). Duration of follow-up was variable across individuals. ^cComposite.

Abbreviations

AHRQ, Agency for Healthcare Research and Quality; AIDS, acquired immunodeficiency syndrome; CI, confidence interval; COPD, chronic obstructive pulmonary disease; COVID-19, coronavirus disease 2019; CPT, Current Procedural Terminology; ECMO, extracorporeal membrane oxygenation; ED, emergency department; HHS, Health and Human Services; HIV, human immunodeficiency virus; HR, hazard ratio; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases, Tenth Revision, Procedure Coding System; ICU, intensive care unit; LRTD, lower respiratory tract disease; RSV, respiratory syncytial virus; RSVPreF3, RSV pre-fusion F3; SD, standard deviation; SMD, standardized mean difference; US, United States; VE, vaccine effectiveness.

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Disclosures

This is an ENCORE of a poster presentation originally presented at RSVVV 2026, 17–20 February 2026, Rome, Italy. Conflicts of interest: CW, DS, EML, EKH, KTN, NJF, and SFG are employed by GSK and hold financial equities in GSK. CW holds equities in AstraZeneca. AS, AB, MGJ, RS, and SH are employees of Optum, and AS, AB, and MGJ hold financial equities in Optum, which received funding from GSK to conduct this study. AK and JBL are employees of RTI Health Solutions, which received funding from GSK to conduct this study.

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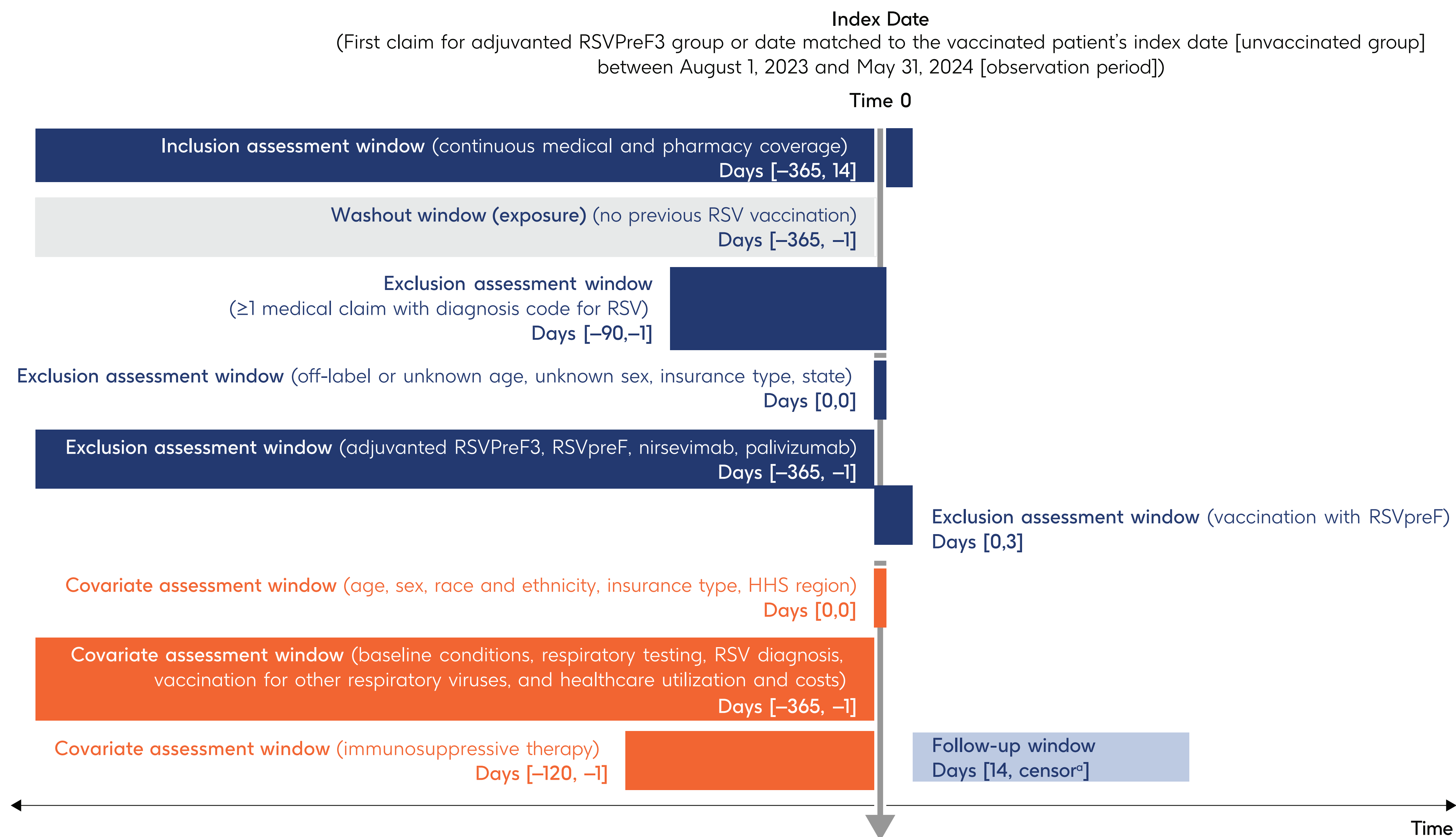
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Supplement

Figure S1: Schematic for assessing eligibility, covariates, and RSV-related outcomes



^aThe variable follow-up period started 14 days after the index date and continued through the first of the following censoring criteria: disenrollment, death, RSV vaccination (any RSV vaccine), or end of the analysis period. The time between the index date and 14 days after the index date was not included in the baseline or variable follow-up periods.

Table S1: Additional propensity score-weighted baseline characteristics

		Vaccinated (N=520,440)	Unvaccinated (N=2,081,760)	SMD ^a (%)			Vaccinated (N=520,440)	Unvaccinated (N=2,081,760)	SMD ^a (%)
Age group					Immunocompromising conditions^d				
60–74 years	n	282,552	1,131,810		HIV/AIDS	n	1,606	6,402	
	%	54.29	54.37	-0.15		%	0.31	0.31	0.02
75+ years	n	237,888	949,950		Hematologic malignancy	n	7,581	30,145	
	%	45.71	45.63	0.15		%	1.46	1.45	0.07
60–79 years	n	399,857	1,600,232		Other immune condition	n	12,417	49,579	
	%	76.83	76.87	-0.09		%	2.39	2.38	0.03
80+ years	n	120,583	481,528		Immunocompromising medications^e				
	%	23.17	23.13	0.09	Chemotherapeutic	n	32,726	131,443	
Baseline clinical characteristics						%	6.29	6.31	-0.11
Baseline Charlson comorbidity score ^b (continuous)	p25	0.00	0.00		Systemic steroids ^f	n	3,900	15,790	
	Median	1.00	1.00			%	0.75	0.76	-0.11
	p75	2.00	2.00		Conditions associated with severe RSV disease				
Baseline Charlson comorbidity score (categorical)					Asthma, severe	n	8,246	26,829	
0	n	220,729	882,860			%	1.58	1.29	2.48
	%	42.41	42.41	0.01	Interstitial lung disease/idiopathic pulmonary fibrosis	n	16,003	57,686	
1	n	103,165	412,890			%	3.07	2.77	1.80
	%	19.82	19.83	-0.03	Cystic fibrosis	n	82	267	
2	n	86,224	344,630			%	0.02	0.01	0.24
	%	16.57	16.55	0.03	Neurological/ musculoskeletal disorder	n	117,176	468,489	
3	n	46,603	186,541			%	22.51	22.50	0.02
	%	8.95	8.96	-0.02	Cerebrovascular disease	n	56,351	238,283	
4	n	28,020	112,145			%	10.83	11.45	-1.97
	%	5.38	5.39	-0.01	Chronic liver disease	n	37,931	147,587	
5+	n	35,699	142,693			%	7.29	7.09	0.77
	%	6.86	6.85	0.02	Diabetes mellitus	n	159,737	638,914	
Faurot Frailty Index^c (categorical)						%	30.69	30.69	0.00
<0.05 (low)	n	445,509	1,782,342		Severe obesity	n	47,353	186,090	
	%	85.60	85.62	-0.04		%	9.10	8.94	0.56
0.05–0.09 (low-medium)	n	44,229	176,477		Other baseline clinical characteristics				
	%	8.50	8.48	0.08	Smoking	n	136,287	545,679	
0.10–0.19 (medium)	n	17,644	70,589			%	26.19	26.21	-0.06
	%	3.39	3.39	0.00	Influenza vaccination	n	397,237	1,588,188	
0.20–0.39 (medium-high)	n	8,359	33,518			%	76.33	76.29	0.09
	%	1.61	1.61	-0.03	COVID-19 vaccination	n	314,950	1,260,761	
≥0.40 (high)	n	4,699	18,835			%	60.52	60.56	-0.09
	%	0.90	0.90	-0.02					

^aAn absolute value <10% indicated balance across groups. ^bDefined based on criteria by Quan et al., 2011.¹ ^cDefined based on criteria by Faurot et al., 2015.² ^d≥1 inpatient medical claim with a diagnosis code or ≥2 ambulatory (non-inpatient) claims with a diagnosis code on separate dates within 365 days. ^e≥1 medical or pharmacy claims with fill/administration within 120 days prior to index date. ^f≥1 pharmacy claim with a fill/administration within 120 days prior to index date with a dose ≥20 mg/day, prednisone equivalents, day supply ≥14 days.

Abbreviations

AIDS, acquired immunodeficiency syndrome; COVID-19, coronavirus disease 2019; HHS, Health and Human Services; HIV, human immunodeficiency virus; p25, 25th percentile; p75, 75th percentile; RSV, respiratory syncytial virus; RSVpreF, RSV prefusion F (non-adjuvanted); RSVPreF3, RSV prefusion F3; SMD, standardized mean difference; US, United States.

References

1. Quan H et al. Am J Epidemiology. 2011;173(6):676–82.
2. Faurot KR et al. Pharmacoepidemiol Drug Saf. 2015;24(1):59–66.

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Supplement

Figure S2: Patient identification and attrition

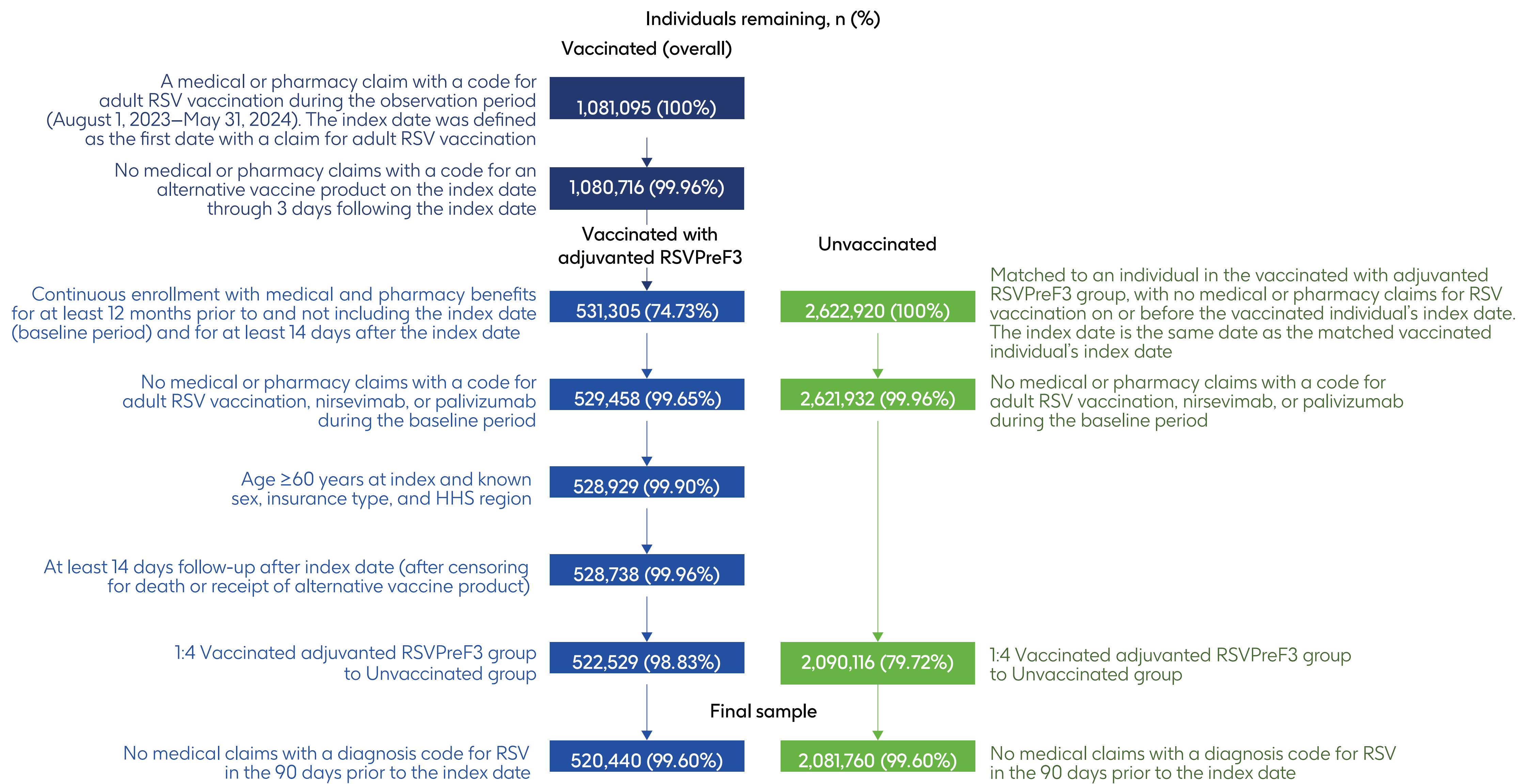


Table S2: Key patient identification and outcome codes used in this analysis

Measure	Code type	Code(s)
Adjuvanted RSVPreF3 vaccination	CPT	90679
	NDC	58160084811, 58160072303, 58160074403
RSV	ICD-10-CM	B974, J121, J205, J210
Mechanical ventilation	CPT	31502, 31613, 31614, 31615, 94002, 94003, 94004, 94660, 94662, 31500, 31600, 31603, 31605, 31610
	ICD-10-CM	J95851, J95859, Z9911
	ICD-10 PCS	0B21XEZ, 0B21XFZ, 5A09357, 5A09358, 5A09359, 5A0935B, 5A0935Z, 5A09457, 5A09458, 5A09459, 5A0945B, 5A0945Z, 5A09557, 5A09558, 5A09559, 5A0955B, 5A0955Z, 5A1935Z, 5A1945Z, 5A1955Z, 5A19054, 0BH13EZ, 0BH17EZ, 0BH18EZ, 0B110F4, 0B110Z4, 0B113F4, 0B113Z4, 0B114F4, 0B114Z4
Extracorporeal membrane oxygenation (ECMO)	CPT	33946, 33947, 33948, 33949, 33954, 33956, 33984, 33986, 33966, 33988, 33989, 33951, 33952, 33953, 33955, 33987, 33969, 33985, 33957, 33958, 33959, 33962, 33963, 33964, 33965
	ICD-10-PCS	5A1522F, 5A15A2F, 5A15A2G, 5A15A2H, 5A1522G, 5A1522H
Intensive care unit (ICU) admission	Revenue code	0200, 0201, 0202, 0203, 0204, 0206, 0207, 0208, 0209, 0210, 0211, 0212, 0213, 0214, 0219, 0233, 0234
	CPT	99291, 99292
	Provider specialty	61

Abbreviations

CPT, Current Procedural Terminology; ECMO, extracorporeal membrane oxygenation; HHS, Health and Human Services; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases, Tenth Revision, Procedure Coding System; ICU, intensive care unit; NDC, National Drug Code; RSV, respiratory syncytial virus; RSVPreF3, RSV prefusion F3; US, United States.