Real-world evidence of the adjuvanted RSVPreF3 vaccine's uptake and effectiveness among chronic obstructive pulmonary disease patients in Denmark: a nationwide cohort study

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Adjuvanted RSVPreF3 vaccination prevents RSV hospitalizations and RSV-related clinical outcomes, such as COPD exacerbations, in **adults aged ≥60 years living with COPD.** Incorporating the RSV vaccine into routine COPD management could further improve outcomes.

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Background

- Respiratory syncytial virus (RSV) causes considerable morbidity and mortality in older adults, with those who have chronic obstructive pulmonary disease (COPD) experiencing higher risk of severe disease.[1-3]
- In 2023, the adjuvanted RSVPreF3 vaccine was approved in the US and the EU for active immunization for prevention of RSV-LRTD[4–7] and, in August 2024, Denmark granted conditional reimbursement for adults aged ≥60y with COPD.[8]
- While clinical trials demonstrated high efficacy of adjuvanted RSVPreF3 vaccine in preventing RSV-LRTD,[5,6] real-world data on RSV vaccine effectiveness remain limited, especially concerning at-risk populations, such as patients with COPD.[9–12]
- Understanding the real-world impact of adjuvanted RSVPreF3 vaccine is critical to inform public health strategies and optimize vaccination programs for populations at increased risk.[13]

Conclusions

Adjuvanted RSVPreF3 vaccine **uptake was 5.9%** across the 2024/2025 RSV season in adults aged ≥60y with COPD in Denmark.

No RSV-hospitalizations were observed among adults aged ≥60y with COPD who received adjuvanted RSVPreF3.

Vaccination with adjuvanted RSVPreF3 **was associated with lower risk of other RSV-related outcomes, and all-cause mortality** in adults aged ≥60y with COPD.

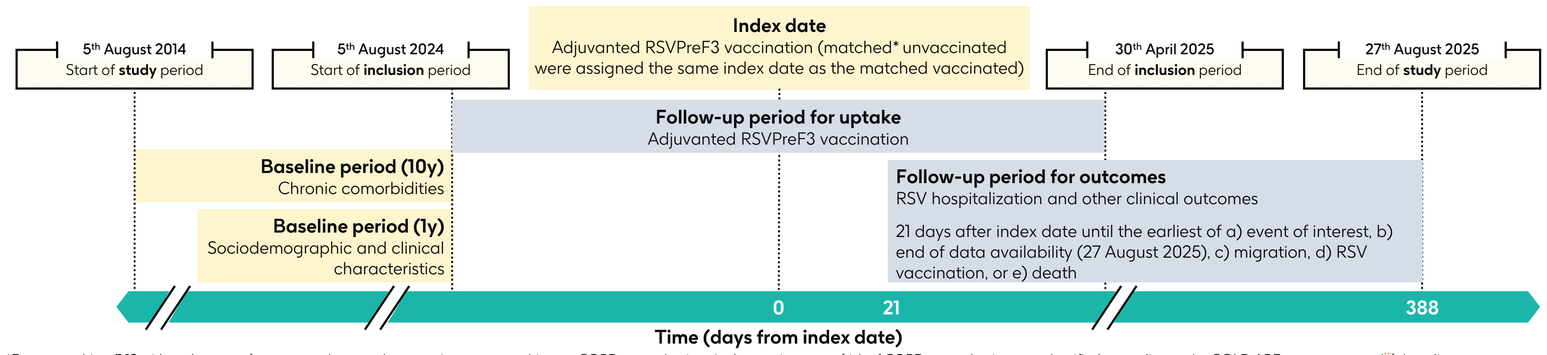
Aims

- To assess the adjuvanted RSVPreF3 vaccine's uptake
- To estimate the vaccine effectiveness against RSV hospitalization
- To describe the occurrence of other relevant clinical outcomes

Among adults aged ≥60 years with COPD in Denmark.

Study design

Nationwide register-based cohort study
All individuals aged ≥60y living with COPD in Denmark were eligible



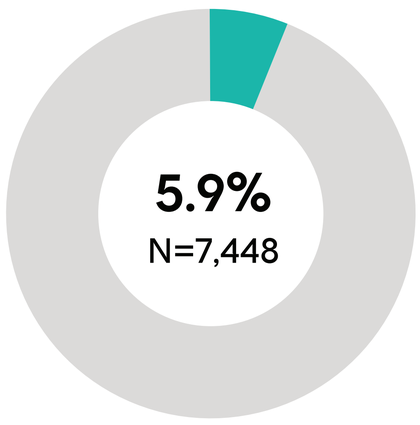
*Exact matching (1:12 with replacement) on age and sex, and propensity score matching on COPD exacerbations in the previous year (risk of COPD exacerbation was classified according to the GOLD ABE assessment tool[15]), baseline comorbidities, educational level, region of residence, vaccination history (influenza, COVID-19 and pneumococcal), and hospitalization in the previous year.

Results

VACCINE UPTAKE IN ADULTS AGED ≥60Y WITH COPD

UPTAKE

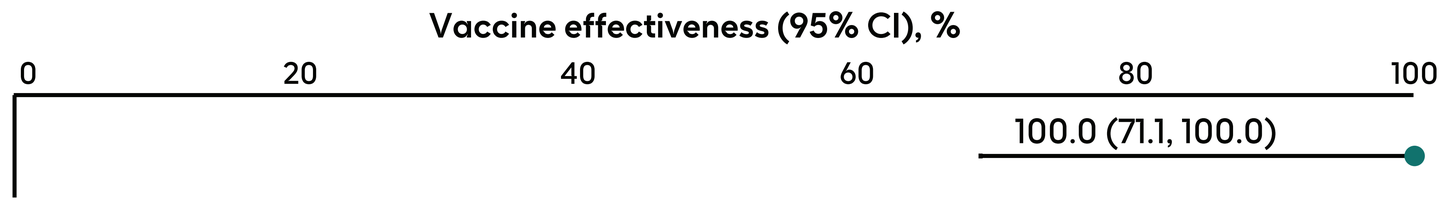
A total of 7,448 individuals received adjuvanted RSVPreF3 vaccine among 126,249 eligible.



VACCINE EFFECTIVENESS AGAINST RSV HOSPITALIZATION

EFFECTIVENESS

High vaccine effectiveness demonstrated against RSV hospitalizations, with no RSV hospitalizations observed among vaccinated individuals during the 2024/2025 season.



	Vaccinated	Unvaccinated
N	7,448	89,376
Events, n	0	115
Follow-up, person-years	5,166	57,328
Incidence rate (95% CI), events per 100,000 person-years	0.0 (0.0, 58.0)	200.6 (165.6, 240.8)

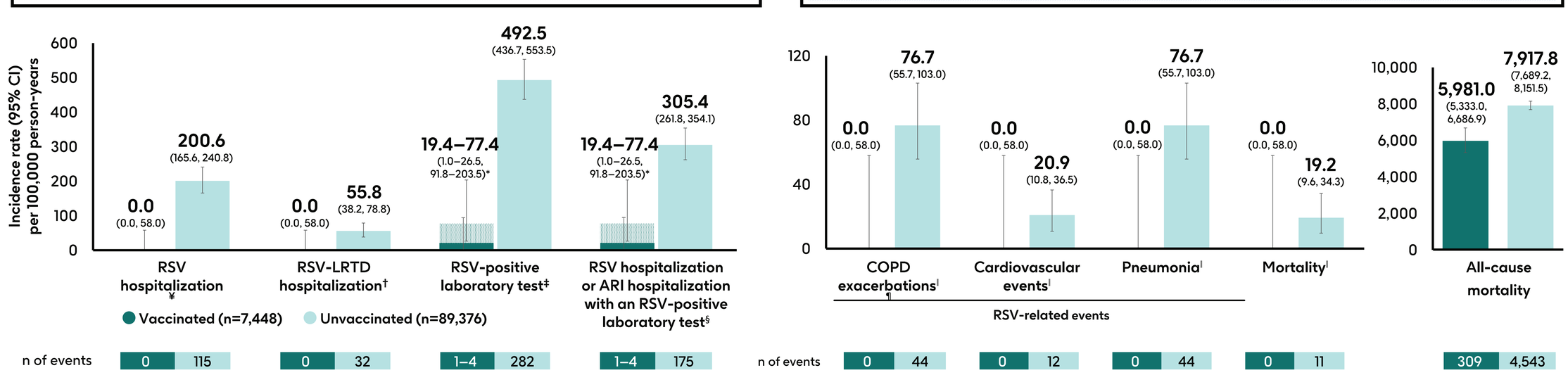
OTHER CLINICAL OUTCOMES AND MORTALITY

RSV-SPECIFIC ENDPOINTS

Vaccination with adjuvanted RSVPreF3 was associated with lower risk of RSV-specific endpoints.

CLINICAL OUTCOMES AND MORTALITY

Vaccination with adjuvanted RSVPreF3 was associated with lower risk of RSV-related outcomes and all-cause mortality.



Note: Outcomes were evaluated using observed event counts and accumulated person-time. Vaccine effectiveness was estimated from incidence rate ratios, while clinical outcomes were summarized using incidence rates per 100,000 person-years. Exact Poisson methods were used to derive confidence intervals; one-sided limits were applied for zero events. *Due to data protection rules, it was not possible to report on <5 units, therefore a 1–4 range was used. ¥B97.4, J12.1, J20.5, J21.0 as a primary or secondary diagnosis code; †J12.1, J20.5, J21.0 as a primary or secondary diagnosis code; ‡Any RSV positive laboratory test in MiBa during follow-up; §An RSV-coded hospitalization or an ARI-coded hospitalization with a positive test in MiBa performed within 7 days before or 48 hours after admission; ‖RSV-related events are events preceded by an RSV coded hospitalization (i.e., the RSV event must have occurred within 28 days prior to or 48 hours after admission); ¶At least 1 moderate or severe exacerbation

Abbreviations

ARI, acute respiratory infection; **CI**, confidence interval; **COPD**, chronic obstructive pulmonary disease; **EU**, European Union; **GOLD**, Global Initiative for Chronic Obstructive Lung Disease; **LRTD**, lower respiratory tract disease; **n**, number; **MiBa**, Danish Microbiology Database; **RSV**, respiratory syncytial virus; **US**, United States; **y**, years.

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Disclosures

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Conflicts of interest: Waldron C, Fonseca MJF, Bratković S, Burns S, Theiss-Nyland K and Gkalapi F are employed and hold financial equities in GSK. Waldron C holds equities in AstraZeneca. Çolak Y declares payment to his institution by Sanofi; consulting fees from GSK and Roche; payment for presentation by Chiesi, GSK and Sanofi; travel expenses to attend the European Respiratory Society International Congress 2023 paid by Sanofi; payment for participation to advisory board by GSK. Helleberg M declares payment for work related to the present poster by GSK, payment of study grant to her institution from AstraZeneca, payment of presentations from GSK, Abbvie, Bavarian Nordic; support for attending meetings from Advance pharma, CSL Behring and Gilead, and participation to advisory board for MSD, GSK, AstraZeneca and Bavarian Nordic. Vestbo J received personal fees from GSK for work related to the present poster, payment for presentation from GSK and AstraZeneca. Spanggaard M and Lundgren KL work for EY Parthenon, a paid vendor of GSK, which received consulting fees from GSK. The authors declare no other financial and non-financial relationship and activities.

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