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Dolna 17, Warsaw,
Poland 00-773
+48 226 0 227 03
editorial_office@rsglobal.pl

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RSV PREVENTION IN OLDER ADULTS: A MINI REVIEW OF APPROVED VACCINES

Martyna Sternik *(Corresponding Author, Email: sternikmartyna@gmail.com)*
4th Military Clinical Hospital with Polyclinic in Wrocław, Wrocław, Poland
ORCID ID: 0009-0003-2235-7932

Agnieszka Dobrowolska
Provincial Hospital in Zgierz them. M. Skłodowska-Curie, Zgierz, Poland
ORCID ID: 0009-0000-5645-7518

Hanna Ćwirko
University Clinical Hospital of Jan Mikulicz-Radecki in Wrocław, Wrocław, Poland
ORCID ID: 0009-0005-4947-5343

Zuzanna Drewniak
Praski Hospital in Warsaw, Warsaw, Poland
ORCID ID: 0009-0006-0426-4312

Marta Rząsa
Provincial Hospital in Zgierz them. M. Skłodowska-Curie, Zgierz, Poland
ORCID ID: 0009-0000-6817-6940

Karolina Rycman
Clinical Hospital of the Poznań University of Medical Sciences, Poznań, Poland
ORCID ID: 0009-0006-8144-6339

Adam Skrobarczyk
4th Military Clinical Hospital with Polyclinic in Wrocław, Wrocław, Poland
ORCID ID: 0009-0006-6391-2666

Kamil Wendrychowicz
Central Teaching Hospital of the Medical University of Lodz, Łódź, Poland
ORCID ID: 0009-0005-5452-5384

Filip Wróbel
Norbert Barlicki Memorial Teaching Hospital No. 1 of the Medical University of Lodz, Łódź, Poland
ORCID ID: 0009-0000-7572-9451

ABSTRACT

Respiratory syncytial virus (RSV) is a major cause of severe respiratory illness, imposing a substantial global health burden on older adults. For decades, the development of a safe and effective vaccine for adults was hindered by challenges, including the experience with an early formalin-inactivated vaccine that caused enhanced disease. A recent advancement in vaccinology, based on structure-guided design of immunogens that stabilize the viral fusion (F) glycoprotein in its prefusion form, has enabled the development and approval of three vaccines for older adults - two protein subunit vaccines: Arexvy, Abrysvo and one mRNA based mRESVIA. This review, based on studies identified through PubMed and Google Scholar using various keywords combinations, introduces the recently approved RSV vaccines, their composition, clinical efficacy, duration of protection, and uptake. Studies have shown that a single dose of these vaccines provides up to 82.6% efficacy against RSV-associated lower respiratory tract disease and 71.7% efficacy against RSV-associated acute respiratory infection within a single RSV season, highlighting their potential to reduce the burden of RSV in this population. As RSV infections continue to pose a significant risk and these vaccines have only been approved within the past two years, it is crucial to raise awareness about preventive measures.

KEYWORDS

Respiratory Syncytial Virus, Respiratory Syncytial Virus Infections, Adult, Aged, Vaccination, Vaccine Efficacy

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Introduction

Human respiratory syncytial virus (RSV), belonging to the Pneumoviridae family, is a widespread respiratory virus that can lead to severe respiratory disease in older adults, potentially requiring hospitalization and posing a risk of death. [1,2] In the elderly population and those with comorbidities, the virus is a significant cause of acute upper respiratory tract infections, lower respiratory tract disease and worsening of pre-existing conditions. [2,3,4] Furthermore, its clinical impact in adults admitted to the hospital has been clarified through the wider use of multiplex molecular testing. [2] The risks associated with infection by this virus in the aforementioned groups underscore the necessity of promoting awareness of preventive RSV vaccination in these populations.

The development of an effective RSV vaccine has been a challenge for scientists and medical researchers for a long time. Initial attempts to develop a vaccine occurred as early as the 1960s, when a formalin-inactivated vaccine was used. This led to vaccine-enhanced disease, which has remained a major safety concern. [5,6] Nevertheless, recent advances in the understanding of the virus, along with novel vaccine technologies, have facilitated the development of vaccine candidates. [6,7] The first RSV vaccines for older adults were approved by the U.S. Food and Drug Administration (FDA) in 2023. These include vaccines such as Arexvy (developed by GlaxoSmithKline) and Abrysvo (developed by Pfizer). [1] They were subsequently followed by the mResvia vaccine (developed by Moderna), which received FDA approval in 2024. [8]

Methodology

Relevant literature was identified through searches of the PubMed and Google Scholar databases. Keywords that were used in various combinations:

- “RSV infections”
- “Respiratory Syncytial Virus in adults”
- “RSV vaccine”
- “Arexvy”
- “Abrysvo”

- "mRESVIA"
- "efficacy"
- "vaccination".

Additionally, the search was limited to English-language publications, with a primary focus on studies published within the last ten years (2015-2025). The sources listed below were identified through this search strategy independently by all authors. Furthermore, case studies were excluded from the review. Vaccination websites were consulted for this review.

Subsequently, the retrieved sources were analyzed, and this review was prepared on the basis of the information contained therein.

Epidemiology

Vaccinations are an important tool for preventing severe diseases, which remains a significant public health concern; therefore, it is essential to address the incidence of infections in adults. Systematic reviews indicate that Respiratory Syncytial Virus (RSV) contributes considerably to the global burden of disease among adults - especially older individuals - leading to notable rates of infection, hospital admissions, and mortality. [9] However, the precise contribution of RSV infections to the overall burden of adult respiratory diseases is difficult to determine. There is no specific antiviral treatment for RSV, and management is primarily symptomatic; therefore, the virus is not consistently diagnosed in patients presenting with respiratory symptoms. [2,10] Moreover, antigen-based tests demonstrate low and often variable sensitivity in adult patients, while the application of more sensitive PCR-based diagnostics remains restricted because of their comparatively high cost. [10,11] The absence of a uniform clinical case definition for RSV, combined with the non-specific nature of its symptoms, further complicates the detection of RSV infections. [12] All of this contributes to an underestimation of the burden of RSV-related disease in older adults, despite growing evidence that its incidence may be comparable to that of influenza. [13,14]

In Nguyen-Van-Tam et. al study [15] based on studies conducted mostly in Europe (50.50%) and North America (38.80%), followed by Australia (7.80%) and Japan (2.90%) and published between 2000 and 2019 the pooled analysis estimated the seasonal incidence of RSV in older adults at 16.11 cases per 1,000 persons per year. However, the authors acknowledged the high variability in the data, with one study reporting an RSV incidence of 0.27 cases per 1,000 persons per year among those aged ≥65. [16] In contrast, Savic et al. estimated the incidence of acute respiratory infections due to RSV at approximately 16.2 per 1,000 persons, compared to 6.7 per 1,000 reported by Shi et al. [17, 18] To further demonstrate the burden of RSV infections, a study by Savic et al. [17] reported that in 2019, high-income countries experienced approximately 5.2 million RSV cases, 470,000 hospitalizations, and 33,000 deaths occurring in hospital among adults aged 60 years and older. The above highlights the need for infection prevention in the elderly population.

Types of RSV vaccines for adults

Two types of vaccine technologies have been used in RSV vaccines approved by regulatory authorities in the EU/EEA and the USA: protein-subunit and mRNA-based platforms. Currently, two protein-subunit RSV vaccines - RSVPreF3 (Arexvy, GSK) and RSVPreF (Abrysvo, Pfizer) - as well as one mRNA-based RSV vaccine, mRNA-1345 (mRESVIA, Moderna), are available. [19, 20] According to the updated ACIP guidance issued on 26 June 2024, a single dose of any FDA-authorized RSV vaccine - Arexvy (GSK), Abrysvo (Pfizer), or mRESVIA (Moderna) - is advised for all individuals aged 75 years and older, as well as for adults aged 60-74 years who have an elevated risk of developing severe RSV infection. [21]

Arexvy (GSK)

This vaccine received FDA approval on 23 May 2023 for the prevention of lower respiratory tract disease caused by RSV in individuals over 60 years of age and in individuals 50 through 59 years of age who are at increased risk, and subsequently obtained EMA approval in June 2023. [22, 23, 24] Arexvy is formulated by stabilizing the RSV/A2 F protein in its trimeric prefusion configuration (RSVPreF3) and incorporating the Adjuvant System 01 (AS01E) to enhance the immune response. [26, 27] In a phase 1/2 study involving both young and older adults, the combination of the AS01E adjuvant with the highest evaluated dose of RSVPreF3 (120 μg) demonstrated strong immunogenicity and a favorable safety profile, leading to its selection as the preferred formulation (RSVPreF3 OA) for subsequent clinical trials. [27,28] Later-phase clinical trials of RSVPreF3 OA in older adults showed a generally acceptable safety profile, with only one reported case of Guillain–Barré syndrome in an ongoing study. [29] Moreover, the vaccine demonstrated high efficacy within a single RSV season: 82.6% against RSV-LRTD (lower respiratory tract disease), 94.1% against severe RSV-

LRTD, and 71.7% against RSV-associated acute respiratory infection (RSV-ARI), irrespective of RSV subtype or underlying comorbidities. [3] Across two RSV seasons, a single dose of the vaccine provided effective protection in older adults, demonstrating 67.2% efficacy against RSV-LRTD and 78.8% against severe RSV-LRTD, while a second dose conferred no additional benefit. [30]

Abrysvo (Pfizer)

The vaccine developed by Pfizer was approved in May 2023 and is a bivalent prefusion F protein formulation (RSVpreF). A single intramuscular dose of the vaccine contains 60 μg of trimeric F glycoproteins from both major RSV subgroups (A and B), engineered for enhanced stability in the prefusion conformation. The vaccine is authorized for active immunization of adults aged 60 years and older, as well as adults aged 18–59 years who are at increased risk of RSV-LRTD. It is also approved for use in pregnant individuals between 32 and 36 weeks of gestation to protect infants from birth to 6 months of age against RSV-LRTD and severe LRTD. [31] Findings from phase 1/2 trials demonstrated favorable safety, tolerability, and immunogenicity profiles, and indicated that the addition of $Al(OH)_3$ or $CpG/Al(OH)_3$ as adjuvants provided no additional benefit in adults and in healthy older adults, respectively. [32,33] The efficacy of the vaccine in older adults was assessed in the RENOIR study. As the data shows Abrysvo vaccine showed 66.7% and 85.7% efficacy against RSV-related lower respiratory tract illness, depending on whether cases were defined by at least two or at least three symptoms, and 62.1% efficacy against RSV-associated acute respiratory illness, with no apparent safety concerns. [34]

mRESVIA

mRNA-1345 vaccine is a single-dose intramuscular vaccine developed by Moderna and approved by the FDA in June 2024 in adults 60 years of age and older.. It includes 50 μg of mRNA encoding the prefusion F protein and is intended to protect adults aged 60 years and older against RSV-associated lower respiratory tract disease (RSV-LRTD). [35] The efficacy and safety of this vaccine in individuals aged 60 years and older were evaluated in the phase 2/3 ConquerRSV study. The vaccine showed 83.7% efficacy against RSV-LRTD with ≥2 symptoms and 82.4% efficacy with ≥3 symptoms. It also showed 68.4% efficacy against RSV-associated acute respiratory disease. Additionally the vaccine provided protection against RSV subtypes A and B in all age groups and in individuals with pre-existing conditions. [36]

Real-world effectiveness of RSV vaccines in adults

Real-world observational studies indicate that RSV vaccines are highly effective in preventing hospitalization among older adults, although early uptake has been modest. Large-scale post-licensure evaluations have reported vaccine effectiveness (VE) against RSV-associated hospitalization ranging from 58% to 83%. [37, 38, 39] A meta-analysis of early data estimated a pooled VE of 79.6% against hospital admission in older adults. [40] However, vaccine effectiveness appears to be reduced in certain high-risk groups, including immunocompromised individuals and those with underlying cardiovascular disease. [37, 39]

Despite this demonstrated effectiveness, found studies show that vaccination coverage has remained low. In the United States, during the first season of availability (2023–2024), uptake among adults aged ≥60 years was estimated at only 10% to 22%. [41, 42] No comparable data were identified for Europe.

Factors associated with lower RSV vaccination rates in adults include racial and socioeconomic inequities, guidance based on shared clinical decision-making and lower uptake among those who forgo other routine adult vaccines. [21, 42, 43]

Duration of protection from RSV vaccines in adults

A single dose of an adult RSV vaccine provides clinically meaningful protection against lower respiratory tract disease (LRTD) for up to two RSV seasons, although efficacy decreases over time. Follow-up data from pivotal phase 3 trials confirm this sustained protection, showing that efficacy against LRTD decreases from the first to the second RSV season but remains significant compared with placebo. [3, 19] This sustained efficacy is corroborated by immunological data indicating that neutralizing antibody titers remain above baseline for at least 12 to 18 months following vaccination. [43,44] This sustained response contrasts with the short-lived immunity following natural RSV infection, in which antibody levels can decline markedly within one year. [45]

The full duration of protection remains unknown, and ongoing studies aim to determine the optimal timing and need for booster doses. [46] Initial investigations into 12-month booster doses have produced mixed findings, with some evidence suggesting minimal additional benefit from early re-vaccination, implying that annual boosters may not be necessary. [43,47]

Conclusions

RSV vaccination represents a promising strategy for preventing and reducing the incidence of severe RSV-associated respiratory disease in older adults and individuals with comorbidities. RSV infections continue to pose a significant concern for these populations, highlighting the importance of raising awareness about preventive measures, including the currently approved vaccines. Findings from this systematic review indicate that the FDA-approved RSV vaccines - Arexvy, Abrysvo, and mRESVIA - demonstrate promising efficacy and the potential to reduce the burden of RSV disease. Given their recent introduction, further studies are warranted to assess long-term efficacy, booster requirements, and safety.

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