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CORRESPONDENCE

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# Revitalizing hope for older adults: The use of the novel Arexvy for immunization against respiratory syncytial virus

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## Abstract

**Introduction:** Respiratory syncytial virus (RSV), an RNA virus of the family Paramyxoviridae, is the most common cause of respiratory tract diseases, including upper and lower respiratory tract infections in adults. Researchers worldwide have been working for decades to develop an RSV vaccine that is both safe and cost-effective.

**Aim:** This correspondence aims to highlight the recent breakthroughs in the immunization against RSV for older adults (60 years and above), encompassing the newly sanctioned prophylactic agent by the FDA, drawing attention to its side effects that need to be taken care of and providing clear recommendations to maximize the potential influence of these advancements on RSV-related diseases globally.

**Methodology:** We did a literature search on RSV among older adults and its treatment on PubMed, Google Scholar, ResearchGate and FDA databases within 10 years. Keywords used for our search were; "Respiratory Syncytial Virus," "Older adults," "FDA," "Arexvy," and "Immunization."

**Result:** We found approximately 6000–10,000 lives and 60,000–160,000 hospital admissions among adults aged 65 years and older each year in the world, especially in the United States of America. Currently, there is no vaccine or targeted treatment for RSV for the most affected individuals, that is, the older adults, who are given supportive care. Recently, the USA- Food and Drug Administration (FDA) approved Arexvy (a recombinant subunit RSV vaccine) based on its encouraging results demonstrating acceptable safety and efficacy in a large-scale multi-centered Phase 3 trial.

**Conclusion:** Authorization of Arexvy, although a breakthrough in the field of research, needs to be approached with a blend of optimism tempered by caution. Robust studies, including large-scale randomized controlled trials, prospective cohort studies and systematic reviews and meta-analyses, need to be conducted to ascertain its safety and efficacy.

KEYWORDS

Arexvy and immunization, FDA, older adults, respiratory syncytial virus

## 1 | INTRODUCTION

Respiratory syncytial virus (RSV), an RNA virus of the family Paramyxoviridae, is the most common cause of respiratory tract diseases, including upper and lower respiratory tract infections in adults, claiming approximately 6000–10,000 lives and 60,000–160,000 hospital admissions among adults aged 65 years and older each year in the United States.[1,2] RSV manifests as an array of symptoms, including coughing, sneezing, high temperature, wheezing, and anorexia. It is contagious and transmitted via respiratory droplets released into the air due to coughing or sneezing, and via person-to-person contact.[3] Although anyone could be affected, RSV-related respiratory tract diseases have a particularly high incidence and are life-threatening in infants and older adults (which could be due to age-related decline in immunity),[4] especially in those with comorbidities such as chronic lung and heart disease.[3]

Currently, there is no vaccine or targeted treatment for RSV for the most affected individuals, that is, the older adults, who are given supportive care. The high cost of screening for RSV and the same clinical manifestations as influenza often lead to misdiagnosis of RSV.[1] A recent study reported that the mean mortality rate for RSV-associated respiratory diseases was as high as 14.7% in patients aged 65 years and above, the highest among all the age groups, thus necessitating the need for immunization against the virus in this population.[5] The first vaccine developed against RSV in children in the late 1960s was an Alum-adjuvanted formalin-induced vaccine, which did more harm than good, as it caused enhanced RSV disease (high-grade fever, wheezing, and bronchopneumonia) in children and led to two casualties.[6] Researchers worldwide have been working for decades to develop an RSV vaccine that is both safe and cost-effective. Currently, vaccine candidates undergoing clinical trials for RSV mainly focus on targeting the fusion glycoprotein F (on the surface of RSV), which helps the virus enter host cells and generates a robust neutralizing antibody response.[7]

This correspondence therefore aims to highlight the recent breakthroughs in immunization against RSV for older adults (60 years and above), encompassing the newly sanctioned prophylactic agent by the US Food and Drug Administration (FDA), including its related side effects that need to be taken care of, and provides clear recommendations to maximize the potential influence of these advancements on RSV-related diseases globally.

## 2 | FINDINGS ABOUT PALIVIZUMAB

To date, Palivizumab (post-F specific monoclonal antibody) is the only licensed prophylactic administered to high-risk infants for immunization against RSV-related lower respiratory tract disease (RSV-LRTD).[7] Because of the temporary protection offered by palivizumab, multiple doses are required (once every month for five consecutive months during the RSV season), which is not only inconvenient for patients but also financially burdensome for their families. Moreover, its use is restricted to premature high-risk infants (immunocompromised and those with cardiac or pulmonary diseases), leaving the needs of older adults (a highly susceptible group) largely unmet.[8] In addition, the prefusion F conformation antigen has shown superiority over the post-F conformation in generating a neutralization response. Research has indicated that immunogens targeting the pre-F antigenic site Ø are 10–100 folds more potent than palivizumab,[7] which has steered research towards the development of a recombinant subunit RSV vaccine containing prefusion F glycoprotein antigen.

## 3 | AREXVY: A BEACON OF HOPE FOR THE OLDER ADULTS

There was no vaccine against RSV until recently when the US FDA approved Arexvy, AS0E1-adjuvanted RSV Prefusion F vaccine (RSVpreF3 OA), the world's first FDA-approved vaccine against RSV for older adults (60 years and older).[9] This is a paramount breakthrough in the field of research, as it is the first RSV vaccine to have shown promising results in terms of both efficacy and safety in individuals aged 60 years and above in a large Phase 3 trial, which enrolled over 24,000 participants from 17 countries to test vaccine efficacy against lower respiratory tract diseases (LRTDs) (primary endpoint), acute respiratory infections (ARIs), and severe lower respiratory tract disease caused by RSV over an average follow-up of 6.7 months.[10] The vaccine group received a single dose of Arexvy, and the placebo group received an equivalent amount of saline placebo before the RSV season. A single dose of RSVpreF3 OA showed an exceptionally high efficacy of 82.6% against RSV-related lower respiratory tract disease (7 instances in the vaccine group vs. 40 in the placebo group), 94.1% and nearly 72% against severe RSV-related lower respiratory tract disease and RSV-related acute respiratory infection, respectively. Notably, the vaccine offered equal protection against the two RSV subtypes A and B.[10]

Due to its encouraging outcomes in a substantial Phase 3 trial conducted across multiple centres, researchers are optimistic about the potential of this innovative RSV vaccine to alleviate the strain on the global healthcare system, owing to its effectiveness and safety profile in older adults, an age group highly susceptible to RSV-related diseases. However, we can only be cautiously optimistic about this due to the incidence of unsolicited adverse effects that was found to be higher among the vaccine recipients than among the placebo recipients (33% vs. 17%).[10] Ten vaccine recipients and four placebo recipients developed atrial fibrillation within a month of vaccination.[10] Also, when Arexvy and the influenza vaccine were given simultaneously, two participants developed acute disseminated encephalomyelitis (ADEM), one of whom died.[9] Among the solicited side effects, pain at the injection site was most commonly reported by vaccine recipients (69%), followed by fatigue (33.6%).[10] Therefore, these side effects should be taken care of to avoid potentially fatal outcomes.

## 4 | RECOMMENDATIONS

The FDA approval of Arexvy presents a beacon of hope in substantially decreasing the RSV-related disease burden worldwide. However, we believe that much work still needs to be done. Ensuring the wide

availability and affordability of vaccines, especially in lower- and middle-income countries should be the utmost priority, as the ageing world population would increase the disease burden in the years to come. This can be achieved if the World Health Organization collaborates with manufacturers to upscale Arexvy vaccine production in the world and organize mass vaccination campaigns, and the national health authorities improve the surveillance system in their countries. Furthermore, the cost-effectiveness of Arexvy, its contraindications, and the need for booster doses should be explored by researchers to enhance its real value in protecting against RSV in older adults. Additionally, it is imperative to ascertain that the RSV vaccine does not interfere with the immunization schedule for other diseases, especially measles, as both measles and RSV peak in winter through early spring.

## 5 | CONCLUSION

The authorization of Arexvy, although a breakthrough in the field of research, needs to be approached with a blend of optimism tempered by caution. Robust studies, including large-scale randomized controlled trials, prospective cohort studies, systematic reviews, and meta-analyses, need to be conducted to ascertain its safety and efficacy. We hope that the advancements in RSV vaccine will pave the way for future research on the development of targeted vaccines for other vulnerable groups, including infants, pregnant women, and healthcare workers (who are at risk of occupational exposure), thus relieving a significant burden on the healthcare system globally.

### AUTHOR CONTRIBUTIONS

**Haleema Qayyum Abbasi**: Conceptualization; data curation; formal analysis; investigation; resources; validation; writing—original draft. **Malik Olatunde Oduoye**: Conceptualization; funding acquisition; methodology; project administration; software; supervision; validation; writing—review & editing.

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### CONFLICT OF INTEREST STATEMENT

All the authors declare no conflict of interest.

### DATA AVAILABILITY STATEMENT

Not applicable to this work.

### TRANSPARENCY STATEMENT

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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### REFERENCES

1. Respiratory Syncytial Virus (RSV) – NFID. Accessed June 22, 2023. https://www.nfid.org/infectious-disease/rsv/
2. RSV Surveillance and Research | CDC. Accessed June 22, 2023. https://www.cdc.gov/rsv/research/index.html
3. Symptoms and Care of RSV (Respiratory Syncytial Virus) | CDC. Accessed May 19, 2023. https://www.cdc.gov/rsv/about/symptoms.html
4. Leroux-Roels I, Davis MG, Steenackers K, et al. Safety and immunogenicity of a respiratory syncytial virus prefusion F (RSVPreF3) candidate vaccine in older adults: phase 1/2 randomized clinical trial. *J Infect Dis*. 2023;227(6):761-772.
5. Hansen CL, Chaves SS, Demont C, Viboud C. Mortality associated with influenza and respiratory syncytial virus in the US, 1999-2018. *JAMA Netw Open*. 2022;5(2):PMC8886548.
6. Bergeron HC, Tripp RA. Immunopathology of RSV: an updated review. *Viruses*. 2021;13(12):2478. https://pubmed.ncbi.nlm.nih.gov/34960746/
7. Ngwuta JO, Chen M, Modjarrad K, et al. Prefusion F–specific antibodies determine the magnitude of RSV neutralizing activity in human sera. *Sci Transl Med*. 2015;7:309.
8. Rogovik AL, Carleton B, Solimano A, Goldman RD. Palivizumab for the prevention of respiratory syncytial virus infection. *Can Fam Physician*. 2010;56(8):769-772.
9. FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine | FDA. Accessed May 19, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine
10. Walsh EE, Pérez Marc G, Zareba AM, et al. Efficacy and safety of a bivalent RSV prefusion F vaccine in older adults. *N Engl J Med*. 2023;388(16):1465-1477. http://www.ncbi.nlm.nih.gov/pubmed/37018468

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