Advisory Committee on Immunization Practices (ACIP)

ACIP Evidence to Recommendations for Use of Protein Subunit RSV vaccines (GSK Arexvy or Pfizer Abrysvo) in All Adults Aged ≥75 years and in Adults Aged 60–74 at Increased Risk of Severe RSV Disease

Questions:

Should RSV vaccination be recommended in all adults aged ≥75 years?

Should RSV vaccination be recommended in adults aged 60-74 years at increased risk of severe RSV disease?

Populations: Persons aged ≥75 years and persons aged 60-74 years at increased risk of severe RSV disease

Intervention: RSV Protein Subunit Vaccine (GSK Arexvy or Pfizer Abrysvo)

Comparison: No RSV vaccine

Outcomes:

- Respiratory Syncytial Virus (RSV) lower respiratory tract illness/disease (LRTI/LRTD)
- Medically attended RSV LRTI/LRTD
- Hospitalization for RSV respiratory illness
- Severe RSV respiratory illness requiring supplemental oxygen or other respiratory support
- Death due to RSV respiratory illness
- Serious Adverse Events (SAEs)
- Inflammatory neurologic events (e.g., Guillain-Barré syndrome)
- Reactogenicity (grade ≥3)

Background:

Respiratory Syncytial Virus (RSV) is a common respiratory virus that usually causes mild, cold-like symptoms, but can lead to severe outcomes, including hospitalization and death, especially for infants and older adults. RSV circulation is typically seasonal, starting during the fall and peaking in the winter.

On May 3, 2023, the Food and Drug Administration (FDA) approved GSK's Arexvy for prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged ≥60 years.[1] Arexvy is a 1-dose (0.5 mL) subunit vaccine containing stabilized RSV prefusion F protein in combination with adjuvant ($AS01_E$).[1]

On May 31, 2023, FDA approved Pfizer's Abrysvo for prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged ≥60 years.[2] Abrysvo is 1-dose (0.5 mL) subunit vaccine containing stabilized RSV prefusion F protein.[2]

The Advisory Committee on Immunization Practices (ACIP) Work Group for RSV prevention in adults reviewed the following data in the Evidence to Recommendations (EtR) framework. The work group's judgements for each domain are presented here for adults aged ≥75 years, and separately, for adults aged 60–74 years who are at increased risk of severe RSV disease.

This EtR framework only reviews protein subunit RSV vaccines (GSK's Arexvy and Pfizer's Abrysvo). For the Evidence to Recommendations Framework on Moderna's mResvia vaccine, please see ACIP Evidence to Recommendations for Use of Moderna RSV Vaccine (mResvia) in All Adults Aged ≥75 years and in Adults Aged 60–74 at Increased Risk of Severe RSV Disease | CDC.

Public Health Problem

Criteria	Work Group Judgements	Evidence

Criteria	Work Group Judgements	Evidence
Is the problem of public health importance?	**Adults aged ≥75 years:** Yes **Adults aged 60–74 years at increased risk of severe RSV disease:** Yes	During 2016-2020, CDC estimates that RSV was associated with 90,000 to 140,000 annual hospitalizations in US adults aged 65 years and older, and an additional 10,000 to 20,000 hospitalizations in adults aged 60 to 64 years.[1] Both age and presence of chronic medical conditions impact risk of severe RSV disease. In terms of age, estimated annual incidence of RSV-associated hospitalization increases with increasing age, including among adults aged 60 years and older, and increases substantially among those aged ≥75 years. Adults aged ≥75 years make up <10% of the U.S. adult population, but account for nearly half of all estimated RSV-associated hospitalizations among U.S. adults and most RSV-attributable deaths. Regarding risk among those with chronic medical conditions, a CDC analysis using data on RSV-associated hospitalizations among those with certain medical conditions from the RSV Hospitalization Surveillance Network (RSV-NET) and prevalence of those conditions among the general U.S. population from the Behavioral Risk Factor Surveillance System (BRFSS) evaluated specific chronic medical conditions as potential risk factors for RSV hospitalization.[2,3] Among community-dwelling adults aged ≥50 years, chronic kidney disease (CKD), chronic obstructive pulmonary disease (COPD), severe obesity (body mass index [BMI] ≥40 kg/m^2), asthma, diabetes mellitus, and current smoking were associated with an increased incidence of RSV-associated hospitalization (adjusted incidence rate ratio >1.0), compared with adults who did not have each condition.[4] Other chronic medical conditions consistently identified as risk-factors for severe RSV disease include heart failure and immune compromise, particularly in the setting of lung transplant or hematopoietic cell transplant. Persons living in nursing homes and other long-term care facilities also experience increased risk of severe RSV disease, with RSV frequently causing large outbreaks of respiratory illness in these settings.[5,6] Importantly, in the RSV-NET analysis a history of ≥2 chronic medical conditions and age ≥75 years were independent risk factors for RSV-associated hospitalization.[4] This suggests that the increased risk among older adults is not just that adults accumulate more chronic medical conditions with age, but that age itself increases risk due to other unmeasured factors. Severity of RSV disease among adults that do develop disease is another important consideration. Prior to RSV vaccine introduction, disease severity of RSV among hospitalized adults 18 years or older was similar to severity of COVID-19 and influenza among hospitalized patients who were unvaccinated against each of those pathogens, respectively.[7] In a recent cross-sectional study, nearly one-quarter of adults 50 years or older hospitalized with RSV infection experienced an acute cardiac event (most frequently acute heart failure), including 1 in 12 adults with no documented underlying cardiovascular disease.[8] Lastly, RSV is associated with long-term sequelae and increased care needs. In a retrospective chart review of adults hospitalized with RSV infection, most patients required follow-up care and 10–16% required skilled nursing (either at home or at an assisted care or nursing facility), compared with 7% before admission.[9] In summary, the annual rate of RSV-associated hospitalization increases with increasing age, with a steep rise at age 75. Certain chronic medical conditions are

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		also independent risk factors for severe RSV disease. RSV causes disease similar in severity to other important respiratory pathogens and has significant post-hospitalization sequelae in older adults.

Benefits and Harms

Criteria	Work Group Judgements	Evidence

Criteria	Work Group Judgements	Evidence
How substantial are the desirable anticipated effects?	**Adults aged ≥75 years:** Moderate or large **Adults aged 60–74** years at increased risk of severe RSV disease: Moderate or large	**GRADE** The body of evidence included in GRADE regarding efficacy of protein subunit RSV vaccines consisted of data from two randomized, placebo-controlled phase 3 clinical trials both conducted in multiple countries.[1–5] **Below are the summary GRADE findings. For full details regarding GRADE, please see GRADE: Protein subunit RSV vaccines (GSK Arexvy and Pfizer Abrysvo) in older adults | CDC.** **Adults aged ≥75 years** Protein subunit RSV vaccination reduces RSV LRTD in adults aged ≥75 years. Protein subunit RSV vaccination likely reduces medically attended RSV LRTD in adults aged ≥75 years. Protein subunit RSV vaccination may reduce hospitalization for RSV respiratory illness in adults aged ≥75 years. Protein subunit RSV vaccination may reduce severe RSV respiratory illness requiring supplemental oxygen or other respiratory support in adults aged ≥75 years, but the effect is very uncertain. **Adults aged 60 – 74 years at increased risk of severe RSV disease** Protein subunit RSV vaccination reduces RSV LRTD. Protein subunit RSV vaccination reduces medically attended RSV LRTD. Protein subunit RSV vaccination may reduce hospitalization for RSV respiratory illness. Protein subunit RSV vaccination may reduce severe RSV respiratory illness requiring supplemental oxygen or other respiratory support, but the effect is very uncertain. Additional information not captured in GRADE, included data from both clinical trials on vaccine protection over time and post-licensure vaccine effectiveness studies. **The Pfizer and GSK clinical trials used different primary endpoint definitions and had different enrollment timing and follow-up time in their trials, so efficacy cannot be directly compared across trials even when similar time-points are considered.** Waning of protection over time is a well-known and expected phenomenon after vaccination, and efficacy in both the GSK and Pfizer phase 3 clinical efficacy trials showed some waning with increasing follow up time after vaccination. In GSK's trial, efficacy of Arexvy in preventing the primary outcome, RSV-associated LRTD, waned from 79% (95% confidence interval [CI] 58–90%) during months 0–12 post-vaccination to 59% (95% CI 34–75%) during months 13–24 post-vaccination. In GSK's trial, the median follow-up time during this period was 24 months. In Pfizer's trial, efficacy of Abrysvo in preventing the two coprimary endpoints, RSV-associated LRTI with ≥2 and with ≥3 lower respiratory symptoms, waned from 62% (95% CI 41–76%) during months 0-12 after vaccination to 55% (95% CI 26–73%) during months 13-24, and from 86% (95% CI 63–96%) to 74% (95% CI 27–92%), respectively. After month 12 in Pfizer's trial, the median follow-up per participant was only 6 months; because data are limited for the 19-24 month follow-up period, Abrysvo may exhibit additional waning during months 19–24 post-vaccination that has not yet been observed.[6] Of the two manufacturers, only GSK evaluated efficacy following revaccination. Efficacy of a second dose of Arexvy 12 months after the first, was not higher than efficacy among recipients of a single-dose only. Efficacy against RSV-associated LRTD during the second RSV season was 59% (95% CI 34–75%) among single-dose recipients and 58% (95% CI 34–75%) among two-dose recipients.[6]

Criteria	Work Group Judgements	Evidence
		Post-licensure data were reviewed from four observational vaccine effectiveness (VE) studies of protein subunit RSV vaccination against RSV-associated hospitalization among adults aged ≥60 years during the first RSV season after vaccination; estimates from the general population or among immunocompetent adults only ranged from 75% (95% CI 50%–87%) to 82% (95% CI 69%–89%)[7]. VE was similar across vaccine product (GSK Arexvy, Pfizer ABYRSVO) and patient age groups (60–74 years, ≥75 years). Additionally, effectiveness was demonstrated among adults aged ≥60 years with certain immunocompromising conditions (broadly defined; no estimates specifically among persons with solid organ or hematopoietic cell transplant are available) and with end-stage renal disease.* **Footnotes:** *After the ACIP presentation on June 26, 2024, a minor coding error was discovered in the analysis of VE among those with end-stage renal disease. The estimate presented was 78% (95% CI = 45%-91%) among those without additional immunocompromise and 80% (95% CI = 31%-94%) among those with additional immunocompromise. The corrected estimates were 72% (95% CI = 41%-87%) and 83% (95% CI = 45%-95%).

Criteria	Work Group Judgements	Evidence
How substantial are the undesirable anticipated effects?	**Adults aged ≥75 years:** Small or moderate **Adults aged 60–74 years at increased risk of severe RSV disease:** Small or moderate	**GRADE** The body of evidence included in GRADE regarding safety of protein subunit RSV vaccines consisted of data from two randomized, placebo-controlled phase 3 clinical trials and two phase 1/2 trials.[3,5,8,9] **Below are the summary GRADE findings. For full details regarding GRADE, please see GRADE: Protein subunit RSV vaccines (GSK Arexvy and Pfizer Abrysvo) in older adults | CDC.** **All adults aged ≥75 years and adults aged 60–74 years at increased risk of severe RSV disease:** Protein subunit RSV vaccination likely results in little to no difference in SAEs. Protein subunit RSV vaccination may increase inflammatory neurologic events, but the effect is very uncertain. Protein subunit RSV vaccination may increase severe reactogenicity events. Additional information not captured in GRADE included data from post-licensure safety surveillance. Post-licensure safety data evaluated included preliminary results of a self-controlled case series analysis from FDA estimating risk of Guillain-Barré syndrome (GBS) attributable to protein subunit RSV vaccination among Medicare Part D beneficiaries aged ≥65 years.[10] The analysis compared GBS incidence during a risk interval (days 1–42 post-vaccination) with that in a control interval (days 43–90 post-vaccination). Among beneficiaries vaccinated prior to October 8, 2023, the GBS adjusted incidence rate ratio was 2.30 (95% CI 0.39–13.72) for GSK's Arexvy and 4.48 (95% CI 0.88–22.90) for Pfizer's Abrysvo during the 42-day risk interval post-vaccination, compared with the control interval (days 43–90 post-vaccination). Attributable risk was estimated to be 0.32 GBS cases (95% CI -0.30–0.95) per 100,000 doses of Arexvy and 1.57 cases (95% CI 0.30–2.85) per 100,000 doses of Abrysvo. Results of rapid cycle analysis performed by the Vaccine Safety Datalink demonstrated a statistical signal for immune thrombocytopenia (ITP) in a risk interval (days 1–21) after GSK Arexvy vaccination, without simultaneous receipt of another vaccine, compared with the comparison interval (11). However, medical record review revealed that most ITP cases had onset before vaccination; only 4 cases identified in the risk interval and 1 case in the comparison interval had onset after vaccination. Due to the overall small number of cases, an association cannot be confirmed between GSK Arexvy vaccination and ITP; supplemental evaluation of identified cases and monitoring for additional cases is ongoing.

Criteria	Work Group Judgements	Evidence
Do the desirable effects outweigh the undesirable effects?	**Adults aged ≥75 years:** Favors intervention **Adults aged 60–74 years at increased risk of severe RSV disease:** Favors intervention	A modeling study was conducted to compare the public health benefits of protein subunit RSV vaccination (preventable RSV-attributable hospitalizations, ICU admissions, deaths) with the potential risk of GBS per 1 million RSV vaccinations among adults aged ≥60 years, stratified by age and risk group.[12] Benefits were estimated using available data on RSV disease burden, observational vaccine effectiveness, and rate of efficacy waning from clinical trials; risk of GBS was estimated using preliminary results of the FDA self-controlled case series. **Adults aged ≥75 years** Over two consecutive RSV seasons, vaccination of 1 million adults aged ≥75 years with a single dose of GSK Arexvy was estimated to prevent 4,283 hospitalizations (range 2,235–6,957), 630 ICU admissions (range 329–1,023), and 605 deaths (range 202–1,263). Vaccine-attributable GBS cases were estimated to be 3 per 1 million RSV vaccinations (range 0–10).* Over two consecutive RSV seasons, vaccination of 1 million adults aged ≥75 years with a single dose of Pfizer Abrysvo was estimated to prevent 3,817 hospitalizations (range 1,927–6,288), 561 ICU admissions (range 283–924), and 539 deaths (range 190–1,106). Vaccine-attributable GBS cases were estimated to be 16 per 1 million RSV vaccinations (range 3–29). **Adults aged 60–74 years at increased risk of severe RSV disease** Over two consecutive RSV seasons, vaccination of 1 million adults aged 60–74 years at increased risk of severe RSV disease with a single dose of GSK Arexvy was estimated to prevent 2,839 hospitalizations (range 1,478–4,699), 647 ICU admissions (range 337–1,071), and 246 deaths (range 83–436). Vaccine-attributable GBS cases were estimated to be 3 per 1 million RSV vaccinations (range 0–10).* Over two consecutive RSV seasons, vaccination of 1 million adults aged 60-74 years at increased risk of severe RSV disease with a single dose of Pfizer Abrysvo was estimated to prevent 2,530 hospitalizations (range 1,363–4,224), 577 ICU admissions (range 311–963), and 219 deaths (range 74–399). Vaccine-attributable GBS cases were estimated to be 16 per 1 million RSV vaccinations (range 3–29). **Footnotes:** * Self-controlled case series analysis estimated attributable risk of 3 (95% CI: -3, 10) GBS cases. However, the range was truncated at zero for benefit-risk analyses.

Values

Criteria	Work Group Judgements	Evidence

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Does the target population feel that the desirable effects are large relative to undesirable effects?	**Adults aged ≥75 years:** Yes/Probably yes **Adults aged 60–74 years at increased risk of severe RSV disease:** Probably yes	In CDC Omnibus Surveys,* 28% of adults aged 60-74 years were very or moderately concerned about RSV disease. Among adults aged ≥75 years, this percentage was 36%. An additional 30-40% in each age group reported being a little concerned. [1] After one full season of RSV vaccine availability, an estimated 20-30% of adults aged 60 years and older have received RSV vaccination, with some variation by age group, based on data from CDC's National Immunization Survey†. [2] Uptake was higher among adults aged 70–79 and 80 and older compared with those aged 60–69, consistent with the above Omnibus data indicating older adults are more concerned about RSV. Higher coverage among older adults may also have been driven by reduced vaccine access among adults ages 60–64, most of whom are not yet Medicare-eligible. While data are lacking regarding how patients value protection against RSV in relation to potential risk of vaccine-attributable GBS, there are a few considerations: 1. Adults are likely willing to accept some rate of vaccine-associated adverse events for the benefit of preventing disease, 2. Individual baseline and vaccine-associated risk of GBS may differ by age group and presence of chronic conditions, and 3. Willingness to accept risk of GBS after vaccination may differ by age and health status and perceived risk of RSV-associated disease.[3,4] **Footnotes:** *Data for this analysis were collected in April 2024 through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults aged 18 years and older. CDC fields questions about vaccination status, intent, knowledge, attitudes, beliefs, and behaviors on each survey for 2 waves each month, for a combined sample size of ~4,000 respondents. Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported. †The National Immunization Survey-Adult COVID Module (NIS-ACM) is a random-digit-dial cellular telephone survey of adults age ≥18 years in the U.S. Respondents are sampled within all 50 states, District of Columbia, five local jurisdictions (Bexar County TX, Chicago IL, Houston TX, New York City NY, and Philadelphia County PA), Guam, Puerto Rico, and the U.S. Virgin Islands (sampled in 2023 only). Data are weighted to represent the non-institutionalized U.S. population.
Is there important uncertainty about or variability in how much people value the main outcome?	**Adults aged ≥75 years:** Probably not important uncertainty or variability **Adults aged 60–74 years at increased risk of severe RSV disease:** Probably not important uncertainty or variability	

Acceptability and Feasibility

Criteria	Work Group Judgements	Evidence

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Is the intervention acceptable to key stakeholders?	**Adults aged ≥75 years:** Yes **Adults aged 60–74 years at increased risk of severe RSV disease:** Yes/Probably yes	This section will review data informing whether an RSV vaccine recommendation would be acceptable to key stakeholders and if RSV vaccines will be feasible to implement. These two EtR domains were covered together at the June 2024 ACIP meeting as much of the evidence to inform them is cross cutting, applicable to both domains. The proposed recommendations would move away from the June 2023 Shared Clinical Decision Making (SCDM) recommendation, so information on how providers experience SCDM was reviewed. In a survey of general internal medicine physicians regarding Pneumococcal and Human Papilloma Virus (HPV) vaccination SCDM recommendations, most physicians strongly or somewhat agreed SCDM required more time with each patient than a routine recommendation.[1] Most respondents also thought SCDM created confusion. Just over 40% either strongly or somewhat agreed SCDM was hard to explain to patients and they did not know how to implement this type of recommendation as ACIP intended. While these data are not RSV-vaccine specific they can inform understanding of the acceptability of SCDM for healthcare providers. CDC and ACIP received feedback that the RSV vaccine SCDM recommendation had been difficult to implement.[2] SCDM conversations are challenging and time-consuming, especially compared with routine, universal recommendations. SCDM also does not have a clear call to action. Standing orders, often used by medical assistants, nurses, and pharmacists, are difficult under SCDM. Complicating this further, approximately 80% of older adult RSV vaccinations during the 2023-2024 season were given in pharmacies.[3] While pharmacists are qualified vaccinators, not all providers who give vaccines are comfortable with the SCDM conversation or feel it is within their scope of practice. For RSV vaccination in particular, there are also concerns about the ability to complete the type of risk-benefit discussion intended by ACIP, which should include the potential risk of GBS. Next, financial and insurance barriers to RSV vaccination were reviewed. RSV vaccines have a relatively high list price and it is a costly upfront investment to carry RSV vaccine, especially for smaller medical practices. As a result, primary care providers may be less likely to stock RSV vaccine and more likely to refer patients to pharmacies. RSV vaccines are also billed under Medicare Part D. Part D is described as more challenging for reimbursement than Part B, which is another reason providers may be less likely to carry RSV vaccine in their practices and instead refer patients to pharmacies. Next, looking at additional complexities regarding RSV feasibility, there are multiple licensed RSV vaccine products, which may cause confusion for both providers and adults seeking vaccination. The RSV vaccine products have different storage and handling requirements, and the adult vaccine schedule is already complex. A universal recommendation in adults aged ≥75 years might improve feasibility and acceptability by making vaccination the *default* and providing a stronger more decisive recommendation. It would also increase ease in generating standing orders and clinical decision-support tools. Standing orders may be particularly desirable among adults aged ≥75 years to facilitate vaccination in nursing homes. Finally, a universal recommendation among those aged ≥75 years covers those at highest risk of severe RSV disease without asking providers to complete an extensive individualized risk assessment. However, some considerations that might *decrease* feasibility and acceptability: the addition of a universal

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Is the intervention feasible to implement?	**Adults aged ≥75 years:** Yes/Probably yes **Adults aged 60–74 years at increased risk of severe RSV disease:** Yes/Probably yes	recommendation **only** for aged ≥75 years might cause confusion. Additionally, these revisions do not decrease the overall complexity of the adult schedule, and in fact, add another new important age cut-off for vaccination not aligned with another vaccine. Lastly, revising the recommendation, when education about the *initial* SCDM recommendation is still ongoing, may lead to confusion. A risk-based recommendation in adults ages 60-74 may provide more clarity to providers and the public about who **should** get an RSV vaccine, compared with the SCDM recommendation. And as with those aged ≥75 years, moving away from SCDM facilitates simplified standing orders, clinical decision support, and clearer overall messaging. However, even if more feasible than a SCDM recommendation, a risk-based recommendation would still be more challenging than a universal recommendation—providers need education on the indicated risk conditions and the risk factors for severe RSV disease qualifying for vaccination would not align completely with those listed in other risk-based vaccine recommendations. Similar to recommendations in adults ≥75 years, revising the recommendation, soon after the *initial* recommendation may lead to confusion.

Resource Use

Criteria	Work Group Judgements	Evidence

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Is the intervention a reasonable and efficient allocation of resources?	**Adults aged ≥75 years:** Yes/Probably yes **Adults aged 60–74 years at increased risk of severe RSV disease:** Yes/Probably yes	A cost effectiveness analysis was conducted to inform the domain of resource use. Incremental cost-effectiveness ratios (ICER) were estimated as societal cost (in 2023 U.S. dollars) per Quality-Adjusted Life-Year (QALY) gained through the vaccination program. In the base case, protein subunit RSV vaccination in the general population of adults aged ≥75 years resulted in an ICER of $51,477/QALY gained.[1,2] Protein subunit RSV vaccination of adults aged 60–74 years with at least one of: COPD, asthma, coronary artery disease, diabetes mellitus, chronic kidney disease, or severe obesity (BMI ≥40 kg/m^2) resulted in an ICER of $60,933/QALY gained. Notably, vaccination of adults ages 60–74 *without* the chronic conditions listed above resulted in an ICER of $505,385/QALY gained. When evaluated individually, results were similar for each vaccine product (GSK Arexvy, Pfizer Abrysvo). There remains substantial uncertainty in key parameters that impact cost effectiveness, including the annual incidence of medically-attended RSV hospitalization, RSV-attributable mortality, and the duration of protection from a single dose of RSV vaccination.

Equity

Criteria	Work Group Judgements	Evidence

Criteria	Work Group Judgements	Evidence
What would be the impact of the intervention on health equity?	**Adults aged ≥75 years**: Increased/Probably increased **Adults aged 60–74 years at increased risk of severe RSV disease:** Probably increased	RSV disease does not impact everyone equally. The median age of adults hospitalized with lab-confirmed RSV infection in RSV-NET* varies by race and ethnicity. During 2014–2023, the median age of hospitalization among Black adults was 62 years (interquartile range [IQR] 50–71), 62 years among Hispanic adults (IQR 48–76), 64 years among American Indian/Alaska Native adults (IQR 54–73) and 73 among White adults (IQR 63–82); this means the median age of hospitalization among Black, Hispanic, and American Indian/Alaska Native adults was almost 10 years younger than White adults.[1] In RSV-NET in 2018–2019, Black adults aged 60–74 years experienced a hospitalization rate 1.5-fold higher than White adults in the same age range.[1] This may be in part due to earlier onset of certain chronic medical conditions that increase risk of severe RSV disease at younger ages among Black adults. This disparity in relative hospitalization rates was absent among adults aged ≥75 years, but this could be due to residual confounding by age with fewer Black adults living to ages >80 or >90 years, compared with White adults. Uptake of RSV vaccine to date has also not been equal. Based on RSV vaccine data from the 2023-2024 RSV season through March 30, 2024, among Medicare beneficiaries aged 65 and older, non-Hispanic White beneficiaries had the highest uptake of RSV vaccine at just over 20%, while non-Hispanic Black beneficiaries had uptake around half that at 11% and Hispanic beneficiaries had only 6% uptake.[2] Looking at RSV vaccine uptake across other sociodemographic categories, in the National Immunization Survey, vaccination coverage was significantly lower among adults who live in rural areas (19.3%), are uninsured (7.0%), have lower household income, and reported an educational level of high school or less (18.0%).[3] Overall, RSV vaccine uptake after the first year of RSV vaccine availability has not been equitable across racial/ethnic groups or among persons with different sociodemographic characteristics. A universal recommendation for RSV vaccination in adults aged ≥75 years may impact equity by issuing a simple and clear message, which may remove barriers to vaccination. In addition, adults with undiagnosed chronic medical conditions, which may be the result of limited access to care, would be included in the recommendation by default. However, a universal recommendation would not guarantee equity. Even if vaccine coverage increases across all groups, disparities between groups may remain as has been seen with influenza vaccination.[4] A risk-based recommendation in adults aged 60–74 may impact equity by transitioning away from the implementation challenges of SCDM and better clarifying who is at risk. Even if a risk-based recommendation is not as simple as a universal recommendation, this change might remove some barriers to vaccination. A risk-based recommendation might also increase coverage among racial/ethnic minority groups in whom the prevalence of chronic medical conditions is higher in the 60–74 year age range. However, adults with undiagnosed chronic medical conditions, who disproportionately reside in communities with less access to healthcare, may be deemed ineligible for vaccination and some of these adults may have obtained RSV vaccination under the SCDM recommendation. Footnotes:

Criteria	Work Group Judgements	Evidence
		*The Respiratory Syncytial Virus Hospitalization Surveillance Network (RSV-NET) conducts population-based surveillance for hospitalizations associated with laboratory-confirmed RSV. Data from RSV-NET are collected by a network of sites from acute-care hospital facilities in 12 states covering almost 8% of the U.S. population. Rates are adjusted using multipliers for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.

Work Group Interpretation Summary

For the policy question of whether all adults aged 75 years and older should receive a single dose of RSV vaccine:

The work group felt that RSV disease is of public health concern.

They believed the desirable effects of protein subunit RSV vaccination were large while the undesirable effects were small to moderate, favoring the intervention over no vaccination.

They believed adults aged ≥75 years generally felt that the desirable effects of RSV vaccination were large, relative to the undesirable effects and that there probably was NOT important variability among older adults in how they value these outcomes. The work group felt that RSV vaccination in this age group would generally be acceptable to key stakeholders, that protein subunit vaccines would be or probably would be feasible to implement, and that they could be a reasonable and efficient allocation of resources. Finally, they believed that equity would be increased or would probably be increased through a universal RSV vaccine recommendation in this age group.

For the policy question of whether adults aged 60-74 years at increased risk of severe RSV disease should receive a single dose of RSV vaccine:

The work group felt that RSV disease is of public health concern in this population.

They believed the desirable effects of protein subunit RSV vaccination were large while the undesirable effects were small to moderate, favoring the intervention over no vaccination.

They believed adults aged 60-74 at increased risk probably felt that the desirable effects of RSV vaccination were large, relative to the undesirable effects and there probably was NOT important variability in how they value these outcomes. The work group felt that RSV vaccination for these adults would be or probably would be acceptable to key stakeholders, that protein subunit vaccines would be or probably would be feasible to implement, and they could be a reasonable and efficient allocation of resources. Finally, the Work Group believed that equity would be increased or would probably be increased through a risk-based RSV vaccine recommendation in this age group.

The Work Group noted that the June 2023 SCDM recommendation was made in the setting of uncertainty about both the estimated benefits and potential risks of RSV vaccination and SCDM was intended to facilitate individualized risk-benefit discussions in the setting of this uncertainty. However, feedback from clinicians and patients has shown that SCDM has drawbacks.

Now there is real-world evidence of robust protection against RSV-associated hospitalization during the first season of RSV vaccination among adults 60 years and older, including among key populations of concern in whom there are limited clinical trial data (adults aged ≥75 years and adults with chronic medical conditions). On the other hand, uncertainty remains regarding the magnitude of potential risk of GBS and the Work Group believes the GBS signal continues to warrant close attention and additional follow-up. The Work Group proposed recommendations intended to maximize RSV vaccination among persons most likely to benefit and minimize RSV vaccination among persons least likely to benefit.

Balance of consequences

Among adults aged ≥75 years:

The Work Group felt that the desirable consequences clearly or probably outweigh undesirable consequences in most settings.

Is there sufficient information to move forward with a recommendation? Yes

Among adults aged 60–74 years at increased risk of severe RSV disease:

The Work Group felt that the desirable consequences probably outweigh undesirable consequences in most settings.

Is there sufficient information to move forward with a recommendation? Yes

Type of recommendation, adults aged ≥75 years:

Adults 75 years of age and older are recommended to receive a single dose of RSV vaccination.[1]

[1]RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.

Type of recommendation, adults aged 60–74 years at increased risk of severe RSV disease:

Adults 60–74 years of age who are at increased risk of severe RSV disease[1] are recommended to receive a single dose of RSV vaccination.[2,3]

[1]Clinical considerations describe chronic medical conditions and other risk factors for severe RSV disease named in this risk-based recommendation.

[2] RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.

[3] These recommendations supplant the 2023 recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are **not** at increased risk of severe RSV disease are NOT recommended to receive RSV vaccination.

References

Background

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Public Health Problem:

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