Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

RSV Vaccination in Older Adults: Benefit-Risk Discussion

Michael Melgar, MD
Lauren Roper, MPH

Advisory Committee on Immunization Practices

February 29, 2024

There are two RSV vaccines approved in the United States and recommended for adults aged ≥60 years, using shared clinical decision-making.

Estimated benefits of RSV vaccination (single dose) with **GSK's Arexvy** and **Pfizer's Abrysvo**, stratified by age

Potential risk of Guillain-Barre syndrome (GBS) after RSV vaccination with **GSK's Arexvy** and **Pfizer's Abrysvo**

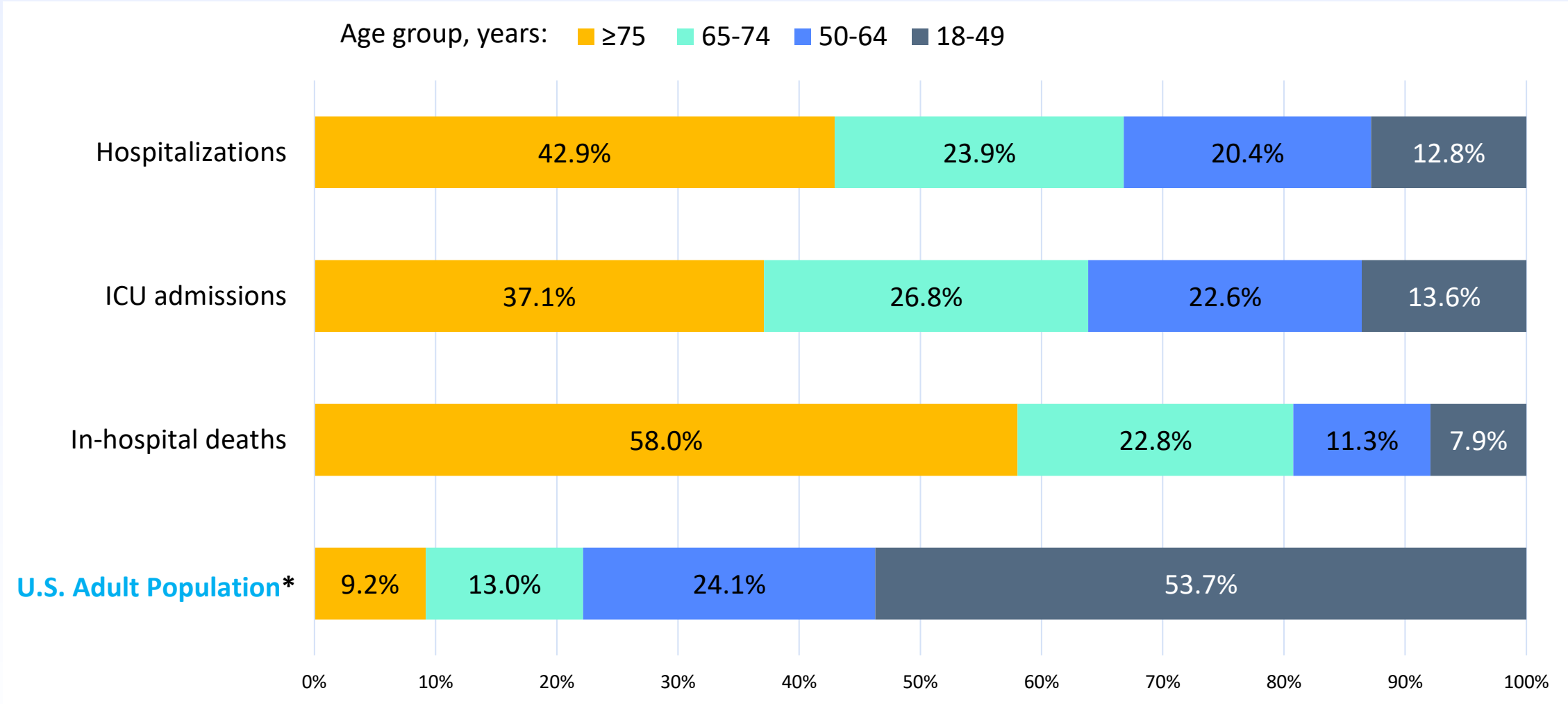
Slide credit: https://stacks.cdc.gov/view/cdc/108883

Overview of comparisons

- **Estimated benefits**
  - Estimated numbers of preventable RSV illnesses over *two consecutive seasons*, **per 1 million vaccine doses administered to adults 60 years and older**[1]
    - Outpatient visits, hospitalizations, intensive care unit (ICU) admissions, in-hospital deaths
  - Informed by published incidence rates, RSV surveillance data from CDC, and estimated vaccine efficacy from clinical trials
- **Potential risk**
  - Informed by rate of GBS **per 1 million vaccine doses administered to adults 60 years and older**[1] observed in FDA analysis of data from the FDA-CMS partnership[2]
  - Preliminary data did not permit estimation of attributable (i.e., excess) risk, so observed rates are also compared with rates expected from background

1. This analysis assumes 100% uptake of RSV vaccine, with a single dose, in a cohort of 1 million older adults.
2. Analysis of administrative claims data using a 42-day risk interval, adjusted for delays in claims data. https://bestinitiative.org/wp-content/uploads/2024/01/BEST_RSV_Safety_Older_Adults_2023-2024.pdf

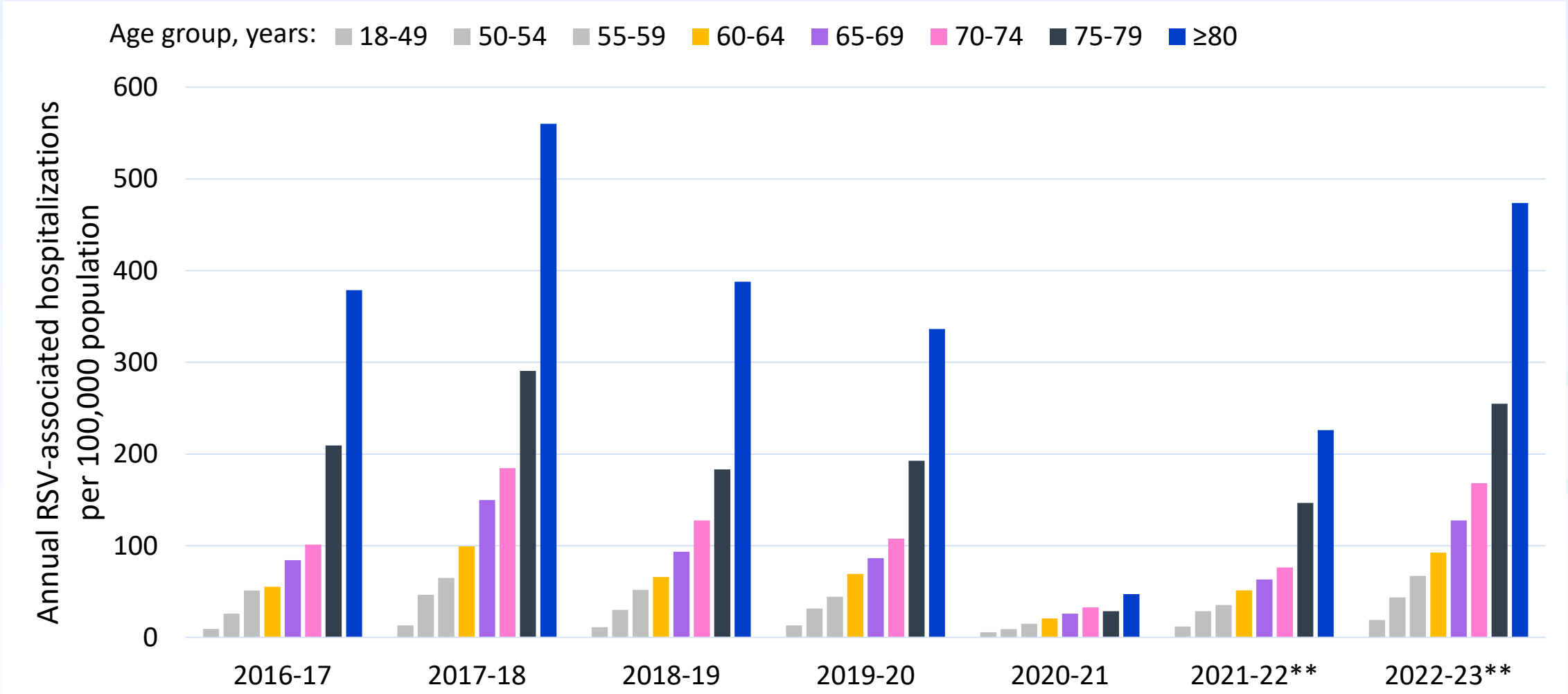
Estimated age distribution of national RSV-associated hospitalizations, ICU admissions, and in-hospital deaths among adults ≥18 years, RSV-NET, 2022–2023, compared with U.S. population



Unpublished data. Underlying rates are adjusted using multipliers for the frequency of RSV testing during each season and for the sensitivity of RSV diagnostic tests. Estimates from 2022-2023 are preliminary. These estimates use the same multipliers as for 2019-2020.

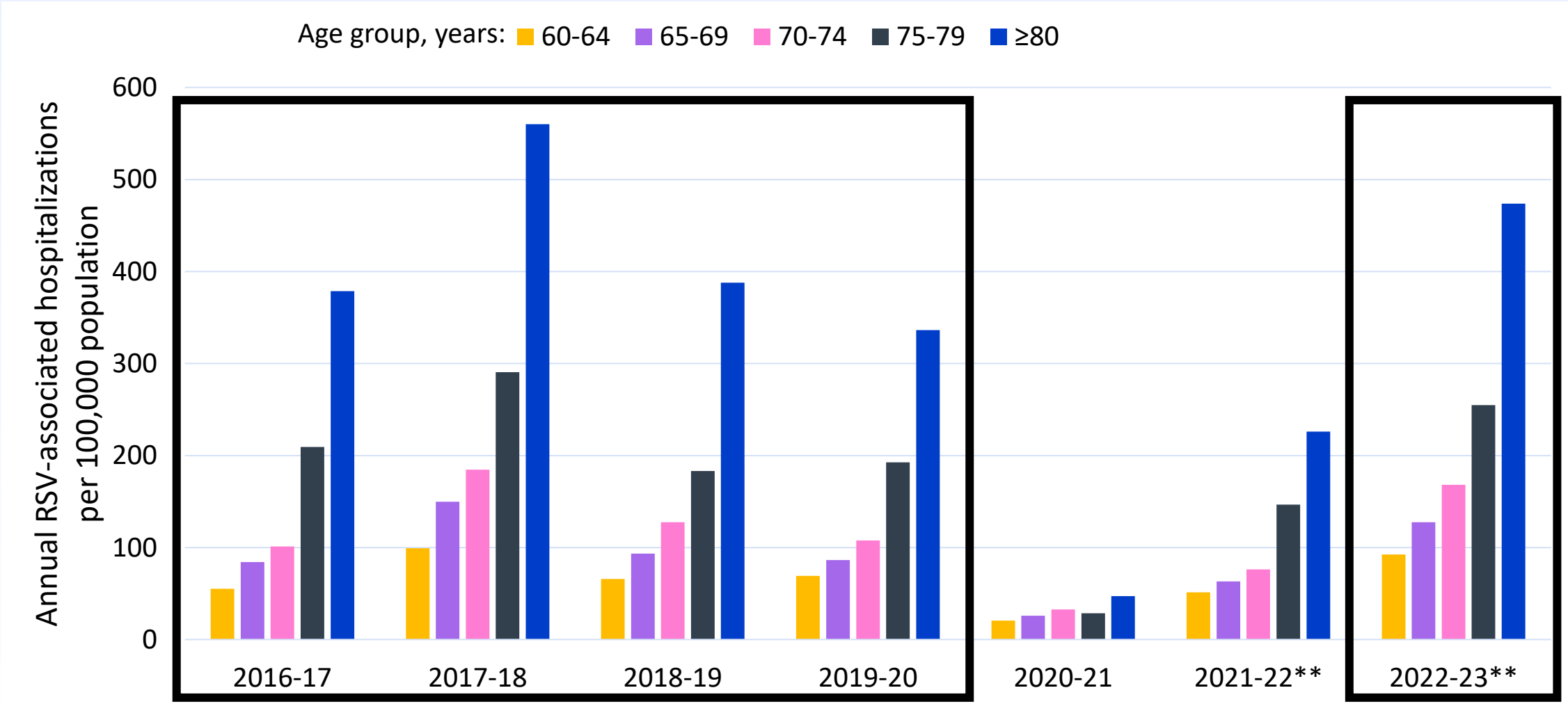
*As of 2022. https://www.census.gov/popclock/

Estimated annual RSV-associated **hospitalization** rates per 100,000 adults* aged **≥18 years** by age group and year, RSV-NET, 2016–17 to 2022–23



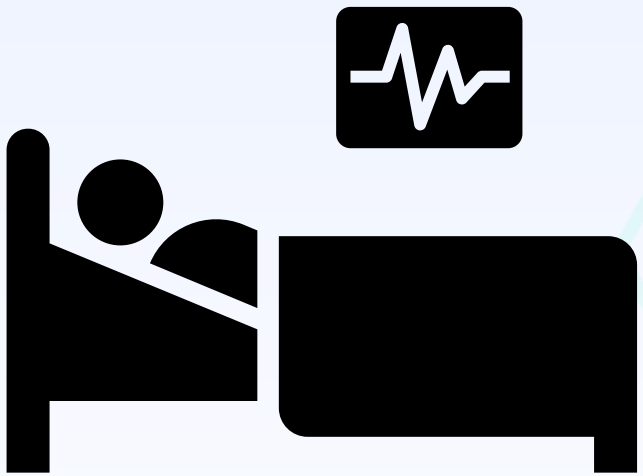
Unpublished data. Rates are adjusted using multipliers for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.
*Estimated rates exclude recorded hospitalizations among pregnant adults.
**Estimates from 2021-2022 and 2022-2023 are preliminary. These estimates use the same multipliers as for 2019-2020.
https://www.cdc.gov/rsv/research/rsv-net/index.html

***Inputs*: Estimated annual RSV-associated hospitalization rates per 100,000 adults* aged ≥60 years by age group and year, RSV-NET, 2016–17 to 2022–23**



Unpublished data. Rates are adjusted using multipliers for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.
*Estimated rates exclude recorded hospitalizations among pregnant adults.
**Estimates from 2021-2022 and 2022-2023 are preliminary. These estimates use the same multipliers as for 2019-2020.
https://www.cdc.gov/rsv/research/rsv-net/index.html

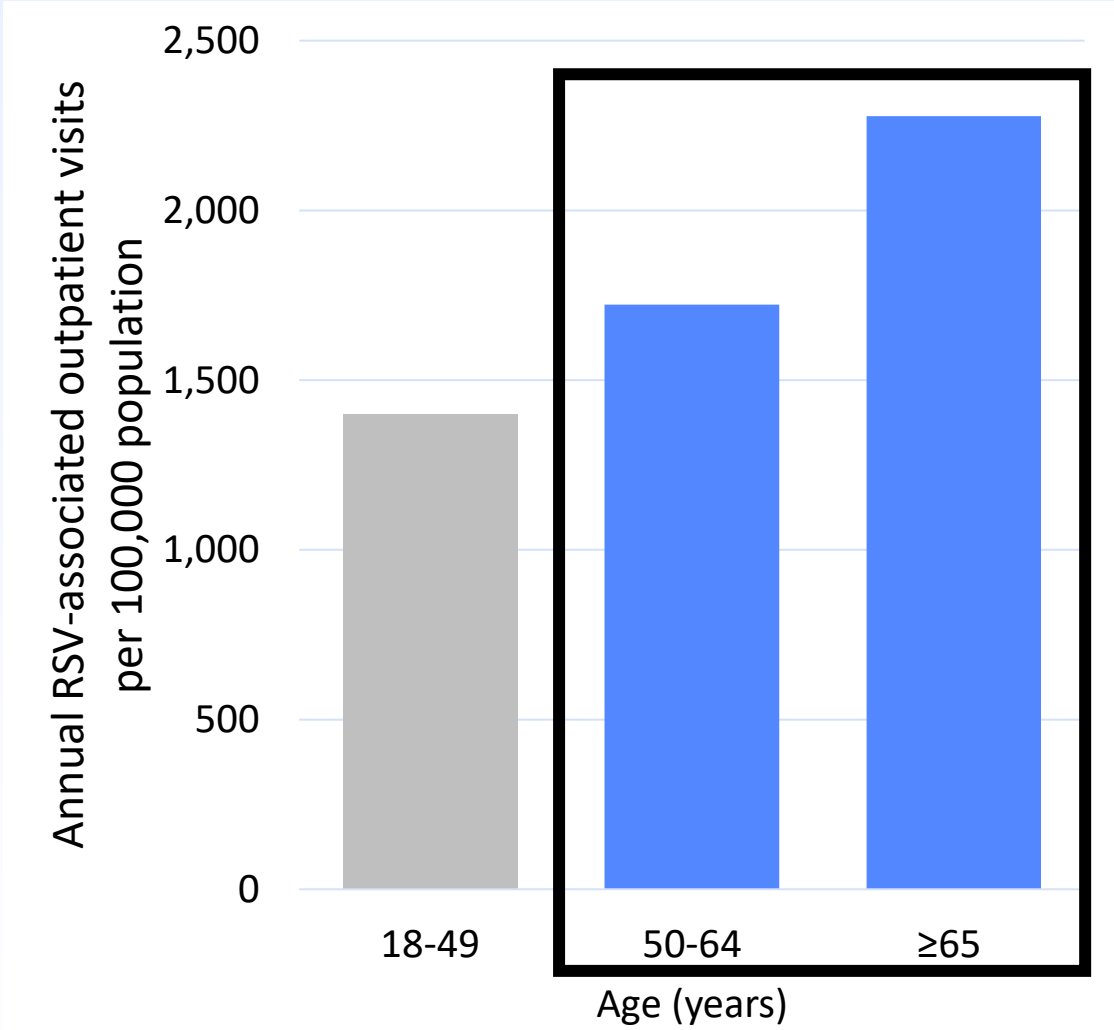
***Inputs*: Estimated annual rates of RSV-associated ICU admission and in-hospital death per 100,000 adults aged ≥60 years (RSV-NET)**



- Over the same surveillance seasons (2016-17 to 2019-20, and 2022-23):
  - Calculated the proportions of hospitalized adults in each age group who
    - Were admitted to ICU
    - Experienced in-hospital death
  - Applied these proportions to the estimated hospitalization rates*
  - Estimated population-based rates of ICU admission and in-hospital death

*Unpublished data. Rates are adjusted using multipliers for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.
Estimated rates exclude recorded hospitalizations among pregnant adults.
Estimates from 2022-2023 are preliminary. These estimates use the same multipliers as for 2019-2020.
https://www.cdc.gov/rsv/research/rsv-net/index.html

***Inputs*: Estimated annual rates of RSV-associated **outpatient visits** per 100,000 adults aged ≥18 years, meta-analysis of active surveillance studies, United States**



Industry-sponsored (Pfizer): McLaughlin JM, Khan F, Begier E, et al. Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis. Open forum infectious diseases 2022 Jul; 9(7):ofac300. https://doi.org/10.1093/ofid/ofac300

Inputs: Summary of annual rates of RSV-associated illness

Outcome	Values
Outpatient visits	Published incidence rates and 95% confidence intervals.[1]
Hospitalizations	RSV-NET[2]; age-dependent rates and 95% confidence intervals are based on laboratory-confirmed RSV infections among hospitalized adults detected through clinician-driven testing, and are adjusted for the frequency of RSV testing among adults hospitalized with respiratory illness and for the sensitivity of diagnostic tests (burden adjustment).[3] Assumed test sensitivity incorporates recent literature showing increased diagnostic yield from multiple specimen types, relative to nucleic acid testing of nasopharyngeal swab alone.[4] Input values are taken as the mean burden-adjusted rates over five RSV seasons (2016-17 to 2019-20, and 2022-23).
ICU admissions	Mean age-dependent rates and 95% confidence intervals of RSV-associated ICU admission from RSV-NET over five seasons[2]
Deaths (in-hospital only)	Mean age-dependent rates and 95% confidence intervals of RSV-associated in-hospital deaths from RSV-NET over five seasons[2]

1. Industry-sponsored (Pfizer): McLaughlin JM, Khan F, Begier E, et al. Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis. Open forum infectious diseases 2022 Jul; 9(7):ofac300. https://doi.org/10.1093/ofid/ofac300
2. CDC RSV-NET data from surveillance seasons: 2016-17 to 2019-20 and 2022-23. Values are based upon the average burden-adjusted rates and 95% confidence intervals over those five seasons. Unpublished data. https://www.cdc.gov/rsv/research/rsv-net/index.html
3. Kujawski SA, Whitaker M, Ritchey MD, et al. Rates of respiratory syncytial virus (RSV)-associated hospitalization among adults with congestive heart failure-United States, 2015-2017. PLoS One. 2022 Mar 9;17(3):e0264890. https://doi.org/10.1371/journal.pone.0264890
4. Industry-sponsored (Pfizer): Onwuchekwa C, Moreo LM, Menon S, et al. Underascertainment of Respiratory Syncytial Virus Infection in Adults Due to Diagnostic Testing Limitations: A Systematic Literature Review and Meta-analysis. The Journal of Infectious Diseases. 2023 July; 228(2): 173–184. https://doi.org/10.1093/infdis/jiad012

Inputs: Vaccine Efficacy (VE)

Outcome (RSV-Associated)	Arexvy, GSK[1] VE (95% CI)		Abrysvo, Pfizer[2] VE (95% CI)	
	Season 1 (months 0-7 post-injection)	Season 2 (months 13-18 post-injection)[3]	Season 1 (months 0-7 post-injection)	Season 2 (months 8-14 post-injection)[3]
Outpatient visits[4] *Trial efficacy against medically-attended RSV ARI*	**79.0%** (54.3, 91.5)	**27.8%** (0, 60.4)	**65.2%** (36.0, 82.0)	**55.0%** (0, 82.0)
Hospitalizations, ICU Admissions, and In-hospital Deaths *Trial efficacy against medically-attended RSV LRTD/LRTI*	**87.5%** (58.9, 97.6)[5]	**52.9%** (0, 81.2)[5]	**84.6%** (32.0, 98.3)[6]	**75.0%** (0, 97.4)[6]

Point estimates were used in this analysis. Uncertainty in vaccine efficacy was not incorporated into uncertainty in estimated preventable outcomes.

Ref (Slide 18): https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/05-RSV-Adults-Ortega-Sanchez-508.pdf

[1] GSK Phase 3 Trial; interim analysis 2023; CDC-calculated vaccine efficacy in participants ages ≥60 years

[2] Pfizer Phase 3 Trial; interim analysis 2023; CDC-calculated vaccine efficacy in participants ages ≥60 years

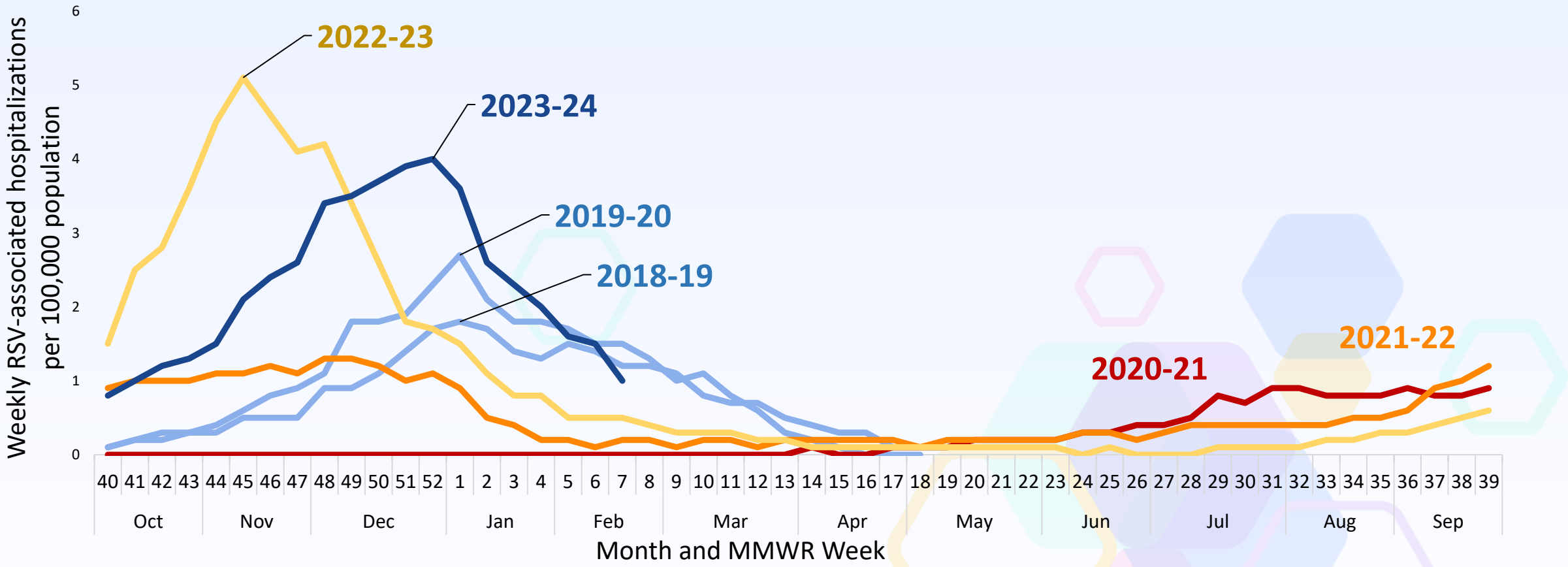
[3] Efficacy estimates are not directly comparable. Clinical trials used different outcome definitions and the follow up time in differed substantially across trials. Further, efficacy estimates are associated with substantial uncertainty.

[4] CDC-calculated VE against medically-attended RSV acute respiratory illness (ARI)

[5] CDC-calculated VE against medically-attended RSV lower respiratory tract disease (LRTD)

[6] CDC-calculated VE against medically-attended RSV lower respiratory tract illness (LRTI) with at least 3 lower respiratory symptoms

Weekly rates of RSV-associated hospitalization,* all ages, RSV-NET, October 2018–February 2024



*RSV-NET hospitalization data are preliminary and subject to change as more data becomes available.

Rates have not been adjusted for testing practices and underestimate actual rates of RSV-associated hospitalizations, as not all people hospitalized with respiratory illness are tested for RSV. In addition, clinician-directed RSV testing practices may have changed over time and may differ by disease severity, age, and/or racial and ethnic group of patients; trends in RSV-associated hospitalization rates across seasons should be interpreted with caution.

For more information on RSV-NET, please visit https://www.cdc.gov/rsv/research/rsv-net/index.html.

Inputs: Vaccine Efficacy (VE), *sensitivity analysis*

*Assumed VE among adults aged ≥75 years is reduced by **half**, compared with adults aged 60–74 years*

- Clinical trials of both vaccines under-enrolled adults 75 years and older and were under-powered to estimate vaccine efficacy in this age subgroup.
- Aging results in lowered immune responsiveness characterized by impairments in both innate and adaptive immunity (immune senescence).*
- Adults 75 years and older might experience reduced VE against all outcomes, compared with adults ages 60–74 years.
- There are no data yet available from post-licensure observational effectiveness studies to estimate protection among adults aged ≥75 years.

*Stephens LM, Varga SM. Considerations for a Respiratory Syncytial Virus Vaccine Targeting an Elderly Population. Vaccines (Basel). 2021 Jun 9;9(6):624. https://doi.org/10.3390/vaccines9060624

Inputs: Vaccine Efficacy (VE), *sensitivity analysis*

Outcome (RSV-Associated)	Arexvy, GSK[1] VE (95% CI)		Abrysvo, Pfizer[2] VE (95% CI)	
	Season 1 (months 0-7 post-injection)	Season 2 (months 13-18 post-injection)[3]	Season 1 (months 0-7 post-injection)	Season 2 (months 8-14 post-injection)[3]
Outpatient visits[3] *Trial efficacy against medically-attended RSV ARI*	Ages 60–74 yrs: **79.0%** Ages ≥75 yrs: **39.5%**	Ages 60–74 yrs: **27.8%** Ages ≥75 yrs: **13.9%**	Ages 60–74 yrs: **65.2%** Ages ≥75 yrs: **32.6%**	Ages 60–74 yrs: **55.0%** Ages ≥75 yrs: **27.5%**
Hospitalizations, ICU Admissions, and In-hospital Deaths *Trial efficacy against medically-attended RSV LRTD/LRTI*	Ages 60–74 yrs: **87.5%**[4] Ages ≥75 yrs: **43.8%**	Ages 60–74 yrs: **52.9%**[4] Ages ≥75 yrs: **26.5%**	Ages 60–74 yrs: **84.6%**[5] Ages ≥75 yrs: **42.3%**	Ages 60–74 yrs: **75.0%**[5] Ages ≥75 yrs: **37.5%**

Point estimates were used in this analysis. Uncertainty in vaccine efficacy was not incorporated into uncertainty in estimated preventable outcomes.

Ref (Slide 18): https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/05-RSV-Adults-Ortega-Sanchez-508.pdf

[1] GSK Phase 3 Trial; interim analysis 2023; CDC-calculated vaccine efficacy in participants ages ≥60 years

[2] Pfizer Phase 3 Trial; interim analysis 2023; CDC-calculated vaccine efficacy in participants ages ≥60 years

[3] Efficacy estimates are not directly comparable. Clinical trials used different outcome definitions and the follow up time in differed substantially across trials. Further, efficacy estimates are associated with substantial uncertainty.

[4] CDC-calculated VE against medically-attended RSV acute respiratory illness (ARI)

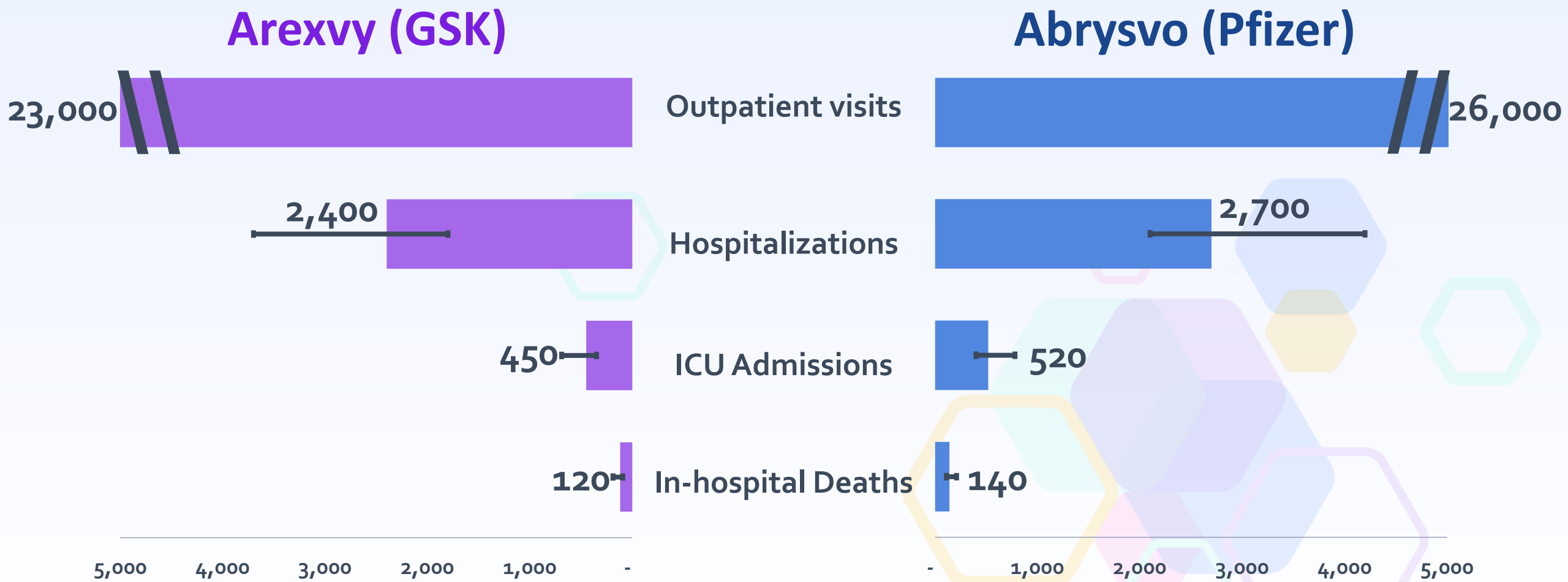
[5] CDC-calculated VE against medically-attended RSV lower respiratory tract disease (LRTD)

[6] CDC-calculated VE against medically-attended RSV lower respiratory tract illness (LRTI) with at least 3 lower respiratory symptoms

Results: Estimated Benefits

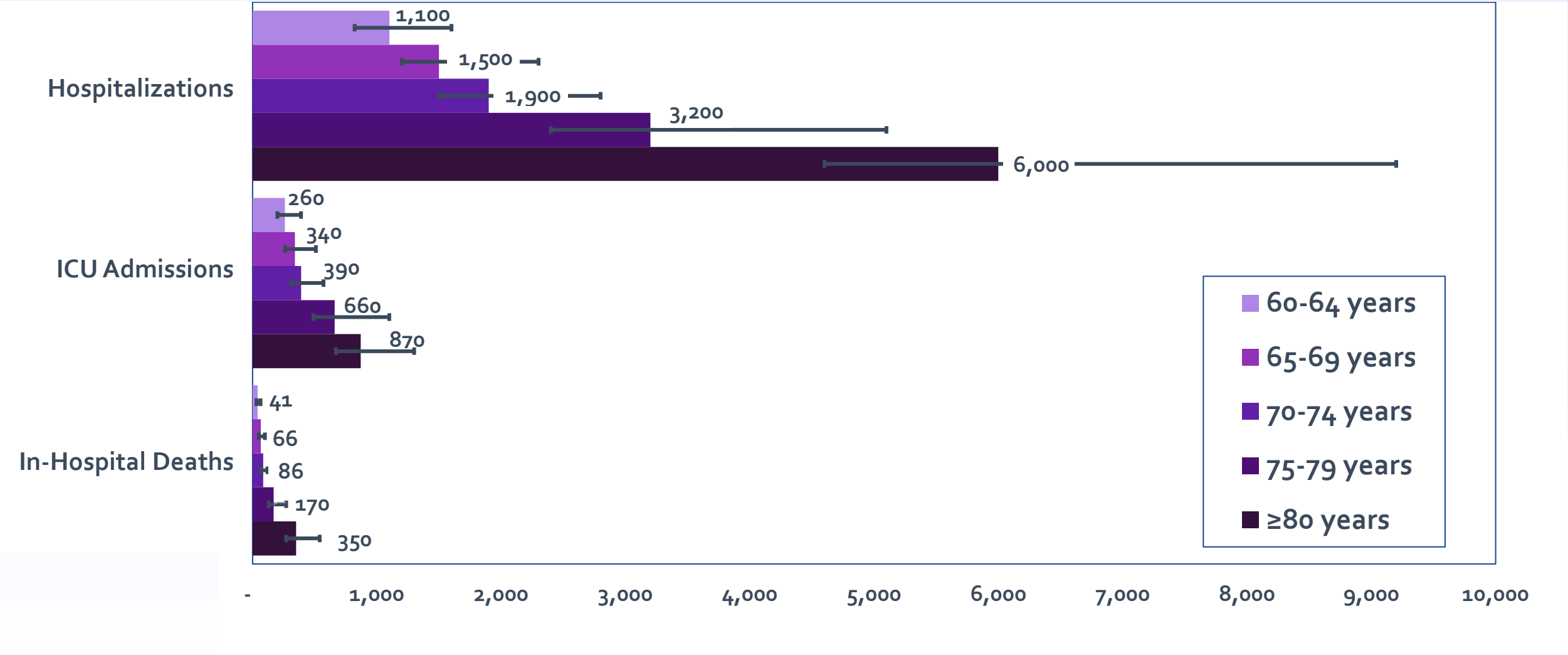
Per 1 million vaccine doses administered

Estimated RSV-Associated Outcomes* Preventable over 2 RSV Seasons per 1 Million Vaccine Doses Administered to Adults Aged ≥60 Years



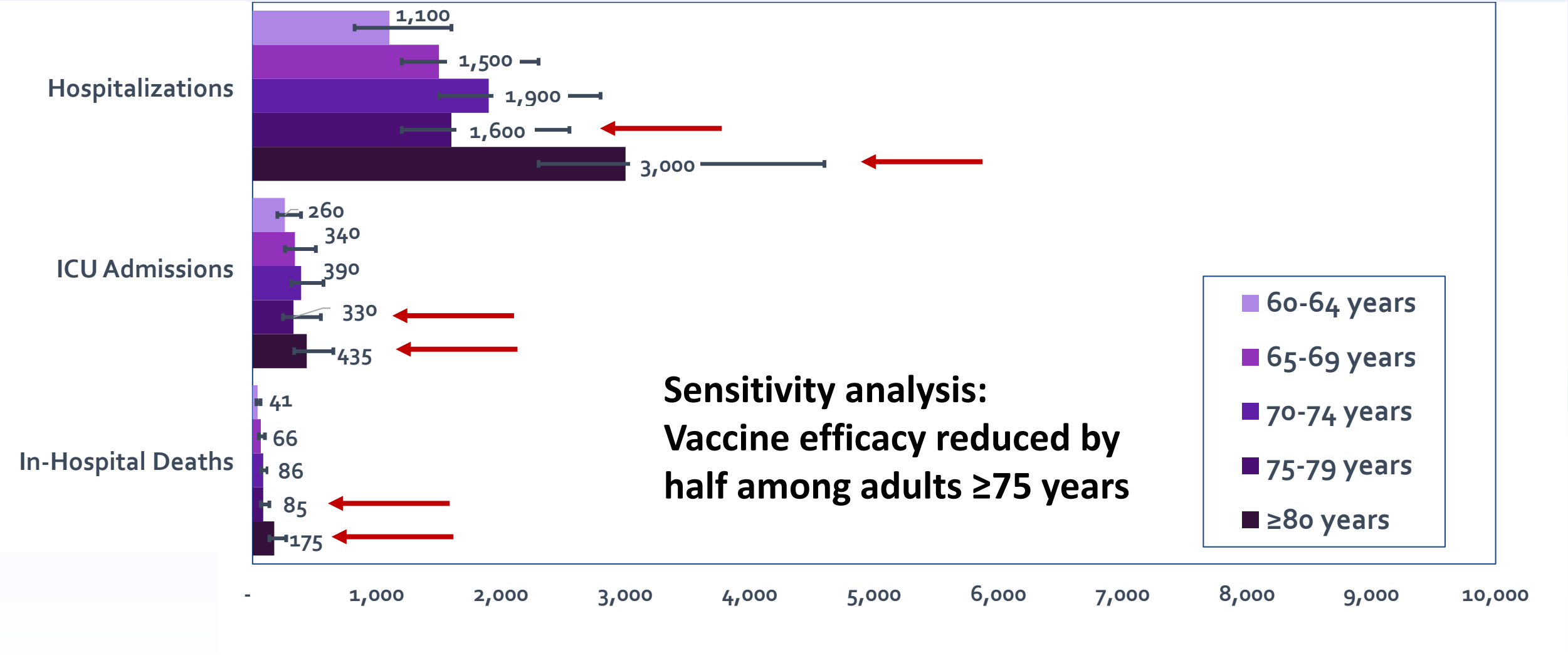
*Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Estimated RSV-Associated Outcomes* Preventable over 2 RSV Seasons per 1 Million Vaccine Doses Administered, Arexvy (GSK)



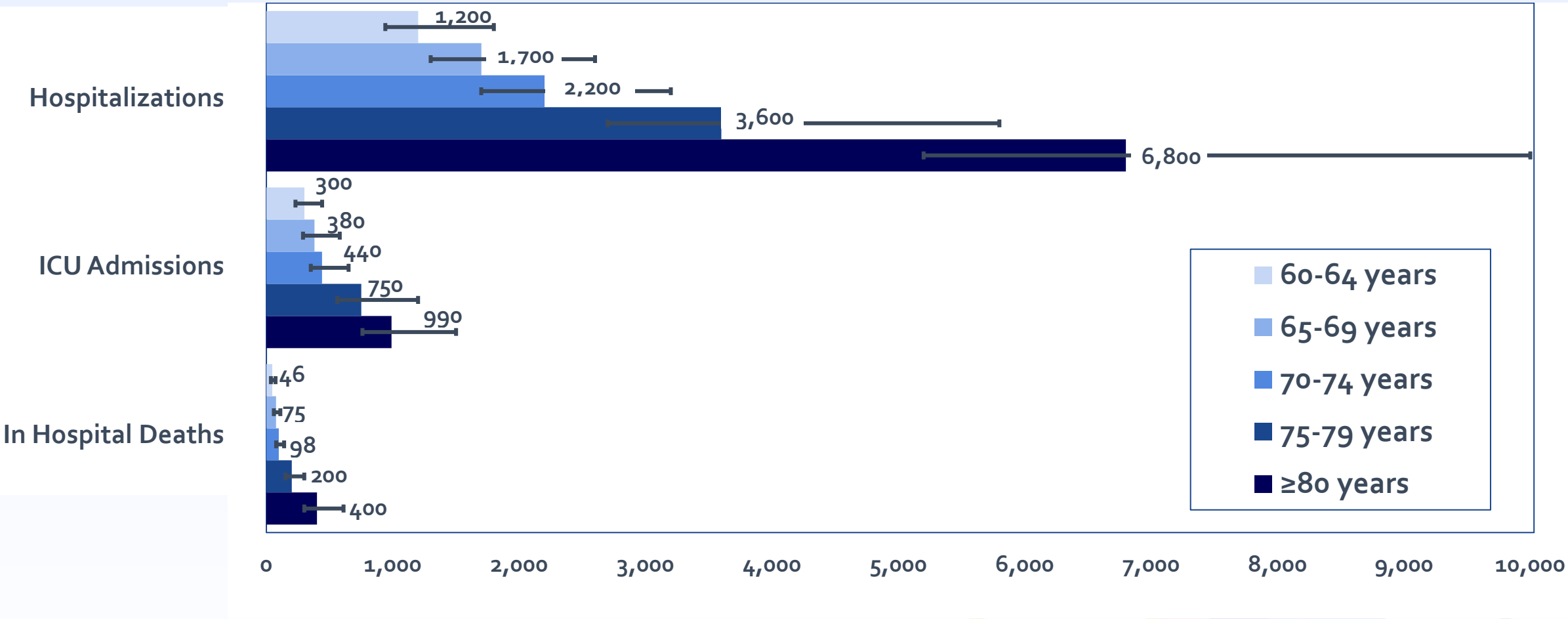
*Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Estimated RSV-Associated Outcomes* Preventable over 2 RSV Seasons per 1 Million Vaccine Doses Administered, Arexvy (GSK)



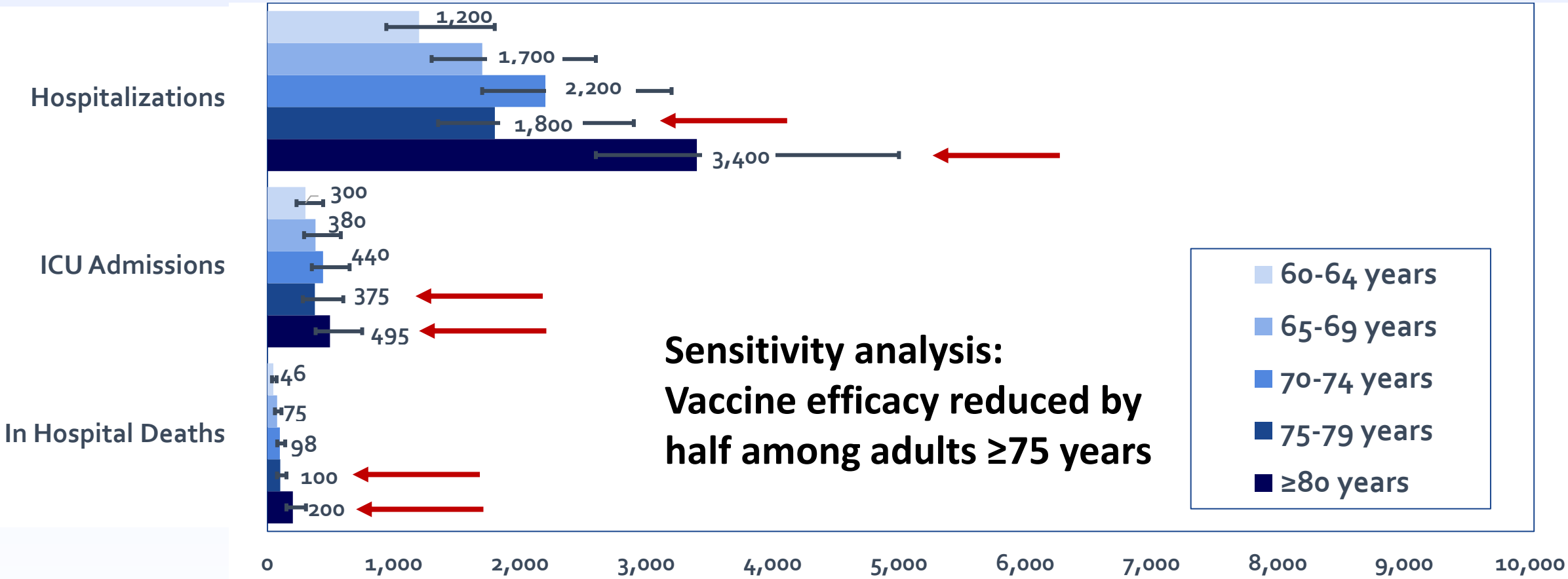
*Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Estimated RSV-Associated Outcomes* Preventable over 2 RSV Seasons per 1 Million Vaccine Doses Administered, Abrysvo (Pfizer)



*Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Estimated RSV-Associated Outcomes* Preventable over 2 RSV Seasons per 1 Million Vaccine Doses Administered, Abrysvo (Pfizer)



*Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Summary:

Estimated preventable RSV-associated outcomes varies by age and incidence of the outcome

- Estimated number of outcomes preventable over **2 RSV seasons** **per 1 million doses administered** were similar between vaccine products:

Arexvy (GSK)		Abrysvo (Pfizer)
23,000 (17,000–28,000)	**Outpatient visits**	26,000 (19,000–32,000)
2,400 (1,800–3,700)	**Hospitalizations**	2,700 (2,100–4,200)
450 (350–690)	**ICU admissions**	520 (400–780)
120 (94–190)	**In-hospital deaths**	140 (110–210)

Ranges of preventable outcomes were calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET. Uncertainty in vaccine efficacy was not incorporated into ranges of preventable outcomes.

Potential Risk of Guillain-Barre syndrome (GBS)

Per 1 million vaccine doses administered

FDA active surveillance through partnership with CMS, Medicare beneficiaries ages ≥65 years[1], May–December 2023

- Claims-based ascertainment of GBS events using administrative data
  - GBS cases observed after RSV vaccination during a **42-day risk interval**[2], adjusted for delays in claims data
  - Adjustment for positive-predictive value of diagnostic codes in identifying chart-confirmed GBS
- **GSK Arexvy**: **10 GBS cases (95% CI 2–18) per 1 million doses administered**
- **Pfizer Abrysvo**: **25 GBS cases (95% CI 7–43) per 1 million doses administered**
- Expected cases based on historical GBS background rate from 2022:
  - **5 GBS cases per 1 million doses administered**[3]
  - Historical background rate may not be applicable to persons electing to receive RSV vaccination using shared clinical decision-making. On average, recipients of each of the two vaccines may be at different baseline risk of GBS. More robust analysis, such as a self-controlled case series, is needed to confirm and quantify a risk of Guillain-Barre syndrome after RSV vaccination.

Abbreviations: CI = confidence interval, CMS = Centers for Medicare & Medicaid Services, FDA = U.S. Food and Drug Administration, GBS = Guillain-Barre syndrome

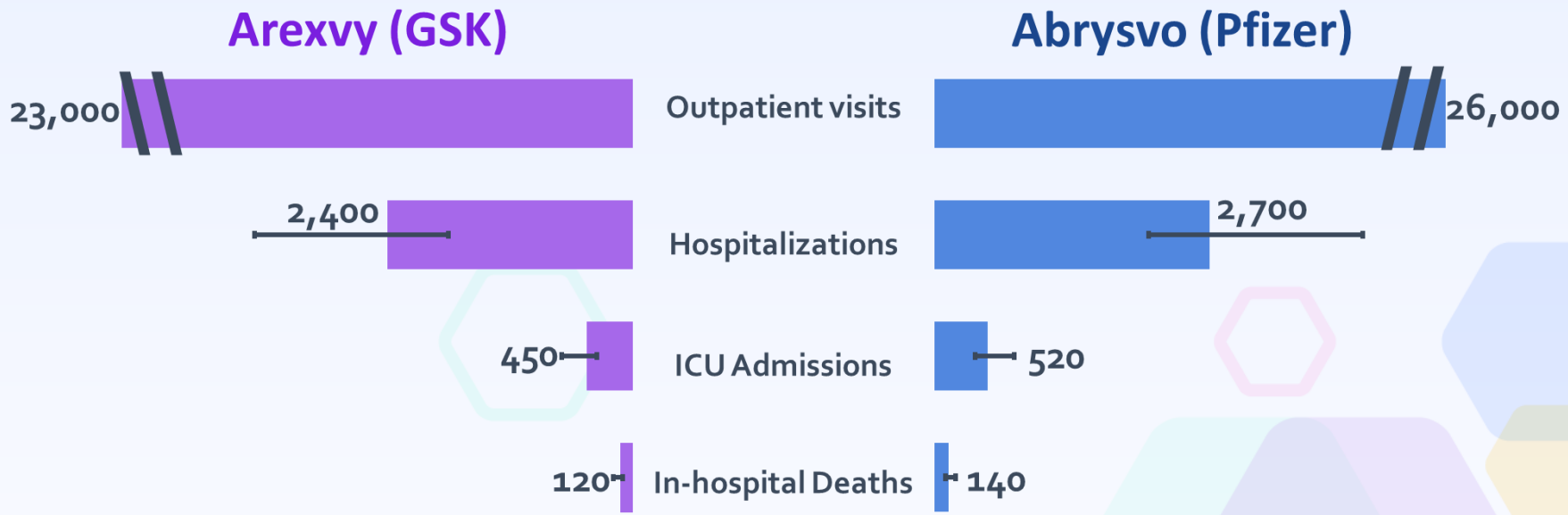
1. Must have been enrolled in Medicare Parts A, B and D. Must not have had a diagnostic code for GBS in the 365 days preceding vaccination.
2. Due to delays in claims data, not all participants have accrued 42 days of effective follow up time. GBS observation rates per 1 million doses over a **21-day risk interval** were also calculated (**GSK Arexvy: 5 cases [95% CI 1–9], Pfizer Abrysvo: 13 cases [95% CI 3–22]**).
3. The lower and upper bounds of the 95% confidence interval for the expected cases both round to 5. With additional precision: 5.06 expected GBS cases (95% CI 4.76 – 5.38) per 1 million doses administered to adults ages 65 years and older.

Estimated Benefits and Potential Risk

Per 1 million vaccine doses administered

Estimated RSV-Associated Outcomes[1] Preventable over 2 RSV Seasons vs. potential cases of GBS (*positive predictive value-adjusted* rate of GBS claims in FDA-CMS partnership data, 42-day risk interval[2])

Per 1 Million Vaccine Doses Administered to Adults Aged ≥60 Years:



10 (95% CI **2–18**) **cases of GBS**

25 (95% CI **7–43**) **cases of GBS**

By comparison, **5** GBS cases would be expected from background over the 42-day risk interval[3].

Historical background rate may not apply to adults electing to receive RSV vaccination using shared clinical decision-making. On average, recipients of each of the two vaccines may be at different baseline risk of GBS. More robust analysis, such as a self-controlled case series, is needed to confirm and quantify a risk of GBS.

1. Range of outcomes avertable was calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET
2. Includes GBS cases in a 42-day risk interval post-RSV-vaccination, adjusted for claims delay, among beneficiaries ≥65 with Parts A, B, and D coverage who did not have a GBS claim in the 365 days before vaccination. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.
3. Background GBS rate (4.4 cases per 100,000 person-years) from 2022 CMS data among Medicare beneficiaries 65 years and older with Parts A, B, and D coverage and without a GBS claim in the 365 days before January 1, 2022. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.

Estimated RSV-Associated Outcomes[1] Preventable over 2 RSV Seasons vs. potential cases of GBS (*positive predictive value-adjusted* rate of GBS claims in FDA-CMS partnership data, 42-day risk interval[2])

Per 1 Million GSK Arexvy Doses Administered to Older Adults:

	60–64 yrs	65–69 yrs	70–74 yrs	75–79 yrs	≥80 yrs
Hospitalizations preventable	1,100	1,500	1,900	3,200	6,000
ICU admissions preventable	260	340	390	660	870
In-hospital deaths preventable	41	66	86	170	350

10 (95% CI **2–18**) **cases of Guillain-Barre syndrome**

By comparison, **5** GBS cases would be expected from background over the 42-day risk interval[3].

Historical background rate may not apply to adults electing to receive RSV vaccination using shared clinical decision-making. On average, recipients of each of the two vaccines may be at different baseline risk of GBS. More robust analysis, such as a self-controlled case series, is needed to confirm and quantify a risk of GBS.

1. Range of outcomes avertable was calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET
2. Includes GBS cases in a 42-day risk interval post-RSV-vaccination, adjusted for claims delay, among beneficiaries ≥65 with Parts A, B, and D coverage who did not have a GBS claim in the 365 days before vaccination. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.
3. Background GBS rate (4.4 cases per 100,000 person-years) from 2022 CMS data among Medicare beneficiaries 65 years and older with Parts A, B, and D coverage and without a GBS claim in the 365 days before January 1, 2022. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.

Estimated RSV-Associated Outcomes[1] Preventable over 2 RSV Seasons vs. potential cases of GBS (*positive predictive value-adjusted* rate of GBS claims in FDA-CMS partnership data, 42-day risk interval[2])

Per 1 Million Pfizer Abrysvo Doses Administered to Older Adults:

	60–64 yrs	65–69 yrs	70–74 yrs	75–79 yrs	≥80 yrs
Hospitalizations preventable	1,200	1,700	2,200	3,600	6,800
ICU admissions preventable	300	380	440	750	990
In-hospital deaths preventable	46	75	98	200	400

25 (95% CI **7–43**) **cases of Guillain-Barre syndrome**

By comparison, **5** GBS cases would be expected from background over the 42-day risk interval[3].

Historical background rate may not apply to adults electing to receive RSV vaccination using shared clinical decision-making. On average, recipients of each of the two vaccines may be at different baseline risk of GBS. More robust analysis, such as a self-controlled case series, is needed to confirm and quantify a risk of GBS.

1. Range of outcomes avertable was calculated using published 95% confidence intervals (outpatient only) and adjusted 95% confidence interval of RSV-associated incidence of the outcome observed in RSV-NET
2. Includes GBS cases in a 42-day risk interval post-RSV-vaccination, adjusted for claims delay, among beneficiaries ≥65 with Parts A, B, and D coverage who did not have a GBS claim in the 365 days before vaccination. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.
3. Background GBS rate (4.4 cases per 100,000 person-years) from 2022 CMS data among Medicare beneficiaries 65 years and older with Parts A, B, and D coverage and without a GBS claim in the 365 days before January 1, 2022. Rates of GBS identified by inpatient claims data are decreased by 29% to account for the positive predictive value of diagnostic codes in identifying chart-confirmed GBS cases.

Limitations (estimation of benefits)

- We assumed optimal timing of vaccination immediately before onset of RSV season.
- We assumed that the real-world vaccine effectiveness is equal to point estimate of vaccine efficacy observed in the phase 3 clinical trials.
  - Assumed vaccine effectiveness against hospitalization was equal to vaccine efficacy against medically attended RSV-associated lower respiratory tract disease from clinical trials
  - Did not incorporate uncertainty in trial efficacy estimates. However, in preliminary analyses, uncertainty in RSV incidence resulted in wider ranges of preventable outcomes than uncertainty in efficacy.
- Clinical trials were performed largely in community dwelling older adults and may not be generalizable to all adults 60+ in the U.S.
- RSV-NET represents ~9% of the United States and hospitalization rates observed in RSV-NET may not be generalizable to the U.S.

- Benefits of a single dose of RSV vaccination may continue to accrue beyond 2 years.
- RSV-NET does not currently estimate out-of-hospital deaths, resulting in an under-estimate of potentially vaccine-preventable deaths.
- Benefits may be greater for subgroups of adults at increased risk of severe RSV illness.

Limitations (estimation of risk)

- GBS rates were calculated using a small number of events observed after RSV vaccination, resulting in high uncertainty.
- A background rate of GBS was not subtracted from the observed rate.
  - The historical background rate from CMS used as a comparator may not apply to adults receiving RSV vaccination using shared clinical decision-making; subject to confounding and bias.
- Older adults receiving each of the two vaccine products may have different prevalence of chronic medical conditions or other risk factors and may therefore have different baseline risk of GBS.
- GBS was identified by diagnostic codes in administrative data and may be subject to coding errors.
- Not all cases of GBS occurring after RSV vaccination may have received a diagnostic code.

Summary

- From a population perspective, the estimated benefits of RSV vaccination outweigh the potential risk of GBS in adults 60 years and older.
- Estimated benefits of RSV vaccination vary by age group and RSV incidence.
- Estimated benefits likely also vary by individual-level risk of severe RSV disease and by timing of vaccination relative to the RSV season.
- There is substantial uncertainty in estimates of both benefit and risk.
- The benefit and risk assessment will be updated as additional data become available:
  - Results from additional vaccine safety studies
  - Additional efficacy follow-up time from clinical trials
  - Vaccine effectiveness from post-licensure observational studies, including effectiveness against more severe clinical outcomes
  - RSV disease burden among subgroups of older adults at increased risk of severe RSV disease

Acknowledgements

- Lauren Roper
- Amadea Britton
- Dani Moulia
- Megan Wallace
- Katherine Fleming-Dutra
- Fiona Havers
- Michael Whitaker
- John Su
- Karen Broder
- Eric Weintraub
- David Shay
- Anne Hause
- Pedro Moro
- Tom Shimabukuro
- Patricia Lloyd
- Richard Forshee
- Steven Anderson

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.