

Advancing RSV Prevention Strategies Across the Life Span

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National Minority Quality Forum

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National Foundation for Infectious Disease



#AccessToHealthCare



sanofi

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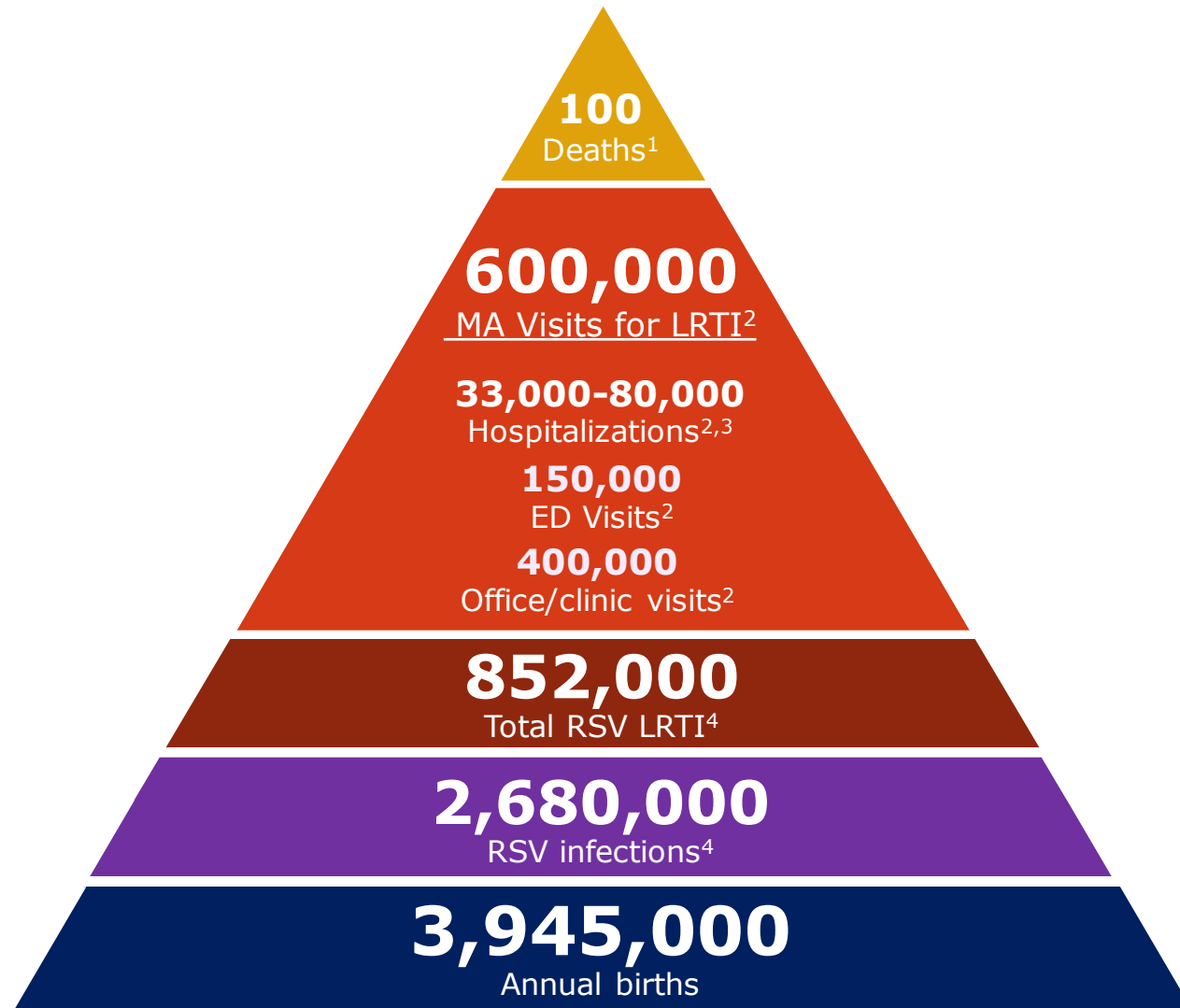
RSV prevention in infants

Policy Opportunities

Christopher Rizzo MD FAAP
Senior Medical Director

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Annual RSV Burden in US Infants <12 Months of Age^a



1 in 7

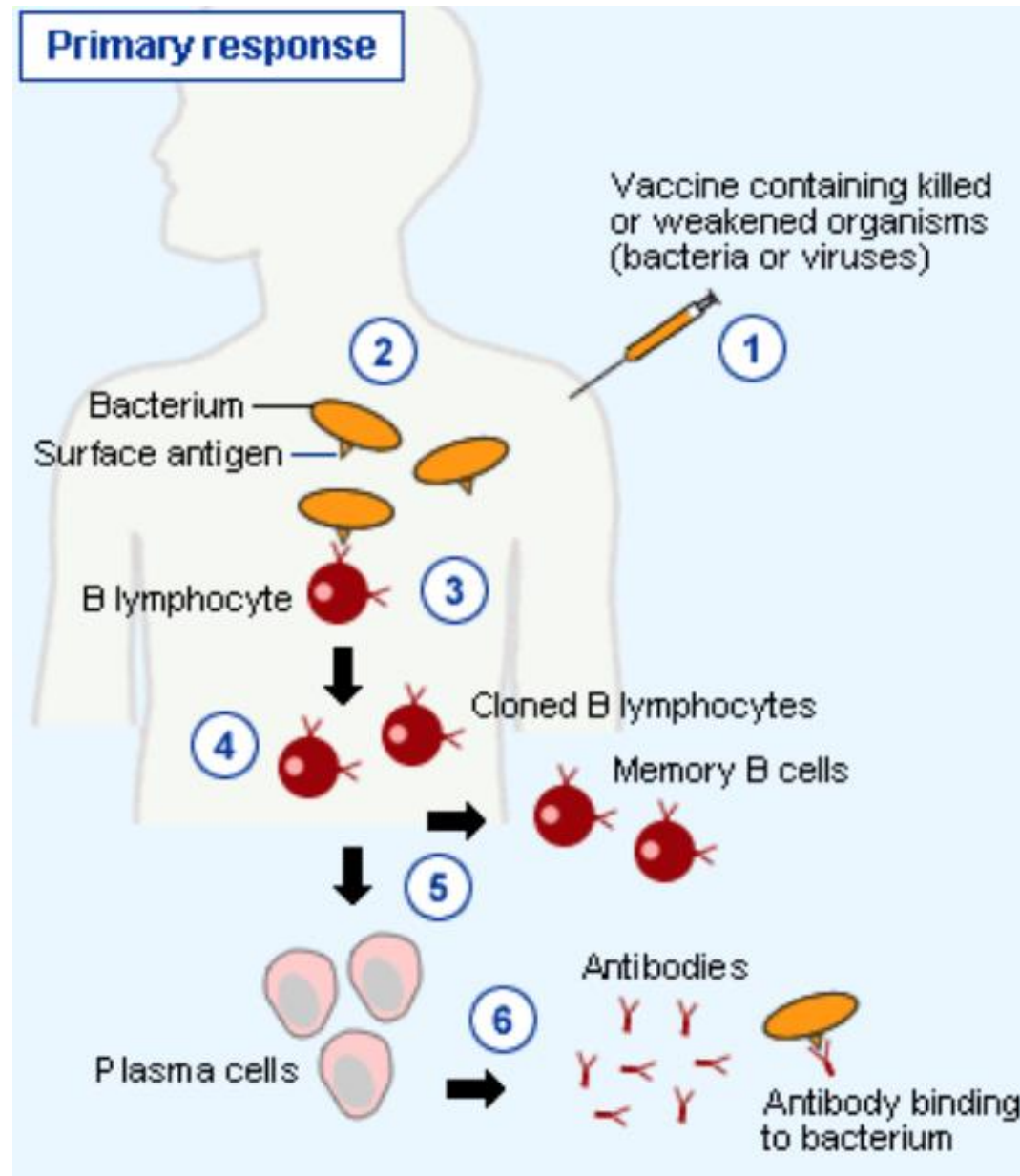
Infants develop
LRTI requiring
medical attention
annually²

^aEstimated typical RSV season based on references.¹⁻⁴

ED, emergency department; LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.

Reference: **1.** Hansen CL, et al. *JAMA Netw Open.* 2022;5(2):e220527. **2.** Rainisch G, et al. *Vaccine.* 2020;38(2):251-257. **3.** McLaughlin JM, et al. *J Infect Dis.* 2020;jiaa752. **4.** Glezen WP, et al. *Am J Dis Child.* 1986;140(6):543-546.

Vaccine vs Monoclonal Antibody (mAb)



Disproportional Impact of Severe RSV in Infants

RSV hospitalization rates

**Medicaid
Infants**

2x higher

Infants enrolled in Medicaid have relative risk for RSVH of 2.03 (1.99-2.06) compared to non-Medicaid payers.¹

**Native
American
Infants**

2.5x higher

The annual rates of RSVH in Navajo and Apache infants are almost 2.5 times more than those of healthy infants in the general US population.²

**Alaskan
Native
Infants**

5x higher

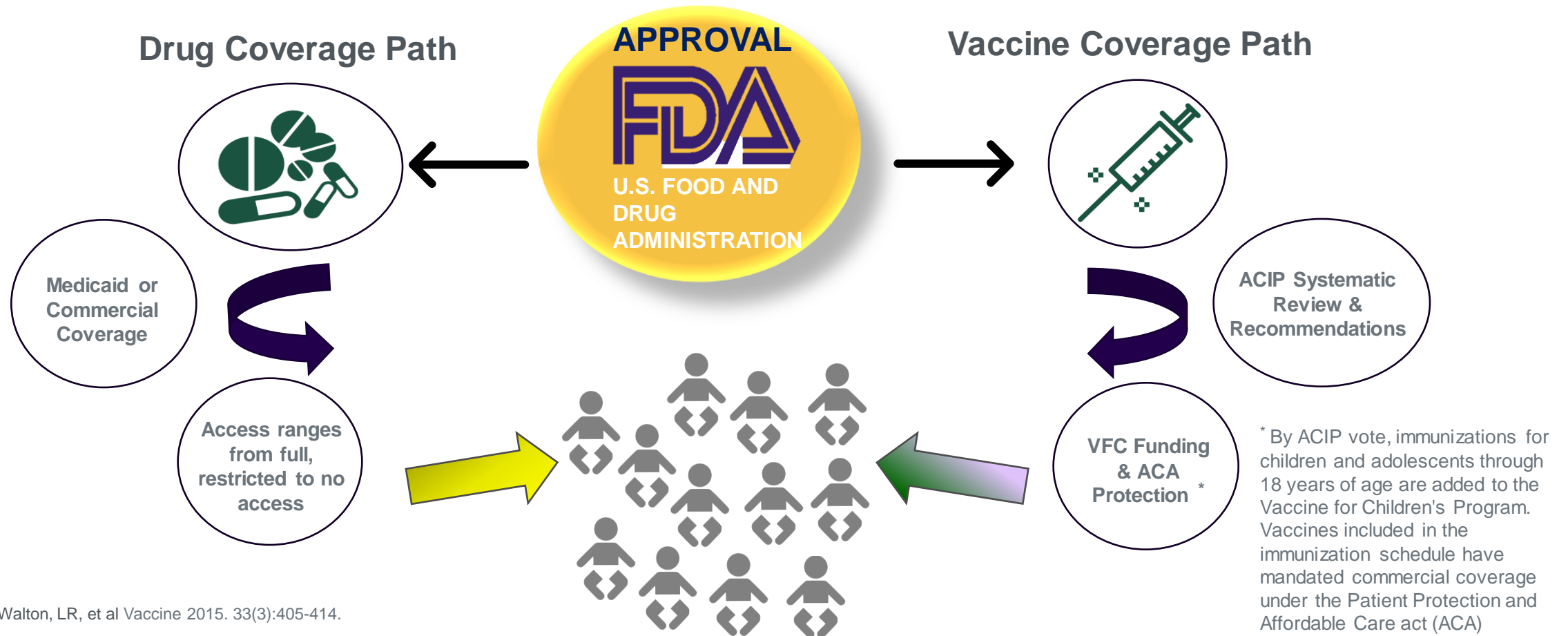
Alaska Native infants in the rural Yukon–Kuskokwim Delta region of Alaska have RSVH rates 5 times higher than the general US infant population.³

RSVH = RSV hospitalization

1. Sangare L et al. J Pediatr 2006; 149:373-377. 2. O'Brien KL et al. Lancet Infect Dis. 2015; 15(12):1398-1408. 3. Borse RH et al. J Pediatr Infect Dis Soc. 2014; 3:201-212.

Unique Access Opportunity for a mAb Used in a Vaccine-Like Manner

No known precedent of a monoclonal antibody (mAb) being used as protection for an infectious disease for the entire birth cohort



Reference: Walton, LR, et al Vaccine 2015. 33(3):405-414.

RSV Disease: Adult

Leonard Friedland, MD

Vice President, Director Scientific Affairs and Public Health

National Legislative Conference-Women in Government

June 9, 2023



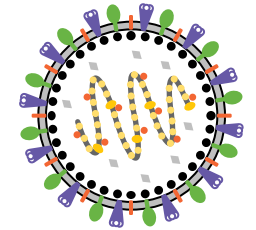
This presentation is provided in response to the request from the organizers of National Legislative Conference.

This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

Disclosure: Leonard Friedland is employed by GSK where he is a vaccine research scientist.

RSV is a common cause of acute respiratory illness¹

- In adults, RSV infection typically results in mild, cold-like symptoms, but may cause hospitalization and death, particularly in vulnerable adults²
- Immunity after natural infection wanes, and re-infection occurs throughout life^{3,4}
- RSV symptoms are like those of other respiratory infections; differential diagnosis requires laboratory confirmation^{5,6}
- Every year, RSV cases in adults result in a substantial clinical and economic burden in the US^{2,7,8}
- No specific treatments for RSV are available for adults⁹

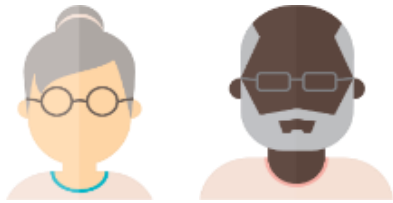


RSV = respiratory syncytial virus.

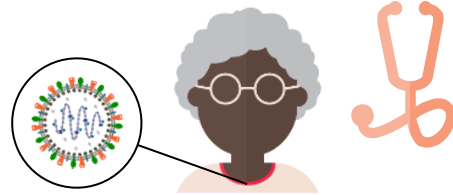
1. Walsh EE. *Clin Chest Med* 2017;38:29–36. 2. CDC, 2020. RSV in older adults and adults with chronic medical conditions. <https://www.cdc.gov/rsv/high-risk/older-adults.html> Accessed August 2022. 3. Graham BS. *Immunol Rev* 2011;239:149–166. 4. Anderson LJ *et al. Vaccine* 2013;31S:B209–B215. 5. Kodama F *et al. Infect Dis Clin North Am* 2017;31:767–790. 6. CDC RSV for healthcare professionals. <https://www.cdc.gov/rsv/clinical/index.html> Accessed April 2022. 7. Amand C *et al. BMC Health Serv Res.* 2018;18:294. 8. Falsey AR *et al. N Engl J Med* 2005;352:1749–1759. 9. Centers for Disease Control and Prevention. Symptoms and Care of RSV (Respiratory Syncytial Virus) | CDC. Accessed September 2022.

RSV is associated with clinical burden in older adults in the US¹

Estimated annual burden of RSV infection among adults aged ≥ 65 years in the US:¹



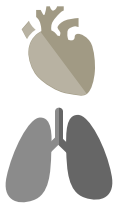
3-7% of older adults develop RSV infection in a typical year¹



**Hospitalization for RSV infection
~177,000 hospitalizations¹**



**Death due to RSV infection
Estimated 14,000 deaths^{1a}**



The burden of RSV hospitalization is particularly high among older adults and those with underlying cardiopulmonary conditions and diabetes^{2,3}



Hospitalization of older adults^b for RSV typically lasts 3–6 days⁴



Among hospitalized older adults^b with RSV, 10–31% are admitted to the ICU⁴



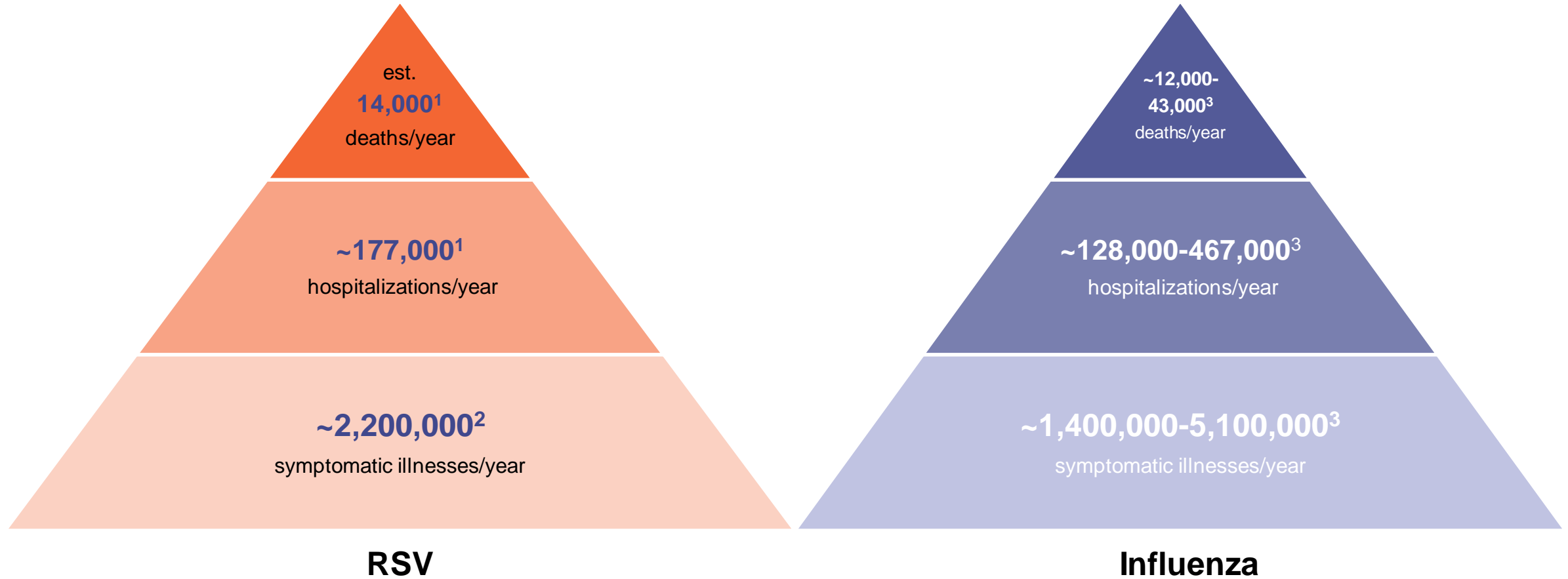
In-hospital case fatality rate of 8% for older adults^a with RSV¹

^a Based on 8% death rate for hospitalized patients ≥ 65 YOA with RSV infection¹ ; ^b Median and average ages ≥ 60 YOA.

ICU = intensive care unit

1. Falsey AR, et al. N Engl J Med. 2005;352:1749–1759. <https://doi.org/10.1056/nejmoa043951>. 2. Branche AR et al. Clin Infect Dis. 2022 Mar 23;74(6):1004-1011. <https://doi.org/10.1093/cid/ciab595>. 3. Belongia EA, et al. Open Forum Infect Dis. 2018;27;5:ofy316. <https://doi.org/10.1093/ofid/ofy316>. 4. Colosia AD, et al. PLoS One. 2017;12:e0182321. <https://doi.org/10.1371/journal.pone.0182321>.

RSV and influenza burden of disease among adults ≥ 65 years of age in the US



est. = estimated.

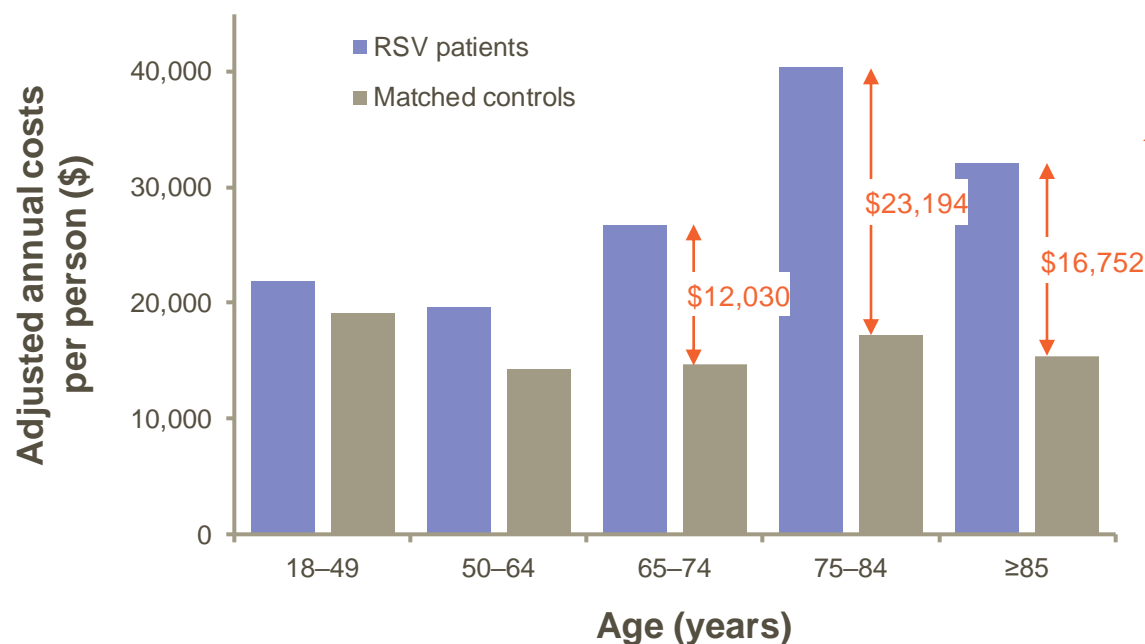
1. Falsey AR, et al. *N Engl J Med*. 2005;352:1749–1759. <https://doi.org/10.1056/nejmoa043951>. 2. Centers for Disease Control and Prevention. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/04-RSV-Havers-508.pdf>. Accessed September 2022. 3. Centers for Disease Control and Prevention. [Past Seasons Estimated Influenza Disease Burden | CDC](#). Accessed September 2022.

Estimates indicate a high economic burden of RSV in older adults in the US

A retrospective case–control database analysis quantified RSV-related healthcare resource use and costs by age group¹

N = 11,432 RSV patients aged > 1 year were matched 1:1 with non-RSV controls, matched for age, sex, region and health plan; 2012–2013^a

Annual healthcare costs for adults with RSV vs matched controls



RSV patients had higher healthcare resource use than controls for all age groups¹

Older adults aged ≥ 65 years showed the greatest difference in costs incurred between RSV and non-RSV groups¹



A prospective surveillance study among older and high-risk adults (N = 2536) estimated the annual cost of RSV hospitalization in the USA

exceeds \$1 billion²

The same results were first published by Amand C *et al.* 2018. The graph was independently created for GSK from the original data.

^a August, 31 2012 – August 1, 2013.

1. Amand C *et al.* *BMC Health Serv Res.* 2018;18:294. <https://doi.org/10.1186/s12913-018-3066-1>. 2. Falsey AR, *et al.* *N Engl J Med.* 2005;352:1749–1759. <https://doi.org/10.1056/nejmoa043951>.

Racial and ethnic disparities in respiratory infection diagnoses and severe outcomes have been reported



Among adults with risk factors for severe RSV, being of **racial and ethnic minority** status, having **exposure to children**, and being insured with **Medicaid or Medicare** are associated with an increased risk of **symptomatic RSV and acute respiratory illness**^{1,2}



Adults of **racial and ethnic minority** status and insured with **Medicaid or uninsured** have higher rates of **emergency department admission** for upper respiratory infections and acute respiratory illness^{3,4}



American Indian/Alaska Native adults experience substantially higher rates of **hospitalization and death** from lower respiratory tract infections than people of other races and ethnicities^{5,6}

1. Mehta et al., 2013; 2. Zou et al., 2018; 3. May et al., 2013; 4. Mellis et al., 2021; 5. Cheek et al., 2014; 6. Gounder et al., 2017.

Chronic conditions that are risk factors for severe RSV-related outcomes are more common among certain racial and ethnic minority groups

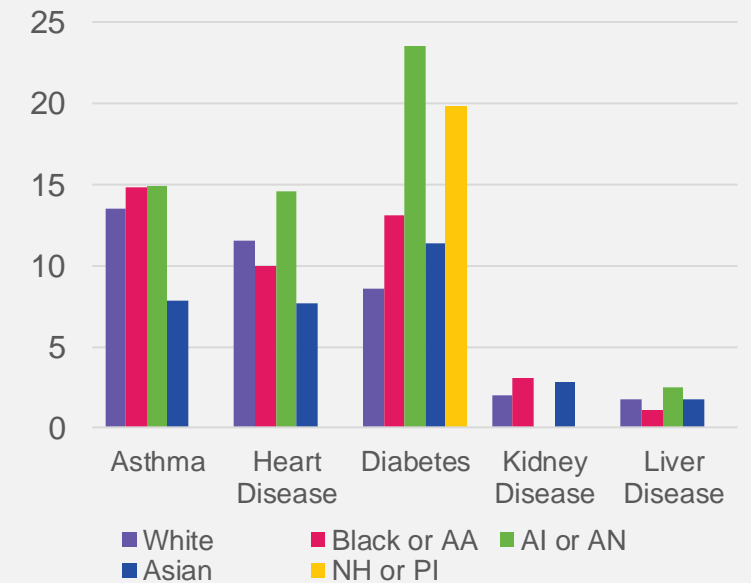
Many previous studies have found that racial and ethnic minority groups are more likely to develop chronic conditions that are risk factors for severe RSV-related outcomes:

Chronic pulmonary conditions	Asthma and COPD are associated with being Black/AA, being AI/AN, lower neighborhood-level SES, and higher poverty levels ¹⁻³
Chronic cardiac conditions	Black/AA individuals have disproportionately high prevalence of cardiovascular diseases, including heart failure ^{4,5}
Diabetes	Racial and ethnic minority groups and adults with lower SES are more likely to have diabetes than White adults or adults with higher SES ^{4,6-8}
Chronic kidney disease	ESRD prevalence is highest among individuals of racial and ethnic minority status, lower SES, and in areas with worse Social Deprivation Index scores ^{4,9,10}
Chronic liver disease	Hispanic individuals, as well as adults living in food insecure households, have the highest prevalence of NAFLD ¹¹⁻¹³

AA = African American; AI/AN = American Indian/Alaska Native; COPD = chronic obstructive pulmonary disease; ESRD = end stage renal disease; NAFLD = non-alcoholic fatty liver disease; NHIS = National Health Interview Survey; NH/PI = Native Hawaiian/Pacific Islander; SES = socioeconomic status.

1. CDC, 2022a; 2. Bhan et al., 2015; 3. Ejike et al., 2021; 4. Tsao et al., 2022; 5. Lewsey and Breathett, 2021; 6. CDC, 2022b; 7. Cheng et al., 2019; 8. Hill-Briggs et al., 2020; 9. USRDS, 2022; 10. Vart et al., 2020; 11. Rich et al., 2018; 12. Kim et al., 2019; 13. Golovaty et al., 2020; 14. CDC, 2019.

NHIS data also demonstrate disparities in age-adjusted percentages of adults aged ≥18 years with chronic conditions (2018)¹⁴



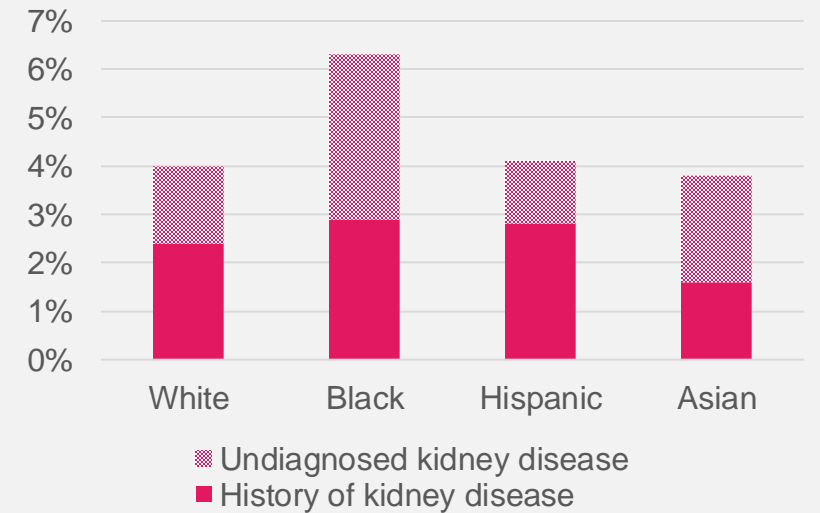
Note: Analysis among adults who indicated only a single race group, including those of Hispanic or Latino origin.

Risk factors for severe RSV-related outcomes are more likely to be undiagnosed in certain racial and ethnic minority groups

The extent to which **racial and ethnic minority** groups have **RSV risk factors** is likely **underestimated** given **disparities in health care access**, particularly in younger ages prior to Medicare eligibility^{1,2}

- Racial and ethnic minority groups have **increased odds** of being **undiagnosed with obstructive lung disease**³
- Hispanic, Black, and Asian adults have a **significantly higher prevalence** of **undiagnosed diabetes**, as well as a **significantly higher proportion** of undiagnosed diabetes among total diabetes prevalence⁴⁻⁶
- Black adults are approximately **twice as likely** to have **undiagnosed kidney disease** compared to White adults⁶
- Asian adults are **more likely** to have **undiagnosed hypertension**, with a **significantly higher proportion** of Asian, Black, and Hispanic adults unaware of their hypertension versus White adults^{6,7}

Total kidney disease prevalence among adults ≥18 years accounting for undiagnosed disease: NHANES 2011-2014⁶



NHANES = National Health and Nutrition Examination Survey.

1. Mahajan et al., 2021; 2. Wallace et al., 2021; 3. Martinez et al., 2015; 4. Cheng et al., 2019; 5. Tsao et al., 2022; 6. Kim et al., 2018; 7. Huang et al., 2022.

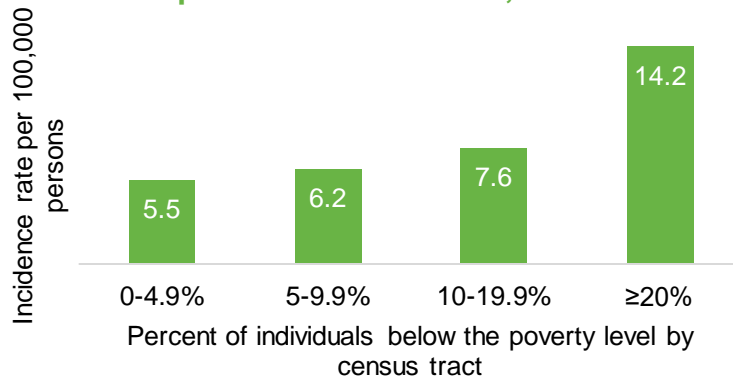
In addition to race and ethnicity, disparities in severe RSV and respiratory infection outcomes have also been observed by other Social Determinants of Health

The incidence rate of RSV-associated hospitalization in adults is **2.58 times higher** in census tracts with the highest versus the lowest percentages of individuals living below the **poverty level** and **1.52 times higher** in census tracts with the highest versus the lowest levels of **crowding**¹

Households reporting **subjective social status** below the median have a **46% higher** incidence of ARI compared with households above the median, while households with **children aged <5 years** have a **47-56% higher incidence** of ARI compared to households with no children aged <5 years²

The estimated annual **hospitalization** incidence for RSV infections among adults in the ZIP codes from the **lowest** tertile for **socioeconomic status** is approximately **double** that of adults in the highest socioeconomic status ZIP codes³

Incidence rate of RSV-associated hospitalizations in adults, 2015-2017¹



Adults who are **homeless** or **drug users** have been found to be at an **increased odds** of hospitalization for RSV as compared to influenza⁴

Estimated annual RSV-attributable respiratory hospitalization rates, July 2005-June 2014³

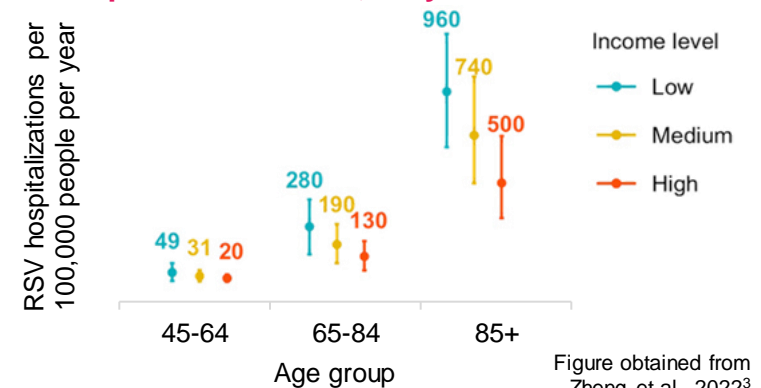


Figure obtained from Zheng et al., 2022³

ARI = acute respiratory infection

1. Holmen et al., 2021; 2. Malosh et al., 2019; 3. Zheng et al., 2022; 4. Boonyaratanakornkit et al., 2019.

State legislators can raise awareness of RSV in adults

Partner with existing community-based programs

- These groups can help educate and share information on the importance of RSV and other adult recommended vaccines your constituents may need or may have recently missed.

Community-based vaccine education and outreach initiatives

- Designed and shared by trusted individuals are effective approaches to increase uptake of adult recommended vaccines.

Access

- While general awareness and prevention should be a top priority. It's also critical that everyone has access to vaccinations where they get their care.

Pharmacy

- Many adults find it easier to get their vaccines at their pharmacy due to proximity and convenience. Increasing the number of vaccinators will reduce many barriers to access.
- States add Pharmacy Technicians to the list of those trained to administer licensed RSV and other Advisory Committee on Immunization Practices (ACIP) recommended vaccines.
- Pharmacy administered vaccines can improve access and convenience, especially in low-income and rural communities.

RSV: A Virus You Should Know

Women in Government National Legislative Conference
June 9, 2023





About NFID

Founded in 1973, the National Foundation for Infectious Diseases (NFID) is a non-profit 501(c)(3) organization

Vision:

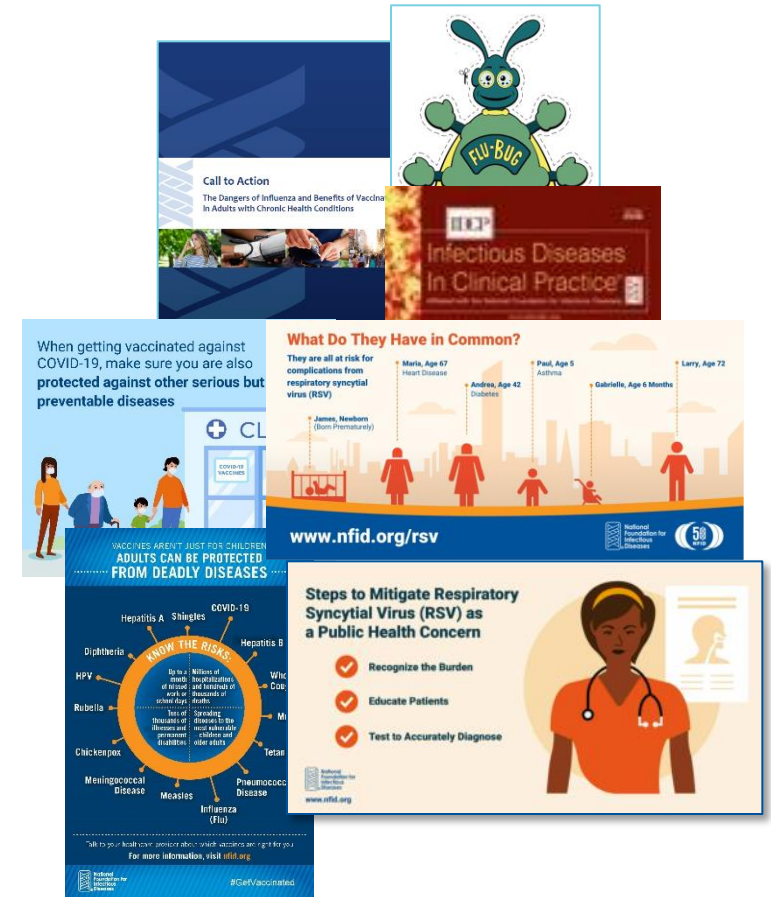
Healthier lives for all through effective prevention and treatment of infectious diseases

Mission:

Educate and engage the public, communities, and healthcare professionals about infectious diseases across the lifespan

Core Values:

- Collaboration
- Diversity, Equity, and Inclusion
- Evidence-Based
- Integrity
- Transparency



Awareness Program Objectives

Challenge:

A greater understanding of RSV disease burden and renewed assessment of standard of care across the lifespan needed as new interventions become available

Solution:

Engage key pediatric and adult experts to review the current RSV landscape and increase awareness of the burden of RSV across the lifespan through the development of a consensus call to action and progress report

Gain alignment on public health need for greater RSV awareness/disease burden data via enhanced surveillance

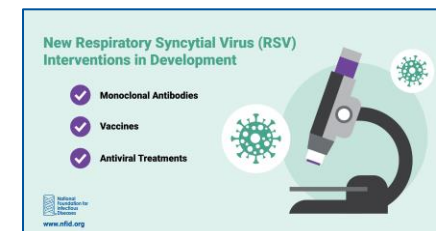
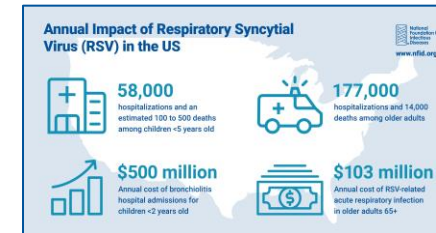
Assess disease burden, evaluate risks of RSV across the lifespan

Build alignment on data gaps/future needs, factors that complicate prevention and treatment

Review available data on new tools (e.g., vaccines, monoclonal antibodies)

Consensus Building

- **Healthcare professional surveys** conducted to establish baseline awareness
- **Built consensus among 20+ public health organizations and thought leaders** on underappreciated risk of RSV across the lifespan and need to reduce the burden of disease through NFID-led virtual roundtable
- Published and disseminated **NFID Call to Action** based on roundtable discussions and strategies to drive progress in RSV surveillance, prevention, and treatment



National Foundation for Infectious Diseases
www.nfid.org

CALL TO ACTION
REDUCING THE BURDEN OF RSV ACROSS THE LIFESPAN
JANUARY 2022

Reducing the Burden of RSV across the Lifespan



Key Strategies to Drive Progress

- Increasing awareness of urgency
- Strengthening public health capacity
- Laying foundation for new tools



Progress Report

- Ongoing challenges
- Progress made in surveillance, tools, access
- Outlines pathways to reducing burden and addressing health disparities

Educational Resources



Developed co-brandable **shareable resources**:

- Animated public service announcement video
- Infographics targeting healthcare professionals, parents/caregivers, and patients
- Fact sheets (English/Spanish)
- Social media graphics and sample posts


www.nfid.org/rsv




RSV Perspectives: Real Stories




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Have you been affected by RSV? Share your story to help others learn more about this common, but potentially serious disease.




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RSV can impact anyone, but infants and older adults are at an increased risk. Help spread the word by sharing your story.




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Have you been affected by RSV? Share your story to help others learn more about this common, but potentially serious disease.



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Using Data for Decision Making

Be a Public Health Leader:
Collaborate with Trusted Voices and Share Important Messages

Prepare for the Future:
Lessons Learned from COVID-19

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Fighting for Equity in RSV Care

Adjoa Kyerematen

VP - Public Affairs & Communications



RSV is a Significant Threat for People of Color

Research on clinical disparities in RSV is limited, but we already know:

- RSV infection can be serious, or even deadly, particularly in vulnerable populations with chronic lung disease, asthma and compromised immune systems. These high-risk groups are more susceptible to severe RSV infections and often require hospitalization and intensive care.
 - **The lowest socioeconomic groups are up to 14 times more likely to have respiratory disease than the highest group**
 - **Black, Hispanic and American Indian/Alaska Native people have the highest asthma rates.**
- RSV is a significant risk factor for ongoing respiratory morbidity characterized by transient early wheezing and recurrent wheezing and asthma within the first decade of life and possibly into adolescence and adulthood.
- RSV infection in the first three years of life has been associated with longer-term respiratory issues including recurrent wheezing and asthma, decreased lung function, and possibly allergic sensitization.

Elevated Burden of RSV on Minoritized Populations

2-3x higher

RSV peak incidence rate in Black and Hispanic children compared to white children.

3x more likely

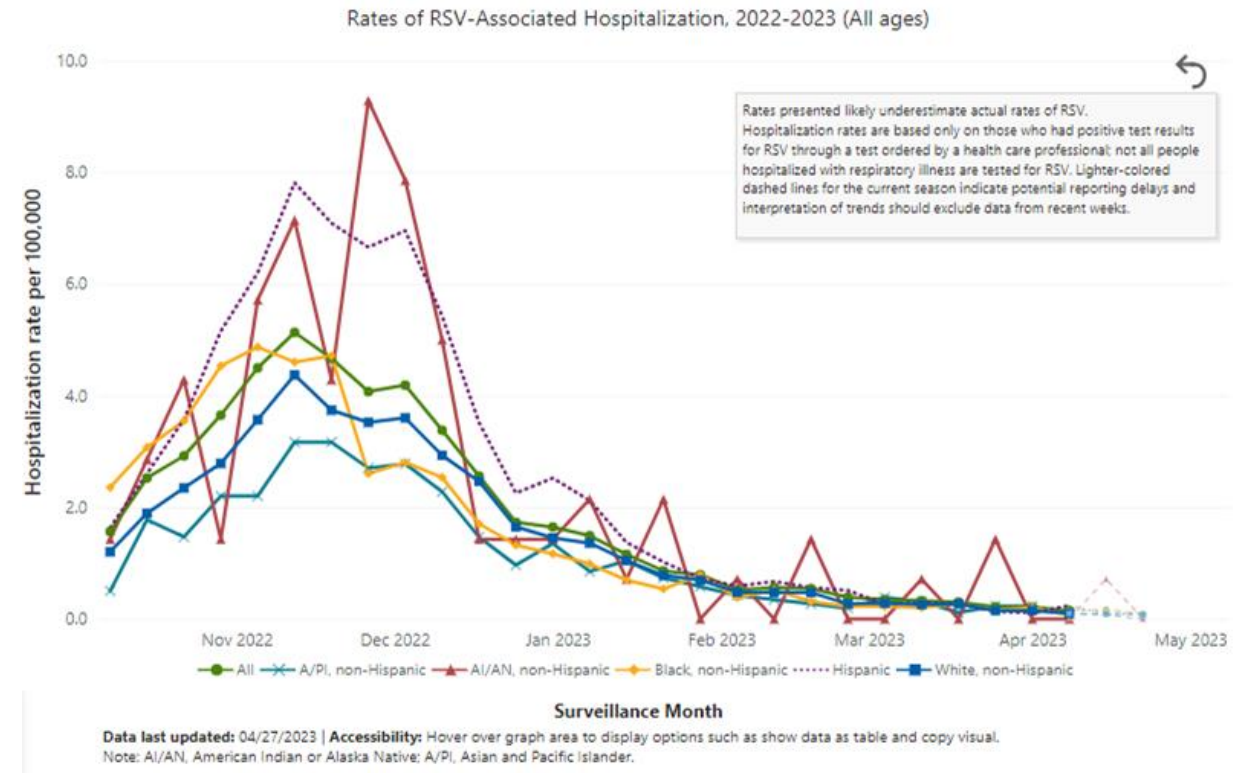
Premature babies are more likely to die from RSV than full-term babies

50% higher

Black women are more likely to give birth to a premature baby.

2.5x more likely

Annual rates of RSV hospitalizations in Navajo and Apache infants



Inequity in Coverage

Infants' treatment costs of RSV total almost \$710 million annually. The burden of RSV is higher in families in low socioeconomic status areas, leading to higher rates of hospitalizations and deaths.

- RSV hospitalizations among children in the lowest SES group are almost double that of children in the highest SES group.
- **Infants born into families that rely on Medicaid coverage represent an estimated 62 percent of RSV hospitalizations and 56 percent of emergency department visits.**
- Medicaid-enrolled infants are 91 percent more likely than commercially insured infants to be hospitalized for RSV in their first year.
- One study found that infants on Medicaid account for 62% of RSV deaths.

In a recent STAT/Harris poll, more than 2/3 of parents in the United States said that RSV also presented their family with a financial burden or financial crisis.





“

Medicaid coverage of RSV care remains inconsistent and is impacted by the decision of each state to expand Medicaid under the Affordable Care Act (ACA).

As of September 2021, 39 states and the District of Columbia have chosen to expand Medicaid, while 12 states have not. This creates a coverage gap for critical RSV care, leaving many low-income individuals without access to affordable health insurance in non-expansion states.

Call to Action

- Strengthen national and regional surveillance systems for RSV to improve reporting accuracy and consistency.
- Educate healthcare providers, particularly those in primary care settings, about the need to report RSV cases and assist low-income mothers to encourage immunization.
- Educate families on new preventative immunization options when available.
- Launch culturally competent public health campaigns to educate families about RSV symptoms, the importance of seeking medical attention, and immunization.
- Encourage collaborative efforts between researchers, public health agencies, and healthcare providers to facilitate comprehensive studies on RSV, including its prevalence, impact, and prevention strategies.
- **Ensure equitable access to new long-acting mAbs for RSV immunization by including them in the Vaccines for Children Program**





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