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RSV Health Equity Action Report



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Letter from the Community

After an alarming season where the nation was caught by surprise by increasing rates of respiratory syncytial virus (RSV), we must renew attention to the critical importance of effective preventative care to combat the threat of the disease. Providing technologies such as monoclonal antibodies for historically disenfranchised, low socioeconomic status, and vulnerable families will ensure no child is left behind.

The fact is parents of color, particularly those of low-income status, are not prepared for the next wave of RSV. RSV poses a significant threat to vulnerable populations, particularly infants and young children with compromised immune systems. It is a highly contagious respiratory virus that can result in severe illness, hospitalizations, and in some cases, even death.

RSV is responsible for more than 58,000 yearly hospitalizations and up to 100 to 300 deaths in children under 5 years. The impact of RSV on affected individuals and their families is not only physical but also emotional and financial, necessitating immediate action to improve access to care and stop the spread of this preventable disease.

Access to RSV care is critical to reducing the impact of the virus on vulnerable populations. Infants that are especially vulnerable to severe hospitalization related to RSV are Black, Hispanic, American Indian/Alaskan Native children. The disparities are a culmination of inadequate health insurance coverage, access to primary care, and lack of culturally competent care.

Addressing these disparities and promoting equal access to RSV care can improve early detection, timely treatment, and effective management of RSV among racially diverse populations. By enhancing access to care, we can significantly reduce the burden of RSV on patients and their families while easing the strain on our healthcare system.

Whereas the pharmaceutical industry has recently advanced a major breakthrough to provide effective immunizations against RSV with a monoclonal antibody that neutralizes RSV in the bloodstream, children from low-income families may experience barriers to receiving immunization as readily as the well-insured. It is imperative to ensure equitable access to RSV immunization.

RSV has been described as an “opportunistic” killer. It awaits the opportunity to spread, feasts upon our most vulnerable children, acts unpredictably, exacerbates comorbidities, thrives when there isn’t timely, effective care, and poses a greater future threat to infants of color without immunization to stop it.

We firmly believe that addressing these issues is paramount to safeguarding the health and well-being of countless individuals and their families. The creation of an effective immunization is a game-changer in preventing severe infections, reducing hospitalizations, and ultimately saving lives. Collaboration among governmental bodies, healthcare providers, researchers, and pharmaceutical companies is of utmost importance to advance approval of RSV immunization, increase education and awareness of effective therapy, and drive adoption by eliminating barriers.

Together, we can make a substantial difference in the lives of those affected by RSV, protecting the most vulnerable members of our society and preventing unnecessary suffering.

By,



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The RSV landscape in the United States

Respiratory Syncytial Virus (RSV) is a viral infection of the respiratory tract that causes cold-like symptoms such as runny nose, decreased appetite, coughing, sneezing, fever, and wheezing. In babies, the symptoms may present as irritability, decreased activity, and trouble breathing.

RSV infections exhibit a seasonal pattern, typically occurring during the fall, winter, and early spring in temperate regions. However, the exact timing and intensity of RSV outbreaks can vary from year to year. Prior to the start of the COVID-19 pandemic in 2020, RSV trends were fairly consistent in the US. These trends were disrupted during the pandemic, however, the rates of RSV began to rise in the spring of 2021 and surged in 2022 as well.¹ Nationally, RSV epidemics during the three surveillance years preceding the COVID-19 pandemic (2017–2020) began in October, peaked in December, and lasted a median of 27 weeks before the offset during March–April. In contrast, the 2021–22 epidemic began 21 weeks earlier, peaked in July, and lasted 33 weeks until January 2022. During the 2022–23 surveillance year, onset occurred in June, the proportion of positive PCR results peaked in November, and the peak was higher (19%) than that during pre-pandemic seasons which experienced a range of 13%–16%. The epidemic lasted 32 weeks until the offset occurred in January.¹

Prior to the start of the COVID-19 pandemic in 2020, RSV trends were fairly consistent in the US. These trends were disrupted during the pandemic, however, the rates of RSV began to rise in the spring of 2021 and surged in 2022 as well.

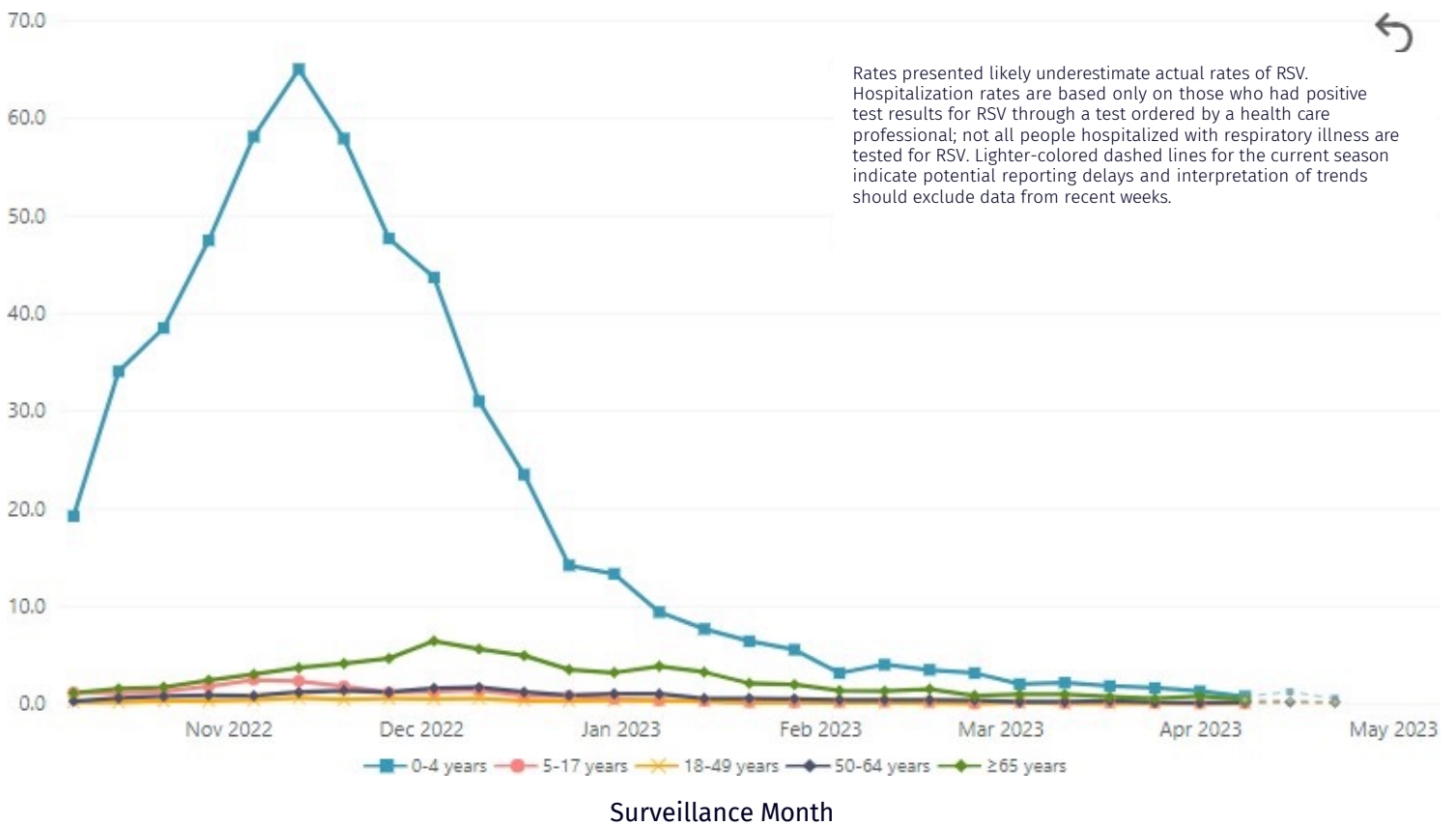
In both the pre-pandemic and pandemic periods, RSV epidemics began earliest in Florida and the Southeast and later in regions further north and west. The timing and severity of RSV seasons are influenced by factors such as climate, population immunity, and viral dynamics, making it difficult to predict the exact onset and duration of RSV activity.

While most RSV infections will clear on their own within a week or two, infection can be more serious, or even deadly, particularly in vulnerable populations such as young children, premature infants, infants with chronic lung disease, and individuals with compromised immune systems. These high-risk groups are more susceptible to severe RSV infections and often require hospitalization and intensive care. The unpredictable nature of RSV in these vulnerable populations adds to the complexity of managing the disease.

There is currently no treatment for RSV other than symptom management. An immunization was approved for adults 60 years and older in May 2023 and immunizations will soon be available for other populations including pregnant parents and infants.²

While RSV can affect anyone, it commonly affects young children. In fact, practically all children get an RSV infection by the time they are 2 years old.³

Rates of RSV-Associated Hospitalization, 2022-2023 (All ages)



Data last updated: 04/27/2023

Although common, RSV can be particularly deadly for young children. According to the research, each year in the United States, RSV leads to approximately:

2.1 M
outpatient (non-hospitalization) visits among children younger than 5 years old⁴

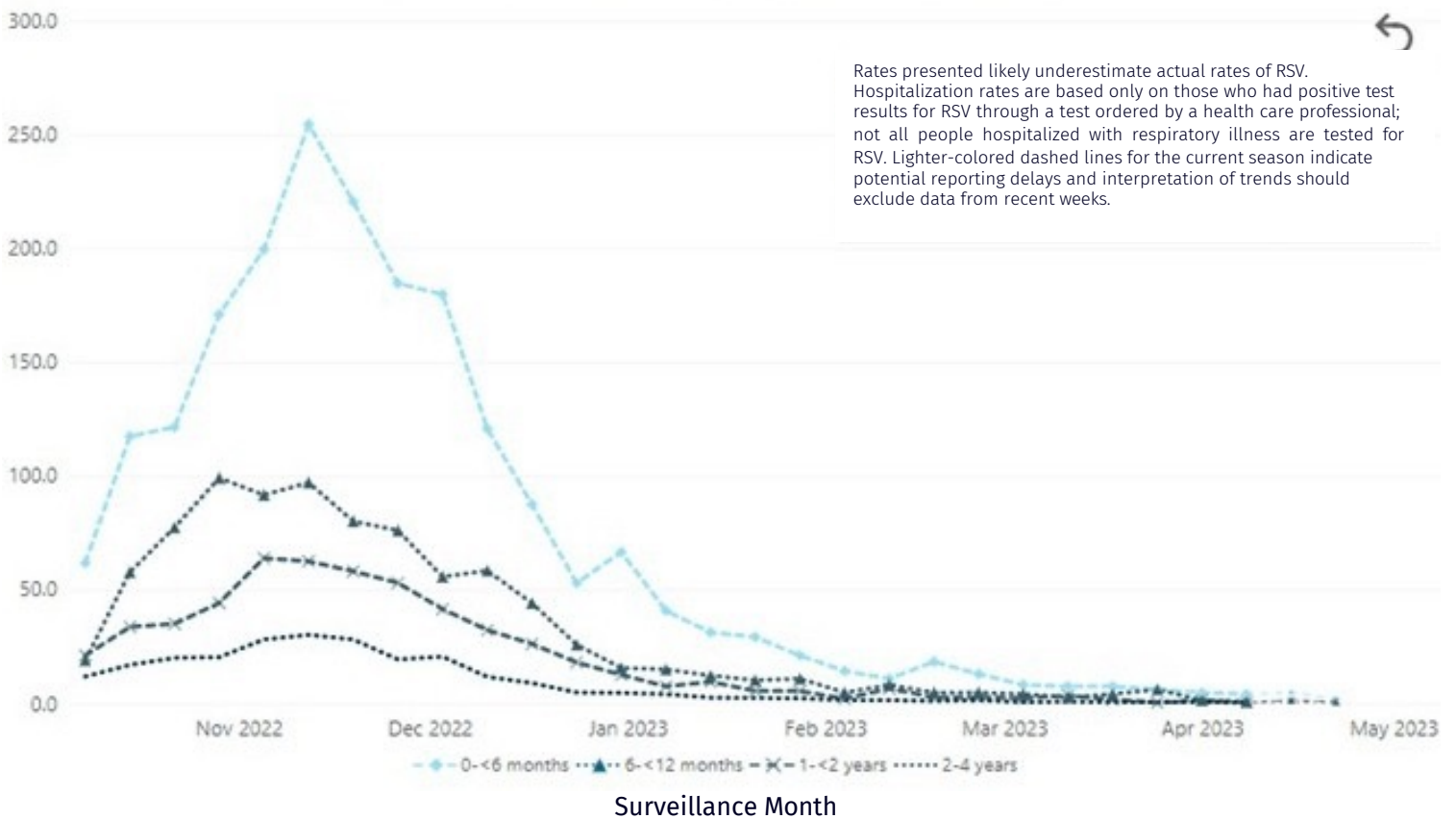
58-80k
hospitalizations among children younger than 5 years old⁵

15-20%
of hospitalized infants spend a portion of their stay in the intensive care unit (ICU)⁶

100-300
deaths in children younger than 5 years old⁷

While RSV can affect people at any age, **children under the age of five have the highest rate of hospitalization due to RSV by far.** Among children, those younger than six months have the highest hospitalization rates. Infants that are most at risk for severe RSV include those who were born prematurely, have chronic lung or heart disease, or a weakened immune system.⁸

Rates of RSV-Associated Hospitalization, 2022-2023 (All ages)



Rates presented likely underestimate actual rates of RSV. Hospitalization rates are based only on those who had positive test results for RSV through a test ordered by a health care professional; not all people hospitalized with respiratory illness are tested for RSV. Lighter-colored dashed lines for the current season indicate potential reporting delays and interpretation of trends should exclude data from recent weeks.

Data last updated: 04/27/2023

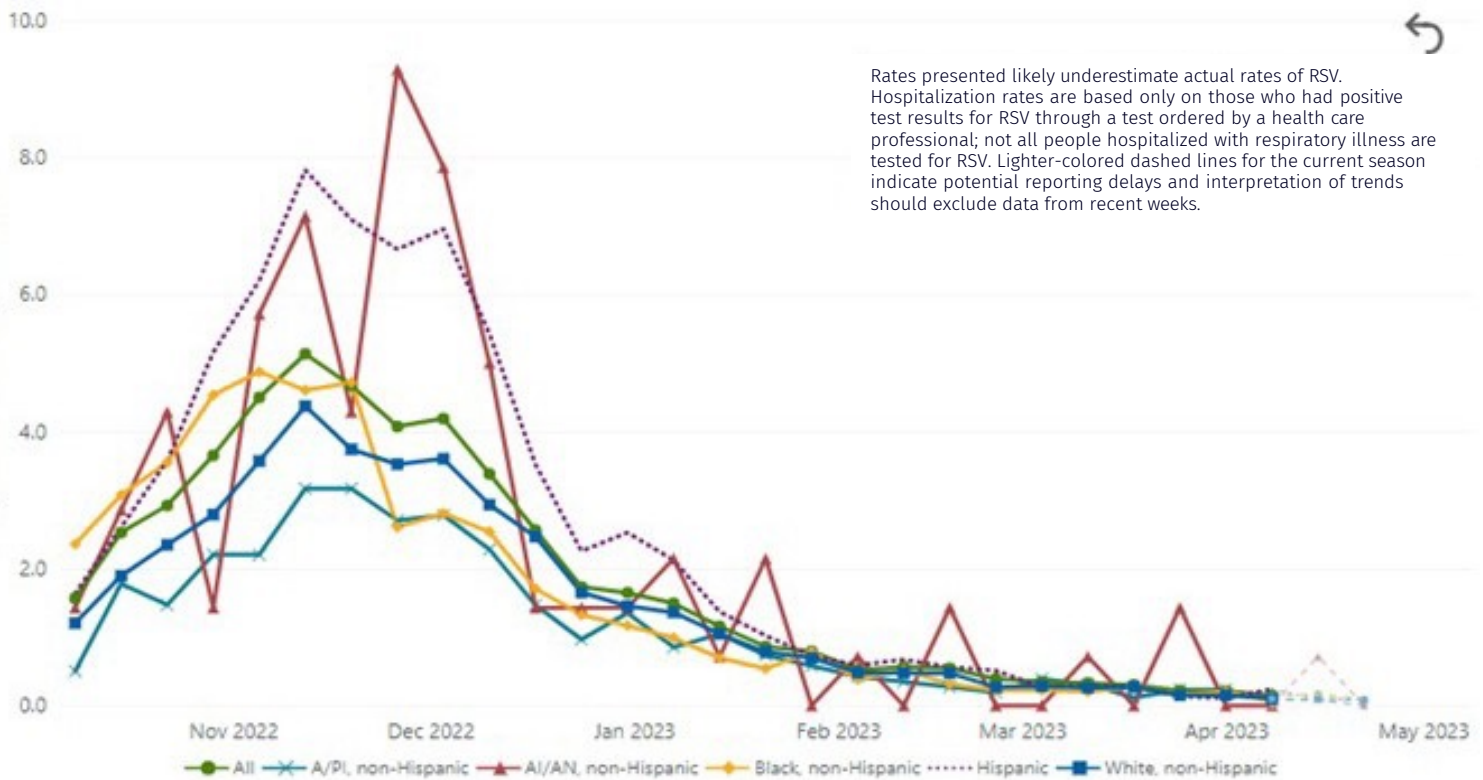
The impact of RSV on premature babies is a particular concern for Black women, who are 50 percent more likely to give birth to a premature baby than white or Hispanic women.⁹ Premature babies are three times more likely to die from RSV than full-term babies and also have a higher risk of needing to be hospitalized, cared for in the ICU and respiratory failure.¹⁰

Black women are 50% more likely to give birth to a premature baby than white or Hispanic women.

Since the COVID-19 pandemic, healthcare providers say that children showed up to the hospital sicker on average compared to previous years.¹¹ This trend is cause for real concern and has exposed a widening equity gap and socioeconomic inequalities as minoritized, historically disenfranchised, and low-income populations are disproportionately impacted by RSV.

Although research on racial disparities in RSV is limited, across all ages, American Indian/Alaskan Native (AI/AN) people and Hispanic people are the most likely to be hospitalized due to RSV. The annual rates of RSV hospitalizations in Navajo and Apache infants are 2.5 times more than those of healthy infants in the general US population.¹² Additionally, research has shown that Hispanic and Black children carry the burden of infectious respiratory disease occurrence and this is also mitigated by higher rates of poverty and chronic conditions.¹³

Rates of RSV-Associated Hospitalization, 2022-2023 (All ages)



Surveillance Month

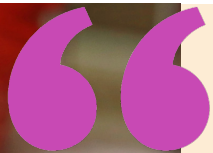
Data last updated: 04/27/2023

Infants enrolled in Medicaid have relative risk for RSV hospitalizations of 2.03 (1.99-2.06) compared to non-Medicaid payers. One study found that infants on Medicaid account for 62% of RSV deaths.

The burden of RSV is higher in children of families in low socioeconomic status areas, leading to higher rates of hospitalizations.¹⁴ Infants enrolled in Medicaid have relative risk for RSV hospitalizations of 2.03 (1.99-2.06) compared to non-Medicaid payers.¹⁵ One study found that infants on Medicaid account for 62% of RSV deaths.¹⁶ The elevated burden of RSV in infants of color and specifically those in lower socioeconomic areas may be attributed to several causes including persistent inequities in social determinants of health related to poverty, household crowding, lack of indoor plumbing, maternal smoking, indoor air pollution, malnutrition, limited access to care, daycare attendance, older siblings in school/daycare, lack of breastfeeding and family history of asthma.^{17,18}

Impact of RSV

Aside from the prevalence and incidence of RSV, particularly in the aforementioned populations, the impact of RSV can be seen in the impacts on financial, mental, physical and social parts of patients, caregivers and providers.



Baby Kai was 8 months when he was admitted to the hospital with RSV and was hospitalized for seven days:

“He actually got it from my middle son who was 4 at the time, he was in preschool and came home with a bad cold, and they literally are inseparable so I just figured it was just a common cold. After a few days, the baby stopped drinking his milk and was becoming dehydrated and not giving me wet diapers, that’s when I knew I had to take him in. He was in respiratory distress by then and for that we were admitted. The hard thing with RSV is that they get real bad before they get better, and the days and nights were long. What was the scariest thing was when they had given him the highest level of oxygen and they had mentioned taking him to another floor which was basically ICU for intubation, that was when I lost all my marbles.”

Jenny W.
Orlando, Florida

RSV can lead to bronchiolitis, an infection that causes airways to become inflamed and clogged with mucus, making it difficult to breathe. If the infection travels to the lung sacs, it can result in pneumonia. Many epidemiologic studies have consistently shown that 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.¹⁹

In addition to the immediate burden of acute illness, potential hospitalization and emergency visits, 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.

\$710 M
total annual
treatment
costs of RSV
for Infants ²⁰

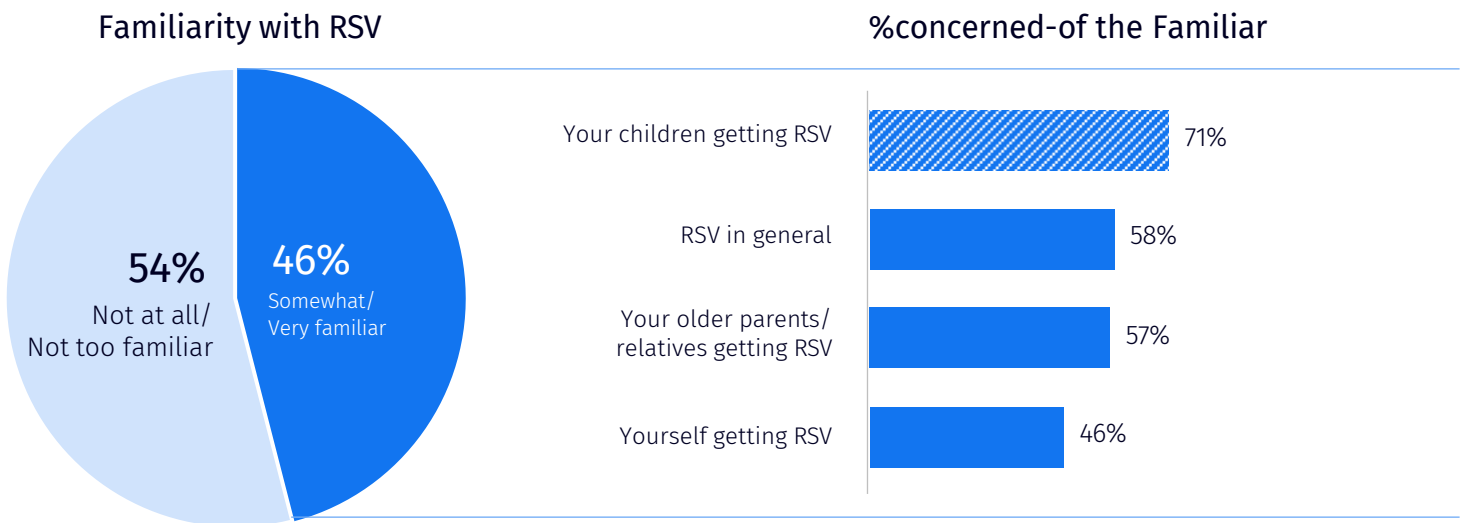
69%
of parents felt
guilty they could
not do more to
prevent their child’s
experience with RSV ²¹

>2/3
of parents said that
RSV also presented
their family with a
financial burden of
financial crisis ²²

48%
of providers said they
found it difficult to
decide whether to send
a young RSV patient to
the emergency room ²³

In a recent STAT/Harris Poll, 46% of Americans are familiar with RSV, an increase from previous years, and about 71% of Americans who are familiar with RSV are concerned about their children contracting the disease.²⁴

Almost half of Americans familiar with RSV; 71% concerned about children



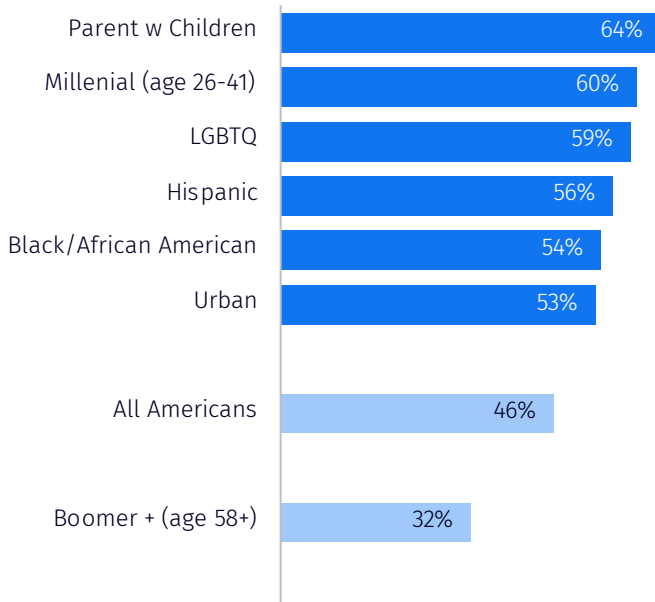
Roughly two-thirds of Hispanic Americans, Black Americans, and those identifying as LGBTQ reported they are familiar with – and concerned about – RSV. Unsurprisingly, the concern increases among families living in highly populated, urban areas.

Several groups of Americans stand out on high familiarity and concerns:

Parents w kids <17, Millennials, LGBTQ, Hispanic, Black/African American, Urbanites

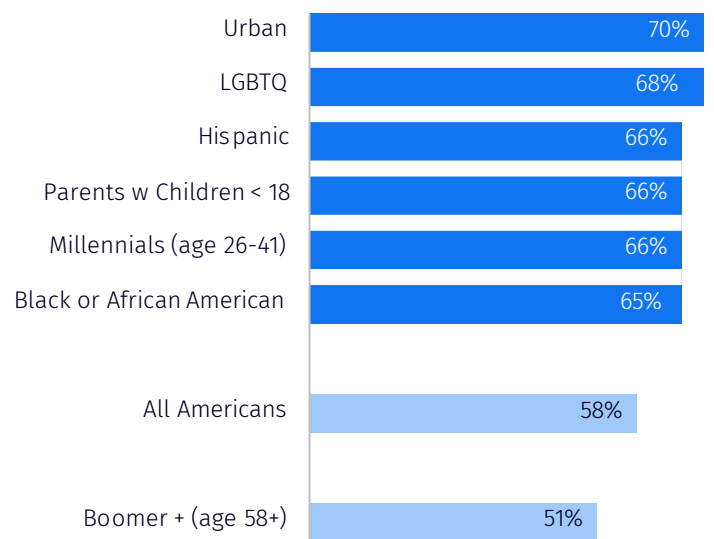
Familiar with RSV

(% of somewhat/very familiar)



% Concerned- Of those Familiar

(% somewhat/very concerned – Avg of four concerns tested)



Only 40% of Boomers are concerned about getting RSV themselves

According to a report from the Alliance for Patient Access and the National Coalition for Infant Health:²⁵

69%

of parents felt guilty they could not do more to prevent their child’s experience with RSV ²¹

68%

of parents said watching their child suffer affected their mental health

>1/3

of parents said the burden of RSV placed a strain on their relationship with their partner

>2/3

of parents said that RSV also presented their family with a financial burden of financial crisis

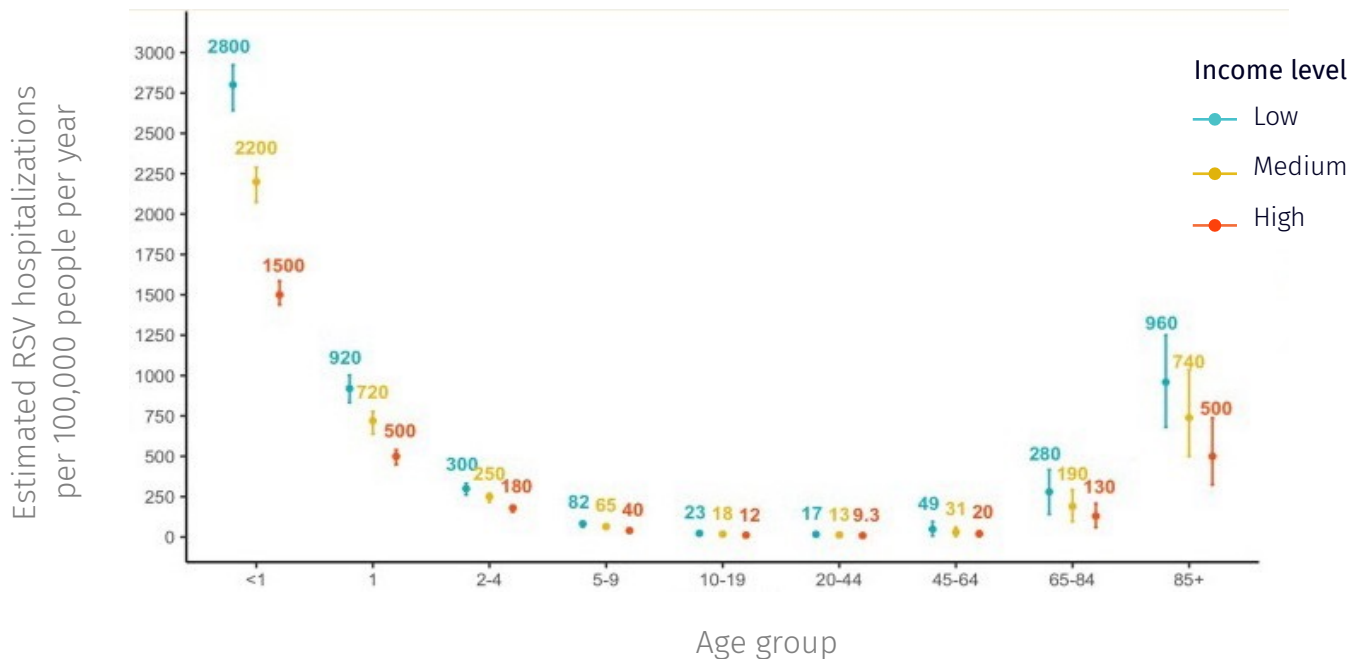
48%

of providers said they found it difficult to decide whether to send a young RSV patient to the emergency room ²³

Inequity in coverage & the silent burden of disease on underserved communities

Hospitalizations due to RSV have demonstrated a consistent upward trend over the five-year period, reflecting the impact of the virus on the healthcare system. Acute bronchiolitis due to RSV was the leading primary diagnosis, accounting for 9.6% of total infant hospitalizations from January 2009 through September 2015 and October 2015 through December 2019, respectively.

In a study examining RSV hospitalizations by socio-economic status (SES) conducted from July 2005 to June 2014, the estimated number of RSV hospitalizations among children in the lowest SES group was almost double that of children in the highest SES group. The results showed that the most at-risk were infants, less than 1 year old with a low socio-economic status, followed by children 1 to 2 years of age.²⁶



The economic burden associated with RSV is significant, encompassing both direct medical costs (hospitalizations, medications, and outpatient visits) and indirect costs (loss of productivity due to caregiver time off work). Hospitalization expenses account for a significant portion of the overall healthcare costs related to RSV treatment and management.

RSV burden on the public insured, uninsured and underinsured

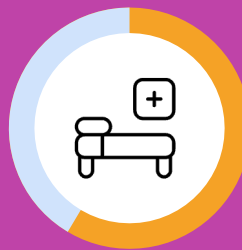
Historically, lack of coverage has plagued childhood immunization. Low-income uninsured and underinsured children have been at greatest risk for not being able to pay the cost of childhood immunization, and millions of families with preschool children, not yet eligible for free public health vaccination clinics as a school entry rule, simply went without.

RSV, which we know can have worse impact on children not yet one year old and therefore not in the school system, has a significant impact on publicly insured families, including challenges related to healthcare access, financial burdens, and healthcare outcomes.

Inconsistent Medicaid Coverage



The burden of RSV falls disproportionately on the roughly **1.5 million infants** born annually with public insurance, typically Medicaid coverage.



62%

RSV Hospitalization

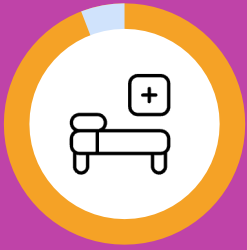


56%

ER department visits

However, Medicaid coverage 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, leaving many low-income individuals without access to affordable health insurance in non-expansion states.



91% Medicaid infants

Medicaid-enrolled infants are 91% more likely than commercially insured infants to be hospitalized for RSV in their first year.

\$709.6 M annually

Medicaid pays approximately for infant RSV prevention and treatment costs.²⁷

Underinsured families often face financial burdens related to copayments, deductibles, and other out-of-pocket expenses associated with RSV-related healthcare services.

These financial burdens can deter families from seeking timely medical care for RSV symptoms, leading to more severe infections and increased healthcare utilization in the long run.

After hospitalization or outpatient treatment for RSV, underinsured families may face challenges in accessing appropriate follow-up care, including pediatric specialists and developmental support services. The lack of adequate post-treatment care may contribute to suboptimal recovery and potential long-term health implications.



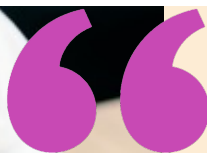
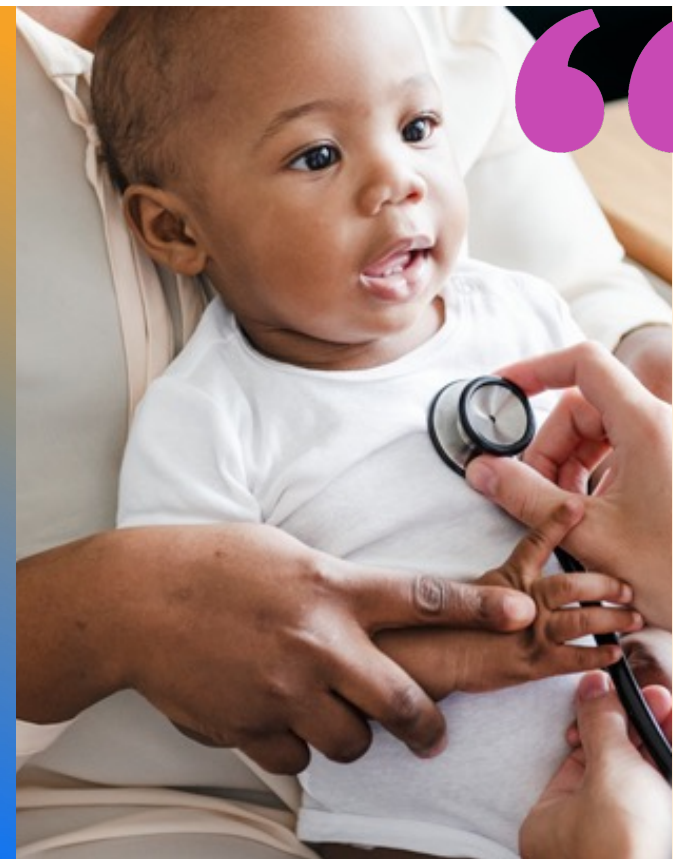


The silent burden: underreporting of RSV

Most experts believe that there is severe underreporting of RSV infections, which are often diagnosed based on clinical symptoms and without laboratory confirmation, especially in underserved communities. RSV shares symptoms with other respiratory infections, such as the common cold and influenza which increases the likelihood of misdiagnosis or grouping RSV cases under broader respiratory infection categories.

Diagnostic testing for RSV is not routinely performed in all healthcare settings, particularly in outpatient and primary care settings for the publicly insured, underinsured and uninsured, which can result in missed opportunities for reporting.

Underreporting of RSV cases hampers public health agencies' ability to accurately assess the disease burden and allocate resources effectively. The lack of comprehensive data on RSV cases can hinder efforts to raise awareness about the virus and implement preventive measures, such as vaccination campaigns and public health interventions.



From birth my son Demarion came out with a runny nose and his doctors told me it was normal...then when he turned 3 months old he battled RSV to the point where we had to get admitted into the hospital for four days. I almost lost my infant son not once but twice to severe RSV.

When he turned one he got sick again and battled RSV and this time he had to be taken by helicopter to hospital for a week. My biggest fear is heights but that didn't stop me from jumping on that helicopter with my baby. His pediatrician suggested that we get his adenoids removed and I think that helped him fight off RSV better the last go-round.

As a single mom, I have experienced fighting RSV three times. Sometimes when he sleeps he develops a terrible cough. Can't wait for him to experience life being able to breathe fully!

Patrice W.
Little Rock, Arkansas



Innovation is RSV prevention

In the early stages of RSV research, the virus was identified as a significant cause of respiratory illness in infants and young children. The recognition of RSV as a distinct pathogen and its association with severe respiratory disease laid the foundation for further understanding and management of the infection.

Initially, the clinical care for RSV primarily focused on providing supportive care to affected individuals. This included maintaining hydration, administering oxygen therapy, and ensuring appropriate nutrition. Supportive care remains a crucial component of RSV management, especially for infants and young children with severe symptoms.

With advancements in medical knowledge, preventive strategies for RSV infection emerged. These included infection control measures, such as hand hygiene, isolation precautions, and minimizing exposure to infected individuals. Additionally, efforts were made to identify high-risk populations, such as preterm infants and infants with chronic lung disease, who would benefit from prophylactic interventions. The development and use of prophylactic interventions have significantly influenced RSV clinical care. Palivizumab, a monoclonal antibody, was the first approved prophylactic therapy for RSV in high-risk infants. It has been used to reduce the severity of RSV infection and hospitalizations in susceptible populations.

More recently, nirsevimab, another monoclonal antibody, was approved by the Food and Drug Administration for the prevention of RSV in infants and young children and is an effective preventative measure to address the burden of RSV infection, including the reduction of morbidity.

Monoclonal antibodies (mAbs), which famously helped in the development of COVID-19 immunizations, have emerged as a significant class of therapeutics in drug development and patient care. They are laboratory-produced molecules that mimic the natural antibodies produced by the immune system. Monoclonal antibodies have demonstrated remarkable success in various therapeutic areas, including oncology, immunology, and infectious diseases due to their specific targeting capabilities and ability to modulate specific biological pathways make them valuable tools.²⁸

The development of nirsevimab began with the identification of RSV as a significant cause of respiratory illness, particularly in infants and young children. RSV was recognized as an important target for intervention due to its prevalence and associated morbidity. Researchers employed various techniques, including phage display libraries and screening of human B-cell repertoires, to identify potential monoclonal antibodies capable of neutralizing RSV.²⁹ Nirsevimab was derived from these efforts and selected for further development based on its binding affinity and neutralizing properties against RSV.

Multiple clinical trials have been conducted to assess the efficacy of nirsevimab in preventing RSV infection. The pivotal trial, the IMpact-RSV study, included over 1,500 preterm infants and demonstrated a significant reduction in medically attended lower respiratory tract infections associated with RSV compared to placebo. Nirsevimab achieved a relative reduction of 70% in RSV-associated lower respiratory tract infections and a 78% reduction in hospitalizations due to RSV.

Nirsevimab achieved



70% reduction
in RSV-associated lower
respiratory tract infections

78% reduction
in hospitalizations due
to RSV³⁰

Furthermore, a phase 2b trial conducted in healthy term infants also showed a statistically significant reduction in RSV infections with nirsevimab compared to placebo. Overall, nirsevimab has demonstrated substantial efficacy in reducing RSV-associated lower respiratory tract infections and hospitalizations in both preterm and healthy term infants.³¹ Most importantly, Nirsevimab is effective with all infants with one dose at the start of the season to protect them through the entire season.





Prevention and doing things differently

People are more hesitant to get vaccinated when they believe there is a cost associated with immunization. Even though the COVID-19 was provided for free, people were concerned that there were hidden costs associated with it. A 2021 Kaiser Family Foundation poll found that about one third of unvaccinated adults were not sure if their insurance would pay for the newly approved COVID-19 immunization and were concerned about what they would have to pay.

This concern was greatest among Hispanic and Black survey respondents.³² Furthermore, a 2018 NORC study found that among the 41% of adults who did not intend to get the flu immunization that season, 15% cited cost as a reason.³³

There has been a rising conversation nationally about equitable maternal care, including the need to ensure optimal prenatal care. This conversation should also include postnatal care and the delivery of appropriate immunizations to newborns.

As immunizations against RSV become available for pregnant women and infants, providers will have to consider the appropriate conversations to have with mothers. According to the CDC, 2 in 3 pregnant women do not receive the recommended flu and tdap immunizations during pregnancy.³⁴ The most common reasons for not receiving the vaccinations are not receiving an offer or referral from a health care provider and concerns about safety risks for the fetus.³⁵ The most commonly reported adverse events in nirsevimab-treated patients were nasopharyngitis, pyrexia, and diarrhea. However, these events were mild to moderate in severity and did not result in any significant safety concerns.



According to the CDC,

2 in 3 pregnant women

do not receive the recommended flu and tdap immunizations during pregnancy.³⁴

Black, non-Hispanic women and those of lower socioeconomic status have lower vaccination rates than women of other races and are less likely to report a health care provider offer or referral for vaccination.³⁶ Studies have found that less than half of Black women accept the flu vaccine and just over half accept the tdap vaccine when offered. This may be due to lower levels of trust in the vaccines, their doctors and information from the CDC.³⁷



My name is Ashley and my triplet daughters caught RSV after being born 28 weeks premature and spending 61 days in the NICU. They were home for just a short time before being rushed back to the hospital due to the RSV. One was taken by ambulance.

My girls were admitted to the PICU and stayed there for over two weeks. On top of RSV, the triplets developed pneumonia. They were on high-flow oxygen and feeding tubes. Nothing like the feeling of helplessness when there is nothing you could do but let the illness run its course.

It was not long before all the medical bills began flowing in. Because I had the girls early, I had to take off work longer than expected. My deductible was supposed to be \$6,400 but my health insurance did not cover a lot of the claims. I was denied Medicaid because my income was a few dollars over their guidelines.

Ashley S.
Conway, South Carolina







This could present a challenge for future recommended immunizations against RSV that could be provided to pregnant women. Providers will have to provide culturally competent, comprehensive education about available immunization options for pregnant women to consider in order to achieve protection for their infants against RSV.

However, adoption of the RSV immunization in the country's Vaccine for Children (VFC) program has tremendous promise to ensure widespread vaccination and equitable access for the children most affected by RSV hospitalizations.

Coverage for routine vaccination for children has been the norm since 1994 under the VFC program. The program enables the federal government to provide free immunizations through pediatric and primary care clinics to children who are uninsured, underinsured, or on Medicaid — more than half of all American kids.

VFC was founded to protect the most vulnerable after public outcry during the 1980s on the terrible health disparities attributable to broad health care system failures that especially impacted the nation's poorest children and children of color. Since its inception, the VFC program has increased immunization levels above 90 percent for many conditions and avoided more than 20 million hospitalizations and 700,000 deaths due to preventable conditions.

Recommendation:

-  Strengthening national and regional surveillance systems for RSV can improve reporting accuracy and consistency. Standardizing reporting criteria, expanding routine testing, and promoting awareness among healthcare providers about the importance of reporting RSV cases are vital steps.
-  Educating healthcare providers, particularly those in primary care settings, about the clinical presentation, diagnosis, and reporting requirements for RSV can help increase case identification and reporting.
-  Educate families on new preventative immunization options when available.
-  Launching culturally competent public health campaigns to educate families about RSV symptoms, the importance of seeking medical attention, and reporting cases can help capture a more accurate representation of the disease burden.
-  Encouraging collaborative efforts between researchers, public health agencies, and healthcare providers can facilitate comprehensive studies on RSV, including its prevalence, impact, and prevention strategies.
-  Ensuring equitable access to new long-acting mAbs for RSV immunization by including them in the Vaccines for Children Program.

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