RSV IMMUNIZATION AND IMMUNITY: IMPACT ON MATERNAL, PEDIATRIC, AND GERIATRIC HEALTH

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Objectives

- Overview of the development and implementation of the RSV immunization and monoclonal antibody
- What we know so far about uptake
- What we know so far about outcomes

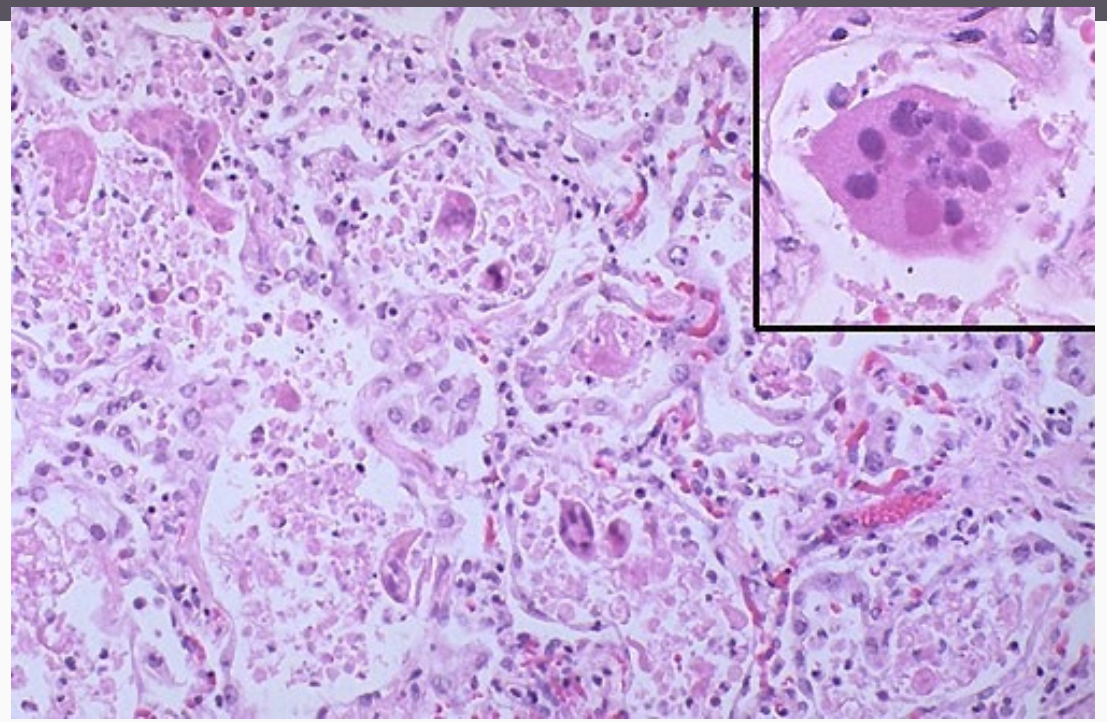
What is RSV?

- **RSV = Respiratory Syncytial Virus**
- **First isolated from chimpanzees in 1955**
- **First isolated from babies in 1957**

What is RSV?

- **Single stranded RNA virus**
- ***Orthopneumovirus* genus of the family *Pneumoviridae* in the order *Mononegavirales***

What is RSV?



Giant cells with inconspicuous, round, pink intracytoplasmic inclusions and acute inflammation

Transmission

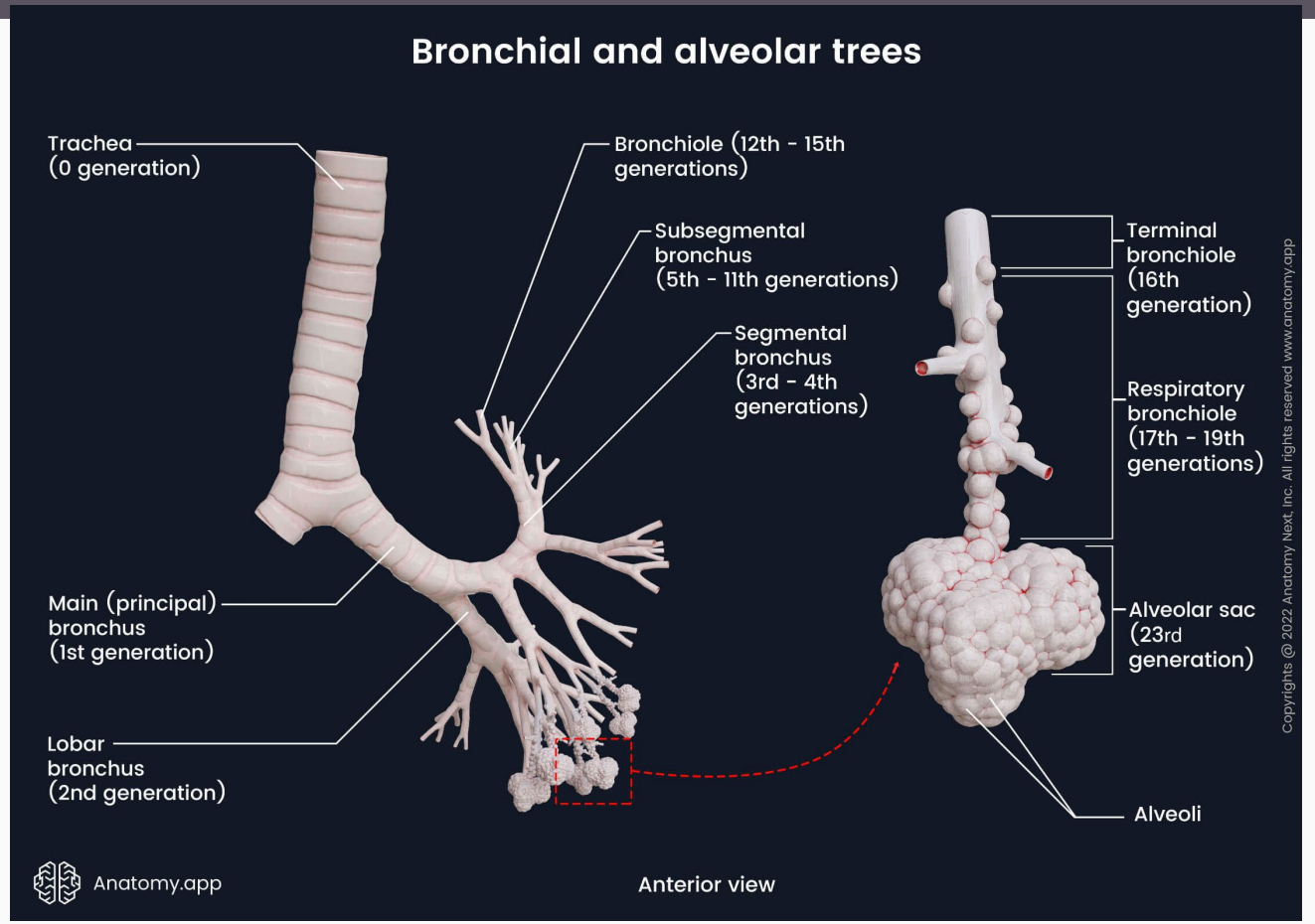
- Transmitted by close contact with saliva/mucous
- Replicated in the upper airways
- Travels to lower airways

Disease

- **The virus particles cause an immune response in which neutrophils to infiltrate and narrow the airways**

- **3 to 7 days after infection do symptoms occur**

Bronchioles



RSV Symptoms

Runny nose

Congestion

Decrease in appetite

Coughing

Sneezing

Fever

Wheezing

Treatment

- **Supportive care**
- **Usually bronchodilators and steroids not recommended unless in special circumstances such as pre-existing lung conditions**

RSV Pathogenicity

- All infants <2 usually affected
- ½ will be infected twice during this time period

Infant morbidity and mortality

- **Globally, RSV causes 60K deaths of hospitalized children under 5**

- **Leading cause of infant hospitalization globally**
- **Second leading cause of infant death globally (after malaria)**

Adult Morbidity and Mortality: JAMA (2024)

- **RSV Hospitalization Surveillance Network (RSV-NET), which captures RSV-associated hospitalizations in 58 counties in 12 states — approximately 8% of the US population**

- **The authors estimated the burden of RSV across seven seasons, 2016-2017 through 2022-2023**

Adult Morbidity and Mortality: JAMA (2024)

- In total during the seven seasons, there were 16,575 RSV-associated hospitalizations in adults (median age, 70)
- Fifty-eight percent of those hospitalized for RSV were women
- 48.9 per 100,000 adults in 2016 to 2017 to 76.2 per 100,000 adults in 2017 to 2018 were hospitalized

Adult Morbidity and Mortality: JAMA (2024)

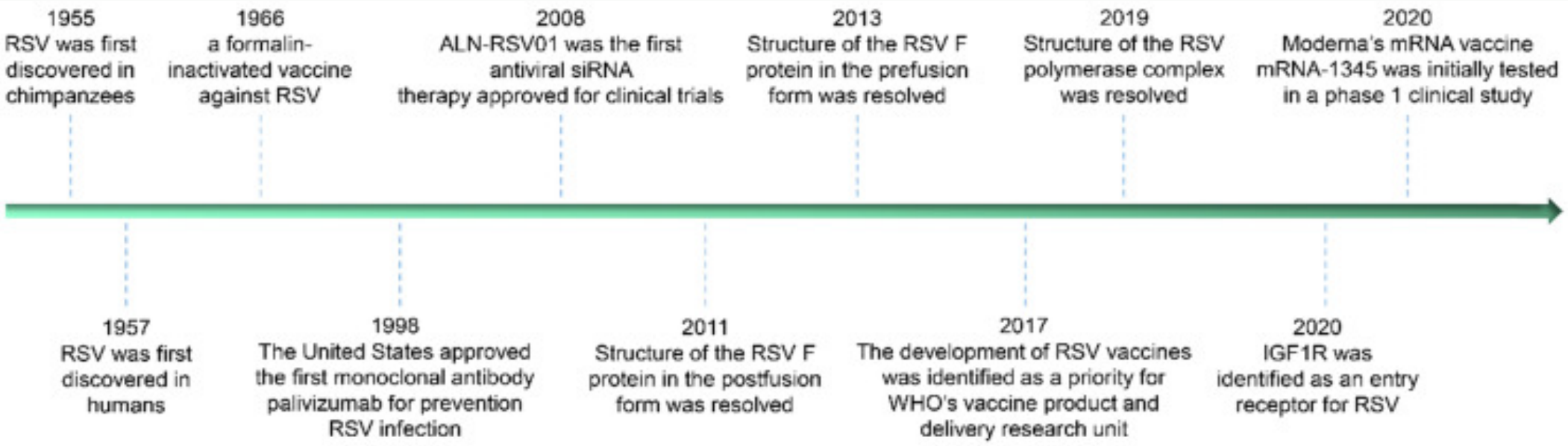
- Adults ages 18 to 49 were hospitalized less frequently than adults 75 and older

- For all outcomes, the 2017-2018 season carried the highest burden of severe illness, with 8,620 in-hospital deaths

Adult Morbidity and Mortality: JAMA (2024)

- Across all seasons, RSV hospitalization was associated with significant use of the ICU, with at least 20% of adult patients requiring intensive care during their hospital stay

Timeline leading to vaccine development



Advent of RSV Immunization

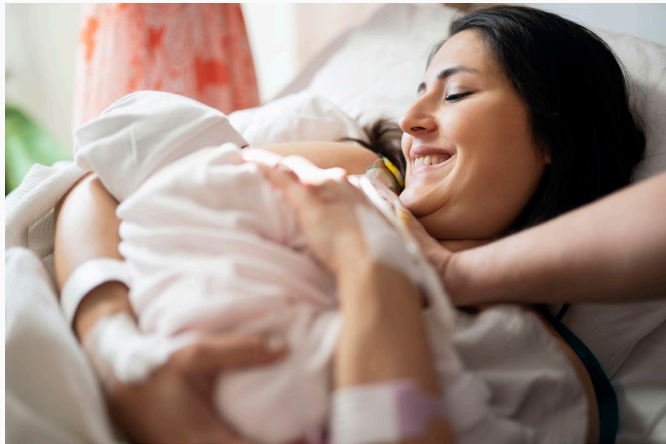
- 2023-2024 season marked the first season an RSV vaccine was available

Medical Society Guidelines and Statements


ACOG

ACOG

- **The American College of Obstetricians and Gynecologists recommends a single dose of Pfizer's bivalent RSVpreF vaccine (Abrysvo) using seasonal administration, to prevent RSV lower respiratory tract infection (LRTI) in infants for eligible pregnant individuals meeting the following criteria:**



ACOG

- are between 32 0/7 and 36 6/7 weeks of gestation
- do not have a planned delivery within 2 weeks
- did not receive the maternal RSV vaccine during a previous pregnancy
- are not planning to have their infant receive a monoclonal antibody, nirsevimab or clesrovimab

ACOG

- In most of the continental United States, based on the seasonal circulation of RSV, pregnant patients are eligible to receive the maternal RSV vaccine from September 1 through January 31 to provide protection during the time of circulation of RSV. (VARIABILITY ALLOWED GIVEN SEASONALITY)

- Can be administered with other vaccines in pregnancy

ACOG

- It is currently not recommended that pregnant patients who received the maternal RSV vaccine during their last pregnancy receive an additional dose during a subsequent pregnancy

- If a pregnant patient received the immunization in a prior pregnancy, then the infant should receive immunization

ACOG

- At least 14 days are needed from the time of maternal vaccination for development and transplacental transfer of maternal antibodies to protect the infant

- Infants born at less than 14 days after receiving the vaccine should receive a monoclonal antibody regardless of maternal vaccination status

ACOG

- Obstetricians are advised to counsel patients that the maternal immunization is not superior to infant immunization

- If infant immunizations are not readily available at birthing hospitals, then maternal immunization should be encouraged

ACOG

- The only RSV vaccine approved for use during pregnancy is Pfizer's bivalent RSVpreF vaccine, Abrysvo
- January 2025 requirement for safety labeling changes to the Prescribing Information for Abrysvo describing an increased risk of Guillain-Barré syndrome (GBS)
- Safety labeling update is due to the results of an observational study suggesting an increased risk of GBS during the 42 days following vaccination in a population of people aged 65 years and older only. Guillain-Barré syndrome has not been reported after vaccination during pregnancy. The FDA has determined that the benefits of vaccination with Abrysvo continue to outweigh its risks

ACOG

- **Noted risks of the immunization include hypertensive disorders in pregnancy and preterm delivery, although data conflicting.**

- **Studies indicating the increase risk of preterm delivery were not statistically significant (incidence of those immunized were close to overall incidence of preterm delivery)**

ACOG

- One dose of nirsevimab (2023) or clesrovimab (2025) is now recommended for all infants younger than 8 months, born during—or entering—their first RSV season, if their mothers did not receive the maternal RSVpreF vaccine or infants were born 14 days or earlier after maternal vaccination

- The optimal timing for administration is at birth or within the first week of birth when infants are born during the RSV season. Infants who do not receive a monoclonal antibody at birth can receive it at any time through 7 months of age (before they turn 8 months), regardless of gestational age at birth or the presence of underlying medical conditions


ACP
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ACP (2026)

Adults aged 75 years or older should receive a protein subunit RSV vaccine

Adults aged 60 to 74 years who are at increased risk for severe RSV may consider receiving a protein subunit RSV vaccine

GSK's Arexvy and Pfizer's Abrysvo

ACP (2026)

- **ACP did not recommend mRNA based vaccine (Moderna's mResvia) due to insufficient data to evaluate long term benefits vs risks**

- Although the evidence was insufficient in adults aged 18 to 59 years who were not pregnant or immunocompromised but were at increased risk for severe RSV, clinicians may consider RSV vaccination based on clinical judgment

Only FDA approved vaccine for this age group that is a protein subunit is Pfizer's Abrysvo

ACP (2026)-GBS risk?

- In adults aged 60 to 74 years who are at increased risk for severe RSV, between 70 (those with 1 chronic condition) and 279 (those with ≥2 chronic conditions) RSV-related hospitalizations per 100,000 person-years are expected to be prevented, while about 1 case of Guillain–Barré syndrome is expected to occur

- These data show a favorable balance of benefits and harms in adults aged 60 to 74 years who are at increased risk for RSV, but the benefits are not as large as in adults aged 75 years or older

ACP

- RSV vaccine is currently administered only once. The need for additional vaccination is unknown

- Adults with recent or active RSV infection should recover before being vaccinated


CDC

CDC-Adults

- CDC recommends a single dose of respiratory syncytial virus (RSV) vaccine for all adults ages 75 and older and adults ages 50–74 at increased risk of severe RSV illness.

- There are three FDA-licensed RSV vaccines recommended for use in adults ages 50 and older: GSK's Arexvy, Moderna's mResvia, and Pfizer's Abrysvo. There is no preference for which vaccine adults 50 and older should receive.

CDC-Adults

- Eligible adults can get an RSV vaccine at any time, but the best time to vaccinate patients is in late summer and early fall before RSV usually starts to spread in the community

- The RSV vaccine is not currently an annual vaccine. People who have already received one dose have completed their vaccination and should not receive another dose at this time

CDC-Adults

- Data on immunogenicity of RSV vaccines and other vaccines when coadministered are currently limited. These limited data show coadministration of RSV with other respiratory virus vaccines may result in lower antibody titers, but the clinical significance of this is unknown.

CDC-Adults

- FDA has approved use of two RSV vaccines — Pfizer's Abrysvo and Moderna's mResvia — in adults ages 18-49 years who are at increased risk for RSV-associated lower respiratory tract infection

RSV Vaccines for Adults

CDC recommends RSV vaccination for:

- Alladultsages75 years and older
- Adults ages 50–74 who are at increased risk for severe RSV (see list below)

Adults who have already received one RSV vaccine dose (including last year) **should not receive** *another dose at this time. RSV vaccine is not currently an annual vaccine.*

Factors associated with increased risk* for severe RSV disease include:


Chronic lung disease


Chronic cardiovascular disease


End-stage renal disease or dependence on dialysis


Diabetes mellitus with end-organ damage or requiring insulin or SGLT2 inhibitor


Moderate or severe immunocompromise


Chronic or progressive neurological or neuromuscular conditions

Other factors include:

» Chronic liver disease
» Chronic hematologic conditions
» Severe obesity (BMI ≥40 kg/m2)
» Residence in a nursing home
» Other conditions or factors that put your patient at increased RSV disease risk

*Self-attestation is sufficient evidence of a risk factor.

What else to know about RSV vaccines for adults:

Benefits: Vaccination reduces a person's risk of RSV hospitalization by 75%.

Risks: Side effects are usually mild and resolve quickly. GSK and Pfizer RSV vaccines have been linked to a higher risk of Guillain-Barré Syndrome (GBS), but GBS after RSV vaccine is still rare, with about 10 extra cases per 1 million adults ages 60+ vaccinated.

Benefits of RSV vaccine outweigh risks. For every 1 million people vaccinated, CDC estimates:

- 2,000-5,400 RSV hospitalizations are prevented
- 130-690 RSV deaths are prevented

For additional Information, scan here:

CS 355818-B 7/9/2025

CDC-Maternal-Infant

- To prevent severe RSV disease in infants, either maternal RSV vaccination (Pfizer's Abrysvo) or infant immunization with a long-acting RSV monoclonal antibody (nirsevimab or clesrovimab) is recommended. Most infants will not need both maternal vaccination and infant RSV antibodies

- Administration of infant RSV antibody is recommended during October through March in most of the U.S. The optimal timing for infant RSV antibody administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization)

CDC-Maternal-Infant

- An infant RSV antibody is recommended for infants younger than 8 months of age who are born during or are entering their first RSV season (typically fall through spring) if:

The mother did not receive RSV vaccine during pregnancy

The mother's RSV vaccination status is unknown

The infant was born within 14 days of maternal RSV vaccination.

CDC-Maternal-Infant

- Children ages 8–19 months are recommended to get nirsevimab shortly before or as early as possible during their second RSV season
- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

CDC-Maternal-Infant

- Clesrovimab is not recommended for children over 8 months of age and does not have FDA approval for children entering their second RSV season

- CDC does not currently recommend nirsevimab for anyone aged 20 months or older

CDC-Maternal-Infant (Ab + IZ)

- Infants born to mothers who may not mount an adequate immune response to RSV vaccination (e.g., people with immunocompromising conditions)
- Infants born to mothers who have medical conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO), or exchange transfusion, leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge)

CDC-Maternal-Infant

- Infant RSV antibodies and routine childhood vaccines can be administered during the same visit. No interval between infant RSV antibodies and live vaccines (such as measles, mumps, and rubella [MMR] and varicella) is necessary


AAFP

AAFP-Adults

- **The AAFP endorses the following RSV vaccination recommendations from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention:**
- **All adults 75 and older should receive a single dose of an RSV vaccine**
- **Adults 60 to 74 who are at increased risk for severe RSV illness should receive a single dose of an RSV vaccine**
- **The RSV vaccine is not currently an annual vaccine, so people who have previously received it do not need to get another dose**

AAFP-Pregnancy

The bivalent RSVpreF maternal RSV vaccine for pregnant patients during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection infants

AAFP-Infants

- In the setting of increasing supply, healthcare providers should administer a single dose of nirsevimab or clesrovimab to all infants aged less than 8 months, as well as children aged 8 through 19 months at increased risk (niresvimab)

U.S. Preventive Services

TASK FORCE

USPSTF

- Recommendation for immunizations not updated since 1996
- Recommends immunizations but defers to other organizations with regard to timely evidence and recommendation

American Academy of Pediatrics

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AAP

Monoclonal antibody administration in infants <8 months (chronological age and not corrected gestational age) born during or entering their first RSV season if:

- pregnant parent did not receive RSVpreF vaccine during this pregnancy
- pregnant parent's RSVpreF vaccination status is unknown
- infant was born <14 days after the pregnant parent's RSVpreF vaccination

AAP

- **Infants and children 8 through 19 months of age at high risk of severe RSV disease and entering their second RSV season, regardless of the RSV vaccination status of the pregnant parent or the child's prior receipt of nirsevimab or clesrovimab when <8 months of age in their first RSV season. High-risk criteria include the following:**

○ Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season

○ Children with severe immunocompromise

○ Children with cystic fibrosis who have either:

– ▪ manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or

– ▪ weight-for-length that is less than the 10th percentile

○ American Indian or Alaska Native children

AAP

- Simultaneous administration of RSV immunization with age-appropriate vaccines is recommended

AAP (Ab + IZ)

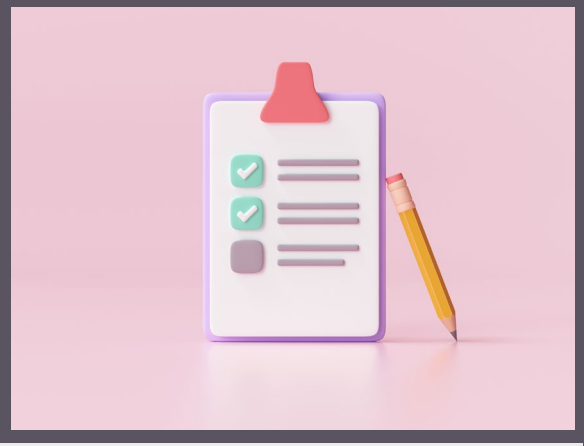
- Infants born to pregnant people who may not mount an adequate immune response to RSV vaccination (eg, pregnant people with immunocompromising conditions)

- Infants born to pregnant people who have medical conditions associated with reduced transplacental antibody transfer (eg, pregnant people living with HIV infection)

- Infants who have undergone cardiopulmonary bypass (see nirsevimab or extracorporeal membrane oxygenation (ECMO), leading to loss of maternal antibodies

- Infants with substantial increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge)

UPTAKE AND OUTCOMES



GSK's Arexy

Arexvy was approximately 77% effective in preventing RSV-associated emergency department encounters and 83% effective in preventing RSV-associated hospitalizations in adults 60 and older. In addition, effectiveness was demonstrated among adults ages 60 years or older with certain immunocompromising conditions and those with end-stage renal disease and in all adults 75 years or older.-CDC

Second season data pending

Abrysvo

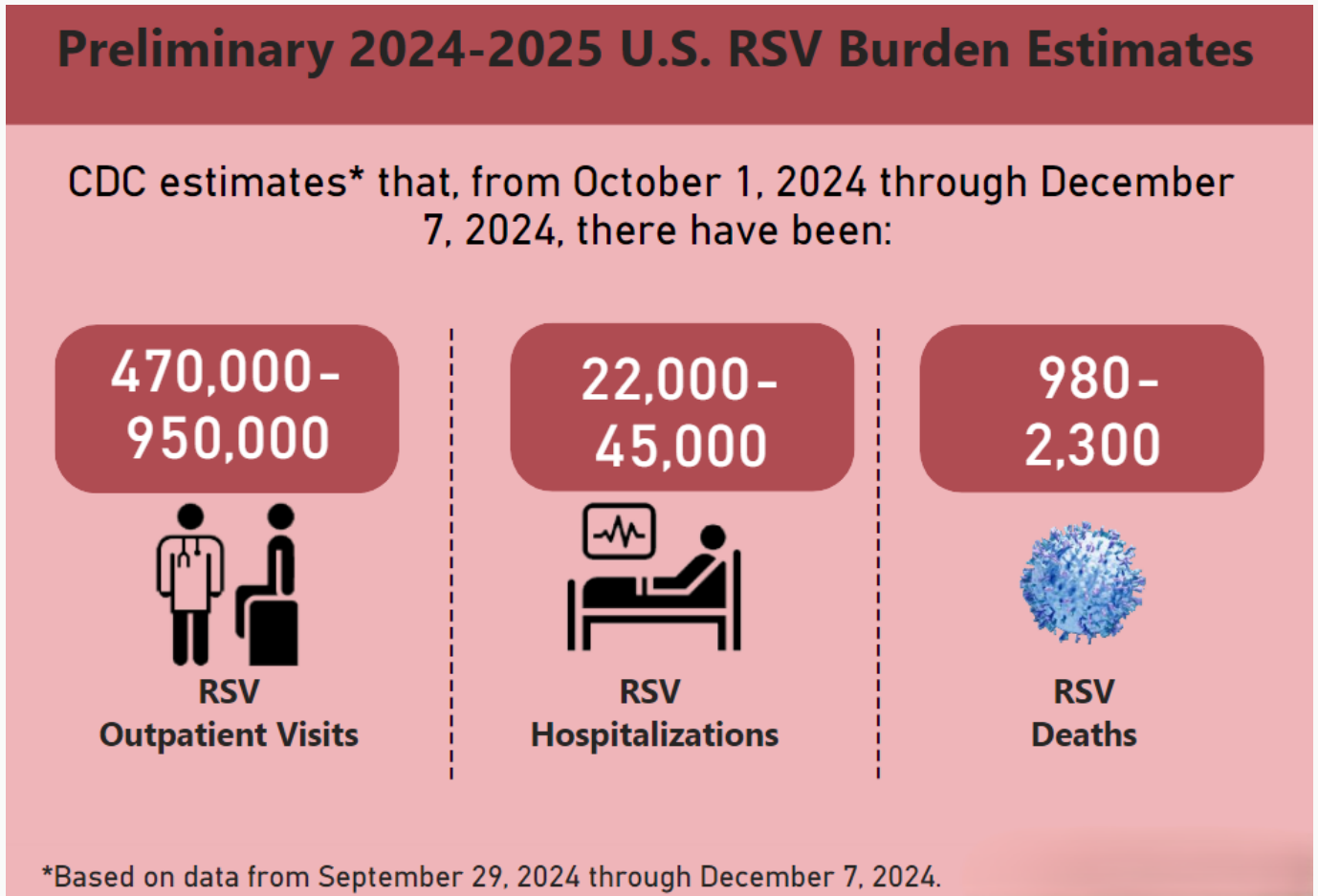
In studies of the real-world effectiveness of Abrysvo during the 2023–2024 RSV season, the first RSV season after licensure, Abrysvo was approximately 79% effective in preventing RSV-associated emergency department encounters and 73% effective in preventing RSV-associated hospitalizations in adults 60 and older. In addition, effectiveness was demonstrated among adults ages 60 years and older with certain immunocompromising conditions and those with end-stage renal disease and in all adults ages 75 years and older.-CDC

Second season data pending

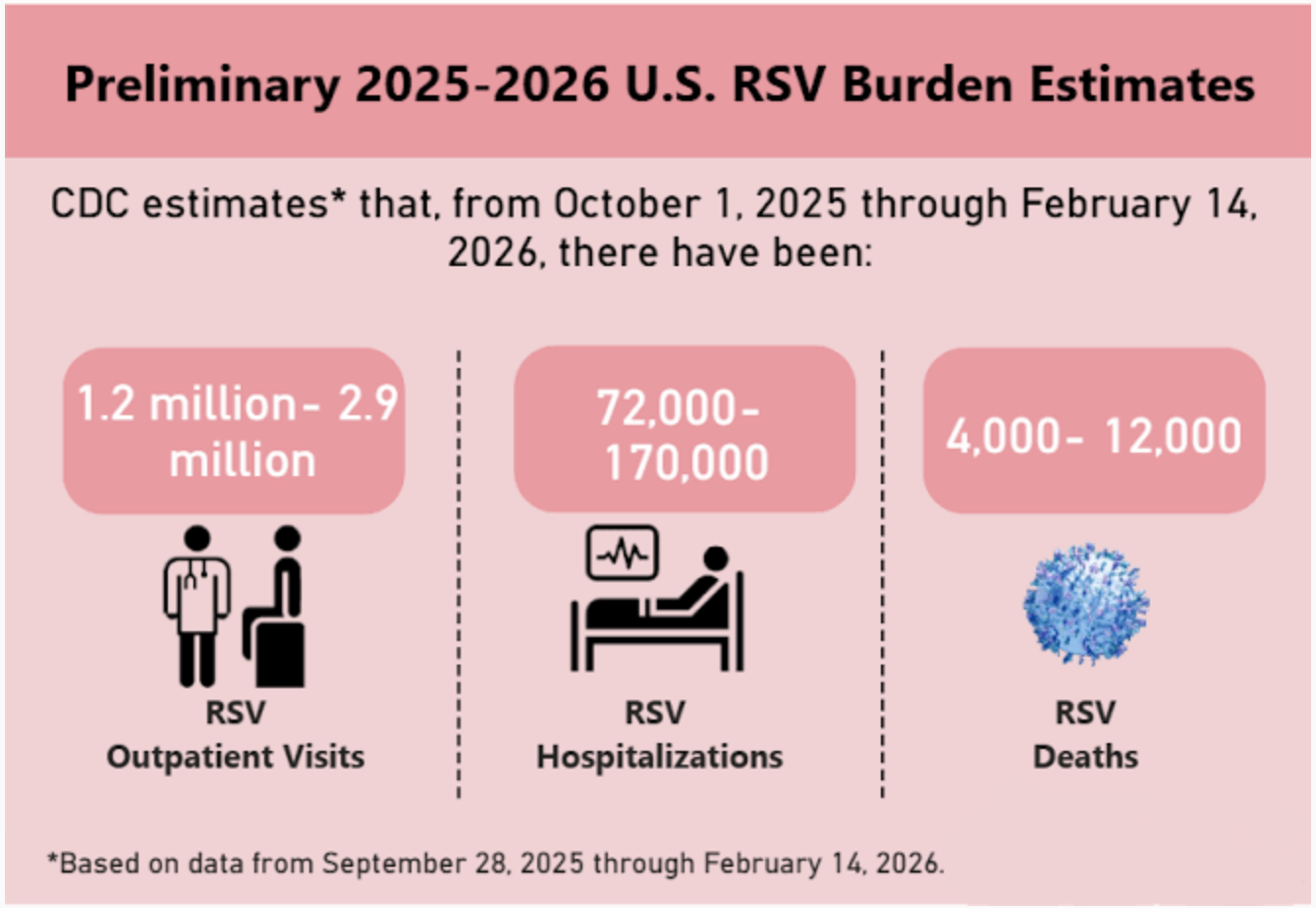
MResvia

Due to the recency of mResvia licensure, real-world vaccine effectiveness against RSV-associated hospitalization and other severe illness cannot yet be estimated

2024-2025-CDC



2025-2026-CDC



Maternal-Infant Outcomes

Administration of nirsevimab (Beyfortus) was 90% effective in preventing infants from being hospitalized with respiratory syncytial virus (RSV), according to a new report led by the Centers for Disease Control and Prevention (CDC)

Maternal-Infant Outcomes

CDC telephone survey- just over 500 women with an infant under 8 months, 41% said their infant received nirsevimab and 22% said their infant definitely would receive it.-March 2024

In September 2023, health officials maternal RSV vaccine was approved. About 17.5% of eligible pregnant people had been vaccinated as of Jan. 31 2024

Maternal-Infant Outcomes

699 infants hospitalized with acute respiratory illness from October 2023 through February 2024 were evaluated. About 1% of those who tested positive for RSV had received nirsevimab at least a week prior to developing symptoms, while 18% of those with a negative RSV test had received nirsevimab. The median time from monoclonal antibody administration to symptom onset was 45 days.-AAP

CONCLUSIONS-Pregnancy

- Pregnant patients who do not plan giving their infant the monoclonal antibody should be immunized with Pfizer's Abrysvo (only approved immunization for pregnancy) 32-36 weeks gestational age
- Some limited data showing possible increase in pregnancy hypertensive disorders and preterm labor
- No cases of Gulllian Barre Syndrome as side effect in pregnant patients
- Only approved for one pregnancy

Conclusion-Adults

- **CDC endorses all 3 commercially available RSV vaccines for adults 75 and older**
- **ACP endorses only the protein subunit vaccine (GSK's Arexvy and Pfizer's Abrysvo) for ages 75 or older and adults with increased risk 60-74 years of age**
- **18-59 age group (ACP): Certain circumstances and only Abrysvo is recommended (protein subunit vaccine)**
- **18-59 age group (CDC): Certain circumstances and Abrysvo and mResvia acceptable**

Conclusion-Infants

- 2 monoclonal antibodies now available (nirsevimab or clesrovimab)
- Nirsevimab is shown to be 90% effective to prevent hospitalization
- Give under 8 months and if mother was not immunized or special circumstances that warrant maternal immunization + monoclonal antibody (< 14 days after maternal immunizations, neonatal bypass/ECMO, immunocompromised mother)
- AAP and CDC expands circumstance of hemodynamically significant CHD and hospitalization which discharge oxygen required

Conclusion-Infants

- Give at 8-19 months of age for second season high risk conditions (immunocompromised, chronic lung disease, congenital heart disease, Native Alaskan or American Indian)

- Nirsevimab

Thank you!!!!

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Friday, May 15

Infectious Disease & Immunization Summit 2026

RSV Immunization and its Impact on Maternal, Pediatric, and Geriatric Care

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