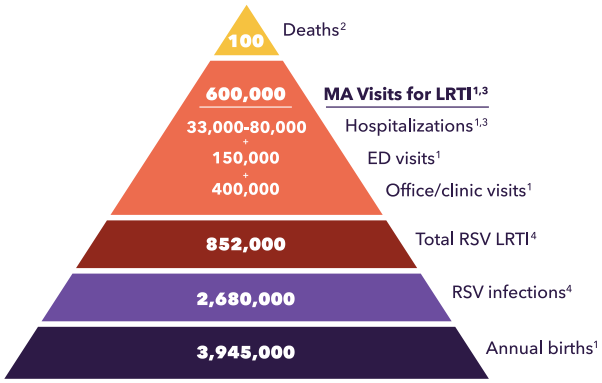
All Infants Need Protection From RSV During Their First RSV Season

1 in 7 infants developed RSV LRTI requiring medical attention annually[1]



Annual RSV burden of infants <12 months of age in the United States*

Data from prior to broad availability of routine prevention

- Based on the Houston Family Study, two-thirds of all infants were infected with RSV in the first year of life, which begins with cold-like symptoms. One-third of those RSV infections progressed to more severe LRTIs; such as bronchiolitis and pneumonia[4]
- Most of the healthcare utilization related to RSV in children <12 months occured in outpatient settings in the US[5]

RSV bronchiolitis has been the leading cause of infant hospitalization in the US[6]

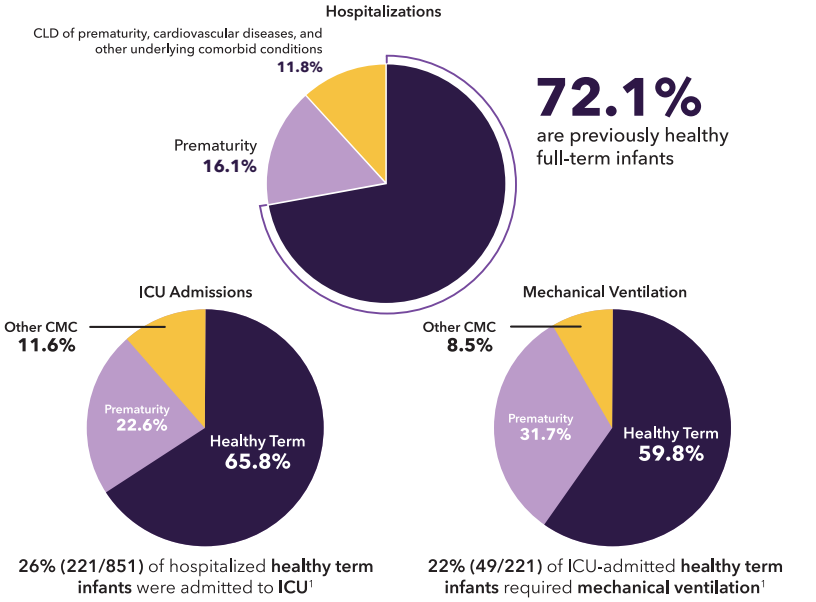
Most infant hospitalizations due to RSV are in healthy, term infants

Infant, laboratory-confirmed RSV hospital admissions (n=1180) from a study of 20 hospitals in 4 states of US population from Oct 2014-Apr 2015[7]

Severe RSV Disease is Unpredictable

- Severe RSV disease is unpredictable in that any infant (born at term and healthy, premature, or with co-morbid conditions) can be hospitalized in their first RSV season

Morbidity due to RSV infection is not confined to pre-term infants with underlying conditions. **Term infants without known comorbidities account for about 75% of medically attended RSV LRTI burden in the US during an infants' first RSV season[7-9]**



26% (221/851) of hospitalized **healthy term infants** were admitted to **ICU**[1]

22% (49/221) of ICU-admitted **healthy term infants** required **mechanical ventilation**[1]

Data from the Influenza Hospitalization Surveillance Network between October 2014 and April 2015

CLD, chronic lung disease; ED, emergency department; ICU, intensive care unit; LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus
*Estimated typical RSV season based on references.[1-4]

References: 1. Rainisch G, et al. *Vaccine*. 2020;38(2):251-257. **2.** Hansen CL, et al. *JAMA Netw Open*. 2022;5(2):e220527. **3.** McLaughlin JM, et al. *J Infect Dis.* 2020;jiaa752. **4.** Glezen WP, et al. *Am J Dis Child.* 1986;140(6):543-546. **5.** Tong S, et al. *J Glob Health.* 2020;10(2):020422. **6.** Suh M, et al. *J Infect Dis.* 2022;226(Suppl 2):S154-S163. **7.** Arriola CS, et al. *J Pediatric Infect Dis Soc.* 2020;9(5):587-595. Suppl. Tables 4-6. **8.** Gantenberg et al. *J Infect Dis.* 2022;226(suppl 2):S164-S174. **9.** Hall CB, et al. *Pediatrics.* 2013;132(2):e341-e348.

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Understanding RSV Season and Prevention

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No broadly recommended drug treatment

There are limited options for targeted treatment of RSV. Treatment with antivirals is largely restrictive and most cases need to be managed with supportive care. Highlighting the importance of preventative and protective measures[1]

RSV Prevention Strategies and Seasonality[2,3]

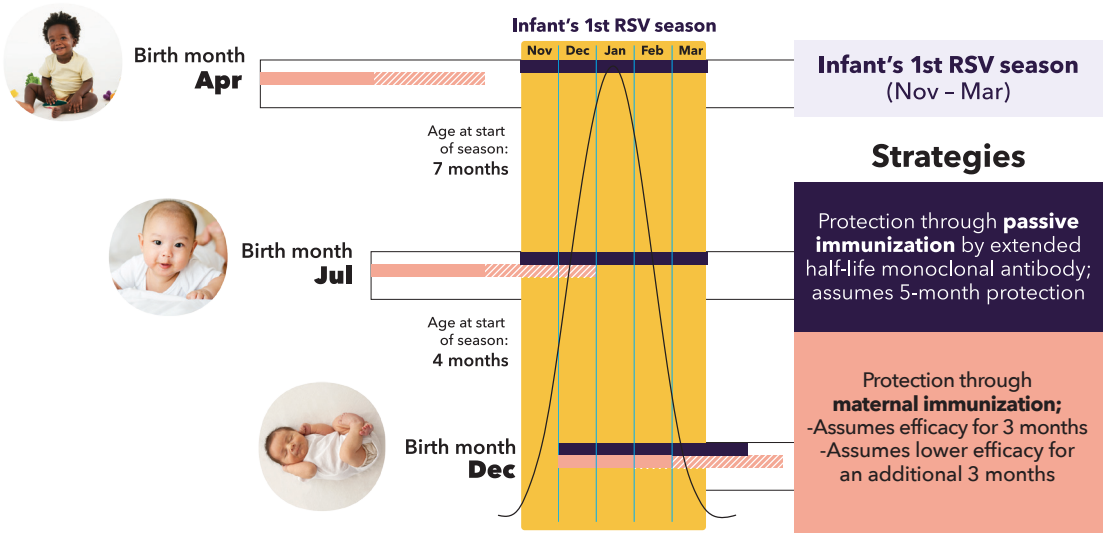

Figure adapted from Janet S, et al. 2018. November to March season shown.

CDC: Relative Advantages and Disadvantages of Maternal RSVPreF Vaccination and Nirsevimab Administration to Infants to Prevent RSV LRTI in Infants[4]

Maternal RSVpreF vaccination

Advantages

- Provides protection immediately after birth
- Might be more resistant to potential mutations in F protein*

Disadvantages

- Protection potentially reduced if fewer antibodies are produced or are transferred from pregnant person to baby (eg, pregnant person is immunocompromised or infant born soon after vaccination)
- Potential risk for preterm birth and hypertensive disorders of pregnancy

Infant nirsevimab administration

Advantages

- Studies of antibody levels suggest that protection might wane more slowly than protection from the maternal RSV vaccine
- Assures direct receipt of antibodies rather than relying on transplacental transfer
- No risk for adverse pregnancy outcomes

Disadvantages

- Requires infant injection

Figure adapted from Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR, October 13, 2023, Vol. 72, No. 41

RSV, respiratory syncytial virus.
*Maternal RSV vaccination results in a polyclonal immune response, which is expected to be more resistant to potential mutations in the RSV F protein than a monoclonal antibody product.

References:1. Domachowske JB, et al. *Infect Dis Ther.* 2021;10(Suppl 1):47-60. **2.** Janet S, et al. *Hum Vaccin Immunother.* 2018;14(1):234-244. **3.** Kampmann B, et al. *N Engl J Med.* 2023;388(16):1451-1464. **4.** Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR, October 13, 2023, Vol. 72, No. 41.

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