

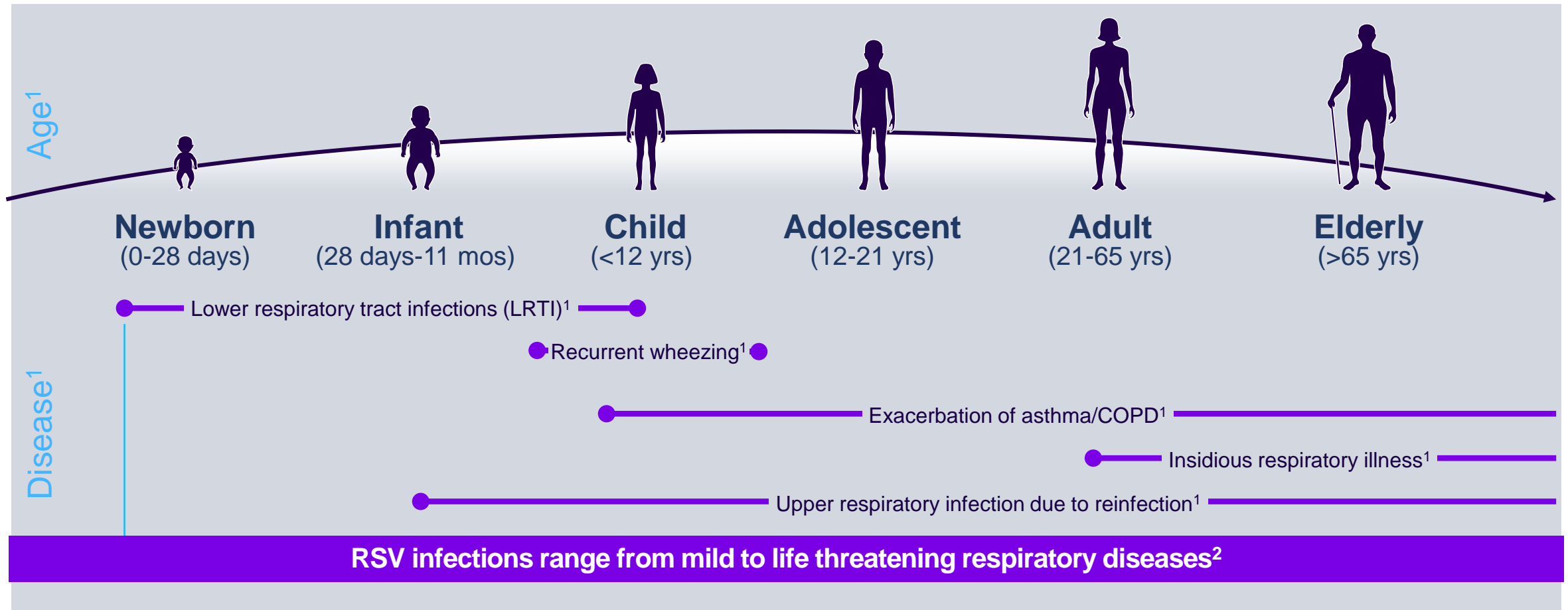


# The burden of RSV in infants

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# RSV Is a Common Respiratory Virus With Symptoms Varying by Age Group

MAT-BE-2400348 V1.0 April 2024

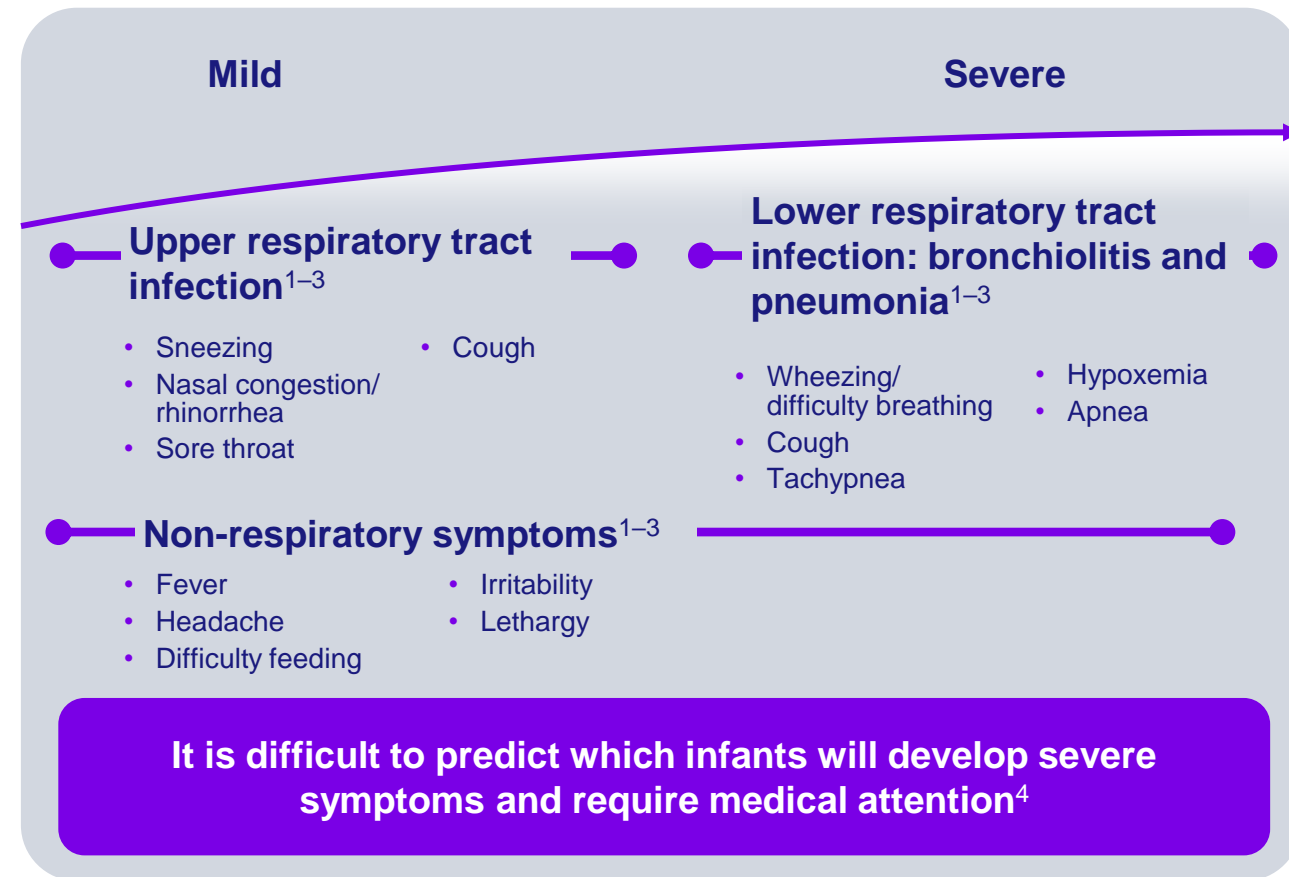


**COPD:** chronic obstructive pulmonary disease; **LRTI:** lower respiratory tract infections; **MOS:** months; **YRS:** Years

1. Adapted from: Openshaw PJM, et al. *Annu Rev Immunol.* 2017;35:501-532. 2. Carvajal JJ, et al. *Front Immunol.* 2019;10:2152.

# The severity of symptoms of RSV ranges from mild to severe

- RSV infections can vary from a **mild upper respiratory illness** to **life-threatening bronchiolitis** and **pneumonia**<sup>1,2</sup>
- For most individuals, RSV infections are **mild** and **self-limiting**; however, **some people**, particularly infants under 12 months of age, **may develop severe symptoms**<sup>2</sup>
- During the **first RSV season**, **all infants** may be susceptible to **severe RSV disease**<sup>4</sup>
- Severe disease is **unpredictable** in all infants<sup>5</sup>
- RSV remains the **leading cause of hospitalization** in the first year of life<sup>6</sup>



RSV, respiratory syncytial virus.

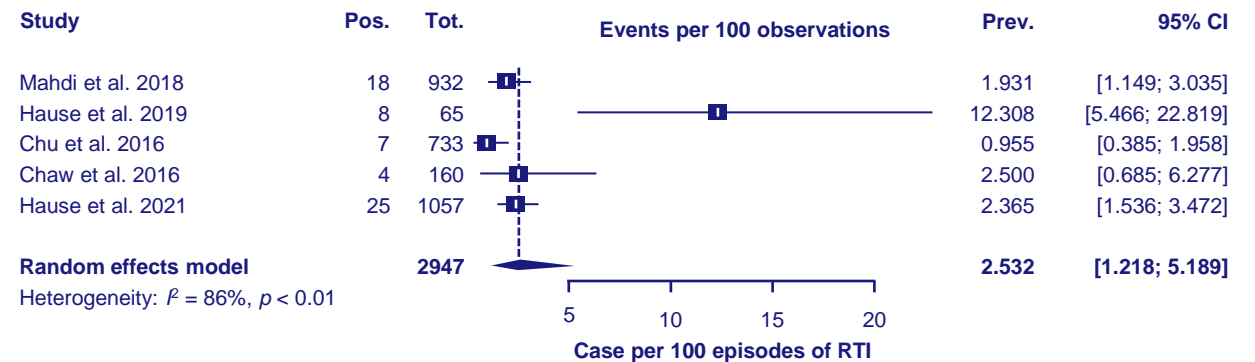
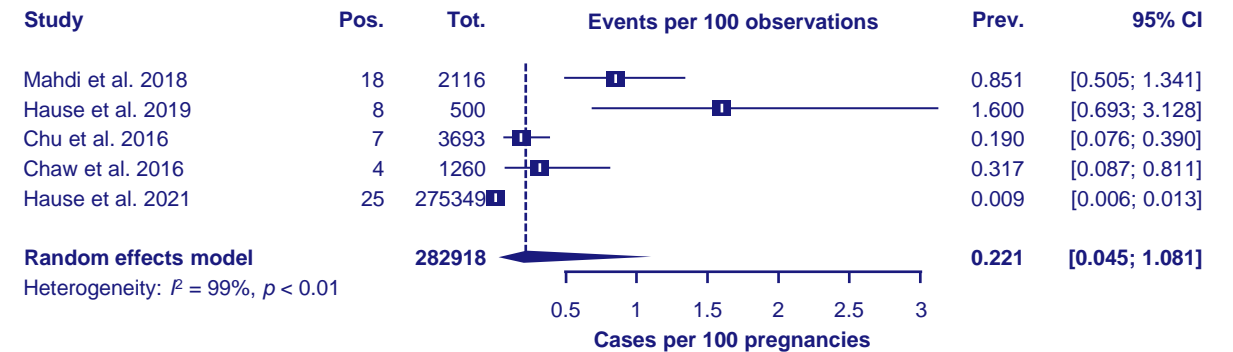
1. Smith DK, et al. *Am Fam Physician* 2017;95:94-9; 2. Mayo Clinic. Respiratory syncytial virus (RSV). <https://www.mayoclinic.org/diseases-conditions/respiratory-syncytial-virus/symptoms-causes/syc-20353098> (Accessed Aug 2023); 3. Eiland LS. *J Pediatr Pharmacol Ther* 2009;14:75-85; 4. Esposito S, et al. *Front Immunol* 2022;13:880368; 5. Hall CB, et al. *Pediatrics* 2013;132:e341-8; 6. Suh M, et al. *J Infect Dis* 2022;226(Suppl 2):S154-63.

# For most adults, RSV infections are mild and self-limiting

## Severe RSV infection in pregnant women seems to be uncommon

- RSV is not commonly detected among pregnant women
  - in some rare cases RSV can result in severe infections requiring hospitalization (0.003% of all pregnancies)

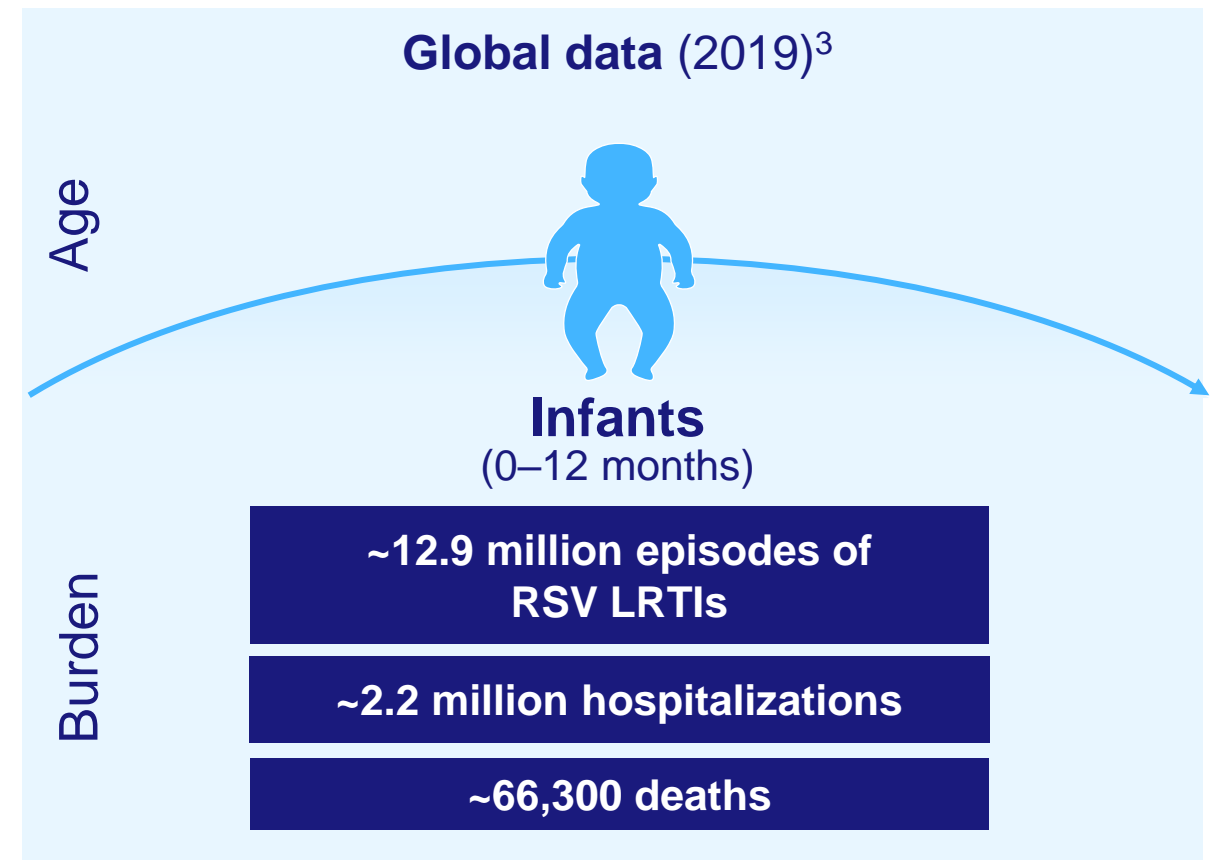
Incidence of RSV infections among sampled pregnancies and cases of RTIs in sampled pregnancies



CI, confidence interval; pos., positive; prev., prevalence; RTI, respiratory tract infection; RSV, respiratory syncytial virus; tot., total.  
 Riccò, M, et al. *Women* 2022;2:147–60.

# RSV results in a large disease burden for newborns and infants globally

- Globally, **LRTIs** associated with RSV infection are a **leading cause of hospitalizations** among newborns and infants<sup>1–4</sup>
- As RSV disease is associated with a **high health and economic burden**, the development of RSV prevention strategies is a **public health priority**<sup>5</sup>



LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.

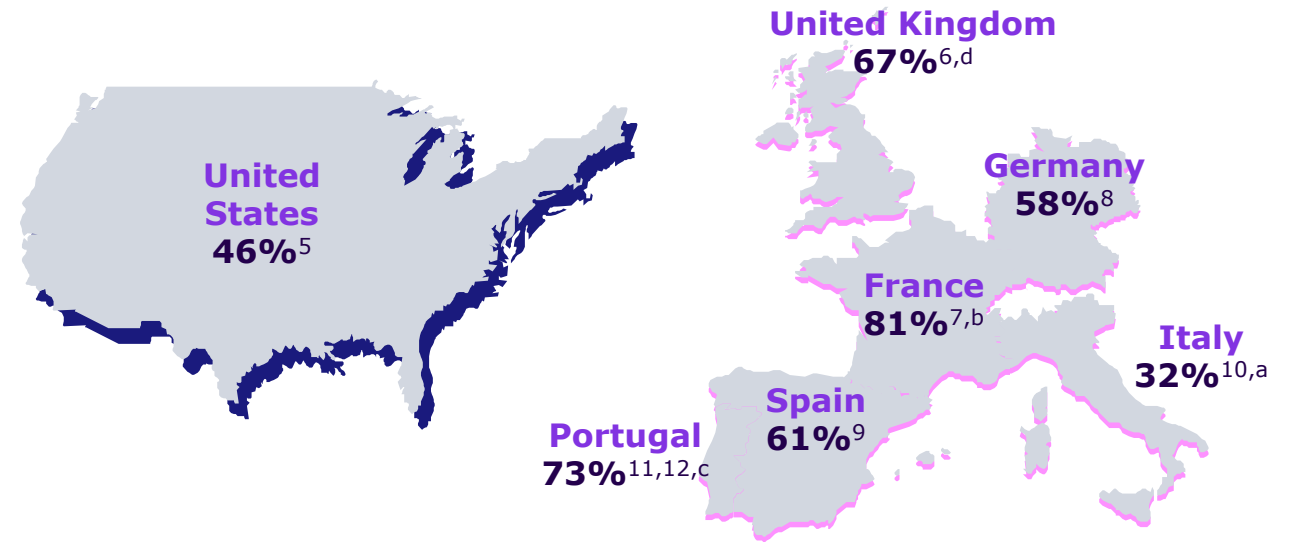
1. Shi T, et al. *Lancet* 2017;390:946–58; 2. Rha B, et al. *Pediatrics* 2020;146:e20193611; 3. Li Y, et al. *Lancet* 2022;399:2047–64; 4. Wildenbeest JG, et al. *Lancet Respir Med* 2023;11:341–53;

5. WHO. WHO Preferred Product Characteristics for Respiratory Syncytial Virus (RSV) Vaccines. 1 Jan 2017. <https://www.who.int/publications/i/item/WHO-IVB-17.11> (Accessed May 2023).

# RSV is the leading cause of LRTIs among infants and young children worldwide<sup>1,2</sup>

- RSV is a commonly contracted during **early infancy**, but may be **recurrent** throughout life<sup>3</sup>
- Almost **70% of infants** will be infected with RSV in their **first year of life**, and **virtually all children** contract the disease before the **age of 2**<sup>4</sup>
  - **~1 in 3** infections can progress to a **LRTI** in an infant's first year<sup>4</sup>

Estimated percentage of acute LRTI attributable to RSV infection\*



LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus. Data are derived from different studies and over different years.


<sup>a</sup>Only includes hospitalizations due to bronchiolitis; bRSV was a cause of 28% of all hospitalization cases in infants in France. <sup>c</sup>Includes children under 4 years of age. <sup>d</sup>Refers to data from England only 0-11 months.  
1. Nair H, et al. *Lancet*. 2010;375(9725):1545-1555. 2. Shi T, et al. *Lancet*. 2017;390(10098):946-958. 3. Mayo Clinic. Respiratory syncytial virus (RSV). <https://www.mayoclinic.org/diseases-conditions/respiratory-syncytial-virus/symptoms-causes/syc-20353098> (Accessed Aug 2023); 4. Glezen WP, et al. *Am J Dis Child* 1986;140:543-6. 5. Rha B, et al. *Pediatrics*. 2020;146(1):e20193611. 6. Reeves RM, et al. *Infl Other Respir Vir*. 2017;11(2):122-129. 7. El-Hajje MJ, et al. *Eur J Pediatr*. 2008;167(4):435-436. 8. Wick M, et al. 2022-11, ISPOR Europe 2022, Vienna, Austria. 9. Sanchez-Luna M, et al. *Curr Med Res Opin*. 2016;32(4):693-698 10. Cangiano G, et al. *Pediatr Pulmonol*. 2016;51(12):1330-1335. 11. Sáez-López E et al. *J Clin Virol*. 2019;121:104200. 12. Bandeira T et al, *Infl Other Respir Vir*. 2022;17(1):e13066.

# RSV is the leading cause of acute bronchiolitis in infants

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***“RSV accounts for 50 to 80% of all hospitalizations for bronchiolitis during seasonal epidemics in North America”***

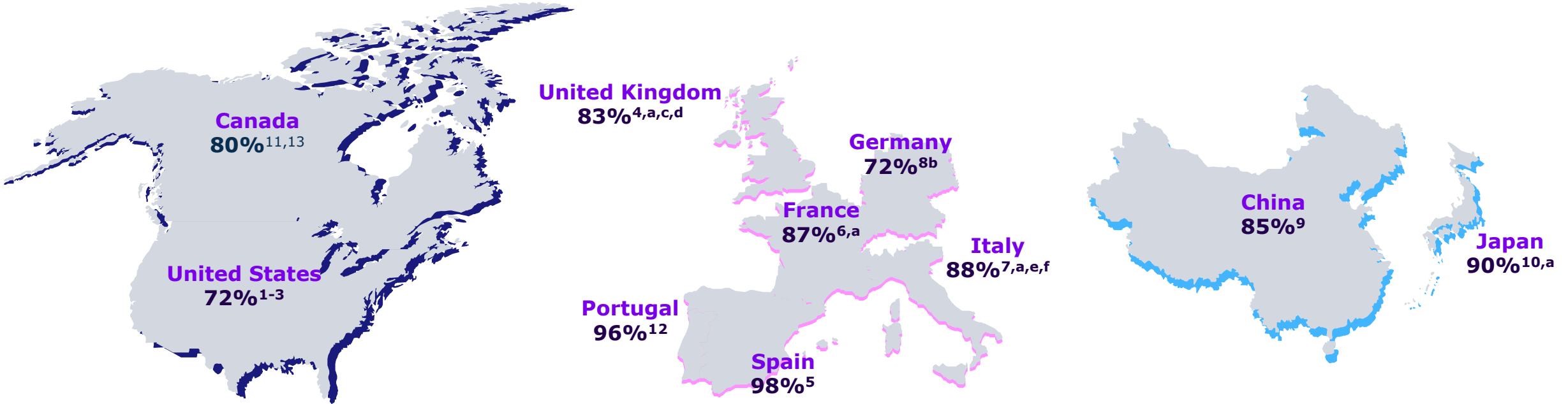


Virus 	Approximate percentage of viruses in hospitalized children with bronchiolitis
RSV	50–80%
Human rhinovirus	5–25%
Parainfluenza virus	5–25%
Human metapneumovirus	5–10%
Coronavirus*	5–10%
Adenovirus	5–10%

\*OC43, 229E, NL63, HKU1 (non-SARS seasonal coronaviruses). RSV, respiratory syncytial virus. Meissner HC *N Engl J Med* 2016;374:62–72.

# Most hospitalizations for RSV occur in healthy full-term infants and young children

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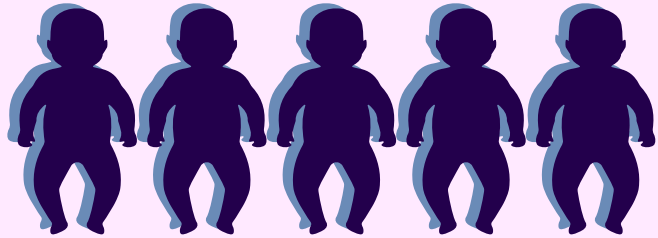


Data are derived from different studies and over different years <sup>a</sup>Includes children  $\geq 1$  year of age. <sup>b</sup>Data may include preterm healthy infants. 82% of the full cohort was born at term c.May include infants with comorbid conditions. 93% of the full cohort was born healthy. <sup>d</sup>UK data relates to national data from Scotland. <sup>e</sup>Includes infants born between week 34-37 which consisted around 18% of the full cohort. <sup>f</sup>Cardio-respiratory disease (CHD, CLD) were excluded from the healthy cohort.

1. Hall CB, et al. *Pediatrics*. 2013;132(2):e341-e348. 2. Arriola CS, et al. *J Pediatric Infect Dis Soc*. 2020;9(5):587-595. 3. Rha B, et al. *Pediatrics*. 2020;146(1):e20193611. 4. Thwaites R, et al. *Eur J Pediatr*. 2020;179(5):791-799. 5. Sanchez-Luna M, et al. *Curr Med Res Opin*. 2016;32(4):693-698. 6. Demont C, et al. *BMC Infect Dis*. 2021;21(1):730. 7. Barbati F, et al. *Vaccines*. 2020;8(1):15. 8. Hartmann K, et al. *J Infect Dis*. 2022;jiac137. 9. Ren L et al. (2021) ESPID 2021,24-29 May 2021 [https://www.sanofipasteurscientificevents.com/posterbook/esp/abstracts/1298/ESPID - Sanofi Pasteur Supported Abstracts \(sanofipasteurscientificevents.com\)](https://www.sanofipasteurscientificevents.com/posterbook/esp/abstracts/1298/ESPID - Sanofi Pasteur Supported Abstracts (sanofipasteurscientificevents.com))10. Kobayashi, et al. *Ped Intl*. 2021;0:1-7. 11. Mitchell I, et al. *Can Respir J*. 2017;2017:4521302. 12. Mendes-da-Silva A, et al. *Pulmonology*. 2019;25(3):154-161. 13. Pisesky A, et al. *PLoS One*. 2016;11(3):e0150416.

# The burden of RSV in infants is huge

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## Virtually ALL

children will be infected by RSV by 2 years of age<sup>3</sup>

### Outpatient Visits



## 1 in 5

children will need outpatient care **by age 2** due to RSV<sup>1</sup>

### Hospitalization



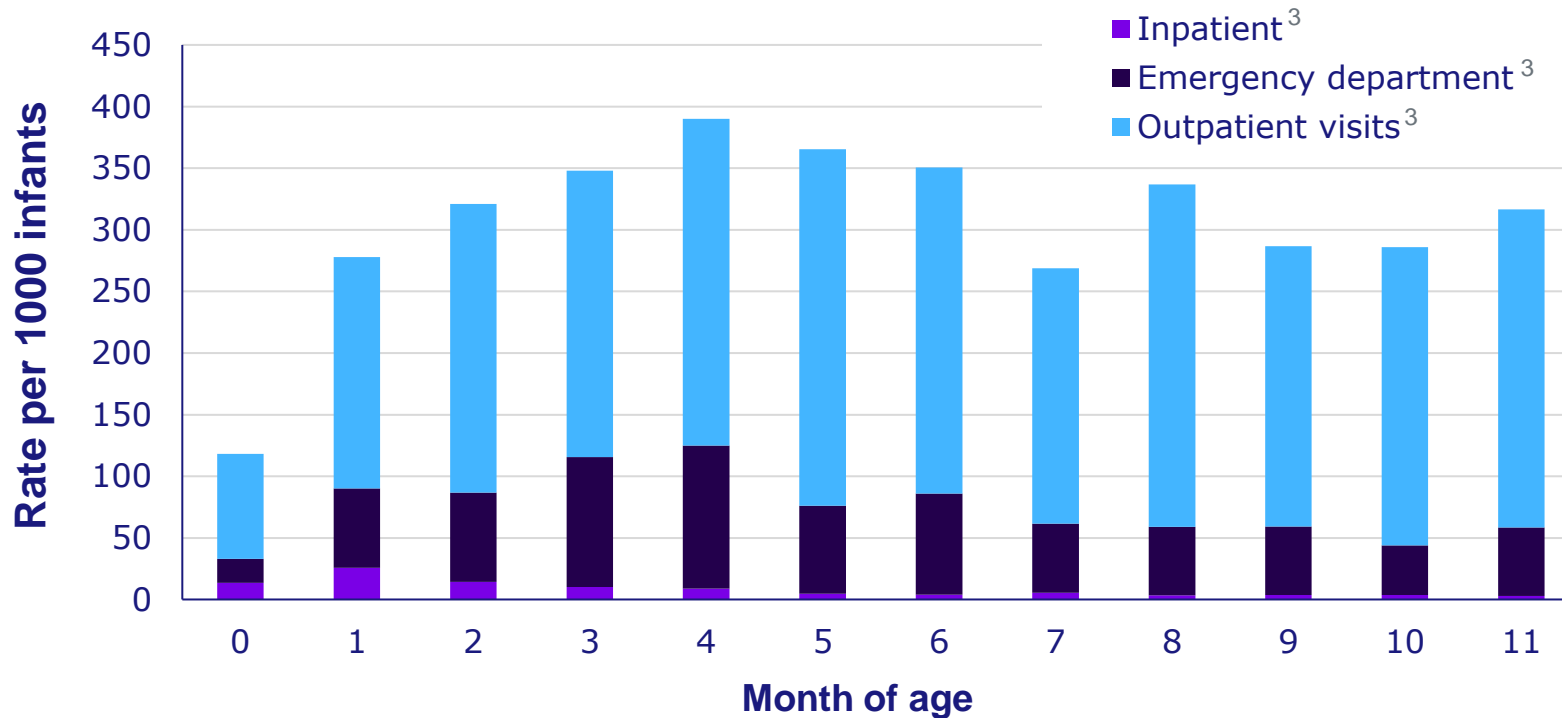
## 1 in 50

infants will be hospitalized within the **first year of life**<sup>2</sup>

1. Lively JY, et al. *J Pediatric Infect Dis Soc.* 2019;8(3):284-286. 2. McLaughlin, et al. *JID*, 2020;jjaa752. 3. Glezen, WP, et al. *Am J Dis Child* 1986;140(6):543-546.

# As well as hospitalizations, RSV is also responsible for a large outpatient burden among infants

## Estimated rate of medically attended RSV in first year of life by month of age in the US



The rate of outpatient clinic and emergency care visits is a major burden throughout the entire first year of life<sup>1-3</sup>

RSV, respiratory syncytial virus.

1. Hall CB, et al. *Pediatrics* 2013;132:e341-8; 2. Lively JY, et al. *J Pediatric Infect Dis Soc* 2019;8:284-6; 3. Rainisch G, et al. *Vaccine* 2020;38:251-7.

# RSV infection in infants does not only cause acute disease

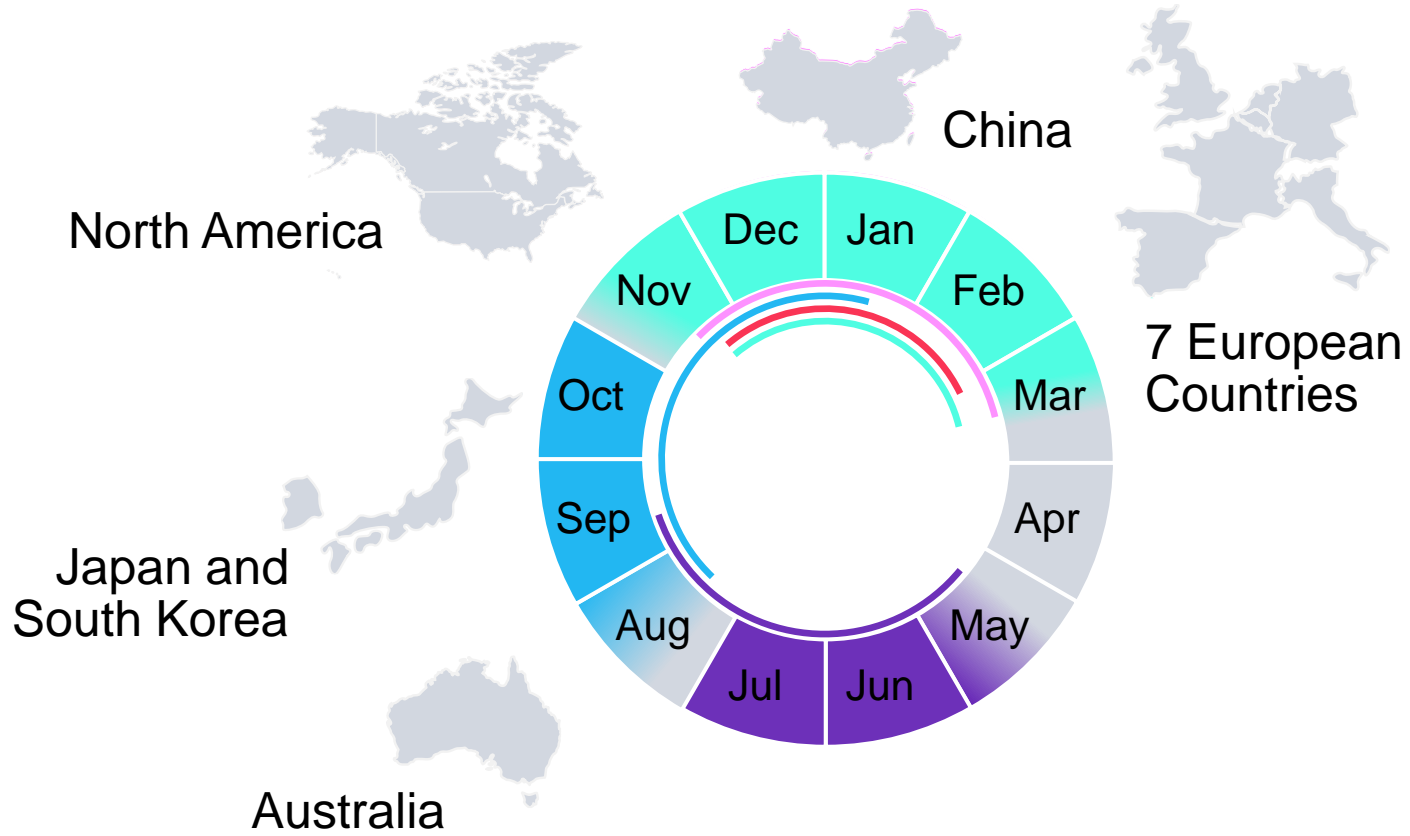
- Although there are conflicting data, there is evidence that **RSV infection** in early childhood is associated with **subsequent childhood recurrent wheeze and asthma**<sup>1</sup>
- There is also evidence to suggest that **respiratory sequelae** may also continue into **early adulthood**<sup>2</sup>

CI, confidence interval; OR, odds ratio; RSV, respiratory syncytial virus.

1. Shi T, et al. *J Infect Dis* 2020;222 (Suppl 7):S628–S633; 2. Ruotsalainen M, et al. *Pediatr Infect Dis J*. 2010 Sep;29(9):872-4.

# RSV Is Seasonal, With Peak Incidence Varying by Region<sup>1,2</sup>

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## Duration of Season

### Northern Hemisphere:

generally, from **October/November** to **February/March**.

### Southern Hemisphere:

generally, from **May to September** (aligned with cold season temperatures)

### Tropical and Subtropical Climates:

less consistent—peak closely aligned with **rainy season** and/or higher temperatures

1. Staaedgaard L, et al. *Influenza Other Respir Viruses*. 2021;10.1111/irv.12885. 2. Obando-Pacheco P, et al. *J Infect Dis*. 2018;217(9):1356-1364.

# Summary



For most adults, RSV infections are mild and self-limiting



RSV results in a large disease burden for infants globally



RSV is the leading cause of LRTI hospitalization in infants



Most infants hospitalized for RSV-associated LRTIs are otherwise healthy and born at full term



There is an urgent need to prevent RSV disease in all infants<sup>1-3</sup>

LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.

1. WHO preferred product characteristics of monoclonal antibodies for passive immunization against respiratory syncytial virus (RSV) disease. Available from: <https://www.who.int/publications/i/item/9789240021853> [Accessed Aug 8, 2022]. 2. World Health Organization. WHO Preferred Product Characteristics for Respiratory Syncytial Virus Vaccines. 2017. <https://apps.who.int/iris/bitstream/handle/10665/258705/WHO-IVB-17.11-eng.pdf> [Accessed Aug 8, 2022]. 3. Esposito S et al. *Front Immunol.* 2022;13:880368.