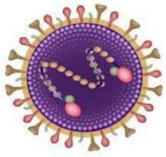
Respiratory Syncytial Virus

What is RSV?

Respiratory syncytial virus



- Enveloped single-strand RNA pneumovirus within the *Paramyxoviridae* family[1]
  - 2 main subgroups: A/B – antigenically related
- In temperate climates, annual epidemics occur during winter[2]
- Circulation overlaps with seasonal influenza[2]

Most common cause of ALRI in children <5 years, and a major cause of ALRI-associated hospitalisation[3]

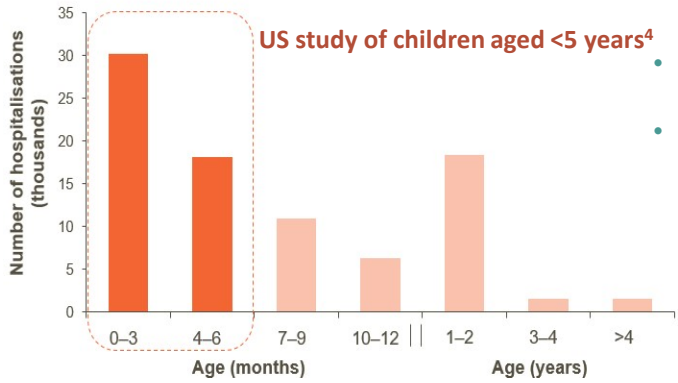
- In children <5 years there were an estimated:

33.1 millior annual case of RSV-associated ALRI[3]

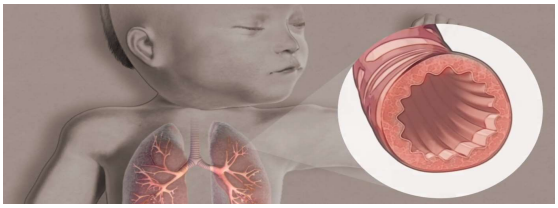
3.2 million RSV-associated ALRI requiring hospitalisation (of which 1.4 million ~45% in children < 6 months of age) [3]

94,600–149,400 deaths due to RSV-associated ALRI[3]

Who is most at risk of RSV?



- Almost all children will have experienced an RSV infection by 2 years of age[5]
- Very young infants have the greatest risk of severe illness caused by RSV
- The highest priority target population is the RSV-naïve child[6]



No specific treatment[5] or currently approved vaccine[1]

Treatment of RSV infection in children is primarily **limited to supportive care**: supplemental oxygen and fluid replacement[7]

Passive immunization through maternal vaccination could potentially prevent RSV disease after birth, by protecting vulnerable infants.[8]

"The development of effective new vaccines … to tackle RSV have the potential to make major contributions to reducing severe disease and deaths from RSV in children globally"[9]

In children < 5 years among 72 GAVI (Global Vaccine Alliance)-eligible countries, mostly low-income and lower-middle-income and, applying a 3% discount rate (per WHO guidelines)[8]

- Treatment costs account for a total 611 million USD
- Disability-adjusted life years (DALYs) for 1.2 million

More than one third of the RSV-associated disease burden occurs **in the first year of life**.[8]

Maternal vaccination could, in those countries and for children < 1y:[8]

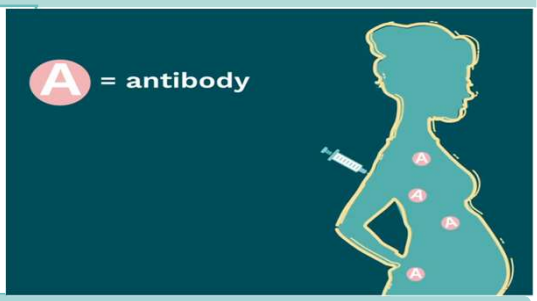
- Prevent 1.2 million cases, 104 thousand hospital admissions and 3 thousand deaths
- Avert 98 thousand discounted DALYs and 186 million USD

References: 1. Graham BS *et al. Curr Opin Immunol* 2015;35:30–38; 2. Walsh EE. *Clin Chest Med* 2017;38:29–36; 3. Shi et al. Lancet 2017; 390:946–958; 4. Figure adapted from *Pharmacoeconomics*, Economic Impact of Respiratory Syncytial Virus-Related Illness in the US, Vol. 22, 2004, 275–284. Paramore LC *et al.* © Adis Data Information BV with permission of Springer; RSV, respiratory syncytial virus; 5. Centers for Disease Control and Prevention (CDC), 2018. Respiratory syncytial virus infection (RSV): symptoms and care. http://www.cdc.gov/rsv/about/symptoms.html (accessed July 2019); 6. Anderson LJ *et al. Vaccine* 2013;31S:B209–B215; 7. Dawson-Caswell M, Muncie HL. *Am Fam Physician* 2011;83:141–146; 8. Li, X., Willem, L., Antillon, M. et al. Health and economic burden of respiratory syncytial virus (RSV) disease and the cost-effectiveness of potential interventions against RSV among children under 5 years in 72 Gavi-eligible countries. BMC Med 18, 82 (2020). https://doi.org/10.1186/s12916-020-01537-6. 9. Campbelll H *et al. J Global Health* 2015;5:02010;

RSV GRACE Study

What is GRACE study?

- **Phase 3 Global** Clinical study
- Approximately 10,000 pregnant women
- Double-blind study
- **Single** dose administered intramuscularly
- Robust safety data is available from prior studies



What is the Purpose of the study?

- Evaluate the ability of the vaccine in preventing medically assessed RSV associated Lower Respiratory Tract Illnesses (LRTIs) in infants born to vaccinated mothers.
- Evaluate the safety and immunogenicity of the investigational RSV Maternal vaccine both in vaccinated mothers and in their corresponding infant.

Who is eligible to take participate in the study?

Inclusion*

- ✓ Healthy woman aged 18 to 49 years
- ✓ In second or third trimester of pregnancy (between ~24 and 34 weeks of gestation)
- ✓ LMP date corroborated by first or second trimester ultrasound examination or certain LMP, corroborated by U/S performed after 28 weeks
- ✓ No significant congenital malformations, as assessed by fetal anomaly ultrasound scan conducted at or beyond 18 weeks of gestation.
- ✓ Willing to provide cord blood & infant followed-up after delivery for a period of 12 months

Exclusion*

- ✗ Significant complications in current pregnancy
- ✗ Known HIV infection
- ✗ Known or suspected HBV/ HCV infection
- ✗ Known or suspected in current pregnancy infection with Toxoplasma, Parvovirus B19, Syphilis, Zika, Rubella, Varicella, CMV or primary genital Herpes Simplex
- ✗ Known or suspected impairment of the immune system
- ✗ Administration of any vaccine from 29 days before study vaccine or planned administration through delivery (except for COVID vaccine and routine pregnancy vaccines)

*Note: other eligibility criteria apply

GRACE study | clinicaltrials.gov | resvinet.org

Help Us Help You

- Before the Tdap vaccine was used and approved in pregnancy, neonatal intensive care units (NICUs) had a high rate of admissions for whooping cough. Now that most women are vaccinated with the Tdap vaccine in their 3rd trimester, there has been a significant decrease of whooping cough infections in infants. Today instead of whooping cough, **RSV** has become a prevalent cause of infants in the NICU.
- Together, we can learn more about the potential to help prevent RSV disease among babies.
- The Future is in Your Hands

the Journey begins here

Site Name/ Address:
PI Contact Info: