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# **What's New with RSV This Year? Vaccines.**



Monroe Carell Jr.

**children's Hospital**

at Vanderbilt®

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# Disclosures

## Funding Disclosures:

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No funding from Pfizer, GSK or other makers of RSV vaccines

# Who we are



**Hannah** – 18 mo (19<sup>th</sup> Ave Sycamores)

**James** – 4 yrs (19<sup>th</sup> Ave Red Oaks)

**Alex** – 6 yrs (former 19<sup>th</sup> Ave)

# What's New with RSV This Year?

## 1. New 'vaccine' for infants

 CDC

[CDC Recommends a Powerful New Tool to Protect Infants from the Leading Cause of Hospitalization | CDC Online ...](#)

CDC is recommending a new immunization starting this fall to help protect all infants under 8 months and some older babies at increased risk...

## 2. New vaccine for the elderly

 The New York Times

[F.D.A. Approves Pfizer's R.S.V. Vaccine for Older Adults](#)

The Food and Drug Administration on Wednesday approved Pfizer's vaccine against the respiratory syncytial virus, or R.S.V., for adults age...

## 3. New vaccine pregnant woman

 CBS News

[CDC recommends Pfizer's RSV vaccine during pregnancy as protection for newborns](#)

An advisory panel for the U.S. Centers of Disease Control and Prevention on Friday recommended that a vaccine for respiratory syncytial...

# What is RSV?

- **Virus that causes respiratory symptoms**
  - Bronchiolitis
  - Viral pneumonia
- **~60,000-100,000 children are hospitalized in the US each year**
  - Most common cause of hospitalization in young children
- **High risk children:**
  - Children < 2 years, especially < 9 months
  - Premature infants
  - Chronic lung disease or congenital heart disease
  - Children with weakened immune systems
  - Two viruses at same time (RSV and flu, RSV and COVID etc)



# What is RSV?

## Mild infection:

- Runny nose
- Nasal congestion
- Cough
- Fever

## Serious infection:

- Difficult or rapid breathing
- Wheezing
- Persistent, high fever
- Irritability and restlessness
- Poor appetite leading to dehydration



# Previous Prevention

- Prophylaxis for High-Risk Infants and Young Children with Palivizumab (Synagis)



Slide courtesy of Ali Carroll, MD, MPH

<https://www.cdc.gov/rsv/infographic.html>

# What's New with RSV This Year?

 The New York Times

## RSV Vaccines: What to Know For Babies, Pregnant Women and Older Adults

New vaccines for older adults and pregnant women, and an antibody therapy for infants, provide options for preventing severe infection.



# Nirsevimab (Beyfortus™)

- **Long acting monoclonal antibody**
  - Studied in term and preterm babies
  - Studied in healthy babies and those with lung/heart disease
- **Single shot-passive immunization**
  - Duration of protection ~ 5 months
- **Available this month**
  - Covered by insurance
- **Approved for:**
  - $\leq$  8 months of age, including newborns
  - Children 8-19 months at  $\uparrow$  risk



# Pediatric Studies

## The NEW ENGLAND JOURNAL of MEDICINE

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### Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants

M. Pamela Griffin, M.D., Yuan Yuan, Ph.D., Therese Takas, B.S., Joseph B. Domachowske, M.D.,  
Shabir A. Madhi, M.B., B.Ch., Ph.D., Paolo Manzoni, M.D., Ph.D., Eric A.F. Simões, M.D., Mark T. Esser, Ph.D.,  
Anis A. Khan, Ph.D., Filip Dubovsky, M.D., Tonya Villafana, Ph.D., and John P. DeVincenzo, M.D.,  
for the Nirsevimab Study Group\*

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE



**Safety of Nirsevimab for RSV in Infants with Heart  
or Lung Disease or Prematurity**

The NEW ENGLAND JOURNAL of MEDICINE

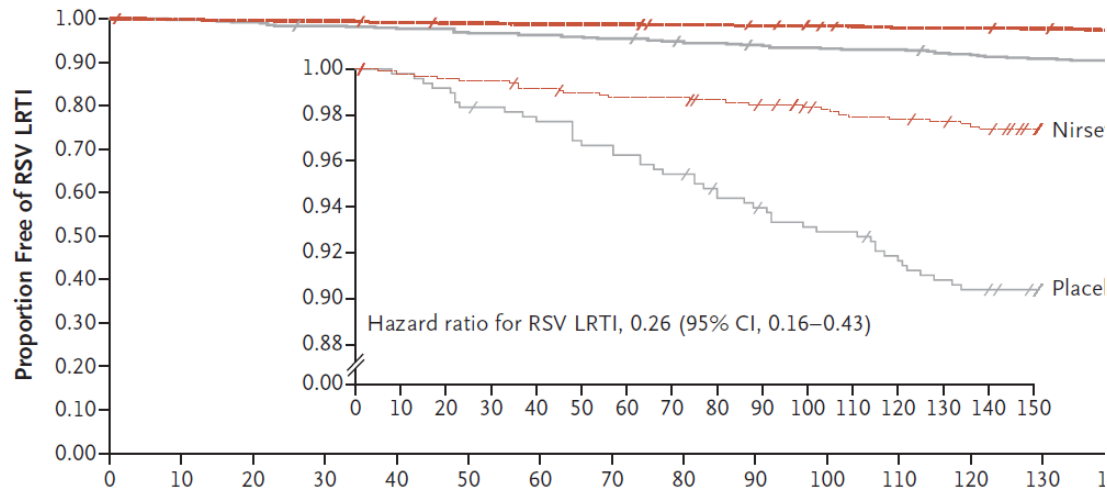
ORIGINAL ARTICLE

### Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

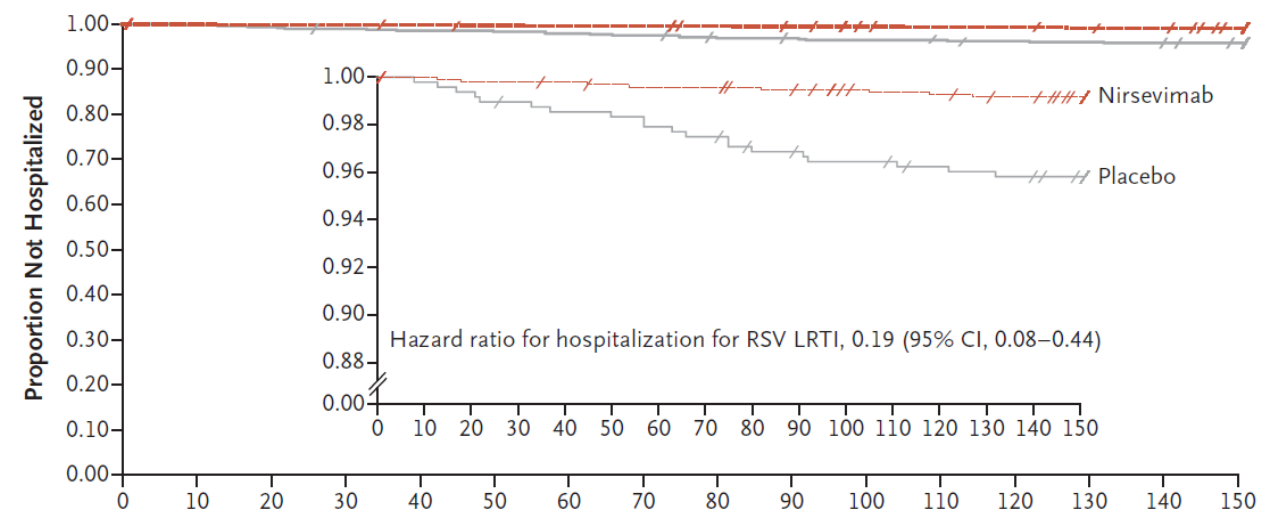
Laura L. Hammitt, M.D., Ron Dagan, M.D., Yuan Yuan, Ph.D.,  
Manuel Baca Cots, M.D., Miroslava Bosheva, M.D., Shabir A. Madhi, Ph.D.,  
William J. Muller, Ph.D., Heather J. Zar, Ph.D., Dennis Brooks, M.D.,  
Amy Grenham, M.Sc., Ulrika Wählby Hamrén, Ph.D., Vaishali S. Mankad, M.D.,  
Pin Ren, Ph.D., Therese Takas, B.Sc., Michael E. Abram, Ph.D.,  
Amanda Leach, M.R.C.P.C.H., M. Pamela Griffin, M.D.,  
and Tonya Villafana, Ph.D., for the MELODY Study Group\*

# Effectiveness of Nirsevimab

Time to First Medically Attended RSV Lower Respiratory Tract Infection



Time to First Hospitalization for RSV Lower Respiratory Tract Infection



| End Point  | Placebo<br>(N=1003)<br>no. of participants with event (%) | Nirsevimab<br>(N=2009)<br>no. of participants with event (%) | Efficacy (95% CI) |
|--|---|--|-------------------|
| Medically attended RSV-associated LRTI             | 54 (5.4)  | 24 (1.2)   | 76.4 (62.3–85.2)  |
| Hospitalization for RSV-associated LRTI            | 20 (2.0)  | 9 (0.4)  | 76.8 (49.4–89.4)  |
| Very severe medically attended RSV-associated LRTI | 17 (1.7)  | 7 (0.3)  | 78.6 (48.8–91.0)  |

-50      0      50      100  
← Placebo Better      Nirsevimab Better →

- **70-75% ↓ RSV office visits**
- **~80% ↓ RSV hospitalization**

# Nirsevimab Safety

- **Similar profile to palivizumab**
- **Adverse reactions uncommon**
  - 1.3% Nirsevimab group vs. 1.5% placebo groups
  - Pain, redness or rash at injection site
- **No serious adverse reactions in clinical trials**

# RSV Vaccine for Older Adults

- **2 FDA Approved RSV Vaccines**
  - GSK (Arexvy)
  - Pfizer (Abrysvo)
- **Adults > 60 years**
- **~70% ↓ RSV infection**
- **~85% ↓ RSV pneumonia**
- **~95% ↓ RSV hospitalization**



*The NEW ENGLAND JOURNAL of MEDICINE*

ORIGINAL ARTICLE

## Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults

A. Papi, M.G. Ison, J.M. Langley, D.-G. Lee, I. Leroux-Roels, F. Martinon-Torres, T.F. Schwarz, R.N. van Zyl-Smit, L. Campora, N. Dezutter, N. de Schrevel, L. Fissette, M.-P. David, M. Van der Wielen, L. Kostanyan, and V. Hulstrøm, for the AReSVi-006 Study Group\*

*The NEW ENGLAND JOURNAL of MEDICINE*

ORIGINAL ARTICLE

## Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults

E.E. Walsh, G. Pérez Marc, A.M. Zareba, A.R. Falsey, Q. Jiang, M. Patton, F.P. Polack, C. Llapur, P.A. Doreski, K. Ilangovan, M. Rämets, Y. Fukushima, N. Hussen, L.J. Bont, J. Cardona, E. DeHaan, G. Castillo Villa, M. Ingilizova, D. Eiras, T. Mikati, R.N. Shah, K. Schneider, D. Cooper, K. Koury, M.-M. Lino, A.S. Anderson, K.U. Jansen, K.A. Swanson, A. Gurtman, W.C. Gruber, and B. Schmoele-Thoma, for the RENOIR Clinical Trial Group\*

# RSV Vaccine for Pregnant Women

- **Pfizer (Abrysvo, Sep 2023)**

- **Protects mother + baby**

**~80% ↓ in Office visits for RSV in baby**

**~70% ↓ in RSV hospitalization in baby**

*The* **NEW ENGLAND**  
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## Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group\*

# Coming Soon: More Vaccines for kids

 News Channel 5

## RSV vaccine research for children and adults in full swing in Nashville

RSV can be deadly for older adults and young children, so that's why research to find a vaccine that works is full steam ahead.

Dec 2, 2022



# What Can You Do?

- **Nirsevimab if  $\leq$  8 months of age**
- **Vaccinate grandparents**
- **Consider vaccination if pregnant**
  
- Wash your hands (A LOT)
- Time!!! Most cases of RSV are mild
- Nasal saline and suctioning for infants
- Tylenol and ibuprofen
- No OTC cold and cough medications
- Get flu and COVID vaccines


## Are you RSV aware?

#RevealRSV  
#RSVPrevention  
#AllInfantProtection

### What are the signs and symptoms of RSV in infants?

Unlike adults, who can sometimes get RSV infections and not have symptoms, infants almost always show symptoms. Some of the most common are:

- A runny nose
- Cough, which may progress to wheezing
- Irritability
- Decreased activity
- Decreased appetite
- Apnea (pauses while breathing)
- Fever (does not always occur with RSV infections)



© Shutterstock

### How do I recognize severe RSV?




- 1 **Coughing or wheezing** that does not stop
- 2 A **bluish colour** around the mouth or fingernails
- 3 **Spread-out nostrils** and/or **caved-in chest** when trying to breathe
- 4 A **fever** (especially **greater than 38°C** in infants under 3 months of age)

If you see any of these symptoms listed above, call your paediatrician, midwife or general practitioner (GP) right away!



# Summary

## New Immunizations to Protect Against Severe RSV

| Who Does It Protect?  | Type of Product                    | Is It for Everyone in Group?   |
|---|------------------------------------|--|
| <br>Adults 60 and over | RSV vaccine                        | Talk to your doctor first  |
| <br>Babies            | RSV antibody given to baby         | All infants entering or born during RSV season. Small group of older babies for second season. |
| <b>OR</b>   |                                    |  |
| <br>Babies           | RSV vaccine given during pregnancy | Can get if you are 32–36 weeks pregnant during September–January                               |

[www.cdc.gov/rsv](http://www.cdc.gov/rsv)



# RSV Resources

- **Center for Disease Control and Prevention (CDC)**
  - RSV: <https://www.cdc.gov/rsv/index.html>
  - Flu: <https://www.cdc.gov/Flu/Index.htm>
- **American Academy of Pediatrics (AAP)**
  - RSV: When It's More Than Just a Cold: <https://tinyurl.com/4f7rsmcn>
  - Acetaminophen (Tylenol) dosing chart: <https://tinyurl.com/yc6scdan>
  - NSAID (Motrin) dosing chart: <https://tinyurl.com/y6d2vapr>

# Questions?

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