Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

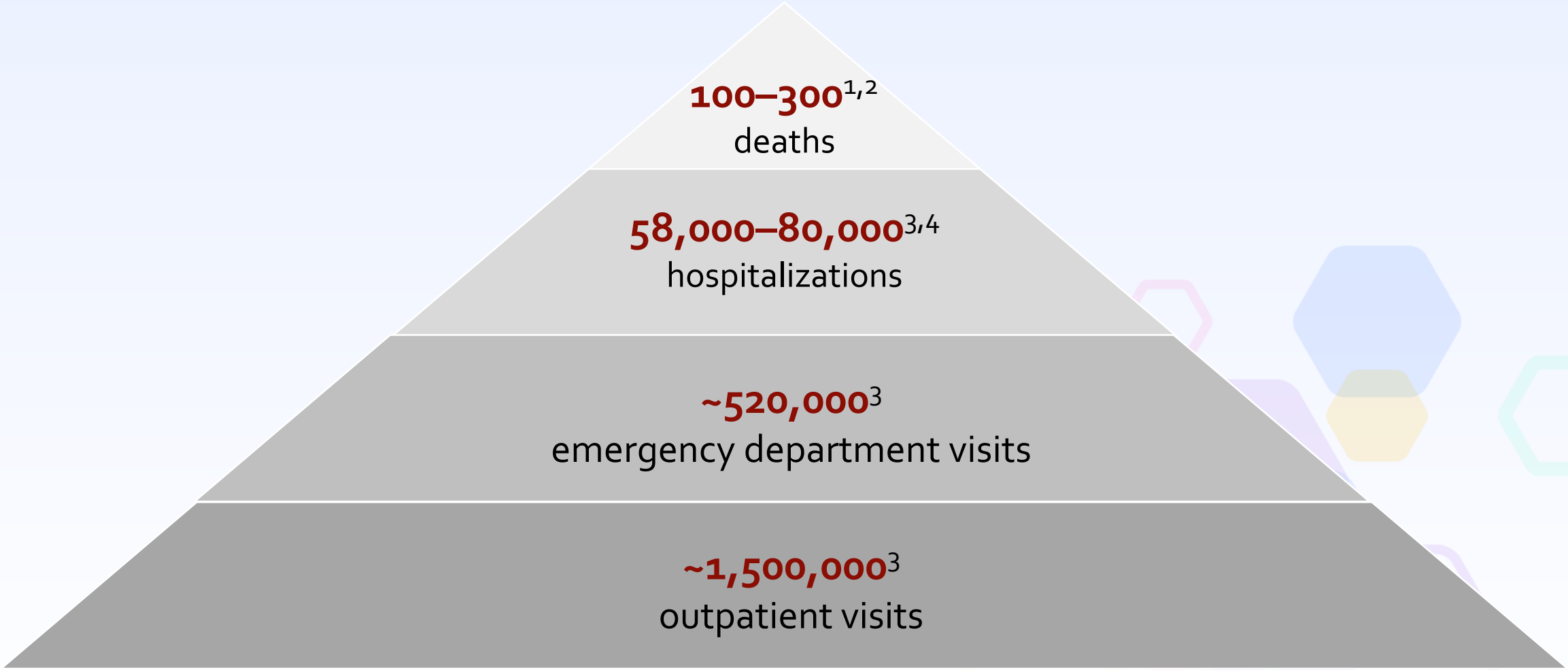
Sarah S. Long, MD

Chair, Maternal/Pediatric RSV Work Group

ACIP General Meeting

September 22, 2023

Each year in U.S. children aged less than 5 years, RSV is associated with…



[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022 (*estimate 80,000 hospitalizations in infants <1y)

RSV is the leading cause of hospitalization in U.S. infants[1]

- Most (68%) infants are infected in the first year of life and nearly all (97%) by age 2 years[2]
- 2-3% of young infants will be hospitalized for RSV[3,4,5]
- RSV is a common cause of lower respiratory tract infection in infants
- Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood[3,5]
- 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[3]

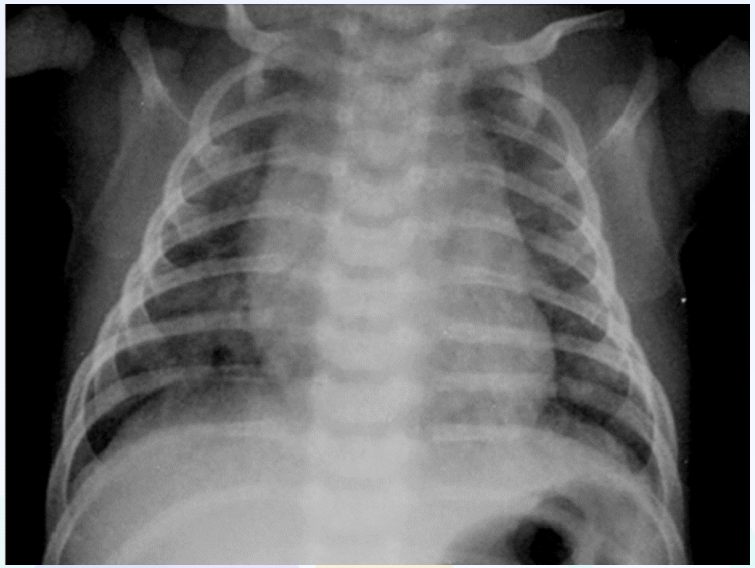


Image: Goncalves et al. Critical Care Research and Practice 2012

[1]Suh et al. JID 2022; [2]Glezen et al, Arch Dis Child, 1986; [3]Hall et al, Pediatrics, 2013; [4]Langley & Anderson, PIDJ, 2011; [5]CDC NVSN data

Previous maternal/pediatric RSV ACIP presentations on RSVpreF vaccine

- Epidemiology and burden of RSV in infants
- Virology and immunology of RSV
- Safety and efficacy of RSVpreF
- Cost effectiveness analysis for RSVpreF – CDC model
- Cost effectiveness analysis for RSVpreF – Comparison with manufacturer model
- Evidence to Recommendations framework for RSVpreF
- Clinical considerations for RSVpreF

FDA approval for RSVpreF vaccine

- On August 21, 2023, FDA approved Pfizer RSVpreF vaccine for use in pregnant people for the prevention of RSV lower respiratory tract disease and severe lower respiratory tract disease in infants from birth to 6 months of age
- Approved as a single dose to be given at 32–36 weeks gestation
  - In phase 2b and 3 trials, vaccination was given during 24–36 weeks gestation
  - A numerical imbalance in preterm births was observed in RSVpreF vaccine compared to placebo recipients in two clinical studies
  - Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF
  - Additionally, a numerical imbalance in hypertensive disorders of pregnancy was observed in RSVpreF vaccine compared to placebo recipients

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants | FDA
Package Insert - ABRYSVO (STN 125768) (fda.gov)
August 21, 2023 Approval Letter - ABRYSVO (STN 125768) (fda.gov)

FDA approval for RSVpreF vaccine (cont.)

- Starting dosing at 32 weeks gestation can reduce the potential risk of and complications from preterm birth until additional safety data are available
  - Avoids the risk of extremely preterm births, where there is substantive morbidity and mortality, and very preterm births
  - Similar vaccine efficacy in 32-36 weeks gestation compared to the overall study population

- FDA has required the manufacturer to conduct post-marketing studies to assess preterm birth and hypertensive disorders of pregnancy, including pre-eclampsia

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RSVpreF vaccine is one of two available preventive products for RSV in infants

- On August 3, 2023, ACIP recommended nirsevimab for RSV prevention in infants
  - Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg)
  - Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg)

Both nirsevimab and maternal RSV vaccine provide passive immunity

- A person develops active immunity from infection or vaccination
  - Triggers an immune response
  - Immunologic memory provides prolonged protection that may be lifelong

- Passive immunity is transfer of preformed antibody produced externally to provide protection to the recipient
  - From mother to baby through transplacental or breastmilk transfer
  - Direct administration of antibodies, such as IVIG or monoclonal antibodies
  - Provides temporary protection that wanes with time

IVIG= Intravenous Immunoglobulin Therapy

https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm

Agenda: Friday September 22, 2023

RSVpreF Vaccine Safety Surveillance in Pregnancy from The Vaccine Safety Datalink	Dr. Malini DeSilva (HealthPartners Institute)
Maternal RSV vaccine safety monitoring in the Vaccine Adverse Event Reporting System (VAERS) and V-safe	Dr. Pedro Moro (CDC/NCEZID)
Economic analysis of RSVpreF maternal vaccination	Dr. David Hutton (University of Michigan)
Economics of Preventing Respiratory Syncytial Virus Disease among US Infants by Maternal Vaccination Prior to Birth	Dr. Ismael Ortega-Sanchez (CDC/NCIRD)
Evidence to Recommendations Framework Updates: Pfizer Maternal RSVpreF Vaccine	Dr. Katherine Fleming-Dutra (CDC/NCIRD)

Agenda: Friday September 22, 2023 (cont.)

Updated clinical considerations for use of both nirsevimab and Pfizer RSVpreF vaccine	Dr. Jefferson Jones (CDC/NCIRD)
Implementation considerations for maternal RSV vaccine	Dr. Georgina Peacock (CDC/NCIRD)
Vaccines for Childrens Resolution	Dr. Jeanne Santoli (CDC/NCIRD)
Break	
Public Comment	
Break	
Vote on recommendation and Vaccines for Children	
Adult and Pediatric Immunization Schedule Addendum	Dr. Sarah Schillie (CDC/NCIRD)

Policy Question

- Should Pfizer RSVpreF vaccine be recommended for pregnant people to be given during 32 through 36 weeks gestation to prevent RSV lower respiratory tract infection in infants?

Work group members (External)

ACIP Members

Sarah Long (chair)

Pablo Sanchez

Oliver Brooks

Camille Kotton

Liaisons

James McAuley (IDSA)

Patsy Stinchfield (NFID)

Brenna L. Hughes (ACOG)

Nicole Chaisson (AAFP)

Sean O'Leary (AAP)

Jennifer Schuster (PIDS)

Molly Howell (AIM)

Ex Officio Members

Rachel Zhang (FDA-CBER)

Nicholas Geagan (FDA-CBER)

Judy Beeler (FDA-CBER)

Yodit Belew (FDA-CDER)

Prabha Viswanathan (FDA-CDER)

Sonnie Kim (NIH-NIAID)

April Killikelly (Public Health Agency of Canada)

Winnie Siu (Public Health Agency of Canada)

Valerie Marshall (OIDP/OASH)

Jessica Lee (CMS/CMCS)

Terry Dalle-Tezze (HRSA)

Lucia Lee (FDA-CBER)

Robin Wisch (FDA-CBER)

Consultants

Cody Meissner (Dartmouth Geisel School of Medicine)

Helen Chu (University of Washington)

Natasha Halasa (Vanderbilt University)

Denise Jamieson (Emory University School of Medicine)

Daniel Feikin (World Health Organization)

Carol Baker (University of Texas Health Science Center)

Kevin Ault (Western Michigan University)

GRADE/EtR Consultants

Doug Campos-Outcalt

Rebecca Morgan

Work group members (CDC)

CDC

Katherine Fleming-Dutra (co-lead)
Jefferson Jones (co-lead)
Meredith McMorrow
Mila Prill
Natalie Thornburg
Aron Hall
Ismael Ortega-Sanchez
Melissa Coughlin
Jamison Pike
Lauren Roper
Amber Winn
Chris Taylor
Tami Skoff
Angie Campbell
Michael Melgar
Amanda Payne
Nicole Dowling
Noelle Molinari
Claire Midgley
Fiona Havers
Pragna Patel
Andrea Sharma
Amadea Britton
Ruth Link-Gelles
Danielle Moulia
Megan Wallace
Monica Godfrey
Karen Broder
Naomi Tepper
Heidi Moline
Hannah Rosenblum
Derrell Powers
Raigan Wheeler
Sally Ezra
Elizabeth Greene
Manisha Patel
Tom Shimabukuro
Demorah Hayes
Latifah Boyce
A. Patricia Wodi
Neil Murthy
Christine Olson
Anne Hause
Andrew Leidner
David Shay
Sarah Meyer

CDC ACIP Staff

Melinda Wharton
Stephanie Thomas
Jessica MacNeil

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.