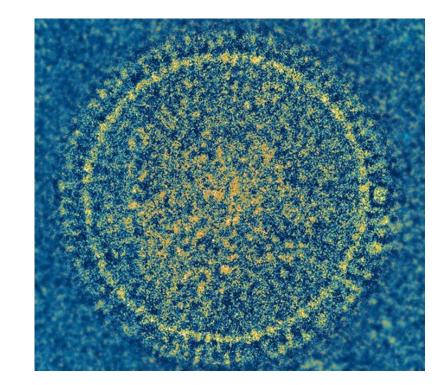
Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases



Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

Sarah S. Long, MD Chair, Maternal/Pediatric RSV Work Group

ACIP General Meeting February 23, 2023



Work group members

ACIP Members

Sarah Long (chair) Pablo Sanchez Oliver Brooks Camille Kotton

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)

<u>Consultants</u>

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)

<u>Liaisons</u>

James McAuley (IDSA) Patsy Stinchfield (NFID) Brenna L. Hughes (ACOG) Nicole Chaisson (AAFP) Sean O'Leary (AAP) Jennifer Schuster (PIDS) Molly Howell (AIM)

<u>CDC</u>

Katherine Fleming-Dutra (co-lead) Jefferson Jones (co-lead) Meredith McMorrow Claire Midgley Mila Prill **Fiona Havers** Natalie Thornburg Tami Skoff Aron Hall Angie Campbell Ismael Ortega-Sanchez Michael Melgar Tamara Pilishvili Amanda Payne Melissa Coughlin Nicole Dowling Jamison Pike Noelle Molinari Lauren Roper Pragna Patel Amber Winn Andrea Sharma Chris Taylor

GRADE/EtR consultants

Doug Campos-Outcalt Rebecca Morgan

Previous maternal/pediatric RSV ACIP presentations

- Epidemiology and burden of RSV in infants
 - RSV seasonality in United States
 - Outpatient, emergency department (ED) visits, hospitalizations, and deaths
- Virology and immunology of RSV
- Safety and efficacy of nirsevimab
 - Phase 3 study in infants born ≥35 weeks gestation (initial and updated results)¹
 - Phase 2b study in infants born 29–34 weeks gestation
 - Phase 2/3 safety and pharmacokinetic study in infants at high risk of RSV disease²

¹Initial results from start of trial until pause for COVID-19 pandemic and updated results that included entire sample. ²Eligible for palivizumab.

Agenda: Thursday February 23, 2023

- Cost effectiveness analysis for nirsevimab CDC model
- Cost effectiveness analysis for nirsevimab –
 Comparison to manufacturer model
- Evidence to Recommendations framework for Dr. Jefferson Jones (CDC) nirsevimab
- Clinical considerations for nirsevimab
- Safety and Efficacy of RSV Bivalent PreF Maternal Vaccine
- Workgroup considerations

Dr. Jefferson Jones (CDC) Dr. Iona Munjal (Pfizer)

Dr. David Hutton (University of

Dr. Ismael Ortega Sanchez (CDC)

Michigan)

Dr. Katherine Fleming-Dutra (CDC)

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.

