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Supporting public health guidance on infant RSV prevention: comparative effectiveness of RSV intervention strategies in the United States

Maternal vaccination and long-acting monoclonal antibodies are now available in the U.S. to prevent RSV. Long-acting monoclonal antibody administration in the U.S. commonly occurs after hospital discharge in outpatient settings, leaving some infants unprotected early in life when severe RSV risk is highest. Comparative effectiveness between the two interventions and whether real-world delays affect effectiveness estimates have not been quantified.

RESPIRATORY SYNCYTIAL VIRUS

RSV in Infants

#1

Cause of infant hospitalization in the U.S.

2.1M

Childhood illnesses treated every year (under age 5)

97%

Of children infected by their 2nd birthday

RESPIRATORY SYNCYTIAL VIRUS

Two preventive interventions

*The decision for which intervention to get often falls on the family, but **no clear guidance provided in the United States***

Maternal RSVpreF Vaccine

GIVEN TO THE PREGNANT PERSON

WHEN GIVEN

32–36 weeks of pregnancy

WHO IT PROTECTS

Babies born during RSV season

HOW IT WORKS

Antibodies pass to baby before birth

Long-Acting Monoclonal Antibody

GIVEN DIRECTLY TO THE INFANT

WHEN GIVEN

ASAP after birth — ideally week 1 if born in-season

WHO IT PROTECTS

Babies in their first RSV season

HOW IT WORKS

Ready-made antibodies given to the baby

Source: U.S. Centers for Disease Control and Prevention (CDC) — ACIP recommendations

RESPIRATORY SYNCYTIAL VIRUS

When Protection Actually Starts

Monoclonal antibodies work best on day one — but many U.S. infants don't receive them until weeks or months later

32–36 WEEKS OF PREGNANCY	WEEK 1 OF LIFE — IDEAL	WEEKS–MONTHS LATER
Maternal RSVpreF Vaccine	**Monoclonal Antibody, On Time**	**Monoclonal Antibody, Delayed**
Antibodies transfer, protecting infants from day one	Protection early on in life if provided as intended by public health policy	Common in the U.S. — leaves infants unprotected in the meantime

STUDY METHODS

Target Trial Emulation

Using clone-censor-weighting to emulate a randomized trial from observational data, so four real-world strategies can be compared fairly

THE APPROACH

1. **Define the target trial** — Specify eligibility, treatment strategies, and follow-up in advance — as if designing a randomized trial
2. **Emulate with real-world data** — Apply that protocol to observational birth-cohort data
3. **Clone-censor-weight approach**

THE COMPARISONS

Monoclonal Antibody – within 1 week from birth	HEAD-TO-HEAD	RSVpreF Vaccine

Captures a comparison when monoclonal antibodies are provided as intended by public health policy

Monoclonal Antibody – within 6 months from birth	HEAD-TO-HEAD	RSVpreF Vaccine

Captures a comparison when monoclonal antibodies are provided under a more realistic scenario

RESULTS

Delay in monoclonal antibody receipt increases RSV risk

*Monoclonal antibody timing strategies vs. maternal RSVpreF vaccination — adjusted hazard of RSV disease in the **first 5 weeks of life***

mAb WITHIN 6 MONTHS vs. MATERNAL VACCINE

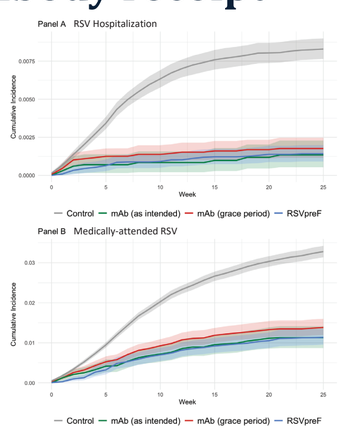
2.0 aHR — **RSV Hospitalization** — 95% CI: 1.0–4.9

1.6 aHR — **Medically-Attended RSV** — 95% CI: 1.0–2.7

mAb WITHN 1 WEEK vs. MATERNAL VACCINE

0.9 aHR — **RSV Hospitalization** — *95% CI: 0.3–1.9*

Takeaway: **delayed monoclonal antibody dosing increases the hazard of RSV disease.**



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