

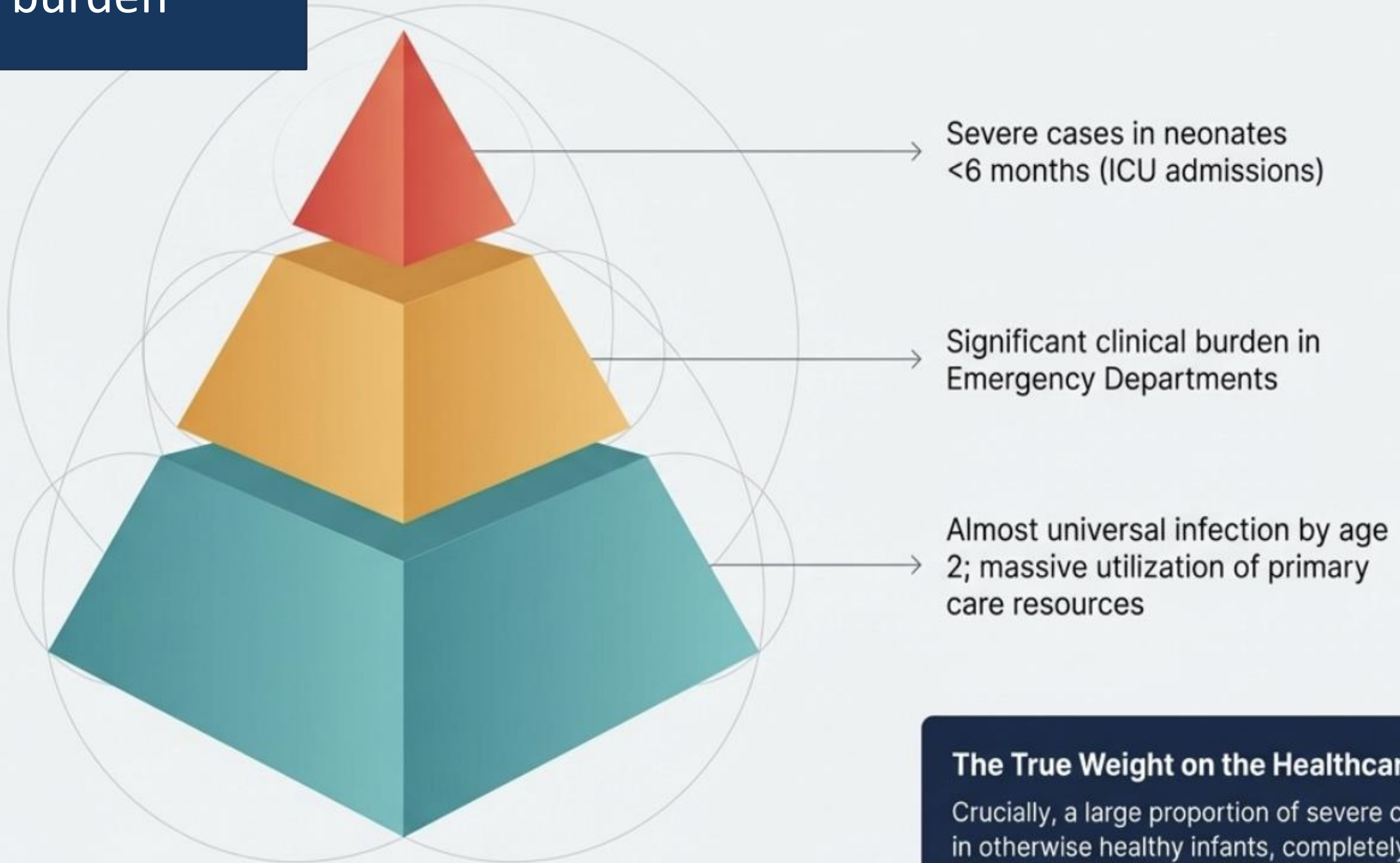
# RSV Impact in EU and the different immunization strategies that aim to directly prevent RSV disease in infant

“Protecting the value of prevention across Europe: focus on RSV & Maternal Vaccination”.

EU Policy & Advocacy Workshop.  
Active Citizenship Network  
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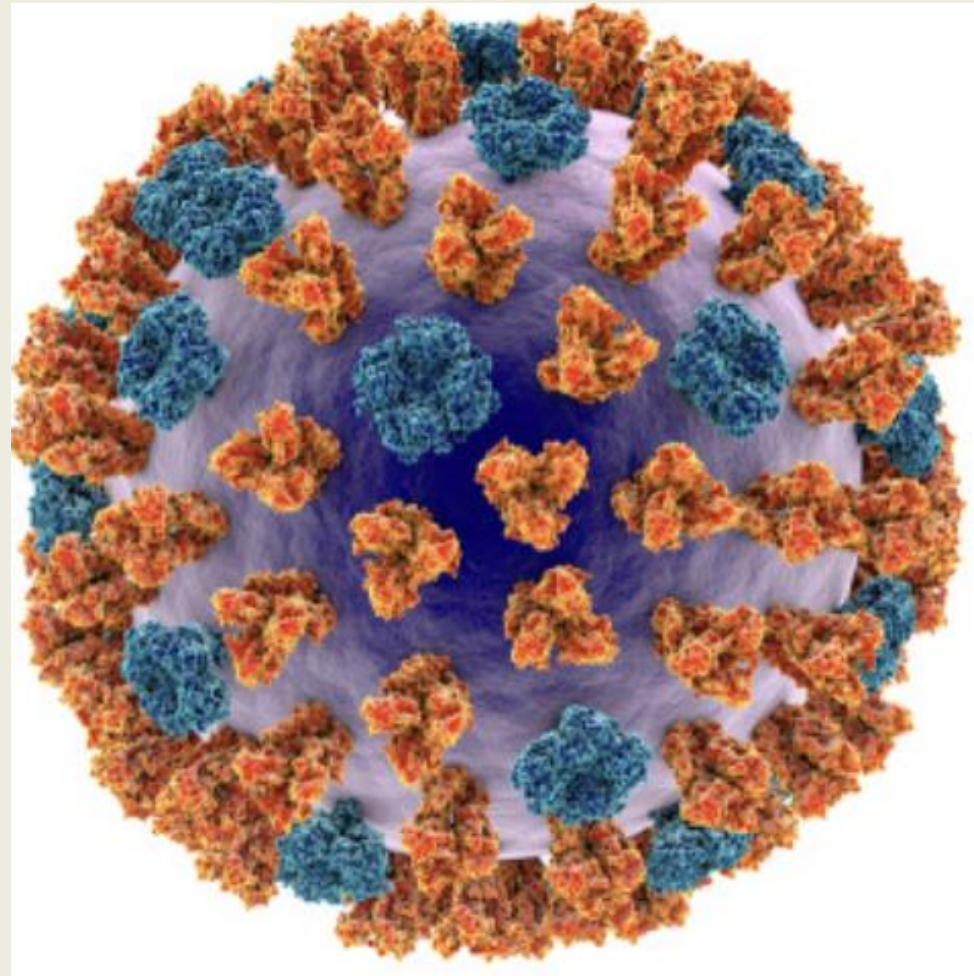
# RSV burden



## The True Weight on the Healthcare System

Crucially, a large proportion of severe cases occur in otherwise healthy infants, completely challenging purely risk-based prevention strategies.

# RSV prevention strategies overview



## **Pathway 1: The Mab Shield**

Long-Acting Monoclonal Antibodies (e.g. Nirsevimab).  
Extending passive protection across an entire RSV  
season with a single dose

## **Pathway 2: The Maternal Shield.**

Maternal RSV Vaccines. Targeting extreme early-life  
vulnerability by leveraging the gestational biological  
bridge.

# The Biological Bridge of Maternal Immunization



## Step 1: Maternal Vaccination

Active production of antibodies by the mother.

## Step 2: Transplacental Transfer

The active transport of maternal IgG across the placenta via the Fc receptor.

*Maximal efficiency observed strictly in the third trimester.*

## Step 3: Neonatal Protection

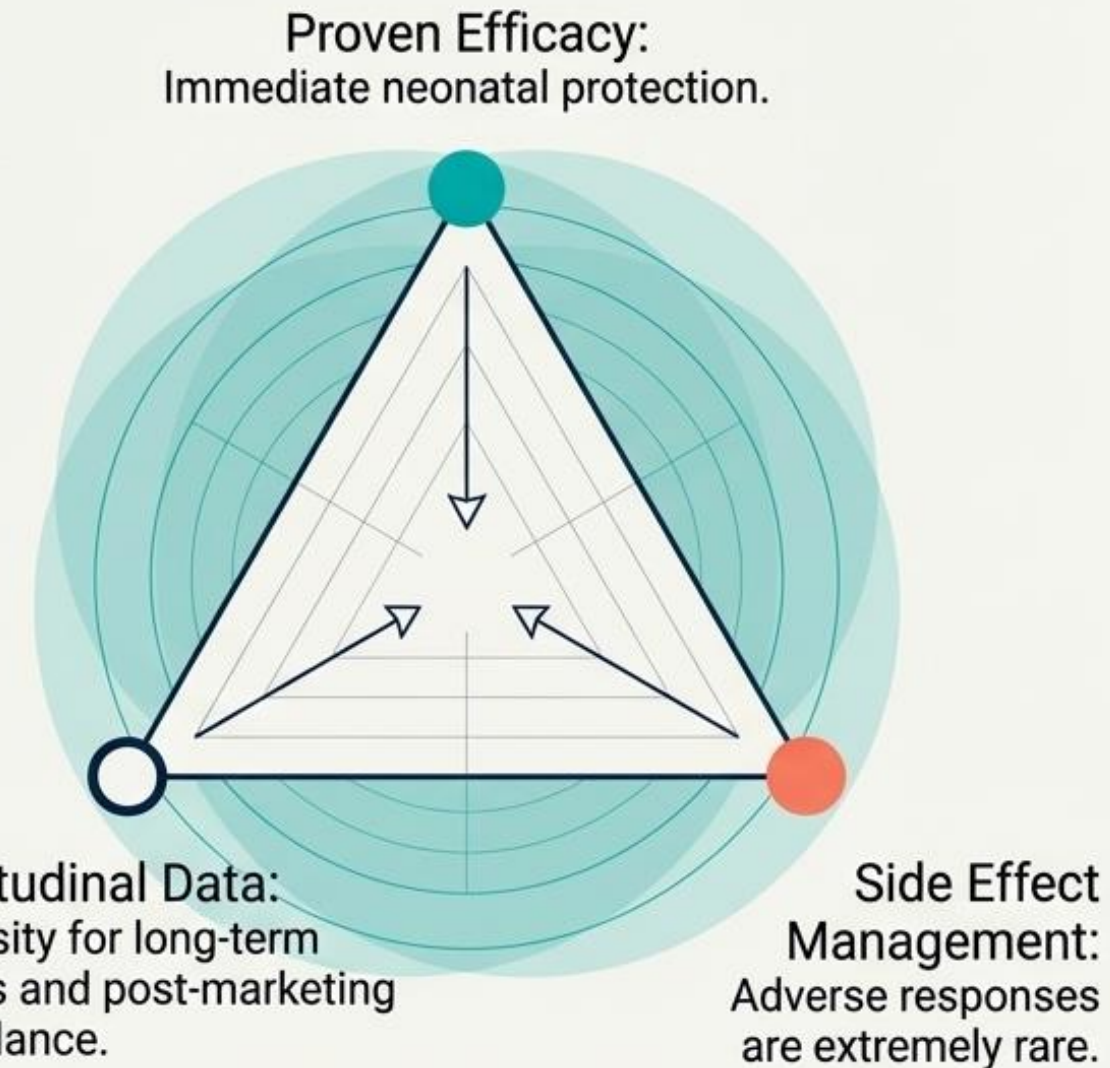
Passive immunity active from the newborn's very first breath.

Vaccinating pregnant mothers represents the primary strategic opportunity to confer an immune shield to newborns at the exact moment of their maximum vulnerability.

# Infants immunization

Reduction in the risk of  
severe respiratory disease  
in neonates  
- 49%

(Saad et al., 2025; Torres-Torres et al., 2026)



The scientific debate does not question the utility of the vaccine; it demands a dynamic balance between rapid implementation to save lives and continuous long-term safety data collection.

# Safety/Efficacy Evidence Summary

ER Visits Reduction



Hospitalizations Reductions



## Randomized Trials & Meta-Analyses

Significant reduction in RSV infections and Lower Respiratory Tract Disease (LRTD).

## Safety Profile

Highly favorable, confirmed across multiple global study contexts.

## The Real-World Breakthrough

A single dose guarantees direct protection of the newborn. Real-world data confirms a systemic, consistent impact across diverse healthcare systems, protecting both the general neonatal population and preterm infants. (Sumsuzzman et al., 2026; Wang et al., 2025).

# The dual arsenal is complementary, not mutually exclusive

*Do monoclonal antibodies replace maternal vaccination? No. They address different strategic needs.*

	Maternal Vax	Monoclonal (Nirsevimab)
Mechanism	Active maternal antibody production	Passive, direct infant immunization
Timing	3rd Trimester Gestation	Perinatal / Start of RSV Season
Primary Strategic Strength	Broad, population-level early shield	Highly controlled, targeted guarantee
Ideal Use Case	Universal baseline protection	High-risk infants, or when maternal vaccination was missed/unsuccessful.

# RSV Prevention Strategies in Selected European Countries (2025–2026)

Success in Spain, France, and Germany in relevant outcomes as mortality and hospitalisation have prompted recent modifications in Sweden and USA guidelines. .EMA, 2023, ECDC and WHO 2025.

Country	Implementation Status	Primary Strategy	Maternal Vaccination	Infant mAb (nirsevimab)	Public Funding	Level of Centralization
<b>France</b>	<b>Fully implemented</b>	Combined strategy	Yes (routine offer)	Yes (universal)	Yes	High (national program)
<b>Spain</b>	<b>Fully implemented</b>	Infant-focused	Limited / not central	Yes (universal)	Yes	High (national coordination)
<b>United Kingdom</b>	<b>Fully implemented</b>	Maternal-focused	Yes (routine NHS program)	Limited (targeted only)	Yes	Very high (NHS centralized)
<b>Greece</b>	<b>Fully implemented</b>	Combined strategy	Yes	Yes (universal)	Yes	High
<b>Germany</b>	<b>Fully implemented</b>	Infant-focused	Not widely implemented	Yes (universal)	Yes	High (federal, but coordinated)
<b>Netherlands</b>	<b>Implemented (recent rollout)</b>	Infant-focused	Not central	Yes (universal, scaling)	Yes	High
<b>Italy</b>	<b>Implemented (regional)</b>	Infant-focused	Emerging / not yet routine	Yes (widely used, region-based)	Yes	Low–moderate (regionalized)

# Cost-effectiveness

## Stage 1: The Investment

Initial investment in universal maternal and infant vaccination programs.

## Stage 2: The Clinical Return

Prevention of thousands of hospital admissions, ER visits, and neonatal deaths.

## Stage 3: The Systemic Yield

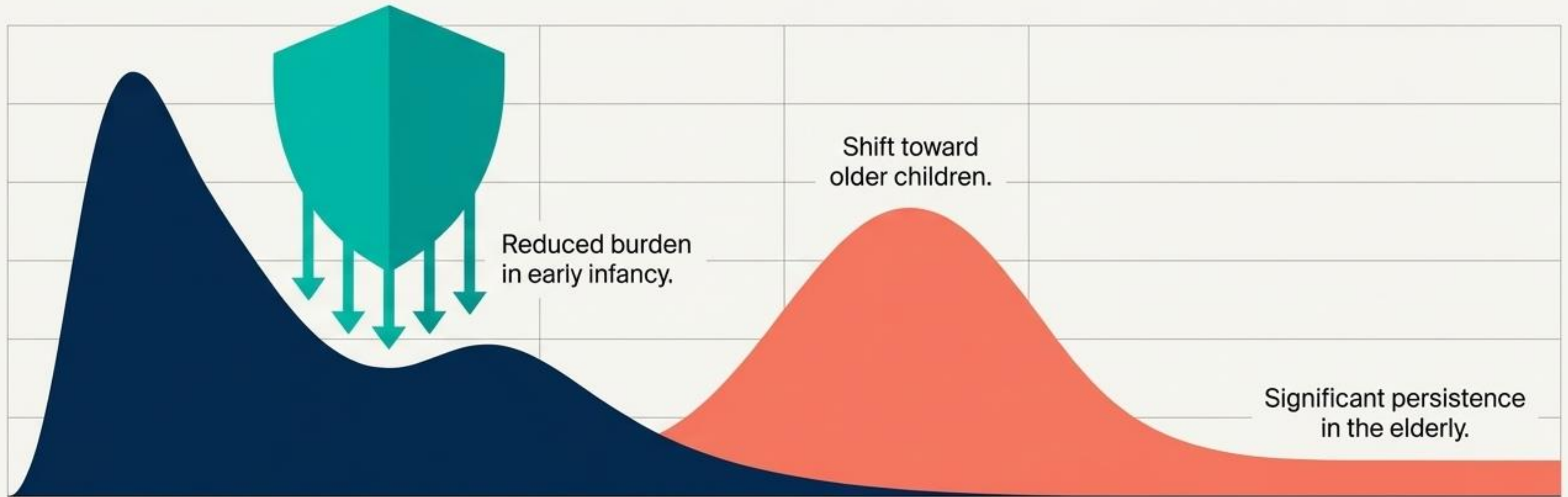
Significant systemic cost savings and net improvement in long-term health outcomes (Zeng et al., 2024).

“

*Investing in targeted vaccination programs yields a massive economic return for health systems, virtually guaranteeing the operational sustainability of pediatric intensive care units.”*

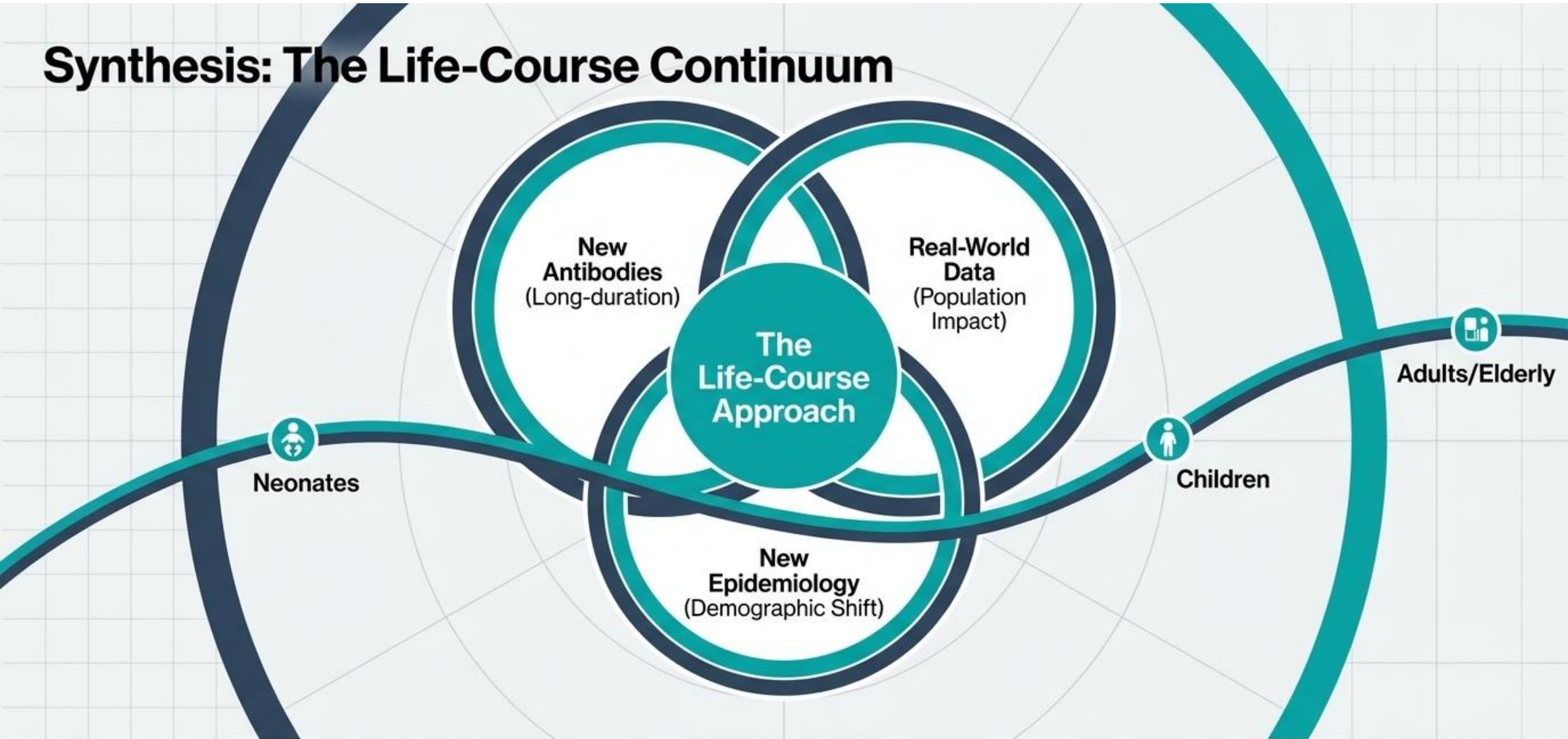
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# The Demographic Wave: An Evolving Epidemiology



The extraordinary success of protection in the first months of life is modifying the **epidemiological footprint** of the virus. We are observing a reduced burden in early infancy, which reveals a relative **shift toward older children** and a **significant persistence of the disease in the elderly**. (Hak et al., 2025; Heemskerk, 2025)

# Synthesis: The Life-Course Continuum



Prevention as a Continuum: The advent of universal prophylaxis is only the beginning. The virus's new epidemiological evolution requires us to abandon siloed, compartmented logic. We must embrace an integrated 'life-course' approach capable of protecting vulnerable populations at every stage of life.

# Frontline Activation: Role of the Family Pediatrician

*From maternal vaccination to infant protection*



## Education & Counseling

Inform parents about RSV risks and prevention options. Address hesitancy with clear, evidence-based communication.

## Clinical Assessment & Follow-up



Identify high-risk infants (preterm, chronic illness). Monitor safety and record outcomes in health files.



## Coordination of Care

Collaborate with OB-GYNs, midwives, and public health services. Ensure maternal vaccination and timely infant prophylaxis (e.g., nirsevimab).

## Advocacy & Public Health



Promote RSV prevention in the community. Support national immunization and surveillance programs.

# The Imperative for International Collaboration



Fragmentation reduces efficacy. RSV requires an integrated, cohesive, continent-wide healthcare response to monitor changing outcomes over time and re-evaluate overarching strategies.

# The Paradigm Shift: From the Niche to the System

## Yesterday – The Niche

**Focus:** Exclusive to high-risk neonates.

**Method:** Reactive, short-duration protection.

**Impact:** High, constant strain on hospitals and ERs.

**Scope:** An isolated, pediatric clinical problem.

## Today and Tomorrow – The System



**Focus:** Universal protection for the entire infant population.



**Method:** Proactive, single-dose, long-acting shields (Nirsevimab, Maternal Vax).



**Impact:** Systemic reduction in healthcare resource utilization.



**Scope:** Evolution toward an integrated life-course prevention continuum.

# Key points and final recommendations

- Maternal and infant RSV immunization is not merely a medical progression, It is an instrument of public health. Success depends on the fusion of continuous scientific rigor and courageous adoption policies at the European level
- The window of opportunity  
Proven efficacy targeting the absolute most vulnerable population at the precise right time
- The health system costs reduction  
Guaranteed reduction of intensive care costs and hospital gridlock
- National integration  
The necessity of equitable access and long-term , life-course monitoring

# Possible Questions

## Will mAbs replace maternal vaccination?

**No. They address different needs.** The most effective strategy is a combination: maternal vaccines for population-level baseline defense, and mAbs for targeted, controlled protection.

## What are the remaining clinical uncertainties?

Duration of protection, effectiveness in extreme preterms, and real-world implementation dynamics. Long-term population surveillance remains essential.

## Is maternal vaccination definitively cost-effective?

**Highly effective** regarding hospitalization reduction, though specific ROI depends heavily on local coverage rates, seasonality, and existing healthcare infrastructure.

## Is there interference with future infant vaccines?

While a theoretical concern with other vaccines, there is currently no clear evidence of clinically significant interference in the context of RSV. Ongoing research continues.

# Possible Questions

## **Q1. How do you position maternal vaccination versus nirsevimab?**

At present, the two strategies should be considered complementary rather than mutually exclusive. Maternal vaccination provides early, population-level protection, while monoclonal antibodies offer a more controlled and direct approach, particularly useful in high-risk infants or when maternal vaccination has not occurred.

## **Q2. What are the main uncertainties still to be addressed?**

The main areas of uncertainty include duration of protection, effectiveness in preterm infants, and the impact of implementation in real-world settings. In addition, ongoing surveillance will be essential to confirm long-term safety at population level.

## **Q3. Is maternal vaccination cost-effective?**

Current models suggest that maternal vaccination can be cost-effective, particularly when considering reductions in hospitalizations. However, cost-effectiveness is highly context-dependent and influenced by coverage, seasonality, and healthcare system organization.

## **Q4. Could maternal antibodies interfere with future infant vaccines?**

This is a theoretical concern observed with other vaccines, but at present there is no clear evidence of clinically significant interference in the context of RSV. It remains an area for ongoing research.

## **Q5. “Do you think monoclonal antibodies will replace maternal vaccination?”**

No, they address different needs. Maternal vaccination provides early, population-level protection, while monoclonal antibodies allow a more targeted and controlled approach. The most effective strategy is likely a combination of both.

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# RSV vaccination relevant Reports and Documents

- European Centre for Disease Prevention and Control: “Protecting infants against respiratory syncytial virus this winter” (13 Nov 2025)
- WHO position paper on immunization to protect infants against respiratory syncytial virus disease, May 2025.
- European Medicines Agency: “First RSV vaccine to protect infants up to 6 months of age and older adults” (21 July 2023)