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# Protecting young infants through immunoprevention

Implementation research needs for monoclonal antibodies  
and maternal vaccines through the lens of respiratory  
syncytial virus (RSV)

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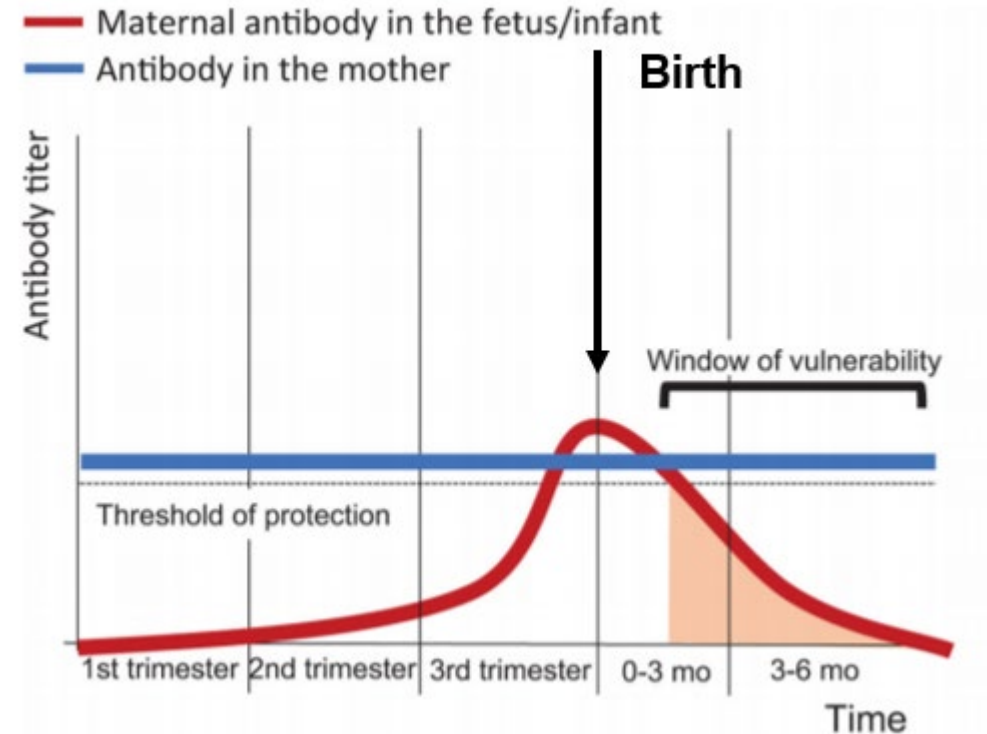
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# Why is immunoprevention important for very young infants?

- Young infants vulnerable to infectious pathogens
- Infants rely on maternal antibody transfer for protection
- “Window of vulnerability”—waning maternal antibodies while infant unable to mount adequate immune response on their own against some pathogens
- Prevention particularly important for young infants in LMICs, where disease burdens are highest and health coverage is often limited



Boonyaratanakornkit and Chu. *Pediatr Infect Dis J*, 2019



# Current state of immunoprevention in early life



## Birth-dose vaccine



## Monoclonal antibody



## Maternal vaccine

### RATIONALE

Directly immunizing neonates soon after birth can elicit an immune response sufficient to protect against some pathogens

Directly immunizing neonates soon after birth provides antibodies for critical protection in early life.

Vaccination in pregnancy can directly enhance the pregnant vaccinee's immunity and increase natural antibody transfer to baby across the placenta for protection in early life.

### HOW IT WORKS

Vaccine induces infant antibody response

mAbs are manufactured antibodies that have functional activity against the pathogen. Protection is transient.

Vaccine induces antibodies that pass through the placenta to the infant and neutralize the pathogen. Protection is transient.

### TIMING

Infant at birth or as soon as possible

Infant at birth or as soon as possible; at first EPI visit.

Expectant mother in second or third trimester of pregnancy to optimize transfer of antibodies to infant.

### LICENSED PRODUCTS

Hepatitis B, BCG, OPV

RSV (short-acting)  
RSV (long-acting)

Tetanus  
Tetanus-diphtheria-pertussis  
Influenza  
Hepatitis A

Yellow fever  
Japanese encephalitis  
COVID-19



# New monoclonal antibody and maternal vaccine products in the pipeline targeting early life



**Monoclonal antibody**



**Maternal vaccine**

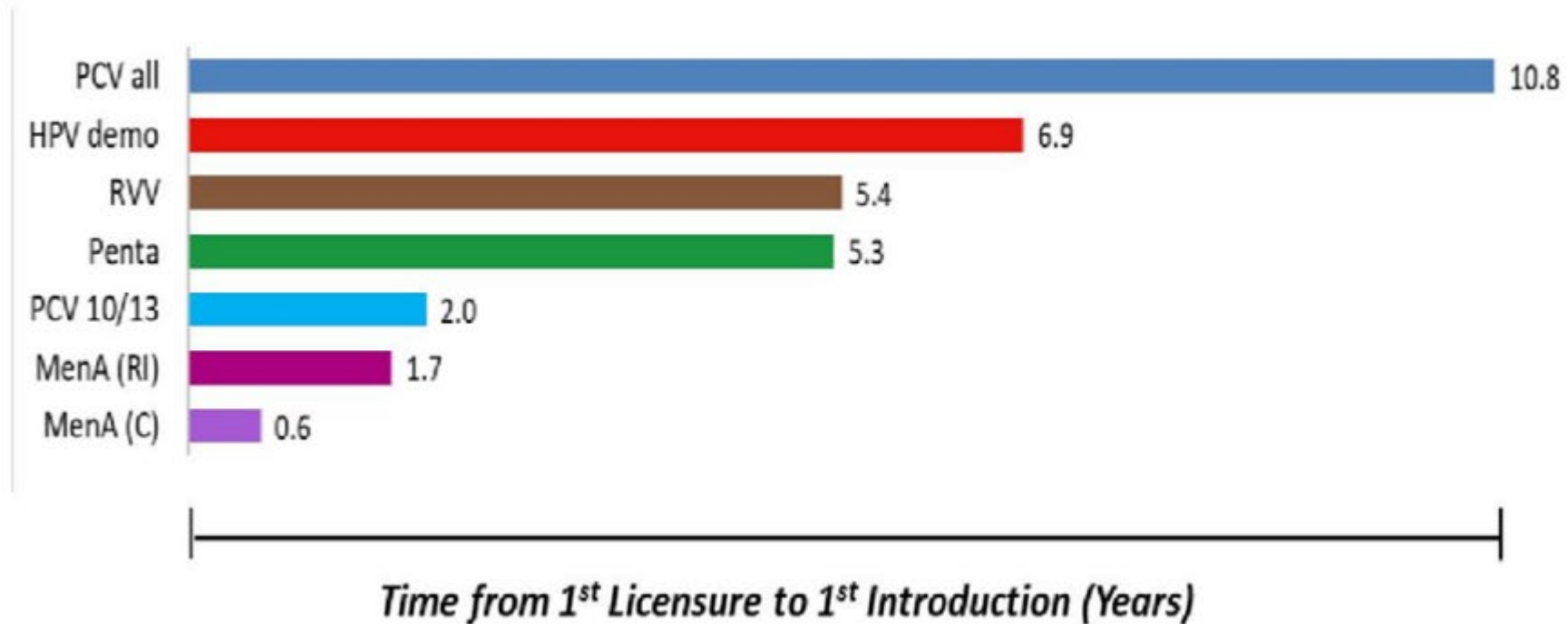
FORTHCOMING

RSV (long-acting)

RSV  
Group B *Streptococcus* (GBS)  
Hepatitis E



# Let's avoid vaccines taking years to reach Gavi-eligible countries

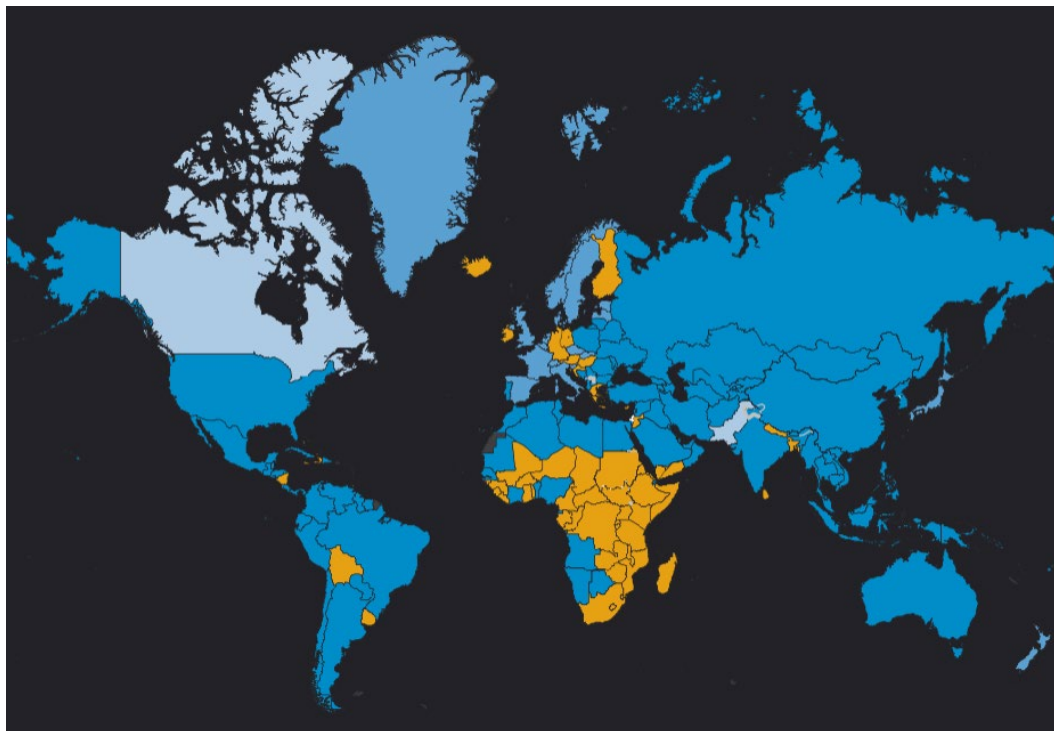


Implementation research can help shorten this timeline by generating evidence needed for global and country decision-making

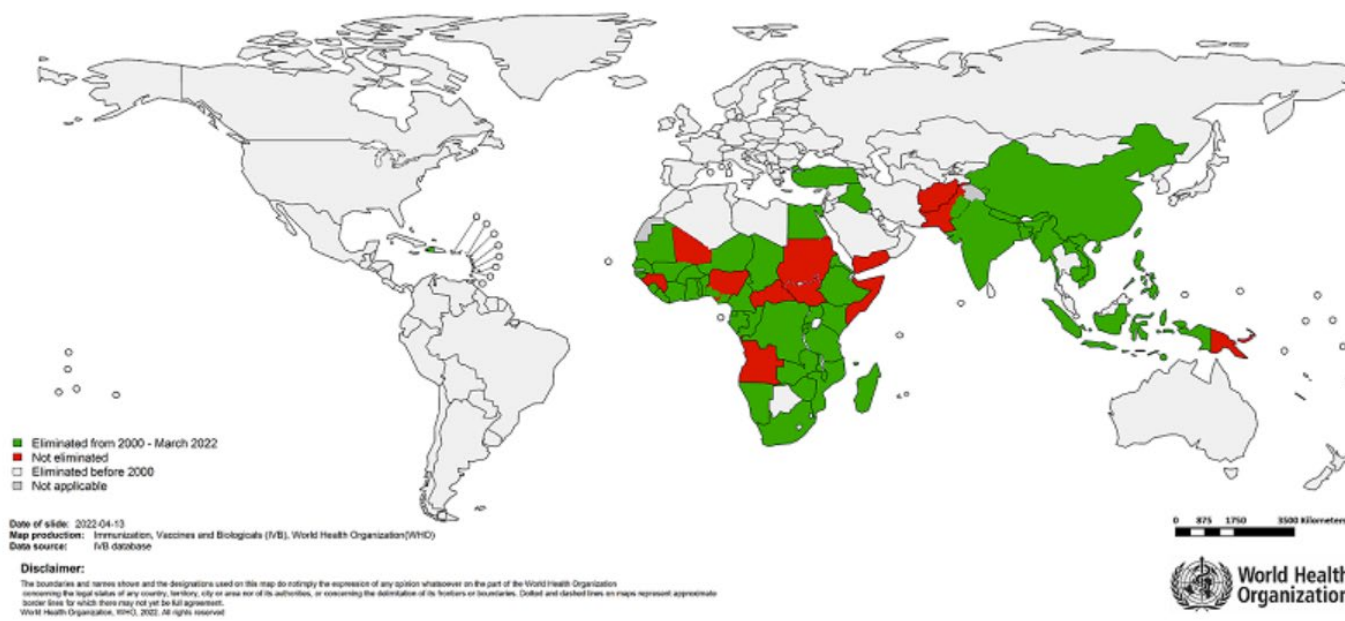


# To inform implementation, we have a lot to build upon

Vaccine introduction – Hep B birth dose by country (2021)<sup>1</sup>



47 countries have been validated as having achieved maternal, neonatal tetanus elimination (March 2022)<sup>2</sup>

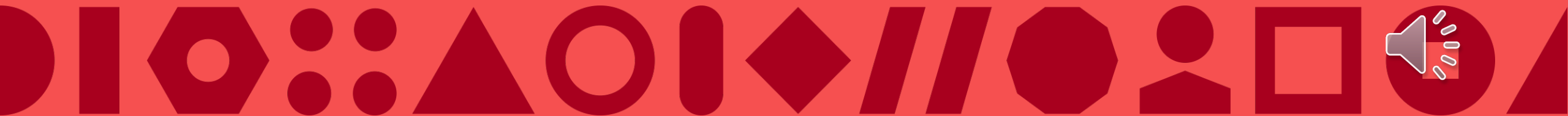


■ Yes   ■ Yes (Risk groups)   ■ Yes (Partial)   ■ No   ■ Not applicable

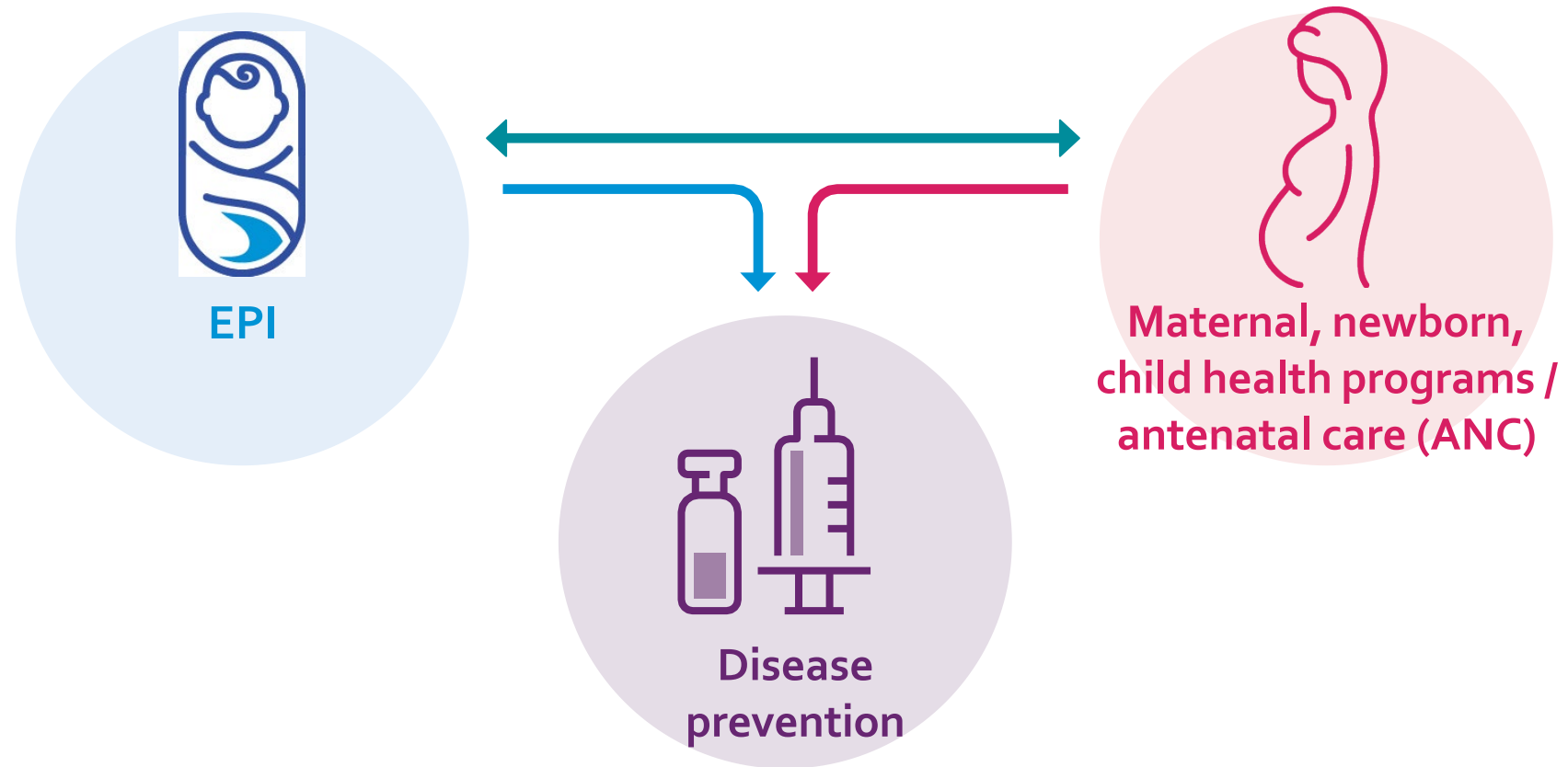
<sup>1</sup> [immunizationdata.who.int/](https://immunizationdata.who.int/); <sup>2</sup> [www.who.int/initiatives/maternal-and-neonatal-tetanus-elimination-\(mnte\)/progress-towards-global-mnt-elimination](https://www.who.int/initiatives/maternal-and-neonatal-tetanus-elimination-(mnte)/progress-towards-global-mnt-elimination)



# Implementation research— focus on RSV



# Delivery will depend on coordination across two platforms



Cross-cutting engagement across antenatal care, obstetric, pediatric, and immunization programs and experts will be needed, regardless of product(s) chosen.





# Implementation research: awareness and acceptance

Questions	Potential approaches	Stakeholders
<ul style="list-style-type: none"><li>• Awareness of the disease, its burden, and new interventions?</li><li>• Attitudes toward interventions?</li><li>• Health worker willingness &amp; empowerment to recommend &amp; provide interventions?</li><li>• Acceptability of concomitant injections in young infants/ pregnant women? Limits?</li><li>• Optimal strategies for information to be communicated and by whom?</li></ul>	<ul style="list-style-type: none"><li>• Landscaping, literature reviews, stakeholder mapping</li><li>• Knowledge, Attitudes, Perceptions (KAP) research</li><li>• Surveillance database reviews and synthesizing information for various audiences</li><li>• Communications materials and message testing</li></ul>	<ul style="list-style-type: none"><li>• Policy/decision-makers</li><li>• Healthcare managers and providers (ANC, EPI, obstetric, pediatric, midwifery, nursing)</li><li>• Others as contextually appropriate (e.g., professional societies, NGOs, media)</li><li>• Community outreach workers</li><li>• Families/communities</li><li>• Community leaders and other influencers</li></ul>



# Implementation research: programmatic considerations

Questions	Potential approaches	Stakeholders
<ul style="list-style-type: none"><li>• How does current ANC attendance align with gestational age vaccination windows? If not, how can coverage be improved?</li><li>• How will premature infants be protected?</li><li>• How to reach pregnant women not accessing ANC and infants born outside formal healthcare system?</li><li>• How can job flows be adapted to include new interventions without overburdening health workers?</li></ul>	<ul style="list-style-type: none"><li>• Landscaping, literature review</li><li>• Demographic surveillance and health record reviews</li><li>• ANC visit exit interviews</li><li>• Mixed methods study using semi-structured interviews or focus group discussions</li><li>• Design thinking workshops</li></ul>	<ul style="list-style-type: none"><li>• Healthcare providers (ANC, EPI, obstetric, pediatric, midwifery, nursing)</li><li>• Community outreach workers</li><li>• Academics</li><li>• Surveillance data managers</li><li>• Families/communities</li></ul>



# Importance of implementation research—for RSV and beyond

- RSV monoclonal antibodies and maternal vaccines are coming, need to do the work now that will support timely introduction in LMICs
- Implementation research can provide the evidence needed to
  - Inform global policy decisions and country vaccine adoption decisions
  - Empower implementers and communities
  - Ensure that the introduction gap between HICs and LMICs is as small as possible
  - Ensure that interventions are delivered effectively, efficiently, and equitably.
- **The expertise in this room has a lot to contribute. Now is a good time to get engaged.**



**PATH**

