Maternal influenza vaccines: How has the VIS process influenced the vaccine research agenda

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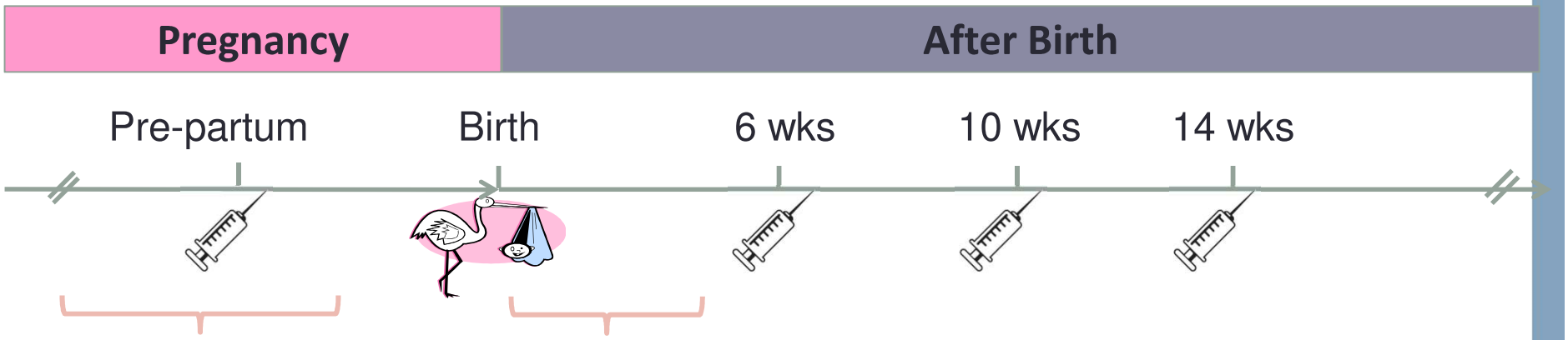


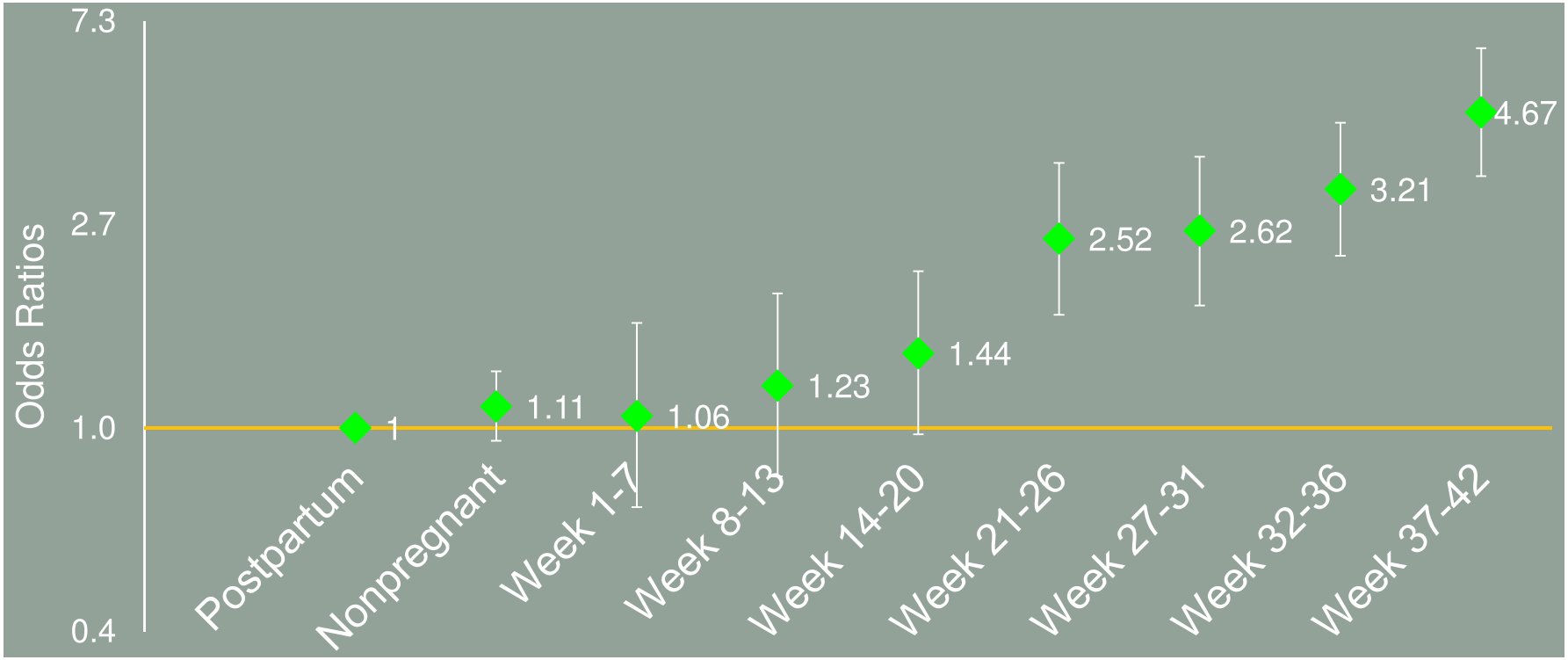
Some infections more dangerous in pregnancy (e.g. influenza, Hepatitis E)

3 mil. deaths (0-27 days)

Mortality data: Liu et al., Lancet; 2012

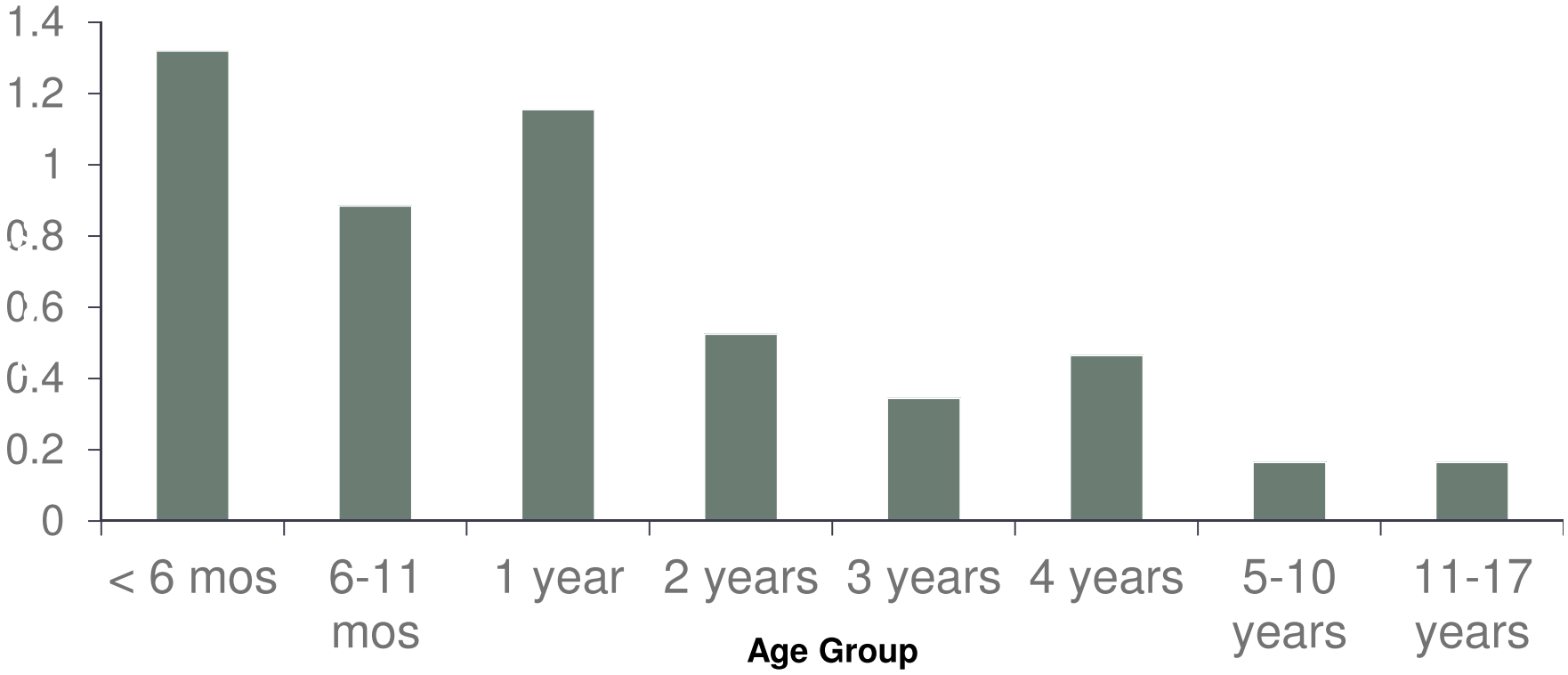
Odds Ratios of Influenza-related Cardiopulmonary Events by Pregnancy Status

Tennessee Medicaid Program 1974-1993



Data Source: Neuzil et al, AJE, 1998

Influenza-Associated Mortality Rate Among Children in the United States, 2003-2004



Bhat N, NEJM; 2005.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effectiveness of Maternal Influenza Immunization in Mothers and Infants

63% reduction in infant influenza after maternal vaccination in pregnancy

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Zaman et al., New Eng Journal of Medicine, 2008

VIS 2013 on Influenza Vaccines

The Board noted the potential public health impact of vaccinating pregnant women against seasonal influenza and the need to assess the emerging evidence of impact of vaccination on neonates, but decides not to open a funding window for influenza vaccines at this time

Further evidence to support reconsideration of maternal influenza vaccination in 2018 VIS: key questions / activities

Health impact beyond pregnant women

- Impact on neonates and infants in low and lower-middle income countries

Supply and logistics

- What is the optimal approach to allow year-round supply?
- What are the implications on country cold-chain capacity?
- Leverage distribution platform of maternal and child health services and/or EPI?

Delivery strategy

- Campaign based approach or year-round routine provision? Operational feasibility, impact?
- Synergies with other (future) maternal vaccination (e.g. Tetanus toxoid, RSV, GBS, malaria) and ANC activities?

Regulatory and policy

- Regulatory and policy changes needed (e.g., expiry date); how to expedite?

Demand generation

- Analyze/re-package and disseminate data on burden disease and health impact

Gavi
The Vaccine Alliance

Pooled Analyses of Bill & Melinda Gates Foundation-Supported Randomized Trials of Maternal Influenza Immunization in Mali, Nepal, and South Africa


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UNFPA/ANNA ADHIKARI


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Synthesis Document, Final

The Bill & Melinda Gates Foundation is supporting large, randomized trials of maternal influenza immunization in Mali, Nepal, and South Africa, evaluating the efficacy and safety of maternal immunization to prevent maternal and newborn influenza disease. This document summarizes similarities, differences, and study endpoints across the three trials.

Omer et al., Vaccine, 2015

Maternal Influenza Immunization Update I

All trials show an impact on infant flu (VE Range: 30%- 63%)

Variability in impact on birth outcomes

e.g. sites with lower baseline birth weight show impact

Greater focus on severe outcomes in neonates and infants

Focus on high-risk groups (e.g. HIV+)

Maternal Influenza Immunization Update II

Exploration of optimal distribution platform (integrated vs. vertical)

Building a maternal immunization platform

Work on removing regulatory & policy barriers

Assessment of determinants of demand at multiple levels

Thank You!

Proposed Analyses

1. Pooled efficacy against infant and maternal lab confirmed influenza.
2. Birth outcomes such as pre-term and small for gestational age births.
3. Immunogenicity of maternal & dynamics of mother to infant antibody transfer.
4. Safety outcomes
5. Impact of maternal TIV on neonatal mortality –both all cause and, where possible, cause specific mortality.

Proposed Analyses (cont'd)

6. Infant pneumonia
7. Infant pneumococcal carriage
8. Maternal mortality
9. Infant growth by maternal vaccination status.
10. Indirect/"herd" effects of maternal TIV. Influenza-like illness and laboratory confirmed influenza among household contact
11. Medically Attended Acute Respiratory Illness (MAARI)