

Pregnancy is a physiologically dynamic state. The immune profile of a pregnant woman is responsive to the changing levels of sex hormones, and evolves through the course of pregnancy.<sup>2</sup> However, the current knowledge base for vaccine response draws from observational studies mostly conducted in the latter part of pregnancy, with limited data available from the first and early second trimester. On the other hand, clinical, practical and public health considerations require that vaccine use not be restricted to advanced gestational age.

Robust safety evaluation is a cornerstone of any vaccine development and deployment program. While there has been increased attention on evaluation of safety of immunization in pregnancy, barriers remain. For example, a review commissioned by the WHO highlighted that there is a lack of standard definitions of outcomes, and standards for measurement of these outcomes, relevant to evaluation of vaccines in pregnancy.<sup>3</sup> This lack of standardization poses a challenge for conduct of clinical trials, generalizability of safety data, and the merging of large safety datasets. This last point is critical because large multi-location datasets would optimize the evaluation of rare but clinically important outcomes, such as microcephaly.

#### References:

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### Maternal Immunization: Perspective of PATH

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**Objective:** Discuss opportunities and challenges in the implementation of maternal immunization programs in limited-resource settings.

**Abstract:** The greatest burden of severe influenza and pertussis in children occurs during the first few months of life, yet vaccines against these diseases are not effective at that age. Immunization of pregnant women against both influenza and pertussis, however, has been shown to be effective in protecting infants.<sup>1-2</sup> These interventions have therefore been recommended by global policy makers<sup>3-4</sup>, yet their adoption in most countries has been slow, particularly in low-resource settings. Major reasons for this include a lack of quality data regarding disease burden and the impact of the intervention, uncertainties regarding the programmatic feasibility, regulatory and legal constraints, and low levels of awareness. This presentation will discuss many of the opportunities and challenges for implementing maternal immunization programs in low-income countries, and current efforts to address them.

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3. Vaccines against influenza WHO position paper – November 2012. *Wkly Epidemiol Rec*. 2012 Nov 23;87(47):461-76.
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