



Pregnancy Research Ethics  
for Vaccines, Epidemics,  
and New Technologies

PREVENT

# Vaccines, Pregnancy, and the R&D Agenda: Challenges and Opportunities

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**2<sup>nd</sup> Meeting of the Task Force on Research Specific to  
Pregnant Women and Lactating Women**

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## Vaccines in pregnancy

- **Immunization in pregnancy can offer significant benefits**
  - To the pregnant woman (e.g., Flu, Yellow Fever)
  - To the developing fetus (e.g., Zika, CMV)
  - To the infant via conferred immunity (e.g., Pertussis)
- **We now routinely recommend certain vaccines in pregnancy**
- **However, pregnant women have been largely excluded from research trials**
- *Not a single vaccine has been licensed with a specific indication for use in pregnancy*



## **Vaccines for use in pregnancy are *critically important***

- **Pregnant women (and their fetuses) often face higher susceptibility to and severity of illness**
- **Many women who have limited interaction with the health system will not have pre-existing immunity**
- **Pregnancy as a critical window of contact w/ the health system**
- **Past efforts to vaccinate *ahead of and around pregnancy* have not been sufficient**
- **Pregnant women and their offspring should not be unjustly denied the benefits of advancements in vaccine science**



## Needed: an evidence base for vaccines in pregnancy

- Immunological differences in pregnancy
- Need maternal and fetal safety data
- Critical for public health officials, clinicians, and pregnant women to ensure:
  - informed, responsible, and timely adoption of beneficial vaccines in pregnancy
  - responsible management of inadvertent exposure to vaccines during pregnancy
    - Reduce unnecessary anxiety and/or terminations of wanted pregnancies

“

*Pregnant women deserve an evidence base for the prevention and treatment of their illnesses equal to others as a matter of justice.*

-The Ethics Working Group on ZIKV Research & Pregnancy

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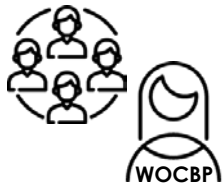


## Perceived challenges & sources of reluctance



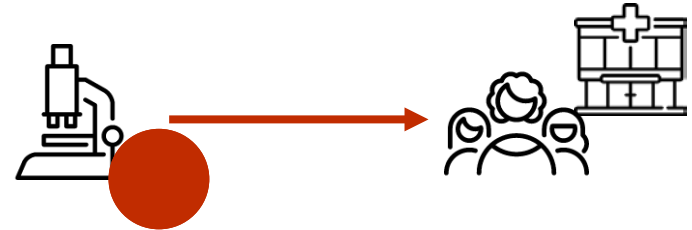
**Legal, financial and reputational risk**

**Fetal risk inflation/distortion**



**Over-reliance on alternative strategies**

**Tendency to push data  
collection post-market**



**Lack of market incentives – with  
potentially large disincentives**



## Additional Challenges

- **Lack of data on background rates of adverse maternal, fetal, infant outcomes**
  - Potential for misattribution of harms to vaccine
- **Novel vaccine platforms, adjuvants, and delivery mechanisms**
  - Keeping pace with innovations – not leaving pregnant women behind
- **Emerging and re-emerging pathogens**
  - When R&D is accelerated and pathogens intermittent, sequential approaches to evidence generation may not be possible



## Potential Solutions

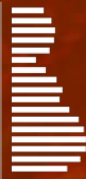
- **Explicit calls for vaccines acceptable in pregnancy w/ funding & incentives**
- **Policies that shift to presumption of *inclusion***
- **Insurance and injury compensation programs**
- **Engaging maternal-fetal experts in research design, ethics review, implementation, and ultimate communication of findings**
- **Data collection on background rates**
- **Earlier inclusion of pregnant women in efficacy trials when acceptable risk-benefit profile**
- **Prospective and systematic data collection from inadvertent exposures**



## Progress

- **Pipeline for vaccines specifically targeted for maternal immunization (GBS, RSV, CMV)**
- **GAIA work on guidelines for standardized and harmonized data collection in vaccine trials of outcomes relevant to pregnancy**
- **21<sup>st</sup> Century Cures Act expanding coverage under the VICP of vaccines given in pregnancy**
- **PLLR → more nuanced information about products in pregnancy**





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