



INFECTIOUS DISEASE RESEARCH INVOLVING PREGNANT WOMEN: EPIDEMIC VACCINES

Ruth Faden
Stavros Niarchos Foundation
Bioethics Academy
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Animation can be viewed at:
vax.pregnancyethics.org



THE PROBLEM

- Pregnant women and their offspring are among those most severely impacted by outbreaks and epidemics

EBOLA

60-90%

case fatality

100%

fetal loss

LASSA

up to

90%

case fatality & fetal loss
in 3rd trimester

ZIKA

Lifelong disability
for affected infants
& family hardship

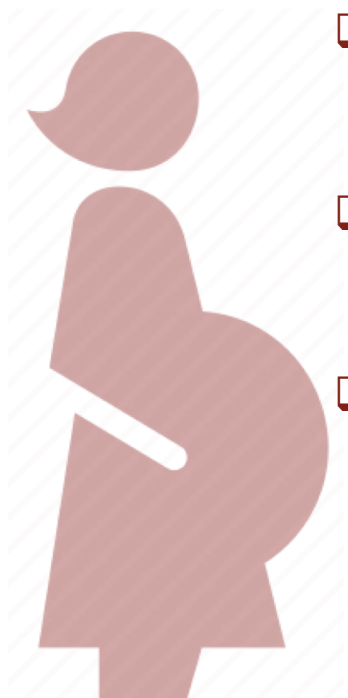
- Epidemic vaccines are rarely developed with pregnant women in mind, and pregnant women are often excluded from trials and denied access to vaccines



WHY WE NEED EVIDENCE SPECIFIC TO PREGNANCY

- **Pregnant women have unique physiologies**

- ❑ $\uparrow\downarrow$ drug metabolism, changes in respiratory function, cardiac output, immune system, reproductive tract, etc.
- ❑ Pregnancy can change the **susceptibility** and **severity of disease**
- ❑ Pregnancy can alter dosing and efficacy of interventions
- ❑ Interventions may carry risks unique to pregnant women and/or their fetuses



SOME PRINCIPLES FOR RESEARCH WITH PREGNANT WOMEN

1

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

2

Pregnant women should not be categorized as a “vulnerable population” for purposes of human subjects research review.

3

It is ethically permissible to conduct research with pregnant women that meets specific risk standards.

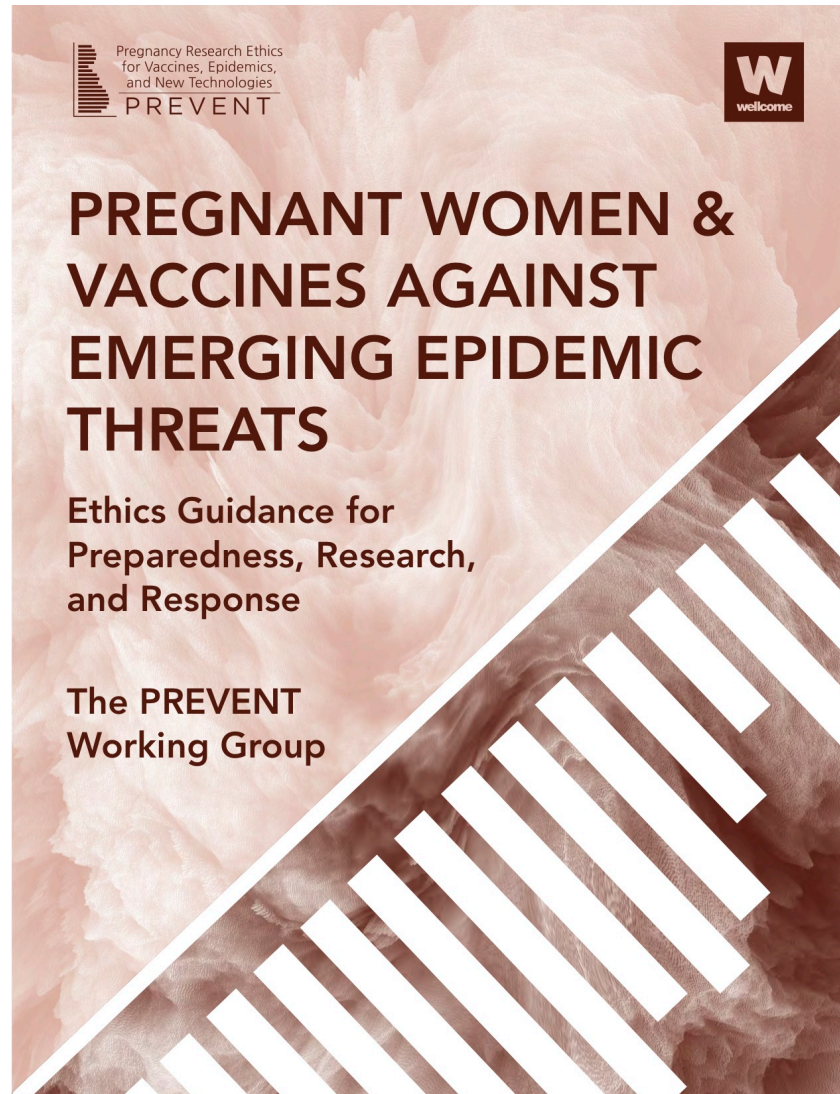
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Justice requires that pregnant women have fair access to research that offers the prospect of direct benefit.

THE HARMS & INJUSTICE OF EXCLUSION IN EPIDEMIC VACCINE R&D

- Unjust exclusion of individual women from the potential benefits of research participation
- Unjust exclusion of pregnant women as a class from benefits of biomedical science
- Inadequate data to inform public health decisions
- Reluctance to administer
- Significant delays in access to vaccines; outright denial

THE PREVENT GUIDANCE



<https://doi.org/10.1016/j.vaccine.2019.01.011>

THE PREVENT WORKING GROUP

Multidisciplinary international team:

- Bioethics
- Maternal-fetal medicine
- Maternal immunization
- Pediatrics
- Philosophy
- Public Health
- Vaccine Research & Policy

Ruth Faden Principal Investigator Johns Hopkins Berman Institute of Bioethics	Carleigh Krubiner Co-Principal Investigator Johns Hopkins Berman Institute of Bioethics	Ruth Karron Co-Principal Investigator Johns Hopkins Bloomberg School of Public Health
Margaret Little Co-Investigator Georgetown University Kennedy Institute of Ethics	Anne Lyerly Co-Investigator University of North Carolina Center for Bioethics	
Jon Abramson Wake Forest University School of Medicine	Richard Beigi Magee-Womens Hospital of University of Pittsburgh Medical Center	
Alejandro Cravioto Universidad Nacional Autónoma de México Faculty of Medicine	Anna Durbin Johns Hopkins Bloomberg School of Public Health	
Bruce Gellin Sabin Vaccine Institute	Swati Gupta International AIDS Vaccine Initiative (IAVI)	
David C. Kaslow PATH Essential Medicines	Sonali Kochhar Global Healthcare Consulting	
Florencia Luna FLACSO-Argentina Bioethics Program & CONICET	Carla Saenz Pan American Health Organization Regional Program on Bioethics	
Jeanne Sheffield Johns Hopkins University School of Medicine	Paulina Tindana Navrongo Health Research Centre	

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RECOMMENDATIONS

I

Preparedness

II

R&D

III

Vaccine Delivery

RESEARCH & DEVELOPMENT

Inclusion in Vaccine Pipeline

Rec 7 & 8

- Include investments in vaccines appropriate for use in pregnancy
- Assess suitability of novel platforms for use in pregnancy

Inclusion in Clinical Development

- Conduct required non-clinical studies when candidates move to phase 2
- Include studies to evaluate vaccines in pregnancy – pregnant women have opportunity to enroll/remains in studies conducted during outbreaks and epidemics when prospect of benefit > risk
- Systematic capture of data from unintended exposures

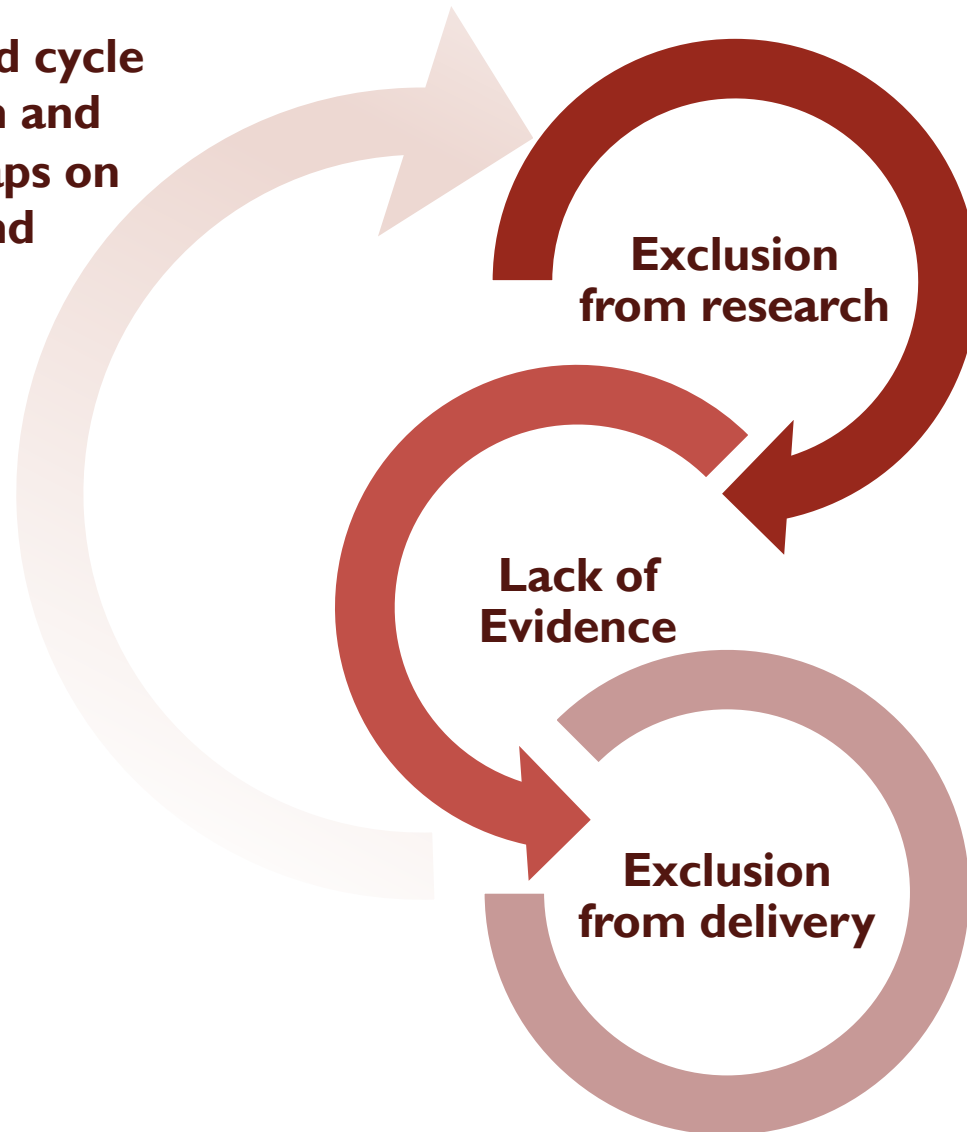
Rec 9

Rec 11 & 13

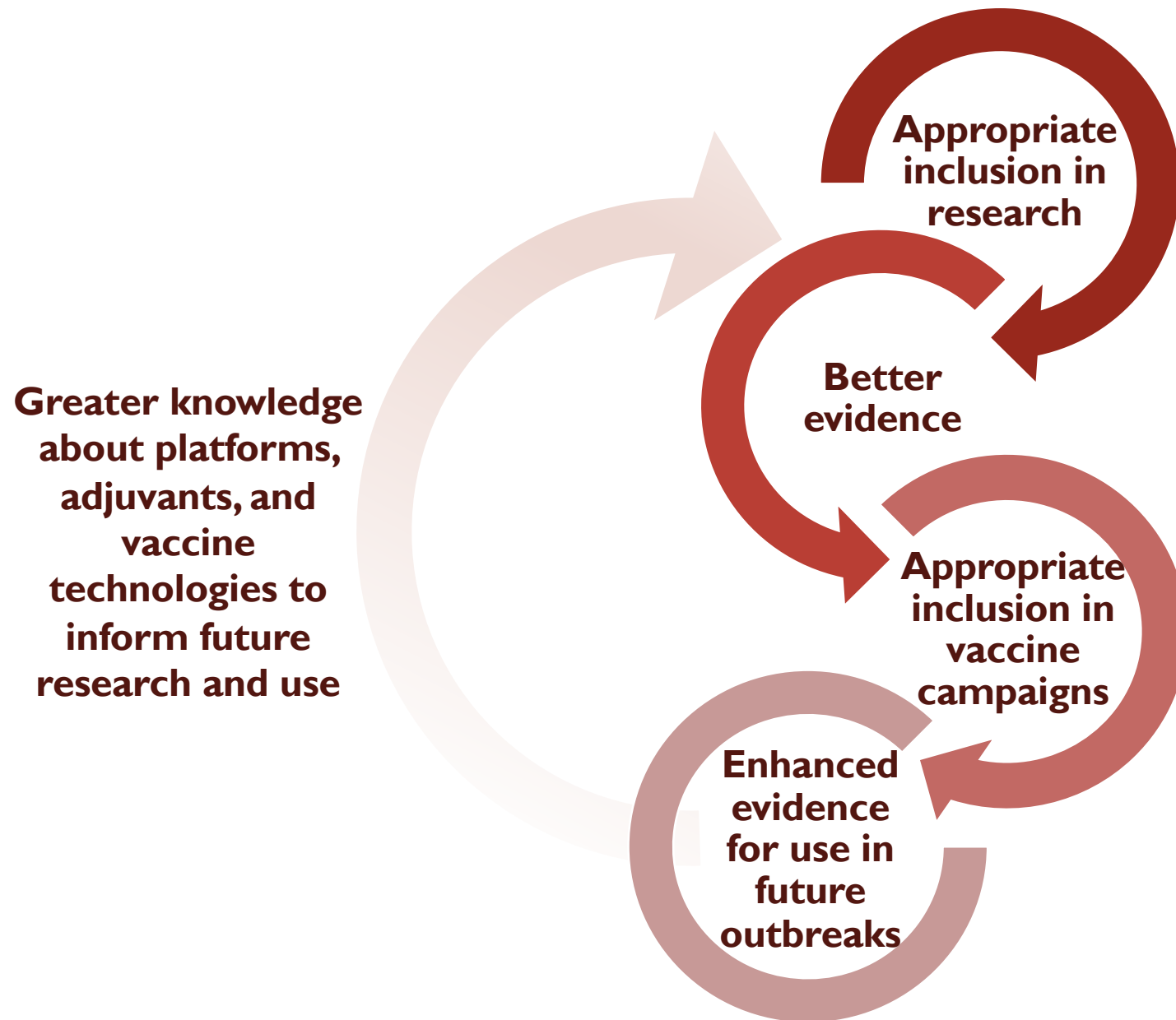
Rec 12

THE PRESUMPTION OF EXCLUSION

perpetuated cycle
of exclusion and
evidence gaps on
products and
platforms



THE PRESUMPTION OF INCLUSION





QUESTIONS & DISCUSSION