

PREGNANT WOMEN & VACCINES AGAINST EMERGING EPIDEMIC THREATS

Ethics Guidance for Preparedness,
Research, and Response

Presented to WHO SAGE

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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



THE PREVENT WORKING GROUP

Multidisciplinary international team:

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

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PREVENT: OUR APPROACH

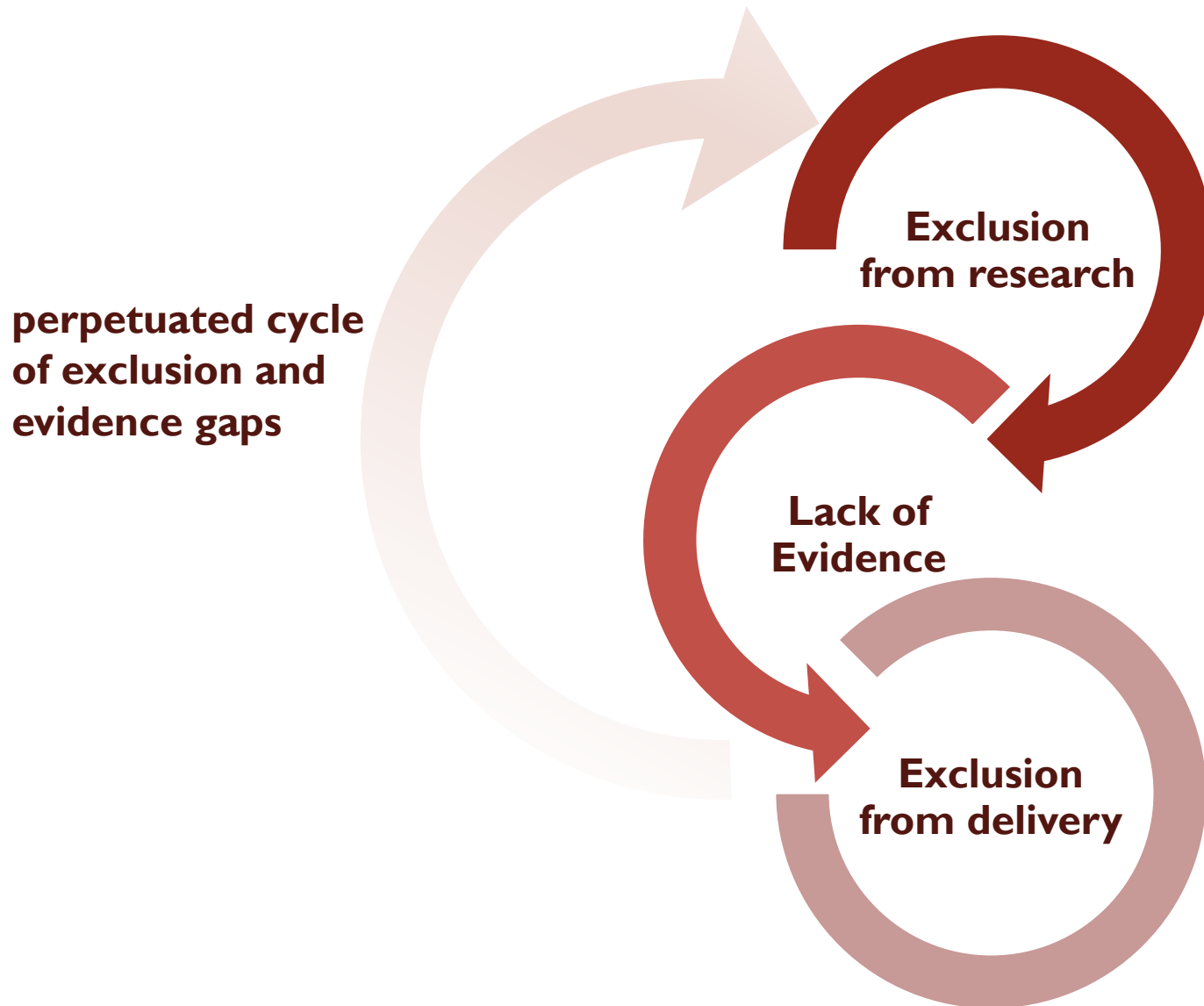


PREVENT Working Group

Additional Consultations

Previous & Ongoing Work

THE PRESUMPTION OF EXCLUSION



INVERTING THE PRESUMPTION: INCLUSION OF PREGNANT WOMEN

Include pregnant women
in vaccine R&D and deployment
UNLESS
scientific & ethical justification for exclusion
(e.g., *that risks > benefits*)

Presumption of inclusion does **not** mean
automatic or absolute inclusion of pregnant
women in every vaccine study or campaign

LIVE VACCINES IN PREGNANCY: THEORETICAL RISKS VS. ESTABLISHED HARMS

- Live vaccines are generally contraindicated for routine administration during pregnancy
 - Greatest concern for live vaccines that replicate systemically and could therefore cross the placenta
- Data for unintended exposures during pregnancy for rubella, smallpox, YF
- Convincing evidence of harm only for smallpox vaccine (fetal vaccinia with 1st trimester administration)



RECOMMENDATIONS

I

Preparedness

II

R&D

III

Vaccine Delivery

STRENGTHEN SURVEILLANCE

Assess risk and understand risks in pregnancy (Recommendation 1)

- Collect baseline data on maternal, obstetric, and neonatal health outcomes
- Include and report pregnancy status and obstetric and neonatal outcomes in infectious disease surveillance

THE VACCINE PIPELINE

Invest in vaccines appropriate for use in pregnancy

- When pregnant women or their offspring are affected, suitability for use in pregnancy should be a strong consideration (Recommendation 7)
- When pathogens pose a risk of severe harm, and promising vaccine candidates are unsuitable for pregnant women, investments should be made in alternative candidates (Recommendation 8)

Assess suitability of novel platforms

- Pregnant women should not be left behind as new technologies are developed (Recommendation 7)

CLINICAL DEVELOPMENT

Enroll pregnant women in clinical studies (Recommendation II)

- Studies conducted during outbreaks should include pregnant women when prospect of benefit > risk for pregnant women, their offspring, or both.
 - Pregnant women as a class
 - Pregnant women as individuals

FAIR INCLUSION IN VACCINE DELIVERY

The default presumption should be that *pregnant women are included* in vaccine campaigns as part of an epidemic response

(Recommendation 17)

- Include unless a review of available evidence by relevant experts concludes that the risks to pregnant women and their offspring from the vaccine are greater than the risks of not being vaccinated



GENERATING EVIDENCE

When pregnant women are included

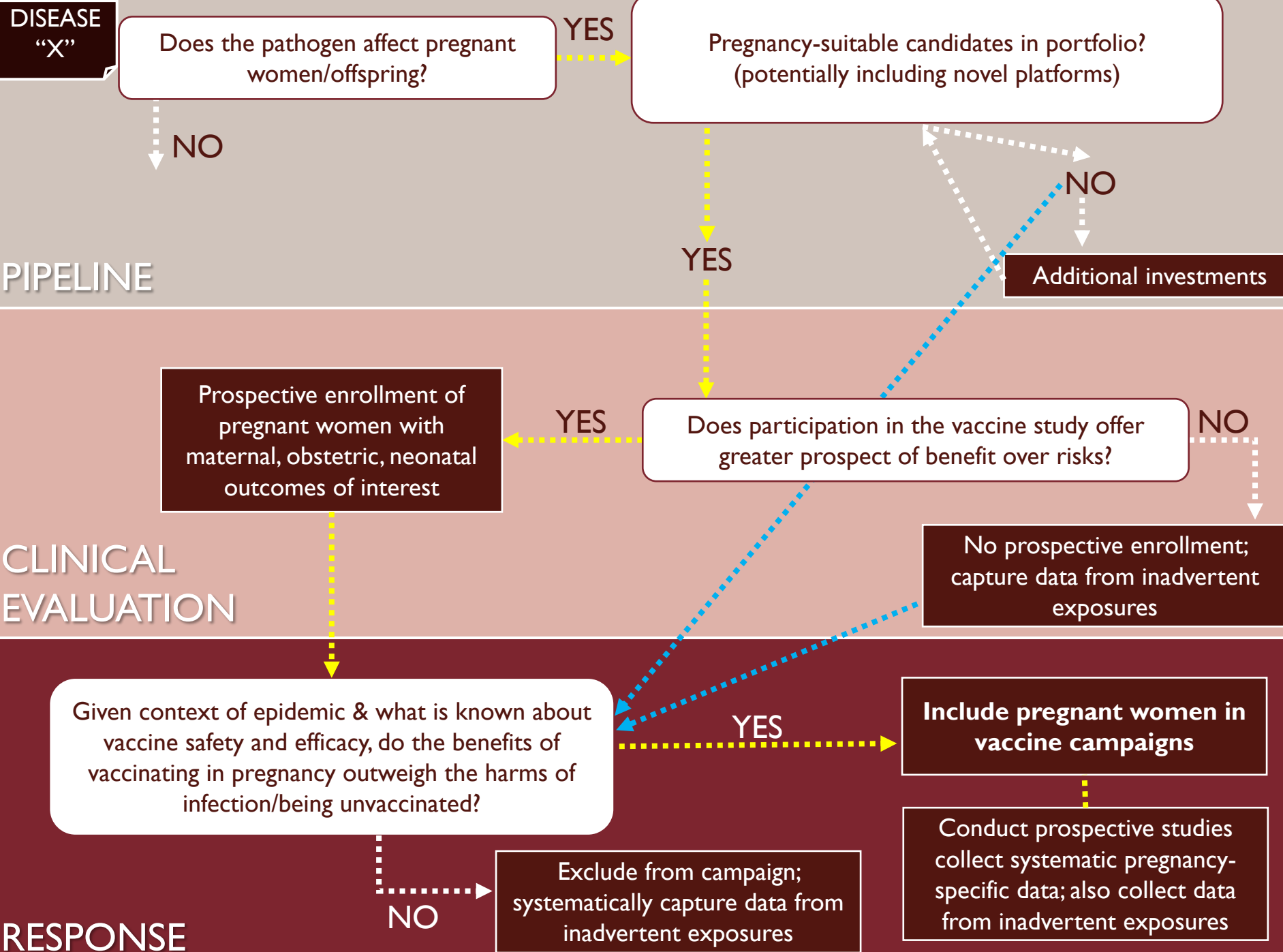
- Prospective observational studies conducted to advance the evidence base for use in pregnancy
(Recommendation 19)

When pregnant women are not included

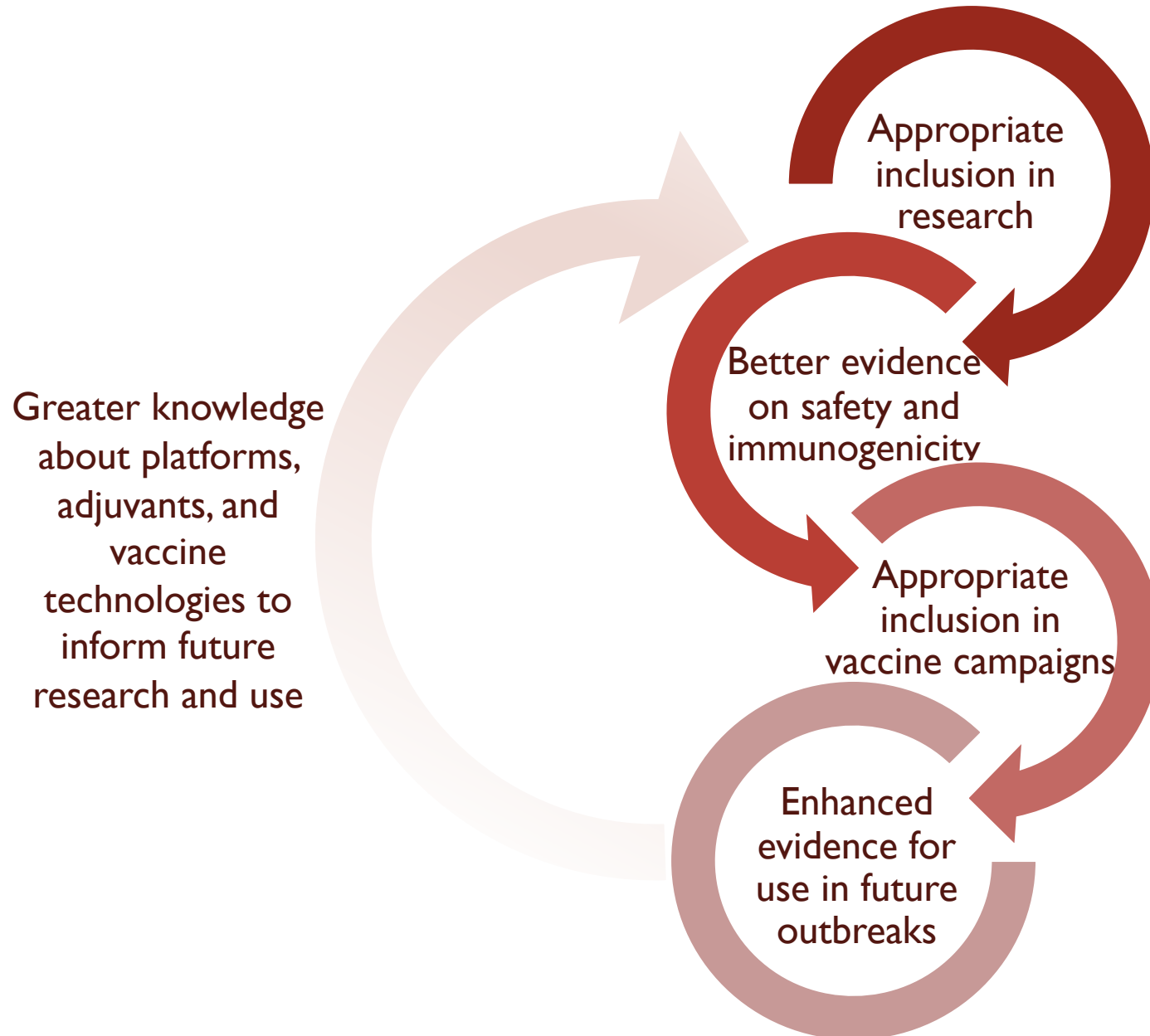
- Inadvertent vaccine exposures during pregnancy should be anticipated
- Data on relevant indicators and outcomes should be systematically captured and analyzed
(Recommendation 22)



THE PRESUMPTION OF INCLUSION IN ACTION: DISEASE “X”



THE PRESUMPTION OF INCLUSION



ESTABLISHING THE PRESUMPTION OF INCLUSION

Convene a global consultation of diverse stakeholders & experts

(Recommendation 6)

- Identify strategies to ensure the presumption of inclusion in vaccine research and deployment
- Determine whether a standing body is needed



QUESTIONS & DISCUSSION