

PREGNANT WOMEN & VACCINES AGAINST EMERGING EPIDEMIC THREATS

**Ethics Guidance for
Preparedness, Research,
and Response**

**The PREVENT
Working Group**

Johns Hopkins Berman Institute of Bioethics
The Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies
(PREVENT) Project

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EXECUTIVE SUMMARY

Recent epidemics, including Zika virus, Lassa Fever, Ebola, and H1N1 influenza, have highlighted the ways in which infectious disease outbreaks can severely—and at times uniquely—affect the health interests of pregnant women and their offspring.ⁱ For some pathogens, pregnant women are at significantly higher risk of serious disease and death. Infection in pregnancy can also result in pregnancy loss or severe congenital harms. Even if the disease caused by the pathogen is no worse in pregnancy, the harms of infection in pregnant women can potentially affect two lives.

These serious and often disproportionate risks underscore the critical need to proactively consider the interests of pregnant women and their offspring in efforts to combat epidemic threats. This is especially true for vaccines, essential tools in the public health response to infectious diseases. Despite increasing support of maternal immunization strategies and efforts to develop certain vaccines specifically targeted to pregnant women, the vast majority of new vaccine products are rarely designed with pregnant women in mind. Moreover, widespread failure to appropriately include pregnant women in vaccine research means that evidence about safety and efficacy in pregnancy has been limited and late in coming. As a result, in numerous outbreaks and epidemics, pregnant women have been denied opportunities to receive vaccines that would have protected them and their offspring from the ravages of these diseases.

This way of treating pregnant women in vaccine research and deployment is not acceptable. Business as usual can no longer continue.


To ensure that the needs of pregnant women and their offspring are fairly addressed, new approaches to public health preparedness, vaccine research and development (R&D), and vaccine delivery are required. This Guidance provides a roadmap for the ethically responsible, socially just, and respectful inclusion of the interests of pregnant women in the development and deployment of vaccines against emerging pathogens. The Guidance is a product of the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies (PREVENT) Working Group—a multidisciplinary, international team of 17 experts specializing in bioethics, maternal immunization, maternal-fetal medicine, obstetrics, pediatrics, philosophy, public health, and vaccine research and policy—in consultation with a variety of external experts and stakeholders.

We recognize the recommendations contained in this Guidance will not always be easy to follow. For some, it will require a new way of thinking about pregnant women and vaccines. For many, it will require a commitment of will and of financial resources. Addressing inequities in biomedical research and public health rarely comes cheaply or without hard work. In terms of the lives saved and the suffering averted, the resources and the effort needed to ensure that pregnant women and their offspring are treated fairly will be more than worth it.

ⁱ We use the term “women” throughout this document, and while we appreciate that individuals who do not identify as women can still become pregnant, transgender and gender non-conforming individuals face different (though also substantial and problematic) barriers to participating in clinical research and having their health needs met that lie beyond the scope of this work. We use the term “offspring” throughout this report to broadly refer to fetuses as well as any persons born whose interests may be affected by *in utero* exposures to pathogens or vaccine administrations.

VISION

The guidance aims to realize a world in which:



Pregnant women
are not unjustifiably
excluded from participating
in vaccine studies.

Pregnant women and their
offspring benefit from advances in
vaccine technologies and are
not left behind as new vaccine
products are developed.

Pregnant women
have access to safe and effective
vaccines to protect them and their
offspring against emerging
and re-emerging pathogenic
threats.

RECOMMENDATIONS

PUBLIC HEALTH EMERGENCY PREPAREDNESS

RECOMMENDATION 1

Health information systems and infectious disease surveillance systems should be strengthened and integrated to ensure that data relevant to maternal, obstetric, and newborn health outcomes can inform scientific and public health responses to emerging pathogenic threats.

- **DIRECTED TO:** public health authorities; the World Health Organization (WHO) and regional health organizations; developers and users of routine health information and global health security systems, including organizations with a focus on maternal and child health outcomes; organizations developing innovative approaches to data collection and surveillance; funders and sponsors of maternal health studies and global health surveillance

Routine health information systems and infectious disease surveillance systems are both essential to an appropriate and rapid response to emerging pathogenic threats. Collecting baseline data on maternal, obstetric, and newborn health can advance the interests of pregnant women and their offspring by enabling detection of increases in adverse events that may signal the presence of infectious disease threats. These baseline rates are also needed to help interpret whether adverse events surrounding pregnancy have any causal link to vaccination. Infectious disease surveillance systems should routinely include pregnancy status and maternal, obstetric, and newborn outcomes in case reports. These data, when integrated with baseline rates from health information systems, can help determine whether a circulating pathogen causes additional or more severe harms in pregnancy.

RECOMMENDATION 2

Evidence-based strategies to promote confidence about vaccination in pregnancy should be developed and implemented ahead of outbreaks, including stakeholder engagement with health care providers, women, their families, and their communities.

- **DIRECTED TO:** public health authorities; health care providers; professional medical associations; medical and health training programs; community leaders; civil society organizations and vaccine advocacy groups; research institutes; funders and sponsors; the media

For immunization programs to be successful, it is critical that populations have confidence in the benefits of a vaccine and its safety, and in the health benefits of vaccination more broadly. Inadequate confidence in vaccines can be especially pronounced among pregnant women and those who care for them. Evidence about safety in pregnancy is limited because of the historic absence of vaccine trials in pregnant women. Moreover, pregnant women and health care providers are understandably concerned about fetal harm, and they are frequently bombarded with mixed messages about what may or may not be harmful in pregnancy. Working now to better understand and address the various sources and drivers of vaccine confidence among pregnant women and their communities will be critical to ensure appropriate vaccine uptake by pregnant women during outbreaks and epidemics.

RECOMMENDATION 3

Communication plans should be developed for clear, balanced, and contextualized dissemination of vaccine study findings, recommendations for vaccine use in pregnancy, and any pregnancy-specific adverse events.

- **DIRECTED TO:** clinical investigators; scientific journal editors; funders and sponsors; public health authorities; global, regional, and local vaccine advisory groups; professional medical associations; regulatory authorities; civil society organizations and vaccine advocacy groups; the media

Because pregnant women, health providers, and the public often overestimate potential fetal harms associated with medications and biologics, effective communication in vaccine development and delivery is critical. In research studies, the required timely reporting of clinically relevant signals and findings on vaccine safety and efficacy in pregnancy to regulatory authorities is not enough. Effective communication to the public and to clinicians through a variety of channels, including traditional and social media, is essential. In an epidemic response that recommends vaccination in pregnancy, communication plans must be clear about any known risks to pregnant women and their offspring, and why the anticipated benefits of vaccination outweigh these risks. When immunization in pregnancy is not recommended, communication plans should be sensitive to fears and concerns about the pathogenic threat that pregnant women share with the rest of the population, and provide them with information about what alternatives, if any, are available to them. In both research and epidemic responses, one best practice for communicating reports of adverse pregnancy or birth outcomes is to present the findings alongside the best available information about the baseline rates of these adverse events, and to acknowledge that many of them have no known cause.

RECOMMENDATION 4

Research efforts that aim to advance vaccine development by using new technologies to study human immune system function and response should include investigations specific to pregnant women and their offspring.

- **DIRECTED TO:** clinical investigators; basic research scientists; funders

Because pregnancy can alter immune response and because both maternal and fetal immune responses may change over the course of gestation, it is important that these foundational studies examine the distinctive characteristics of maternal and fetal immune systems. Understanding these differences could critically inform the development and identification of new vaccines that are safe and effective in pregnancy.

RECOMMENDATION 5

Mechanisms for incentivizing vaccine development for emerging and re-emerging infections and mitigating existing disincentives should include and address pregnancy-specific concerns of vaccine developers.

- **DIRECTED TO:** policymakers; regulatory authorities; funders and sponsors; vaccine developers; civil society organizations and those who are positioned to influence vaccine research, adoption, and delivery, including WHO, the World Economic Forum, and the Coalition for Epidemic Preparedness Innovations (CEPI)

Vaccine developers and manufacturers face significant market challenges and uncertainties in pursuing products targeting emerging and re-emerging pathogens. These challenges can become even more complicated when vaccine products are studied in and ultimately offered to pregnant women—for whom there may be heightened concerns of legal and financial liability. Current mechanisms in place to encourage development of

beneficial biomedical products and protect developers and manufacturers against liability concerns—as well as new incentive programs being explored for vaccines against epidemic threats—need to be intentionally inclusive of the needs and interests of pregnant women.

RECOMMENDATION 6

To help ensure systematic and enduring change in the treatment of pregnant women in global vaccine policy and practices, the World Health Organization should convene a consultation of relevant stakeholders and experts. The Consultation should identify specific strategies to establish for pregnant women the presumption of inclusion in both vaccine research and deployment, including whether a dedicated, standing expert group is needed.

Throughout this Guidance we make multiple recommendations to help ensure that pregnant women and their offspring can fairly benefit from the protection that vaccines offer against emerging epidemic threats. These recommendations outline specific actions that need to be taken, but institutional change at every level—globally, regionally, and nationally—will be required to operationalize these new approaches and move advisory and decision-making bodies toward the new default of presumptive inclusion of pregnant women. To seed this institutional change and explore specific strategies for the

Institutional change at every level will be required to establish a new default of presumptive inclusion of pregnant women.

The Presumptive Inclusion of Pregnant Women

“Presumption of inclusion” does not entail the automatic or absolute inclusion of pregnant women in every vaccine study or every vaccine campaign. Instead, a presumption of inclusion changes the default position. It normalizes the position that pregnant women are to be included in vaccine deployment programs and vaccine R&D. With inclusion of pregnant women as the default position, the burden of proof, both scientific and ethical, falls on those who want to argue for their exclusion. There will certainly be cases where the exclusion of pregnant women from a particular vaccine trial or vaccine campaign will be justified, but starting from a presumption of inclusion helps instantiate and maintain a fundamental shift in the way pregnancy and pregnant women are viewed in the field of vaccines.

systematic consideration of pregnant women in international policies and practices governing vaccine research and delivery, WHO should convene a multi-day, global Consultation of relevant stakeholders. The Consultation should provide a critical opportunity to discuss and determine the best strategies to systematically integrate consideration of the interests of pregnant women and their offspring throughout all relevant WHO-supported activities, including whether a dedicated, standing group of relevant and diverse experts is needed. The Consultation should also consider ways to support regional and national public health authorities who may wish to establish similar expert groups.

VACCINE RESEARCH & DEVELOPMENT

RECOMMENDATION 7

Suitability for use in pregnancy should be a strong consideration in development and investment decisions for vaccines against emerging pathogenic threats.

- **DIRECTED TO:** CEPI, U.S. Biomedical Advanced Research and Development Authority (BARDA), and other funders and sponsors; WHO emergency response teams, R&D Blueprint teams and TPP Working Groups; vaccine developers

If pregnant women, and the offspring they carry, are among those threatened by an emerging pathogen, then suitability for use during pregnancy should be an important vaccine development priority. Organizations investing in the vaccine pipeline against emerging pathogenic threats should try to ensure that, among candidates prioritized for development, at least some use platforms and adjuvants that would make them suitable for use in pregnancy. Early investment in options that are most likely to be acceptable in pregnancy can pave the way for pregnant women and their offspring to realize benefits from vaccine candidates that ultimately prove successful—and help ensure that they, like other population groups, will be protected against emerging infectious diseases. For pathogens that pose significantly greater threats in pregnancy—of fetal harm, maternal harm, or both—funding calls should designate greater investment priority to candidates likely to be suitable for use in pregnancy. When pregnant women or their offspring are at higher risk of harm, it would be particularly unjust for their needs not to be included in vaccine development priorities.

RECOMMENDATION 8

When pathogens pose a risk of severe harm to pregnant women or their offspring and the most promising vaccine candidates are likely to be contraindicated for routine use in pregnancy, investments should be made in alternative vaccine candidates that could be more readily used in pregnancy.

- **DIRECTED TO:** CEPI, BARDA, and other funders; vaccine developers

It is possible that the vaccine candidates that move most rapidly through the R&D pipeline are found to be problematic for use in pregnancy. Unless other vaccines with more favorable profiles for use in pregnancy are then prioritized, it is possible that pregnant women and their offspring will end up without any vaccine protection against the emerging pathogenic threat. This prospect is particularly dire when the target pathogen has more severe consequences in pregnancy. When pregnant women and their offspring suffer disproportionately compared with other population groups from an emerging infectious disease threat, justice calls for the vaccine enterprise to make every reasonable effort to bring to market a safe and effective product that pregnant women can use.

Pregnant women need to be on the agenda when decisions about investment and funding are made.

RECOMMENDATION 9

Non-clinical studies that are a prerequisite for clinical trials in pregnant women, such as developmental toxicology studies, should be initiated early in the clinical development of promising vaccine candidates, before efficacy trials are planned.

- **DIRECTED TO:** CEPI, BARDA, and other funders and sponsors; vaccine developers; national regulatory authorities

Current regulatory guidance often requires that certain non-clinical studies must be completed prior to including pregnant women in clinical trials. Because pregnant women should be able to participate in large-scale efficacy studies conducted during outbreaks whenever the benefits outweigh the risks (see Recommendation 11), any non-clinical studies required prior to clinical evaluation in pregnant women should be conducted as soon as promising vaccine candidates move from phase 1 to phase 2 clinical trials.

RECOMMENDATION 10

Studies to assess immune responses to vaccines in pregnancy should be conducted before or between outbreaks whenever scientifically possible and ethically and legally acceptable.

- **DIRECTED TO:** CEPI, BARDA, and other funders and sponsors; vaccine developers; clinical investigators

Although much of the work to evaluate vaccines in pregnancy will be done during outbreaks and epidemics (see Recommendation 11), there will be some cases in which it will be both beneficial and feasible to generate immunogenicity data in pregnancy before or between outbreaks. Because immune system functioning is altered in pregnancy, it is possible that a vaccine will be less immunogenic or induce atypical immune responses in pregnant women, with potential implications for its effectiveness as well as the

dosing and frequency required in pregnancy to generate sufficient protection. Such immunogenicity studies would be particularly valuable if a correlate of protection for the vaccine has already been established. In the absence of an outbreak or epidemic, it may be difficult to demonstrate that studies to assess immune response in pregnant women have a favorable risk-benefit profile. However, there may be instances in which the future exposure to a pathogen among a particular population is likely enough to conclude that the potential benefits of being protected would outweigh the risks associated with a particular candidate vaccine.

RECOMMENDATION 11

Clinical development plans for investigational vaccines against emerging and re-emerging pathogens should include studies designed to evaluate vaccines in pregnancy. Pregnant women should have opportunities to enroll in vaccine studies conducted during outbreaks and epidemics whenever the prospect of benefit outweighs the risks to pregnant women, their offspring, or both.

- **DIRECTED TO:** CEPI, BARDA, and other funders and sponsors; vaccine developers; clinical investigators and trial implementation partners; research ethics committees; national regulatory authorities

This recommendation rests on two claims of justice about the importance of treating pregnant women and their offspring fairly in the conduct of research on vaccines for emerging and re-emerging infections. The first of these justice claims pertains to pregnant women as a class: as a matter of equity, as well as public health, the evidence base for pregnant women should be as good as possible and generated as contemporaneously as possible to the evidence for the general population. The second, independent reason motivated by justice is that pregnant women, as the moral equals of others,

should have fair access to the prospect of direct benefit that may ensue from receiving an experimental vaccine. For both of these reasons, it is critical that vaccine research conducted during outbreaks include appropriate plans for research with pregnant women when there is a reasonable judgment that the prospective benefits of enrollment outweigh the risks.

RECOMMENDATION 12

Vaccine studies that include women of childbearing potential should have plans to systematically collect data on immunogenicity and pregnancy-specific indicators of safety from participants who are unknowingly pregnant at the time of exposure or become pregnant within a relevant window following vaccine administration.

- **DIRECTED TO:** CEPI, BARDA, and other funders and sponsors; vaccine developers; clinical investigators and trial implementation partners; research ethics committees; national regulatory authorities

In trials enrolling women of childbearing potential, including vaccine trials conducted in outbreak contexts, it is predictable that some women not known to be pregnant at the time of enrollment will nevertheless be pregnant at enrollment, or become pregnant in the course of the trial. Historically, data from inadvertent exposures during pregnancy have been a key source of information regarding the safety profiles of vaccines in pregnancy. Having a plan to systematically generate evidence from participants who are unknowingly pregnant at the time of administration also enables capturing data from vaccine exposures earlier in pregnancy than would be likely in trials prospectively enrolling pregnant women. Wherever possible, systematic observational studies that are designed to capture inadvertent exposures to vaccine during pregnancy should also include longitudinal

evaluation of safety, immunogenicity, and other relevant outcomes. Data from inadvertent exposures during pregnancy should be collected using standardized methods and case definitions and must be cautiously interpreted, particularly when adverse events occur in early pregnancy, as these very commonly occur unrelated to vaccine exposure.

RECOMMENDATION 13

Women participating in vaccine trials who become aware of a pregnancy during the trial should be guaranteed the opportunity, through a robust re-consent process, to remain in the trial and complete the vaccine schedule when the prospect of direct benefit from completing the schedule can reasonably be judged to outweigh the incremental risks of receiving subsequent doses.

- **DIRECTED TO:** clinical investigators and trial implementation partners; vaccine developers; research ethics committees; national regulatory authorities

In vaccine trials that include prospectively enrolled pregnant women, participants who become pregnant after enrollment should be provided the opportunity to continue to receive vaccine doses after a renewed consent process. In trials that exclude pregnant women from prospective enrollment, determinations about continued dosing should be based on assessment of the potential benefits and harms specific to the circumstances of the pregnant participant, including possible risks associated with receiving an incomplete vaccination series and the risks already incurred from the first vaccination. In both cases, a robust re-consent process will be essential to allowing pregnant women to determine whether they want to receive additional doses. Regardless of whether they choose or are permitted to continue with the vaccine schedule, participants who become pregnant should be provided all study-related benefits and ancillary care to which they would otherwise be entitled.

RECOMMENDATION 14

When a pregnant woman of legal standing to consent is judged eligible to enroll or continue in a vaccine trial, her voluntary and informed consent should be sufficient to authorize her participation.

- **DIRECTED TO:** clinical investigators and trial implementation partners; research ethics committees; national authorities in charge of governance and oversight of human subjects research

As a matter of respect, and as a key aspect of ensuring fair access to investigational vaccines, the consent of pregnant women who are judged eligible to participate in or continue receiving doses in a vaccine trial should be sufficient for participation. Pregnant women are the moral equals of other self-governing adults. Further, requiring the consent of additional actors can present a material barrier to the benefits research may offer to the offspring. At the same time, researchers should support pregnant women who wish to involve partners, family members, and other personal supports in decisions to join or remain in vaccine trials.

RECOMMENDATION 15

Experts in maternal and perinatal health, pediatrics, and research ethics should be involved in decisions about funding; trial design; research ethics oversight; and the generation, analysis, and evaluation of evidence on vaccine use in pregnancy.

- **DIRECTED TO:** funders and sponsors; vaccine developers; clinical investigators; research ethics committees; national health authorities in charge of research governance and regulations; data safety monitoring boards

Pregnant women deserve that decisions affecting them will be made in careful, thoughtful, and evidence-based ways, involving the most informed experts possible. Experts

in obstetrics and gynecology, maternal-fetal medicine, pediatrics, and neonatology, especially those who have experience with infectious diseases, immunology, and maternal immunization, have specialized knowledge that is critical to properly identifying and addressing the needs and interests of pregnant women and their offspring in research and development.

RECOMMENDATION 16

Whenever possible, the perspectives of pregnant women should be taken into account in designing and implementing vaccine studies in which pregnant women are enrolled or in which women enrolled may become pregnant.

- **DIRECTED TO:** clinical investigators; vaccine developers; research ethics committees; community advisory boards; funders and sponsors; public health authorities

Community engagement and participatory-based approaches to biomedical research have been increasingly recognized as good practice in the design and conduct of human subjects research. In the context of vaccine studies enrolling pregnant women, soliciting the perspectives of pregnant women from the communities in which the research will be conducted offers a way to demonstrate respect, and can be critical to the success of a study. The perspectives of pregnant women can improve various aspects of study design by, for example, determining what information and outcomes are most important to pregnant women, ascertaining culturally relevant considerations for the consent process, and establishing the appropriate frequency and location of study visits based on the daily demands on women's lives throughout pregnancy and after delivery.

VACCINE DELIVERY DURING THE EPIDEMIC RESPONSE

RECOMMENDATION 17

Pregnant women should be offered vaccines as part of an outbreak or epidemic response. Pregnant women should only be excluded if a review of available evidence by relevant experts concludes that the risks to pregnant women and their offspring from the vaccine are demonstrably greater than the risks of not being vaccinated.

- **DIRECTED TO:** public health authorities; national immunization programs; recommending and advisory bodies, including professional medical associations, SAGE, and other relevant WHO advisory committees; teams overseeing the epidemic response, such as Public Health Emergency Operations Centers and incident management teams; organizations involved in vaccine delivery in the outbreak response, including UNICEF, MSF, and International Federation of Red Cross

Because pregnant women are the moral equals of others, and because there is nothing about being pregnant that would make them or their offspring less susceptible to the harms of emerging pathogenic threats, the default position of advisory bodies and public health authorities should be that pregnant women are offered vaccines alongside other affected populations during an epidemic response. Any recommendations or decisions not to use vaccines in pregnancy during an outbreak or epidemic requires justification of exclusion based on a reasonable determination that the risks to pregnant women and their offspring from vaccination are demonstrably greater than the likely benefits of being protected from the pathogen. This determination should be made by relevant experts, including those in maternal, perinatal, and pediatric health. ***The absence of evidence and the mere theoretical or even documented risk of fetal harm is generally not sufficient to justify***

denying pregnant women access to a vaccine in an outbreak or epidemic. Even when the risk of fetal harm from the vaccine is significant, if the likelihood and severity of harms from the pathogen are high enough for pregnant women and their offspring, then the benefits of vaccination may still outweigh the risks.

RECOMMENDATION 18

When there is a limited supply of vaccine against a pathogenic threat that disproportionately affects pregnant women, their offspring, or both, or when only one vaccine among several is appropriate for use in pregnancy, then pregnant women should be among the priority groups to be offered the vaccine.

- **DIRECTED TO:** public health authorities; national immunization programs; teams overseeing the epidemic response, such as Public Health Emergency Operations Centers and incident management teams; WHO; organizations involved in vaccine delivery as part of the outbreak response, including UNICEF, MSF, and International Federation of Red Cross

It is not uncommon in outbreak and epidemic settings for vaccine demand to exceed supply. For some pathogenic threats, pregnant women and their offspring may be among the hardest hit groups; in these cases, as with any other high-risk group, they should be a priority in the allocation of a vaccine that is in short supply. Additionally, even when the threat is no worse for pregnant women than it is for other affected population groups, vaccinating a pregnant woman protects not only the pregnant woman but also her offspring. Particularly for high-consequence pathogens with significant mortality rates, there may be considerable additional benefit in vaccinating pregnant women.

During an epidemic, the default should be to offer vaccines to pregnant women alongside other affected populations.

RECOMMENDATION 19

When vaccines are offered to pregnant women during outbreaks or epidemics, prospective observational studies should be conducted with pregnant women and their offspring to further advance the evidence base for use in pregnancy.

- **DIRECTED TO:** vaccine manufacturers; public health and regulatory authorities; national immunization programs; organizations involved in vaccine delivery as part of the outbreak response, including UNICEF, MSF, and International Federation of Red Cross; researchers; funders; groups that oversee research with human subjects, including research ethics committees

Implementing prospective observational studies in pregnant women and their offspring who receive the vaccine as part of the outbreak or epidemic response provides an important opportunity to narrow the evidence gap between pregnant women and other population groups. If such studies are not conducted, decision-makers in future outbreaks and epidemics will be faced with the same evidence gap as current decision makers—an unacceptable outcome from both an equity and a public health perspective. Moreover, safety data obtained from evaluating a vaccine derived using a novel platform in pregnant women may inform future decision-making regarding the suitability of that platform for development of vaccines against other pathogens.

RECOMMENDATION 20

When vaccines are offered to pregnant women during outbreaks and epidemics, the consent of the pregnant woman should be sufficient to authorize administration whenever the pregnant woman is of legal standing to consent to medical care.

- **DIRECTED TO:** public health authorities; national immunization programs; teams overseeing the epidemic response, such as Public Health Emergency Operations Centers and incident management teams; organizations involved in vaccine delivery as part of the outbreak response, including UNICEF, MSF, and International Federation of Red Cross; clinicians and obstetricians; pregnant women and communities

As a matter of respect, and as a key aspect of ensuring fair access to vaccines during an outbreak or epidemic, when vaccines are offered to pregnant women, their consent should be sufficient to authorize administration. Women should be presumed to have authority for decisions about their own medical care. Women are no different from men in this respect, and pregnant women are no different than women who are not pregnant. All adults, regardless of gender or pregnancy status, have rights of self-determination over decisions that affect their bodies and their health. Pregnant women who wish to engage or consult with their partners or other family or friends in making their decisions about vaccination should be supported in doing so.

Ensuring that pregnant women have vaccines to protect them and their offspring will require generation of evidence from pregnant women.

RECOMMENDATION 21

When evidence supports a determination that the risk of serious maternal or fetal harm from the vaccine outweighs the vaccine's benefits, pregnant women should be a priority group for access to alternative preventative or treatment measures.

- **DIRECTED TO:** public health authorities; teams overseeing the epidemic response, such as Public Health Emergency Operations Centers and incident management teams; organizations involved in vaccine delivery as part of the outbreak response, including UNICEF, MSF, and International Federation of Red Cross; providers

Despite the best possible research and development efforts, the available vaccine for a given outbreak or epidemic may have sufficiently severe pregnancy-specific risks, even compared with the risks posed by the pathogen, that it is not made available to pregnant women. The moral objective remains, however, of giving pregnant women and their offspring as close to an equal chance of avoiding the harms of infection as the rest of the population. If they cannot be protected by immunization, then pregnant women, along with any other population group that cannot receive the vaccine, should be given preferential access to alternative preventive interventions and treatments.

RECOMMENDATION 22

When vaccines against emerging pathogens are not recommended for use in pregnancy, inadvertent vaccine exposures during pregnancy should be anticipated and mechanisms put in place for the collection and analysis of data from pregnant women and their offspring on relevant indicators and outcomes.

- **DIRECTED TO:** public health and regulatory authorities; vaccine manufacturers; national immunization programs; funders and sponsors

Even when pregnant women are intentionally excluded from the vaccine response effort, it is reasonable to expect that some of the women who are vaccinated will be unknowingly pregnant at the time of vaccine administration, or will become pregnant within a relevant window of its administration. Collecting data about outcomes in these women and their offspring in the midst of an active outbreak or epidemic will be difficult and costly, but there are two sets of ethical and public health reasons why it is critically important to do so. First, collecting data from unintentional exposures to vaccine in pregnancy during an outbreak or epidemic affords an important opportunity to gather evidence about novel vaccine technologies and thus to help ensure that pregnant women are not left behind as vaccine technology advances. Second, research and public health communities have a responsibility to pursue evidence about the likelihood and nature of any associated risks pregnant women and their offspring face from these unintended exposures to inform personal and clinical decision-making.

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