Advancing HIV Prevention Research in Pregnant and Lactating People (PLP)

Think Tank Report & Action Plan

March 2023

AVAC
Global Advocacy for HIV Prevention

PHASES
PREGNANCY + HIV/AIDS
SEEKING EQUITABLE STUDY

Background

Cisgender women face substantial risk of HIV infection during pregnancy and breastfeeding in high burden areas,[1] with a risk of infection that more than doubles per condomless sex act during pregnancy and the postpartum period.[2] Moreover, acute maternal infection is associated with significantly elevated risk of perinatal transmission.[3,4] Yet cisgender, adult pregnant and lactating people (PLP) remain profoundly underrepresented in clinical trials of novel pre-exposure prophylaxis (PrEP) agents. The inclusion of adolescent, transgender and gender-diverse PLP is even more limited. Without evidence specific to PLP, individuals may be inadvertently under- or overdosed, exposed to drugs that carry unacceptable risks to the pregnant person and/or fetus, or denied access to needed products and medication. While the rollout of oral TDF PrEP for PLP in limited high-burden settings is an important step forward, pregnancy and the postpartum periods may pose unique barriers to daily TDF PrEP adherence, and extensive unmet need for effective, acceptable, and accessible HIV prevention options remains.

Growing consensus around the ethical and public health imperative for the responsible inclusion of PLP in clinical research has recently gained critical momentum. However, much work remains to realize the equitable inclusion of PLP in HIV prevention research. To this end, AVAC, as part of the Coalition to Accelerate and Support Prevention Research (CASPR), in collaboration with the PHASES Project, convened a highly diverse, multi-stakeholder think tank to identify priority advocacy objectives informed by consensus recommendations, and to develop an action plan to help advance the responsible study of HIV prevention in PLP to provide urgently needed evidence.

The work of the AVAC/PHASES think tank to advance HIV prevention research with PLP was importantly grounded in a trio of conceptual frameworks: 1. Reproductive Justice, 2. Conceptual shifts articulated in the Pregnancy and HIV/AIDS: Seeking Equitable Study (PHASES) Ethics Guidance,[5,6] and 3. WHO/IMPAACT framework for accelerated inclusion of pregnant women in pre-licensure clinical trials.[7,8]

Reproductive Justice

The Reproductive Justice framework was identified by the think tank as an essential lens and new perspective for understanding the complex challenges faced by PLP most directly affected by the exclusion of this population in HIV prevention research, and for identifying effective pathways forward. **Reproductive Justice is the human right to maintain personal bodily autonomy, have children, not have children, and parent children in safe and healthy communities**. Developed by a Black women's collective in 1994 in response to the failure of a reproductive rights-based approach to address the intersecting oppressions underlying profound systemic inequities, Reproductive Justice elevates and centers the needs, voices, lived experiences, and leadership of African and other Black and Brown women, trans and gender diverse people, and youth. Advancing the core principles of justice and dignity, Reproductive Justice recognizes women's right to reproduce or not as a foundational human right. It acknowledges the social reality of inequalities of opportunity to realize this right and emphasizes the importance of access to evidence-based, comprehensive sexual and reproductive health care.[9,10]

PHASES Conceptual Shifts

Specific to the context of HIV, the **Pregnancy and HIV/AIDS: Seeking Equitable Study (PHASES) Working Group developed ethics guidance** for advancing HIV/co-infections research in pregnancy.[5,6] Foundational to the PHASES guidance and the work of the AVAC/PHASES think tank were the following **three conceptual shifts**:

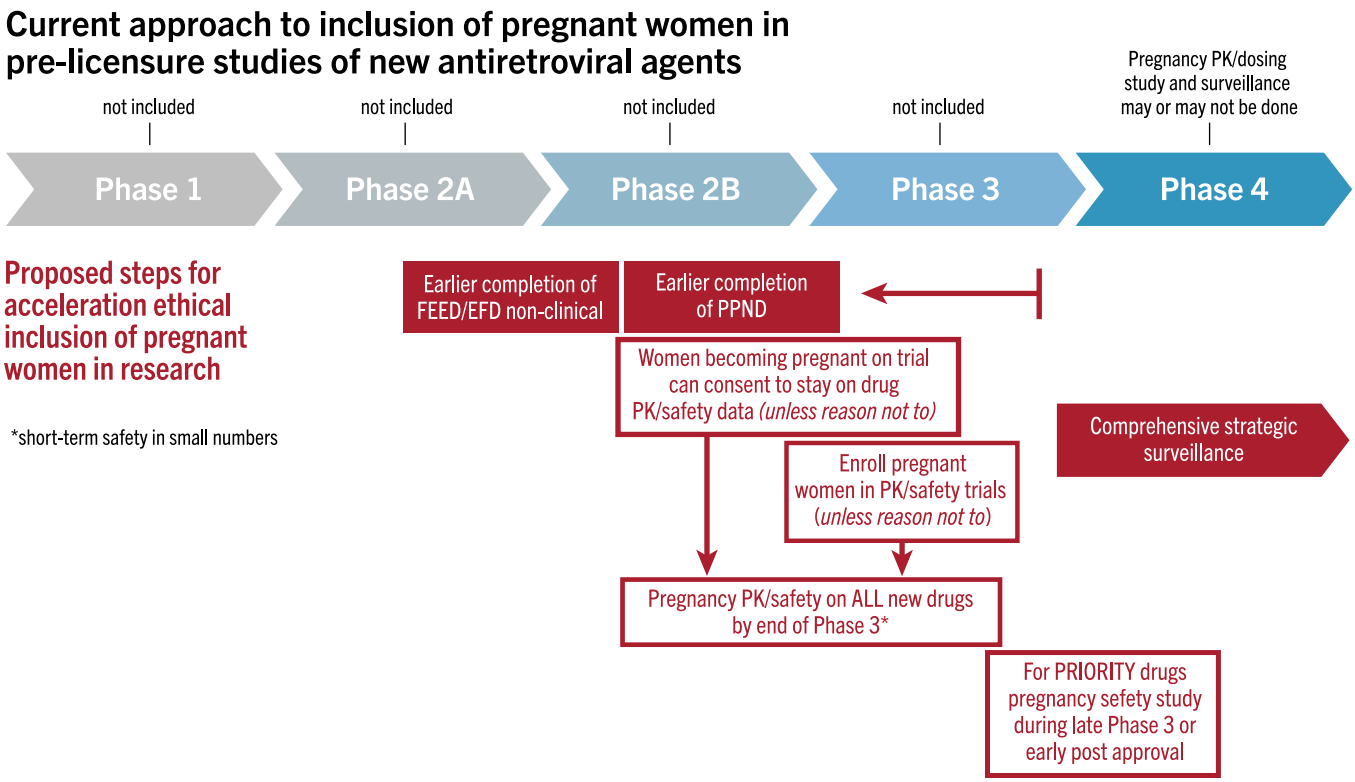
Consider pregnant populations as complex, rather than vulnerable. The term "vulnerable" has been used to describe populations either unable to provide valid consent to research participation (e.g., children), or who are part of a class subject to exploitation (e.g., prisoners) neither of which applies to pregnancy. Moreover, the designation has had an unintentional chilling effect on responsible research with pregnant persons. Thus, ethical and regulatory guidance is increasingly avoiding characterizing pregnant populations in this way. "Complex" better represents the unique cultural, social, ethical, and physiologic complexities that pregnancy carries with it in HIV prevention research.

Protect pregnant people through research, rather than protect them from research. While protection from the risks of research participation is important, not including pregnant people can also increase their risk. When data on medicines likely to be used by pregnant people is not collected in a research context, risks shift to the clinical context where many more individuals may be affected.

Fair inclusion, rather than presumptive exclusion. Trial participation can offer participants access to potentially beneficial interventions not otherwise available. Exclusion from research can also prevent pregnant people from accessing beneficial interventions in a timely way, once they reach the market, as we recently experienced with SARS-CoV vaccines and therapeutics. Advancing research justice requires fair distribution of both the risks of research and the benefits. PLP and their health interests deserve equitable inclusion in the HIV prevention research agenda.[5,6]

WHO/IMPAACT Framework for Accelerated Inclusion of Pregnant Women in Pre-Licensure Clinical Trials

The work of the AVAC/PHASES think tank was also importantly shaped by the **WHO/IMPAACT framework for accelerated inclusion of pregnant women in pre-licensure clinical trials**.[7,8] The framework makes specific recommendations around inclusion of pregnant people in Phase 2 studies and beyond, with the overall "**goal to have PK and preliminary safety data available on all new HIV agents in pregnancy available at the time of drug approval.**"[7] To realize this goal, key principles and recommended actions for a range of stakeholder groups are advanced, including robust involvement of women of childbearing potential affected by HIV in identifying research questions and throughout the research lifecycle,[11] and the important role of civil society and community based organizations in building community literacy and advocacy around the inclusion of pregnant women in pre-licensure trials and active surveillance.[7]



Gender Inclusive Language

Throughout this document, we use the terminology "pregnant and lactating people" (PLP) to be inclusive of trans men and gender nonbinary people who may experience pregnancy and lactation, and who have been underrepresented in HIV prevention research. The term "lactating" refers to the biological production of breast milk which may be fed to the infant at the breast/chest or expressed and fed from a cup or bottle.[12] While the term breast refers to both the male and female body part in medical terminology, colloquially, the words breast and breastfeeding have strong associations with the female sex, and may be perceived as exclusionary or insensitive when applied to trans men or gender nonbinary individuals. However, consensus has yet to be reached around this language choice, and we recognize challenges and confusions that may be encountered when translating this gender inclusive terminology, and/or in cultures where there are no apparent nonfemale lactating people.[13] We will therefore continue to engage with a broad range of advocates and stakeholders around the most appropriate language to apply in their contexts to effectively balance and advance the needs of this diverse population in the HIV prevention research agenda.

Think Tank Approach

Significant stakeholder engagement guided the development of the think tank, in alignment with the Good Participatory Practice Guidelines[12]– including consultations with key stakeholders and a pre-meeting, co-convened with CASPR partner Pangaea Zimbabwe Aids Trust (PZAT), with civil society advocates and former trial participants. Sixty-three global stakeholders, including researchers, industry representatives, trial participants, civil society, regulators, and funders attended a half-day virtual workshop on April 26, 2022, co-facilitated by AVAC and the PHASES Project (see list of participants, Appendix A). Participants were asked to familiarize themselves with the PHASES and WHO/IMPAACT guidance documents prior to the meeting. The workshop included sessions on the state of the HIV prevention evidence base for PLP; viewpoints of former trial participants facilitated by PZAT; the PHASES and WHO/IMPAACT technical consultation; panel discussion with diverse stakeholders discussing priority action areas and facilitated planning sessions to identify priority issues and next steps for advancing HIV prevention research with PLP (see Appendix B. Agenda).

Following the workshop, the planning team distilled draft priority goals from the discussion using the following criteria: 1) represents major themes identified as a priority by numerous participants; 2) identifies unique, under addressed areas in need of coordinated action; 3) perception that attainment of the goal would significantly advance the field. Objectives and action steps were informed by the outcomes of the think tank workshop, subsequent discussions with and feedback from think tank participants, and application of the Reproductive Justice framework to relevant emerging issues. Feedback from think tank participants was solicited and integrated in an iterative process. The resulting action plan outlines four priority goals and concrete steps to advance HIV prevention research in PLP.

Action Plan

Priority Goal 1: Advance responsible HIV prevention research in pregnant and lactating populations (PLP) using a Reproductive Justice framework

Reproductive Justice is the human right to maintain personal bodily autonomy, have children, not have children and parent children in safe and healthy communities, and emphasizes the importance of access to evidence-based, comprehensive sexual and reproductive health care. Reproductive Justice acknowledges the inequalities of opportunity to realize this right, and elevates and centers the needs, voices, lived experiences, and leadership of African and other Black and Brown women.

Center PLP in all efforts to set and advance an HIV prevention research agenda responsive to their needs.

Action Steps:

- Organizations responsible for setting HIV prevention research priorities, including the WHO, funders, product developers and HIV prevention research organizations, should meaningfully engage and center PLP and the organizations that work with these populations in setting HIV prevention research priorities and elevate the importance of evidence on maternal and fetal safety, dosing, access, feasibility and acceptability of biomedical HIV prevention products for PLP.

- Researchers, civil society, and advocates - with the support of funders - should identify, co-develop and disseminate resources and tools to strengthen, inform, and advocate for and support the meaningful participation of PLP, as well as organizations that work with these populations, in HIV prevention research agenda setting.
- To close evidence gaps surrounding HIV prevention in pregnancy are further magnified across these marginalized groups, including adolescent, trans and gender non-binary people and the organizations that work with them, should be intentionally engaged and actively supported to participate in setting an HIV prevention research agenda responsive to their needs.

Join together with key allies addressing intersecting oppressions to identify and develop shared goals to advance equity and reproductive justice.

Action Steps:

- Researchers, civil society and advocates should engage with other stakeholder groups addressing intersecting oppressions to advance the inclusion of PLP in research that is responsive to these issues and achieve the goals of this action plan.
- Researchers, civil society and advocates should join allies, amplifying efforts to affect structural change that promote racial and gender equity, health and wellbeing.

Identify potential challenges to and solutions for advancing equitable clinical research design and conduct with PLP in restrictive reproductive health policy environments.

Action Steps:

- Researchers and civil society, with the support of funders and in partnership with other key stakeholders and allies, should conduct legal, ethical and policy analyses to characterize the potential implications of rescinding the US constitutional right to abortion, as well as the ongoing impact of restrictive policies in global research contexts on the conduct of global HIV prevention research with PLP; and to identify approaches to advance timely conduct of research and ensure protection of research participants in these contexts.
- Researchers, civil society and advocates should widely disseminate these findings to diverse stakeholders and support the implementation of recommendations.

Ensure that contraception requirements for pre-licensure trials are sensitive to actual reproductive risk, as set out in the WHO/IMPAACT/IAS Call to Action[7], and incorporate evidence-based contraceptive counseling when indicated.

Action Steps:

- Product developers should remove contraception requirements in pre-licensure trials once non-clinical reproductive toxicity data are available and indicate no concerning signals and dosing for non-pregnant people is determined, as described in the WHO/IMPAACT/IAS Call to Action.
- When contraception requirements are indicated, product developers should deploy evidence-based and participant-centered contraceptive counseling.
- HIV prevention trial sites should actively facilitate and strongly consider providing access to sexual and reproductive health services that promote women's health and autonomy, including contraceptive counseling, even when contraception requirements are not warranted.

Priority Goal 2: Engage stakeholders in an early, sustained and meaningful way in the design and conduct of biomedical HIV prevention trials tailored to the distinctive complexities of research with PLP.

Early, sustained, and meaningful stakeholder engagement using participatory approaches is critical to the success of HIV prevention research and to help shape ethical research responsive to community needs. Pregnancy introduces unique cultural, social, ethical and scientific complexities to HIV prevention research, necessitating approaches that specifically attend to these complexities.

Develop and disseminate Good Participatory Practice (GPP)[14] best practices specific to biomedical HIV prevention research with PLP in all their diversities.

Action Steps:

- AVAC, with active participation of stakeholder groups, will lead the development of GPP best practices tailored to the design and conduct of biomedical HIV prevention trials with PLP, which should include an emphasis on:
  - Developing research literacy specific to biomedical HIV prevention studies that include PLP for PLP, their communities, immediate and extended family members, healthcare providers who work with PLP and other influential stakeholders.
  - Early, meaningful and sustained community engagement using participatory approaches, with attention to the involvement of PLP, their immediate and extended family members, and other influential stakeholders in trial advisory mechanisms beginning with the formative research process preceding trial design and extending throughout the research lifecycle.
- Stakeholder groups, including AVAC and other sexual and reproductive health and HIV advocates, WHO, and researchers, should leverage existing platforms and networks for wide dissemination of GPP best practices specific to PLP and integrate them into existing GPP trainings.

> *"I think one of the priority issues is improving literacy around pregnant and breastfeeding populations in research. And this literacy is two pronged – firstly, targeting the pregnant and breastfeeding populations themselves and targeting their influencers... (W)hen a person is pregnant, especially in our African context, every family member has a stake in what you do."*
>
> – **Think tank participant**

Robustly implement GPP best practices specific to biomedical HIV prevention research with PLP.

Action Steps:

- Funders, sponsors and implementers of HIV biomedical research should robustly implement GPP best practices in the design and conduct of biomedical HIV prevention trials with PLP, including:
  - Research literacy specific to biomedical HIV prevention studies that include PLP should be developed for PLP, their communities, immediate and extended family members, healthcare providers who work with PLP and other influential stakeholders.
  - Communities being considered for trial site selection should be meaningfully engaged utilizing approaches that attend to the distinctive complexities of designing and conducting biomedical HIV prevention research with PLP. This engagement will include the involvement of PLP, their immediate and extended family members, healthcare providers who work with PLP and other influential stakeholders in trial advisory mechanisms.

Priority Goal 3: Develop and harmonize regulatory frameworks and processes that promote the responsible generation of data specific to PLP for new therapeutics and biomedical prevention products.

Regulatory frameworks across jurisdictions that are harmonized to protect PLP through responsible research have the potential to be pivotal catalysts for advancing the HIV prevention evidence base for this population. The global evolution of regulations around pediatric-specific evidence for drug development holds important lessons and examples of successful approaches to generating needed data for a historically excluded group. Organizations well positioned to lead progress in developing and harmonizing regulatory frameworks to protect PLP through responsible HIV prevention research include the WHO, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), African Medicines Regulatory Harmonisation (AMRH), the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the South African Health Products Regulatory Authority (SAHPRA).

Incentivize and/or require the generation of data specific to PLP for approval of new therapeutics and biomedical prevention products.

Action Steps:

- Advocates should identify and coordinate with key stakeholders to encourage national governments, especially in areas with high HIV burden and/or outsized global influence, to bolster the ability of drug regulatory agencies to incentivize and/or require the generation of data specific to PLP as a component of applications for approval of new therapeutics and biomedical prevention products. However, the absence of PLP-specific data should not be used as a reason to preclude access to therapeutics and prevention products for populations who are pregnant, lactating, or of childbearing potential.

"Industry is highly regulated, and if there is a clear protocol, clear guidance, it makes it a lot easier for sponsors to innovate by following guidance."

– **Think tank participant**

Accelerate the ethical inclusion of PLP in research and generate PLP-specific data as early as possible in product development, as set out in the PHASES Guidance[6] and the WHO/IMPAACT Framework for Accelerated Inclusion of Pregnant Women in Pre-Licensure Clinical Trials[7,8] through harmonized regulatory approaches.

Action Steps:

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), African Medicines Regulatory Harmonisation (AMRH) and other drug regulatory harmonization organizations should be encouraged to develop guidelines for the responsible inclusion of PLP in pre-licensure drug development trials.
- WHO should utilize their convening power to advance the adoption of harmonized regulatory frameworks and processes by regulatory agencies, with particular attention to promoting the inclusive involvement of national and regional regulatory bodies in areas with high HIV burden.

Priority Goal 4: Ensure sound ethics review processes that promote the responsible inclusion of PLP, including adolescent girls and young women, in biomedical HIV prevention research.

Ethics review of research protocols is intended to ensure that the principles and practices for responsible human participants research endorsed by ethics guidelines are followed. However, this process is not without considerable challenges - e.g., guidelines may be conflicting or unclear; and the broad scope of research that institutional review boards (IRBs) and research ethics committees (RECs) are required to review may make it challenging to be familiar with all applicable guidelines for any specific context or population, including around the inclusion of PLP. Tools supporting and building the capacity of researchers and IRB/REC members to consider and apply international ethics guidelines for the inclusion of PLP in biomedical HIV prevention research can facilitate their responsible inclusion.

Develop and disseminate resources to support investigators in developing protocols that facilitate the responsible inclusion of PLP in biomedical HIV prevention research.

Action Steps:

- The HIV AIDS Vaccines Ethics Group (HAVEG, UKZN) in partnership with AVAC and CASPR will collate the current ethics recommendations for PLP inclusion, as set out in leading international ethics guidelines.

- HAVEG, AVAC/CASPR and PHASES will convene a PLP ethics review working group including IRB/REC members, researchers, ethicists and PLP to consider the implications for researchers drafting protocols and to develop user-friendly tools to help them proactively incorporate ethics recommendations in protocol development.
- The working group, stakeholders and allies will widely disseminate the tool through existing platforms, networks and listservs.
- The working group will review the tool on an ongoing basis to assess its accessibility and utility, making updates as needed.

> *"Clinical trials compete for attention with other studies, and ... pregnant person enrollment likely competes for attention with other ethics issues. A tool might help both parties affirm that protocols resonate with current ethics recommendations."*
>
> – **Think tank participant**

Develop and disseminate resources to support REC/IRB members to review protocols and assess if proposed approaches resonate with current ethics standards for the inclusion of PLP in biomedical HIV prevention research.

Action Steps:

- The PLP ethics review working group will consider the implications of current leading ethics recommendations around PLP inclusion for RECs/IRBs reviewing protocols and develop user-friendly tools to assist REC/IRB members in conducting reviews and developing constructive, guidance-informed responses.
- Working group members, stakeholders and allies will widely disseminate the tool through existing platforms, networks, and listservs.
- The working group will review the tool for REC/IRB members on an ongoing basis to assess its accessibility and utility, making updates as needed.

Acknowledgements

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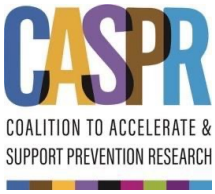

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Appendix B: AVAC/PHASES Think Tank Agenda

Think Tank to Advance HIV Prevention Research in Pregnant and Lactating People (PLP)

Tuesday, April 26th, 2022, 8:00 am - 12:00 pm EST

Agenda

Time	Topic/Activity	Presenters
8:00 – 8:15	Opening of the meeting ■ Welcome & background ■ Think Tank process	**Manju Chatani**, AVAC & **Anne Lyerly**, PHASES & UNC Chapel Hill **Kristen Sullivan**, PHASES & UNC Chapel Hill
8:15 – 8:45	State of the HIV prevention evidence base for PLP	**Lisa Noguchi,** Jhpiego, Johns Hopkins University
8:45 – 9:00	Viewpoints of former trial participants ■ Pre-recorded interviews ■ Personal reflection	**Definate Nhamo**, Pangaea Zimbabwe Aids Trust (PZAT) Shanti
9:00 – 9:30	Consensus frameworks & recommendations ■ PHASES Ethical Framework ■ WHO/IMPAACT Call to Action	**Anne Lyerly**, PHASES & UNC Chapel Hill **Martina Penazatto**, WHO
9:30 – 9:40	Break	
9:40 – 10:40	Moderated Panel Discussion: Identifying & operationalizing critical next steps ■ Civil society & community perspective ■ Investigator perspective ■ Regulatory perspective ■ Focusing on the ethics review process ■ Industry perspective	Moderators: **Manju Chatani**, AVAC & **Kristen Sullivan**, PHASES & UNC Chapel Hill **Definate Nhamo**, PZAT **Lynda Stranix-Chibanda**, University of Zimbabwe **Leyla Sahin**, Food and Drug Administration **Cathy Slack**, University of KwaZulu-Natal, HAVEG **Moupali Das**, Gilead Sciences
10:40 – 11:10 11:10 – 11:50 11:50 – 12:00	Priority advocacy objectives and action plan development ■ Break out room discussions ■ Report back/full group discussion ■ Clarifying next steps for Think Tank	**Anne Lyerly**, PHASES & UNC Chapel Hill **Manju Chatani**, AVAC
12:00	Adjourn	

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