



HIVR4P 2024



Vision to Action: Accelerating Advocacy Momentum on the Inclusion of Pregnant People

Satellite: Catalyzing Progress in the Inclusion of Pregnant and Lactating People in HIV Prevention Research

Manju Chatani-Gada, AVAC

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AVAC's Commitment to Equitable Partnerships



- **GPP:** Ensuring community participation in HIV prevention trials respects the rights and needs of affected populations, leading to **increased relevance** of research, **better study design**, and ultimately **empowering communities and facilitating policy change**.
- **AVAC Strategic Plan 2022-2026:** We believe that equitable partnerships are based on **solidarity, respect, transparent communication, and power sharing**.
- We strive to **transition away from traditional power structures** and towards a model in which **those with lived experience and field expertise have influence and an equal voice** in the design of plans and priorities



The Need for Multi-Stakeholder Collaboration



Move beyond siloed efforts to accelerate change

- Researchers grapple with the issue of greater PLP engagement in research
- Regulators & funders often targets for change rather than change-agents
- Civil society and community representatives in community advisory groups and in community consultations - but lacking in broader discussions

Multi-stakeholder partnerships drive meaningful change: shift research agendas & influence the field.

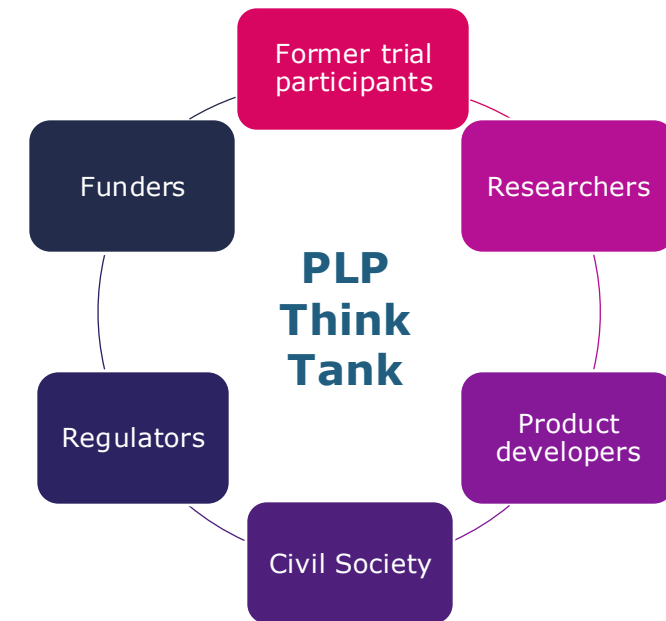
- Different stakeholders can be powerful messengers for change – to change people, processes, and policy.
- Building stronger partnerships for impactful advocacy.

Mobilizing power and influence for change

Think Tank: Advancing HIV Prevention Research in Pregnant & Lactating People

AVAC/CASPR, and the PHASES Project convened a think tank in April 2022

- ❖ Identify **priority advocacy objectives** to advance HIV prevention research with PLP
- ❖ Develop an **action plan** to advance research with PLP
- 63 global stakeholders - former trial participants, civil society, product developers, funders, regulators and researchers
- Informed by significant stakeholder engagement:
 - Desk review: Consensus recommendations (i.e., PHASES, PREVENT, PRGLAC, WHO/IMPAACT/IAS Call to Action)
 - Key informant interviews and advocates' survey
 - Pre-meeting with civil society and former trial participants co-convened with Pangaea Zimbabwe
- Feedback was solicited, integrated; Action Plan and **circulated for final approval** & disseminated through participant networks





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



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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.



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.



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.



Key role of civil society as partners

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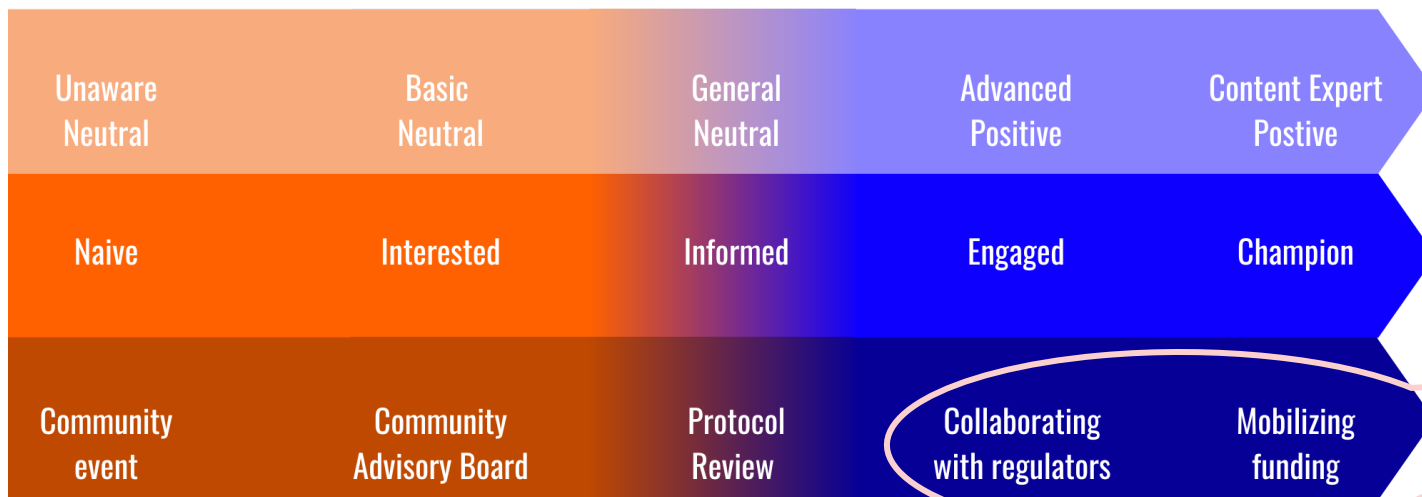
Ask key questions throughout all stages of research and surveillance of research teams

Take the lead in literacy, peer education and advocacy

- o *In partnership with women and gender-diverse people of reproductive age & their communities*

Advocate for regulatory & ethics processes to protect PLP in research

- o *Encourage governments to bolster the ability of drug regulatory agencies to incentivize and/or require PLP data for new products*



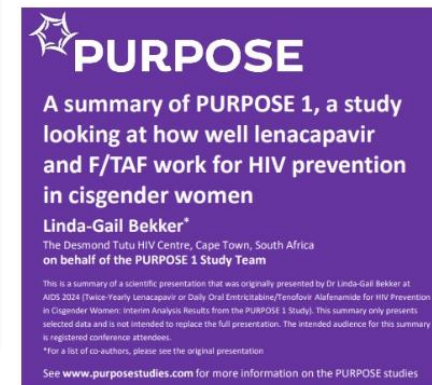
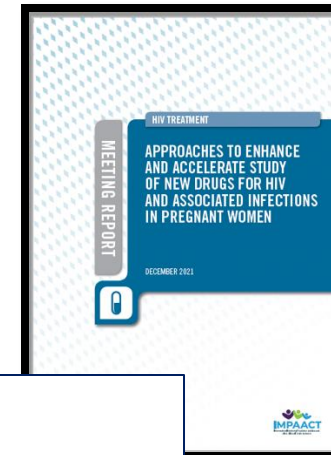
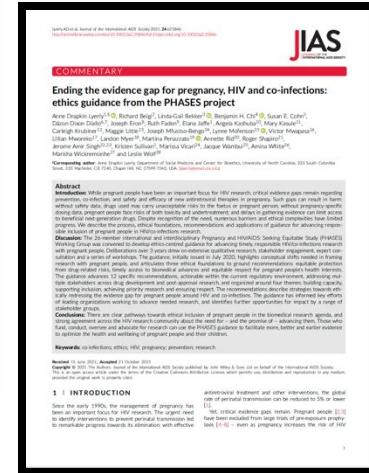
Adapted from MacQueen & Cates, American Journal of Preventive Medicine, 2005



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Participant Actions & Momentum in the Field

- Stakeholder consultation to inform the clinical development plan for broadly neutralizing antibodies (bNAbs) in infant postnatal prophylaxis for HIV
- Convening a session at the annual Bioethics Conference to discuss this issue in the context of IRB responses
- PrEPARE (PRomoting Equity for Pregnant Adolescents in REsearch) Project with reproductive justice as foundational



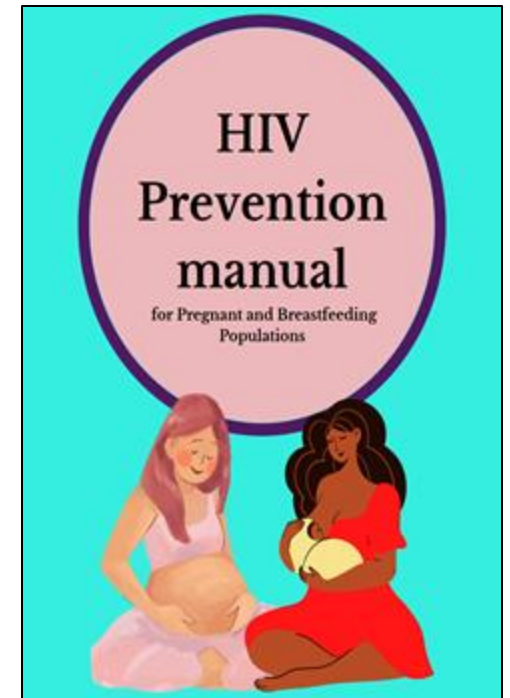
The HIV Prevention Trials Network
<https://www.hptn.org> > announcements > aids-2024-cab...
AIDS 2024: CAB-LA Pregnancy Safety Data from HPTN 084
 Jul 26, 2024 — The findings show that CAB-LA used as pre-exposure prophylaxis (PrEP) was generally well tolerated and generally safe for both pregnant cisgender women and ...



Civil Society Actions & Activities

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- **APHA:** *Urgent appeal to allow all professional nurses and midwives to prescribe pre-exposure prophylaxis (PrEP) in South Africa;*
- **AVAC:** Advocates PLP Research Literacy Campaign; Advocates Guide; podcast; webinars
- **AWPCAB:** Choice Manifesto
- **FHI 360:** *Meta-analysis of Pregnancy Events in Biomedical HIV Prevention Trials in sub-Saharan Africa from 2001-2022*
- **HAVEG:** Tools to support IRB/REC members for reviewing protocols for PLP inclusion & resources for
- **Pangaea Zimbabwe:** HIV prevention manual for PLP; community consultations with PLP
- Influencing COP process, TWGs, guideline review committees



Next Steps



AVAC/CASPR and PHASES (now PrEPARE) continue to work together to push forward the priority goals and action from the Think Tank Action Plan.

- Continued collaboration with key stakeholders to develop resources/tools to support researchers, regulatory authorities, and civil society
- Engaging Think Tank participants and other stakeholders to implement action steps they committed to
- Monitor and support action plan implementation and ongoing engagement.
- Finally, this is our shared advocacy – to tackle the challenges, reach consensus, and ensure a diversity of voices shapes the solutions.



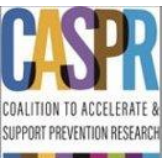
Thank You!

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Special thanks to PHASES for the collaboration
and to Anne Drapkin Lyerly, Kristen Sullivan, Breanne Lievens
And to all the Think Tank. Participants



Coalition to Accelerate and Support Prevention Research (CASPR)



*Cooperative Agreement No. AID-OAA-A-16-00031
HIV Vaccine and Biomedical Prevention Research Project—Objective 3*