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Authors

Sullivan, Kristen
Chatani-Gada, Manju
Lievense, Breanne
et al.

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Advancing ethical biomedical HIV prevention research for pregnant and lactating people

Kristen Sullivan[a], Manju Chatani-Gada[b], Breanne Lievense[c], Catherine Slack[d,e], Elaine Abrams[f,g,*], Katherine Bunge[h,*], Lynda Stranix-Chibanda[i,*], Francis P. Crawley[j,*], Moupali Das[k,*], Dvora Joseph Davey[l,m,*], Lusine Ghazaryan[n,*], Yumnah Hattas[o,*], Vincent Muturi-Kioi[p,*], Definate Nhamo[q,*], Lisa Noguchi[r,*], Khadija Richards[s,*], Marissa Vicari[t,*], Mitchell Warren[c,*] and Anne Drapkin Lyerly[u]

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Introduction

Pregnancy and the postnatal period heighten susceptibility to HIV infection [1,2], and maternal seroconversion is a significant source of pediatric HIV infections [3–6]. Yet pregnant and lactating people (PLP) remain underrepresented in HIV prevention clinical trials.[1] Underrepresentation is especially pronounced for adolescent, transgender, and gender diverse PLP. The absence of PLP-specific evidence can potentially lead to risk for the individual and their fetus/infant through misdosing, exposure to undetermined risks, or restricted access to prevention interventions [7]. While global guidelines [8–11] and expanded access to oral tenofovir-based

[a]Department of Population Health and Pathobiology, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, [b]Independent Global Health Consultant, Longmeadow, MA, [c]AVAC, New York, NY, USA, [d]School of Law, University of KwaZulu-Natal, Pietermaritzburg, South Africa, [e]RIO, Medical Research Council, Capetown, South Africa, [f]Mailman School of Public Health, [g]Vagelos College of Physicians & Surgeons, Columbia University, New York, NY, [h]Microbicide Trials Network, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA, [i]University of Zimbabwe Faculty of Medicine, Harare, Zimbabwe, [j]Good Clinical Practice Alliance – Europe (GCPA), Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium, [k]HIV Clinical Development, Gilead Sciences, Inc., Foster City, [l]Division of Infectious Diseases, School of Medicine, University of California Los Angeles, CA, USA, [m]Division of Epidemiology and Biostatistics, School of Public Health, University of Cape Town, South Africa, [n]United States Agency for International Development (USAID), Washington, DC, USA, [o]Frontline AIDS, Cape Town, South Africa, [p]IAVI, Nairobi, Kenya, [q]Pangaea Zimbabwe, Harare, Zimbabwe, [r]Jhpiego, Johns Hopkins University, Microbicide Trials Network, Washington, DC, USA, [s]Independent Advisor on Community Engagement in Research, South Africa, [t]Sterling C&C SARL, Geneva, Switzerland, and [u]Center for Bioethics, Department of Social Medicine, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.

Correspondence to Kristen Sullivan, Campus Box 8401, North Carolina State University, Raleigh, NC 27607, USA.
E-mail: kasulli5@ncsu.edu
[*]E.A., K.B., L.S.-C., F.P.C., M.D., D.J.D., L.G., Y.H., V.M.-K., L.N., K.R., M.V., and M.W. contributed equally to this work.

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[1]We use 'pregnant women', 'pregnant people', and 'pregnant and lactating people (PLP)' intentionally and in alignment with the terminology of the sources cited. For example, 'pregnant women' reflects language used in certain guidelines (e.g. WHO); 'pregnant people' is used when lactating people are not explicitly included; and 'PLP' is used throughout to reflect the focus of this work. We also recognize that not all people who become pregnant identify as women, and our use of inclusive language is intended to reflect this.

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preexposure prophylaxis (PrEP) for PLP have marked important progress, and emerging data on injectable cabotegravir (CAB) for PrEP are encouraging, further work is needed to ensure that effective, acceptable, and accessible HIV prevention options are available to PLP across settings.

In response to ongoing gaps in evidence and inclusion, a global Think Tank was convened in April 2022 by AVAC, through the Coalition to Accelerate and Support Prevention Research (CASPR), and the Pregnancy and HIV/AIDS Seeking Equitable Study (PHASES) project. The Think Tank brought together diverse global stakeholders, including researchers, industry, trial participants, civil society, regulators, and funders to mobilize a collaborative ecosystem of advocacy around advancing biomedical HIV prevention research with PLP by identifying priority goals and concrete actions.

The Think Tank built upon important progress that had taken shape over the preceding years. Leading organizations recognized the importance of conducting responsible research involving pregnant people, including in the context of HIV [7–9,12–16]. WHO efforts, including the Paediatric Antiretroviral Drug Optimization (PADO 4) meeting (2018) [14], highlighted the need for better pharmacokinetic data across populations and helped set the stage for subsequent inclusion of PLP in HIV prevention research [14]. The PHASES Ethics Guidance (2020) [17,18] and the WHO/International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Call to Action (2021) [19,20,21] provided actionable recommendations advancing ethical inclusion. The PRomoting Equity for Pregnant Adolescents in REsearch (PREPARE) project, launched soon after, is building on these efforts to develop similar guidance for involving pregnant adolescents in HIV research [22]. Meanwhile, studies such as PrEP-PP [23] and IMPAACT 2009 [25], among others [e.g., [24,26]], provided critical data on the safety of oral PrEP in pregnancy.

Since the Think Tank, additional advances have further strengthened the evidence base and policy landscape. The pregnancy and infant substudy of HPTN 084 OLE (2023) generated the first pharmacokinetic and safety data on injectable cabotegravir for PrEP during pregnancy [27,28,29]. The DELIVER [Microbicide Trials Network (MTN) 042] [30] and B-PROTECTED (MTN-043) [31] studies investigated the safety, drug levels, and adherence for the dapivirine vaginal ring (DVR) and oral PrEP in pregnant and breastfeeding populations, respectively. The PURPOSE 1 trial (2023) [32], which evaluated twice-yearly injectable lenacapavir (LEN) and daily oral emtricitabine/tenofovir alafenamide in cisgender women, was the first phase 3 PrEP trial without contraception requirements, allowing participants who became pregnant to consent to remain on study medication. Civil society and activists have been key partners in many of these efforts, advocating for expanded access to current treatments and inclusion of PLP in prevention research.

Regulatory and policy milestones have followed. The US Food and Drug Administration (FDA) and European Medicines Agency (EMA) approvals of LEN for PrEP, and regulatory approval of CAB for PrEP and the DVR in some African countries [33] represent major steps forward. Notably, LEN for PrEP is now approved for use in pregnancy and breastfeeding, and despite limited data, CAB for PrEP is not contraindicated in pregnancy, reflecting measured consideration of its potential benefits, absence of adverse safety signals, and responsiveness to PLP and advocates. However, the DVR remains unapproved for use by PLP in several countries [34]. To support a more unified approach, WHO convened a workshop in 2023 to harmonize pregnancy and infant-outcome data for ARV-based prevention and developed a toolkit for researchers – crucial steps towards aligning research efforts and translating findings into policies and actionable prevention strategies for PLP [35,36]. These efforts and others reflect progress towards ethically integrating PLP into HIV prevention research and policy frameworks.

While these steps mark important advances for PLP, the path ahead requires sustained global collaboration. The participation of community organizations, civil society, and advocacy groups will be pivotal in maintaining the drive towards equitable biomedical HIV prevention research.

Think Tank development

Think Tank development was anchored in stakeholder engagement, aligned with the Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (GPP) [37], including consultations with stakeholders and a preliminary discussion with advocates and HIV prevention trial participants, co-hosted with CASPR partner, Pangaea Zimbabwe.

AVAC and the PHASES Project co-facilitated the virtual Think Tank, engaging diverse stakeholders across research, policy, community, and industry. Sessions reviewed gaps for HIV prevention in PLP, provided insights from trial participants and advocates, and presented PHASES and WHO/IMPAACT working group recommendations. A stakeholder panel discussed critical action areas, after which attendees identified priority goals and strategies to facilitate responsible HIV prevention research with PLP.

The organizing team distilled goals from the discussion using three criteria: alignment with major themes identified by participants; attention to under-addressed needs; and potential to advance the field. The final goals, objectives, and action steps were shaped by insights from the workshop, follow-up discussions, and attendee feedback. Reproductive justice emerged as a central organizing principle during the Think Tank and became a

key framework for the Action Plan. The complete Think Tank report is available on AVAC's website [38].

Conceptual foundations

The Think Tank findings are grounded in three conceptual foundations – reproductive justice, the conceptual shifts described in the PHASES Ethics Guidance, and the WHO/IMPAACT framework for accelerating the study of new antiretrovirals in pregnant women.

Advocates highlighted reproductive justice during Think Tank discussions as a critical framework for addressing underrepresentation of PLP in biomedical HIV prevention research, introducing a distinctive perspective to the discussion. Reproductive justice, developed by a Black women's collective, foregrounds the lived realities and leadership of African, Black, and Brown women [39,40], and champions the right to bodily autonomy, the decision to reproduce, and the right to raise children in safe environments. It sheds light on the complex barriers hindering these rights and underscores the need for access to comprehensive, evidence-based, sexual and reproductive healthcare [39–41].

The PHASES Ethics Guidance articulated three conceptual shifts central to the Think Tank. First, it reframes pregnancy as 'complex' instead of 'vulnerable', better capturing the unique cultural, social, ethical, and physiologic aspects of pregnancy within research, while recognizing that pregnant individuals can make decisions for themselves. Second, pregnant people should be protected through – not from – research. While safeguarding against research risks remains crucial, exclusion shifts risk to clinical contexts when data are lacking. Finally, research involving PLP should shift from presumptive exclusion to fair inclusion, as denying research participation prevents access to direct benefits of participation and, potentially, to therapies once on the market, as experienced with SARS-CoV-2 vaccines and treatments [17,18].

Finally, the Think Tank drew on the WHO/IMPAACT framework, which calls for accelerated inclusion of pregnant people in prelicensure trials of new HIV antiretrovirals so pharmacokinetic and preliminary pregnancy safety data are available at or shortly after drug approval [19]. This framework underscores the pivotal role of women of childbearing potential affected by HIV in shaping research and highlights the importance of civil society and community-based organizations in building community literacy and strengthening advocacy efforts [19].

Action plan

Four priority goals with supporting objectives and concrete steps were identified to inform the Think Tank Action Plan [38] (Figure 1).

The first goal emphasizes advancing biomedical HIV prevention research through a reproductive justice lens, with meaningful participation of PLP – especially African and other Black and Brown women, adolescents, and trans and gender diverse individuals – and the organizations that support them. It stresses collaboration with groups addressing intersecting oppressions to promote equity and reproductive justice. Recognizing the challenges of restrictive reproductive health policies, we also call on researchers, community-based organizations, and civil society to identify solutions for conducting equitable research with PLP, including where restrictions exist. Furthermore, we call on product developers to align contraception requirements in trials with actual reproductive risks, and for trial sites to facilitate access to comprehensive sexual and reproductive health services for participants.

The second goal emphasizes early, continuous, and meaningful engagement of PLP and their communities in HIV prevention trials. It acknowledges the cultural, social, ethical, and scientific complexities introduced by pregnancy in HIV prevention research and the need for tailored approaches. AVAC is positioned to lead the development of GPP best practices for HIV prevention research involving PLP, including adolescents. Furthermore, we emphasize early and sustained community engagement, from formative evaluation through implementation and the introduction of new interventions.

The third goal calls for harmonized regulatory frameworks to support responsible PLP-specific data collection for new therapeutics and biomedical prevention products. Pediatric drug regulations provide a model for generating needed data for a historically excluded group. Key global, regional, and national regulatory organizations can drive this, either by incentivizing or requiring PLP-specific data during the approval of new products. At the same time, lack of PLP data must not further restrict access to essential interventions.

The fourth goal emphasizes robust and consistent research ethics review processes to responsibly include PLP, including adolescents and young women. Given challenges in the ethics review processes, including an abundance of ethics guidelines, tools are needed to assist researchers and IRB/REC members in PLP-specific deliberation. The HIV AIDS Vaccine Ethics Group (HAVEG) is called on to lead the development of such tools in collaboration with ethicists, researchers, and advocates [42].

Discussion

The ethos, 'nothing about us without us', remains central to advancing the health and rights of PLP in HIV research,

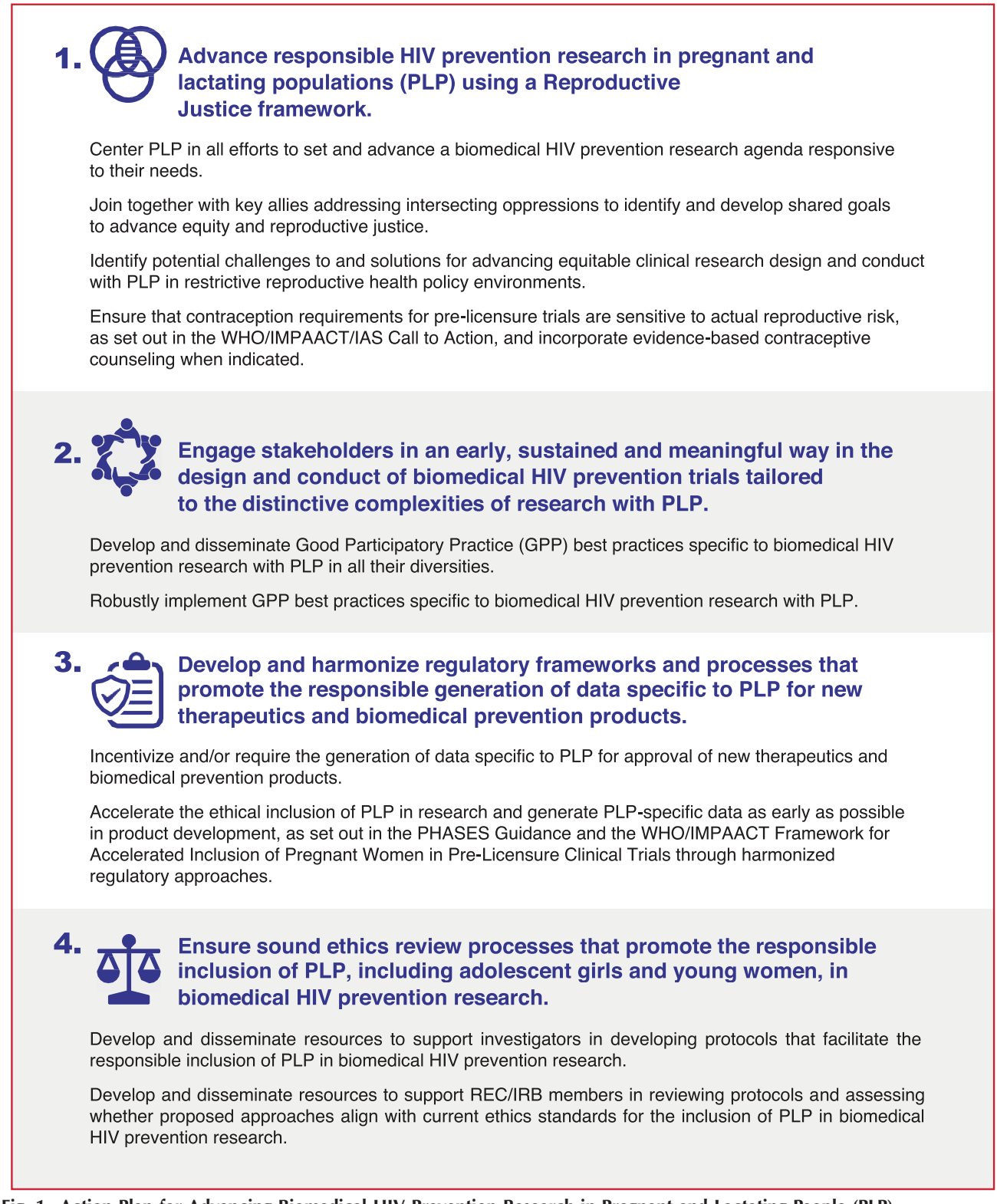

Fig. 1. Action Plan for Advancing Biomedical HIV Prevention Research in Pregnant and Lactating People (PLP)

care, and policy, with activists and civil society playing pivotal roles. Centering these voices in the HIV prevention research agenda is an ethical obligation and a strategic necessity. The frameworks that informed the Think Tank – reproductive justice, the PHASES Ethics Guidance [17,18], and the WHO/IMPAACT's framework [4,19,20] – continue to provide a strong foundation for addressing gaps in evidence and policy. By grounding collective action in these frameworks, elevating the lived experiences and leadership of PLP, and highlighting the

role of civil society and advocates in these efforts, we provide a pathway to strengthen discourse and practice.

Progress since the Think Tank has demonstrated the potential for coordinated, community-informed action. AVAC developed a podcast [43] and an advocate's guide [44] to build advocacy for PLP research inclusion, and CASPR launched a research literacy campaign. While USAID funding cuts halted this campaign and other related efforts, their foundational work continues to inform strategies and advance the Action Plan.

Efforts to support a robust and reasonable ethical review process are advancing. HAVEG and partners developed a tool to support consistent application of ethics guidance for PLP, potentially streamlining the review process [42]. Additionally, the FDA's alignment of informed consent and IRB regulations with the HHS Common Rule may support ethical research involving PLP by reducing barriers to inclusion in minimal-risk studies [45].

Recent global health funding cuts have disrupted momentum and underscored the fragility of progress that relies on uncertain investments. At the same time, they have reinforced the value – and necessity – of a durable, collaborative advocacy ecosystem. The Think Tank's goals and action steps offer a shared map for sustaining and advancing PLP inclusion, even in an evolving landscape.

While inclusion in biomedical HIV prevention research is necessary to realize effective, acceptable, and accessible biomedical HIV prevention options for PLP, it is not sufficient on its own. It must be part of a sustained effort to address health needs and support decision-making autonomy of PLP. The challenges are undeniable. Yet with continued collaboration and focused leadership, we can build on the existing foundation to ensure the rights and health of PLP receive the attention they urgently need in HIV prevention research.

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Conflicts of interest

There are no conflicts of interest.

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