

The Role Community Advocates Can Play to Advance a More Inclusive Research Agenda

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Key Issues in HIV/AIDS/TB Research

1. Balancing people's pregnancies (and pregnancy desires) and breastfeeding decisions with the need to offer a variety of safe, effective, and accessible treatment and prevention modalities
2. Considering health and safety of the pregnant/breastfeeding person **PLUS** the health and safety of the fetus or infant
3. Meaningful community participation can help DAIDS networks generate clinically-relevant and culturally-appropriate treatments

Role of Community Advocates

- How do networks account for pregnant and breastfeeding people's specific issues/concerns?
- All DAIDS networks have mechanisms for collecting community input on studies
 - Considering pregnancy/breastfeeding desires from the start
 - Broader community education and outreach
 - Community advocates can request rationale and explanation for exclusion of pregnant and/or breastfeeding people
- Cross-network bodies can ensure women's issues, priorities, and concerns are heard by the people developing and implementing research
 - Office of HIV/AIDS Network Coordination (HANC), the Legacy Project, Women's HIV Research Collaborative (WHRC), and ACTG-IMPAACT's Women's HIV Inter-Network Scientific Committee (WHISC)
 - Each of these bodies has representation from community, researchers, and staff

How Community Advocates Can Shape Research Agendas

- Providing comments/feedback via formal avenues (PRG-LAC task force, DAIDS input periods, network-specific processes)
- Engaging in education and dialogue with providers—asking questions and insisting on answers
- Engaging in education and dialogue with advocates—highlighting connections and coalitions across specific issues of interest
- Participation in cross-network bodies that already exist

Community Shaping Research Priorities around HIV & TB Treatment

- Many researchers and activists in the ACTG who recognize that trial participants' lives sometimes include pregnancy and breastfeeding
- How to ensure appropriate treatment options are available for all phases of reproductive life?
 - HIV and cure research: impact of pregnancy and lactation on HIV reservoirs?
 - Issues around TB and pregnancy: what are impacts on maternal and child outcomes?
 - ACTG5300 (Phoenix Study) of MDR TB in household contacts is collecting data on pregnancy outcomes

PREGNANCY, BREASTFEEDING, AND HIV PREVENTION

Pregnancy, Breastfeeding, and HIV Prevention

- Some overlap in considerations for treatment versus prevention, but also prevention-specific issues
- Risk of HIV acquisition increases during pregnancy, making PrEP a useful tool for pregnant and breastfeeding people
- HIV Prevention Trials Network (HPTN) 084 is a study of long-acting injectable PrEP, potentially adding another prevention option
 - HPTN 084 will enroll over 3,000 cisgender women
 - Participants who become pregnant will be unblinded and followed every 12 weeks
- However, PrEP may not be an option for everyone so it's important to ensure women have multiple options for HIV prevention during pregnancy and breastfeeding (besides condoms and PrEP)

Pregnancy, Breastfeeding, and HIV Vaccines

- HVTN typically enrolls high numbers of cisgender and transgender women
 - Numerous challenges to including pregnant or breastfeeding women in vaccine trials.
- People who become pregnant while in a vaccine trial are followed after they leave the study to determine if there are any adverse outcomes for the infant or the participant.



Pregnancy, Breastfeeding, and Other Prevention Modalities

- Several MTN studies completed and planned can provide valuable information (and possibly more options) for pregnant or breastfeeding people
- MTN-029/ IPM 039
 - Conducted at 2 US sites among 16 women who were still able to produce milk but were no longer breastfeeding
 - Women used the ring for 14 consecutive days
 - Researchers collected samples of milk and blood plasma at different times
 - Very small amount of drug found in breastmilk

Planned Studies in MTN

- MTN-041: To assess views and attitudes about use of the ring and oral PrEP during pregnancy and breastfeeding
 - Focus group discussions and in-depth interviews with women currently breastfeeding or pregnant; Male partners; Health providers, midwives, social service providers, local leaders
- MTN-042: Open label study of the ring and oral PrEP among approximately 750 pregnant women – and their babies
 - Will assess safety and pharmacokinetics (PK) of the ring and PrEP (randomized 2:1) during different stages of pregnancy
- MTN-043: Safety and PK of dapivirine ring use among women who are breastfeeding

Women's HIV Research Collaborative

The WHRC, a working group of the Legacy Project at the Office of HIV/AIDS Network Coordination (HANC):

- Provides guidance and leadership about HIV research focused on and responsive to the needs of women and girls in the US
- Works to raise the visibility of issues related to HIV in women in the US
- Promotes awareness of scientific research to women in disproportionately impacted communities
- Advocates for HIV research with women in the US
- Maintains a focus on the US with recognition of global interests and considerations