The role of intimate male partners in women's consent for research during pregnancy: A case study from the Partners (PrEP) Demonstration Project:

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Conflicts of Interest

- For some research studies, including that described in the present abstract, PrEP medication has been donated by Gilead Sciences.
- I have no conflicts of interest.

Background

- High HIV incidence during pregnancy
  - Multiple studies in the African setting (1.3-10.7 per 100 women-years)[1,2]
  - Our work among HIV serodiscordant couples reported a two-fold increase in HIV acquisition during pregnancy[3]
- Need for preventive interventions
  - PrEP has the potential to be a very effective prevention tool

1. Kinuthia et al, 2010
2. Gray et al, 2005
3. Mugo et al, 2011

PrEP in Pregnancy

- PrEP is an **attractive, effective** HIV prevention option
  - Limited side-effects, single dose pill
  - Effective (if adherent)
  - Controlled by women
- PrEP has **not been programmatically implemented** in pregnant women
  - Pregnant women excluded from effectiveness trials
  - Lack of consensus from leaders on the state of evidence

Partners Demonstration Project

- The Partners Demonstration Project was an open-label, prospective interventional study of integrated ART and PrEP delivery for HIV prevention among heterosexual HIV serodiscordant couples
- The project was conducted at 4 clinical sites:
  - Kisumu & Thika in Kenya and Kabwohe & Kampala in Uganda
- The overall goal was to evaluate, using implementation science methods, a scalable delivery system for PrEP and ART for HIV prevention in couples
  - **Initiated November 2012 & concluded follow-up June 2016**

Beaten et al. PLoS Med, 2016

Partners Demonstration Project

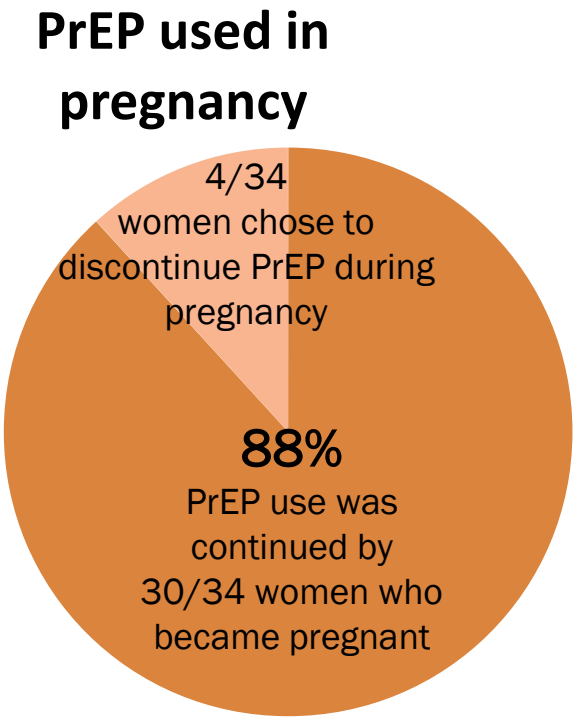
- Women becoming pregnant while using PrEP were counseled about risks and benefits of PrEP use during pregnancy and chose whether to continue or discontinue PrEP

Pregnancy incidence was high, especially among women with a declared fertility intention

	Couples with HIV+ woman	Couples with HIV- woman
Number of incident pregnancies	184	95
Pregnancy incidence rate	18.7	18.5
Among women with immediate fertility intention	50.2	43.7
Among women without immediate fertility intention	13.0	16.0

Heffron et al. abstract THPDC0102 AIDS 2016

Partners Demonstration Project



- 88% of women who became pregnant while on PrEP chose to continue using it.
- Data on outcomes of the pregnancies will be out soon.

Heffron et al. abstract THPDC0102 AIDS 2016

The **Ch**oices **I**n **P**regnancy (ChIP) Study

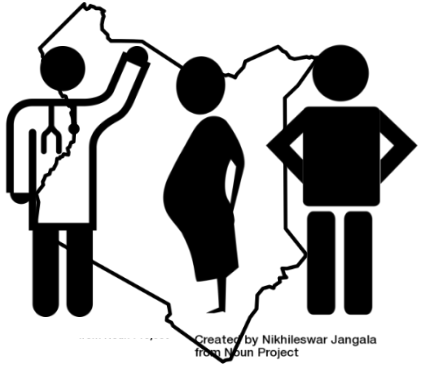
Objective: to explore how couples weigh biologic, social/cultural and ethical value trade-offs in the possible implementation of PrEP in pregnant women.

Study Design

Qualitative Study with female and male partners

PrEP Naive

PrEP Exposed



Data Collection

Group	Site(s)	Description	Data Type	Final # Transcripts	Final # Participant
PrEP Exposed (Demonstration)					
1	Thika; Kisumu	Pregnant or postpartum women taking PrEP	IDI	22	22
2	Thika; Kisumu	Non-pregnant women taking PrEP	IDI	30	30
3	Thika; Kisumu	Male partners of HIV-negative women taking PrEP	FGD	5	35

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Research Questions

- How do male partners view the involvement of a female partner in research during pregnancy?
- Do men expect women to obtain permission from male partners or not, and what ethical rationale is offered?
- How do women think about partners' role in decisions about their own health and health during pregnancy?
- What kinds of concerns do they have, and how do they view the role of women in decision making?

Male partners views on their involvement during research in pregnancy

- Male partners also reported willingness to be involved in the research process in a supportive role, including accompanying the female partners to the health provider to discuss the safety of drugs during pregnancy.

Even her husband to be… should be informed about that research. He should be in that research… so that he can remind her when she forgets to use(study drugs) and if anything happens he knows.(Male FGD001)

I will talk with her (pregnant wife who wants to join research) and then she goes to the doctor, we both talk with the doctor, we agree with her together with the doctor.(Male FGD003)

She(wife) will ask me we go with her there (to the doctor)… she will come we go to the doctor, we go and ask how it (medicine) was there, isn't she mine? (Male FGD003)

He (husband) told me because you are pregnant; you continue with taking medicine (Truvada) and I told him it is okay. (IDI Pregnant woman)

Men's opinions on their need to give permission to their female partners

- There was a consensus in the focus groups for male partners that men should be consulted before their female partners participate in clinical research during pregnancy
- Many male partners reporting that their female partners should not participate without their permission.
- Some female partners reported that they thought their male partners would prevent them from participating in research while pregnant hence best to just consult the doctors

With the partner(referring to who a woman should consult) so that we speak with her first, we discuss well so that I can give her the go ahead. (Male FGD 002)

She should not use(Investigational products)… Because she doesn't know if, if it will harm the baby (Male FGD001)

Women's perspectives on male partners' role in decisions about their participation in research during pregnancy

- Most women believed that male partners should be informed while a few believed consent to participate was exclusively the woman's decision after getting the relevant information from health providers.

Oooh, okay then. And for her to say that she will join this research, whom do you think she should talk with?

R: She can talk with her husband and maybe she can talk with the doctor if they agree with the husband, you know if the husband refuses she cannot use them, she cannot use them" (IDI non-pregnant woman)

Whom do you think she should talk now herself to so that she can make that decision?

R: That is what I am telling you the doctor where she is attending clinic (antenatal clinic)…
Now, that decision(to join research), the husband perhaps can refuse and you know men are different. He might know it is this way and this way and he forbids you. But mostly the doctor is the one people …we follow very much. Because it is your health and you want, you want that health to be good so the doctor can tell them and they feel it is good and she decides." (IDI Pregnant woman)

Concerns of participation of pregnant women in research

- Both men and women were concerned about the risk of safety of the investigational product to the mother and the unborn baby and placed considerable value on health provider opinions and recommendations to understand these risks
- Most of the male partners reporting that their female partners should not participate in research during pregnancy due to safety concerns

I cannot allow mine(pregnant wife to join research) because if it has side effects I will be the one in problems. Taking her to hospital, incurring the cost, that I can't, no.
And you, you have laughed what do you think?
It is the same.
Eeeh?
Just the same.
What about you, what do you think?
It is the same.(Male FGD003)

Again you think what if I take these medicines and they harm me or they harm the child who is in the womb or I get a miscarriage because you can take medicines and they affect you and perhaps the child who is in the womb miscarriages before their time
(IDI non-pregnant woman)

Conclusions

- There was lack of consensus on the role of male partners with male partners wanting to play a bigger role in the decision making process including giving permission – which would interfere with women's autonomy

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- Understanding and addressing partner concerns and clarifying the role of partners in decisions to participate in research are important factors for improving the ethical inclusion of pregnant women in research.

Conclusions

- There was lack of consensus on the role of male partners with male partners wanting to play a bigger role in the decision making process including giving permission – which would interfere with women's autonomy

- Understanding and addressing partner concerns and clarifying the role of partners in decisions to participate in research are important factors for improving the ethical inclusion of pregnant women in research.

- Ethical guidance on the inclusion of pregnant women in research needs to be relevant to the disease burden as well as considerate and culturally sensitive to male partners' concerns in contexts where the sociocultural norms support shared decision-making between partners.

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Partners Demonstration Project Team

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Research participants

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