



# Ethical Considerations of Involving Adolescents in HIV Prevention Clinical Trials in Uganda

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# Presentation outline

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# Introduction

- Adolescents girls and young women (AGYW) are at high risk of HIV infection. <sup>1</sup>
- The number of new HIV infections among AGYW in sub-Saharan Africa remains exceptionally high to date. <sup>1</sup>
- 25% of new *infections* among women of reproductive age in Uganda in 2016 occurred in AGYW. <sup>2</sup>

1. UNAIDS (2017) UNAIDS DATA 2017. Available at: [http://www.unaids.org/en/resources/documents/2017/2017\\_data\\_book](http://www.unaids.org/en/resources/documents/2017/2017_data_book)

2. Uganda AIDS Commission (2016) *The Uganda HIV and AIDS Country Progress Report July 2015-June 2016*. Kampala: Uganda



# Introduction (2)

- In Uganda, 16-17 year-olds can access sexual and reproductive health (SRH) services on ***their own*** including
  - STI, HIV/AIDS treatment and prevention
  - Family planning
  - Pregnancy and post abortal care
- ***However***, it is challenging to include adolescents in investigational drug trials for SRH-related services



# Introduction (3)



- **Truvada** was recently licensed for use in 16-17 in the US, and approvals are anticipated in other countries like Uganda.



- **Dapivirine Vaginal Ring (VR)** currently seeking licensure in adults only, due to lack of clinical trial data in adolescents.



- Without adolescent-specific research, young people be excluded from beneficial products or offered products only tested in adults.



# Introduction (4)

- **MTN-034/REACH** study is a phase 2a Crossover Trial evaluating the safety of and adherence to **Dapivirine Vaginal ring and Oral PrEP** among AGYW
- Designed to seek these answers:
  - *Are PrEP and the ring safe and acceptable in girls and young women?*
  - *Are they willing to use these products?*
  - *Which one do they prefer?*
- **300** AGYW aged 16-21 years from Uganda, Kenya, Zimbabwe and South Africa will participate



# Objective

To describe community perspectives on ethical considerations for involving adolescent girls in the **MTN-034/REACH** study in Uganda.



# Methodology

- In preparation for the REACH study, the MUJHU study team engaged the community from August 2017 to August 2018.
- 2 stakeholder community events with 140 community representatives that included;
  - ❖ Local leaders
  - ❖ Youth community leaders
  - ❖ Women representative
  - ❖ Youth organization leaders
  - ❖ Leaders of ethical/regulatory bodies





# Methodology (2)

- 2 adolescent engagement events held at the site.
- 125 AGYW aged 16- 21 yrs attended the sessions.
- Opinions of adolescents sought about sex, sexuality and SRH services including REACH study participation.



# Methodology (3)

- One moderated dialogue for adolescents and their parents/guardians (50 attendees).
- Aim was to understand/mirror REACH study processes of involving parents/guardians.



# Methodology (4)

- **Facilitated activities during community engagements to;**
  - Create awareness about the study
  - Gain community insights about REACH study
  - Learn more about community perspective on involving adolescents <18 years in SHR related research
  - Propose strategizes for best practices for adolescent and young women participation
- Summary notes were written for all sessions.
- Topics of ethical considerations were highlighted in most sessions.



# Results

- Ethical bodies, community stakeholders and parents/guardians strongly supported conducting the REACH study in Uganda. However;
  - ❖ High risk adolescents who would benefit from the HIV prevention study products should be prioritized.
  - ❖ Emancipated minors should be targeted as they are considered to have prior exposure to sex.
  - ❖ School going adolescents should not be recruited as it could be considered as a means of promoting sex activities among adolescents and pose challenges with retention.
- AGYW felt that the study would be beneficial for those that are sexually active!



## Results (2)



Engaging adolescents in HIV prevention research requires many ethical considerations including;

- Assent of the minor (below 18yrs)
- Parental/guardian consent
- Confidentiality
- Privacy

*These issues if not well handled may deter adolescent participation in research*

# Results (3)

- Parental/Guardian consent perceived as a principal barrier to study participation by all stakeholders.

## Concerns

- Sexual activity disclosure considered a cultural taboo according to parent/guardians and AGYW.
- Of the 125 adolescents who participated, 119 (95%) feared **inadvertent disclosure** of their sexual activity to their parents.



# Results (4)

- Majority of the girls 16-17yrs felt that they did not need parental/guardian consent to participate in the trial

*“Why do I have to involve my parent to participate in research yet I don’t seek their consent to have sexual relationships?”*

*“If I can get family planning without my parent’s permission, why should I get parental consent for research participation?”*

*Questions from adolescents young during the discussion*



# Recommendations

## Key insights from the community:

- ✓ Informing adolescents about the information to be disclosed to parents: *Specification of information to help address issues of privacy and confidentiality.*
- ✓ Stakeholders involvement in recruitment is crucial: *Stakeholders were very delighted to have been involved prior to study start.*
- ✓ Partnering with community youth organizations to maximize recruitment and retention: *Youth organizations were eager to identify and refer potential participants to study.*





# Conclusion

- Conducting stakeholder events prior to study implementation is critical when recruiting adolescents for HIV prevention studies.
- Diverse community representation should be engaged, including adolescents, their parents/guardians etc.
- Outcomes will identify;
  - Specific ethical considerations that can inform study design
  - Practical strategies to ensure high ethical standards during implementation



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