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

Dr. Rita Nakalega
MU-JHU Research Collaboration
Kampala
Uganda
Presentation outline

• Introduction
• Objective
• Methodology
• Results
• Recommendations
• Conclusion
• Acknowledgements
Introduction

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

• Adolescents and young women, parents/guardians, community members including various stakeholders
• The MU-JHU study team
• FHI 360-Tara McClure
• The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health