

# **Challenges of Identifying high risk women in a Microbicide trial MTN 020 (ASPIRE)**

## **Lilongwe, Malawi**

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# Outline

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- Background
- Definition of high risk
- Challenges
- Activities to ameliorate challenges
- Outcome
- Remarks/Conclusion

# Background

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- Data from UNC Project Lilongwe for the HPTN 035 Study showed an overall HIV incidence of just above 1%.
- However some subpopulations (18-25 year olds) of that study showed HIV incidence of above 2.5%
- Malawi national data also shows the highest prevalence of HIV infections in 18-25 year group



# Background contd....

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- Our observations from previous studies show that women coming from some communities had very low HIV incidence.
- For ASPIRE Study, the site is taking extra steps to ensure that women are recruited from potentially HIGH HIV incidence populations within our catchment area.

# Definition of high risk women

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- ❑ Age group of 18-25 years
- ❑ History of STI from attending nearby STI clinics
- ❑ Multiple sexual partners ( for the prospective participants)
- ❑ Occupation (e.g. young female bar tenders, hair dressers etc.)
- ❑ Partner Occupation (truck driver, bar tender, street vendor)
- ❑ Polygamous associations
- ❑ Area of residence (squatter homes, high density areas in the city, areas with high number of brothels).

# Challenges

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- High risk women have high rates of HIV incidence therefore challenging to screen and enroll HIV negative participants (i.e. High screening to enrolment ratio)
- High risk independent women of 18- 25 years old are hard to find and recruit
- Young women are not willing to be on long term family planning methods because they are in prime of their reproductive age
- High risk young women do not have steady homes and re-locate often in search of greener pastures

# Challenges contd....

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- Non commitment of younger age group - we feel women of 18-25 years do not take research as seriously as older women (suspicious reports of ring expulsion and incidents of unreturned rings)
- 18-25 years old girls are not as independent as we believe (experiences of cases where parents or partners came to clinic demanding that their daughters/partners withdraws from the study or stop using the ring and family planning)

# Activities to ameliorate Challenges

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Two pre-screening sessions

- Registration
- Verification of age
- Establishing sexual relationships status
- Finding out about occupation of participant and partner(s)
- Discussing the need and commencement of long term family planning methods
- Ascertaining HIV status
- Establishing pregnancy and Breast feeding status
- Establishing area of residence where appropriate



# Activities to ameliorate Challenges contd.....

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- Meetings were organized with the following stakeholders:
  - Theatre for Change (TFAC)
  - Bar and rest-house owners
  - Queen mothers
  - STI clinic managers
  - HIV Counseling centers i.e. Macro, clinics/hospitals, BLM
- Referral slips were formulated and given to TFAC, STI and HIV Counseling centers,
- Inclusion criteria developed.

# Outcome of Site Prescreening

|                              |            |
|------------------------------|------------|
| <b>No prescreened</b>        | <b>276</b> |
| No qualifying for screening  | 146        |
| No. qualifying for enrolment | 47         |

| <b>Reasons for Ineligibility for Screening</b>             | <b>Total (%)</b> |
|--|------------------|
| Breast feeding   | 8 (5%)           |
| Pregnant/Intending to be Pregnant                          | 17 (12%)         |
| HIV Positive/on ART's                                      | <b>43 (29%)</b>  |
| Under age < 18 years                                       | 4 (3%)           |
| Over Age > 25 Years  | <b>25 (17%)</b>  |
| Not/Willing to be on Family Planning                       | <b>20 (14%)</b>  |
| Outside Catchment Area                                     | 4 (3%)           |
| Other reasons (not willing, to consult partner or parents) | 25 (17%)         |

# Remarks/Conclusion

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- As the prevalence of HIV decreases in general population, there are still many pockets of the population with high incidence for HIV who can be a good source of HIV prevention studies in Lilongwe.
- Even though women between 18 – 25 years old are hard to identify and recruit, it is still possible with the right approach, as we have shown that only 17% of our prospective participants were above 25 years.



# Remarks/Conclusion cont.....

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- When an individual is an adult and allowed to make independent decisions is still a challenge in Malawian culture even though the constitution defines an adult to be one 18 years and above.
- The concept of research is still foreign in this age group of interest and more effort and resource is needed to sell the concept.

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