

Experience in Recruiting Young Women in Kampala

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MU-JHU Research Collaboration

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It's been quite the Journey...



The Beginning...

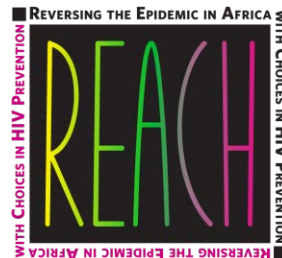
In preparation for the MTN 034/REACH study (2017 – 2018)

- The Community team conducted;
 - 2 stakeholder community events
 - 2 adolescent engagement events
 - 1 dialogue between adolescents & their Parents/Guardians
 - Purpose was to discuss the best approach for recruitment of minors
 - Anticipated challenges / solutions



Stakeholder Recommendations

- Regulatory bodies, Community stakeholders, Parents/Guardians strongly recommended;
 - In Uganda, REACH should be conducted among **high risk adolescents** – benefit from HIV prevention
 - **Emancipated minors** should be targeted
 - **School going adolescents** should **NOT** be recruited (retention challenges & may **“contaminate”** others!)



Recruitment Strategies

- Multifaceted Approach including;
 - Interested “*Dialogue participants*” prioritized
 - Recruitment from the community (emancipated minors)
 - Former study participants (HI-4-TU , Bone Care)
 - Recruitment from Youth Organizations providing SRH, FP, skills building etc.
 - Former HOPE study participant’s children / referrals
 - Referrals from fellow participants/self referrals
- “Mix” of participants for REACH– FP naïve as well as those already on FP

Recruitment Approach

■ Community

- Target communities mapped; goal – to enrol about **2 to 5** in a community from far apart households!
- Community contact persons mobilise AGYW and study community educators sensitize them
- Door to door approach for identified minors – *discuss with parent/guardian*
- Youth CAB involved
- Male Mobilizers have played a key role in recruitment!



Recruitment Approach...

■ Youth organizations

- Formed partnerships to recruit target population
 - Naguru Teenage and Information Centre
 - Marie Stopes Uganda
 - Uganda Youth Alliance For Family Planning & Adolescent Health (UYAFPAH)
 - Reproductive Health Uganda (RHU)
 - Uganda Youth Development Link (UYDEL)
- Sensitize about REACH, Identify contact persons



Tools used in Recruitment

- IC Flip Charts
- Sample Rings and tablets
- Pelvic Models
- **Pre-screening Checklist** – Identifies those motivated to participate & use the study products
- REACH Video, MTN 041 video



Prescreening flow

Pre-screened in Community



Referred to REACH clinic



Education on Family planning and the REACH study provided



FP method provided in clinic if agreeable



Appointment given for screening if interested

Recruitment outcomes

Recruitment Source	Sensitized	Pre-screened in community	Pre-screened at the clinic/ FP provision		No. screened	Enrolled
Dialogues	81	14	17	12	12	09
Community	280	116	52	28	24	18
Studies (HI-4-TU, Bone care)	00	00	12	02	04	03
Naguru Teenage Centre	03	03	00	00	01	00
Self-Referrals	00	00	07	01	01	00
Former Hope Participant's Children	04	04	01	00	00	00
Total	368	137	89	43	42	30

Ineligible from the community

Reasons for being ineligible

Not willing to use family planning!

Fear swallowing tablets

No interest in participating in research

Breastfeeding/ Pregnant

Above 21 years of age

Unstable location/ Plan to travel

No phone contact

Studying/working – unable to attend regular clinic visits

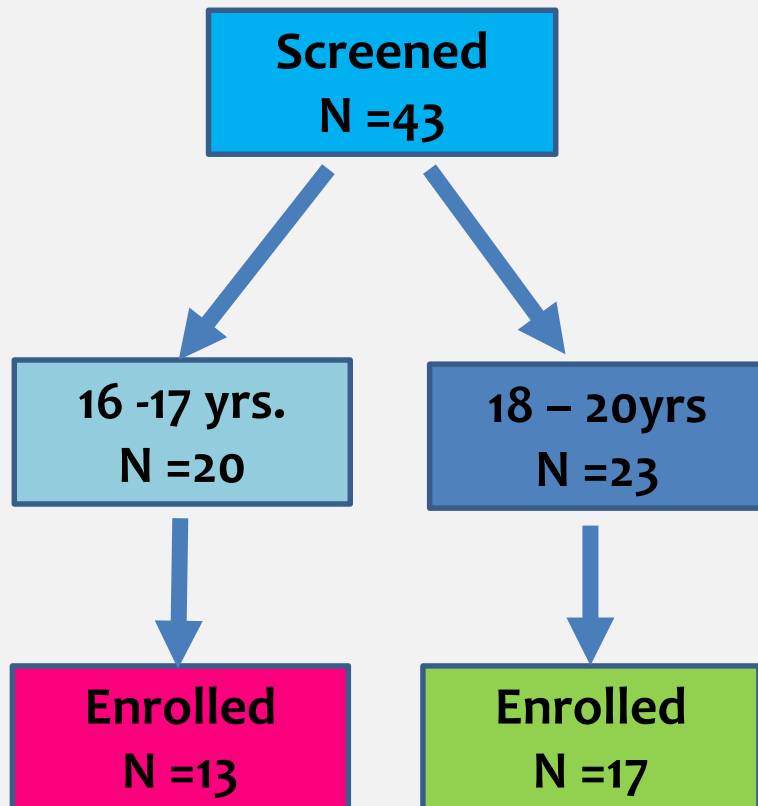
Known HIV positive

Language Barrier

No parent to consent

Accrual Updates (30 Aug)

Site Activation 14 Jan 19, Enrolment – 29 Jan 19!
1st participant screened 24 Jan 18, Enrolled 06 Feb 19



Screen Failures (minors)

- HIV Positive – 4 (3)
- IOR Discretion - 2
- Declined Pelvic Exam – 3 (1)
- Incomplete locator information – 1 (1)
- Intends to relocate away from study site – 1



LESSON
LEARNED





Minors!

Recruitment of minors has been possible!

Concern: Sex, parents and consent





Minors!..

Inclusion criterion: Girls must have had sex in their lifetime

- In Uganda – if under 18, parent’s permission needed to enroll
 - Parental waiver not requested as Ring is an IND
 - Sexual activity disclosure considered a cultural taboo
 - Parental consent perceived as a principal barrier to study participation

- **Surprise!!!** Minors having sex was an open secret!
 - Parents (mothers) embraced REACH for HIV prevention and contraception!

- Some were skeptic ...
 - Won’t REACH promote promiscuity?
 - Can a girl who has not yet given birth use contraception?





Minors...

- Site developed a risk assessment tool based on VOICE risk score

Responses in Prescreening Checklist	Risk Category		
	Low Risk	Moderate Risk	High Risk
Responses with *	None	1 – 2	>2
Responses with **	None	1	≥2

Risk-assessment score: # responses with * ____ # responses with ** ____

Note: Adolescent girls aged 16 – 17 yrs. in the high risk category shall be considered, however moderate/low risk adolescents who are eligible and the parent/guardian is also interested in her study participation may also be considered

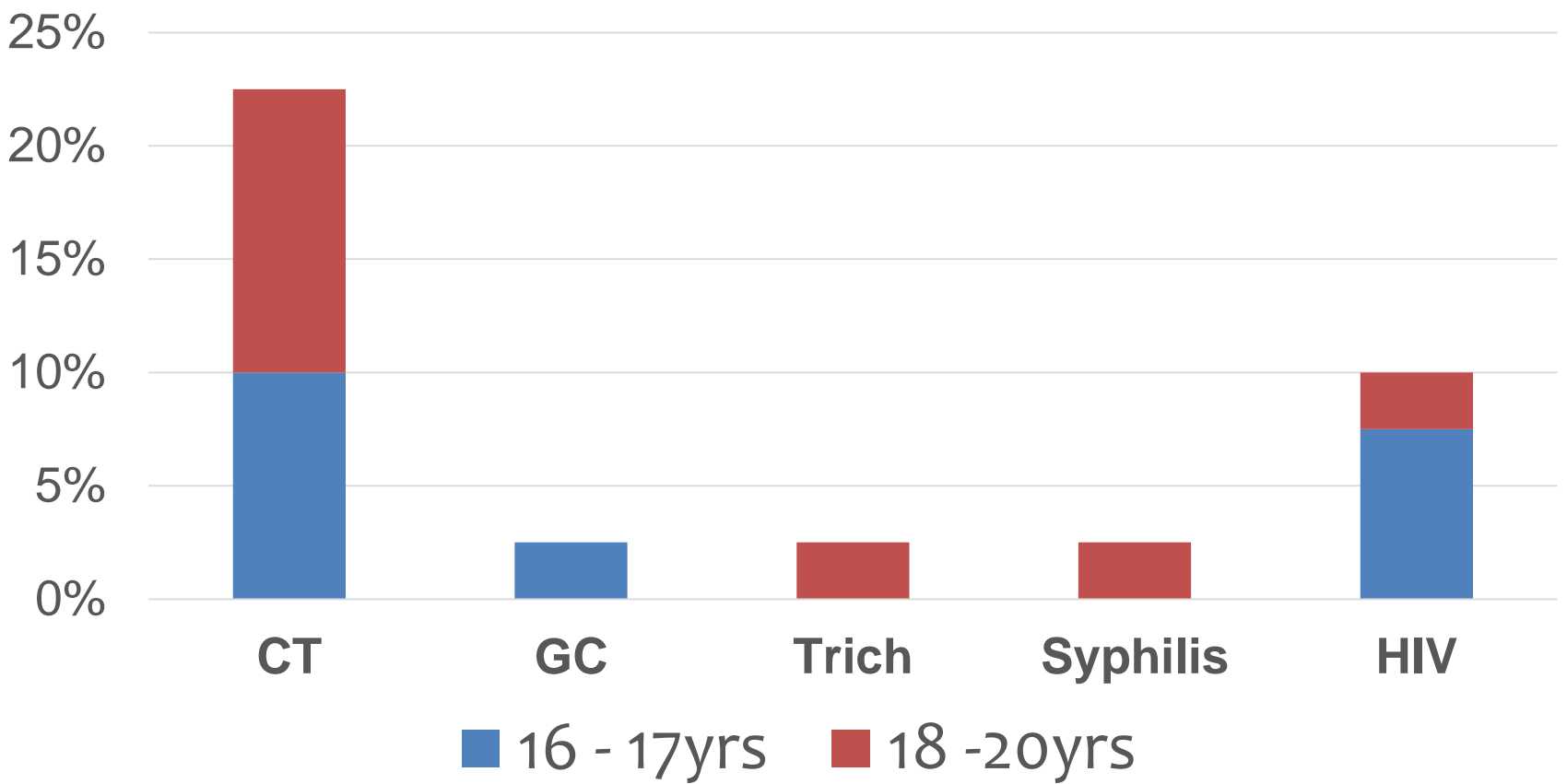


Characteristics	N
Does not live with Parent/Guardian*	2
Currently sexually active*	13
Partner >25 yrs*	4
Never tested for HIV*	0
Has other sexual Partners**	6
Not Living with partner **	13
Partner has other sexual partners**	8
Unknown partner HIV status**	6
Previously treated for STIs**	2
Has no income**	1
Occupation (Sex Work =6, factory=1, Dancer=1, Sales girl =3, Food Vendor=2)	



STIs at Screening

STI Prevalence by Age





IRBs interest in minors...

The primary IRB was interested to see if we would be able to recruit minors and the approach we used..

Concern: – do we really have high risk minors?

Do we need such a study to be done in Uganda?

- Monitoring visit by the primary IRB led by **IRB Chair** was conducted in 30 April 19
 - *Check on implementation of REACH thus far*
 - *Accrual of minors and challenges in recruitment*



Never have we had such a heated discussion when approving a study as we had during the REACH approval!. It is a great relief to see that REACH is providing us with insights on minors that we would not have otherwise known! The study team has executed the study well and have managed to overcome the challenges we anticipated when recruiting AGYW especially minors! It would be great if the study team can recruit more minors...!

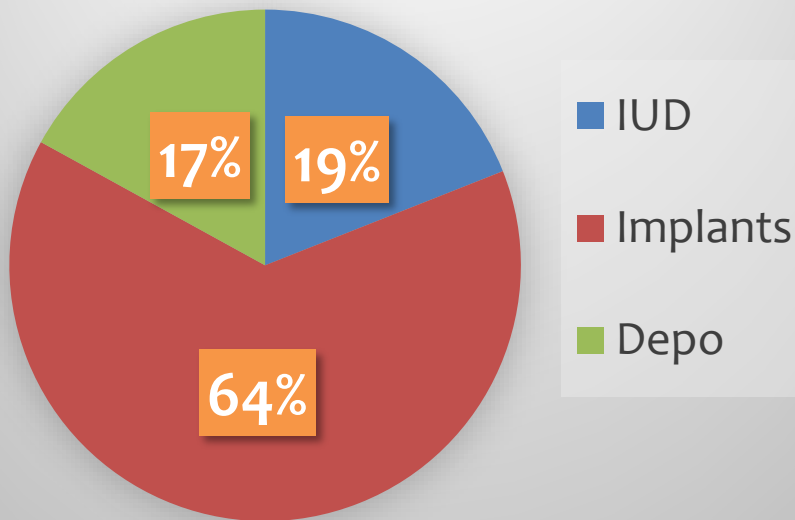
JCRC IRB Chair



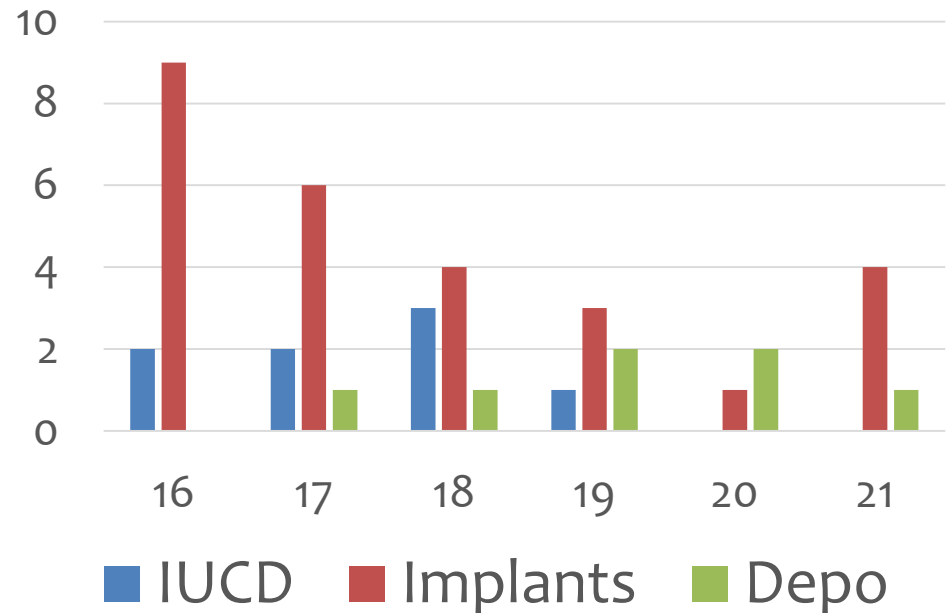
Contraception!

It is possible for AGYW to use LARCs!

Contraceptive Method Mix



Contraceptive Method Mix by age Group





Contraception..

- Low Contraceptive uptake among AGYW!
- AGYW from the **community have little/no information** about contraception! Undecided
- Myths/Misconception
 - FP provided before one gives birth **“burns the eggs!”**
 - IUCD and implants may move to the heart, lungs and one may die!
 - IUCD causes cancer because of the copper released
 - Depo results in uterine swellings
- Method **immediately** given if interested!

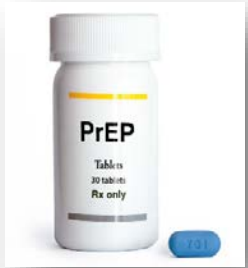




Study Design and Products

Young women are willing to use both products...

- Cross-over study design is appreciated by the AGYW – experience both methods then **CHOOSE!**
- Study rationale understood & study products accepted by AGYW
 - PrEP not widely available in Uganda
 - Little or no information about PrEP among AGYW
- Myths/Misconception
 - *PrEP makes someone gain so much weight!*
 - *PrEP results in liver damage!*
 - *Oral PrEP doesn't prevent HIV; tablets have HIV!*



Ring is new, most skeptic about it... size.. but willing to try it

Education Sessions

- **Pre-enrolment sessions**
 - provide more information about REACH, study products
 - Feedback from AGYW obtained
 - Recommendations useful to provide more adolescent friendly services
- Ring & PrEP ambassadors, *fellow participants* provide lived experiences





Study Procedures

Pelvic Exams were a challenge...



- Screening PE is usually the first PE ever!
 - Shy, scared
 - Uncomfortable (cold speculum, many staff in the room, feel naked)
 - Initially procedure too long!
 - 3 Screened out – declined PE
- Myths/Misconception
 - Some body organs may be removed during PE – *procedure explained + instruments/swabs*








The “Right” participant...

The “Right” participant may not be “right” always!

Following Feedback Results, noted that some AGYW had Adherence Challenges

Question: Are we targeting right participants for REACH?

- **Recruitment strategies changed;**
 - Communities marked where poor adherers were obtained from
 - Research naïve communities targeted
 - *Staff scrutinize motives for joining study*

Score	
High	
Medium	
Low	

Conclusion

- Recruitment of AGYW especially minors is possible!
 - Rigorous education on contraception is critical – on-site/immediate provision can increase uptake
 - **Minors are at high risk of HIV/STI acquisition** – information from REACH will be important to expand approval to those below 18
 - Dispelling myths and misconceptions is crucial ! Even the “**right**” participant can be corrupted
 - Use of ring or PrEP ambassadors and fellow participants has been very helpful
 - *Sensitize, Sensitize, Sensitize continuously*
- ***REACH is well poised to find the answers it seeks!***

I thank the REACH study for doing what I am not able to do ... hmmm there is great improvement in my daughter; she is no longer jumping around with men and now seems to have a purpose for her life. I got her when I was 14 and I am glad that my daughter will not follow in my footsteps, thanks to REACH!!

Mother to Minor

Acknowledgements

- Adolescents and young women!
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