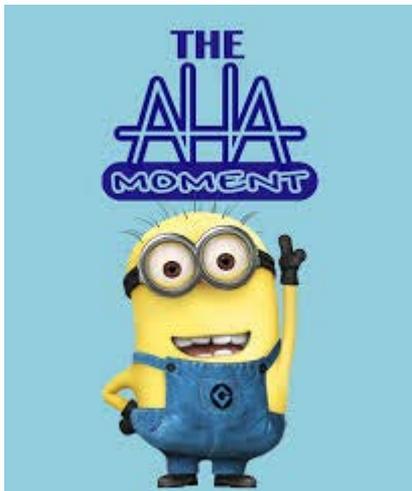


Insights from MTN-032

Assessment of ASPIRE and HOPE Adherence (AHA) : Phase 1



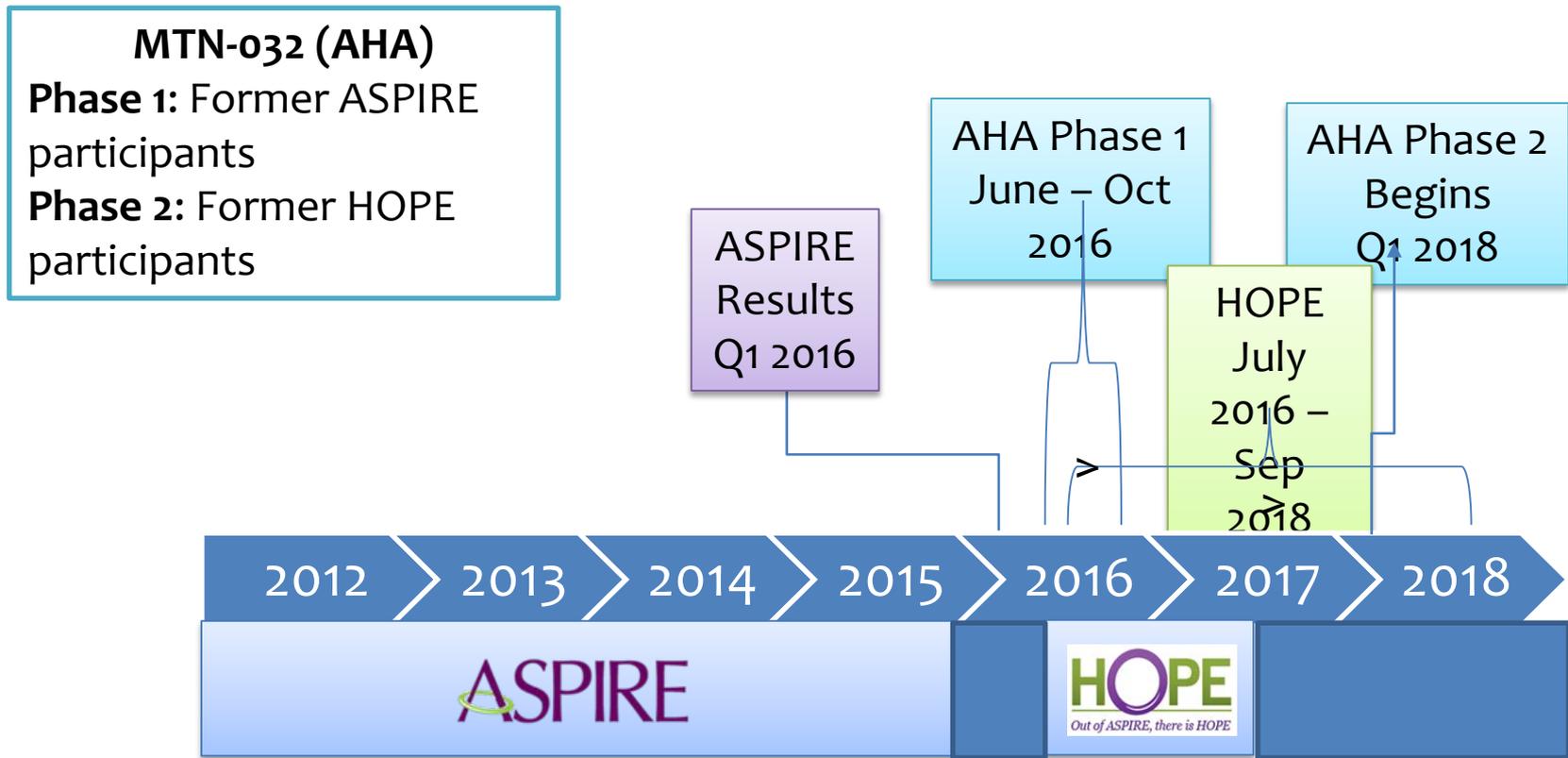
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Introduction

- MTN-020/ASPIRE and IPM-027/Ring Study proved that the **dapivirine vaginal ring was safe and effective with consistent use.**
- To optimize the impact of this promising female-initiated prevention method, **adherence barriers need to be understood and addressed.**
- MTN-032 explored women's ring use challenges through open-ended discussion of their “objective” adherence data from stored plasma and returned rings.



MTN-032 Study Timeline



Methods

In Phase 1, Former ASPIRE participants were:

- Stratified by age group (18-21; 22-45) and
- Randomly selected at 7 sites in Malawi, South Africa, Uganda and Zimbabwe
- 12-17 months after trial exit



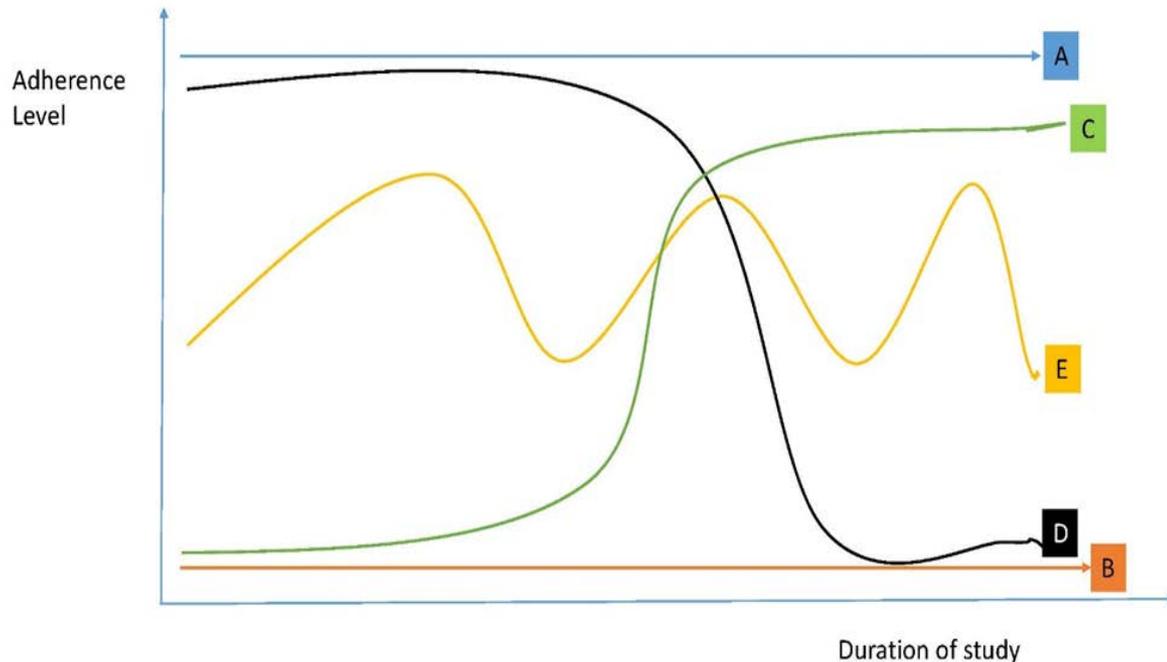
Methods

- Ring use challenges were explored via in-depth interviews (IDI) or focus group discussions (FGD) using structured guides
- Visual tools used included:
 - adherence trajectory tool and
 - Individual depiction of dapivirine levels detected in plasma and returned rings.
- Coding of transcribed interviews was conducted in Dedoose™



Methods

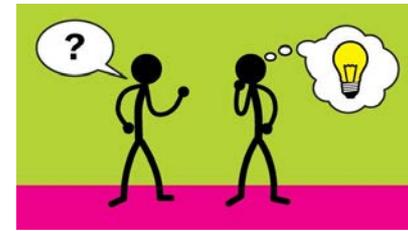
ADHERENCE TRAJECTORY TOOL



- A) Consistently adherent,
- B) Consistently non-adherent,
- C) Non-adherent at the beginning and adherent by end,
- D) Adherent at the beginning and non-adherent by the end, or
- E) Inconsistently adherent throughout the study.

Helped participant understand how participants may have used the ring differently

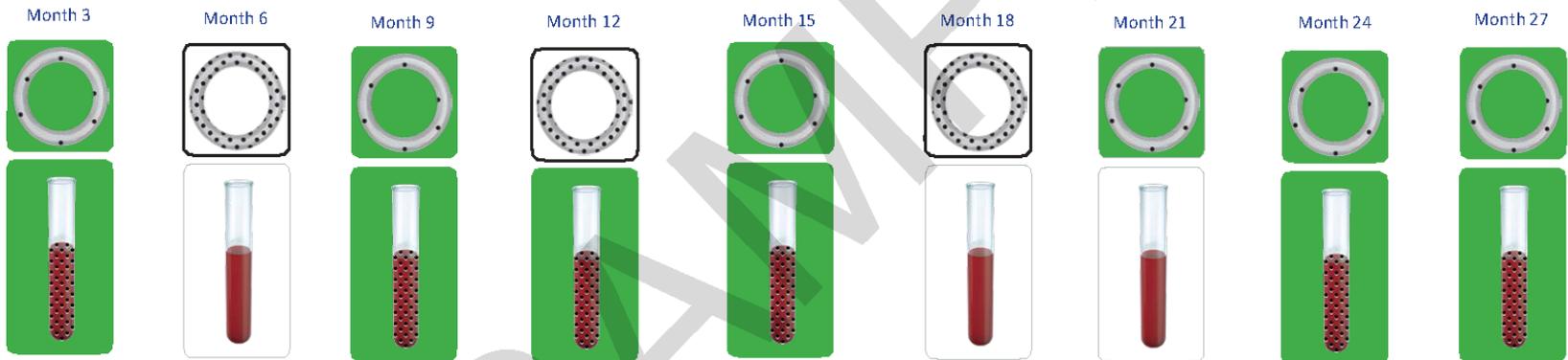
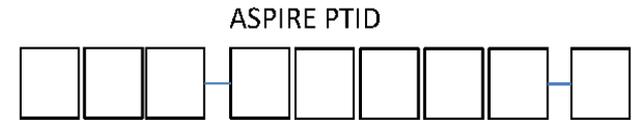
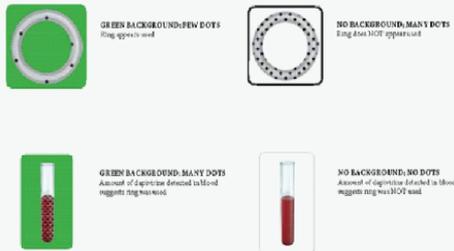
Methods



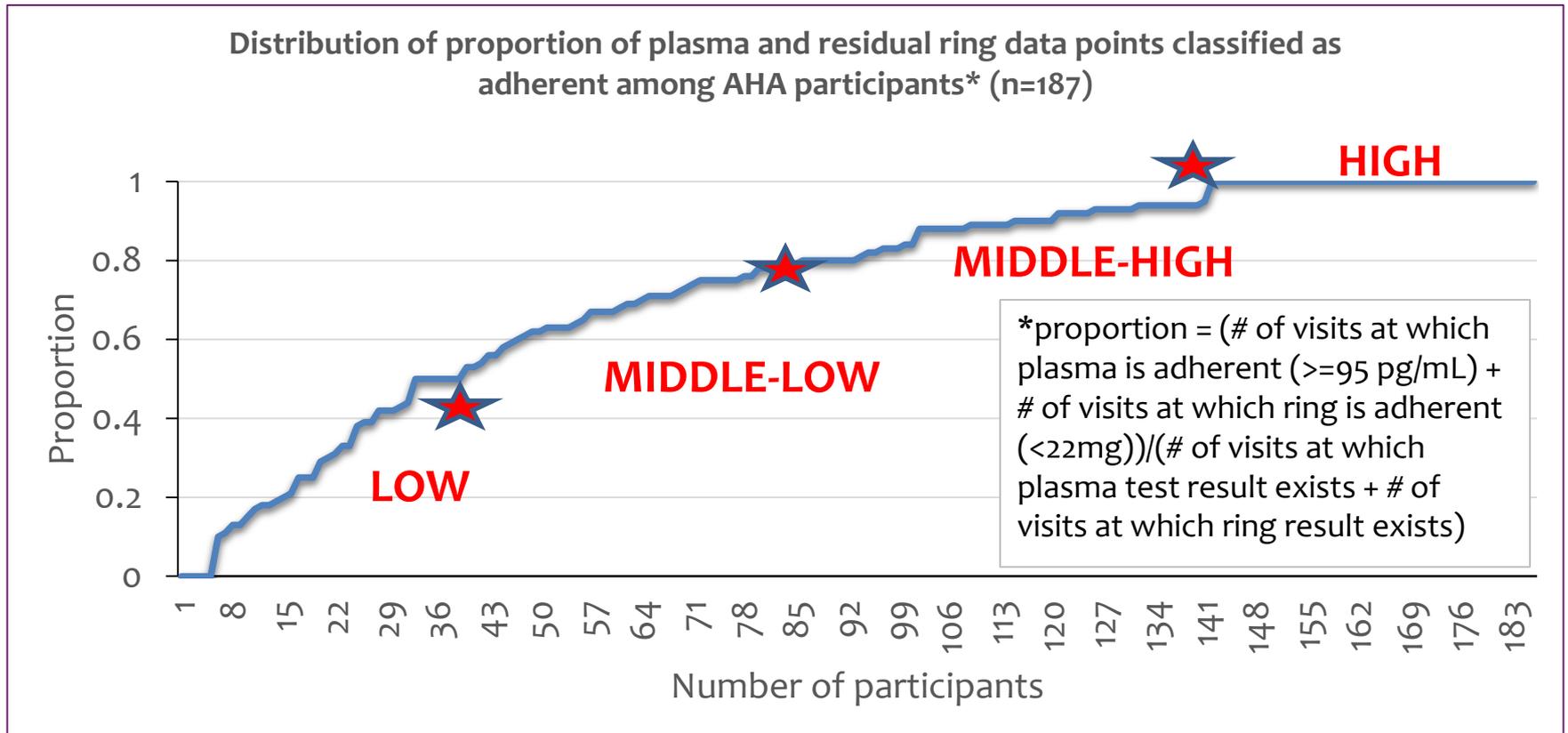
INDIVIDUAL DEPICTION OF RESULTS

MTN-032 Individual Drug Level Results Visual Tool

MTN-032 INDIVIDUAL DRUG LEVEL RESULTS TOOL LEGEND



Methods

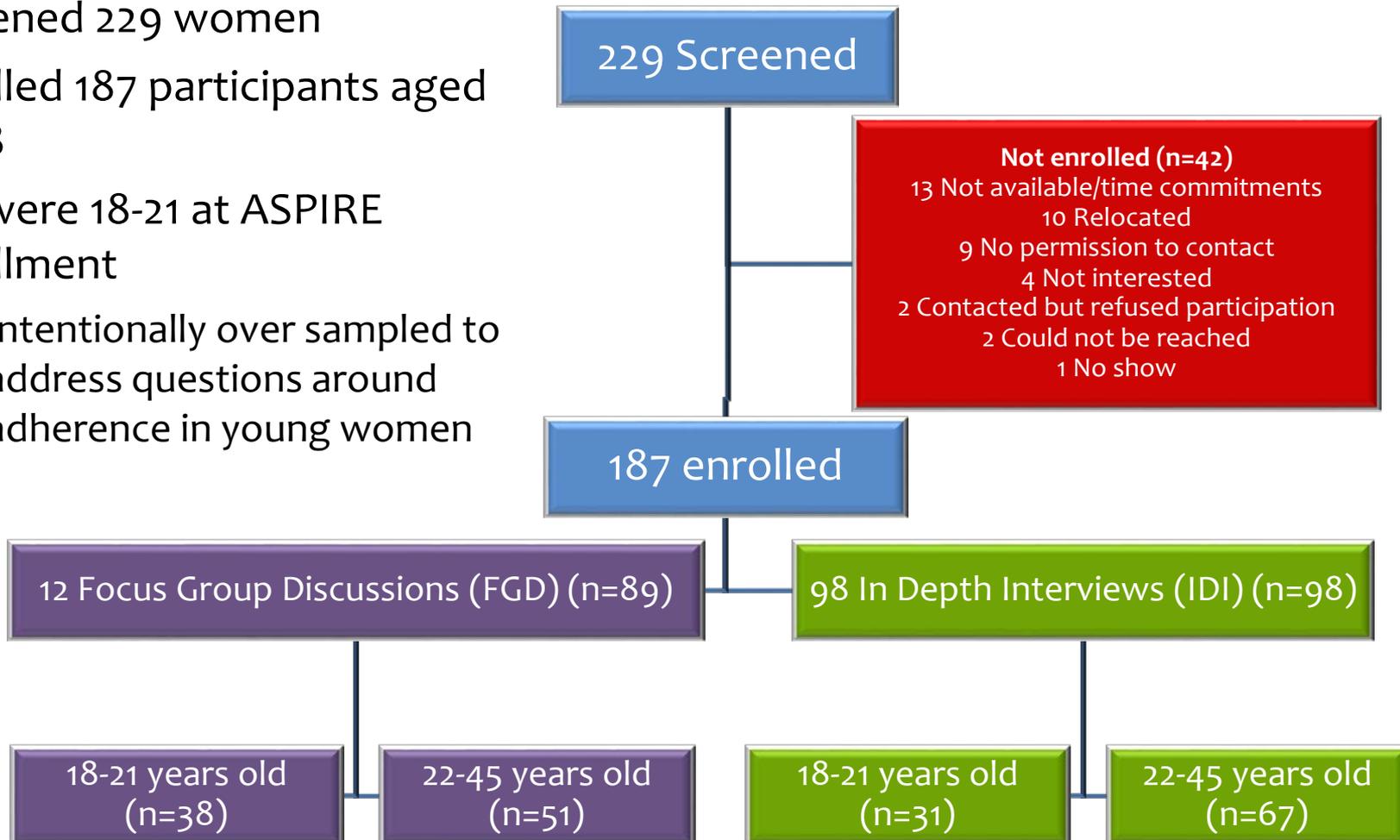


- The information gained from the Individual drug level results were divided into 4 analysis groups in terms of adherence

Results:

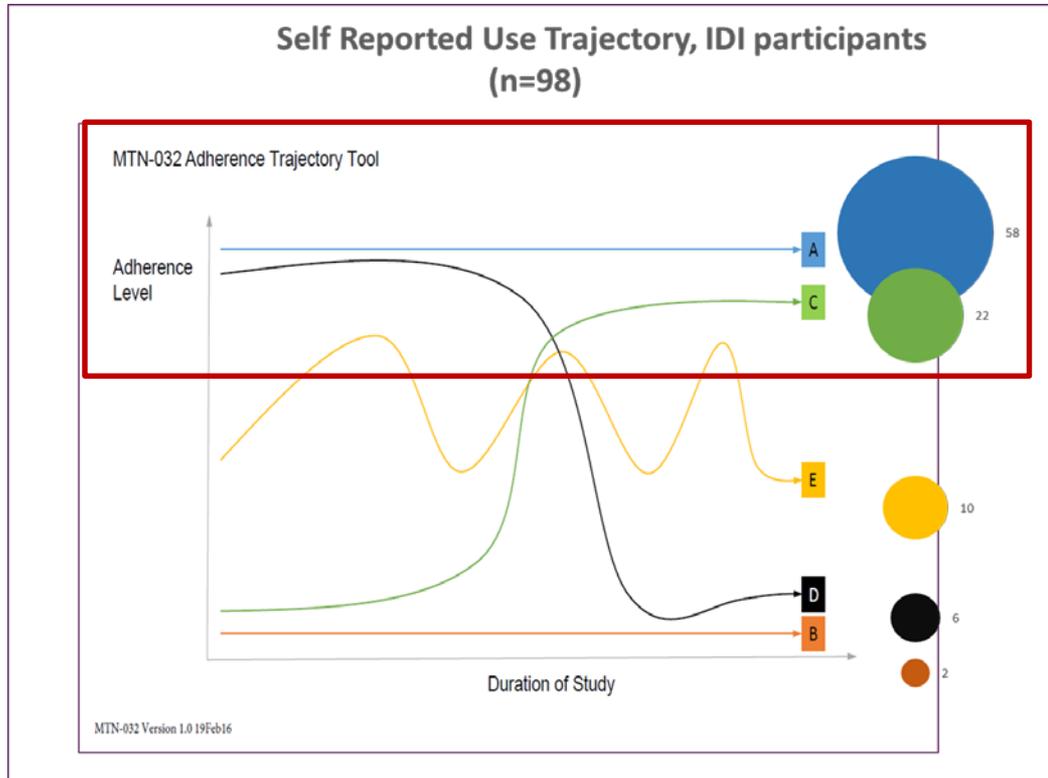
Participants

- Screened 229 women
- Enrolled 187 participants aged 19-48
- 37% were 18-21 at ASPIRE enrollment
- Intentionally over sampled to address questions around adherence in young women



Results:

Self Reported Use



- In IDIs, most women (80%) described their trajectory of ring use throughout the study as consistently high (58%), or high after the first few months (22%).



Results:

Explanations for Non-use

- Use of these tools elicited participant descriptions of many instances of non-adherence, including **removals** from **short-term, multiday, multi-week** (often with reinsertion 1-3 days before the next visit).
- Reasons for non adherence included
 - For sex or bathing
 - Menses
 - Worries about ring causing cancer or infertility;
 - Experience of discomfort or side effects.
 - Influence from peers and communities;
 - Mistrusting researchers (particularly foreign)
 - Non-disclosure to partners and partner objections;

Analysis

- Stratified analysis was done for the 4 adherence groups
- This was also done by age group and by IDI and FGD
 - Based on the many questions related to factors impacting adherence in younger women
- Allowed us to observe differences by adherence group and age
- **Many of the reasons were the same across groups - motivators were different**

Results

	Younger Women (18-21)	Older Women (22-45)
Health Issue attributed to the ring	X	X
Partner opposition	X	X
Fear of partner opposition	X	X
Thinks ring blocks menses blood flow	X	X
Motivated by money, not ring	X	X
Did not get new ring or replace ring from clinic	X	X
To clean ring while bathing	X	X
To clean ring during menses	X	X
Experiences of pain symptoms in menses	X	X
Concerns about rumors spread by community/ peers/ family	X	X
Believes ring is a placebo/ not effective	-	X
Product holds	X	-
Opposition from peers/family	X	X
Believes ring will cause cancer	-	X
Removes ring to bathe	X	-
Removes during menses	X	-
Concerns that ring will cause side effects	X	X
Concerns about wearing ring during sex	X	X
Lack of partner	X	-
Concerns about ring storage	X	-
Partner removed ring	X	-

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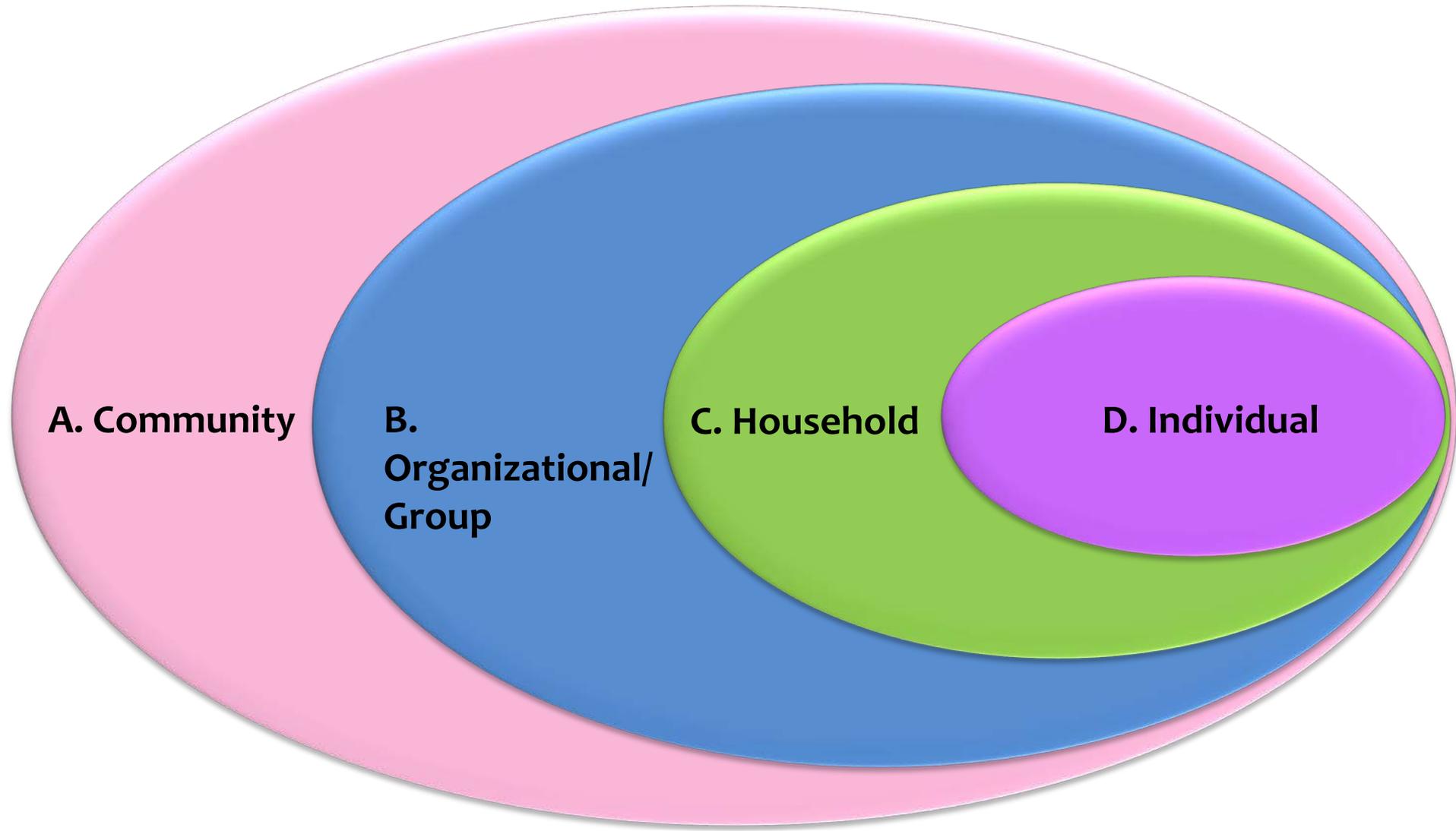
Results

FGDs

- ASPIRE result indicated younger women were less adherent
- Discussed during FGD
- Both younger and older women provided similar information with young women's non-adherence attributed to being:
 - less “serious” about the future, HIV prevention and the study (and motivated predominantly by benefits);
 - more fearful of childbearing/fertility-related consequences;
 - more into partying;
 - not appreciating the potential consequences of non-use;
 - and to having less confidence and control in their partnerships



Motivators to Adherence



Motivators to Adherence: Community

Information flow/beliefs

- Not susceptible to rumors or concerns expressed by others

Altruism

- Protecting future generations from HIV
- Believing in importance of proving efficacy

I think knowing that like in the future I am going to empower other young ladies like me not to be exposed to the HIV virus. That was my goal and it was at the back of my mind that I was doing this and I'm not going to remove the ring. (IDI #2031; Age 21; High Adherence Group; Johannesburg, South Africa)



Motivators to Adherence

Organizational/Group

Encouragement from other participants

- Others non-experiencing side effects
- Others wearing ring consistently

Trial Led Activities:

- Adherence workshops
- Site Level Adherence Feedback
- Waiting room talks
- Discussions/assurances from staff

I never had any fear because I would get confidence from friends who I often asked their experience and they would confirm that they haven't had any problem and in a way it would make you strong. (IDI #6013; Age 23; Middle- High Adherence Group; Kampala, Uganda)



Motivators to Adherence: Household

Male Partner Support

- Disclosure to male partner
- Not feeling ring during sex

“Ah, he (male partner) just spoke- He even mentioned the names of staff and asked, “How are they? Don’t stop using the ring. You removed the ring in the first days. When I see them [staff] I will report that you removed the ring. So persevere in using the ring.” (IDI #4005; Age 30; Middle-Low Adherence Group; Harare, Zimbabwe)



Motivators to Adherence:

Individual

Not experiencing side effects

Feeling protected

- Regular HIV testing
- Believing the ring is protective

While I was using the ring, I was very proud of myself, yes, that is what I am going to say! I use to pride myself in my ring use. I told myself that this ring that I am using, is protecting me. That is the first thing. (IDI #3001; Age 30; Middle-High Adherence Group; Durban, South Africa)



Conclusions

- Most women believed (or described) themselves to be adherent or mostly adherent to the ring, despite plasma and ring data demonstrating variable use.
- When presented with objective individual-level adherence data, participants provided numerous explanations/challenges resulting in non-adherence during ASPIRE:
 - Non-disclosure/disapproval of ring use by male partners,
 - Hygiene-related worries (especially related to menses) and
 - Concerns about side effects or adverse health effects
- These reasons were reported in almost all adherence and age subgroups

Conclusions

- Several motivators to consistent ring use were also identified, particularly a feeling of altruism among the high adherers.
- Motivators are equally as important as challenges to understand so as to encourage consistent use.



Overall, these data can be used to pre-emptively mitigate adherence challenges in future ring studies/ activities

Acknowledgements

- All MTN-020 (ASPIRE) & MTN-032 (AHA) site staff and participants
- RTI International
- FHI 360
- MTN

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.



**Thank
You!**

