



Study Product Adherence: A Continuing Challenge in HIV PrEP Trials With User Dependant Products

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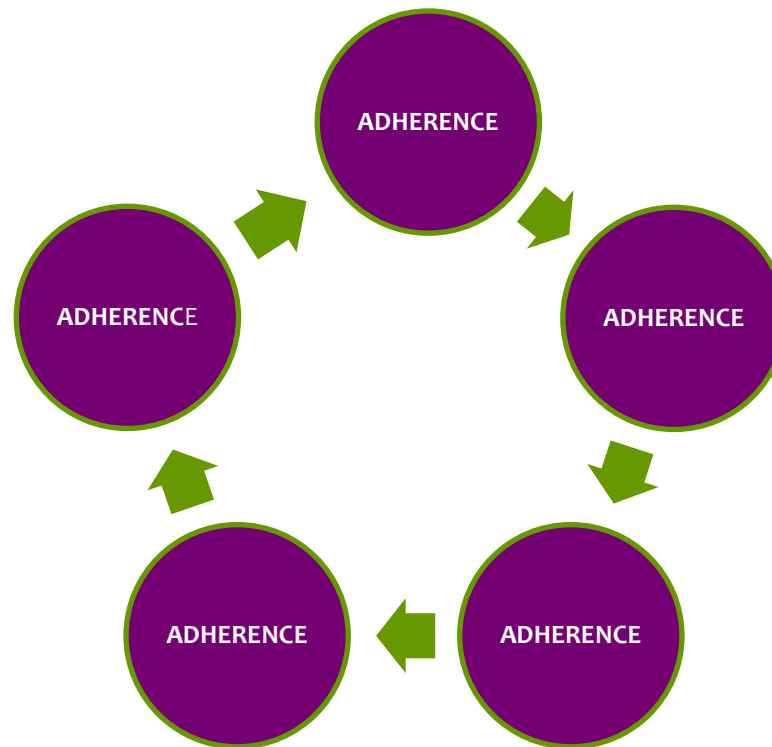
Outline

- Introduction
- Lessons learnt from previous trials
- What are we seeing now in ASPIRE
- Conclusion
- Way forward for future studies



Introduction

- A lot of resources (finances, time, manpower e.t.c) are put into running clinical trials hence study success is important
- Study product adherence is one of the key factors into study success besides other factors like data quality, retention etc



Lessons Learnt From Previous Trials

- Studies without evidence of efficacy mostly due to poor adherence
 - FEM-PrEP (Truvada)
 - VOICE (Oral tenofovir, tenofovir gel and Truvada)

Study	Estimated Adherence	
	Self Report	Drug Level (in subset)
FEM PrEP	95%	<40%
VOICE – TDF	90%	30%
Truvada	91%	29%
TFV Gel	91%	25%

Lessons Learnt From Previous Trials (cont.)

- Why this low adherence? !!! Possible reasons could be
 - Stigma attached to using ARV drug
 - Benefits from trials *outweighed* product use e.g STI/HV screening, cervical cancer screening, contraception
 - HIV may not be a priority (*vs contraception*)
 - Other factors like socioeconomic status, culture, male partner decline, community myths / misconceptions etc.

Lessons Learnt From Previous Trials (cont.)

- Some suggestions after release of VOICE results were;
 - To stealthily deliver anti HIV agents in combination with contraceptives
 - Develop a coitally dependent product
 - Develop long acting products
- Hence researchers continued with the vaginal ring- (currently under ASPIRE and RING studies) hoping for better adherence

What Are We Seeing Now In Aspire in Regard To Product Adherence

- Enrolled similar study population as VOICE
- Some observations that may indicate poor product adherence:

Observations	N
Participant requested not to take more rings at one of her visits	1
Participant took out ring before leaving the clinic citing that her menses had started	1
Participant who fidgeted to remove ring when she actually knew it was not in; then requested to go to toilet. . . <i>Ring was in her bag</i>	1

What Are We Seeing (cont.)

Observations Cont'd	N
Participant who always did not have the ring at most of her visits – <i>taken by one of partners, fell in pit latrine. . .</i>	1
Participant not having ring in situ during an unscheduled visit	2
Participant who had not disclosed ring use so removed ring before sex. . . <i>her ring was taken by rats</i>	1
Participant whose primary partner discovered the ring and stopped her from ring use but could continue with the study	1



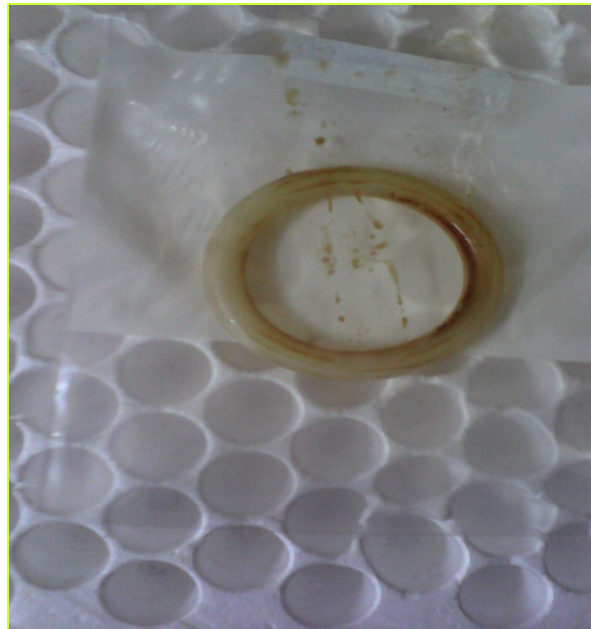
What Are We Seeing (cont.)

What we *think* are some of the “used rings”

“Normal used ring”



“Menses Ring”



“Amenorrhoeic
Ring”



What We Are Seeing (cont.)

Ring color appearance

“Orange Ring”



What We Are Seeing (cont.)

“Lime Green Ring”



What We Are Seeing (cont.)

“Lavender Ring”



What We Are Seeing (cont.)

“Straw Colored Ring”



What We Are Seeing (cont.)

“seemingly unused ring”



Conclusion

- We continue to see that some women are not adherent to product
 - Some observations are obvious poor adherence i.e. removing ring before leaving clinic
 - Some of the observations are subjective so we cannot draw conclusions of non adherence (ring appearance) –Some women *maybe using contraindicated vaginal products*

Conclusion (cont.)

- What is it that we are not doing right/ are we missing something?



Conclusion (cont.)

- Continuing adherence counseling and passing on messages of adherence at every opportunity e.g. DSMB dissemination meetings, milestone events is key with the “**hope**” of changing the poor adherers



Conclusion (cont.)

- Male involvement workshops – Men play key role in decision making



Conclusion (cont.)



We need a variety of products for women to choose from, both user & provider dependant

Way Forward For Future Researches

- Community sensitization is still key
- Male involvement – need to find ways of maximizing this
- We may have to revise our recruitment processes
- We need to continue understanding circumstances affecting women's lives as we design future trials
 - Socioeconomic status
 - Issues of stigma
 - Motivations besides risk perception
 - Sexual life Dynamics
 - Cultural factors

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