

Sexual relationships outside primary  
partnerships and abstinence are  
associated with lower adherence and  
adherence gaps

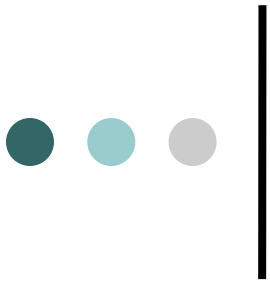


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I have no conflict of interest to declare



# Outline

- Background information on relevant key findings in the Partners PrEP and Adherence Studies
- Methods used in this study
- Key findings
- Conclusions and future directions



# Partners PrEP and Adherence Studies

- Double-blind, three-arm, randomized, placebo-controlled trial of daily oral PrEP among 4758 serodiscordant African couples.
- Ancillary adherence study (AAS) in Uganda at three of the nine study sites.



# Ancillary Adherence Study:

- **Key findings** (*Haberer et al., PLoS Medicine, 2014*):
  - 1,147 HIV negative participants enrolled
  - Median adherence: 99% by UPC and 97% by MEMS.
  - High adherence that was achieved in this study was associated with a high degree of protection from HIV acquisition.



# Sexual behavior and adherence

	AOR (95% CI)	p-value
Sexual behavior (Quarterly)		<0.001
Primary partner only, 100% condom use	reference	
Primary partner only, <100% condom use	1.1 (0.8-1.6)	
Other partner only	2.3 (1.3-3.8)	
Other partner + primary partner	1.6 (1.1-2.4)	
No sex	2.3 (1.5-3.3)	
Polygamous marriage	0.6 (0.4-1.0)	0.03

Controlled for age, study duration and heavy alcohol use

Haberer et al. Plos Medicine 2014



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Haberer et al. Plos Medicine 2014



# Polygamy associated with better adherence

	AOR (95% CI)	p-value
Sexual behavior (Quarterly)		<0.001
Primary partner only, 100% condom use	reference	
Primary partner only, <100% condom use	1.1 (0.8-1.6)	
Other partner only	2.3 (1.3-3.8)	
Other partner + primary partner	1.6 (1.1-2.4)	
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# Objectives for this analysis

- Short-term effect (monthly) of sexual behavior
- Assess patterns of sexual behavior
- Assess the effects of polygamy within strata of sexual behavior



# Categorization of sexual behavior

- Monthly sexual behavior categorized as
  1. Abstinence
  2. Primary partner only
  3. Other partner only
  4. Both primary and other partner (stratified by polygamy status)
- Categories 2-4 stratified into 100% condom use & <100% condom use



# Categorization of adherence

- Electronically assessed using MEMS
- Adherence execution
  1. Low adherence:  $<80\%$
  2. High adherence:  $\geq 80\%$
- Adherence patterns (Number of gaps)
  1.  $\geq 48$  hours
  2.  $\geq 72$  hours
  3.  $\geq 1$  week



# Covariates

- *Baseline:* Age, gender, SES, Level of education
- *Time varying:* Primary source of income, heavy alcohol use, depression, # of study drug side effects, perceived risk of HIV acquisition
- *Partner characteristics:* Duration of cohabiting, # of children, polygamous marriage, duration of knowledge of discordance
- Used Generalized Estimating Equations (GEE) with robust standard errors



# Enrollment characteristics

<b>HIV-negative partner characteristics</b>	<b>N=1147</b>
Female	539 (47%)
Years of education*	6 [3, 7]
Age in years*	34 [30, 40]
Placebo	402 (35%)
Clinic visit of AAS enrollment	
At PrEP enrollment	290 (25%)
Months 1 - 6	182 (16%)
Months 7-12	202 (18%)
After month 12	473 (41%)
<b>Partnership characteristics</b>	
Married	1135 (99%)
Living together	1129 (98%)
Number of years living together*	8.5 [3.7, 15.3]
Number of children in partnership*	2 [1-4]
Polygamy	282 (25%)
Age difference between partners*	0 [-5, 5]
Unprotected sex in prior month	321 (29%)
HIV-1 infected partner CD4 count*	491 [368, 667]
HIV-1 infected partner viral load*	4.0 [3.3, 4.6]

\*median[IQR]



# Distribution of sexual behavior

Sexual behavior	Months (N, %)	Participants (N,%)
Abstinence	1503 (13)	468 (43)
Primary partner only		
100% condom use	6867 (59)	930 (85)
<100% condom use	1850 (16)	418 (38)
Other partner only		
100% condom use	143 (1)	76 (7)
<100% condom use	261 (2)	93 (9)
Other partner + primary partner & polygamous		
100% condom use	227 (2)	56 (5)
<100% condom use	418 (4)	81 (7)
Other partner + primary partner & non-polygamous		
100% condom use	130 (1)	60 (6)
<100% condom use	320 (3)	91 (8)



# Distribution of adherence rates

Adherence	Months		Participants	
	N	%	N	%
Low*	1521	13.3	402	36.8
High	10175	86.7	691	63.2
Total	11736	100	1093	100

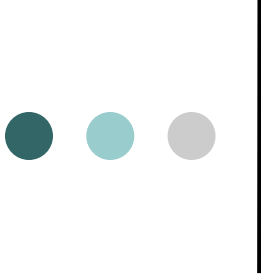
\* < 80%



# Abstinence and sex with other partners associated with low adherence

Risk Category	N,%	OR	95% CI	P value
Primary partner only				
100% condom use	929 (85)		Reference	
<100% condom use	418 (38)	1.06	0.90-1.25	0.52
Abstinence	465 (43)	1.32	1.13-1.54	0.01
Other Partner Only				
100% condom use	76 (7)	1.50	0.99-2.27	0.06
<100% condom use	92 (8)	2.09	1.52-2.86	0.01
Other partner + primary partner & polygamous				
100% condom use	60 (5)	0.96	0.67-1.37	0.82
<100% condom use	91 (8)	0.92	0.61-1.39	0.68
Other partner + primary partner & non-polygamous				
100% condom use	60 (5)	1.10	0.65-1.88	0.72
<100% condom use	91 (8)	1.40	0.99-1.98	0.06

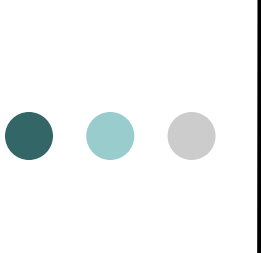




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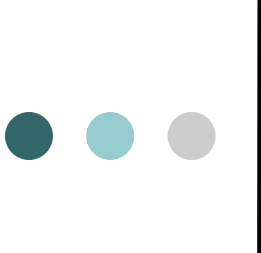
Risk Category	N,%	AOR	95% CI	P value
Primary partner only				
100% condom use	929 (85)		Reference	
<100% condom use	418 (38)	0.95	0.70-1.30	0.76
Abstinence	465 (43)	1.30	1.05-1.62	0.02
Other Partner Only				
100% condom use	76 (7)	1.71	1.06-2.76	0.03
<100% condom use	92 (8)	2.48	1.70-3.62	0.01
Other partner + primary partner & polygamous				
100% condom use	60 (5)	1.10	0.49-2.53	0.82
<100% condom use	91 (8)	1.45	0.86-2.43	0.16
Other partner + primary partner & non-polygamous				
100% condom use	60 (5)	1.76	1.01-3.08	0.04
<100% condom use	91 (8)	1.41	0.88-2.27	0.16

\*Controlled for age, sex, SES, study duration, duration of knowledge of discordance and perceived risk of HIV transmission



# Distribution of 48 and 72-hour gaps

Description	48-hr gap		72-hr gap	
	Prevalence*	Months with at least 1 gap (N, %)	Prevalence*	Months with at least 1 gap (N, %)
Overall	85	5001 (43)	55	1966 (17)
Sexual Behavior				
Abstinence	83	3466 (30)	46	1268 (11)
Primary partner only	63	722 (6)	37	329 (3)
Other partner only	67	248 (2)	45	140 (1)
Both primary & other partner	73	551 (4)	46	220 (2)
Condom use				
100%	71	2968 (25)	39	1133 (10)
<100%	36	1310 (11)	19	503 (4)
Polygamous relationship				
Yes	83	1088 (9)	54	386 (3)
No	86	3891 (33)	55	1565 (14)



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# Abstinence and sex with other partners associated with gaps in adherence

Risk Category	N,%	OR	95% CI	P value
Primary partner only				
100% condom use	929 (85)		Reference	
<100% condom use	418 (38)	0.94	0.81-1.09	0.43
Abstinence	465 (43)	1.20	1.03-1.40	<b>0.02</b>
Other Partner Only				
100% condom use	76 (7)	1.51	0.93-2.44	0.09
<100% condom use	92 (8)	1.69	1.26-2.26	<b>0.01</b>
Other partner + primary partner & polygamous				
100% condom use	60 (5)	1.00	0.72-1.40	0.98
<100% condom use	91 (8)	1.09	0.79-1.51	0.61
Other partner + primary partner & non-polygamous				
100% condom use	60 (5)	1.18	0.62-2.23	0.62
<100% condom use	91 (8)	1.21	0.91-1.62	0.19



# Abstinence and sex with other partners associated with gaps in adherence

Risk Category	N,%	AOR	95% CI	P value
Primary partner only				
100% condom use	929 (85)		Reference	
<100% condom use	418 (38)	0.91	0.78-1.06	0.21
Abstinence	465 (43)	1.17	1.01-1.35	<b>0.04</b>
Other Partner Only				
100% condom use	76 (7)	1.32	0.93-1.87	0.12
<100% condom use	92 (8)	1.50	1.19-1.91	<b>0.01</b>
Other partner + primary partner & polygamous				
100% condom use	60 (5)	1.01	0.65-1.55	0.98
<100% condom use	91 (8)	1.16	0.84-1.62	0.36
Other partner + primary partner & non-polygamous				
100% condom use	60 (5)	1.01	0.65-1.55	0.98
<100% condom use	91 (8)	1.16	0.84-1.62	0.36

\*Controlled for age, SES, sex and study duration



# Conclusions and Future Directions

- Outside relationships and abstinence are associated with low adherence and adherence gaps
- Similar overall findings to quarterly assessment
- Weaker association for abstinence (1.3 vs. 2.3)
- Many long gaps of non adherence
- Polygamy associated with better adherence



# Conclusions and Future Directions

- Planned PrEP breaks for some people?
- Need for extra counseling support for categories with high risk for non-adherence
- Emphasis of combination prevention
- More studies on:
  - Effects of polygamy
  - Amount of drug required in plasma for effective PrEP
  - Efficacy of periodic PrEP/ PrEP breaks



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