Evaluation and process outcomes from an adherence intervention to support HIV pre-exposure prophylaxis (PrEP) adherence in HIV serodiscordant couples in Uganda

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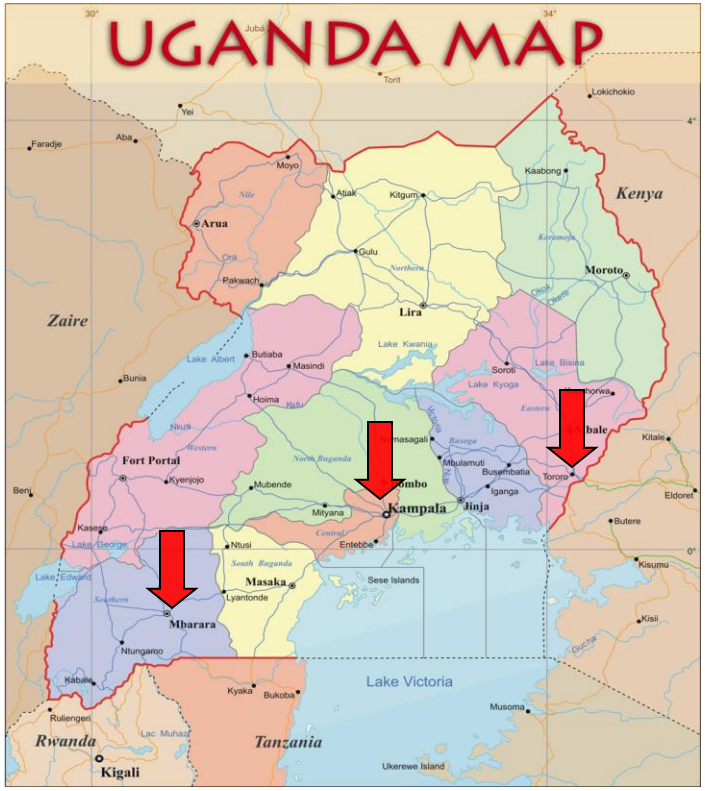
Outline

- Relevant background information about the Partners PrEP study
- Process of developing a PrEP adherence intervention and core components of PrEP adherence intervention
- Overview of process data
- “Lessons learned” and implications for the future

Partners PrEP Study



- Ongoing phase III, double-blind, three-arm, randomized, placebo-controlled trial of daily oral PrEP among 4700 serodiscordant African couples.
  - Ancillary adherence study in Uganda at three of the nine study sites
- DSMB recommended discontinuation of placebo on July 10, 2011.
  - 62% fewer infections in TDF group and 73% fewer infections in FTC/TDF group.

Ancillary Adherence Study (AAS)

- Goals: To determine the level, pattern, and predictors of PrEP adherence using objective adherence measures (e.g., MEMS, unannounced home pill counts, random drug levels).

- Preliminary AAS findings (*Haberer et al., CROI, 2012*):
  - 1,147 HIV negative participants enrolled
  - Median adherence: 99% by UPC and 92% by MEMS.
  - PrEP efficacy within AAS was 100% (95% CI 87-100%, p<0.001).

Ancillary Adherence Study: Intervention Aim

- To deliver an intervention targeted to HIV-negative participants with low (<80%) unannounced pill count adherence
  - To examine process of intervention delivery and predictors of intervention success
  - Refine and enhance existing adherence counseling messages to better meet specific needs of participants
  - Develop the best adherence counseling protocol based on behavioral science, site experience, and relevant cultural concerns
    - Product to be tested for efficacy in future trials

Intervention Fundamentals

- Intervention based on the work of Safren and colleagues on adherence to ART *(Safren et al., 1997; 2001; 2007)*
  - Combines elements of Cognitive Behavioral Therapy (CBT) and Motivational Interviewing (MI)
- Modular / checklist format:
  - Standardized provision of information while still tailoring counseling messages to individual needs
  - Delivery by a variety of study staff members with various levels of training
  - Provides a reference for future counseling sessions

Intervention Development

- Iterative process of intervention development
  - Informal focus groups with study participants
  - Ongoing feedback from sites and counselors
  - Counselors trained over a two day-period; participate in monthly supervision calls and yearly site visits

Intervention Delivery

- After the intervention is triggered, counseling occurs in two phases:
  - With individual on PrEP
    - Monthly contact with interventionist
    - Number of sessions tailored and variable
  - With their HIV infected partner (optional)
    - Participant on PrEP dictates information to be shared with their partner

Intervention Content

- Module 1: Psychoeducation
- Module 2: Brief motivational interviewing
- Module 3: Assessment of family, community, social support and privacy concerns
- Module 4: Assessment of daily routine, and development medication schedule, reminder strategies
- Module 5: Identification of barriers to adherence
- Module 6: Brief problem-solving
- Module 7: Couples session
- Module 8: Follow-up sessions

Enrollment Characteristics

	HIV-1 seronegative enrolled; never triggered intervention N=1023	HIV-1 seronegative enrolled; triggered intervention* N=124
Individual characteristics		
Female gender	491 (48%)	48 (39%)
Years of education	6 (3,7)	6 (3,9)
Age in years	34 (30,40)	32 (28, 38)
18-24	74 (7%)	14 (11%)
25-34	444 (43%)	58 (47%)
35+	505 (49%)	52 (42%)
Any income	916 (90%)	110 (89%)
Clinic visit of AAS enrollment**		
At PrEP enrollment	234 (23%)	56 (45%)
Months 1 - 6	164 (16%)	18 (15%)
Months 7-12	183 (18%)	19 (15%)
After month 12	442 (43%)	31 (25%)

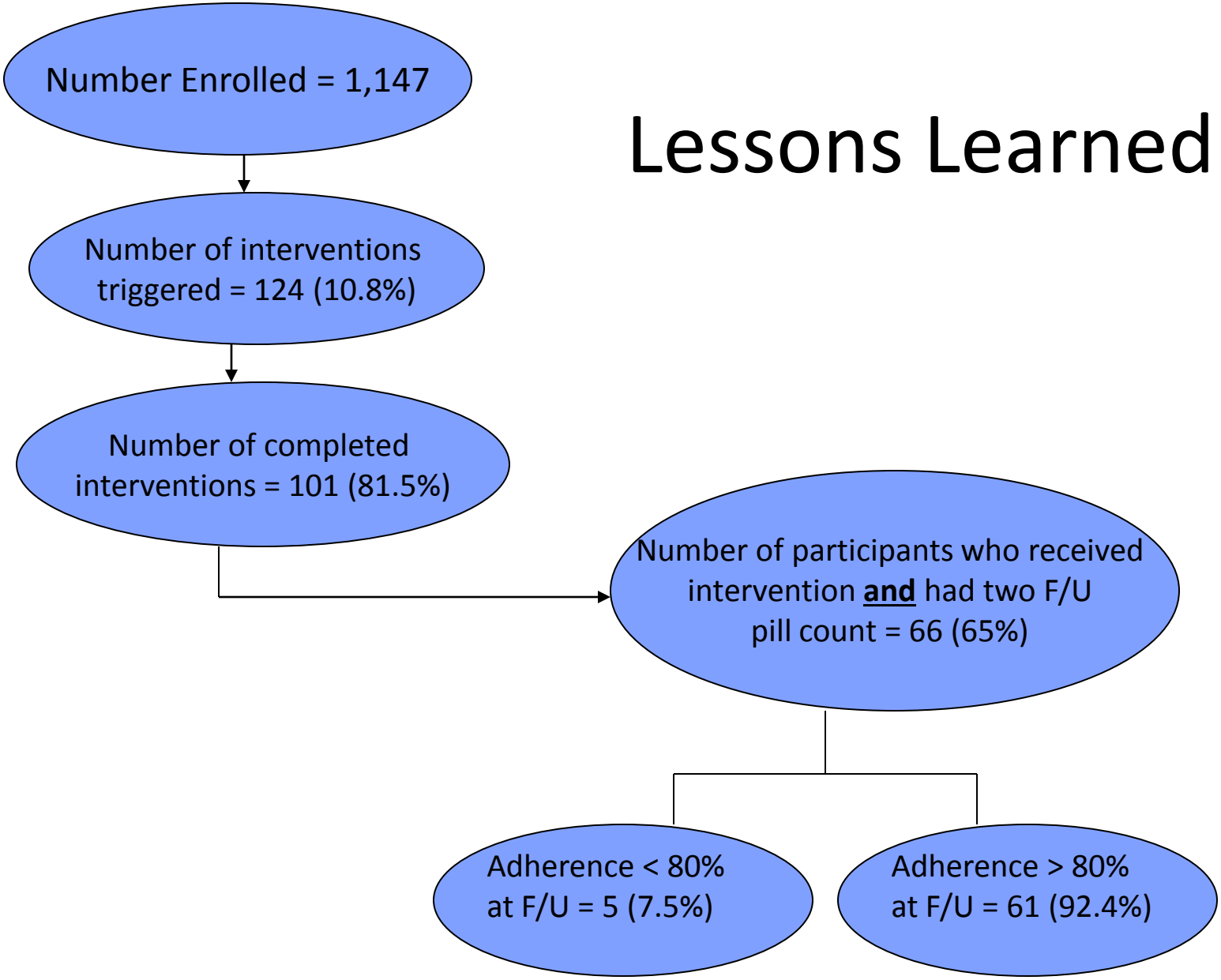
*Participants shown who had <80% UPC adherence, but may not necessarily have received the intervention (N=101)
**Enrollment means when MEMS cap was issued.

Partnership Enrollment Characteristics

Partnership characteristics	HIV-1 seronegative enrolled; never triggered intervention N=1023	HIV-1 seronegative enrolled; triggered intervention* N=124
Married	1012 (99%)	123 (99%)
Living together	1007 (98%)	122 (98%)
Number of years living together	8.8 (4.0, 16.0)	7.0 (2.8, 11.5)
Years known HIV discordant	0.8 (0.1, 2.3)	0.5 (0.1, 1.4)

*Participants shown who had <80% UPC adherence, but may not necessarily have received the intervention (N=101)

Lessons Learned



Lessons Learned

- Average length of sessions = 30.2 minutes
- Average number of intervention sessions = 6.8 (range = 1-16)
- Most frequently delivered modules across all sessions:
  - Reminder strategies 71.0%
  - Psychoeducation on adherence 71.0%
  - Review of sexual behavior 64.4%
  - Concrete medication schedule 51.4%
  - Problem-solving 45.2%

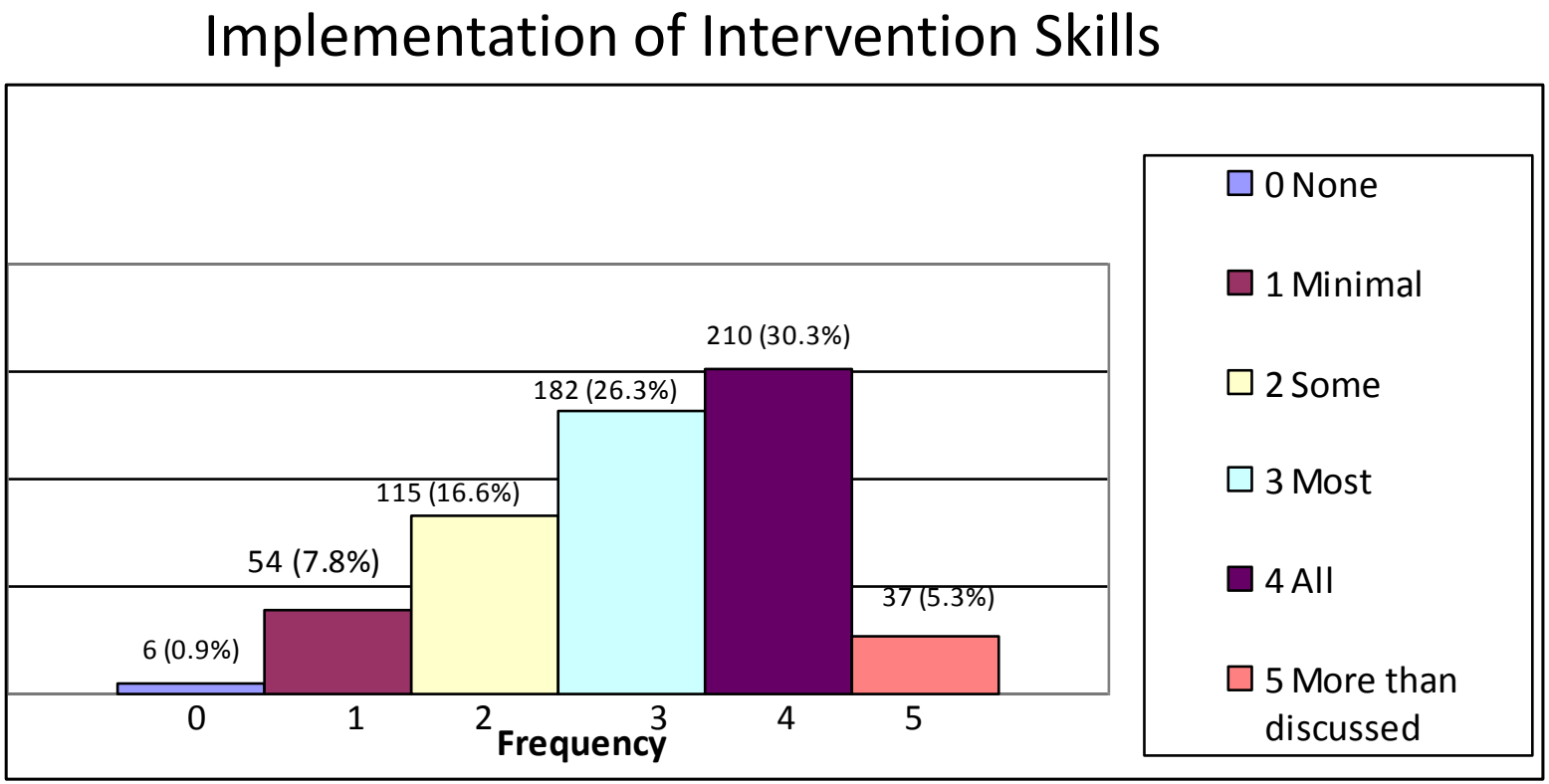
Lessons Learned

- Most frequently endorsed barriers across <u>all</u> sessions:
  - Travel 19.2%
  - Forgetting 18.0%
  - Perceived PrEP side effects 4.0%
  - Partner discord 3.8%
  - Stigma/privacy concerns 3.8%
  - **58% of sessions indicated no barrier to adherence was identified**

Lessons Learned

- Least frequently endorsed barriers across <u>all</u> sessions:
  - Missing clinic due to lack of transport 2.7%
  - Pill burden 1.9%
  - Missed clinic due to childcare or family matters 1.9%
  - Missing clinic to avoid loss of income 1.0%
  - Conflict between religious beliefs and study procedures 0.3%
  - Substance abuse 0.3%

Lessons Learned



Conclusions and Future Directions

- Adapting evidenced-based treatment adherence interventions to PrEP adherence, with culturally-relevant topics is feasible and acceptable to counselors and participants.
  - Interventions developed in the clinical trial setting may differ than those delivered in the “real world”.

Conclusions and Future Directions

- Further follow-up will address efficacy and sustainability of increasing adherence after this intervention in those with <80% adherence to daily PrEP.
- Future research must identify PrEP users with low adherence for intervention and determine optimal duration of intervention to maximize PrEP effectiveness.
- Such work will increase confidence in interpretation of results from biomedical HIV prevention trials and will facilitate adherence and proper use of these strategies as PrEP becomes more available.