HIV ORAL SELF-TESTING

Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Intended Population
- Male partners of pregnant female persons attending antenatal care

Goal of Intervention
- Increase HIV testing
- Increase linkage to HIV care

Brief Description

HIV Oral Self-Testing is a combination HIV prevention intervention designed to increase HIV self-testing and encourage linkage to HIV care among antenatal female persons and their male partners in Uganda. The intervention provides four free HIV self-testing (HIVST) kits for female participants, their male partners, and other adults in the household. The intervention also includes health education, communication counseling, and training on result interpretation. Participants watch a demonstration by the site coordinator and a video in the local language (Luganda) demonstrating HIVST procedures. Participants are encouraged to contact site coordinators if they experience any form of interpersonal violence (IPV) both related to HIV self-testing and otherwise. During follow-up both female participants and their partners are asked if they experienced IPV; referrals are given as needed.

Theoretical Basis
- None

Intervention Duration
- Not specified

Intervention Setting
- Residence
- Health care setting (hospital, clinic)

Deliverer
- Study site coordinator
- Nurse counselor

Delivery Methods
- Counseling
- Demonstration/modeling
- HIV testing
- Video

Structural Component

Access
- Increased access to HIV testing, antenatal HIV care, linkage to HIV medical care, and ART

Physical Structure
- Services provided in non-traditional setting - HIV self-tests provided for testing at home
- Integrated services – HIV self-testing kits made available in antenatal clinic

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Jeffrey E. Korte**, Department of Public Health Sciences, Medical University of South Carolina, 135 Cannon Street, Suite 303, Charleston SC 29425.

Email: korte@musc.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information
The original evaluation study was conducted in central Uganda between 2016 and 2018.

Key Intervention Effect
- Improved HIV testing

Study Sample
The baseline study sample of N = 1,514 is characterized by the following:
- 14% persons 15-19 years old
  39% persons 20-24 years old
  26% 25-29 persons years old
  21% 30-49 persons years old
  1% persons with missing age
- Mean age of 25 years
- 17% currently married persons
  79% co-habiting persons
  4% never married persons
  <1% divorced persons
  2% persons with missing marital status

Percentages may not add up to 100% due to rounding.

Recruitment Settings
Antenatal care clinic

Eligibility Criteria
Pregnant female persons aged 14 years or older, either living with HIV or not, were eligible if they attend ANC in Central Uganda at any time during pregnancy and had male partners 18 years or older with negative or unknown HIV status who were not tested in the last 6 months.

Assignment Method
Clinic patients were cluster-randomized to either the HIVST intervention (n = 777) or a standard-of-care control (n = 737) using study days. Study days were randomized to the intervention or control creating nominal clusters of female persons who came to the clinic on that day. Simple randomization was used to assign each study day to the intervention or control, and this random assignment was the same each day for the three study sites. The study days were randomized before the study began and each day's assignment placed into a numbered sealed envelope. The study coordinator opened the day's envelope and informed the site coordinators by telephone whether it was an intervention or control day. All female persons who attended any of the three clinics on a specific day were randomized to the same study arm.

Comparison Group
The standard of care includes education for female participants to encourage their partners to test at the health facility, rather than using a self-testing kit.

Relevant Outcomes Measured and Follow-up Time
HIV testing was measured as self-reported HIV testing by any means (e.g., HIVST or clinic-based testing) at 1- and 3-month follow-up.

Participant Retention
Participant retention is not a criterion for the Structural Interventions Chapter.

Significant Findings on Relevant Outcomes
- A significantly greater percentage of intervention participants reported that their male partners tested for HIV than control participants at 1-month post-intervention (70.8% vs. 16.9%, Risk Ratio [RR] = 4.19, 95% Confidence Interval [CI]: 3.49 – 5.05).
- A significantly greater percentage of intervention participants reported that their male partners tested for HIV than control participants at 3-months post-intervention (28.4% vs. 22.4%, RR = 1.27, 95% CI: 1.02 – 1.57).
- In the cumulative report, a significantly greater percentage of intervention participants reported that their male partners tested for HIV compared to control participants at 1 month- and 3-month post intervention (70.6% vs. 26.8%, RR = 2.64, 95% CI: 2.31 - 3.01).
- In the combined measure considering a positive report from either the female or the male person across the study period, a significantly greater percentage of male partners in the intervention group tested for HIV than the control group (77.2% vs. 37.2%, RR = 2.07, 95% CI: 1.87 - 2.30).
- A significantly greater percentage of intervention participants (combined female and male reports) reported HIV testing as a couple vs. control participants over the study period (74.9% vs. 31.3%, $p < 0.0001$).
- A significantly greater percentage of male partners in the intervention arm were first time testers for HIV compared to the control arm (67.7% vs. 24.2%; RR = 2.79; 95% CI: 2.26 to 3.46).
- After controlling for baseline HIV status, employment status, and study site, the study authors found an adjusted overall RR of 2.60 (95% CI: 2.30–2.90) for male partner HIV testing uptake comparing intervention participants versus control participants.

Considerations
The intervention study was not considered for the Linkage to, Retention in, and Re-engagement in HIV Care chapter because the linkage to HIV care outcomes were self-reported.

Additional significant positive findings on non-relevant outcomes
- None reported

Non-significant findings on relevant outcomes
- None reported

Negative findings
- No negative findings reported.

Other related findings

- For female participants, there were no differences in the intervention effect on HIV testing rates stratified by age and education, but there were differences when stratified by employment status: employed for wages (RR = 1.42, 95% CI: 0.56 - 3.60), self-employed (RR = 5.89, 95% CI: 3.21 - 15.03) or other (RR = 2.60, 95% CI: 2.28 - 2.97).
- In the intervention arm at 1 month, 98.5% of the female participants took HIV oral self-testing kits and 92.6% offered them to their male partners.
- Using a combined measure considering an HIV positive report from either the female participant or male partner, 44 male partners (34 intervention and 10 control) tested positive for HIV over the 3-month follow-up period. Of these, 32 reported whether they linked to HIV care. Six of the 26 men (23.1%) linked to HIV care in the intervention arm, versus 4 of 6 men (66.7%) in the control arm (unadjusted RR = 0.35, 95% CI: 0.14 to 0.85
- Based on the female participants' report at 1 month, 9 male partners tested positive for HIV (8 in the intervention arm and 1 in the control arm). One of the 8 male partners (12.5%) in the intervention arm and the one male partner in the control arm were linked to HIV care.
- Based on the female participants' report over 3 months, 18 males tested positive for HIV (15 in the intervention arm and 3 in the control arm). Two out of the 15 male partners (13.3%) in the intervention and all 3 male partners (100%) in the control arm were linked to HIV care. *
- Based on the male partners' report over 3 months, 21 men (17 intervention and 4 control) tested positive for HIV over the 3-month follow-up period. Of these, 6 of 17 males (35.3%) in the intervention and 2 of 4 males (50%) in the control arm linked to HIV care. *

*The authors suggest that linkage to HIV care could be lower among individuals testing positive in the intervention group (HIVST) due to inconvenience of accessing clinic services (travel, waiting times, expense, opportunity costs), fear, or avoidance of needle-stick needed for confirmatory testing, or privacy concerns.

Implementation research-related findings

- None reported

Process/study execution findings

A cost-effectiveness analysis was conducted, assessing implementation costs at and above the costs associated with the local clinic. Estimated costs (USD) included personnel time, operational costs, training, assets, and supplies. The intervention was evaluated based on cost per partner tested and cost per partner with HIV identified. Incremental cost-effectiveness ratios were based on incremental costs between intervention and comparison arms, and incremental effects including incremental number of partners tested and partners with HIV identified.

- In the base-case analysis, the total cost was $15,717.27 (US dollars) for the intervention and $5826.10 for comparison.
- The cost per partner tested was $30.30 for the intervention and $31.20 for the comparison.
- The cost per person with HIV identified was $462.30 for the intervention and $582.60 for the comparison.
- The incremental cost per additional partner tested (incremental cost-effectiveness ratio) was $29.80 and the incremental cost-effectiveness ratio per additional partner testing positive for HIV was $412.10.
- The high costs in the control arm were driven by costs associated with administrators/directors who may not be located at the local clinic, which contributed 55% of total cost, followed by facility personnel time costs (27% of total cost). The facility personnel time was computed from the time they spent on activities related to recruitment, follow-up of recruited participants, and linkage to HIV care of those who tested positive for HIV

Adverse events

- According to the participants' report at month 1, a higher proportion in the intervention arm reported that male partners humiliated or threatened to harm participants compared to the control arm (31/620 [5.0%] vs. 10/625 [1.6%], p = 0.001). However, only a few reported this to be related to HIV testing (6/31 vs. 1/10, p = 0.65), providing no clear evidence for the concern that HIVST might lead to gender-based violence.
- Two couples in the intervention arm separated during the study period (judged to be related to the study).
- No instance of interpersonal violence detected during the study.
- There were 3 participant deaths (none judged to be related to the study).

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REFERENCES AND CONTACT INFORMATION

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