Secondary distribution of HIV self-tests in Kenya: opportunity for health facilities to promote partner and couple testing

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Impact Research and Development Organization
Presentation Outline

• Questions motivating HVST studies in Kenya
• Results of two studies on secondary distribution in Kenya
• Ongoing/upcoming studies on secondary distribution strategy
• Other studies on HIVST by IRDO and collaborators
Questions motivating recent studies in Kenya

• What are optimal HIVST distribution strategies for furthering key HIV prevention goals? Specifically:
  • Male partner and couples testing
  • Testing of priority and key populations
  • Testing as part of PrEP delivery ????

• How can HIVST be used in cost-effective ways to achieve prevention objectives?

• How might HIVST affect sexual decision-making?
  • Can HIVST reduce new infections because individuals make safer sexual decisions on the basis of test results?
    • Can this lead to sero-sorting? Increase condom use? Reduce partners?
Secondary distribution of self-tests – 2 completed studies by IRDO-UNC team

• Provision of multiple self-tests to index persons accessing routine healthcare may be useful in enhancing access to HIV testing within social networks

  • Pilot study in Kenya to test this strategy among pregnant and postpartum women, and FSW (Thirumurthy et al Lancet HIV 2016)

  • A randomized trial among women seeking antenatal and postpartum care (Masters et al PLOS Medicine 2016)
Self-test provision and follow-up

• Index participants (IPs)
  • Given multiple OraQuick Rapid HIV Tests
    • Study 1 (Pilot): 3 kits for ANC/PPC, 5 for FSWs
    • Study 2 (RCT): 2 kits for all participants
  • Educated on how to use self-tests and provided with written and pictorial instructions
  • Some encouragement to distribute self-tests to partners and clients; others *at own discretion*

• Follow-up interviews at 1, 2, 3 months
  • Focus on self-test usage and experience, violence and adverse events
  • Qualitative in-depth interviews with selected ppts
Aims of the two studies

• **Both studies**: Determine whether providing *multiple* self-tests to women who access routine healthcare services can promote partner and couple testing *and* facilitate safer sexual decision-making

  • Describe who receives self-tests through secondary distribution (sexual partners, FSWs’ clients, friends, etc.)
  • Describe how self-tests are used (independently, as couple)
  • Describe decisions on sexual behavior following couple testing
  • Assess uptake of confirmatory testing and linkage to care
  • Assess safety of secondary distribution strategy

• **Study 2 only**: Evaluate the impact of HIVST on uptake of partner and couple testing compared to standard invitation coupons for testing at a clinic
Study 1: Key findings
How self-test kits were distributed and used

- **280** enrolled (61 ANC, 117 PPC, 102 FSW)

- Total of 901 self-tests reported used by IPs or distributed by IPs to others
  - 192 self-tests used by IPs
  - 709 self-tests distributed to others (97%, 691 used)

- About 20% of kits offered were declined, and 15% of test kits distributed did not get used

Distribution by ANC and PPC women

Distribution by FSW
Couples testing occurred frequently

- For each self-test given to other persons, IPs were asked how self-testing took place (n=709)

<table>
<thead>
<tr>
<th>Relationship to participant of sexual partner who used self-test</th>
<th>Antenatal care</th>
<th>Post-partum care</th>
<th>Female sex workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-tests distributed by participant to male sexual partners, n</td>
<td>53</td>
<td>91</td>
<td>301</td>
</tr>
<tr>
<td>Self-tests distributed to and used by male sexual partners, n</td>
<td>53</td>
<td>91</td>
<td>298</td>
</tr>
<tr>
<td>Relationship to participant of sexual partner who used self-test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary sexual partner</td>
<td>53 (100%)</td>
<td>91 (100%)</td>
<td>64 (21%)</td>
</tr>
<tr>
<td>Non-primary sexual partner</td>
<td>...</td>
<td>...</td>
<td>23 (8%)</td>
</tr>
<tr>
<td>Commercial sex client</td>
<td>...</td>
<td>...</td>
<td>211 (71%)</td>
</tr>
<tr>
<td>Participant reported being present when sexual partner used self-test</td>
<td>53 (100%)</td>
<td>88 (97%)</td>
<td>248 (83%)</td>
</tr>
</tbody>
</table>

- Couples testing occurred with 51-83% of primary partners in the 3 study groups
- 4/280 (1.4%) IPs reported adverse events
HIVST and safer sexual decision-making

- Sexual intercourse less likely and condom use more likely when partner tested HIV-positive

<table>
<thead>
<tr>
<th></th>
<th>Antenatal care</th>
<th>Post-partum care</th>
<th>Female sex workers</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participant had sexual intercourse with sexual partner after he used a self-test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV-negative self-test result</td>
<td>38/51 (75%)</td>
<td>66/87 (76%)</td>
<td>131/242 (54%)</td>
<td>235/380 (62%)</td>
</tr>
<tr>
<td>HIV-positive self-test result</td>
<td>0</td>
<td>1/2 (50%)</td>
<td>7/41 (17%)</td>
<td>8/45 (18%)</td>
</tr>
<tr>
<td>p value†</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

| Condom used during last sexual intercourse with sexual partner* |                |                  |                   |                |
| HIV-negative self-test result | 1/38 (3%)      | 12/66 (18%)      | 91/131 (69%)       | 104/235 (44%)  |
| HIV-positive self-test result | --             | 1/1 (100%)       | 7/7 (100%)         | 8/8 (100%)     |
| p value†                  | --             | --               | --                 | 0.0018         |

Data are n (%), unless otherwise specified. *Among participants who reported sexual intercourse with sexual partner after he used a self-test. †p value from Fisher’s exact test comparing means for participants whose sexual partners obtained an HIV-negative and HIV-positive self-test result.

Table 5: Sexual decision making of participants

Study 2: Design and Key findings
Study design

- Women recruited from 3 ANC and PPC clinics in Kisumu

- Randomized to one of two groups
  - **Intervention:** Shown how to correctly use HIV self-tests (Oraquick) and given two self-tests
    - Written & pictorial instructions provided with each self-test
    - Modest encouragement to distribute self-tests to male partner at their own discretion
  - **Control:** Given referral cards that invited their partner to obtain HIV testing at VCT clinics, alone or as a couple
# Impact of HIVST on uptake of partner and couple testing in Kenya

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Partner invitation group, No. (%) (N=286)</th>
<th>Self-testing group, No. (%) (N=284)</th>
<th>Absolute difference, % (95% CI)*</th>
<th>Risk Ratio, RR (95% CI)**</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male partner HIV testing</td>
<td>148 (51.7)</td>
<td>258 (90.8)</td>
<td>39.1% (32.4% to 45.8%)</td>
<td>1.76 (1.56-1.98)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Couples testing for HIV</td>
<td>95 (33.2)</td>
<td>214 (75.4)</td>
<td>42.1% (34.7% to 49.6%)</td>
<td>2.27 (1.90-2.71)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval

*-Estimates and CI are marginal effects from unadjusted modified Poisson regression

**-Estimates and CI are risk ratios from unadjusted modified Poisson regression

- **Partner testing** was 90.8% in HIVST group and 51.7% in the comparison group; the proportion of partners tested was 39% higher in the HIVST group
- **Couples testing** also significantly higher in HIVST group (75% vs. 33%, p<0.01)

Masters et al *PLOS Medicine* 2016
Intervention effective even among women who reported IPV at baseline

<table>
<thead>
<tr>
<th></th>
<th>Control Group N</th>
<th>Control group, No. (%) (n=286)</th>
<th>Self-testing group N</th>
<th>Self-testing group, No. (%) (n=284)</th>
<th>Absolute difference, % (95% CI) *</th>
<th>P-value for subgroup*</th>
<th>P-value for interaction*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intimate partner violence at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>210</td>
<td>114 (54.3%)</td>
<td>206</td>
<td>185 (89.8%)</td>
<td>48.9% (36.4% to 61.3%)</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>Yes</td>
<td>76</td>
<td>34 (44.7%)</td>
<td>78</td>
<td>73 (93.6%)</td>
<td>35.5% (27.6% to 43.4%)</td>
<td>&lt;0.001</td>
<td>0.111</td>
</tr>
</tbody>
</table>

Notes: *-Estimates are marginal effects from a modified Poisson regression of outcome on study group for the subsample described.

**-P-value from interaction coefficient between subsample and first category (urban clinic, or no IPV)
Also effective among women whose partner had not tested recently

<table>
<thead>
<tr>
<th>Partner HIV testing in 12 months prior to enrollment</th>
<th>Control group, No. (%) (n=286)</th>
<th>Self-testing group, No. (%) (n=284)</th>
<th>Absolute difference, % (95% CI) *</th>
<th>P-value for subgroup*</th>
<th>P-value for interaction*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tested ≥ 1 time</td>
<td>173 102 (59%)</td>
<td>149 142 (95.3%)</td>
<td>36.3% (28.3% to 44.4%)</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>Did not test</td>
<td>35   16 (45.7%)</td>
<td>42 37 (88.1%)</td>
<td><strong>42.4% (23.1% to 61.7%)</strong></td>
<td>&lt;0.001</td>
<td>0.389</td>
</tr>
<tr>
<td>Do not know if tested</td>
<td>78   30 (38.5%)</td>
<td>93 79 (84.9%)</td>
<td>46.5% (33.5% to 59.5%)</td>
<td>&lt;0.001</td>
<td>0.057</td>
</tr>
</tbody>
</table>

Notes: *-Estimates are marginal effects from a modified Poisson regression of outcome on study group for the subsample described.

**P-value from interaction coefficient between subsample and first category (yes ever tested or yes tested in past 12 months)
Conclusions

• Secondary distribution of HIV self-tests by women is promising strategy for promoting male partner testing compared to the current practice of partner invitation to clinic-based testing
  
  • Facilities can utilize this approach given that women access health services more than their partners
  
  • The approach is potentially cheaper than facility-based or home-based partner and couple testing

• The strategy has potential for facilitating safer sexual decision-making and reducing HIV incidence among high-risk individuals hence needs further testing
Ongoing/Upcoming studies
Cluster randomized trial among FSW and women in fishing communities in Kenya (starts in May 2017)

- Condomless sex can be more lucrative for FSW and women in fishing communities who engage in transactional sex, resulting in greater risk-taking for financial reasons (Jakubowski et al JAIDS 2016)

- Given the high HIV incidence among women in Nyanza region, self-tests may be useful for facilitating safer sexual-decision making

- Cluster randomized trial planned for 2017 to test this hypothesis (R01MH111602)
  - Study population will include FSW and women in fishing communities
  - Multiple self-test kits to women in intervention clusters over a period of 18 months
  - Proposed activities include cost-effectiveness modeling
Other studies testing the secondary distribution strategy

- Two other studies have explored the feasibility and impact of secondary distribution of HIVST to promote partner testing:
  - Factors Associated with Acceptability of HIV Self-Testing Among Health Care Workers in Kenya (Kalibala et al, *AIDS Beh.*)
  - Provision of Oral HIV Self-test Kits Triples Uptake of HIV Testing among Male Partners of Antenatal Care Clients: Results of a Randomized Trial in Kenya (Gichangi et al, JHPIEGO and Medical University of South Carolina)

- A randomized controlled study to determine the impact of HIVST on uptake of HIV testing by partners of adolescent girls age 15-19 years living in Siaya County, Nyanza region
  - Feasibility phase completed; funds being sought for the main study (RCT)
  - Partially funded by the University of North Carolina at Chapel Hill & implemented by Impact Research and Development Organization (IRDO)

- DREAMS Innovation Challenge and other NIH-funded studies led by the University of Washington
  - In 8 public sector MCH and FP clinics, all women will be offered multiple self-tests – partner self-testing will be used to refine identification of women at high risk for HIV that could benefit from PrEP counseling in addition to standard of care PrEP delivery
    - Similar approach to be tested in Uganda
Other HIVST studies in Kenya

• GIRLS study – different testing modalities (HIVST, community-based testing, home-based testing) and linkage strategies (SMS vs incentive) will be tested among AGYW age 15-24 years in Homabay County
  • To start in April, 2017
  • Funded by NIH, through Yale University (implemented by University of Nairobi and IRDO)

• KPIS Study – implementation science study to assess the impact of HIVST on enrollment of FSWs to drop-in centers (Kisumu, Siaya, Homabay, Migori, Kisii, Nairobi, Mombasa, Kilifi and Kwale counties)
  • Ongoing, to be completed in September 2017.
  • Funded by PEPFAR, through CDC (Implemented by CDC, USAID, NASCOP, IRDO, University of Nairobi, IMC and ICRH)
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