Seek, Test, Treat and Retain (STTR) for People Who Inject Drugs (PWID) in Kenya: Findings from the TLC-IDU stepped wedge study

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TLC-IDU Study

Kenya

test and link to care
Background

- HIV infections in sub-Saharan Africa increasingly occur among people who inject drugs (PWID)

- Needle & syringe programs (NSP) and PWID-specific ART support have been nearly non-existent

- Kenya is among the first to implement gov’t-run NSP at a country-wide level starting in 2013
Study Sites: Nairobi & Coastal Region

- **Seek**
  - Respondent-Driven Sampling (RDS) to find PWID

- **Test**
  - Offer rapid HIV test at NSP service sites (N=10)

- **Treat**
  - Offer point of care (POC) CD4 assay if HIV+

- **Retain**
  - If HIV+ and CD4+ cell count <350/mm³ provide peer case manager (PCM) for linkage to care
    - Conditional cash transfer to participant & PCM
Study Aims

- **Aim 1:** Launch and evaluate TLC-IDU using a stepped wedge cluster randomized design

- **Aim 2:** Conduct mathematical modeling to estimate community viral load in PWID injecting and sexual networks and potential population-level impact

- **Aim 3:** Assess incremental cost-effectiveness ratio of TLC-IDU, compared with standard care
Goals

- Evaluate Gov’t of Kenya NSP intervention using time-series analysis (Number of needles, HIV incidence, and community viral load).

- Evaluate linkage to care study components using original stepped-wedge design (randomized intervention roll-out sites and control sites: testing and data capture over time).
Study Design

- Ten sites, respondent-driven sampling, stepped wedge, repeated surveys, HIV testing, viral load
Study Flow

10 Study Sites

PWID informed of study via staff, RDS, or service site personnel

Informed Consent

Behavioral Survey on Computer Tablets

Rapid HIV Testing

HIV-

HIV+

GoK standard of care, refer for services including addiction treatment as needed

Point of Care CD4 Test

CD4 ≥ 350

CD4 < 350

Peer Case Management

Viral Load testing

Inclusion Criteria:
- ≥ 18 years
- Live in Nairobi or Coast
- Ever injected any non-prescribed drugs
- Any non-prescribed drugs last 12 months

Pre-Intervention Phase

Intervention Phase
Biometrics & Data Management

Eliminates double enrollment in time wave

Tracks mobility, repeat services over time, incidence
Key Outcomes

- Link to successful linkage to care
  - # days between first test positive and first visit with HIV provider

- Time to ART initiation
  - # days between first test positive and ART initiation

- ‘Community Viral Load’
  - Specimens at each site/waves over time from all PWID who tests HIV+, to document changes in infectivity (median viral load)
  - Using Dried Blood Spot (DBS) for VLs
    - We started collecting specimens for phylogenetic analysis
Study Intervention Components

- **NSP program (by KANCO, Global Fund, MDM):**
  - Sterile syringes; supplies for safer injection; peer educators to demonstrate safer injection; risk reduction and safer sex counseling; condoms; referrals for addiction tx/OST; prioritized ART (tx slots) for CD4+ cell count <350/mm3

- **Study-specific elements:**
  - Point of care CD4 testing to determine who needs ART
  - Peer case managers to support HIV care access and ART initiation among PWIDs testing positive and clinically eligible
  - Conditional cash transfers to HIV+ eligible patients and peer case managers for successful linkage to care/ART initiation
NSP Start Date at Study Sites

- **Nairobi Region**
  - Nairobi 1: NOSET – Ngara: April 2013
  - Nairobi 2: NOSET – Racecourse/Kawangware: May 2013
  - Nairobi 3: MDM – Kangemi: June 2013
  - Nairobi 4: SAPTA – Pangani: June 2013

- **Coastal Region**
  - Coast 1: Bomu Likoni: No NSP
  - Coast 2: Omari Project – Malindi: December 2012
  - Coast 3: MEWA – Kilifi: March 2013
  - Coast 4: Reachout – Oldtown Mombasa: November 2012
  - Coast 5: Bomu Hospital – Changamwe: No NSP
  - Coast 6: Teens Watch – Ukunda: November 2012
# Recruitment and Demographics

<table>
<thead>
<tr>
<th></th>
<th>Period One</th>
<th>Period Two</th>
<th>Period Three*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened</td>
<td>1947</td>
<td>1739</td>
<td>1048</td>
</tr>
<tr>
<td>Enrolled</td>
<td>1785</td>
<td>1489</td>
<td>984</td>
</tr>
<tr>
<td>Median Age</td>
<td>30</td>
<td>31</td>
<td>32</td>
</tr>
<tr>
<td>% Male</td>
<td>86.8</td>
<td>87.9</td>
<td>91.0</td>
</tr>
<tr>
<td>% Married/Living as Married</td>
<td>14.2</td>
<td>14.8</td>
<td>14.9</td>
</tr>
<tr>
<td>% Nairobi</td>
<td>37.1</td>
<td>41.4</td>
<td>41.3</td>
</tr>
<tr>
<td>% Coast</td>
<td>62.9</td>
<td>58.6</td>
<td>58.7</td>
</tr>
<tr>
<td>% Homeless</td>
<td>20.1</td>
<td>25.3</td>
<td>22.4</td>
</tr>
<tr>
<td>% Participated Before</td>
<td>--</td>
<td>34.5</td>
<td>61.1</td>
</tr>
</tbody>
</table>

* Survey Period Three is in progress.
Years Injecting

![Bar charts showing the distribution of years injecting for three periods: Period One, Period Two, and Period Three. The x-axis represents years injecting, and the y-axis represents the number of people. Each period shows a different distribution pattern.]

NYU NURSING

GLOBAL
Times Injecting on an Average Injecting Day

- Period One
- Period Two
- Period Three

Number of People

Site

1, 2, 3, 4+
## Injection Equipment Sharing

<table>
<thead>
<tr>
<th></th>
<th>Period One: (May–Dec 2012) NSP Start: Nov - Dec 2012 (Sites C7, C8, C9)</th>
<th>Period Two: (April-Nov 2013) NSP Start: April – June 2013 (Sites N1, N2, N3, N4, C6)</th>
<th>Period Three (In progress. Started Feb 2014) NSP started at 8 sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Receptive sharing of</td>
<td>10.6</td>
<td>4.0</td>
<td>2.4</td>
</tr>
<tr>
<td>the most recent needle/syringe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Receptive sharing of</td>
<td>39.0</td>
<td>13.2</td>
<td>6.9</td>
</tr>
<tr>
<td>cooker, cotton, or water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>at last injection</td>
<td>31.7</td>
<td>31.4</td>
<td>23.0</td>
</tr>
<tr>
<td>% Ever frontload/backload</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Ever flashblood</td>
<td>2.8</td>
<td>3.3</td>
<td>1.5</td>
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</table>
Taking HIV Medication

Number of People

Period One
Period Two
Period Three

Taking HIV Medication
- No
- Yes
Viral Load among Participants with HIV Infection
CD4 Levels

Period 2

Period 3

CD4 cells/µL

Nairobi-2 May 2013
Nairobi-4 Jun 2013
Coast-1 No NSP
Coast-5 No NSP
Nairobi-2 May 2013
Nairobi-4 Jun 2013
Coast-1 No NSP
Coast-5 No NSP
Accessed NSP in the Last 12 Months

Period Two

Period Three

Number of People

NSP Accessed
No
Yes

Nairobi-1
Nairobi-2
Nairobi-3
Nairobi-4
Coast-1
Coast-2
Coast-3
Coast-4
Coast-5
Coast-6

Nairobi-1
Nairobi-2
Nairobi-3
Nairobi-4
Coast-1
Coast-2
Coast-3
Coast-4
Coast-5
Coast-6
Services Received at NSP

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<thead>
<tr>
<th>Service</th>
<th>Period Two</th>
<th>Period Three</th>
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<tr>
<td>Syringes</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Needles</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Cotton</td>
<td>500</td>
<td>600</td>
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<tr>
<td>Water/Solution</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Alcohol swabs</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Filters</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Tourniquets</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Condoms</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Opioid Substitution Therapy</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Referrals to counseling</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Referrals to health care</td>
<td>500</td>
<td>600</td>
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<tr>
<td>Other service</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Voluntary Counseling and Testing</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Waters/Isolation</td>
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<td>600</td>
</tr>
<tr>
<td>Alcohol swabs</td>
<td>500</td>
<td>600</td>
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<tr>
<td>Filters</td>
<td>500</td>
<td>600</td>
</tr>
<tr>
<td>Tourniquets</td>
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<tr>
<td>Condoms</td>
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<td>600</td>
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<tr>
<td>Other service</td>
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Number Needles Received Last Visit

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<thead>
<tr>
<th>Period</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
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<tr>
<td>Two</td>
<td>526</td>
<td>6.55</td>
<td>4.18</td>
<td>6</td>
<td>0</td>
<td>30</td>
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<tr>
<td>Three</td>
<td>645</td>
<td>7.20</td>
<td>4.04</td>
<td>6</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>Period</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
<td>Min</td>
<td>Max</td>
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<td>------</td>
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<tr>
<td>Two</td>
<td>526</td>
<td>4.33</td>
<td>3.73</td>
<td>4</td>
<td>0</td>
<td>30</td>
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<tr>
<td>Three</td>
<td>645</td>
<td>4.82</td>
<td>4.10</td>
<td>5</td>
<td>0</td>
<td>40</td>
</tr>
<tr>
<td>Period</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
<td>Min</td>
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<td>------</td>
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<tr>
<td>Two</td>
<td>526</td>
<td>62</td>
<td>68</td>
<td>40</td>
<td>0</td>
<td>300</td>
</tr>
<tr>
<td>Three</td>
<td>669</td>
<td>84</td>
<td>63</td>
<td>72</td>
<td>0</td>
<td>420</td>
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</tbody>
</table>
Clinically Eligible Participants Retained in Care

Number of Participant Eligible for ART (N= 42)

124 HIV+ participants were assessed for eligibility. Only 42 were clinically eligible for ART.

- Initiated ART, N = 40
- N = 2
- N = 6
- N = 2
- N = 2
- Declined Services
- Retained in care
- Stopped ART
- Died
- In jail

All eligible participants were linked to ART within 24 hours after testing. Initiation of ARVs took a maximum of 2 weeks.
PWID readily able to recruit each other

Long recruitment chains

Fast convergence to sample equilibrium for HIV prevalence estimate

Discordant HIV status among PWID with social connections
- Recruiter positive and recruit negative
- Recruiter negative and recruit positive
Conclusion

• Combination of RDS and rapid testing effective strategy for finding PWID with HIV infection, including those not previously diagnosed
• Some way to go to get to suppression
• Linkage to care by Peer Case Managers can be effective for ART initiation
• Use of PCM to link clinically eligible PWID to ART helpful
• Relationships built among the PCMs, HIV-positive PWID, and HIV clinic staff have made linking to care easier and seems to have reduced some discrimination towards PWID
Team Members

- **NASCOP/MOH KENYA**
  - Peter Cherutich (co-PI)
  - Mercy Nyakowa, Eva Muluve, Paul Macharia, Daniel Fedha
  - Research Assistants (RAs)
  - Helgar Musyoki
  - Martin Sirengo

- **Expert Advisors, CAB**
  - Claris Obiero, Elizabeth Ngugi, Fred Owiti
  - Don Des Jarlais, Steffanie Strathdee

- **NYU**
  - Ann Kurth (co-PI)
  - Chuck Cleland
  - Scott Braithwaite
  - John Lizcano

- **Population Council**
  - Jerry Okal, Scott Geibel

- **NSP Implementers (NGOs)**

- **Thanks to NIH – NIDA**
  - 1R01 DA032080
    - Redonna Chandler
    - Shoshana Kahana
    - Dionne Jones
Implementers & Staff
PCMs, RA & Participants

All photos have consent