COMBINED INTERVENTION STRATEGIES (CIS)

Evidence-Based for Linkage to Care and Retention in Care

Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Goal of Intervention

- Increase linkage to care
- Increase retention in care

Target Population

- Adults clinic patients newly diagnosed with HIV in Mozambique

Brief Description

Combination Intervention Strategy (CIS) is a multi-level intervention intended to target prevalent health system, structural, and behavioral barriers patients face across the HIV care continuum. CIS includes a combination of three evidence-based strategies that simplify the clinic flow and encourage linkage to and retention in care. The first strategy includes equipping voluntary counseling and testing (VCT) clinics with CD4 assay machines that provide CD4 test results immediately following diagnosis. All patients are given a paper-based referral to on-site HIV services. Patients receive their CD4 count and instructions to present for their first clinical consultation within 1 week. Second, patients with CD4 cell count ≤ 350 cells/mm3 are provided with accelerated ART initiation. Patients receive a same-day individual ART preparatory counseling session in the VCT clinic, expedited appointments, ART initiation at the first clinical visit, a 2-week ART supply, and counseling to follow the recommended visit schedule. Third, participants receive health messages and appointment reminders via short message service (SMS). These messages address behavioral barriers associated with deferring care engagement and forgetting appointments. The health messages are sent weekly for 1 month following diagnosis and then monthly thereafter. Appointment reminders are sent 3–7 days before each scheduled clinic visit.

Theoretical Basis

None Reported

Intervention Duration

- One year

Deliverer

- Health facility staff
- Study staff

Intervention Setting

- Primary health facilities providing HIV testing, care, and treatment services

Delivery Methods

- Appointments
- Counseling
- Point-of-care CD4 test
- Referrals
- Reminders
- Text messages
- Two week supply of ART

Structural Components

- Access
  - Enabled HIV testing counselors to provide real-time, point-of-care CD4 cell test results immediately following diagnosis
  - Provided same-day ART initiation and 2-week supply of ART to patients with CD4 cell count ≤ 350 cells/mm^3 to facilitate accelerated initiation of ART
  - Provided prepaid cellular air-time cards to offset structural barriers associated with direct and indirect costs of coming to the health facility to receive HIV care
- Capacity-Building—Technology
  - Added Pima CD4 assay machines in HIV clinics to enable HIV testing counselors to provide real-time, point-of-care CD4 cell test results immediately following diagnosis
- Policy/Procedure—Institutional policy/procedure
  - Revised clinic procedures to provide CD4 test results immediately after diagnosis, accelerate ART initiation for patients with CD4 cell count ≤ 350 cells/mm^3
- Physical Structure – Integration of Services
  - Point-of-care CD4 testing was in the same physical location as the HIV testing site

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. For intervention materials, please contact **Batya Elul**, Columbia University, Mailman School of Public Health, 722 W. 168th Street, Room 528, New York, NY, 10032.

Email: **be2124@columbia.edu** for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location

This study was conducted in Maputo and Inhambane Province, Mozambique between April 2013 and June 2015.

Key Intervention Effects

- Increased linkage to care
- Increased retention in care

Recruitment Settings

Primary health facilities

Eligibility Criteria
Clinic patients at primary health facilities were eligible if they were aged 18 years or older, newly diagnosed with HIV, spoke Portuguese or Xitsua, able to provide informed consent, and were not enrolled in HIV care or initiated ART in the past 6 months.

Study Sample
The baseline study sample of 2,004 adults is characterized by the following:
- *64% female, 36% male*
- *Median age of 34 years*
- *54% lived in the Maputo region, 46% lived in the Inhambane region*

Assignment Method
The unit of randomization in this study were the primary health facilities operated by the Ministry of Health providing HIV testing, care, and treatment services. Ten facilities were randomized into either the CIS arm (5 study units; n = 744) or the SOC arm (5 study units; n = 767) using matched pair randomization.

Comparison
Standard of care (SOC). Newly diagnosed HIV patients received post-HIV test counseling in the VCT clinic and were verbally referred to HIV services at the diagnosing facility. Comparison participants were also referred to the laboratory for CD4 cell count, chemistry, and hematology testing. Participants who were eligible for ART (based on CD4 cell count ≤ 350 cells/mm^3 and/or WHO stage 3/4) received at least 1 individual counseling session before starting treatment, and were requested to return to the healthy facility every 2 weeks for the first month, at 2 months, at 6 months, and every 6 months thereafter. ART-ineligible participants were instructed to return at 6 months for repeat clinical evaluation and laboratory testing.

Relevant Outcomes Measured
- The primary outcome was a combined outcome of linkage to HIV care within 1 month of diagnosis and being retained in care 12 months after diagnosis.
  - Linkage to care was defined as at least 1 clinical consultation for HIV that included an assessment of the patient's medical history and a physical exam.
  - Retention in care was defined as a clinic visit in the 90 days prior to the end of the 12-month study follow-up period, with no documentation that the patient had transferred to another facility or had died.

Participation Retention
Because participation retention is not a criterion for evaluating linkage, retention or re-engagement studies, PRS does not evaluate this information.

Significant Findings on Relevant Outcomes
- A significantly greater percentage of intervention participants than comparison participants were linked to care at their diagnosing facility within 1 month of diagnosis and were retained in care 12 months after diagnosis (57% vs. 35%; RR = 1.58, 95% CI =1.05 – 2.39, p = 0.03; adjusted RR (for patient-level differences) = 1.55, 95% CI =1.07 – 2.25, p = 0.04).
- A significantly greater percentage of intervention participants than comparison participants were linked to care at any facility within 1 month of diagnosis and retained in care 12 months after diagnosis (74% vs. 47%; RR = 1.47, 95% CI = 1.08 – 2.01, p = 0.02; adjusted RR (for patient-level differences) = 1.46, 95% CI =1.05 – 2.04, p = 0.03).

- A significantly greater percentage of intervention participants than comparison participants were linked to care on the same day as HIV diagnosis at the diagnosing facility (89% vs. 16%; RR = 9.13, 95% CI=1.65 – 50.40, p = 0.02).
- A significantly greater percentage of intervention participants than comparison participants were retained 12 months after HIV diagnosis at the diagnosing facility (58% vs. 44%; RR = 1.32, 95% CI=1.12 – 1.54, p = 0.004).

Strengths
None reported

Considerations
Additional significant positive findings on non-relevant outcomes
- A significantly greater percentage of intervention participants than comparison participants were linked to care at the diagnosing facility within 12 months after diagnosis (p = 0.03), but this outcome is not relevant for the PRS Project because linkage to care must occur within 6 months.

Non-significant findings on relevant outcomes
- There were no significant intervention effects for linkage to care within 1 week (p = 0.14) and within 1 month (p = 0.09).
- There were no significant intervention effects for retention in care at 6 months (p = 0.09).

Other related findings
- The study also compared CIS with CIS with financial incentives (CIS+) in a comparative effectiveness analysis nested within the CIS arm. CIS+ participants were enrolled after CIS enrollment was completed at each facility randomized to the intervention arm. There was no additional benefit of adding financial incentives to the CIS intervention.
- This intervention is also determined to be evidence-based for the Structural Interventions chapter.

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