SLATE (SIMPLIFIED ALGORITHM FOR TREATMENT ELIGIBILITY)

Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Goal of Intervention
- Increase and accelerate same-day initiation of antiretroviral therapy (ART) for adult HIV clinic patients

Target Population
- Adult HIV clinic patients in Johannesburg, South Africa and western Kenya

Brief Description

The *SLATE (Simplified Algorithm for Treatment Eligibility)* study utilizes a simple clinical algorithm to guide nurses and other clinical staff in determining eligibility for same-day ART initiation for adult HIV clinic patients without requiring laboratory results prior to initiation. The algorithm includes four screening tools—1) symptom self-report, 2) medical history questionnaire, 3) physical examination, and 4) readiness assessment—to determine eligibility for same-day initiation and potential clinical, historical, or personal reasons for referral to additional care or services prior to initiating ART. Patients who are "screened in" by the algorithm (i.e., the algorithm did not report or demonstrate any reason to delay ART initiation) receive an initial supply of medication and assistance with scheduling their next clinic appointment. Patients who are "screened out" by the algorithm (i.e., the patient did not meet same-day initiation criteria on one or more of the four screens) are referred to the clinic for further investigation or care. Following the initial study enrollment visit, all patients received follow-up care under routine procedures. The algorithm does not require technology or infrastructure beyond what is available in public sector clinics.

Theoretical Basis
- None reported

Intervention Duration
- One clinic visit

Intervention Setting(s)
- Three public-sector primary care clinics in Johannesburg, South Africa
- Three public-sector outpatient clinics in western Kenya

Deliverer
- Nurses (South Africa)
- Clinical officers (Kenya)

Delivery Methods
- Clinical algorithm

Structural Component

- Access
  - Provided same-day ART initiation
- Policy – Institutional policy/procedure
  - Implemented clinical algorithm to determine eligibility for same-day ART initiation without requiring laboratory tests results

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Sydney Rosen,** Department of Global Health, Boston University School of Public Health, Boston, MA.

Email: **sbrosen@bu.edu** for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in Johannesburg, South Africa & western Kenya between March 2017 and April 2018.

Key Intervention Effects

- Increased uptake of ART within 28 days

Recruitment Settings

Public-sector primary care clinics in Johannesburg, South Africa and public-sector hospital-based outpatient clinics in western Kenya

Eligibility Criteria

HIV clinic patients were eligible if they were adult (≥ 18 years), not pregnant, and either not yet on ART or re-starting after interruption of ART. Pregnant women were ineligible because standard-of-care prevention of mother-to-child transmission (PMTCT) was provided by the antenatal clinic, and not by the general ART clinic.

Study Sample

The analytic study sample of 1077 HIV clinic patients is characterized by the following:

South Africa (n = 600):

- *63% female, 37% male*
- *Median age of 34 years*
- *Median CD4 count: 286*

Kenya (n = 477):

- *58% female, 42% male*
- *Median age of 35 years*
- *Median CD4 count: 283*

Assignment Method

South Africa:

Clinic patients were randomized to 1 of 2 study arms: SLATE intervention (n = 298) or a standard-of-care comparison (n = 302).

- Two SLATE intervention participants did not complete study steps and were withdrawn after randomization.

Kenya:

Clinic patients (N = 477) were randomized to 1 of 2 study arms: SLATE intervention (n = 240) or a standard-of-care comparison (n = 237).

Comparison

The standard-of-care comparison followed standard-of-care procedures for ART initiation, which generally followed national guidelines at the time of the study in each country.

South Africa: Guidelines recommended most patients initiate ART within two weeks of a CD4 count and as soon as patients expressed readiness, and within one week for those presenting very ill.

Kenya: Guidelines recommended all patients initiate ART within two weeks of HIV care enrollment but allowed same-day initiation for those perceived to have "strong motivation." During study enrollment, the standard-of-care ART initiation process required an HIV test, a complete medical and psychosocial history, a thorough physical exam, HIV-specific and nonspecific laboratory investigations, screening for TB, and a variety of other assessments and counseling activities addressing reproductive health, noncommunicable diseases, mental health, nutrition, alcohol and substance abuse, and education on HIV and its treatment.

Relevant Outcomes Measured

- ART uptake was defined as ART initiation ≤ 28 days of study enrollment
  - Time to ART uptake was also measured for initiating ART within 0 (same-day), 7, 14, and 90 days
- Viral suppression was defined as an undetectable viral load (<400 copies/mL) within 8 months of study enrollment
- Retention in care was defined as initiating care within 28 days of study enrollment and having a clinic visit or viral load test between 5 to 8 months after study enrollment.

Participant Retention

Because participant retention is not a criterion for the Structural Interventions chapter, the Prevention Research Synthesis project does not evaluate that information.

Significant Findings on Relevant Outcomes

- South Africa:
  - A significantly greater percentage of intervention participants initiated ART within 28 days than comparison participants (78% vs 68%), (RR = 1.15, 95% CI: 1.04-1.27).
  - A significantly greater percentage of intervention participants than comparison participants initiated ART within the following days
    - 0 days (same day): 54% vs 11% (RR = 4.94, 95% CI: 3.52-6.94)
    - 7 days: 65% vs 38% (RR = 1.72, 95% CI: 1.45-2.03)
    - 14 days: 69% vs 56% (RR = 1.23, 95% CI: 1.09-1.40)
    - 90 days: 86% vs 79% ((RR = 1.09, 95% CI: 1.01-1.17)
- Kenya:
  - A significantly greater percentage of intervention participants initiated ART within 28 days than comparison participants (94% vs 89%) (RR = 1.06, 95% CI: 1.01-1.12).

- A significantly greater percentage of intervention participants than comparison participants initiated ART within the following days
  - 0 days (same day): 70% vs 54% (RR = 1.30, 95% CI: 1.12-1.50)
  - 7 days: 86% vs 73% (RR = 1.18, 95% CI: 1.08-1.30)
  - 14 days: 90% vs 85% (RR = 1.07, 95% CI: 1.00-1.14)

Considerations

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

- There were no significant intervention effects on viral suppression or retention in care.
- There was no significant intervention effect on ART uptake at 90 days among participants in Kenya.

Other related findings

- In both study countries, most intervention benefits occurred at facilities that were least efficient to start with, and thus had more room for improvement. For example, in South Africa, the largest improvement in ART initiation occurred at Site 3, which appeared to be the least efficient of the three sites. It experienced frequent staff turnover and absences, poor procedures for filing records and tracing patients, and long queues and waiting times.
- In an analysis of absolute effect modification, site was found to be the most important effect modifier in both countries. For example, in Kenya, most of the difference in ART initiation was due to Site 1. Additional modifiers of the effect include the sex of study participants in both countries, and age and reason for clinic visit in South Africa.
- In both study countries, patients ineligible for same-day initiation according to the SLATE algorithm were screened out for multiple reasons.
  - In South Africa, 50% (n = 149) of the 298 intervention participants were screened out, with the most common reasons being report of one or more tuberculosis symptoms (73%, n = 109), persistent headache (11%, n = 17), or previously discontinued ART (9%, n = 14).
  - In Kenya, 45% (n = 131) of the 240 intervention participants were screened out, with the most common reasons being report of one or more tuberculosis symptoms (85%, n = 93), persistent headache (28%, n = 31), previously discontinued ART (17%, n = 18), or having substance abuse issues (11%, n = 12).
  - Tuberculosis symptoms were the most common reason for not being eligible for same-day initiation under the SLATE algorithm.

Implementation-research related findings

- Not considered an implementation-research study.

Process/Study execution-related findings

- The intervention arm of the study was implemented by trained study staff who achieved near perfect fidelity to intervention procedures; such consistent implementation in routine care settings may not be expected, and the effect reported may not reflect what would be seen in practice.

Adverse events

- None reported

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