SLATE II (Simplified Algorithm for Treatment Eligibility)

Evidence-Based Structural Intervention
Evidence-Based for Engagement in HIV Care
Evidence-Based for Viral Suppression

INTERVENTION DESCRIPTION

Intended Population
- People with HIV (PWH) who are presenting for antiretroviral therapy (ART) initiation including those who are re-initiating treatment with mild TB symptoms

Goals of Intervention
- Improve ART initiation and retention

Brief Description

SLATE II (Simplified Algorithm for Treatment Eligibility) is a revised algorithm of SLATE I, an evidence-based intervention, that focuses on a simple, accelerated algorithm for ART initiation that requires no point-of-care laboratory testing and may be administered entirely by primary care clinicians, including nurses with prescribing authority. The SLATE I algorithm consists of four screening tools: (1) symptom report, (2) medical history, (3) brief physical examination, and (4) patient readiness assessment, each as an evaluation area for eligibility requirements for same-day ART initiation. SLATE II uses the 4 screening tools and allows same-day ART initiation for patients with mild tuberculosis (TB) symptoms and other less serious reasons for delay. Participants determined to be eligible based on all four screening tools were offered ART initiation on the same day as study enrollment. Participants found to be ineligible on any of the screening tools were referred to routine care at the study site clinic for further management.

Theoretical Basis
- None reported

Intervention Duration
- Ongoing

Intervention Settings
- High volume, public-sector primary health care clinics in South Africa

Deliverers
- Primary care clinicians, primarily nurse practitioners able to dispense ART

Delivery Methods
- Interviewing
- Mobile tablet
- Physical examination

Structural Components
- Access— HIV health care
  - Increased access to HIV testing and referral to HIV medical care
- Capacity building— Provider/supervisor training
  - Trained staff on interviewing and data capture of eligible participants and on use of SLATE II algorithm

- Physical Structure – Integration of services
  - Integration of services for TB treatment
- Policy/Procedure—Institutional policy/procedure
  - Implemented same-day ART initiation for eligible patients who tested HIV positive

INTERVENTION PACKAGE INFORMATION

Contact study author for training and intervention materials. Please contact **Mhairi Maskew**, Health Economics and Epidemiology Research Office, University of the Witwatersrand School of Clinical Medicine, 1 Jan Smuts Avenue, Braamfontein, Johannesburg, 2000, South Africa.

Email: mmaskew@heroza.org for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location

The original evaluation study was conducted in Johannesburg, South Africa between March 2018 through September 2018.

Key Intervention Effects

- Increased ART initiation
- Increased engagement in HIV care
- Increased viral suppression

Recruitment Settings

- High volume, public sector, primary care clinics (n=3) based in both urban formal and informal settings

Study Sample

The baseline sample (N = 593) is characterized by the following:

Intervention arm (n = 296)

- 64% female persons, 36% male persons
- Median age of 35 years
- 90% living in peri-urban areas, 10% living in urban areas
- 58% single persons, 32% married persons or persons living with long-term partner, 10% divorced/ separated/widowed persons
- 47% persons presented with TB symptoms
- Median CD4 count of 298 cells/mm^{3}25th-75th percentile: 137-483 cells/mm^3

Standard arm (n = 297)

- 62% female persons, 38% male persons
- Median age of 35 years
- 90% living in peri-urban areas, 10% living in urban areas
- 53% single persons, 36% married persons or persons living with long-term partner, 11% divorced/ separated/widowed persons
- 52% persons presented with TB symptoms
- Median CD4 count of 293cells/mm^3, 25th - 75th percentile: 127-514 cells/mm^3

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

Eligibility Criteria
Adults over the age of 18 years, who were not pregnant, confirmed HIV-positive test result, not currently on ART nor prescribed ART in the past 3 months, and presented at the study clinic for any reason that led to referral for HIV testing or care.

Assignment Method
This study used an individually randomized, non-blinded, parallel-group design. Participants were randomized 1:1 to the intervention and standard (comparison) arm.

Comparison
Participants in the standard group received usual care per national guidelines for ART initiation, which could include same day initiation.

Relevant Outcomes Measured
- Engagement in HIV care was measured as having initiated ART within 28 days of study enrolment and an observed clinic visit in either the participant's paper record or the site's electronic patient register between 5 and 8 months after study enrollment. The PRS Project considers the outcome of ART initiation within 1 month and retention on ART 8 months after study enrollment as engagement in HIV care (i.e., 1 visit in a time period).
- Viral suppression was measured as having a viral load < 400 copies/mL.

Participant Retention
Participant retention was not reported. Participant retention is not a criterion for the Structural Intervention (SI) chapter. The PRS Project does not evaluate this information.

Significant Findings on Relevant Outcomes
- A greater percentage of intervention arm participants-initiated ART ≤ 28 days and engaged in care at 8 months after study enrollment compared to standard arm participants. (74% v. 59%, respectively; Crude Relative Risk [CRR] = 1.26, 95% Confidence Interval [CI]: 1.12–1.42).
- A greater percentage of intervention arm participants-initiated ART and were known to be virally suppressed ≤ 8 months after study enrollment compared to standard arm participants (44% vs. 32%, respectively; CRR = 1.39, 95% CI: 1.12–1.71).
- A greater percentage of intervention arm participants-initiated ART after study enrollment compared to standard arm participants, respectively, within:
    - the same day (87% vs. 38%; CRR = 2.26, 95% CI: 1.95 – 2.63)
    - 7 days (91 % vs 68 %; CRR = 1.34, 95% CI: 1.23 – 1.46)
    - 14 days (93% vs. 77%; CRR = 1.21, 95% CI: 1.12 – 1.29)
    - 28 days (94% vs. 82%: CRR = 1.14, 95% CI: 1.08 – 1.22)

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

Non-significant findings on relevant outcomes
- None reported

Negative findings
- None reported

Other related findings
- None reported

Implementation research-related findings
- None reported

Process/study execution findings
- None reported

Adverse events
- Six patients who initiated ART within ≤28 days of study enrollment were known to have died during study follow-up. One additional standard arm patient died without having initiated ART. Investigators concluded that none of these deaths were related to study procedures.
- One intervention arm patient who was eligible for same-day initiation and did start ART on the same day was found to have an elevated serum creatinine.
- Only about 1 out of 10 patients had serious TB symptoms or other reasons for not starting ART that day. None of the patients who had mild TB symptoms and started ART on the same day reported any serious TB-related illness after ART initiation.

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REFERENCES AND CONTACT INFORMATION

Maskew, M., Brennan, A. T., Fox, M. P., Vezi, L., Venter, W. D., Ehrenkranz, P., & Rosen, S. (2020). A clinical algorithm for same-day HIV treatment initiation in settings with high TB symptom prevalence in South Africa: The SLATE II individually randomized clinical trial. *PLoS Medicine*, *17*(8), e1003226. doi: 10.1371/journal.pmed.1003226

Rosen, S., Maskew, M., Larson, B. A., Brennan, A. T., Tsikhutsu, I., Fox, M. P., Vezi, L., Bii, M., & Venter, W. D. (2019). Simplified clinical algorithm for identifying patients eligible for same-day HIV treatment initiation (SLATE): Results from an individually randomized trial in South Africa and Kenya. *PLoS Medicine*, *16*(9), e1002912. doi: 10.1371/journal.pmed.1002912

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