A STRUCTURED ALGORITHM FOR SAME-DAY ART INITIATION: SLATE II TRIAL PRIMARY OUTCOMES

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BACKGROUND

In 2017 the WHO recommended same-day initiation (SDI) of antiretroviral therapy (ART) for patients considered eligible and ready. Many countries, including South Africa, encourage SDI, but evidence on how to implement SDI and its impact on outcomes remains scarce. Most research on SDI to date has either excluded patients with symptoms of illness, including TB, from the study or delayed initiation for these patients. Building on the Simplified Algorithm for Treatment Eligibility trial (SLATE I), in which nearly half of participants were ineligible for same day initiation due mainly to TB symptoms, we evaluated the revised SLATE II algorithm, which allowed SDI for patients with mild TB symptoms and other less serious reasons for delay.

METHODS

- **Design**: Individually randomized trial at 3 public sector clinics in South Africa. Adult, non-pregnant patients presenting for any HIV care, including an HIV test, but not yet on ART were randomized to the SLATE II algorithm or standard care. Follow up was by passive record review.
- **Intervention**: The SLATE II algorithm (Figure 1) used a symptom self-report, medical history questionnaire, brief physical examination, and readiness assessment to distinguish between patients eligible for immediate ARV dispensing after completing the algorithm and those who should have further care, tests, or counseling before starting treatment.
- **Intervention arm patients** eligible for SDI were dispensed ARVs; those requiring additional services were referred to standard care. **Standard arm patients** were referred for routine initiation after randomization.
- **Outcomes**: ART initiation ≤7 days of enrollment and time to initiation; ART initiation ≤28 days and retention on ART 8 months after study enrollment.
- **New in SLATE II**: SLATE II included a new TB module for distinguishing between mild and severe TB symptoms; patients with mild symptoms and a negative LAM test were eligible for SDI.

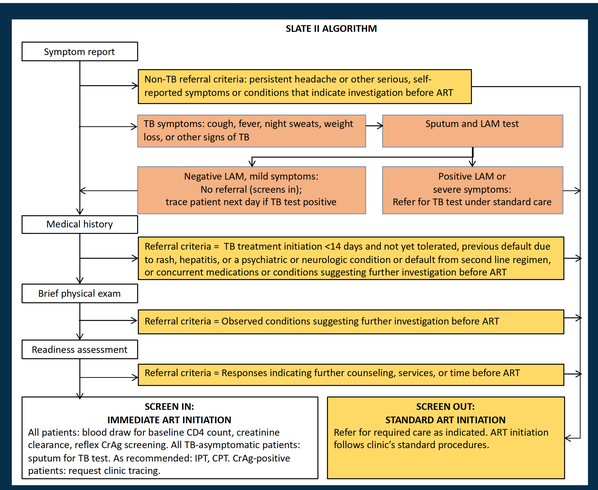

Figure 1. The SLATE II algorithm

The SLATE II same-day initiation algorithm **increased ART initiation** within 7 days from 68 to 91% and **increased retention in care** at 8 months from 59 to 74%. Nearly 9 out of 10 patients started ART on the same day.

Table 1. Outcomes

Outcome	Standard arm (n=297)	Intervention arm (n=296)	Crude risk difference (95%CI)	Crude relative risk (95% CI)
Time to ART initiation				
Initiated ≤ 7 days (primary outcome)	202 (68%)	270 (91%)	**23% (17 to 29%)**	**1.34 (1.23-1.46)**
Initiated in 0 days (same day)	114 (38%)	257 (87%)	49% (42 to 55%)	2.26 (1.95-2.63)
Initiated within 14 days	228 (77%)	274 (93%)	16% (10 to 21%)	1.21 (1.12-1.29)
Initiated within 28 days	243 (82%)	277 (94%)	12% (7 to 17%)	1.14 (1.08-1.22)
Retention in care				
Initiated ART ≤ 28 days and retained in care 8 months after study enrolment (primary outcome)	175 (59%)	220 (74%)	**15% (8 to 23%)**	**1.26 (1.12-1.42)**
Not retained after initiation – died	4 (2%)	2 (1%)	-1% (-2 to 1%)	0.50 (0.09-2.72)
Not retained after initiation – transferred	3 (1%)	5 (2%)	1% (-1 to 3%)	1.67 (0.40-6.93)
Not retained after initiation – confirmed or assumed LTFU	59 (20%)	50 (17%)	-3% (-10 to 3%)	0.85 (0.60-1.20)
Did not initiate ≤ 28 days	54 (18%)	19 (7%)	-11% (-17 to -7%)	0.35 (0.21-0.58)

RESULTS

Enrollment

- 593 patients were enrolled in the study from 3/14/18-9/17/18, with follow-up through 8/31/19.
- Arms were balanced on important demographic and clinical characteristics.

Primary outcome 1 (initiation ≤ 7 days of study enrollment) (Table 1)

- In the intervention arm, 86% of patients (255/296) were found to be eligible for same-day initiation under SLATE II.
- The other 14% in the intervention arm (41/296) met ≥1 algorithm criteria for referral for additional services before initiation (95% for TB symptoms).
- Same-day initiation was provided to 38% of standard arm patients and to 87% of intervention arm patients.
- ***Within 7 days, 91% of intervention arm patients and 68% of standard arm patients had initiated ART.***
- Within 28 days, 94% of intervention arm patients and 82% of standard arm patients had initiated ART.
- More than a third of patients (36%) had CD4 counts ≤200 cells/mm^3 at enrollment; of these, 83% of intervention arm patients and 62% of standard arm patients initiated ART ≤7 days.

Primary outcome 2 (initiated ≤ 28 days and retained by 8 months) (Table 1)

- ***By 8 months after enrollment (i.e., by the routine 6-month clinic visit), 74% of intervention arm patients and 59% of standard arm patients were retained in care.***
- For patients who did initiate ≤28 days, retention in care at 8 months was similar between study arms

CONCLUSIONS AND LIMITATIONS

- The SLATE II algorithm, comprising simplified steps for ART initiation, **increased uptake of ART within 28 days** by an absolute differences of 23% and **increased retention in care at 8 months** by an absolute difference of 15%.
- Retention after same-day initiation using the SLATE II protocol (20%) did not differ from retention after standard-of-care initiation (23%).
- NIMART nurses **were able to implement the algorithm in routine care settings** without additional equipment or clinical supervision.
- **Post-initiation attrition was very high in both arms** (>25%) at the time of the routine 6-month visit; more attention must be paid to early retention support.
- Limitations include small number of sites, high fidelity to the study protocol that may not be achieved in routine care, and missing viral load data for some patients.
- SLATE II demonstrates that a simple, structured algorithm for same-day initiation greatly increases initiation of ART without sacrificing retention in care, resulting in an overall improvement of treatment rates and outcomes.

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