Same-Day ART Initiation in the SLATE Trial in South Africa: Primary Outcomes

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Abstract LBPEE0049

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BACKGROUND

The World Health Organization recommends "same-day" initiation of ART for patients who are eligible and ready and "rapid" initiation (≤7 days) for all patients. Little is known, however, about how to determine if a patient is ready for same-day initiation, the minimum package of services required for initiation, or how to provide these services in a single clinic visit. Identifying efficient operational procedures for determining same- day eligibility is now a priority. The Simplified Algorithm for Treatment Eligibility (SLATE) trial is testing a clinical algorithm in South Africa and Kenya that allows nurses or clinical officers to determine eligibility for immediate ARV dispensing at the same clinic visit.

METHODS

- Design: SLATE was an individually randomized trial at three public outpatient clinics in Johannesburg, South Africa and three in western Kenya. Adult, non-pregnant patients presenting for any HIV care, including an HIV test, but not yet on ART were enrolled, consented, and randomized to the SLATE algorithm or standard care. Follow up was by passive record review. (Figure 1)
- Intervention: The SLATE algorithm (Figure 2) 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.
- Outcomes: We report two primary outcomes: 1. ART initiation ≤28 days of study enrollment; and 2. ART initiation ≤28 days and retention on ART 8 months after study enrollment for the South Africa cohort, where follow up to primary endpoints has been completed. (Completion of follow-up for the Kenya cohort anticipated early 2019.)

Figure 1. Study design

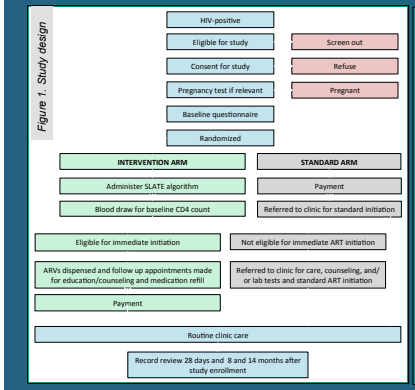
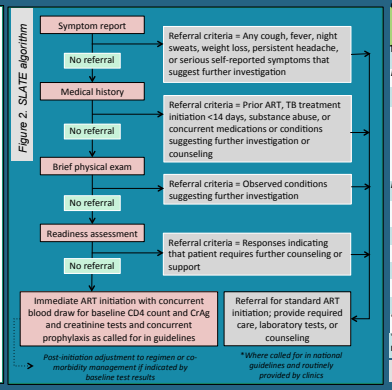


Figure 2. SLATE algorithm



RESULTS

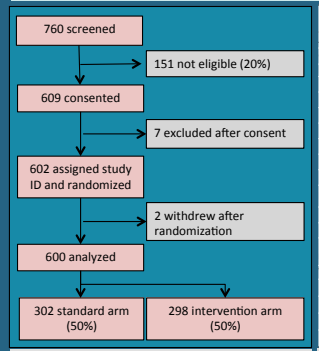


Figure 3. Study enrollment (South Africa)

Characteristic	Standard arm (N=302)	Intervention arm (N=298)
Age (median [IQR]	34 (28-40)	34 (29-41)
Gender (female)	190 (63%)	189 (63%)
Baseline CD4 count (cells/mm³)		
Median (IQR)	314 (156-520)	279 (127-464)
<100	30 (14%)	60 (21%)
100-200	43 (20%)	44 (15%)
201-350	45 (21%)	69 (24%)
351-500	40 (18%)	52 (18%)
>500	60 (28%)	60 (21%)
Missing or rejected	84 (28%)	13 (4%)
Reason for today's clinic visit		
HIV test	162 (54%)	148 (50%)
Visit between test and treatment	140 (46%)	150 (50%)
First time visiting this clinic, for any reason (% yes)	97 (32%)	88 (30%)
When would patient want to start ART, if given a choice?		
Today	282 (94%)	286 (96%)
Within a week	13 (4%)	7 (2%)
Within a month	4 (1%)	2 (1%)
Not ready	3 (1%)	3 (1%)

Table 1. Sample characteristics at baseline

Outcome	Control	Intervention	Crude risk difference (95%CI)*	Crude relative risk (95% CI)*
N enrolled	302	298		
Primary outcome 1: Initiation				
Initiated ≤ 28 days	**204 (68%)**	**232 (77%)**	**10% (3-17%)**	**1.15 (1.04-1.27)**
Initiated in 0 days (same-day)	33 (11%)	161 (53%)	43% (36-50%)	4.94 (3.52-6.94)
Initiated in 1-7 days ("rapid")	114 (38%)	193 (64%)	27% (19-35%)	1.72 (1.45-2.03)
Initiated in 29-90 days	238 (84%)	256 (90%)	6% (0-11%)	1.07 (1.00-1.14)
No record of initiation ≤90 days	20 (7%)	14 (5%)	-2% (-6%-2%)	0.70 (0.37-1.38)
Primary outcome 2: Retention				
Initiated ≤ 28 days and retained at 8 months after enrollment**	**137 (45%)**	**147 (49%)**	**4% (-4%-11%)**	**1.09 (0.92-1.29)**
Initiated ART, deceased	1 (0%)	2 (1%)	0% (0%-1%)	2.03 (0.18-22.23)
Initiated ART, lost to follow up	55 (18%)	63 (21%)	3% (-3%-9%)	1.16 (0.84-1.61)
Initiated ART, transferred	5 (2%)	15 (5%)	3% (1%-6%)	3.04 (1.12-8.26)
Not initiated ≤ 28 days	78 (26%)	52 (17%)	-8% (-15%- -2%)	0.68 (0.49-0.92)
No record of any visit after enrollment	26 (9%)	19 (6%)	-2% (-6%-2%)	0.74 (0.42-1.31)

* Reference group: control arm

**Follow up for 8 months=1 month for initiation + 6 months' follow up + 1-month window for 6-month routine visit; retained= clinic visit 5-8 months after enrollment

Table 2. Primary outcomes, by study arm

Enrollment

- 600 patients were enrolled in the study from March 7 to July 28, 2017 (Figure 3 and Table 1).
- Arms were balanced on important demographic and clinical characteristic.

Primary outcome 1 (initiation ≤ 28 days of study enrollment)

- In the intervention arm, 149 patients (50%) were found to be eligible for immediate initiation and were dispensed ARVs on the same day.
- The other 50% in the intervention arm met one or more algorithm criteria for referral for additional services before initiation (3/4 due to TB symptoms.
- Within 28 days, 82% of intervention arm patients and 72% of standard arm patients had initiated ART.
- Within 7 days, 68% of intervention arm patients and 40% of standard arm patients had initiated ART.

Primary outcome 2 (initiation ≤ 28 days and retained by 8 months after study enrollment)

- By 8 months after enrollment (i.e., by the routine 6-month clinic visit), 53% of intervention arm patients and 50% of standard arm patients had initiated and were retained.
- Most differences in outcomes were in ART uptake (initiation), not retention after initiation, which did not differ between arms.
- More intervention arm patients transferred to a different clinic after initiation, suggesting that some standard arm patients who did not initiate ≤ 28 days may instead have transferred to a different clinic.

CONCLUSIONS AND LIMITATIONS

- The SLATE algorithm, comprising simplified steps for ART initiation, increased uptake of ART within 28 days by 16% and 7 days by 68%.
- There was no difference in the proportion of patients who initiated ≤28 days and were retained in care through 8 months (i.e. completed their routine 6-month clinic visit).
- Nurses were able to implement the algorithm in routine care settings without additional equipment or clinical supervision.
- Limitations include small number of sites, all in informal urban settlements, and missing follow-up data for some patients.
- The SLATE algorithm, comprising a simplified set of steps for ART initiation, demonstrates that same-day ART initiation for both new and established HIV patients can be offered safely and effectively at primary health centers without delays for laboratory results, additional education or counseling, or other services.
- A follow-on trial, SLATE II, is currently testing an improved algorithm that incorporates lessons learned from the first SLATE study, particularly for patients with symptoms of TB.

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