SAME-DAY ART INITIATION IN THE SLATE TRIAL IN KENYA: PRIMARY OUTCOMES

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Abstract 1018

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BACKGROUND

The World Health Organization recommends same-day initiation of ART (SDI) for patients who are eligible and ready and rapid initiation (≤7 days) for all patients. Despite widespread reports of routine implementation of SDI in many African countries, little is known about how to determine if a patient is medically eligible and personally ready for same-day initiation, the minimum package of services required for initiation, or how best 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 I) trial evaluated 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. Results from South Africa were presented in 2018[1]; here we report primary outcome results from Kenya.

[1]Rosen S, Maskew M, Brennan AT, Fox MP, Vezi L, Larson B, Tsikhutsu I, Bii M, Venter WD. Same-day ART initiation without laboratory tests is safe and effective: primary outcomes of the SLATE trial in South Africa. AIDS 2018, Amsterdam, 23-27 July 2018.

METHODS

- **Design**: SLATE was an individually randomized trial at three public, hospital-based outpatient clinics 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.
- **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.
- **Intervention arm patients** found eligible for SDI were dispensed ARVs; those requiring additional services were referred back to standard care. **Standard arm patients** were referred back to standard care after randomization. Both standard of care and study ART initiation and monitoring were managed by clinical officers, as is usual in Kenya.
- **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. We also report secondary outcomes of initiation ≤ 0, 7, and 90 days of study enrollment as well as additional retention-related secondary outcomes.
- **Further details** can be found in Rosen S, et al. Simplified clinical algorithm for identifying patients eligible for immediate initiation of antiretroviral therapy for HIV (SLATE): protocol for a randomized evaluation. BMJ Open 2017;7:e016340.

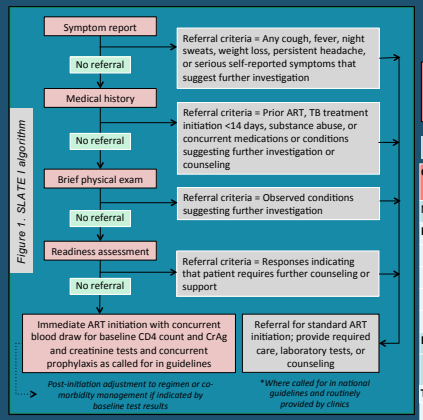

Figure 1. SLATE I algorithm

RESULTS

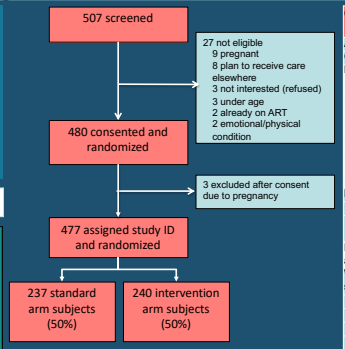

Figure 2. Study enrollment (Kenya)

Characteristic	Standard arm (N=237)	Intervention arm (N=240)
Age (median [IQR]	35 (29-44)	36 (29-44)
Gender (female)	134 (56%)	142 (59%)
Baseline CD4 count (cells/mm^3)		
N valid results	145	221
Median (IQR)	297 (94-577)	272 (124-522)
<100	38 (26%)	46 (21%)
100-200	19 (13%)	36 (16%)
201-350	21 (14%)	52 (24%)
351-500	23 (16%)	27 (12%)
>500	44 (30%)	60 (27%)
Missing or rejected	92	19
Reason for today's clinic visit		
HIV test	109 (46%)	114 (48%)
Visit between testing and starting treatment	97 (41%)	98 (41%)
First time visiting this clinic for any kind of HIV care (yes)	192 (81%)	195 (81%)
When would patient want to start ART, if given a choice?		
Today	231 (97%)	235 (98%)
Within a week	4	3
Within a month	1	1
Not ready	1	1

Table 1. Sample characteristics at baseline

Outcome	Standard	Intervention	Crude risk difference (95%CI)*	Crude relative risk (95% CI)*
N enrolled	237	240		
Primary outcome 1: Initiation				
Initiated ≤ 28 days (primary outcome)	210 (88.6%)	226 (94.2%)	5.6% (0.5%-10.6%)	1.06 (1.01-1.12)
Initiated in 0 days (same-day)	127 (53.6%)	167 (69.6%)	16.0% (7.3%-24.7%)	1.30 (1.12-1.50)
Initiated ≤ 7 days (rapid)	173 (73.0%)	207 (86.3%)	13.3% (6.1%-20.4%)	1.18 (1.08-1.30)
Initiated ≤ 90 days	222 (93.7%)	231 (96.3%)	2.6% (-1.4%-6.5%)	1.03 (0.99-1.07)
Primary outcome 2: Retention				
Initiated ≤ 28 days and retained at 8 months after enrollment (primary outcome)**	136 (57.4%)	137 (57.1%)	-0.3% (-9.2%-8.6%)	0.99 (0.85-1.16)
Timing of attrition occurring by 8 months after enrollment				
Lost or died before ART initiation	13 (5.4%)	8 (3.3%)	-2.2% (-5.9%-1.5%)	0.61 (0.26-1.44)
Lost or died ART after ART initiation	82 (34.6%)	79 (32.9%)	-1.6% (-10.2%-6.8%)	0.95 (0.74-1.22)
Transferred (outcome unknown)	6 (2.5%)	16 (6.7%)	4.1% (0.5%-8.2%)	2.6 (1.05-6.62)

* Reference group: standard 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

- 477 patients were enrolled in the study from 7/13/17 to 4/17/18 (Fig 2, Tbl 1).
- Arms were balanced on important demographic and clinical characteristics.

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

- In the intervention arm, 55% of patients (131/240) were found to be eligible for immediate initiation under SLATE I; 96% of these were dispensed ARVs on the same day by the intervention clinician.
- The other 45% in the intervention arm (109/240) met ≥ 1 algorithm criteria for referral for additional services before initiation (85% due to TB symptoms).
- Same-day initiation was provided to 54% of standard arm patients and to 38% (41/109) of intervention arm patients referred back to standard care after being found ineligible by SLATE algorithm.
- Within 28 days (primary outcome), 94% of intervention arm patients and 89% of standard arm patients had initiated ART.
- Within 7 days, the WHO's definition of rapid initiation, 86% of intervention arm patients and 73% of standard arm patients had initiated ART.

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

- By 8 months after enrollment (i.e., by the routine 6-month clinic visit), 57% of patients in both arms had initiated and were retained.
- Of the 43% not achieving primary outcome 2, a majority were lost to follow up or died after ART initiation, not before (Table 2).

CONCLUSIONS AND LIMITATIONS

- The SLATE algorithm, comprising simplified steps for ART initiation, **increased uptake of ART within 28 days** by absolute differences of 5.6% and 7 days by 13.3%.
- There was **no difference** in the proportion of patients who initiated ≤28 days and were retained in care through 8 months.
- Standard of care in Kenya during the study period included same-day initiation at the clinician's discretion, reducing differences between the arms.
- Clinical officers and other regular staff **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** (≈35%) at the time of the routine 6-month visit; more attention must be paid to early retention support.
- Limitations include small number of sites, all in large, hospital-based clinics, and missing data for some patients.
- SLATE demonstrates that **same-day ART initiation for both new and established HIV patients can be offered safely and effectively** at primary health centers.
- A follow-on trial, SLATE II, is currently testing an improved algorithm in South Africa that incorporates lessons learned from the first SLATE study, particularly for patients with symptoms of TB.

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