Same-Day ART Initiation in the SLATE Trial in South Africa: Preliminary Results

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Abstract 1418

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BACKGROUND

The World Health Organization recommends "same-day" initiation of ART for patients who are eligible and ready and initiation within 7 days of diagnosis for all patients. Both the WHO guidelines and the subsequent South African recommendation state that a patient should be started on ART on the same day if the patient is "ready." Little guidance is provided, however, on how to determine if a patient is ready or how to provide the specific services required for ART initiation in a single clinic visit. Identifying efficient operational procedures for determining same- day eligibility and readiness is now a priority. The Simplified Algorithm for Treatment Eligibility (SLATE) trial is testing a clinical algorithm that allows nurses to determine eligibility for immediate ARV dispensing at the same clinic visit. We report early results.

METHODS

SLATE is 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. The SLATE algorithm 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. Follow up was by passive record review. We report the primary outcome of ART initiation ≤28 days of study enrollment for the South Africa sites.

The SLATE algorithm is illustrated in Figure 1 and the study design in Figure 2.

Figure 1. SLATE algorithm

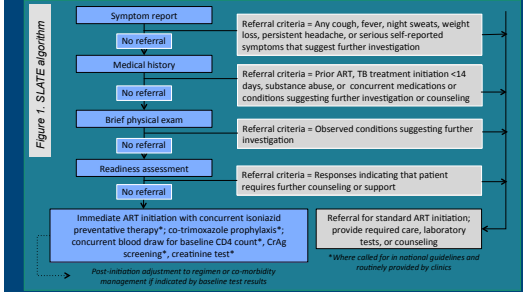

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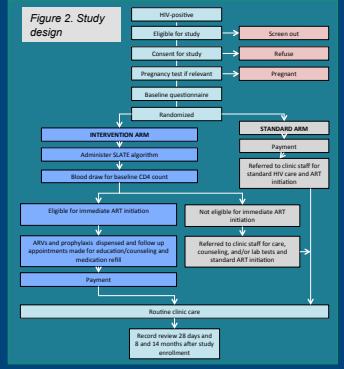
Figure 2. Study design



RESULTS

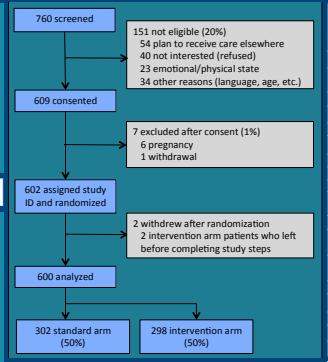


Figure 3. Study enrollment (South Africa)

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/mm^3)		
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%)
Other 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 arm	Intervention arm	Crude risk difference (95%CI)*	Crude relative risk (95% CI)*
N enrolled	302	298		
Record traced, outcome ascertained	282 (93%)	284 (95%)		
Of those with record traced, initiated ART within specified days after enrollment				
0 days (same day)	33 (12%)	161 (56%)	45% (38-52%)	4.84 (3.46-6.78)
7 days	114 (40%)	193 (68%)	28% (20-35%)	1.68 (1.43-1.98)
14 days	170 (60%)	207 (72%)	13% (5-20%)	1.21 (1.07-1.36)
28 days (primary outcome)	204 (72%)	232 (82%)	10% (2-16%)	1.13 (1.03-1.24)
90 days	238 (84%)	256 (90%)	6% (0-11%)	1.07 (1.00-1.14)

* Reference group: control arm

Table 2. Time to ART initiation, by study arm

- 600 patients in the study from March 7 to July 28, 2017 (Figure 3 and Table 1).
- In the intervention arm, 149 patients (50%) were found to be eligible for immediate initiation and were dispensed ARVs at the same visit.
- The other 50% in the intervention arm met one or more algorithm criteria for referral for additional services before initiation
  - Almost three quarters (109/149) of those referred had TB symptoms; 8 patients were found to have TB
  - 17/149 reported persistent headache; none of these were positive for cryptococcal antigen (1 CrAg+ patient did not report headache)
  - 14/149 were previous ART defaulters, referred for additional counseling before starting ART
  - 7/149 were referred for other clinical conditions
  - 6/149 were referred for substance abuse
  - Only 5 patients said that they were not ready to start ART.
- The primary outcome (ART initiation within 28 days) was available for 94% of patients (records missing for 6%) (Table 2).
- Within 28 days, 82% of intervention arm patients and 72% of standard arm patients had initiated ART (risk difference (RD) [95% CI] 10% [2-16%]; relative risk (RR) 1.16 [1.06-1.28]).
- Within 7 days, 68% of intervention arm patients and 40% of standard arm patients had initiated ART (RD 28% [20-35%], RR 1.68 [1.43-1.98]).

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%.
- Half the patients administered the algorithm had to be referred for additional services; most of these had 1 or more TB symptoms, but very few had TB; a better approach to screening for active TB is needed.
- Nearly all patients enrolled in the study said that they were ready to start ART on the same day, including those who came to the clinic for initial HIV diagnosis.
- 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; missing follow-up data for some patients.
- Longer follow-up is needed to draw conclusions about overall effectiveness and cost-effectiveness, but early results suggest that simpler treatment initiation procedures are feasible and can increase and accelerate ART uptake and reduce the visit burden on patients and facilities.