

## THE SLATE ALGORITHM FOR SAME-DAY HIV TREATMENT INITIATION: RESULTS OF THE SLATE TRIAL IN SOUTH AFRICA AND KENYA

### Background

The World Health Organization recommends "same-day" initiation of antiretroviral therapy (ART) for HIV patients eligible and ready<sup>1</sup>. This recommendation has been adopted by both South Africa<sup>2</sup> and Kenya<sup>3</sup>. Identifying efficient, safe, and feasible procedures for determining same-day eligibility and readiness is now a priority. The WHO guidelines cited evidence from clinical trials suggesting that offering treatment to patients at their first clinical encounter has the potential to increase relative uptake of ART within 90 days by 30% and from observational studies that showed an overall relative increase of 53%. All of the trials cited by the WHO, however, relied on access to point-of-care (POC) laboratory instruments, which are not feasible in most routine care settings.

The Simplified Algorithm for Treatment Eligibility (SLATE) study evaluated a clinical algorithm that allows healthcare workers to determine eligibility for same-day treatment and to initiate ART at the patient's first clinic visit. The study's goal was to determine whether an algorithm for same-day ART initiation that can be implemented in routine care settings without reliance on laboratory results can safely and effectively increase and accelerate uptake of ART in the general adult population<sup>4,5</sup>.

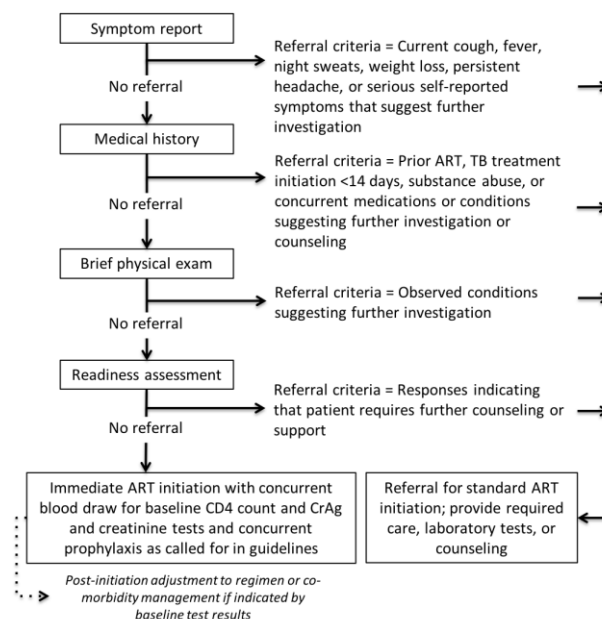
### Methods

SLATE was conducted at three public sector clinics each in western Kenya and Gauteng Province of South Africa. It compared ART initiation using the SLATE algorithm (Figure 1) with standard of care initiation, with outcomes of treatment initiation within 28 days of study enrollment and retention in care 8 months after study enrollment. At the time the SLATE study was launched, treatment initiation, starting with an HIV test, usually required between 4 and 6 clinic visits in South Africa and at least 2 in Kenya.

The study enrolled adult ( $\geq 18$ ), non-pregnant, HIV-positive patients not yet on ART who presented at one of the study clinics to have an HIV test, enroll in care or prepare to start or re-start ART if already diagnosed, or receive other unrelated medical care that led to referral for an HIV test. After consent and a questionnaire, patients were randomized 1:1 to either the standard arm or the intervention arm. Patients in the intervention arm were then administered the four "screens" of the SLATE algorithm pictured in Figure 1 by a study nurse (South Africa) or clinical officer (Kenya). Those who "screened out" due to any TB symptoms or the other criteria shown in the figure were referred

back to the regular clinic queue for routine care and treatment initiation. Those "screened in" were offered same-day initiation and dispensed their initial supply of ARV medications at that same visit. Follow up was by medical record review only—we did not have personal contact with patients after the enrollment visit.

Figure 1. The SLATE algorithm



### Results

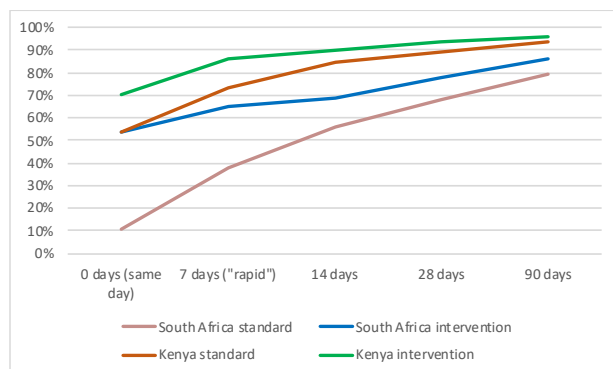
Patients were recruited in South Africa from March to July 2017 and in Kenya from July 2017 to April 2018. After screening for study eligibility, we enrolled 600 patients in South Africa and 477 in Kenya. About 60% of participants were female, the median age was 35, and median baseline CD4 counts were 277 cells/mm<sup>3</sup> (IQR 141-484) in South Africa and 283 cells/mm<sup>3</sup> (IQR 117-541) in Kenya. In both countries, roughly one third of patients presented with CD4 counts  $\leq 200$  cells/mm<sup>3</sup>, and about half had come to the clinic that day to have HIV tests, while the other half already knew their status and had come for pre-ART care. Nearly all patients in all study groups—between 93 and 98%—said that they would like to start ART on that same day if they could.

Initiation of ART within 0, 7, 14, and 28 days of study enrollment was higher in the intervention arm in both countries, as illustrated in Figure 2. Substantially more intervention arm patients started ART on the same day or within 7 days than did standard arm patients.

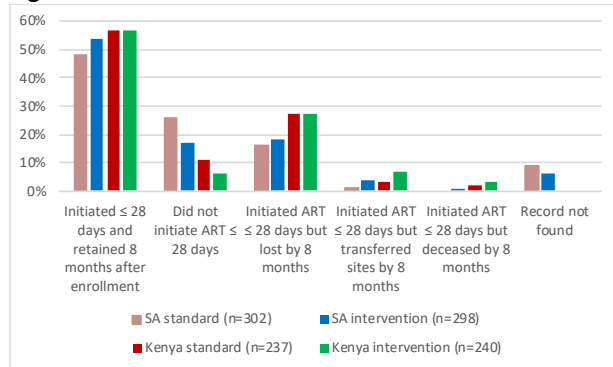
At eight months after study enrollment, only between 50 and 60% patients in either arm in either country had achieved the outcome of "initiated ART within 28 days

and retained in care at 8 months.” Figure 3 illustrates these results. Retention in care at the study site after ART initiation was poor across all groups, suggesting that early retention continues to require improvement.

**Figure 2. Time to ART initiation by country and arm**



**Figure 3. Patient status 8 months after enrollment**



Among patients included in the first column in Figure 3 (initiated ≤28 days and retained by 8 months), roughly two thirds were known to be virally suppressed, with the rest not having viral load results reported in their records. There was no difference in suppression by arm.

Half of all intervention patients in South Africa and 45% in Kenya “screened out” of the SLATE algorithm (i.e., were determined to be not eligible for same-day initiation and referred back to the clinic for additional care). The vast majority who screened out—83% in Kenya and 75% in South Africa—had one or more symptoms of tuberculosis (TB): cough, fever, weight loss, or night sweats. TB symptoms were either alone or accompanied by other reasons for screening out, such as other symptoms or previous default. Many of these patients were started on the same day anyway by clinic staff after referral from SLATE, particularly in Kenya, suggesting that clinic staff found the SLATE algorithm too conservative or were able to provide the additional services needed at that same visit.

In both countries, there was a large difference in outcomes among the study sites. In South Africa, one of the three sites accounted for most of the intervention

effect observed. In Kenya, two sites experienced a larger effect than did the third.

## Policy relevance

In much of the world, uptake of ART among those already diagnosed remains far below the global target of 90%<sup>6</sup>, and a large share of AIDS-related deaths are among those not on ART. While there are barriers to starting treatment at a number of levels<sup>7</sup>, making procedures for ART initiation more efficient—with efficiency encompassing clinical effectiveness, patient behavior, and resource utilization by both providers and patients—is important if high-prevalence countries are to achieve the 90-90-90 targets for HIV treatment.

The SLATE algorithm was designed to rely on the human resources and infrastructure already available at public sector clinics in South Africa. Study clinicians were drawn from the same workforce cadre as clinicians responsible for ART initiation in the two countries, and no additional laboratory equipment or tests were required. It thus offers a systematic way for existing clinicians to structure same-day ART initiation, collecting a standard set of data on each patient and providing guidance on what to do when confronted with individual patients’ conditions and needs.

It is reasonable to speculate that an intervention like SLATE, which is intended to improve the efficiency of clinic procedures, is most effective at facilities that are least efficient to start with, and thus have more room for improvement. If the SLATE intervention were to be rolled out in the study countries, targeting facilities with the worst indicators for placing new patients on treatment, rather than all facilities at once, could thus make sense.

Finally, the low retention rates seen at 8 months across countries and arms in this study were striking. Regardless of mode of initiation, retaining patients on ART in their first half year of treatment remains a major challenge for national HIV treatment programs.

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