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# Improved simplified clinical algorithm for identifying patients eligible for immediate initiation of antiretroviral therapy for HIV (SLATE II): protocol for a randomized evaluation

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**Title:** Improved simplified clinical algorithm for identifying patients eligible for immediate initiation of antiretroviral therapy for HIV (SLATE II): protocol for a randomized evaluation

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SR, MPF, PDE, ATB, and MM conceived and designed the work. LV and WDFV contributed to designing the work. SR wrote the first draft of the manuscript. All authors reviewed and revised the manuscript. All authors read and approved the manuscript's results and conclusions. All authors have read, and confirm that they meet, International Committee of Medical Journal Editors (ICMJE) criteria for authorship.

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**Description:** (mention here if relevant the article that the dataset (or supplementary material) is part of)

1. Rosen S, Maskew M, Brennan AT, Fox MP, Vezi L, Ehrenkranz PD, Venter WDF. Improved simplified clinical algorithm for identifying patients eligible for immediate initiation of antiretroviral therapy for HIV (SLATE II): protocol for a randomized evaluation. *Trials*. 2018 Oct 11;19(1):548. doi: 10.1186/s13063-018-2928-5. PMID: 30305142; PMCID: PMC6180640.28;7(5):e016340. doi: 10.1136/bmjopen-2017-016340. PMID: 28554939; PMCID: PMC5726128.
2. Scott NA, Maskew M, Fong RM, Olson IE, Brennan AT, Fox MP, Vezi L, Ehrenkranz PD, Venter WDF, Rosen S. Patient perspectives of quality of the same-day antiretroviral therapy initiation process in Gauteng Province, South Africa: qualitative dominant mixed-methods analysis of the SLATE II trial. *The Patient - Patient-Centered Outcomes Research*. September 10 2020. <https://doi.org/10.1007/s40271-020-00437-4>.
3. Brennan AT, Maskew M, Larson BA, Tsikhutsu I, Bii M, Vezi L, Fox MP, Venter WDF, Ehrenkranz P, Rosen S. Prevalence of TB symptoms, diagnosis and treatment among HIV-positive adults not yet on ART presenting at outpatient clinics in South Africa and Kenya. *BMJ Open* 2020;10:e035794. doi: 10.1136/bmjopen-2019-035794.
4. Maskew M, Brennan AT, Fox MP, et al. A clinical algorithm for same-day HIV treatment initiation in settings with high TB symptom prevalence in South Africa: The SLATE II individually randomized

clinical trial. PLoS Med. 2020;17(8):e1003226. Published 2020 Aug 27.  
doi:10.1371/journal.pmed.1003226.Abstract:

**Background:** The World Health Organization recommends rapid ( $\leq 7$  days) or same-day initiation of antiretroviral treatment (ART) for HIV-positive patients. South Africa adopted this recommendation in 2017, but multiple clinic visits, long waiting times, and delays for laboratory tests remain common. Streamlined approaches to same-day initiation that allow the majority of patients to start ART immediately, while ensuring that patients who do require additional services receive them, are needed to achieve national and international treatment program goals.

**Methods/design:** The SLATE II (Simplified Algorithm for Treatment Eligibility) study is an individually randomized evaluation of a clinical algorithm to reliably determine a patient's eligibility for immediate ART initiation without waiting for laboratory results or additional clinic visits. It differs from the earlier SLATE I study in management of patients with symptoms of tuberculosis (under SLATE II these patients may be started on ART immediately) and other criteria for immediate initiation. SLATE II will randomize (1:1) 600 adult, HIV-positive patients who present for HIV testing or care and are not yet on ART in South Africa. Patients randomized to the standard arm will receive standard-of-care ART initiation from clinic staff. Patients randomized to the intervention arm will be administered a symptom report, medical history, brief physical exam, and readiness assessment. Symptomatic patients will also have a tuberculosis (TB) module with lipoarabinomannan antigen of mycobacteria test. Patients who have satisfactory results for all four components will be dispensed antiretrovirals (ARVs) immediately, at the same clinic visit. Patients who have any negative results will be referred for further investigation, care, counseling, tests, or other services prior to being dispensed ARVs. Follow-up will be by passive medical record review. The primary outcomes will be ART initiation in  $\leq 7$  days and retention in care 8 months after study enrollment.

**Discussion:** SLATE II improves upon the SLATE I study by reducing the number of reasons for delaying ART initiation and allowing more patients with TB symptoms to start ART on the day of diagnosis. If successful, SLATE II will provide a simple and streamlined approach that can readily be adopted in other settings without investment in additional technology.

**Trial registration:** ClinicalTrials.gov, [NCT03315013](https://clinicaltrials.gov/ct2/show/study/NCT03315013) . Registered on 19 October 2017.

**Keywords:** Africa; Antiretroviral therapy; Protocol; Randomized trial; Same-day; South Africa; Treatment initiation.

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