Rapid Initiation of Antiretroviral Therapy Reduces Attrition Between HIV Testing and Treatment: The RapIT Study

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The Problem

- Despite new guidelines, the national HCT campaign, and other DOH efforts, most HIV patients in South Africa start ART too late
  - Over half started with CD4 < 200 in 2012/13 (NDOH 2013)
- Why? One cause is poor linkage to and retention in pre-ART care
  - More than 1/3 of patients testing HIV-positive don't obtain CD4 count results and 1/2 don't enroll and remain in care
  - About 1/3 of patients already known to be eligible for ART don't start treatment within 6 months (Rosen and Fox 2011)

A Proposed Solution

- Make it faster and easier for patients to start ART after testing HIV-positive
  - Use rapid, point-of-care laboratory tests for immediate determination of treatment eligibility and readiness
  - Compress and accelerate initiation procedures to allow all steps to be completed in one clinic visit, ideally on the day of testing positive
- Potential benefits of this strategy
  - Reduces pre-ART loss to follow up—patients who start ART immediately don't have a chance to get lost before starting
  - Reduces burden on clinics and patients—fewer clinic visits
  - But does it work?

RapIT — A Randomized Controlled Evaluation of Rapid Treatment Initiation

- Enrolled adult, non-pregnant patients after positive HIV test or first CD4 count
  - Patients having repeat CD4 count excluded from study but would not be excluded if intervention were offered in routine practice
- Randomized to rapid or standard initiation
- Study conducted at two clinics: Thuthukani PHC in Ivory Park and Themba Lethu Clinic at Helen Joseph Hospital
- Enrolled April 2013-August 2014
- NIH/PEPFAR funding with indirect support from USAID
- Preliminary results presented here

Study Procedures

STANDARD INITIATION PROCEDURESa

HIV-positive patient

VISIT 1:
- Take blood sample for CD4 count
- Perform TB symptom screen
- Take sputum sample if symptomatic

VISIT 2 (1 WEEK AFTER VISIT 1):
- Provide CD4 count results
- Provide TB test results and initiate TB treatment if required

VISIT 3 (1 WEEK AFTER VISIT 2):
- Provide individual counseling (education/adherence)

VISIT 4 (SAME WEEK OR WEEK AFTER VISIT 3):
- Provide group counseling (education/adherence)

VISIT 5 (SAME WEEK OR WEEK AFTER VISIT 4):
- Provide results of other blood tests
- Confirm treatment buddy

VISIT 6 (SAME WEEK OR WEEK AFTER VISIT 5):
- Conduct physical examination
- Dispense ARVs

TOTAL: 2-6 WEEKS

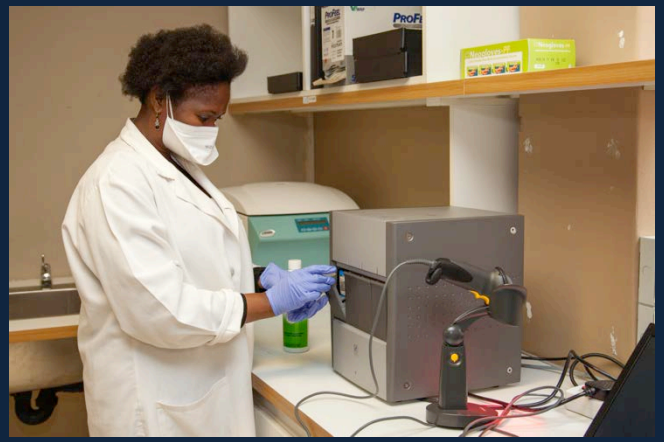
RAPID INITIATION PROCEDURESa

HIV-positive patient

VISIT 1:
- Take blood sample for CD4 count and perform rapid CD4 count (Pima CD4 Count)
- Perform TB symptom screen
- Take sputum sample if symptomatic and perform rapid TB test; initiate TB treatment if required (ART initiation delayed if TB treatment initiated) (Xpert MTB/RIF)
- Perform other blood tests (rapid) (Reflotron Plus)
- Conduct physical exam (ART initiation delayed if referred off site for specific conditions)
- Conduct education/adherence and individual counseling session
- Dispense ARVs

TOTAL: 1 DAY

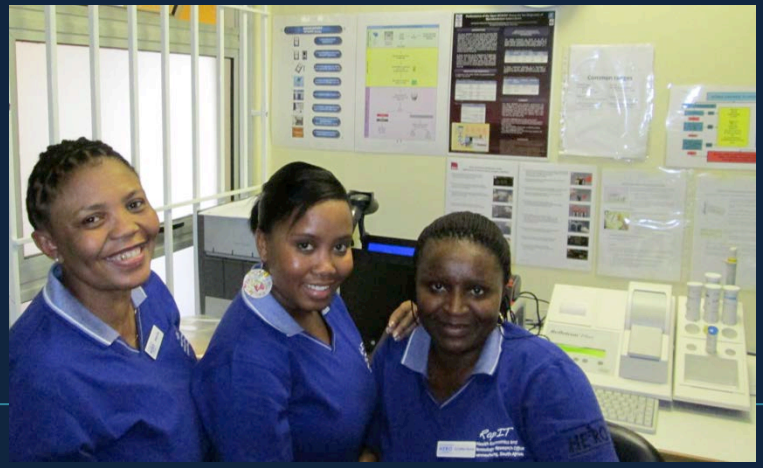
Point of Care Instruments Used



Xpert MTB/RIF

Pima CD4 Analyzer

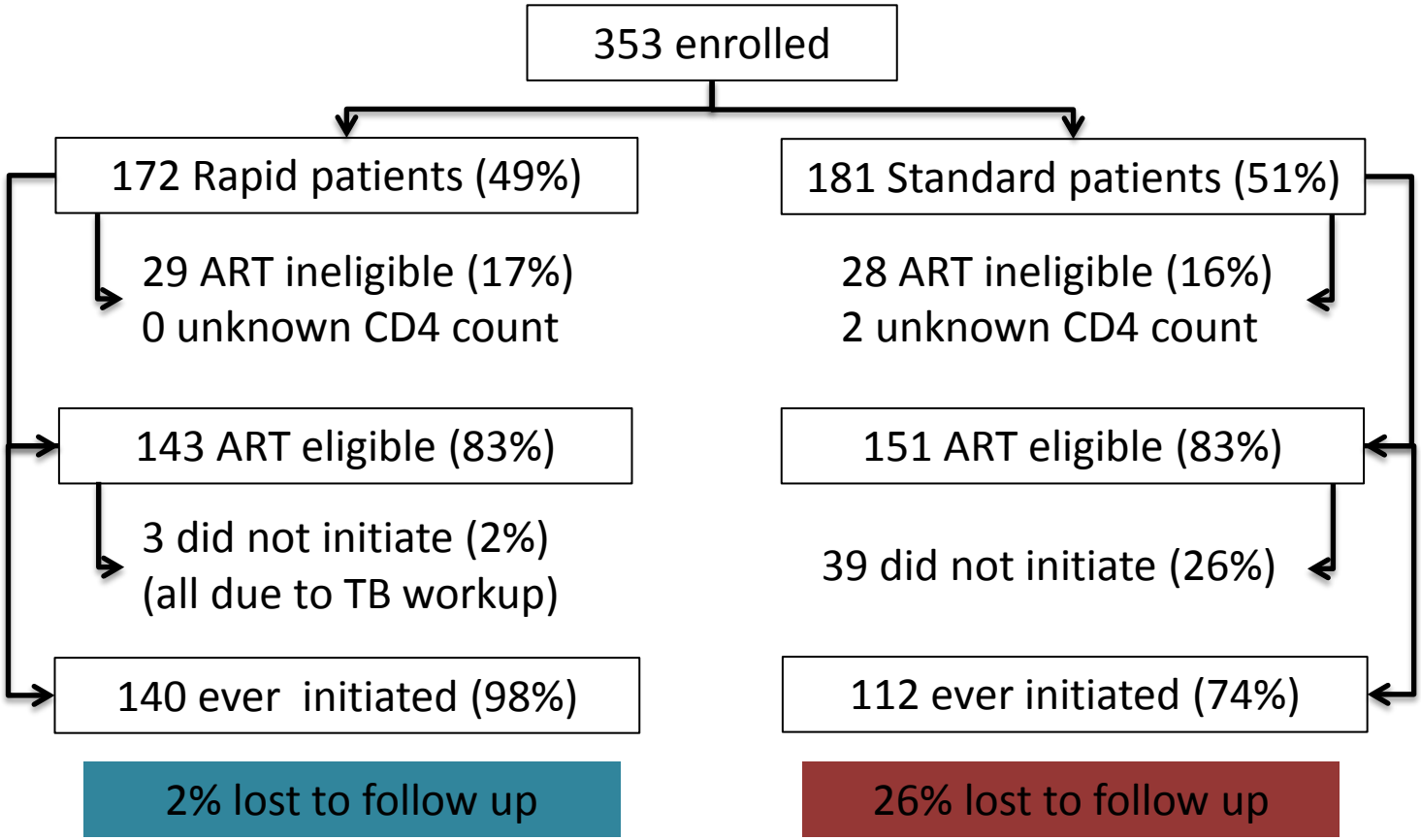
Reflotron Plus



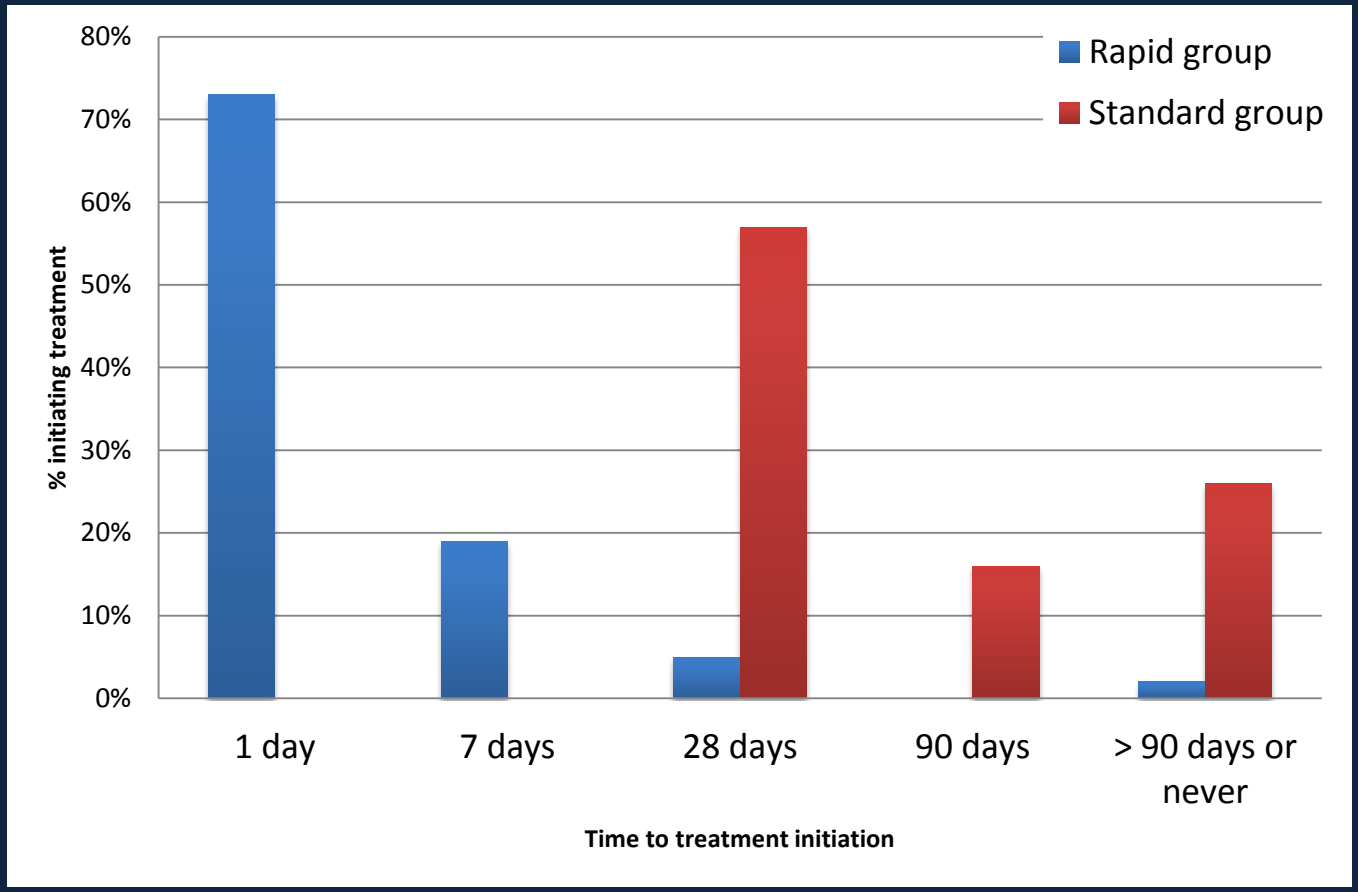
Results: Who Did We Enroll?

Variable	Rapid group	Standard group
N	172	181
Age (median, IQR)	34.2 (29.5-39.7)	34.7 (29.8-41.5)
Sex (% female)	52%	57%
CD4 count (median, IQR)	223 (130-318)	189 (101-314)
Purpose of clinic visit (%)		
Have HIV test (diagnosed today)	69 (40%)	76 (42%)
Provide blood sample for CD4 count	9 (5%)	6 (4%)
Receive CD4 count results	94 (55%)	98 (54%)
Study site (%)		
Thuthukani PHC	106 (48%)	113 (52%)
Themba Lethu Clinic (Helen Joseph)	66 (49%)	68 (51%)

Results: ART Initiation Within 90 Days



Results: How Long Did It Take?



Average time in clinic between study enrollment and ARV dispensing in rapid group:

2.8 hours

Challenges and Limitations

- Primary study outcome—viral suppression or retention at six months—not reached yet
- Clinics must have secure, temperature-controlled room for point of care instruments and good inventory management
- Getting procedures right takes training and practice
  - But can be done by existing NIMART nurses and counselors
- Cost? Not yet determined but reduction in visits may offset cost of instruments
  - Point of care CD4 count and blood tests essential; Xpert optional if low TB-burden clinic
- Study resources (staff, supplies) could have led to improved results for both groups, compared to routine practice

Conclusions

- Rapid ART initiation is feasible at PHCs and acceptable to patients
  - >40% of patients testing HIV-positive today were already ART-eligible under old guidelines (CD4<350)
- Early results suggest significant improvement in proportion of patients starting treatment within 3 months of determining eligibility
- Cost and cost-effectiveness still to be estimated
- Next step is evaluation in routine practice by DOH staff

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