

# Initiating ART at a Patient's First Clinic Visit: The *RapIT* Randomized Trial

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# Background

# The Problem

- Most HIV patients in South Africa start ART too late
  - 50% started with CD4 count < 200 in 2012/13<sup>1</sup>
- One cause is failure to start ART even after being found eligible
  - 25-40% of treatment-eligible patients don't start treatment ≤ 6 months<sup>2-5</sup>

Why? In part it's because...

<sup>1</sup> National Department of Health 2013; <sup>2</sup>Plazy et al 2014; <sup>3</sup>Clouse et al 2013; <sup>4</sup>Rosen and Fox 2011; <sup>5</sup>Larson et al 2010

# Starting Treatment Isn't Easy!



## Visit 1

- HIV test; result positive
- Give blood sample for CD4 count
- Complete TB symptom screen
- Provide sputum sample if symptomatic

## Visit 2

- Provide CD4 count results; treatment eligible
- Provide TB test results and initiate TB treatment if required

## Visit 3

- Individual counseling session (education/adherence)

## Visit 4

- Group counseling session (education/adherence)

## Visit 5

- Provide results of other blood tests
- Treatment buddy session

## Visit 6

- Conduct physical examination
- Dispense ARVs

*I am exhausted...*



# Why Have We Made Initiating ART So Onerous?



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**Lab tests are  
centralised**



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**Lack of  
momentum**



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**Legacy of the  
previous ARV era**

# Methods

# A Proposed Solution: Same-Day Initiation

Make it faster and easier for patients to start ART



**COMPRESS**



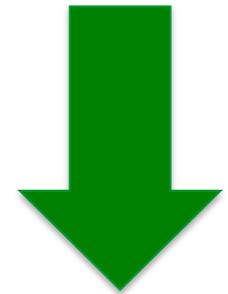
**ACCELERATE**



**UPTAKE**



**OUTCOMES**



**BURDEN**



**Visit 1**

- Take blood sample for CD4 count and perform rapid 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);
- Perform other blood tests (rapid);
- Conduct physical exam (ART initiation delayed if referred off site for specific conditions);
- Conduct education/adherence session;
- Conduct individual counseling session;
- Dispense ARVs

# *RapIT* Randomized Controlled Trial of Same-Day Treatment Initiation

Enrollment Visit



$\geq 18$



Outcomes



Initiated



Retained



Suppressed

Initiation of ART by 90 days of

Enrolled adult, non-pregnant patients after

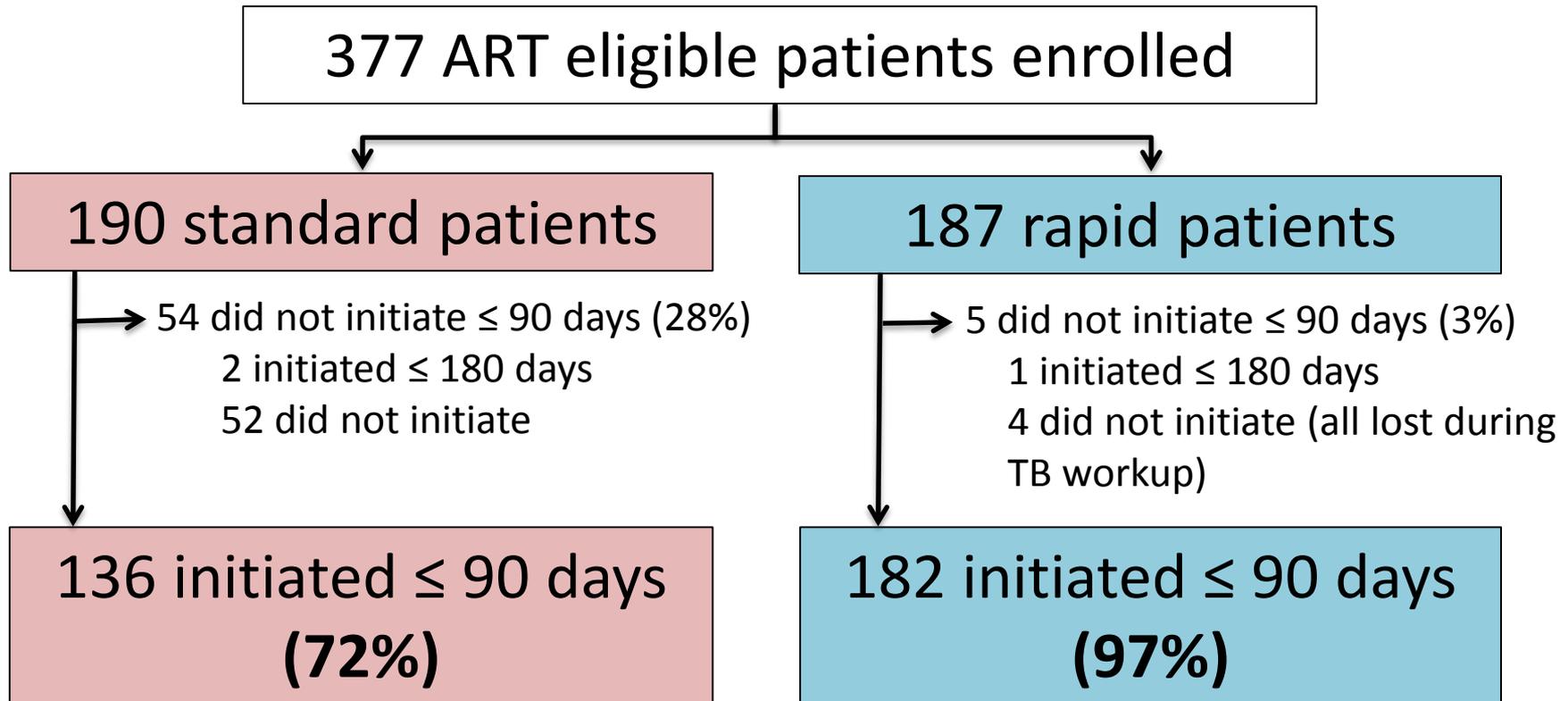
study enrollment exclusively through medical record  
AR study procedures for enrollment based on either a  
positive HIV test or first CD4 count

Initiated, retained in care, and

virally suppressed by 10 mo

# Results

# Major Programmatic Outcome: ART Initiation $\leq$ 90 Days



**Risk difference 25% (95% CI 19 to 33%)**

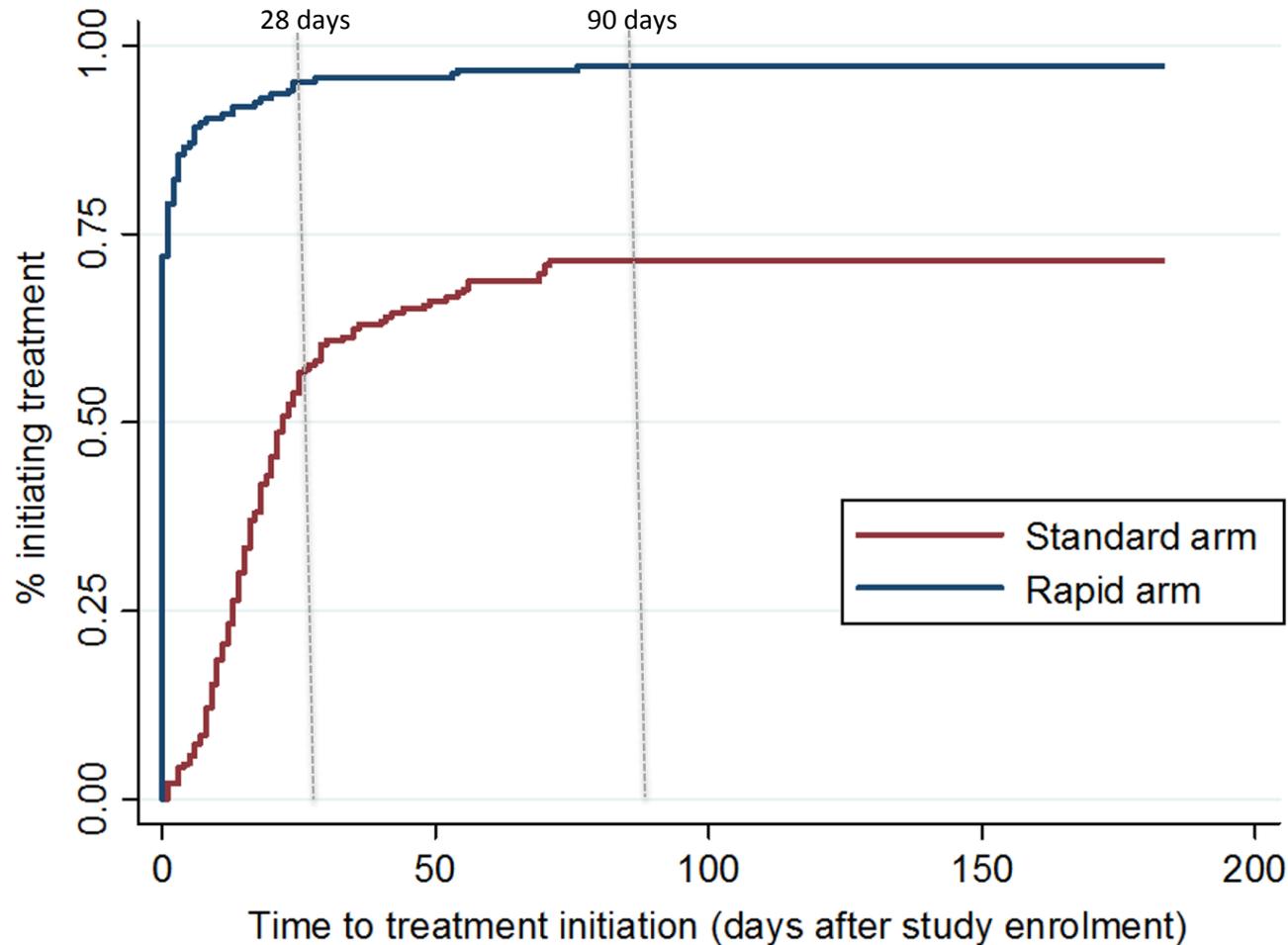
**Crude relative risk 1.36 (95% CI 1.24 to 1.49)**

# Primary Protocol Outcome: Initiated, Retained, and Suppressed $\leq$ 10 Months

Outcome	Standard arm (n, %) n=190	Rapid arm (n, %) n=187	Crude risk difference [95% CI]	Crude relative risk* [95% CI]
Initiated $\leq$ 90 days	136 (72%)	182 (97%)	25% (19-33%)	1.36 (1.24-1.49)
<b>Initiated <math>\leq</math> 90 days and retained and suppressed by 10 months</b>	<b>96 (51%)</b>	<b>119 (64%)</b>	<b>13% (3-23%)</b>	<b>1.26 (1.05-1.50)</b>
<i>Of those not initiated <math>\leq</math> 90 days and suppressed by 10 months:</i>				
Not initiated	54 (28%)	5 (3%)		
Initiated but not suppressed or with no viral load reported	40 (21%)	63 (34%)		
Initiated $\leq$ 90 days and retained at 10 months	121 (64%)	151 (81%)	17% (5-23%)	1.27 (1.12-1.44)
<i>Of those not initiated <math>\leq</math> 90 days and retained at 10 months:</i>				
Not initiated	54 (28%)	5 (3%)		
Initiated but not retained	15 (8%)	31 (17%)		

\*Adjusting for sex and baseline CD4 count did not alter these results

# How Long Did It Take?



Median time in clinic between study enrollment and ARV dispensing in rapid group: 2.4 hours (IQR 2.1-2.8 hours)

# Effect Modification by Site and by Age and Sex

Initiated $\leq$ 90 days and retained and suppressed by 10 months	Standard arm	Rapid arm	Crude relative risk [95% CI]*
Full sample	96/190 (51%)	119/187 (64%)	1.26 (1.05-1.50)
Site			
Primary health clinic	46 (43%)	67 (64%)	<b>1.50 (1.15-1.95)</b>
Hospital-based HIV clinic	50 (61%)	52 (63%)	1.04 (0.82-1.32)
Age and sex			
Male < 35	12/32 (38%)	32/45 (71%)	<b>1.90 (1.17-3.08)</b>
Male $\geq$ 35	31/53 (58%)	28/45 (62%)	1.06 (0.77-1.47)
Female < 35	28/60 (47%)	32/53 (60%)	1.29 (0.91-1.83)
Female $\geq$ 35	25/45 (56%)	27/44 (61%)	1.10 (0.78-1.57)

\*Effect observed in study; p-values for interaction terms for absolute risk differences were not significant

# Conclusions

It is possible to initiate nearly all eligible patients on ART (75% on the same day) and improve overall health outcomes

36%



**ART Initiation**

26%



**Viral Suppression**

# Conclusions (2)



Young



PHC



**Largest effect**

**Acceptable & Feasible**

Loss to follow up after ART initiation was higher,  
but not enough to offset benefits; adherence  
support after initiation remains a priority

# Recommendations / Next steps

“Consolidate and adjust the treatment guidelines to make rapid treatment initiation the standard rather than the exception”

## **NEXT STEPS**

- Estimate the cost and cost effectiveness of this approach
- Investigate the effectiveness of this approach without the use of rapid laboratory tests

# Acknowledgments

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