Does nurse initiation of ART improve access?


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Field Reports of Non-Physician Initiated ART

Setting	Programme	Impact on ART initiations
Lusikisiki, South Africa (MSF)[1]	12 more clinics	Reached 95% universal coverage in 2006
Thyolo, Malawi (MSF)[2]	7 more health centres Doubling of HSAs	Doubled ART enrolment
Scott Catchment area, Lesotho (MSF)[3]	14 more clinics	Doubled ART enrolment
Rwanda (FHI)[4]	3 clinics High level of doctor support	Not reported

1. Bedelu M et al. *J Infect Dis* 2007; 196(Suppl 3):S464-8.
2. Bemelmans et al. *Trop Med Int Health* 2010; 15(12):1413-20
3. Cohen R et al. J AIDS 2009; 12:23.
4. Sumbusho F et al. PLoS Med 2009; 6(10): e1000163

The Free State ART Programme 2004/5

Excellent outcomes among those who received ART

Mortality reduced by 86%

Each month of ART associated with an increase in CD4 cell count of 15.1 cells/µL

Demand for ART outweighed service capacity to prescribe it

14,500 patients had sought care

Only 2,500 had started ART

83% of deaths before ART could be started

Fairall L et al. *Arch Intern Med.* 2008;168(1):86-93.

STRETCH Trial Design

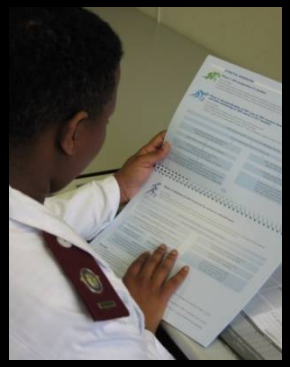
Cluster (clinic) trial with outcomes measured on 15,573 patients

QUESTION	PARTICIPANTS	PRIMARY OUTCOME	DESIGN
Nurse-led service as effective as a doctor-led one for patients on ART?	On ART ≥ 6 months	Viral load suppression	Equivalence
Improve on status quo, expanding access and reducing "waiting list" mortality?	CD4 ≤350 not yet on ART	Time to death	Superiority

Fairall L *et al*. *Lancet* 2012;380:889-98
Fairall L *et al*. *Trials* 2008; 9:21

STRETCH

Streamlining
Tasks and
Roles to
Expand
Treatment and
Care for
HIV



Educational outreach training using PALSA PLUS model

Change facilitator : STRETCH provincial co-ordinator

Participatory action approach to re-organisation of care:

- Local facility management teams
- STRETCH toolkit
- Phased introduction

Uebel K *et al*. *Implementation Science* 2011;6(1) 86

Pragmatic Trials

"The pragmatic attitude favours design choices that maximize applicability of the trial's results to usual care settings, rely on unarguably important outcomes such as mortality and severe morbidity, and are tested in a wide range of settings."

Zwarenstein M e*t al*. *BMJ* 2008;337:a2390

The context of the STRETCH trial

Cohort 2 (on ART ≥ 6 months) Outcomes

	Intervention group	Control group	Effect estimate*		p value	Intra-cluster correlation coefficient	Regression model*
			Type	Estimate (95% CI)			
Primary outcome							
Suppressed viral load†	2156/3029 (71%)	2230/3202 (70%)	Risk difference	1·1% (−2·3 to 4·6)	0·534	0·010	Binomial
Secondary outcomes							
Time to death‡	..	..	Hazard ratio	1·05 (0·84 to 1·31)	0·684	0·005	Cox
Programme retention§	2733/3029 (90%)	2926/3202 (91%)	Risk difference	−0·3% (−2·1 to 1·54)	0·758	0·013	Binomial
New tuberculosis diagnosis	119/3029 (4%)	113/3202 (4%)	Risk difference	0·21% (−0·40 to 0·84)	0·487	0·019	Binomial
Received co-trimoxazole prophylaxis	2143/3029 (71%)	2578/3202 (81%)	Risk difference	9·8% (−33·7 to 14·2)	0·424	0·477	Binomial
Change in ART drugs during trial	161/3029 (5%)	57/3202 (2%)	Risk difference	1·25% (0·65 to 1·86)	<0·001	0·044	Binomial
Weight at follow-up (kg)	63·0 (13·5); n=2136	63·2 (14·1); n=2271	Difference in means	0·62 (0·01 to 1·23)	0·045	0·010	Linear
CD4 count at follow-up (cells per μL)	438·8 (219·5); n=1733	418·4 (201·8); n=1691	Difference in means	24·2 (7·2 to 41·3)	0·007	0·007	Linear

Fairall L *et al*. *Lancet* 2012;380:889-98

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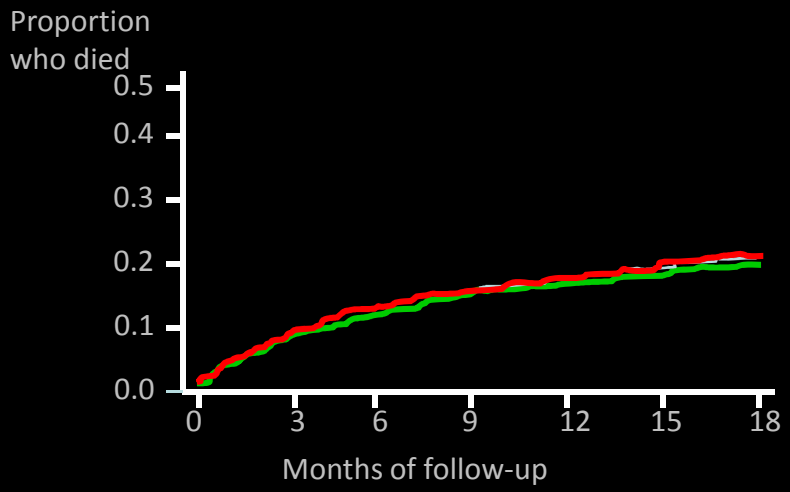
Cohort 2 (CD4 ≤ 350 not yet on ART) Secondary outcomes

	Intervention group	Control group	Effect estimate*		p value	Intra-cluster correlation coefficient	Regression model*
			Type	Estimate (95% CI)			
Started on ART	3712/5390 (69%)	2418/3862 (63%)	Risk ratio	1·24 (0·88 to 1·73)	0·218	0·065	Binomial
Time to ART†‡	..	..	Subdistribution hazard ratio	1·14 (0·92 to 1·43)	0·232	0·065	Competing risk
New tuberculosis diagnosis	1057/5390 (20%)	510/3862 (13%)	Risk ratio	1·46 (1·18 to 1·81)	0·001	0·051	Binomial
Received co-trimoxazole prophylaxis	3899/5390 (72%)	2767/3862 (72%)	Risk ratio	1·03 (0·93 to 1·13)	0·608	0·149	Binomial
Programme retention§	3373/5390 (63%)	2254/3862 (58%)	Risk ratio	1·10 (1·04 to 1·16)	<0·001	0·019	Binomial
Baseline CD4 cell count of patients starting ART	132 (82); n=3470	131 (82); n=2083	Difference in means	0·102 (−13·1 to 13·4)	0·988	0·030	Linear
Suppressed viral load in patients who started ART¶	1706/2375 (72%)	1062/1449 (73%)	Risk ratio	0·97 (0·90 to 1·03)	0·324	0·040	Binomial
Proportion with a missing viral load in patients who started ART	1274/3712 (34%)	945/2219 (43%)	Risk ratio	0·86 (0·71 to 1·04)	0·120	0·014	Binomial
Weight at follow-up (kg)	62·6 (14·0); n=2712	62·4 (13·7); n=1503	Difference in means	0·10 (−1·35 to 1·56)	0·884	0·019	Linear
CD4 count at follow-up (cells per μL)	161·3 (175·2); n=2345	141·7 (161·6); n=1544	Difference in means	22·3 (3·6 to 40·9)	0·021	0·026	Linear

Fairall L *et al*. *Lancet* 2012;380:889-98

Cohort 1 (CD4 ≤ 350 not yet on ART)
Primary outcome

STRETCH in green
Control in red



HR 0.92 (95% CI 0.76 – 1.15; p 0.532)

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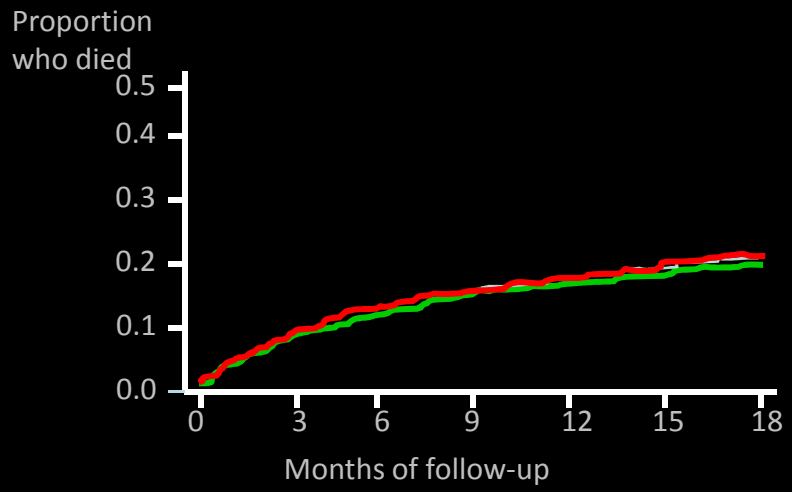

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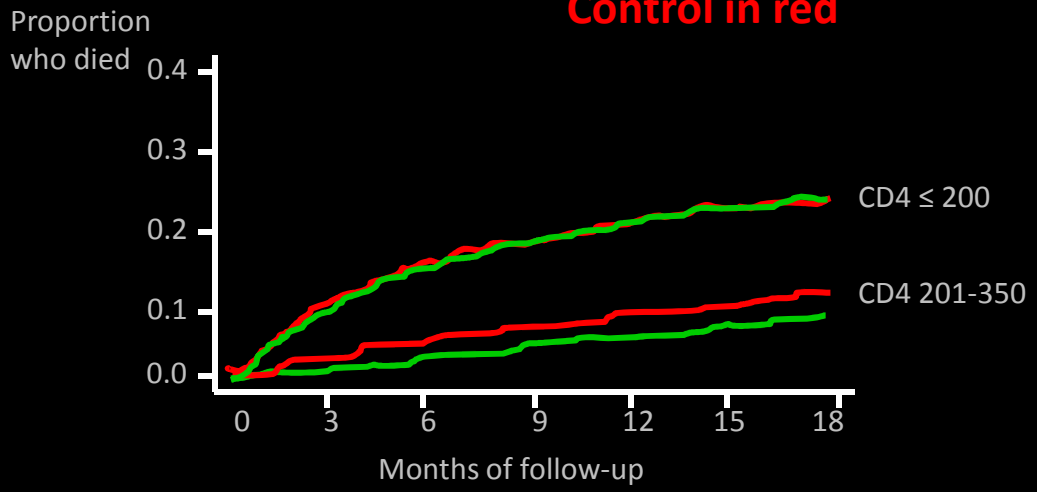

CD4 count ≤ 200
HR 1.00 (95% CI 0.52 – 1.00; p 0.020)

CD4 count 201-350
HR 0.73 (95% CI 0.54 – 1.00; p 0.052)

Interaction term p 0.050

Cohort 2 (CD4 ≤ 350 not yet on ART) Secondary outcomes

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Profile of ART initiators at trial clinics

ART INITIATORS	INTERVENTION n=16	CONTROL n=15
Baseline		
Doctor	5	8
Nurse	0	0
Either	5	8
Follow-up		
Doctor	7	11
Nurse	14	0
Either	14	11

26% *Proportion of intervention group patients started on ART who were initiated by a nurse*

Why so low?

Didn't intend for nurses to start 100% who needed treatment

Context not always supportive ("breaking the law")

Initiation more complex than re-prescribing

Clinical confidence grew slowly

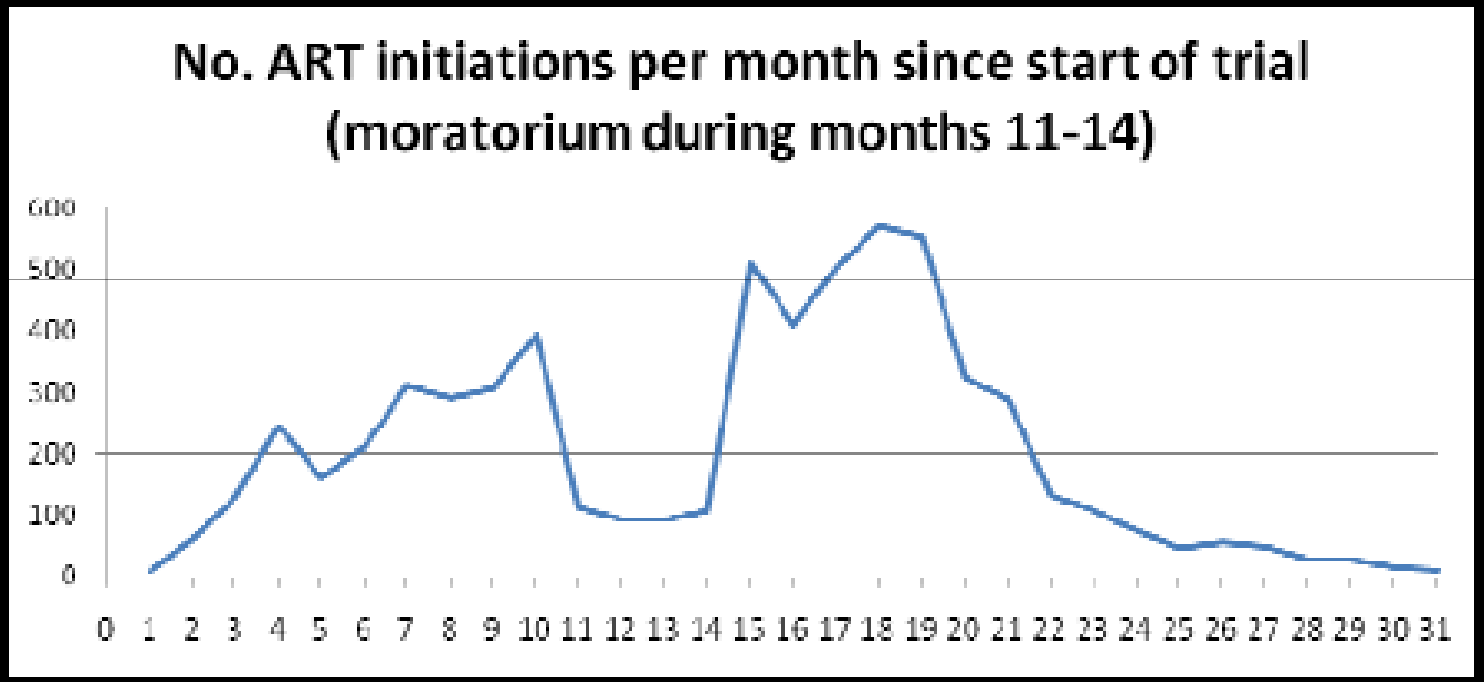
Tendency to defer to doctors if available

Tendency to practise as a collective

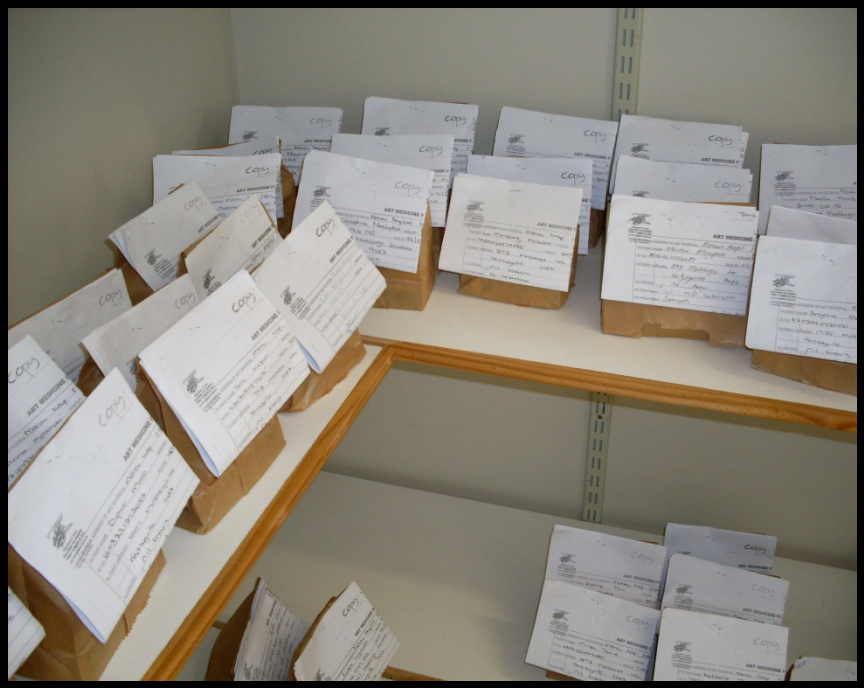
Moratorium on ART initiations

Fairall L et al. *Arch Intern Med.* 2008;168(1):86-93.
Georgeu D et al. *Implementation Science* 2012,7:66

Effect of moratorium on ART initiations



Streamlining Tasks and Roles…
but *not* drug distribution!



Lesson 1

Nurses are safe

Lesson 2

Number of initiating sites more important than number of initiators

Lesson 3

Nurses practise collectively and follow guidelines

Lesson 4

There are other obstacles to scale-up

Lesson 5

“The nurses can do everyone’s job, but no one can do the professional nurse’s job. That is a problem, so we are overloaded. We are really exhausted.”

Task-shifting has ripple effects


STRETCH trainer
"We can stretch ourselves very far. This is our sisters, our brothers, our mothers we are nursing. Otherwise we would have gone to Australia or UK to work."
60

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• Their patients especially those who died before they could be started on ART

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