

“Task-shifting” for HIV Care

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The human resources crisis:

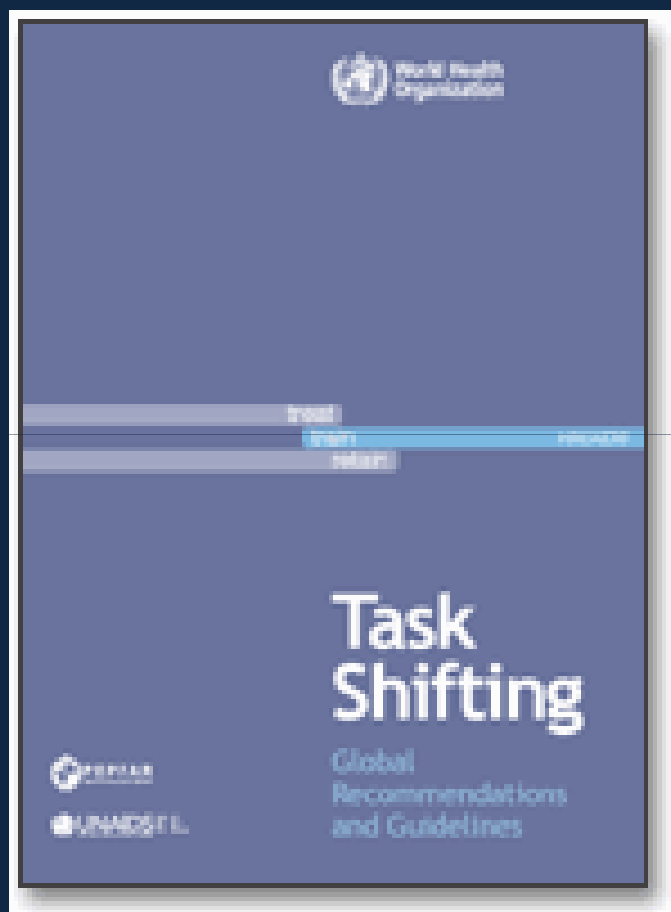
Health care personnel (doctors and nurses)
per 100 000 population

	South Africa	Botswana	Ghana	Tanzania	Malawi	USA	UK
Doctors	69.2	28.7	9.0	2.3	1.1	230	256
Nurses	388	241	64	113	36.6	1212	937

Source: The world health report – Working together for health. Geneva, World Health Organization, 2006

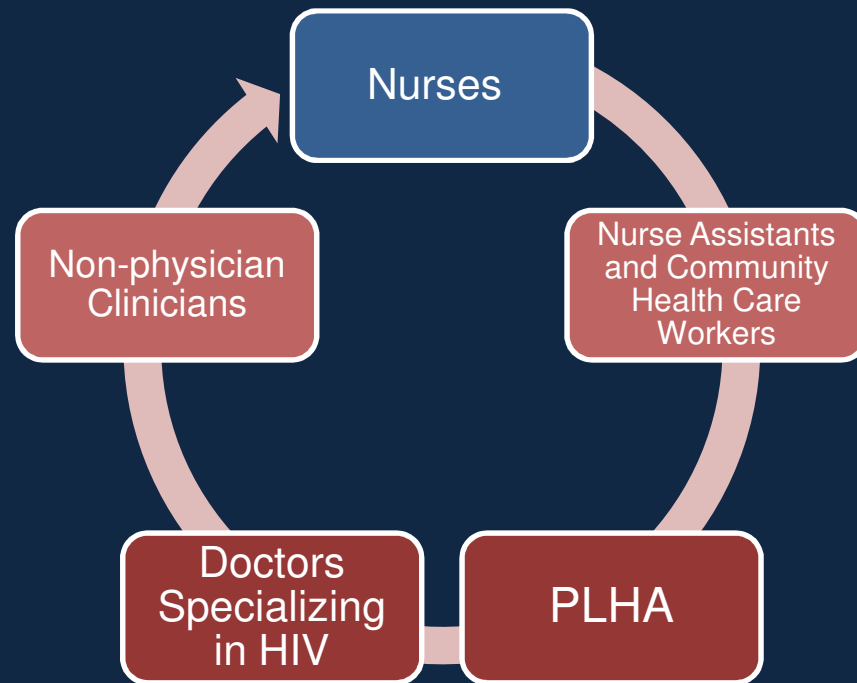
<http://www.who.int/whr/2006/en>. accessed 27 April 2007.

Addis Abba Declaration Jan 2008



- Africa qualifies 5100 doctors per year
- Americas qualify 68,500 per year

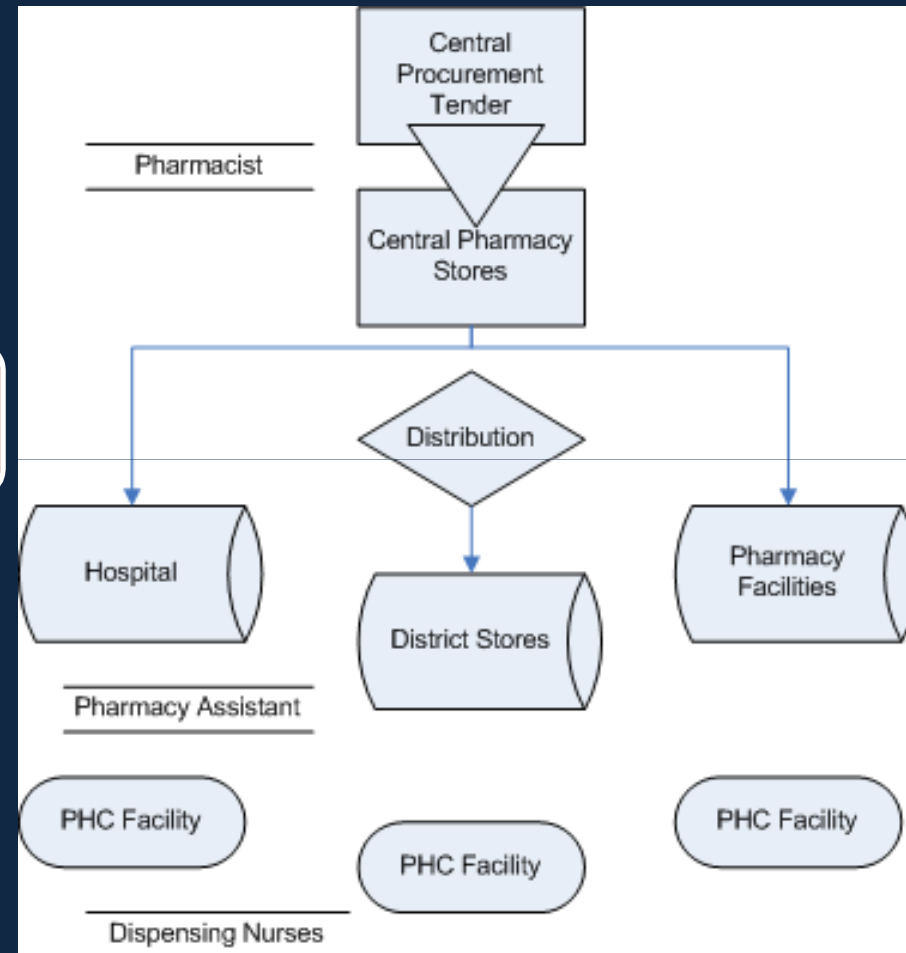
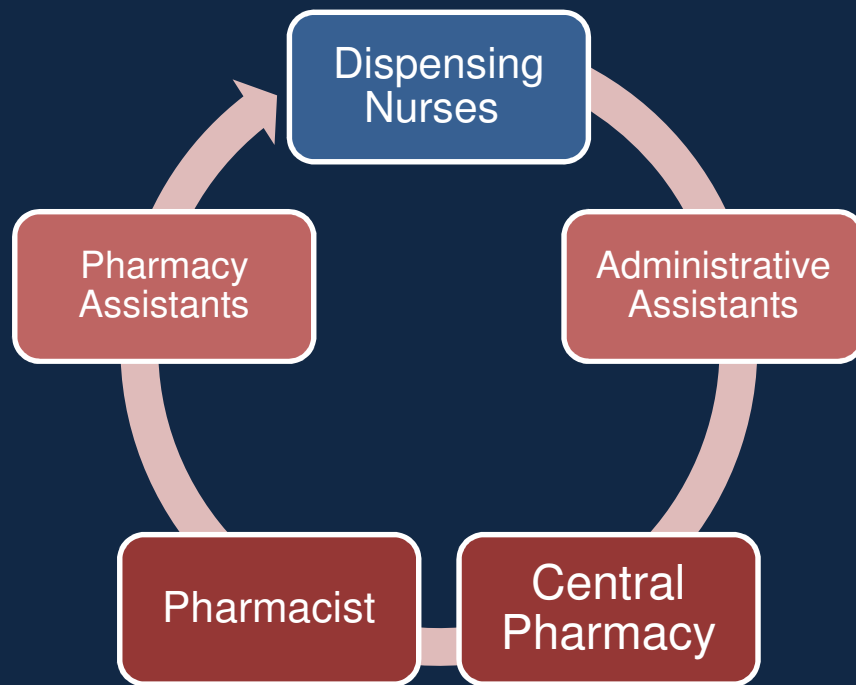
Definition of “Task-Shifting”



“....a process of delegation whereby tasks are moved, where appropriate, to less specialized health workers. By reorganizing the workforce in this way, task shifting can make more efficient use of the human resources currently available.

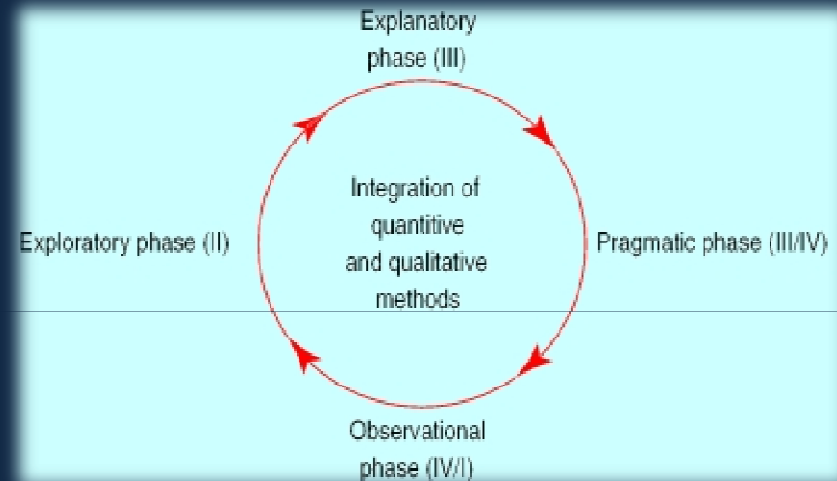
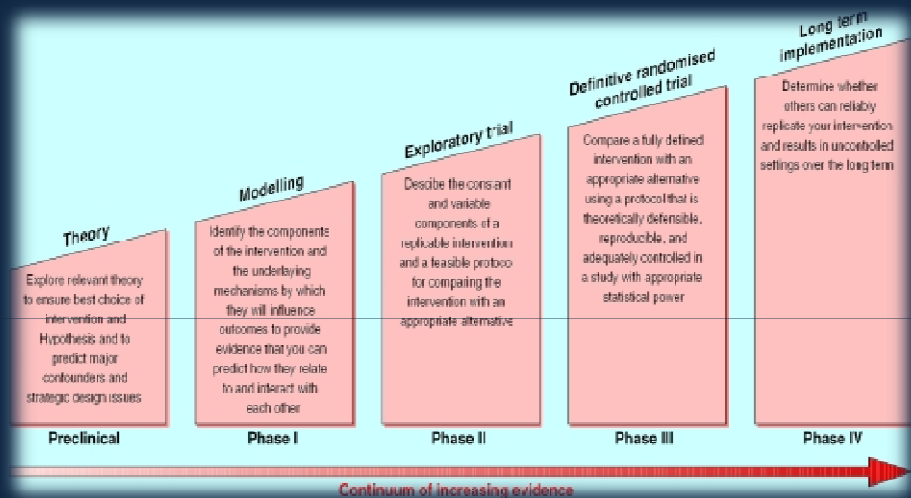
For example, when doctors are in short supply, a qualified nurse could often prescribe and dispense antiretroviral therapy. Further, community workers can potentially deliver a wide range of HIV services thus freeing the time of qualified nurses. Training a new community health worker takes between one week and one year depending on the competencies required. This compares with three or four years of training required for a nurse to fully qualify.”

Definition of “Task-Shifting”



REF: Ian's Modification for Pharmacy Personnel

Sequencing Pragmatic and Explanatory Trials



Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ*. 2000;321:694–696

“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 et al. *BMJ* 2008;337:a2390

Summary of Presentation

- Randomized clinical trial
- Cluster Randomized Trial
- Implementation research
- Pharmacy programme
- Regulatory environment
- Closing

Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised non-inferiority trial



Ian Sanne, Catherine Orrell, Matthew P Fox, Francesca Conradie, Prudence Ive, Jennifer Zeinecker, Morna Cornell, Christie Heiberg, Charlotte Ingram, Ravindre Panchia, Mohammed Rassool, René Gonin, Wendy Stevens, Handré Truter, Marjorie Dehlinger, Charles van der Horst, James McIntyre, Robin Wood, for the CIPRA-SA Study Team*

Lancet 2010; 376: 33-40

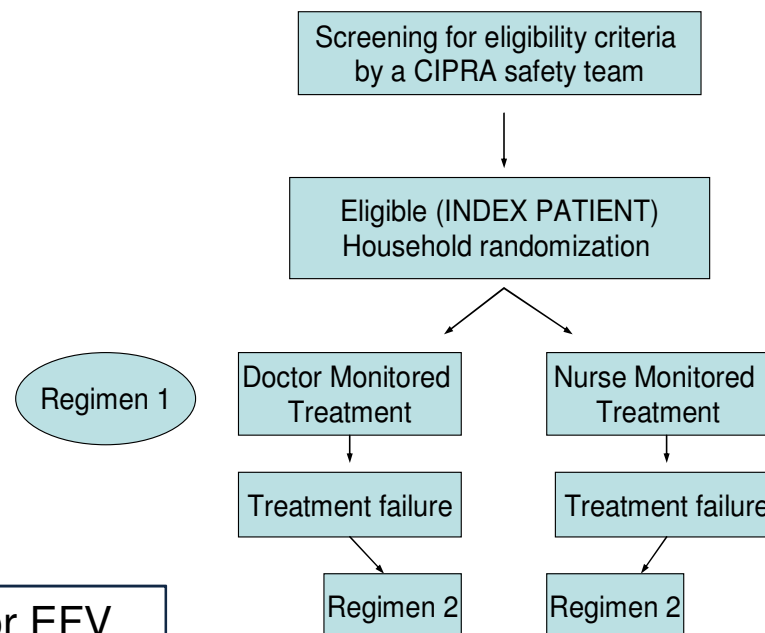
This online publication has been corrected.
The corrected version first appeared at TheLancet.com September 24, 2010

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Guideline regimens: D4T, 3TC, NVP or EFV
AZT, DDI, LPV/rit



Objective, study population

- To demonstrate that a first line antiretroviral therapy regimen, administered at a primary health care level monitored by sisters (investigative arm), is not inferior to a doctor monitored treatment (standard/control arm), as measured by cumulative treatment failure rate.
- Inclusion criteria
 - Adults >16 yrs
 - CD4 + <350 and or WHO 3 and 4 AIDS defining illness
- Exclusion criteria
 - Current active OI
 - Use of prior HAART (excluding MTCT)
- 80% power to demonstrate a 1.40 difference

Randomisation

	Nurse Arm		MO Arm	
Female	297	(73.5%)	273	(67.4%)
Age median years (IQR)	32.3	(28.0-36.6)	32.2	(28.0-37.4)
BMI (kg/m ²), median (IQR)	23.5	(21.3-27.6)	23.5	(20.4-26.8)
CDC Classification				
Class A (%)	159	(39.4%)	140	(34.4%)
Class B (%)	110	(27.2%)	117	(28.8%)
Class C (%)	134	(33.2%)	150	(36.8%)
Missing (%)	1	(0.2%)	1	(0.2%)
CD4 Count (cell/mL)				
< 200 (%)	260	(64.4%)	257	(63.1%)
200 - 350 (%)	119	(29.5%)	130	(31.9%)
350 - 500 (%)	23	(5.7%)	18	(4.4%)
>500 (%)	2	(0.5%)	2	(0.5%)
Median (IQR)	157	(100-230)	161	(105-218)
Viral load (copies/mL)				
<= 100,000 (%)	181	(44.8%)	169	(41.5%)
> 100,000 (%)	223	(55.2%)	238	(58.5%)
Log mean viral load (Std Dev.)	5.09	(0.75)	4.99	(0.73)

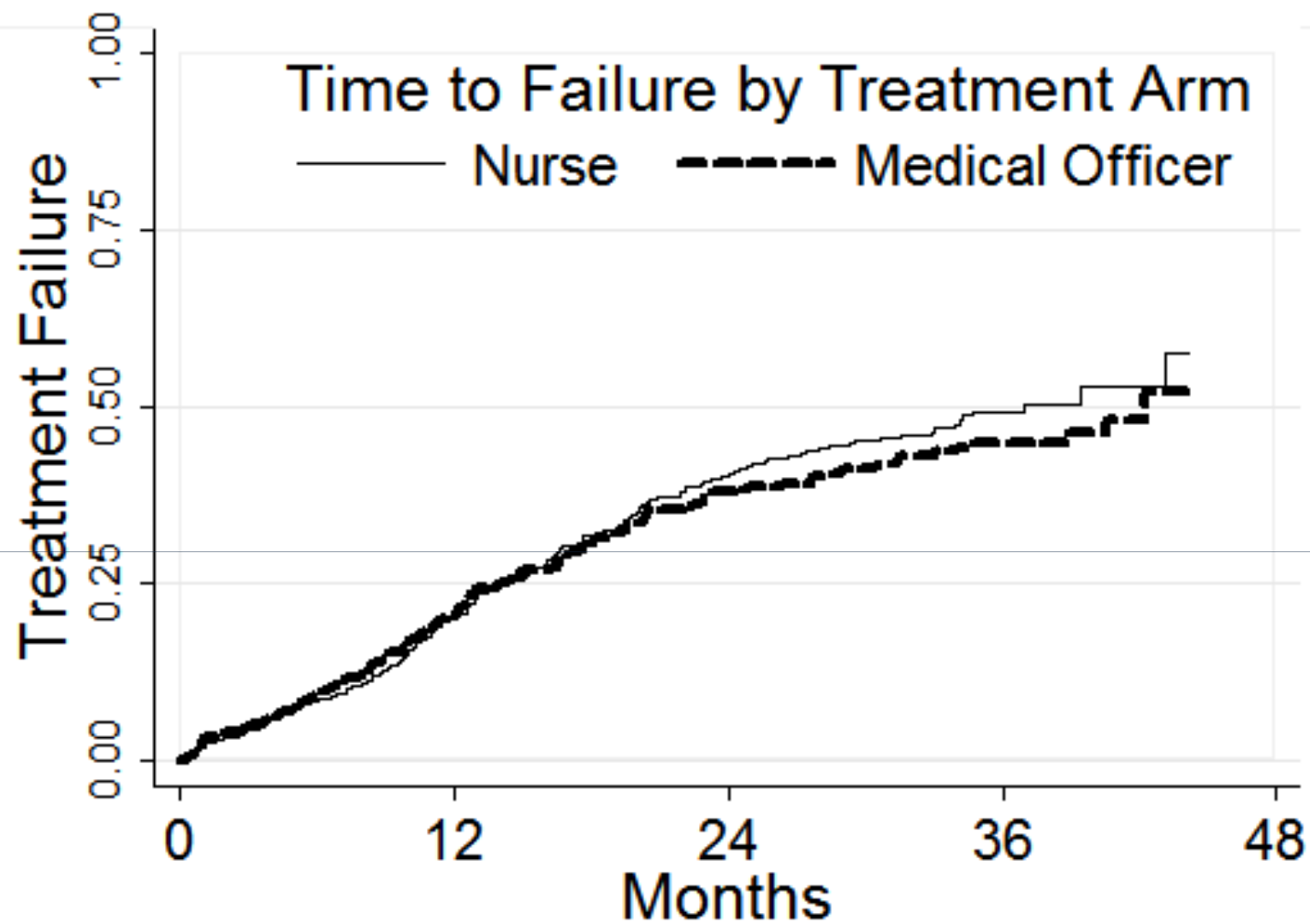
ART Regimens Table 2

Assigned regimens	Nurse Arm		MO Arm	
	No	Percent	No	Percent
D4T+3TC+EFV (%)	293	(72.5 %)	304	(74.5 %)
D4T+3TC+NVP (%)	72	(17.8 %)	81	(19.9 %)
D4T+3TC+LPV/r (%)	35	(8.7 %)	20	(4.9 %)
D4T+3TC+NFV (%)	4	(1.0 %)	3	(0.7 %)

Primary analysis

Variable		Medical Officer	Relative Risk (95% CI)
CUMULATIVE FAILURE	192/404 (47.5%)	179/408 (43.9%)	1.09 (0.89 – 1.33)

- Nurses are non-inferior to doctors in monitoring first line ART treatment in treatment naïve HIV-1 infected patients
- CI boundary within HR < 1.40 as set in the protocol



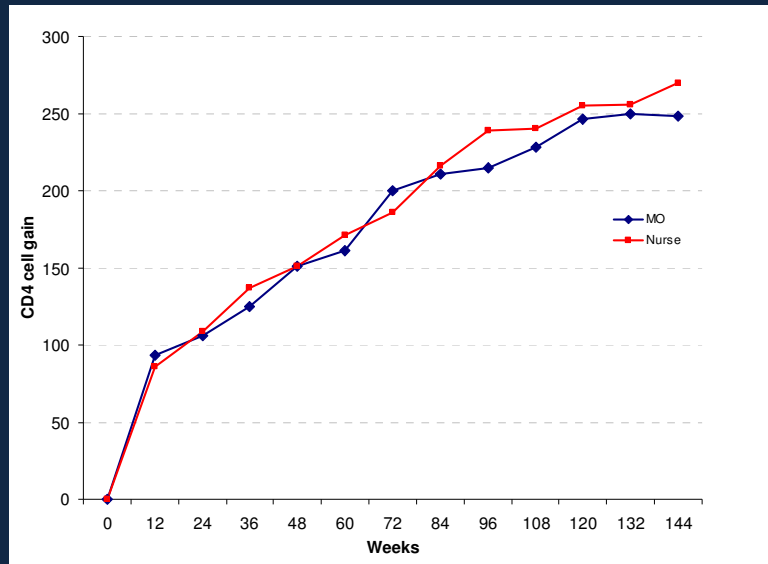
N - (Event)

Nurse	404	(83)	319	(78)	235	(26)	61	(4)	0
Medical Officer	408	(81)	325	(73)	243	(19)	66	(3)	0

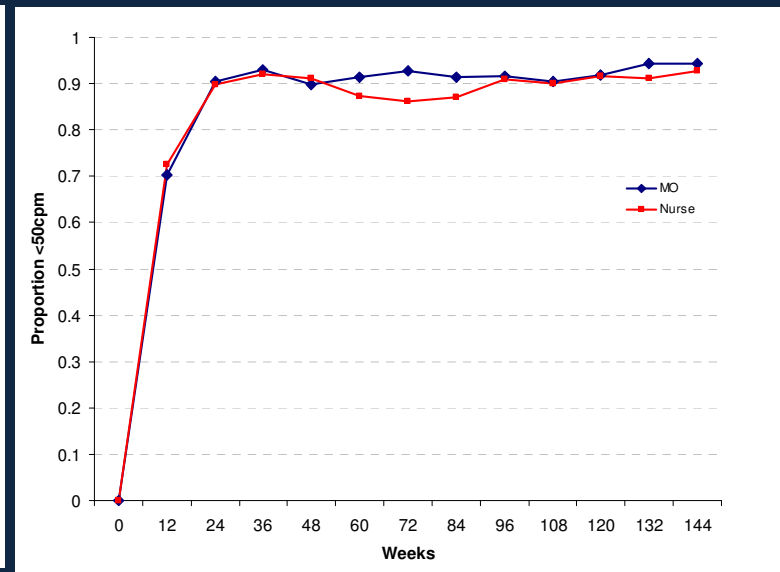
Toxicity Failures

- Protocol mandated end point if the following criteria were met
 - >42 days Treatment interruption due to Grade 3 or 4 adverse drug reaction
 - ACTG toxicity tables were modified during the study including lactate
 - After DSMB in June 2007, the grading of hyperlactataemia was changed with retraining at sites.

HIV treatment outcomes

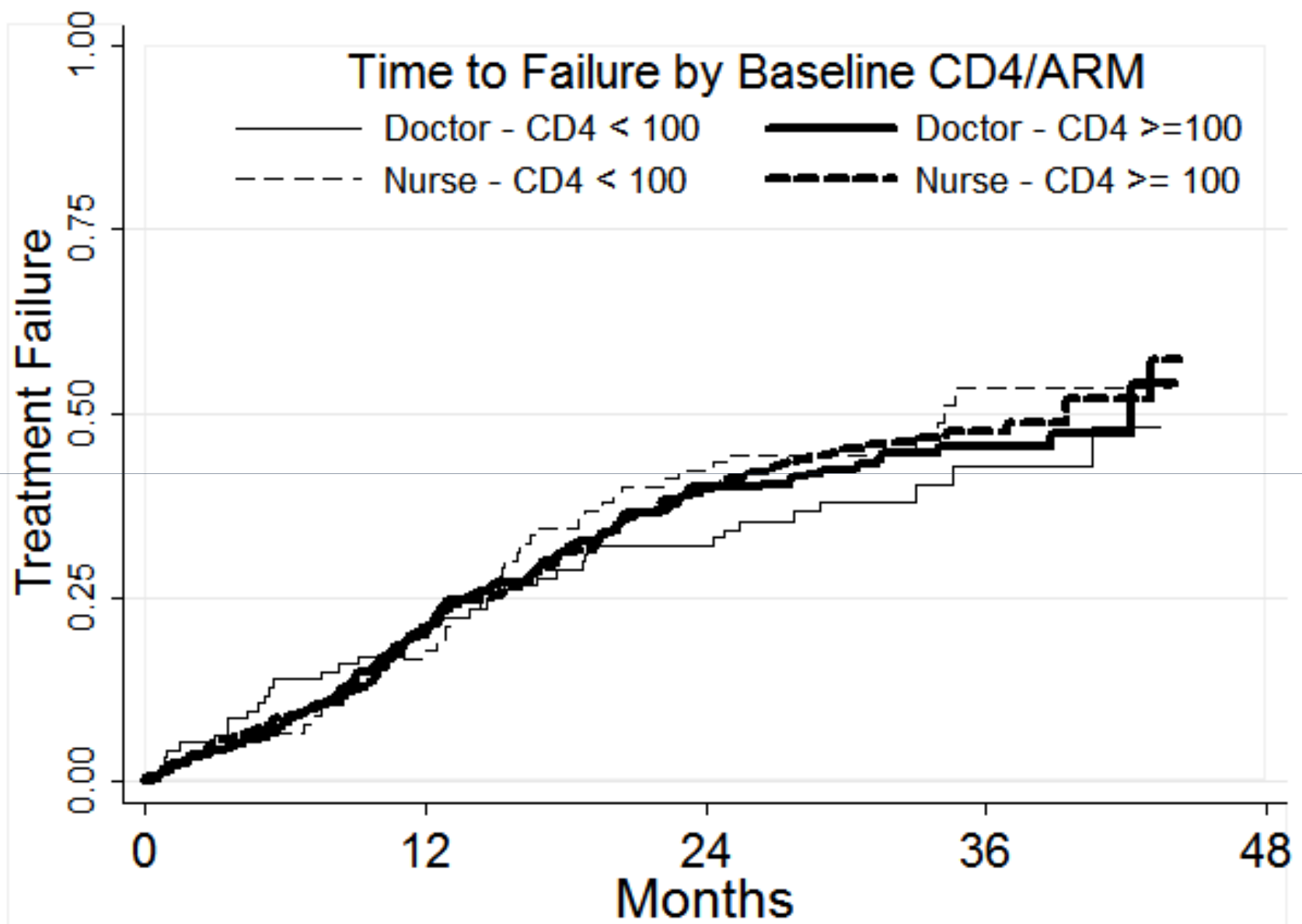


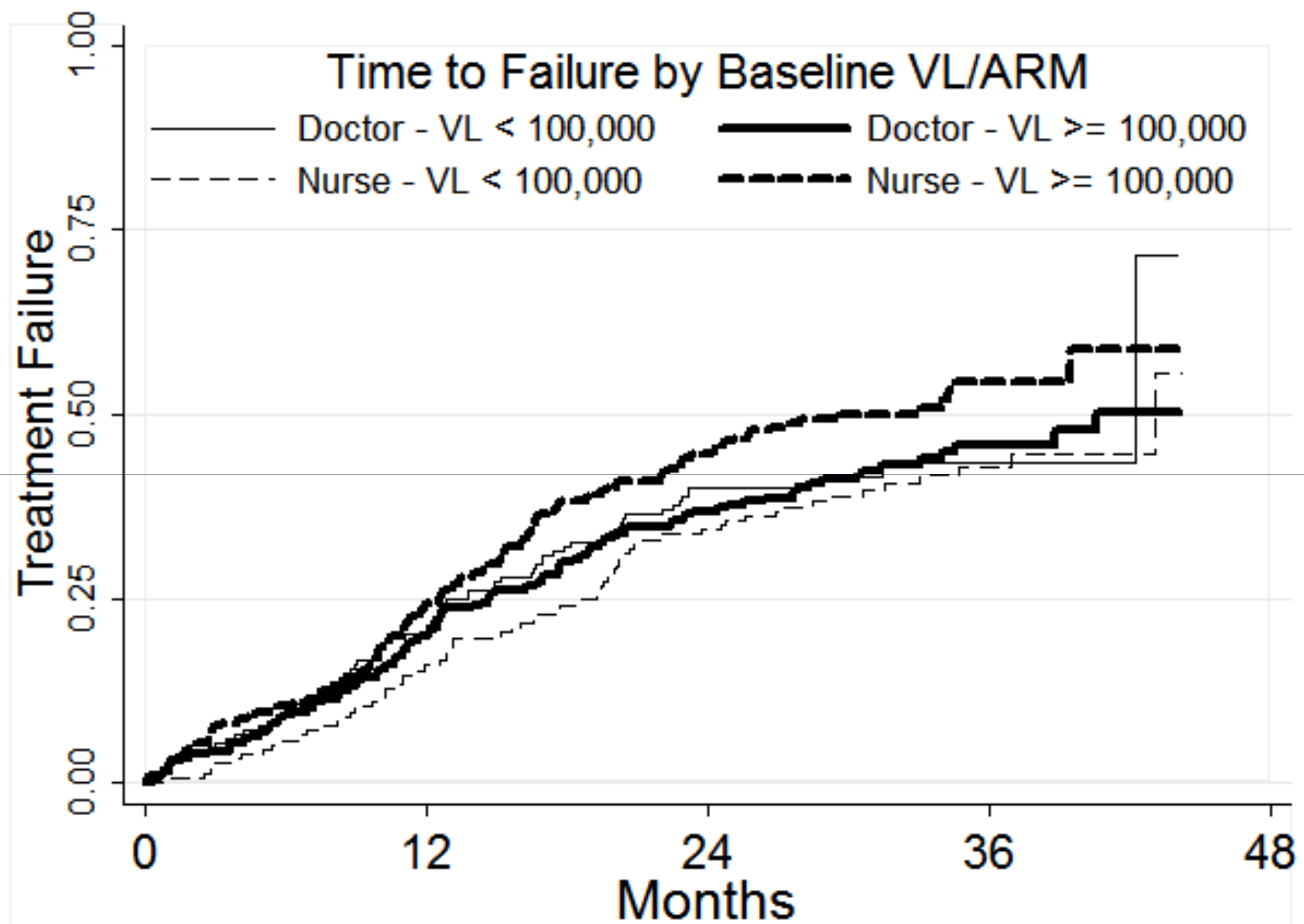
Treatment CD4+ count gain

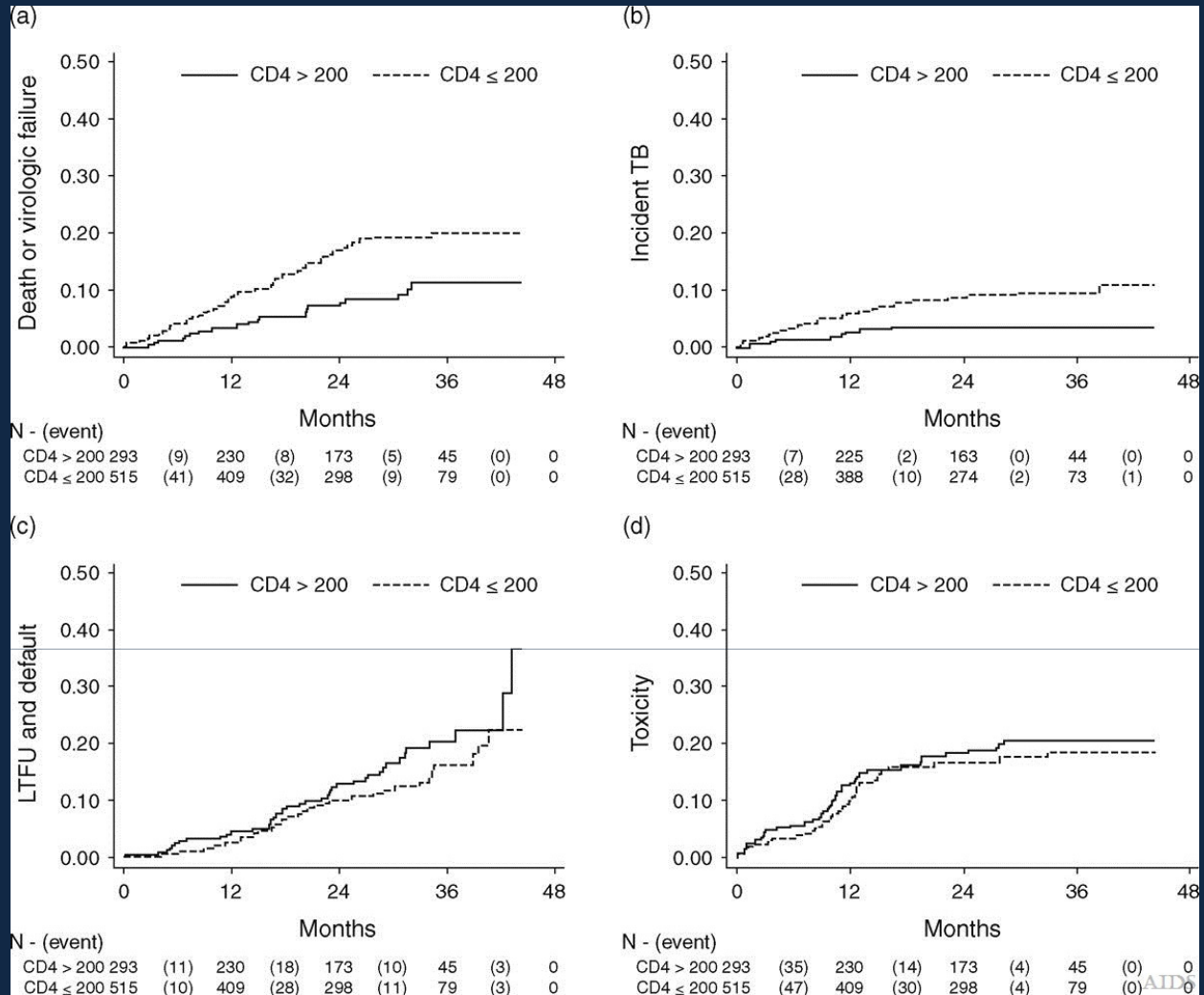


Proportion viral load undetectable <50c/ml

- Modified intention to treat
- No difference in the treatment efficacy
- Increased recognition of Respiratory, Cardiovascular and Peripheral Neuropathy adverse events







Initiating patients on antiretroviral therapy at CD4 cell counts above 200 cells/ μ l is associated with improved treatment outcomes in South Africa

Fox, Matthew Pa,b,c,d; Sanne, Ian Mc; Conradie, Francesca^c; Zeinecker, Jennifer^e; Orrell, Catherine^e; Ive, Prudence^c; Rassool, Mohammed^c; Dehlinger, Marjorie^f; van der Horst, Charles^g; McIntyre, James^h; Wood, Robin^e

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Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial



Lara Fairall, Max O Bachmann, Carl Lombard, Venessa Timmerman, Kerry Uebel, Merrick Zwarenstein, Andrew Bouille, Daniella Georgeu, Christopher J Colvin, Simon Lewin, Gill Faris, Ruth Cornick, Beverly Draper, Mwala Tshabalala, Edivan Kotze, Cloete van Vuuren, Dewald Steyn, Ronald Chapman, Eric Bateman

Lancet 2012; 380: 889-98

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[S0140-6736\(12\)60730-2](http://dx.doi.org/10.1016/S0140-6736(12)60730-2)

See Comment page 885

Knowledge Translation Unit,
University of Cape Town Lung
Institute (L Fairall PhD)

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

STRETCH

Streamlining

Tasks and

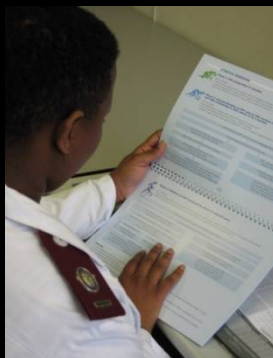
Roles to

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

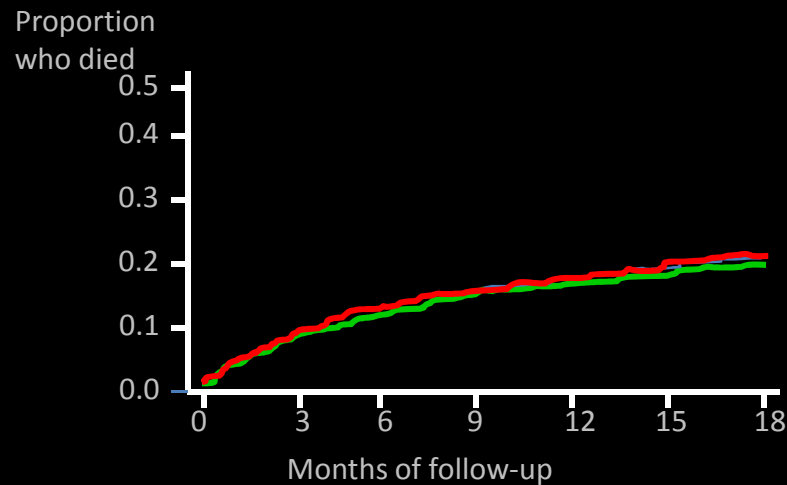
Results: STRETCH

- Similar treatment outcomes, VL suppression, no improvement in survival
- No difference in the % started on ART
- Improvements in proportion of patients on ART CD4+ 200-350
- started at the same mean ART=132 cells/mm³

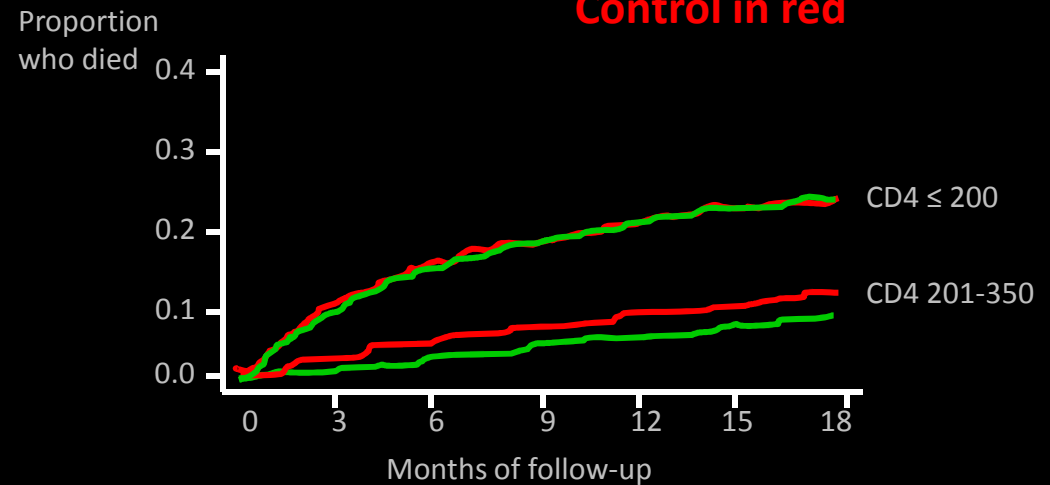
Cohort 1 (CD4 \leq 350 not yet on ART)

Primary outcome

STRETCH in green
Control in red



HR 0.92 (95% CI 0.76 – 1.15; p 0.532)



CD4 count \leq 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

The context of the STRETCH trial



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

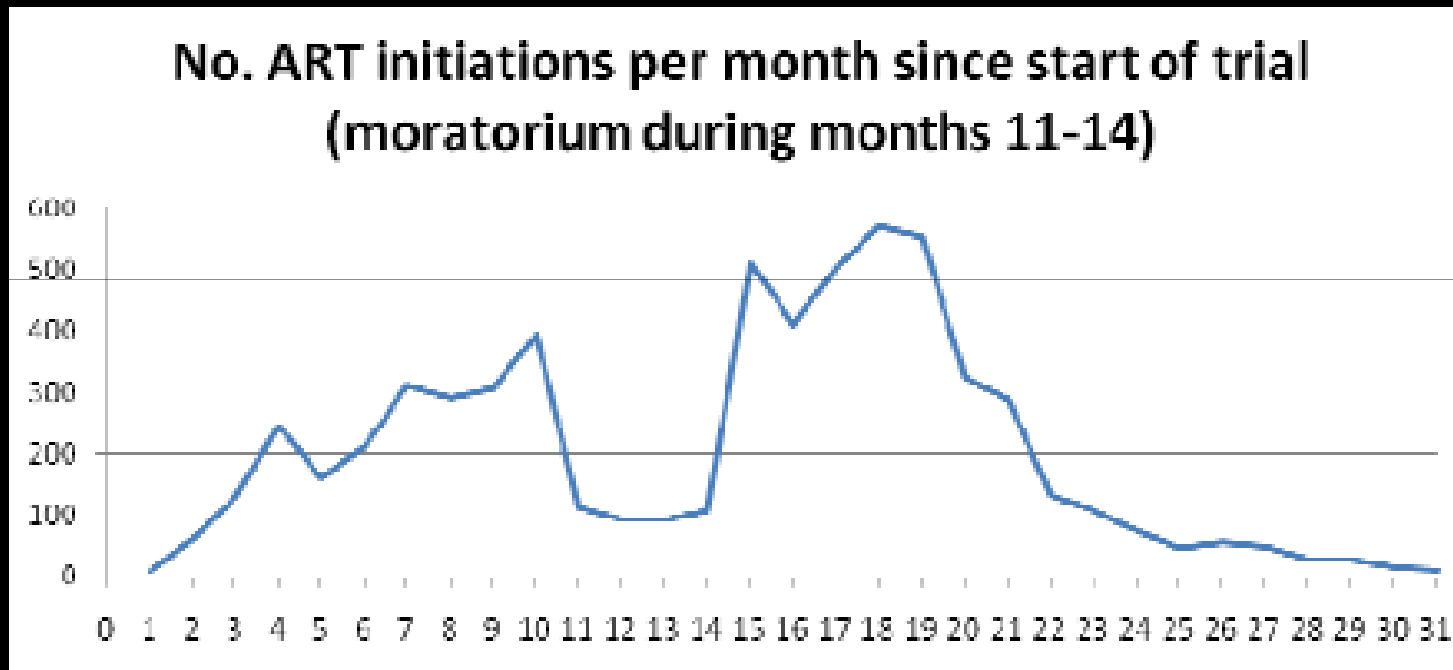
Tendency to practise as a collective

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

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Treatment Outcomes and Cost-Effectiveness of Shifting Management of Stable ART Patients to Nurses in South Africa: An Observational Cohort

Lawrence Long^{1,2*}, Alana Brennan^{1,2,3}, Matthew P. Fox^{1,2,3,4}, Buyiswa Ndibongo^{1,2}, Imogen Jaffray⁴, Ian Sanne^{1,2,4}, Sydney Rosen^{1,2,3}

1 Health Economics and Epidemiology Research Office, Wits Health Consortium, Johannesburg, South Africa, **2** Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, **3** Center for Global Health and Development, Boston University, Boston, Massachusetts, United States of America, **4** Department of Epidemiology, Boston University School of Public Health, Boston University, Boston, Massachusetts, United States of America, **5** Right to Care, Johannesburg, South Africa

PLoS Med. 2011 Jul;8(7):e1001055. Epub 2011 Jul 19.

To evaluate this strategy, we compared doctor initiated patients eligible for nurse management who received either:

Doctor management (N=1620)

Nurse management (N=540)

Conducted a retrospective cohort study

Matched on age, gender, CD4 count, time on ART, and regimen using propensity scores

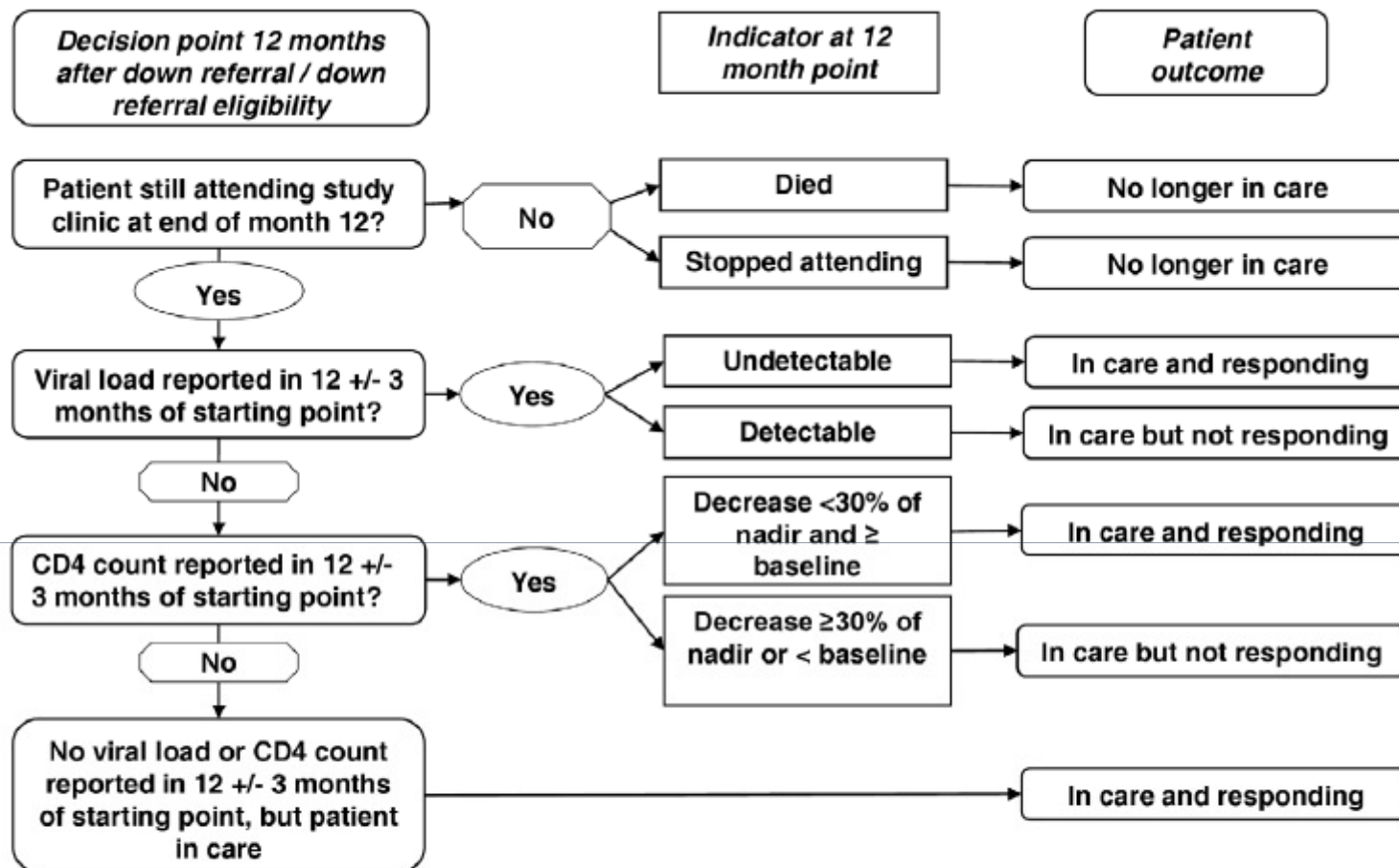


Figure 1. Decision process for assigning HIV treatment outcomes. Patients were placed in a mutually exclusive patient outcome category 12 mo after study enrolment – no longer in care, in care and responding or in care and not responding. Patient outcomes were defined based on the patient's vital status, presence in the clinic, viral load or CD4 count at 12 mo after study enrolment. For those patients alive and in treatment, viral load was the preferred outcome indicator, but in the absence of viral load CD4 count was used and if neither were available then it was assumed the patient was in care and responding based on their presence in the clinic. The diagnostic result closest to 12 mo, but within 3 mo (9–15 mo) was used. doi:10.1371/journal.pmed.1001055.g001

Results: Baseline Characteristics

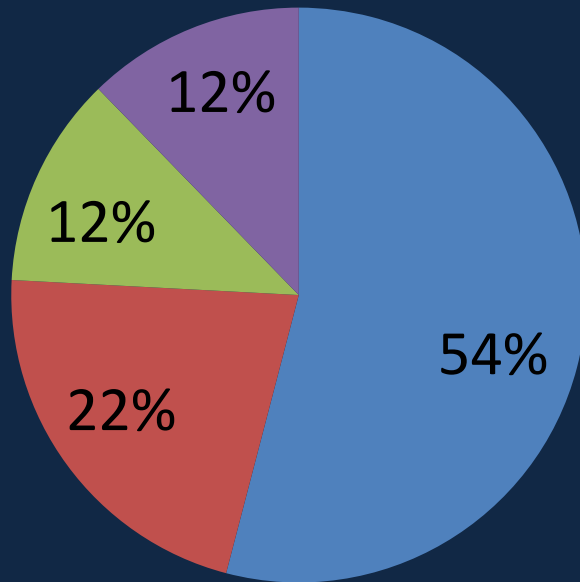
Variable	Nurse managed	Doctor managed
N	540	1620
Mean age at study enrolment (years)	38.7	38.9
Median CD4 count at ART initiation (cells/mm ³)	103	94
Median CD4 count at study enrolment (cells/mm ³)	393	384
Mean duration on ART at study enrolment (months)	13.2	13.2
ARV regimen at study enrolment (%)		
D4T-3TC-EFV	67.4	66.9
AZT-3TC-EFV	27.2	26.9
Other	5.4	6.2

Results 2 – 12 Month Outcomes

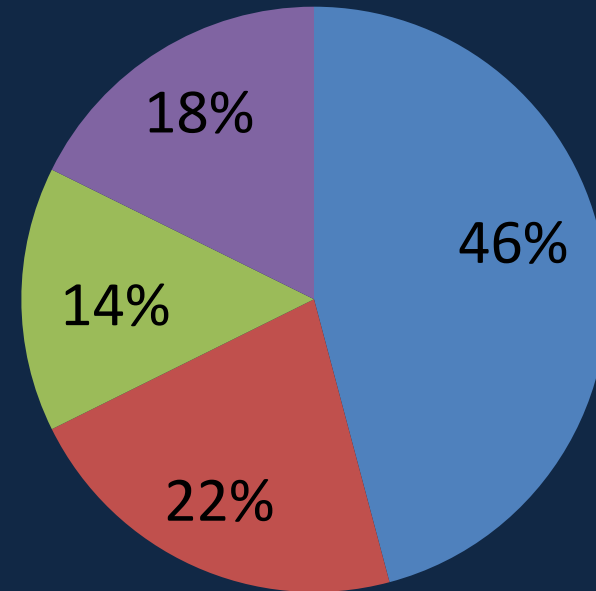
	Number events (n, %)	Rates / 100 pyrs	Crude RD (95% CI)
Loss to follow-up (defined as having not attended the clinic in four months)			
Nurse managed	12 (1.7%)	1.7	0
Doctor managed	94 (4.4%)	4.6	2.7% (1.4%-4.0%)
Mortality			
Nurse managed	1 (0.14%)	0.1	0
Doctor managed	24 (1.1%)	1.2	1.0% (0.5%-1.5%)
Viral load rebound (unsuppressed ≥ 400 copies/mL by 12 months)			
Nurse managed	22 (3.1%)	-	0
Doctor managed	102 (4.8%)	-	2.4% (0.7%-4.1%)
		Difference (95% CI)	
Difference in mean CD4 response (cells/mm³)			
Nurse vs. Doctor		-7 (-19.3-5.0)	

Results 4: Cost Breakdown

- Treatment outcomes in care and responding nurse vs. doctor 95% vs. 89%
- \$ 67/ann. cost



Nurses



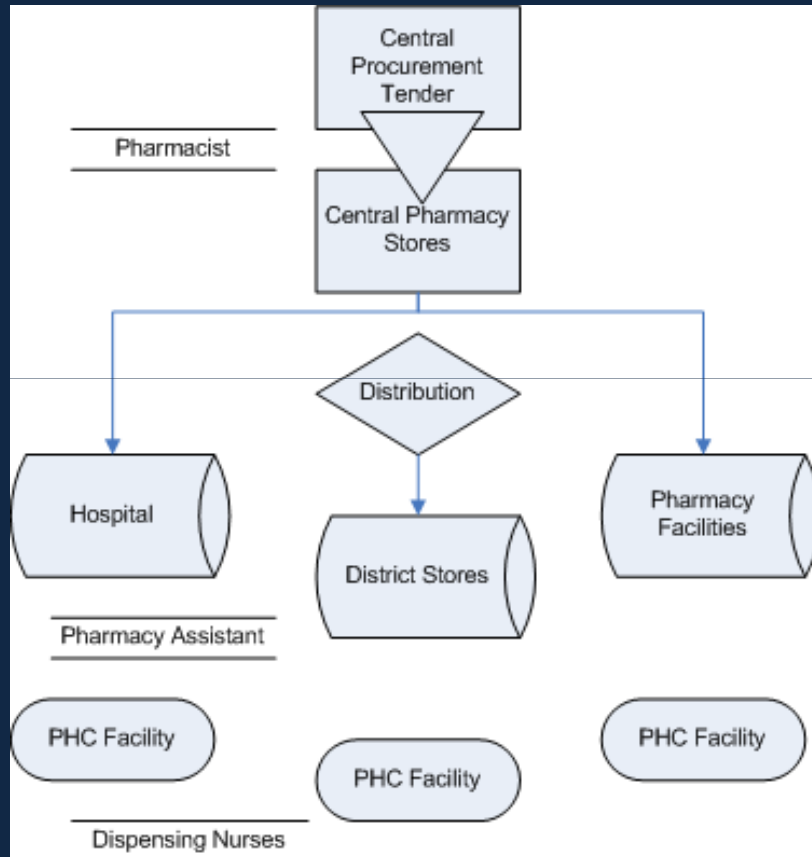
Doctors

■ Drugs ■ Lab tests ■ Outpatient visits ■ Fixed costs

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Pharmacy programme



- Procurement success
- Pharmacy management systems
- Pharmacy Assistants (register closes 2017)
- Pharmacy Technicians (first training 2013)
- District Pharmacy Systems

Scope of practice

Regulatory environment

- Pharmacy regulations
- Nursing council
- Health Professionals Council

- Community Health Care Workers
- Pharmacy Technicians
- Primary Health Care Nurses

Conclusions

- Task-shifting may be facilitated by guideline changes:
 - Less toxic treatment regimens
 - Fixed dose combinations
 - TDF, FTC, EFV
 - AZT, 3TC, ATV/r
 - Higher CD4+ count
 - Simplified laboratory monitoring schedule

Conclusions

- Nurses are the backbone of the health system and are equivalent to doctors in managing HIV
- Pharmacy programmes depend on task-shifting
- Training and capacity is limited by the scope of practice discussions (HPCSA, Nursing Council, Pharmacy Council)
- Health system decisions require more dedicated planning and a responsive regulatory environment

Acknowledgements

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Robin Wood

Lind-Gail Bekker

Catherine Orrell

Jennifer Zeinecker

HEERO – Boston University

Sydney Rosen

Mathew Fox

Gesine Meyer-Rath

Jonathan Simone

Kate Bistline

National Health Laboratory Services

Wendy Stevens

Carole Wallis

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Gauteng Department of Health

National Department of Health

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