THE LANCET

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Fairall L, Bachmann MO, Lombard C, et al. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. *Lancet* 2012; published online Aug 15. http://dx.doi.org/10.1016/S0140-6736(12)60730-2.

Appendix

Table 1. Components of the intervention compared to model of care at control clinics

Component	Intervention clinics	Control clinics
Patient management guidelines	STRETCH edition of the PALSA PLUS* guidelines with algorithms for starting and monitoring ART. Patients were eligible for ART if: • CD 4 count ≤200 cells per μL or • Stage IV infection (AIDS) or • Pregnant with CD4 count ≤350 cells per μL Patients were eligible for nurse initiation of ART if: • CD4 count 51-200 cells per μL • No Stage IV infection (AIDS) • No previous ART ≥ 1 month • Not bed- or wheelchair bound • Not using drugs other than cotrimoxazole or vitamins • Weight >40kg and BMI <28 Patients were eligible for nurse re-prescription of ART if: • Undetectable viral load • No severe side-effects • No new opportunistic infections Patients not fulfilling these criteria were referred to a doctor for initiation or re-prescription of ART.	PALSA PLUS guidelines covering the management of HIV/AIDS, sexually transmitted infections and tuberculosis. Eligibility criteria for ART were the same, but all ART was to be initiated and/or re-prescribed by a doctor.
Nurse training	Educational outreach training in PALSA PLUS Educational outreach training in the use of STRETCH edition of the PALSA PLUS guidelines: • Median of 4 sessions to all nurses (n=128) at the clinic • Sessions delivered by 16 PALSA PLUS trainers prepared for STRETCH during 2.5 day training	Educational outreach training in PALSA PLUS No STRETCH educational outreach
ART prescribing and dispensing	ART prescribers: • Doctors and • Professional nurses who completed STRETCH training (n=104) ART dispensed by pharmacists and pharmacy assistants Dispensed drugs given to patients by nurses	ART prescribers: • Doctors only ART dispensed by pharmacists and pharmacy assistants Dispensed drugs given to patients by nurses
Management support	Establishment of a STRETCH team at each facility • Led by the facility manager • Included doctors nurses, pharmacists, local managers, clerks, community health workers • Managed changes during the intervention including ART drugs delivery to clinics, ensuring supplies of blood tubes and forms, and setting up communication infrastructure enabling nurses to contact doctors, and clinics to contact pharmacists. • Implementation Toolkit – 30 page manual describing new staff roles, phases of the intervention, tips of dealing with anticipated problems, contact details for managers and letters authorising nurse prescribing	Standard management support by a facility manager and district ART co-ordinator
Phased introduction	Phase 1: STRETCH educational outreach training & establishment of STRETCH team at facility (median of 1 month, range 1-9 months) Phase 2: Nurses assumed responsibility for repeating ART prescriptions in stable patients (median of 3.5 months, range 1-35 months) Phase 3: Nurses assumed responsibility for initiating ART in selected patients (median of 30.5 months, range 0-32 months)	Not applicable

* PALSA PLUS: Practical Approach to Lung Health and HIV/AIDS in South Africa

Table 2: Characteristics of clinics at time of allocation to intervention and control groups

Characteristic	Intervention group	Control group
No. of clinics	16	15
No. of clinics per stratum. Median (range).	2 (1-4)	2 (1-3)
No. adult attendances in previous year (2007). Median (IQR)	40183 (12,079-89,302)	30062 (17,651-93,631)
No nurses per clinic in previous year (2007). Median (IQR).	6 (4-18)	6 (3-16)
Doctor support for ART initiations available at clinic		
All the time	2/16 (12.5%)	3/15 (20.0%)
On a sessional basis	3/16 (18.8%)	5/15 (33.3%)
Not available	11/16 (68.8%)	7/15 (46.7%)
Pharmacy staff situated on-site	7/16 (43.8%)	6/15 (40.0%)
Distance from referral treatment site (km). Median (IQR).	7.4 (0-54)	10.9 (0-57)
Electronic medical record system in place	14/16 (87.5%)	13/15 (86.7%)

Table 3. Cohort 1: Hazard ratios of the associations of arm and patient level characteristics with time to death: Cox proportional hazards model

Factor	N (%)	Hazard Ratio (95% CI)*
Arm of trial		
Control	3862 (41.7)	1 (reference)
Intervention	5390 (58.3)	0.92 (0.76 – 1.12)
Patient characteristics		
Sex		
Female	6285 (67.9)	1 (reference)
Male	2967 (32.1)	1.30 (1.19 – 1.43)
Age at enrolment		
16-24 years	772 (8.3)	1 (reference)
25-34 years	3429 (37.1)	1.32 (1.01 – 1.72)
35-44 years	3162 (34.2)	1.40 (1.05 – 1.85)
45-54 years	1477 (16.0)	1.55 (1.14 – 2.11)
≥55 years	412 (4.5)	2.04 (1.53 – 2.71)
CD4 at enrolment (cells per μL)		
≤100	3314 (35.8)	4.59 (3.84 – 5.47)
101-200	3680 (39.8)	1.84 (1.53 – 2.22)
201-350	2258 (24.4)	1 (reference)
Presence of ID number		
Not available	1301 (14.1)	1 (reference)
Available	7951 (85.9)	2.05 (1.16 – 3.63)
Started antiretroviral treatment†	6130 (66.3)	0.54 (0.42 – 0.68)

* Mutually adjusted for all characteristics in the table and for randomisation strata and intra-cluster correlation of outcomes. † Time-varying covariate.

Table 4. Cohort 2: Risk differences of the associations of arm and patient level characteristics with viral load suppression: binomial regression model

Factor	N (%)	Risk difference (95% CI)*
Arm of trial		
Control	3202 (51.4)	0% (reference)
Intervention	3029 (48.6)	1.1% (-2.3, 4.6)
Patient characteristics		
Sex		
Female	4445 (71.3)	0% (reference)
Male	1786 (28.7)	-9.4% (-12.0, -6.7)
Age at enrolment		
16-24 years	217 (3.5)	0% (reference)
25-34 years	1934 (31.0)	3.8% (-1.4, 9.0)
35-44 years	2543 (40.8)	8.6% (4.3, 12,8)
45-54 years	1191 (19.1)	11.6% (7.3, 16.0)
≥55 years	346 (5.6)	7.9% (2.8, 13.0)
Presence of ID number		
Not available	414 (6.6)	0% (reference)
Available	5817 (93.4)	8.8% (4.0, 13.5)

* Mutually adjusted for all characteristics in the table and for randomisation strata and intra-cluster correlation of outcomes.

Table 5. Healthcare utilisation

Outcome	Intervention group		Control group		Incidence rate ratio*	95% CI	p value	Intracluster correlation coefficient
	Mean	SD	Mean	SD				
Cohort 1								
No. clinic visits with nurse	8.49	7.32	6.63	6.63	1.29	1.0, 1.67	0.054	0.223
No. clinic visits with doctor	2.09	2.40	0.93	1.72	2.11	1.05, 4.25	0.035	0.353
No. hospital admissions	0.19	0.54	0.19	0.53	0.86	0.80, 0.96	0.005	0.036
No. inpatient days	1.03	3.77	0.98	3.59	0.87	0.84, 0.91	<0.001	0.019
Cohort 2								
No. clinic visits with nurse*	10.83	6.58	8.97	5.600	1.24	1.01, 1.53	0.048	0.445
No. clinic visits with doctor*	1.64	1.97	1.92	1.78	0.79	0.53, 1.17	0.236	0.606
No. hospital admissions†	0.08	0.37	0.09	0.43	0.91	0.64, 1.30	0.615	0.018
No. inpatient days†	0.47	2.38	0.47	3.58	0.86	0.58, 1.29	0.474	0.010

SD standard deviation. * Poisson regression models adjusted for intra-cluster correlation of outcomes, randomisation strata and duration enrolled in the trial.