

REVIEW

The effectiveness and cost implications of task-shifting in the delivery of antiretroviral therapy to HIV-infected patients: a systematic review

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Introduction Human resource shortages are a challenge to the rollout of antiretroviral therapy (ART) for HIV-infected patients, particularly in sub-Saharan Africa. Task-shifting has been recommended as an approach to reduce the impact of human resource shortages. We conducted a systematic review of randomized controlled trials and quasi-experimental studies to assess the effectiveness of task-shifting, and its impact on costs of ART provision.

Methods We searched MEDLINE, EMBASE, PSYCINFO, Cochrane Library, Web of Knowledge and the Current Controlled Trials Register for articles published up to January 2011. We included studies evaluating any task-shifting model against any other intervention using any of the following outcomes: mortality (all causes); occurrence of new AIDS-defining illness; virological outcomes; CD4 cell count; adherence to ART medicines (e.g. self-report and pill counts); hospital admissions; clinic visits; toxicity or adverse events; quality of life indicators; costs and cost-effectiveness. We did not pool the results because of high levels of clinical heterogeneity.

Results We identified six effectiveness studies including a total of 19 767 patients. Non-inferior patient outcomes were achieved with task-shifting from doctors to nurses, or from health care professionals to mid-level workers or lay health workers. However, most of the identified studies were underpowered to detect any difference. Three studies were identified on the cost implications of task-shifting. Task-shifting resulted in substantial cost and physician time savings.

Conclusions The reviewed evidence suggests that task-shifting from doctors to nurses, or from health care professionals to lay health workers can potentially reduce costs of ART provision without compromising health outcomes for patients. Task-shifting is therefore a potentially effective and cost-effective approach to addressing the human resource limitations to ART rollout. However, most of the studies conducted were relatively small and more evidence is needed for each task-shifting model as it is currently limited.

Keywords Task-shifting, human resources, HIV/AIDS, antiretroviral therapy, effectiveness, cost-effectiveness

KEY MESSAGES

- Task-shifting from doctors to nurses or from health care professionals to lay health workers can result in substantial cost and physician time savings without compromising the quality of care or health outcomes for patients.
- Task-shifting is therefore a potentially effective and cost-effective approach to addressing the human resource limitations to ART rollout.
- However, more evidence is required as it is currently very limited.

Introduction

As antiretroviral therapy (ART) for HIV/AIDS becomes more available in resource-limited settings, human resource shortages have become one of the main barriers to rapid scaling-up of ART programmes (Hischhorn *et al.* 2006; Muula *et al.* 2007). In particular, reliance on doctor-led care and inefficient use of the health workforce hinders ART scale-up (Kurowski *et al.* 2007; Miles *et al.* 2007; Shumbusho *et al.* 2009; Price and Binagwaho 2010). In some developing countries, ART scale-up has become one of the main drivers of increased need for more health care professionals (Kurowski *et al.* 2007; Walsh *et al.* 2010). The World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS)/U.S. President's Emergency Plan for AIDS Relief (PEPFAR) recommends task-shifting, training and creation of new capacity as an approach to reduce the impact of human resource shortages (WHO 2008). Task-shifting involves shifting specific tasks, where appropriate, to health workers with shorter training and fewer qualifications. For example, certain tasks presently carried out by doctors but are considered to not necessarily require a doctor can be delegated to nurses instead. The objective is to use the health workforce more efficiently, whilst maintaining quality of care standards and increasing access to health care (WHO 2008).

The extent of task-shifting in various ART programmes depends on the staff and skill mix required by the chosen ART service delivery model (Hischhorn *et al.* 2006). Some programmes rely heavily on nurses and/or clinical officers for clinical decisions such as ART initiation and monitoring and management of opportunistic infections (OIs), whilst doctors take a supervisory role and see only cases that need specialized care (Stringer *et al.* 2006; Bedelu *et al.* 2007). Some programmes have gone further by creating new capacity through training lay health workers such as community health workers in delivering antiretroviral medicines (ARVs) to patients and monitoring them in their homes (Mermin *et al.* 2008). However, national ART programmes in resource-limited countries have been slow in adopting task-shifting because of uncertainty over its effects on patient outcomes and quality of care (Bedelu *et al.* 2007; Shumbusho *et al.* 2009; Assefa *et al.* 2010; Selke *et al.* 2010).

Task-shifting interventions are complex, with many components other than just shifting responsibilities to lower level workers (Hirschhorn *et al.* 2006). Task-shifting also occurs in the context of treatment programmes involving many other components. For effective design and implementation, it is important to understand what the different components of these interventions are and the environment in which these interventions were implemented (Michie *et al.* 2009; Glasziou *et al.* 2010). Some components that could be important in

evaluating the appropriateness and feasibility of implementing a particular task-shifting model include: the ART delivery model (i.e. home-based ART, mobile clinics or health facility-based ART); national regulation for prescribing and dispensing ART; drug supply management; programme management and co-ordination support; financial or other incentives for the health care providers or patients; and monitoring and evaluation mechanisms (Uebel *et al.* 2011). In addition, measures to ensure adherence and competent delivery of the intervention are needed, such as availability of appropriate patient management and implementation guidelines, and training and supervision (Glasziou 2010).

There is rapidly emerging evidence on the effectiveness of, and costs associated with, different task-shifting models for ART. A synthesis of 25 earlier studies concluded that task-shifting could reduce costs, improve overall efficiency, and increase access and affordability of treatment without compromising the quality of care or health outcomes for patients (Callaghan *et al.* 2010). The review, however, included only two randomised controlled trials (RCTs). Twenty-one of the studies were observational, which do not control for other factors that might affect outcome and tend to over-estimate the effect size (Torgerson and Torgerson 2008). For the present review, we will limit the study design to experimental and quasi-experimental research designs.

Another review, which focused on interventions delivered by lay health workers that intended to improve maternal or child health (MCH) or the management of infectious diseases, did not find any studies on ART (Lewin *et al.* 2010). A planned systematic review by Araoyimbo and Bateganya (2008) focused on substitution of nurses for doctors in managing ART. Whilst these two reviews are focused on particular task-shifting models, our review is much broader, including any task-shifting model for ART.

Studies and reviews in other disease areas such as hypertension have demonstrated the effectiveness of task-shifting in particular settings (Logan *et al.* 1979; Brown and Grimes 1995; Horrocks *et al.* 2002; Laurant *et al.* 2004). However, most of them are on substitution of nurses for doctors, whereas other task-shifting models exist today for ART such as the use of lay health workers. Most of these studies were also in developed countries, and thus applicability of these results to developing countries is questionable.

We aimed to systematically review the evidence on the effectiveness, costs and cost-effectiveness of task-shifting models in managing ART. As a conceptual framework to examine the components of the task-shifting model evaluated in each study, we used the components described above as potentially important in evaluating the appropriateness and feasibility of implementing a particular task-shifting model. The

review provides useful information for decision making for ART programme funders, policy makers, planners and implementers, as well as researchers interested in this area.

Methods

Literature search

We searched the following electronic sources on Ovid SP: Medline(R) In-Process & Other Non-Indexed Citations and Medline (1948–31 January 2011), Embase (1980–2011 Week 4), PsycInfo (1806–January Week 4 2011). We also searched the Cochrane Library (Issue 1, January 2011), Web of Knowledge (1900–31 January 2011), Current Controlled Trials Register and Google Scholar. The searches were conducted in January 2011. The search strategy showing the keywords used for Medline is presented in Appendix 1. This search strategy was adapted accordingly for each of the other databases.

We also hand searched the reference lists of the retrieved studies, protocols and reviews; contacted some authors and experts in the area for any unpublished work; and searched the websites of World Health Organization, UNAIDS and the Department for International Development (DFID) for potentially relevant articles. We did not apply any language filters, publication date limits, or geographic limits.

Study selection criteria

For effectiveness studies, randomized controlled trials (RCTs), cluster randomized controlled trials (CRCT), non-randomized trials with a control group and interrupted time series (ITS) were eligible. For cost-effectiveness data, we included studies using empirical data from RCTs as well as those using other techniques such as modelling. Studies that recruited HIV/AIDS-positive patients, with or without prior exposure to ART, were eligible. We included studies evaluating any task-shifting model against any other intervention using any of the following outcomes: mortality (all causes); occurrence of new AIDS-defining illness; virological outcomes; CD4 cell count; adherence to ART medicines (e.g. self-report and pill counts); loss to follow-up; health care utilization; toxicity or adverse events; quality of life indicators; costs and cost-effectiveness; and other measures of treatment success or failure as reported by the studies.

Study selection, data extraction and analysis

Two authors (NM and SC) independently screened all titles and abstracts retrieved from the search process to identify eligible articles, and extracted data from the articles. Differences in opinion were resolved through consensus or otherwise by referral to a third author (SA).

Risk of bias and heterogeneity assessment

Risk of bias assessment was performed by two authors (NM and SC) using the following domains for randomized controlled trials: sequence generation, allocation concealment, blinding, sample size calculation and incomplete outcome data (CRD 2008; Higgins and Green 2008). For non-randomized trials with a control group we used the following criteria: use of objective outcomes/blinded assessment of primary outcome, and discussion of sources of bias (Callaghan *et al.* 2010).

We used clinical judgement to establish whether trials were sufficiently similar to allow pooling of data by considering the task-shifting model under investigation, study participants, outcome definitions and models of ART delivery. We also planned to use a chi-square test to test for statistical heterogeneity, and I^2 to measure the magnitude of heterogeneity where it exists.

We critically assessed the studies on the cost implications of task-shifting using the criteria proposed by Drummond *et al.* (2005). The criteria are given in Appendix 2.

Results

Literature search

The literature search yielded 3127 records from which 812 were duplicates and 2252 were irrelevant (Figure 1). The full text articles of the remaining 63 records were assessed for eligibility and 56 articles were ineligible (41 observational or descriptive studies; 10 commentaries and opinions; four reviews; one study protocol). Five original effectiveness studies and two studies evaluating the cost implications of task-shifting met the eligibility criteria for inclusion. One effectiveness study initially excluded because of unavailability of study results was later included as some of the results became available from a conference presentation. Thus six effectiveness studies were included in this review. One of the effectiveness studies also evaluated cost implications. Therefore three studies provided information on the cost implications of task-shifting. Although we did not have any language or geographic filters in our search strategy, all studies that met the eligibility criteria were in English, and conducted in sub-Saharan Africa.

Characteristics of included studies

Six effectiveness studies which included a total of 19 767 participants were eligible for this review: four CRCT, one RCT and one non-randomized study with a control group (Table 1). Tasks were shifted from health care professionals to lay health workers in four studies (Jaffar *et al.* 2009; Chang *et al.* 2010; Kipp *et al.* 2010; Selke *et al.* 2010); and from doctors to nurses in two studies (Sanne *et al.* 2010; Fairall *et al.* 2011).

Chang *et al.* (2010) conducted a CRCT in rural Uganda where tasks were shifted from health care workers to peer health workers (PHW). The equivalence CRCT conducted by Jaffar *et al.* (2009) in rural and semi-urban Uganda involved task-shifting from health care workers to field officers. Kipp *et al.* (2010) conducted a non-randomized, non-inferiority study with a control group in rural Uganda where the control patients received their care from health workers at a hospital-based ART clinic, and the intervention group received home-based ART from community volunteers. Selke *et al.* (2010) conducted a CRCT in rural Kenya where tasks were shifted from health care workers to Community Care Coordinators (CCC).

Fairall *et al.* (2011) evaluated the effectiveness of ART initiation and re-prescription by nurses in comparison with doctors in South Africa. Two cohorts were recruited for this study. In cohort 1 were adults with CD4 cell counts below 350 cells/ μ L and not yet started on ART. Cohort 2 comprised adults already receiving ART for at least 6 months. Sanne *et al.* (2010)

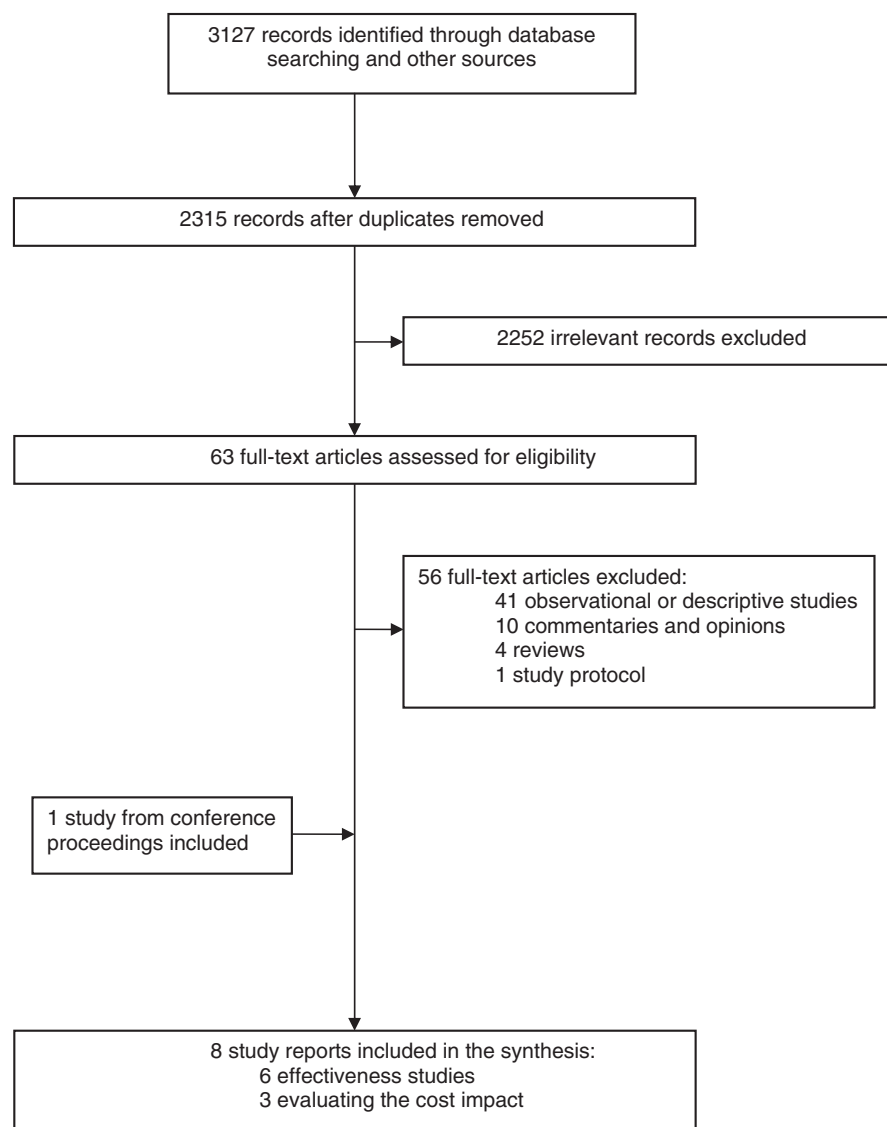


Figure 1 Flow of articles through the systematic review process

conducted a non-inferiority RCT on substituting nurses for doctors in the monitoring of patients on ART in South Africa.

A more detailed description of the control and task-shifting conditions, using the components described above as important in evaluating the appropriateness and feasibility of implementing a particular task-shifting model, is given in the Supplementary Data online. Monitoring and evaluation is not discussed as these were studies actually designed to evaluate the effectiveness of the different models. Most studies did not provide information on a number of these components. However, in all cases task-shifting was coupled with many other best-practices such as: use of patient management guidelines for nurse initial and repeat prescription of ARVs (Fairall *et al.* 2011); use of checklists by lay health workers that included signs and symptoms of drug toxicity or disease progression (Jaffar *et al.* 2009); use of standardized patient record forms by lay health workers (Chang *et al.* 2010); use of Personal Digital Assistant (PDA) that was pre-programmed to

collect specific patient data and to trigger alert if specific parameters were met (Selke *et al.* 2010); involving the patient's family and friends as daily treatment supporters at home (Kipp *et al.* 2010); and continuing training, support and supervision (Jaffar *et al.* 2009; Chang *et al.* 2010; Kipp *et al.* 2010; Sanne *et al.* 2010; Selke *et al.* 2010; Fairall *et al.* 2011). In the case of lay health workers, in some studies motivation strategies included monthly monetary allowances in addition to supplies to assist them in their duties such as bicycles and motorcycles (Jaffar *et al.* 2009; Chang *et al.* 2010). However in some, the lay health workers did not receive any monetary incentives but they were motivated by the recognition and support they received from the health care programme and the community in addition to other small incentives (Kipp *et al.* 2010). The education levels of the lay health workers varied from those with degrees and diplomas (Jaffar *et al.* 2009), to those with only a primary or secondary education (Chang *et al.* 2010; Kipp *et al.* 2010; Selke *et al.* 2010).

Table 1 Characteristics of studies included in the review

Reference	Design	Task-shifting model	ART service delivery model	Population	Setting, country	Number of clusters (Int/Con)*	N (Int/Con)	Follow-up period
Chang <i>et al.</i> (2010)	Cluster randomized controlled trial (CRCT)	<i>From:</i> Health care workers <i>To:</i> Persons living with HIV working as peer health workers (PHW)	Mobile clinics	Adult patients either already on ART or starting ART during the study period	Rural, Uganda	10/5	970/366	Median (IQR) PHW clusters: 103 weeks (97–111) Control clusters: 103 weeks (94–113)
Fairall <i>et al.</i> (2011) Fairall <i>et al.</i> (2008) (Superiority trial for cohort 1; Equivalence trial for cohort 2)	CRCT	<i>From:</i> Doctors <i>To:</i> Nurses	Facility-based ART at primary health care sites	Patients aged ≥ 16 years who are: ART naïve (Cohort 1); or have already receive ART for at least 6 months (Cohort 2)	South Africa	16/15	Cohort 1: 5390/3862 Cohort 2: 3029/3202	At least 12 months
Jaffar <i>et al.</i> (2009)	CRCT (equivalence trial)	<i>From:</i> Health care workers <i>To:</i> Field officers	Facility-based ART at clinics for control group Home-based ART for intervention group	ART naïve adults ≥ 18 years old	Rural and semi-urban, Uganda	22/22	859/594	Median (IQR) Facility-based ART clusters: 27 months (13–34) Home-based ART clusters: 28 months (18–35)
Kipp <i>et al.</i> (2010)	Non-randomized controlled, non-inferiority study	<i>From:</i> Health care workers <i>To:</i> Community volunteers	Facility-based ART at clinics for control group Home-based ART for intervention group	ART naïve adults ≥ 18 years old	Rural, Uganda	N/A	185/200	6 months
Sanne <i>et al.</i> (2010)	Randomized controlled trial (RCT) (non-inferiority trial)	<i>From:</i> Doctors <i>To:</i> Nurses	Facility-based ART at primary health care sites	Adults > 16 year old who have received less than 6 weeks of ART	Urban townships, South Africa	N/A	404/408	Median (IQR) 120 weeks (60–144)
Selke <i>et al.</i> (2010)	CRCT	<i>From:</i> Health care workers <i>To:</i> Persons living with HIV working as community care coordinators (CCC)	Facility-based ART clinics for control Home-based ART for intervention clusters	Adults ≥ 18 years old who were clinically stable on ART for at least 3 months	Rural, Kenya	8/16	96/112	12 months

Note: *Intervention/Control. IQR = Interquartile Range.

We identified three studies on the impact of task-shifting on costs of ART. Two of these studies did not collect data on outcomes alongside the costs analysis but rather used modelling techniques (Chung *et al.* 2008; Babigumira *et al.* 2009). Babigumira *et al.* (2009) estimated the impact of task-shifting on costs of ART and physician supply in Uganda. They built an aggregate cost-minimization model both from the societal and the Ministry of Health perspectives, comparing physician-intensive follow-up to two task-shifting models: nurse-intensive follow-up and pharmacy worker-intensive follow-up, using data obtained from 400 patients. Chung *et al.* (2008) evaluated the impact of having nurses as primary providers of ART care on physician time saved on a national level in Rwanda. They created a simulation model of the HIV care for 946 patients using data from a pilot study in three health centres where nurses provided HIV treatment under the supervision of physicians. Jaffar *et al.* (2009) used empirical data from an RCT for costs analysis.

Impact of task-shifting on patient outcomes

We did not perform any quantitative synthesis (meta-analysis) due to high levels of clinical heterogeneity between studies on: the task-shifting model under evaluation; types of patients; outcome used; and models of ART delivery. We therefore present a narrative summary of the results, with the studies in two groups: task-shifting from health care professionals to lay health workers (Jaffar *et al.* 2009; Chang *et al.* 2010; Kipp *et al.* 2010; Selke *et al.* 2010); and task-shifting from doctors to nurses (Sanne *et al.* 2010; Fairall *et al.* 2011). We refer to the groups that received the task-shifting model as intervention groups and those that received usual care as control groups.

Task-shifting from health care professionals to lay health workers

Overall, in the studies where tasks were shifted from health care professionals to lay health workers, the task-shifting models were not inferior on mortality, virologic outcomes, CD4 cell count, adherence, loss to follow-up, health care utilization, occurrence of new AIDS-defining illness and incidence of opportunistic infections, toxicity, quality of life and other measures of treatment failure.

In the study by Chang *et al.* (2010), deaths were similar between those receiving the PHW intervention and those in the control clusters by the end of the study at 26 months (Table 2). The study also found no significant differences on virological failure (>400 HIV-RNA copies/ml) and time to first failure between the intervention and control groups. However, the intervention group was associated with better virological outcomes after longer periods of ART. Chang *et al.* (2010) also looked at cumulative risk of virological failure, i.e. any failure during the follow-up period, and found no significant difference between the two groups. Similar changes were also observed in CD4 cell count at 24 and 48 weeks, and medication adherence between the intervention group and the control. A significant difference in loss to follow-up in favour of the intervention clusters was reported.

Jaffar *et al.* (2009) also found similar deaths and virological failure (>500 HIV-RNA copies/ml) after 6 months of treatment between the group receiving some of their care from field

Table 2 Study results: impact of task-shifting on patient outcomes

Reference	Effect size measure	Effect size (95% CI)	P value
Mortality			
Chang <i>et al.</i> (2010)	Risk ratio	0.99 (0.96, 1.03)	0.60
Fairall <i>et al.</i> (2011)	Hazard ratio:		
	Cohort 1	0.92 (0.76, 1.15)	0.532
	Cohort 2	1.05 (0.84, 1.31)	0.684
Jaffar <i>et al.</i> (2009)	Adjusted rate ratios	0.95 (0.71, 1.28)	–
Kipp <i>et al.</i> (2010)	Difference in deaths per 100 person-years	7.1	0.31
Sanne <i>et al.</i> (2010)	Hazard ratio	0.92 (0.39, 2.17)	–
Virologic outcomes			
Chang <i>et al.</i> (2010) ^a	Risk ratios		
	24 weeks	0.93 (0.65, 1.32)	0.68
	48 weeks	0.83 (0.47, 1.48)	0.54
	72 weeks	0.81 (0.44, 1.49)	0.59
	96 weeks	0.50 (0.31, 0.81)	0.005
	Cumulative risk ^b	0.81 (0.61, 1.08)	0.16
	Time to first failure	Hazard ratio 0.82 (0.56, 1.21)	0.29
Fairall <i>et al.</i> (2011)	Risk difference		
	Cohort 2	1.1% (–2.3, 4.6)	0.534
Jaffar <i>et al.</i> (2009) ^c			
	>6 months of treatment	Adjusted rate ratio 1.04 (0.78, 1.40)	–
Kipp <i>et al.</i> (2010) ^d	Adjusted odds ratio	1.31 (0.62, 2.78)	0.47
Sanne <i>et al.</i> (2010) ^e	Hazard ratio	1.15 (0.75, 1.76)	0.53
Selke <i>et al.</i> (2010) ^a			
	12 months	– (0.54, 3.31)	0.65
Adherence			
Chang <i>et al.</i> (2010)	Risk ratios		
	<95% (pill count)	0.55 (0.23, 1.35)	0.20
	<100% (pill count)	1.10 (0.94, 1.30)	0.23
	Any missed dose – self-report	0.99 (0.96, 1.02)	0.60
Selke <i>et al.</i> (2010)			
	Never missed (6 months) – self-report	–	0.71
	Never missed (12 months) – self-report	–	0.47

(continued)

Table 2 Continued

Reference	Effect size measure	Effect size (95% CI)	P value
Loss to follow-up			
Change <i>et al.</i> (2010)	Risk ratio	0.56 (0.36, 0.88)	0.01
Fairall <i>et al.</i> (2011)	Risk ratio Cohort 1	0.91 (0.86, 0.96)	<0.001
Sanne <i>et al.</i> (2010)	Hazard ratios		
All losses		1.13 (0.81, 1.59)	0.84
Lost to follow-up		1.42 (0.63, 3.20)	–
Withdrew consent		0.87 (0.46, 1.63)	–
Defaulted clinic visits		1.21 (0.76, 1.93)	–
Selke <i>et al.</i> (2010)	–	(0.24, 3.03)	1.0
CD4 cell count			
Change <i>et al.</i> (2010)	β_1 from unadjusted general estimation equation		
Change at 24 weeks		–1.9 (–31.8, 28.0)	0.90
Change at 48 weeks		–10.0 (–37.9, 18.0)	0.49
Fairall <i>et al.</i> (2011)	Change in means Cohort 1 Cohort 2	22.3 (3.6, 40.9) 24.2 (7.2, 41.3)	0.021 0.007
Selke <i>et al.</i> (2010)			
6 months	–	(–19, 74)	0.24
12 months	–	(–38, 77)	0.50
Hospital admissions and clinic visits			
Jaffar <i>et al.</i> (2009)			
Admitted at least once	Adjusted rate ratio	0.91 (0.64, 1.28)	–
Selke <i>et al.</i> (2010)			
Number of clinic visits (12 months)	–	(–7.0, –5.4)	<0.001
New AIDS defining illness and incidence of opportunistic infections			
Selke <i>et al.</i> (2010)			
New WHO stage 3 and 4:			
6 months	–	(0.30, 5.65)	1.0
12 months	–	(0.18, 4.80)	–
Opportunistic infection	Incidence rate ratio	(0.37, 1.34)	0.42
Toxicity			
Sanne <i>et al.</i> (2010)	Hazard ratio	1.04 (0.74, 1.45) ^f	0.47
	Incidence rate ratio	1.31 (1.14, 1.49) ^g	–

(continued)

Table 2 Continued

Reference	Effect size measure	Effect size (95% CI)	P value
Quality of Life			
Selke <i>et al.</i> (2010) (Decline in Karnofsky score at 6 months)	–	n.a.	0.46
Other measures of treatment failure			
Sanne <i>et al.</i> (2010) ^h	Hazard ratio	1.09 (0.89, 1.33)	0.42

Notes: ^aFailure: >400 HIV-RNA copies/ml.^bAny failure during the follow-up period equalling failure.^cFailure: >500 HIV-RNA copies/ml.^dVirologic suppression: <400 copies/ml.^eFailure: a decline of less than 1.5 log₁₀ in viral load from baseline to 12 weeks of treatment (early failure) or two consecutive viral loads 4 weeks apart of more than 1000 copies per ml (late failure).^fGrade 3 or 4 adverse events, or other events needing treatment interruption for more than 42 days.^gGrade 3 and 4 and dose limiting toxic events.^hComposite endpoint including the following outcomes: all-cause mortality, loss to follow-up, virological failure, toxicity failure, withdrawn consent, defaulting clinic schedule visit and HIV-disease progression. CI = Confidence Interval.

officers and those under usual care from health care workers. The study also reported no significant difference in loss to follow-up, and in the proportion of patients admitted at least once during the follow-up period between the intervention and the control clusters.

In the study by Kipp *et al.* (2010), mortality and HIV-1 RNA suppression (<400 HIV-RNA copies/ml) at 6 months after starting ART was not significantly different between the home-based ART participants receiving some of their care from community volunteers, and the hospital-based ART participants receiving care from health care workers.

Selke *et al.* (2010) also reported a non-significant difference for detectable viral load (>400 HIV-RNA copies/ml) at 12 months between the CCC group and the group receiving care from health care professionals. Selke *et al.* (2010) also found similar changes in CD4 cell count at 6 months and 12 months for the CCC group vs the control. Medication adherence, loss to follow-up, incidences of new WHO stage 3 and 4 disease and incidence rates of opportunistic infections per 100 person-years at 6 months and 12 months were similar between the intervention and control groups. The intervention clusters had significantly fewer clinic visits compared with the control ($P < 0.001$). Selke *et al.* (2010) included decline in Karnofsky score as a measure of functional impairment, and found no difference between the intervention group and the control at 6 months ($P = 0.46$) and at 12 months.

Task-shifting from doctors to nurses

In the two studies evaluating task-shifting from doctors to nurses, the task-shifting models were not inferior on mortality, virologic outcomes, CD4 cell count, loss to follow-up and adverse events.

In the study by Fairall *et al.* (2011), in cohort 1 (the number of those with CD4 cell counts below or equal to 350) there was no significantly improved survival among those patients at the clinics where ART was initiated by nurses (intervention group) when compared with the control group followed out to 18 months. 18.5% of the intervention group and 19.3% of the control group died. However, in a pre-planned subgroup analysis of patients with CD4 cell counts ≥ 200 cells/ μL , mortality was lower in the intervention group than in the control (HR 0.76, 95% CI 0.60-0.97). Loss to care was significantly lower in the intervention group when compared with the control at 12 months (Smart 2011). For cohort 2, time to death was equivalent for the intervention and the control groups. The proportion of patients with suppressed viral load was also similar in the two groups. Change in CD4 cell count favoured the intervention groups in both cohorts (Smart 2011).

Sanne *et al.* (2010) found no significant difference on mortality and virological failure [a decline of less than 1.5 \log_{10} in viral load from baseline to 12 weeks of treatment (early failure) or two consecutive viral loads 4 weeks apart of more than 1000 copies per ml (late failure)] between those managed by nurses vs those managed by doctors. The study even considered a composite endpoint of the outcomes all-cause mortality, loss to follow-up, virological failure, toxicity failure, withdrawn consent, defaulting clinic schedule visit and HIV-disease progression, and still found no significant difference between the nurse and the doctor managed groups. There were also no significant differences between the groups on loss to follow-up, and grade 3 or 4 adverse events, or other events needing treatment interruption for more than 42 days. However, grade 3 and 4 and dose limiting toxic events were more common in the doctor group than the nurse group (incidence rate ratio 1.31, 95% CI 1.14, 1.49).

Costs and cost-effectiveness

From the societal perspective, Babigumira *et al.* (2009) estimated the annual mean costs of follow-up per patient as US\$59.98 for physician-intensive follow-up, US\$44.58 for nurse-intensive follow-up and US\$18.66 for pharmacy worker-intensive follow-up. The predicted annual national ART follow-up expenditure was US\$5.92 million for physician-intensive follow-up, US\$4.41 million for nurse-intensive follow-up and US\$1.85 million for pharmacy worker-intensive follow-up.

When considering the Ministry of Health perspective, the estimated annual mean costs of follow-up per patient were US\$31.68 for physician-intensive follow-up, US\$24.58 for nurse-intensive follow-up and US\$10.50 for pharmacy worker-intensive follow-up. The predicted annual national Ministry of Health expenditure was US\$3.14 million for physician-intensive follow-up, US\$2.43 million for nurse-intensive follow-up and US\$1.04 million for pharmacy worker-intensive follow-up.

According to Babigumira *et al.* (2009), in Uganda at national level task-shifting would potentially result in physician personnel savings with the physician-intensive follow-up requiring 108 full time equivalent (FTE) doctors, and nurse-intensive follow-up and pharmacy worker-intensive follow-up requiring 18 FTE doctors each, potentially saving 90 FTE doctors.

Chung *et al.* (2008) concluded that in Rwanda at national level, a nurse-centred ART model could result in a 76% reduction in demand on physician time when compared with a doctor-centred ART model. For the 59 000 people on ART in Rwanda in 2008, a physician-centred model would require 103 physicians working 30 hours/week (69% of the physician capacity), whilst a nurse-centred model nationally would reduce the demand to 25 physicians (17% of the physicians available).

Jaffar *et al.* (2009) reported costs of health-service delivery of US\$793 for the task-shifting model, and US\$838 for the usual care group, per patient per year. The average costs incurred by each patient to access care were US\$29 in the first year and US\$18 per year after the first year for the task-shifting model, and US\$60 in the first year and US\$54 per year after the first year for the usual care group.

Risk of bias from the included effectiveness studies

Sequence generation was judged as adequate for all the CRCTs and RCTs. However, allocation concealment was judged as adequate in only two studies (Jaffar *et al.* 2009; Fairall *et al.* 2011), and unclear in one (Selke *et al.* 2010). The remaining two had inadequate allocation concealment as they used study investigators (Chang *et al.* 2010) and opaque envelopes (Sanne *et al.* 2010) to implement the randomization, both of which are prone to subversion (Hewitt *et al.* 2005). Blinding the participant or the personnel delivering the intervention was not possible because of the nature of the interventions. Only one study mentioned using independent outcome assessors (Jaffar *et al.* 2009). Of the four CRCTs three accounted for cluster design on the sample size calculation (Jaffar *et al.* 2009; Chang *et al.* 2010; Fairall *et al.* 2011) and one did not (Selke *et al.* 2010). Three studies accounted for the cluster design in the analysis (Jaffar *et al.* 2009; Chang *et al.* 2010; Fairall *et al.* 2011) and this was not clear in one (Selke *et al.* 2010). All studies used intention-to-treat analysis and incomplete data were adequately addressed. The non-randomized trial with a control group used objective outcomes (Kipp *et al.* 2010). However, sources of bias in the study were not adequately discussed.

The sample sizes of studies on task-shifting from health care professionals to lay health workers differed hugely, with some of them very small [385 for Kipp *et al.* (2010) and 208 for Selke *et al.* (2010)] and some relatively large [1336 for Chang *et al.* (2010) and 1453 for Jaffar *et al.* (2009)]. For those on task-shifting from doctors to nurses, Sanne *et al.* (2010) enrolled 812 whilst Fairall *et al.* (2011) enrolled 15 573 participants in total (9252 in cohort 1 and 6321 in cohort 2). We did not give different weighting to the different studies according to their sample size in this narrative synthesis as the direction of intervention effect was similar for all the studies. However, this would have been important if the direction of effect was different, or if we had quantitatively synthesized the studies for a pooled effect size.

A number of the studies were likely underpowered to detect differences between the groups for the outcomes of interest. For Selke *et al.* (2010), the required sample size was 320, however only 208 participants were enrolled into the study, with only 189 followed up at the end of the 12 months. For Chang *et al.* (2010), although more participants were actually recruited

(1336) than those required from the power calculation (1000), it is still likely to have been underpowered. This is because, as the authors acknowledge, the study was originally powered to detect cumulative failure as a primary outcome; however, failure at individual time points was reported. Moreover, the rate of virologic failure was lower than anticipated, and virologic outcomes were not available for about 28% of participants. Although Kipp *et al.* (2010) was a very small study, they managed to enrol (385) and follow-up (305) more participants than those required according to the sample size calculation (200). However, loss to follow-up was significantly higher in the intervention group (24.9%) than in the control (15.5%).

The length of follow-up also varied from 6 months to ≥ 30 months, with the smaller studies generally having shorter-term follow-up than the larger studies.

Critical appraisal of the studies on cost implications of task-shifting

We did not appraise the study by Chung *et al.* (2008) because of lack of relevant information at the time this systematic review was conducted. The study was not yet published as a full paper and the only limited information available was from a conference abstract. The appraisal results for the other two studies are presented in Appendix 2.

Some of the limitations from the two studies are that neither performed any incremental analysis of costs and consequences of alternatives or presented results as an index or ratio of costs to effects. Babigumira *et al.* (2009) only examined the costs but not the effects of task-shifting for follow-up. Although Jaffar *et al.* (2009) considered both costs and effects of two alternatives being evaluated through an RCT, the costs were reported separately from effects. The generalizability of the results from both these studies to other settings and patient groups is uncertain.

The method used by Babigumira *et al.* (2009) for costs analysis assumes equivalence of health outcomes. However currently there are no data to conclude that this is in effect the case. The authors acknowledge that sicker patients are more likely to get treatment through physician-intensive follow-up, while patients who are doing well on treatment are more likely to be sent to nurse-intensive and pharmacy worker-intensive follow-up. Their analysis did not include any training, supervision and other start-up costs, which if included could have a big impact on the costs of each alternative. They also assumed equivalent health care utilization in all groups, which if different could result in differences in costs incurred by the patients when accessing care. Although uncertainty in the cost estimates was allowed for through sensitivity analysis, the ranges or distribution of values used for the analysis were not clearly justified and the results from the sensitivity analysis were not adequately discussed in the conclusions.

Jaffar *et al.* (2009) did not report any sensitivity analysis or discounting used. Although there was a comparison of the costs obtained with the costs from another study which reported similar costs, there was no discussion of any differences in study methodology.

Discussion

The results of this review suggest that non-inferior patient outcomes can be achieved with task-shifting from doctors to nurses, or from health care professionals to mid-level workers or lay health workers. These findings provide support to observational data on ART and to research on other disease conditions reporting the effectiveness of different models of task-shifting (Logan *et al.* 1979; Brown and Grimes 1995; Horrocks *et al.* 2002; Laurant *et al.* 2004; Callaghan *et al.* 2010). Chang *et al.* (2010) actually reported better virological outcomes from a task-shifting model after longer periods of ART (>72 weeks). The study suggested that the PHWs may mitigate the effects of 'treatment fatigue'. It would be useful to use empirical data to explore this long-term benefit on virological outcomes further, and the reasons that this might be so. It should also be noted that most of the studies conducted were relatively small and that more evidence is needed.

Long-term retention is increasingly receiving attention as one of the indicators of the success of ART programmes (Assefa *et al.* 2010). This is also evident in this review where only two out of the six effectiveness studies did not have retention or loss to follow-up as one of the outcomes of interest. Whilst Fairall *et al.* (2011) and Selke *et al.* (2010) look at retention after at least 12 months of follow-up, Chang *et al.* (2010) and Sanne *et al.* (2010) look at retention after more than 24 months of follow-up. These studies report non-inferior retention in the intervention groups when compared with the control groups. Chang *et al.* (2010) reported significantly lower loss to follow-up in the intervention group (PHW clusters) compared with usual care. This could have been due to more effective follow-up of patients by PHWs than what would have been possible using health care professionals alone. An earlier observational cohort study attributed the observed low rates of loss to follow-up to the work of lay workers who were working as adherence counsellors (Bedelu *et al.* 2007). In one study, the patients in the intervention clusters had significantly fewer clinic visits which could translate to time savings for the health care professionals, freeing them up for other non-ART work (Selke *et al.* 2010).

Task-shifting could result in substantial cost and physician time savings (Chung *et al.* 2008; Babigumira *et al.* 2009; Jaffar *et al.* 2009). Chung *et al.* (2008) however did not explore the effects of task-shifting on overall costs of providing ART. In Uganda, Babigumira *et al.* (2009) reported potential national annual savings of US\$1.51 million by using the nurse-intensive follow-up and US\$4.07 million by using pharmacy worker-intensive follow-up instead of the physician-intensive follow-up, from a societal perspective. The potential national annual savings for the Ugandan Ministry of Health would be US\$0.70 million by using the nurse-intensive follow-up and US\$2.10 million by using pharmacy worker-intensive follow-up instead of the physician-intensive follow-up. However, Babigumira *et al.* (2009) did not include a number of start-up and operational costs such as training and supervision. This is critical as, from the experience of some programmes, training and mentoring for task-shifting can be very time-consuming and resource intensive (Morris *et al.* 2009). Although cost analysis from these studies suggests that task-shifting is potentially cost-effective as it can be delivered at a lower cost

with no negative impact on health outcomes, more research is needed. In particular, robust cost-effectiveness studies are needed, such as RCTs where data on costs and effects are obtained from the same study population, incremental analysis of costs and consequences of alternatives is performed, and results are presented as an index or ratio of costs to effects.

National statutory requirements or policies which stipulate the tasks that can be performed by the different health professionals can be a barrier to task-shifting. Although WHO/PEPFAR/UNAIDS (WHO 2008) recommend nurse-initiated ART, in some countries this might not be possible due to restrictions that stipulate that only doctors can give prescriptions of ART medicines (Sanne *et al.* 2010). However, evidence from observational studies suggests that with adequate training, preparation, support and supervision, non-physician clinicians such as nurses and clinical officers can successfully prescribe ART and monitor non-complex patients (Bedelu *et al.* 2007; Gimbel-Sherr *et al.* 2008; Cohen *et al.* 2009; Shumbusho *et al.* 2009). Of the studies included in our review, only one evaluated nurse-initiated/prescribed ART in South Africa (Fairall *et al.* 2008; Fairall *et al.* 2011). Although this study did not demonstrate superiority of nurse-initiated/prescribed ART on reducing mortality when compared with doctor-initiated/prescribed ART, it demonstrated that expanding the role of the primary care nurses to include ART prescribing can be done safely. Studies from other disease areas have demonstrated that nurses can successfully prescribe medication and manage uncomplicated cases in particular settings in developed countries (Logan *et al.* 1979; Brown and Grimes 1995; Horrocks *et al.* 2002; Laurant *et al.* 2004). More research is needed on nurse-initiated/prescribed ART in developing countries. It could be relevant in some countries to re-evaluate statutory restrictions to the practice of different health care professionals, not only for HIV treatment but for all disease conditions where this is considered appropriate.

In the United Kingdom, for example, the non-medical prescribers programme allows specially trained nurses [Nurse Independent Prescribers (NIPs)] and other allied health professionals [e.g. Pharmacist Independent Prescribers (PIPs)] to prescribe any medicine for any medical condition within their competence (UK Department of Health, n.d.). The exception is on controlled drugs for which NIPs but not PIPs can prescribe. The initiative recognizes the need for more efficient use of the health workforce and ‘...gives patients quicker access to medicines, improves access to services and makes better use of nurses’, pharmacists’ and other health professionals’ skills’ (UK Department of Health, n.d.). Although the United Kingdom model might not be a best fit for developing countries, there are lessons that could potentially be learnt for application in appropriately adapted models to fit the developing countries’ contexts.

It is important to note that the effectiveness of the task-shifting models in the studies included in this review was probably enhanced by incorporation of many other best practices that have been described earlier. Thus, to preserve the effectiveness of task-shifting, training and creation of new capacity, it might be necessary to incorporate other strategies to maintain quality of care standards, and to motivate, maintain and retain staff (Phillips *et al.* 2008; WHO 2008). Studies therefore need to

adequately describe the different intervention components and the environment in which the intervention was implemented. This is crucial for decision making and effective intervention implementation. There is a need for guidelines on how to report these issues in such studies. The study by Fairall *et al.* (2011), of which the most detailed description of the intervention and its implementation is given in a related publication (Uebel *et al.* 2011), is a potential starting point for the development of such guidelines. Additional issues to consider include how the programmes designed the implementation (e.g. if it was phased implementation, what were the phases and their implementation sequence); managed to foster acceptability from relevant stakeholders, e.g. policy makers, health care workers, communities; and maintained effective communication between the different health care workers.

Three of the six effectiveness studies were conducted in Uganda, a country that is often held up as one of the success stories in Africa in the fight against HIV and AIDS (USAID 2002). Its HIV/AIDS programme has been recognized as having strong government leadership, political commitment and support, broad-based partnerships, a policy of openness enhancing better dialogue and communication, effective public education campaigns, supportive policy and social environment, and availability of local and external resources (USAID 2002; Uganda AIDS Commission 2008). However, the other three studies from South Africa and Kenya also echoed the results from the studies conducted in Uganda (Sanne *et al.* 2010; Selke *et al.* 2010; Fairall *et al.* 2011). The Ugandan studies might also have benefited from the prior existence of other CHW curative services in Uganda, such as administering intermittent preventive treatment for malaria to pregnant women (Mbonye *et al.* 2008) and delivering co-trimoxazole prophylaxis for HIV patients (Weidle *et al.* 2006). In countries where the use of lay health workers in delivering curative health services is uncommon, the effectiveness and acceptability of lay health workers delivering ART could be affected. These factors raise questions about the generalizability of these findings to other developing countries, and highlight the need to consider the local context if implementing task-shifting based on these findings. There is also a need to incorporate methods for robust evaluation of the short- and long-term impact of task-shifting if implemented in other settings.

Some of the limitations to the review include the limited number of studies examining each outcome, the limited number of studies of each task-shifting model, and the inability to perform a meta-analysis mainly because of clinical heterogeneity. Most of the identified studies were underpowered to detect any difference. Although we conducted an extensive search using a variety of search methods, we may have missed some studies, particularly those that are not published. The six effectiveness studies identified by this review enrolled adult participants only; hence application of the results to patient populations including children could be questionable. There is therefore a need for research in patient populations including children.

Conclusion

Our findings suggest that task-shifting from doctors to nurses or from health care professionals to lay health workers can

result in substantial cost and physician time savings without compromising the quality of care or health outcomes for patients. Hence it is a potentially effective and cost-effective approach to addressing the human resource limitations to ART rollout. However, more evidence is needed on the effectiveness and cost-effectiveness of each task-shifting model as it is currently limited.

Supplementary Data

Supplementary data are available at *Health Policy and Planning Online*.

Conflict of interest

We declare that we have no conflict of interest or financial interests.

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Appendix 1 MEDLINE search strategy

- (1) exp Antiretroviral Therapy, Highly Active/ or exp Anti-Retroviral Agents/ or antiretroviral therapy.mp. or exp Anti-HIV Agents/
- (2) ART.mp. or Art/
- (3) antiretroviral drug\$.mp./ or antiretroviral medicine\$.mp./ or anti-retroviral therapy.mp./ or anti-retroviral drug\$.mp./ or anti-retroviral medicine\$.mp.
- (4) or/1-3
- (5) hiv.mp. or exp HIV/ or exp HIV-2/ or exp HIV Seropositivity/ or exp HIV-1/ or exp HIV Infections/
- (6) human immunodeficiency virus.mp./ or human immunodeficiency virus.mp./ or human immunodeficiency virus.mp./ or human immune-deficiency virus.mp.
- (7) acquired immunodeficiency syndrome.mp./ or exp Acquired Immunodeficiency Syndrome/ or acquired immuno-deficiency syndrome.mp./ or acquired immune-deficiency syndrome.mp. or Acquired Immunodeficiency Syndrome/
- (8) or/5-7
- (9) balance of care.mp.
- (10) peer health worker.mp.
- (11) exp Community Health Aides/ or community care giver.mp/ or community care coordinator.mp./ or community care giver.mp.
- (12) exp Voluntary Workers/ or voluntary work*.mp./ or village health volunteer.mp.
- (13) nurs*.mp./ or enrolled nurse.mp.
- (14) exp Allied Health Personnel/ or allied health profession*.mp.
- (15) exp Physician Assistants/ or non-physician clinician.mp. or exp Nurse Practitioners/
- (16) community health work*.mp.
- (17) task shift*.mp./ or task-shift*.mp.
- (18) (assistant and (medical officer or clinical officer or nurse or pharmacist)).mp.
- (19) (auxiliary and (nurse or health worker)).mp.
- (20) exp Nurses' Aides/ or health care assistant*.mp.
- (21) skill mix.mp.
- (22) or/9-21
- (23) 4 and 8 and 22

Appendix 2. Critical appraisal of the studies on cost implications of task-shifting

Appendix 2

Criteria (Drummond et al. 2005)	Babigumira et al. (2009)	Jaffar et al. (2009)
1. Was a well-defined question posed in answerable form?	Examined only the costs but not the effects of task-shifting for follow-up.	Examined both costs and effects.
1.1. Did the study examine both costs and effects of the service(s) or programme(s)?	Compared standard care (physician intensive follow-up), with two other alternatives (nurse intensive follow-up and pharmacy worker intensive follow-up).	Compared two alternatives. However, the study was focused on home-based (with task-shifting embedded) vs facility-based ART.
1.2. Did the study involve a comparison of alternatives?	Compared the alternatives on offer in a particular programme.	Considered the societal perspective.
1.3. Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?	Considered the societal as well as the Ministry of Health perspective.	
2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where and how often)?	Yes A comprehensive description of the competing alternatives was given.	Yes A comprehensive description of the competing alternatives of interest was given.
2.1. Were there any important alternatives omitted?	Compared the alternatives on offer in a particular programme.	
2.2. Was (should) a do-nothing alternative be considered?		
3. Was the effectiveness of the programme or services established?	No The method used for the analysis assumes that health outcomes are equivalent. However, currently there are no data to conclude that the outcomes from these alternatives are equivalent.	Yes The study compared the effectiveness of the two alternatives through a randomized controlled trial.
3.1. Was this done through a randomized, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?	The study used available observational data on task-shifting to non-physician clinicians, nurses or lay health care workers. There are no observational data for the effectiveness of pharmacy worker-intensive follow-up.	
3.2. Was effectiveness established through an overview of clinical studies?		
3.3. Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?		
4. Were all the important and relevant costs and consequences for each alternative identified?	No The analysis did not include any training and supervision costs, or any other start-up costs, which if included could have a big impact on the costs of each alternative. However, the authors discussed the need for training and supervision as some of the issues to consider on implementation.	Yes All important and relevant capital and operating costs were included.
4.1. Was the range wide enough for the research question at hand?	They also assumed equivalent health care utilization in all groups and did not account for differences in costs associated with differences in health care utilization including transport costs or any other costs incurred by the patients when accessing care.	Although they took a societal perspective, in the presentation of the costs results the costs incurred by patients and those incurred by the health care providers are clearly demarcated.
4.2. Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending upon the particular analysis.)	All relevant view points were covered.	
4.3. Were the capital costs, as well as operating costs, included?		
5. Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, lost work-days, gained life years)?	Yes	Yes
5.1. Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?		
5.2. Were there any special circumstances (e.g. joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?		
6. Were the cost and consequences valued credibly?	Yes	Yes
6.1. Were the sources of all values clearly identified? (Possible sources include market values, patient or client preferences and views, policy-makers' views and health professionals' judgements.)		
6.2. Were market values employed for changes involving resources gained or depleted?		

(continued)

Appendix 2 Continued

Criteria (Drummond et al. 2005)	Babigumira et al. (2009)	Jaffar et al. (2009)
6.3. Where market values were absent (e.g. volunteer labour), or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values?		
6.4. Was the valuation of consequences appropriate for the question posed (i.e. has the appropriate type or types of analysis—cost-effectiveness, cost-benefit, cost-utility—been selected)?		
7. Were costs and consequences adjusted for differential timing?	n.a.	No
7.1. Were costs and consequences that occur in the future 'discounted' to their present values?		
7.2. Was there any justification given for the discount rate used?		
8. Was an incremental analysis of costs and consequences of alternatives performed?	No The study was only looking at costs and not consequences.	No Although the study examined both costs and effects, they did not do incremental analysis. The costs were reported separately from effects.
8.1. Were the additional (incremental) costs generated by one alternative over another compared with the additional effects, benefits or utilities generated?		
9. Was allowance made for uncertainty in the estimates of costs and consequences?	Yes Uncertainty in the cost estimates was allowed for through sensitivity analysis conducted by varying wages, physician time and other parameters. However, the ranges or distribution of values used were not clearly justified and the results from the sensitivity analysis were not adequately utilized in the conclusions.	No
9.1. If data on costs and consequences were stochastic (randomly determined sequence of observations), were appropriate statistical analyses performed?		
9.2. If a sensitivity analysis was employed, was justification provided for the range of values (or for key study parameters)?		
9.3. Were the study results sensitive to changes in the values (within the assumed range for sensitivity analysis, or within the confidence interval around the ratio of costs to consequences)?		
10. Did the presentation and discussion of study results include all issues of concern to users?	No The study did not calculate an index or ration of costs to consequences as it only considered the costs.	No The study did not base the conclusions on an index or ration of costs to consequences.
10.1. Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?	As this was the first study of its kind, no comparisons with results from other studies was possible.	The authors compared the costs obtained in their study with the costs from another study which reported similar costs. However, there was no discussion of any differences in study methodology.
10.2. Were the results compared with those of others who have investigated the same question? If so, were allowances made for potential differences in study methodology?	However, the authors discuss the need for training and supervision as some of the issues to consider on implementation.	The generalizability of the results to other settings and patient groups is uncertain.
10.3. Did the study discuss the generalizability of the results to other settings and patient/client groups?		The feasibility of implementation of the task-shifting model is partially discussed. The authors state that the model is achievable in Africa since counsellors and other support staff are more easily available and rapidly trained than clinic staff.
10.4. Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences, or relevant ethical issues)?		
10.5. Did the study discuss issues of implementation, such as the feasibility of adopting the 'preferred' programme given existing financial or other constraints, and whether any freed resources could be redeployed to other worthwhile programmes?		