Titles: Task shifting - physicians (doctors) versus non-physicians (nurses or clinical officers) for initiation and maintenance of antiretroviral therapy

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1. PICO question

a

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<thead>
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<th>a</th>
<th>Task shifting from physicians (doctors) to non-physicians (nurses or clinical officers) for initiation of ART</th>
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<td>P</td>
<td>ART-eligible people living with HIV in a generalized or concentrated epidemic</td>
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<td>Initiation of ART by appropriately trained non-physician health care workers</td>
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<td>Initiation of ART by physicians</td>
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<td>HIV incidence, transmission, mortality, morbidity, access, retention and other outcomes to be noted in the protocol</td>
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<tr>
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<td>HIV incidence, transmission, mortality, morbidity, access, retention and other outcomes to be noted in the protocol</td>
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2. Search strategy
(01 Jan 1996 – 02 April 2012)

- PubMed
- EMBASE
- CENTRAL
- Web of Science
- WHO Global Health Library Virtual Platform
  (AIM, LILACS, IMEMR, IMSEAR, WPRIM, WHOLIS)
- WHO International Clinical Trials Registry Platform (ICTRP)

Also: CROI, IAS, IAC conference abstracts, conference inception to 2012

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<th>Search</th>
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<td>#7</td>
<td>Search #3 AND #4 AND #5 Limits: Publication Date from 1996/01/01 to 2012/04/02</td>
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<tr>
<td>#6</td>
<td>Search #3 AND #4 AND #5</td>
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<td>#5</td>
<td>Search task* OR task-shifting OR referr* OR referral and consultation[mh] OR role*</td>
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<td>#4</td>
<td>Search health personnel[mh] OR doctor OR doctors OR clinician OR clinicians OR physician OR physicians OR &quot;healthcare provider&quot; OR &quot;healthcare providers&quot; OR &quot;health care provider&quot; OR &quot;health care providers&quot;</td>
</tr>
<tr>
<td>#3</td>
<td>Search #1 AND #2</td>
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<td>#2</td>
<td>Search Antiretroviral Therapy, Highly Active[MeSH] OR Anti-Retroviral Agents[MeSH] OR Antiviral Agents[MeSH:NoExp] OR ((anti) AND (hiv[tw])) OR antiretroviral*[tw] OR ((anti) AND (retroviral*[tw])) OR HAART[tw] OR ((anti) AND (acquired immunodeficiency[tw])) OR ((anti) AND (acquired immuno-deficiency[tw])) OR ((anti) AND (acquired immune-deficiency[tw])) OR ((anti) AND (acquired immunedeficiency[tw])) OR ((anti) AND (acquired immunedeficiency[tw]))</td>
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3. Flow diagram of screening process

4. Evidence summaries

4.1. PICO a: Physician (doctors) versus non physicians (nurses or clinical officers) for initiation and maintenance of antiretroviral therapy

Four studies, including one randomized controlled trial (Fairall 2012) and three retrospective cohorts (Assefa 2012; Bedelu 2007; Sherr 2010) were examined in this comparison. The data were grouped by study design.

1. Mortality (12 months)

Evidence from clinical trials

One cluster randomized trial (Fairall 2012), including 31 peri-urban and rural clinics in South Africa, enrolled between January 2008 and June 2009. The specific cohort (cohort 1) within this trial included patients who were eligible for ART or were likely to become eligible during the trial. A total of 9252 patients were enrolled; however, adjusting for the design effect introduced by the clustering, an effective sample size of 2769 adults provided data for this outcome. The participant characteristics were similar at baseline (sex, age and CD4+ cell count), except that there were more WHO clinical stage 1 (52% versus 32%) and fewer WHO clinical stage 3 (24% versus 38%) patients in the intervention group. In addition, 965/3712 (26%) patients were initiated on therapy by a nurse in the intervention group versus none in the control group. The results reported no difference in mortality between nurse-led and doctor-led initiation.
of ART and maintenance HIV treatment, with the adjusted HR being 0.92 (95% CI 0.76–1.12), \( P = 0.40 \), adjusted for age, sex, CD4\(^+\) cell count and available identify number. The unadjusted risk ratio was 0.96 (95% CI 0.82 to 1.12), \( P = 0.55 \). Overall, the clinical trial provided high-quality evidence that there is no difference in mortality outcomes between the patients initiated and followed up by nurses compared to those seen by doctors.

**Evidence from observational studies**

Three retrospective cohort studies examined this outcome (Assefa 2012; Bedelu 2007; Sherr 2010), but only the first two, including 39,160 adults, contributed data for this analysis. Sherr 2010 included patients initiated by clinical officers; however, during follow-up it was not clear whether patients were seen by clinical officers or doctors, as patients were allowed to choose on the day of their appointments who they would see. This provided data that were too confounded to include in our analysis for this comparison. For the other two cohorts included, in addition to the inherent bias and confounding associated with cohort studies, Bedelu (2007), set in rural South Africa, included patients with lower CD4\(^+\) cell counts in the intervention group, presenting a high risk of selection bias. Further, the intervention group also received regular support from experienced clinical staff, resulting in further risk of performance bias. On the other hand, although Assefa (2012), set in rural and peri-urban Ethiopia, had similar baseline CD4\(^+\) cell counts in both groups, other characteristics such as sex, age and clinical stage at baseline were not described. Analysis of mortality at 12 months reported an increased risk of death in the task-shifting group; the RR was 1.23 (95% CI 1.14–1.33), with no statistical heterogeneity detected. In other words, there was a 23% increased risk of death in the task-shifting group although the baseline imbalance in morbidity should bias the result in favour of task shifting.

The use of crude proportions extracted from the study reports does not adjust for important potential confounding or take into account the losses of patients over time. The quality of the data was not further downgraded for risk of bias, since the direction of the bias was expected to favour the intervention and yet the control was favoured in the results. This cohort data provided low-quality evidence that there may be an increased risk of death in models of care that include both decentralization and task shifting.

2. **Lost to care (12 months)**

**Evidence from clinical trials**

The Fairall (2012) trial including a cohort of patients eligible to initiate antiretroviral therapy as described in detail above. Lost to care was defined as patients not having reported to the clinic in the previous three months and whose vital status was not known at the end of the trial. The trial reported a slightly lower rate of losses to care in the task-shifting group (5.5%) compared with the doctor group (7.7%) with an RR of 0.73 (95% CI 0.55–0.97), \( P = 0.03 \). In this trial, retention was defined as patients who are alive and still enrolled in the programme after 12 months, were not known to have withdrawn or relocated and had a documented clinic visit or laboratory test in the previous six months if started on ART or last known CD4\(^+\) cell count was below 200 cells/mm\(^3\); or in the past nine months if they had not yet started ART and had a CD4\(^+\) cell count >200 cells/mm\(^3\). The adjusted risk ratio for programme retention was 1.10 (95% CI 1.04–1.16), \( P = 0.001 \), adjusted for randomisation strata and intracluster correlation of outcomes. This supports the hypothesis that nurse-initiated and -maintained antiretroviral therapy improves retention and minimizes the number of patients lost to care compared to those seen by doctors in this model of treatment.

**Evidence from observational studies**

Two retrospective cohort studies, Bedelu (2007) and Assefa (2012), contributed data for this outcome. There were no adjusted results available, and the crude data are therefore reported. There was no difference in patients lost to care between the task-shifting group and doctor-led care, the relative risk was
0.30 (95% CI 0.05–1.94), \( P = 0.21 \). There was substantial statistical heterogeneity between the studies \( (I^2 = 98\%) \). In addition, we found potential clinical heterogeneity in patients’ baseline characteristics (such as CD4+ cell counts) and methodological heterogeneity in the models of care provided. Although both studies are consistent in favouring lower numbers of patients lost to care in the intervention groups, due to imprecision indicated by the wide confidence interval, we have downgraded the quality of the data. These data provide very-low-quality evidence about patients lost to care.

**Overall findings for PICO a:**

Overall, high-quality evidence indicates no difference in mortality whether nurses or doctors initiate antiretroviral therapy. This is provided that the model of care includes specific training and organizational support for professional nurse practitioners prescribing and following up persons newly initiated on antiretroviral therapy. Overall, moderate-quality evidence from one cluster trial indicates lower losses to care when nurses initiated and maintained patients on antiretroviral therapy compared to doctors. The quality of the data was downgraded for imprecision due to the relatively low number of events.

**4.2. PICO b: Physician (doctors) versus non physicians (nurses or clinical officers) for maintenance of antiretroviral therapy (facility based)**

Three studies examined this comparison, including two randomized controlled trials (Fairall 2012; Sanne 2010) and one retrospective cohort study (Brennan 2011). The data were grouped by study design and describe the two critical outcomes: death and patients lost to care.

**1. Mortality (12 months)**

**Evidence from trials**

Two trials contributed data to this analysis (Fairall 2012; Sanne 2010). Both trials took place in rural or peri-urban (often informal settlement) settings in South Africa. Both had a low risk of bias for all the parameters in our modified criteria for risk of bias, except that Fairall (2012) had an unclear risk of contamination from doctors being drafted to intervention sites by the provincial government. Fairall (2012) recruited a different cohort (cohort 2 in the trial) from that described above, since patients were already receiving antiretroviral therapy and were then referred to care by a nurse, rather than the standard care, which included a doctor. The professional nurses received a specific package of training to enable them to monitor clinical and adverse drug reactions for these patients and received specific support through supervision and involvement of clinic management in the model of care. In the Sanne (2010) trial, primary care nurses and doctors not experienced with ART delivery were provided with specific didactic and clinical training in accordance with national guidelines. Contamination was prevented in this trial by scheduling patients for the respective cadre of health workers on different days. The trial aimed to provide continuity of care, and patients were able to see the same practitioner at each follow-up visit. Lay counsellors provided additional adherence support. Before meta-analysis, data from the cluster randomized trial Fairall (2012) were adjusted for the design effect using the intracluster correlation coefficient reported in the study before being combined in a meta-analysis. The result showed no difference in mortality between task shifting and doctor-led ART maintenance care when ART had previously been initiated by a doctor, with an RR of 0.89 (95% CI 0.59–1.32), \( P = 0.55 \). There was no statistical heterogeneity \( (I^2 = 0\%) \).

**Evidence from observational studies**

One retrospective cohort study (Brennan 2011), reported this outcome. The study used propensity scoring to match patients in the intervention and control groups. In this study, task shifting also involved decentralization from hospital to health centre care. In addition to the propensity scoring, Brennan (2011)
reported adjusted rates of mortality at 12 months, and the adjusted hazard ratio was 0.2 (95% CI 0.04–0.8) per 100 person-years. This was adjusted for important baseline characteristics, including sex, age and CD4+ cell count. The crude result from the data on proportions we extracted provides similar results, a statistically significantly reduced risk of death in the task-shifting group compared to doctor-led care; RR of 0.19 (95% CI 0.05–0.78), \( P = 0.02 \).

2. Lost to care (12 months)

*Evidence from clinical trials*

Analysis of data from the two RCTs that reported on mortality also showed no difference in the numbers of patients lost to care in task-shifted care compared to doctor-led care, with a relative risk of 1.27 (95% CI 0.92–1.77), \( P = 0.15 \). There was no statistical heterogeneity between the results of the studies included in this analysis. The quality of the data was downgraded for imprecision, and we therefore report moderate-quality evidence indicating that there is probably little difference in patients lost to care whether doctors or nurses provide HIV care at similar primary care health centres.

*Evidence from observational studies*

The single cohort (Brennan 2011) showed significantly less loss to follow-up in the task-shifting group compared to doctor-led ART maintenance care, RR 0.34 (95% CI 0.18–0.66), \( P = 0.001 \). These data are considered of very low quality due to the nature of the study design and the imprecision of the results, with low event rates reported.

**Overall findings PICO b (Physician (doctors) versus non physicians (nurses or clinical officers) for maintenance)**

Overall, the GRADE analysis provides moderate-quality evidence indicating that task shifting of antiretroviral maintenance care does not increase mortality compared with doctor-led ART care. The data were downgraded for imprecision due to a wide confidence interval and relatively low event rate. Overall, moderate-quality evidence from two trials indicates that there is probably no difference in the numbers of patients lost to care whether nurses or doctors provide follow-up and maintenance antiretroviral care after one year of follow-up.

**PICO b: physician (doctor) versus non-physician (community health worker) for maintenance of antiretroviral therapy (community model)**

One randomized controlled cluster trial (Jaffar 2009) contributed data for the critical outcomes death and patients lost to care at 12 months.

1. Mortality (12 months)

*Evidence from clinical trial*

One trial investigated task shifting from doctors to specifically trained community workers for ART maintenance care (Jaffar 2009). This trial took place in various parts of urban, peri-urban and rural Uganda and included adults initiated on treatment in hospital by doctors and then down-referred only once stable on their treatment and consenting to down-referral. The intervention group received home-based community worker support and monitoring with a field officer monthly using a checklist and mobile phone, with daily review of the field officers’ notes by the designated medical officer. The
Evidence from observational studies
None provided 12-month data.

2. Lost to care (12 months)

Evidence from clinical trial
The Jaffar (2009) trial also reported on this outcome. No adjusted result was found in the published report, but we adjusted for clustering (using the liberal intracluster coefficient of 0.05). The relative risk for patients lost to care was 0.52 (95% CI 0.12–2.3), \( P = 0.39 \). Moderate-quality evidence from this trial shows that losses to care are probably not different whether doctor or home-based care is provided in this decentralized manner. The quality of the data was downgraded for the small sample size, low number of events and wide confidence interval.

Evidence from observational studies
None provided 12-month data.

Overall findings for PICO b (task shifting from physician (doctor) to non-physician (community worker) for maintenance of antiretroviral therapy)
This GRADE analysis provides moderate-quality evidence indicating that there is probably no difference in mortality when doctors deliver care in the hospital or specially trained field workers provide home-based maintenance care and ART delivery. The quality of the data was downgraded for imprecision due to the small effective sample size and event rate, resulting in a wide confidence interval. Moderate-quality evidence from this trial indicates that losses to care are probably not different whether doctor or home-based care is provided in this decentralized manner. The quality of the data was downgraded for the small sample size, low number of events and wide confidence interval.

Other outcomes

3. Immune changes – CD4+ count
Six of the nine included studies report on CD4+ count. Since they all report the CD4+ cell count variably, these data were not pooled.
For initiation and maintenance, Fairall (2012) (cohort 1) reports a CD4+ cell count mean (SD) at follow-up by nurses of 161 cells/mm\(^3\) (175) versus 141 cells/mm\(^3\) for doctors (161), with the difference in the means of 22.3 cells/mm\(^3\) (95% CI 3.6–40.9), \( P = 0.02 \), favouring nurse care. This was adjusted for randomization strata and intracluster correlation. Bedelu (2007) reports the proportion above 200 cells/mm\(^3\), the crude proportion reports that 303/348 tests done in the health centre under nurse care were above this threshold versus 61/81 of those done at the hospital by doctors. Assefa (2012) does not report on this outcome.
For maintenance of care, Fairall (2012) (cohort 2) reports that the mean (SD) for CD4+ cell count at follow-up by nurses was 438 (219) compared to 418 (201) for doctors, with the difference in the means
reported as 24.2 (95% CI 7.2–41.3), \( P = 0.007 \) favouring nurse care. This was adjusted for randomization strata and intracluster correlation. Sanne (2010) reported the median increase in CD4 cell count; at one year, patients in nurse care had a median increase of 155 cells/mm\(^3\) (interquartile range 119–193) compared to a doctor-led care median increase of 158 cells/mm\(^3\) (interquartile range 125–169). This was sustained to two years, where patients being cared for by nurses had a median increase of 239 cells/mm\(^3\) (interquartile range 217–290) compared to doctor-led care of 220 cells/mm\(^3\) (interquartile range 174–274). These results are not clinically significantly different. Humphreys (2010) reports a mean change at six months only, where patients in nurse care had a CD4\(^+\) cell count of 103 cells/mm\(^3\) compared to those in doctor care with a mean of 103 cells/mm\(^3\) (\( P = 0.7 \)). Brennan (2011) did not report on this outcome.

For the comparison of community field worker follow-up compared to doctor care, the 12-month median (interquartile range) is reported, where patients in the community had a CD4\(^+\) cell count of 250 cells/mm\(^3\) compared to 260 cells/mm\(^3\) (interquartile range 180–350) compared to 260 cells/mm\(^3\) (interquartile range 190–375), which was not statistically significantly different.

Fairall (2012) provides the highest quality data reporting probable benefit if nurses deliver care compared to doctors.

4. Viral load suppression

Four of the included studies report variably on this outcome. Bedelu (2007) reported on the proportion of patients with viral load <400 copies/ml. In the nurse group, 89% compared to 78% in the doctors’ group were below this threshold, but the numbers of CD4\(^+\) cell count tests conducted differed substantially between the groups: 50% versus 10% of patients tested in the nurse and doctor group respectively.

Fairall (2012) found no difference in either cohort for viral suppression. The trial reports an adjusted risk ratio for the patients with a viral load below 400 copies/ml in cohort 1 (initiation and maintenance), with an adjusted RR of 0.97 (95% CI 0.9–1.03), \( P = 0.32 \). In cohort 2 (maintenance of care), the risk difference of those with suppressed viral load is reported as RD 1.1% (95% CI –2.3% to 4.6%), \( P = 0.53 \). Sanne (2010) reports the hazard ratio for all viral failure (including early failure, which is less than a log\(_{1.5}\) decrease in viral load from baseline to 12 weeks of treatment; and late viral failure is two consecutive viral loads four weeks apart of more than 1000 copies/ml. The hazard ratio was 1.15 (95% CI 0.75–1.76), indicating no statistically significant difference between the groups.

Jaffar (2009), the only study reporting this outcome for the comparison of community field officer care with doctor care, reported an adjusted rate ratio for having a viral load above 500 copies/ml of 1.04 (95% CI 0.78–1.4), supporting no difference.

Overall, the reported viral suppression or failure rates were similar across the down-referred and control groups across these varied studies, except Bedelu (2007), which had a relative imbalance in the numbers of patients being tested for viral load between groups and, being a retrospective cohort, may not have been adequately powered for this outcome.

5. Cost to providers and patients

One prospective cohort, Humphreys (2010), reports specifically on the cost of travel for patients. The average cost for a patient seen by a nurse was US$ 0.74 compared to US$ 1.5 for a patient seen at the hospital by a doctor (\( P = 0.001 \)).

Two studies provided data for the outcome on the overall cost to the patient. Both reports come from community based treatment by a field worker compared to standard doctor-led hospital-based treatment (Jaffar 2009; Kipp 2010). Both studies indicate a substantial increase in the cost to the patients when they are required to travel to the hospital, which is usually further from their homes. Kipp (2010) reports a doubling of cost to patients when accounting for transport only. Jaffar (2009), the cluster trial, reports a three times increase in costs, including transport, lost work time, childcare costs and food.
The costs to the health service are also reported. Jaffar (2009) reported the costs to the health service for community care versus doctor-led hospital-based groups. These costs included staff, transport, drugs, laboratory, training, supervision, capital and utility costs and was a mean of US$ 793 per patient per year for each patient in the home-based group versus US$ 838 per patient per year in the hospital-based group.

6. Time to initiation of ART
For initiation and maintenance, Fairall (2012) (cohort 1) reports the adjusted hazard ratio for time to initiation of ART as 1.14 (95% CI 0.92–1.43), \( P = 0.23 \), adjusted for randomization strata and intracluster correlation of outcomes.

7. New tuberculosis diagnosis
For initiation and maintenance, Fairall (2012) (cohort 1) reports on new tuberculosis (TB) diagnoses being made. The risk ratio was 1.46 (95% CI 1.18–1.81), \( P = 0.001 \), supporting the superiority of nurses compared to doctors in this model of care for diagnosing TB. For maintenance of care, Fairall (2012) (cohort 2) reports the risk difference between groups for new TB diagnoses of 0.21% (95% CI –2.1 to 1.54), \( P = 0.76 \), indicating the equivalence of the diagnosis rate regardless of whether a doctor or nurse delivered the care.

8. Patient satisfaction with care
Assefa (2012) and Humphreys (2010) included a qualitative component to their studies, which report on patient satisfaction with the model of care by group.

Assefa (2012) evaluated patient satisfaction with care by conducting two-hour focused group discussions (57 patients in 7 groups). They looked predominantly at the issue of task shifting and its acceptability among patients and health care providers. Patients reported that nurse and health officer (clinical officer) services were “generally well accepted and reduced waiting time”. They also revealed that they were “more comfortable with nurses than with physicians because nurses were friendlier and more supportive”. Patients emphasized that nurses and health officers spent more time with them discussing their medical problems and took enough time examining them. Patients identified three additional benefits of being involved in ART delivery: their life experience helped them to provide appropriate counselling; it helped combat stigma and discrimination in society; and it provided them with an opportunity for employment. In the same study, focused group discussions were held with programme managers and health care providers, who agreed that the model, including task shifting, provides a timely solution for Ethiopia’s needs. They also agreed that nurses and health officers can provide high-quality care given adequate training and supervision.

Humphreys (2010) was a prospective cohort that used the model of decentralization from hospital to health centre and task shifting from doctors to nurses. This study included a qualitative assessment of patient satisfaction as a primary outcome. Those attending the intervention clinic were asked about their level of satisfaction, and 25/31 of those who responded said that they were very satisfied with the care received. The reasons provided included the reduced cost of transport, being nearer to home, shorter queue, being treated better by staff, receiving better care and that they would not be talked about. The two respondents who were not satisfied with the care complained about the lack of a doctor, saying they did not have money to get to the main clinic and that there was a delay because staff from the hospital arrived late at the health centre.

9. Time to initiation of antiretroviral therapy
Fairall (2012) (cohort 1) reports on initiation and maintenance and includes time to initiation of ART as one of the secondary outcomes. The reported hazard ratio is 1.14 (0.92–1.43), \( P = 0.2 \), comparing nurses to doctor-led care. This was adjusted for the competing risk, death.
10. New AIDS-defining illness, any negative effects on health care delivery
None of the included studies specifically reported on new AIDS-defining illness or on general negative effects on health care delivery.

5. Bibliography of included studies

5.1. Doctor versus nurse or clinical officer for initiation and maintenance of antiretroviral therapy

5.2. Doctor versus nurse or clinical officer for maintenance of antiretroviral therapy

5.3. Doctor versus community health worker for maintenance of antiretroviral therapy
6. Excluded studies with reasons

   - Modelling study

   - Descriptive. No clear comparison between doctor-led management and non-doctor-led management of ART

   - Analysis of regulatory framework

   - Not comparing doctor-led care versus non-doctor-led care

   - Mixed methods study, not comparing doctor-led care versus non-doctor-led care

   - Descriptive study for STRETCH (Fairall 2009)

   - Purely qualitative study

   - Mapping descriptive study in Haiti

   - Descriptive study of programme in Zambia


This work was commissioned by the World Health Organization and carried out by The University of California, San Francisco (UCSF), Cochrane Review Group on HIV/AIDS
• Descriptive study in Malawi and Ethiopia

  • Limited access to a doctor in the control arm

  • Descriptive. Substudy of Sherr (2010)

  • Adherence support, not comparing doctor led care versus other carer

  • Cross-sectional study

  • Descriptive. Substudy to Fairall (2009)

  • Qualitative study of agreement between health workers

  • Case-control study design

  • Descriptive study