Decentralising HIV treatment delivery in middle- and low-income countries (Protocol)

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[Intervention Protocol]

Decentralising HIV treatment delivery in middle- and low-income countries

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate retention, and quality of initiation and maintenance of HIV/AIDS care, in HIV treatment care models that decentralise from hospitals to more basic levels of care.

BACKGROUND

Description of the condition

The spread and volume of HIV care and treatment services has increased markedly in low and middle-income countries (LMIC). As of mid-2011, over 6 million people were receiving antiretroviral therapy (ART) in LMIC. In spite of progress to date, the global coverage for ART is still below 50% (UNAIDS 2011). The current rate of enrolment of patients on ART is insufficient to reach the global goal.

An effective service needs HIV testing and counselling services to be linked to HIV care and treatment; requires ART initiation as early as recommended by WHO; and a service that retains patients. This will help decrease AIDS-related mortality, reduce costs and maximize efficiency gains, and avert new infections (Ford 2011). Yet there are a number of constraints at all of these steps; for example, recent systematic reviews have indicated that, for those who do initiate ART, retention in care is a major challenge, with around 30% of patients estimated to be lost to follow-up within 24 months of initiating ART (Fox 2010). Access to care appears to be an important driver of poor retention, with transport costs, time spent travelling to health facilities, and time waiting for services at health facilities all cited as reasons for defaulting (Kagee 2011; Miller 2010; Ware 2009).

Description of the intervention

In order to increase access to care -- both to allow more people to be treated, and for those that are in care, to improve retention -- a number of countries have introduced two important, linked adaptations to the traditional, "Western-based" model of care provision: first, the "task shifting" of treatment from more highly trained specialists and medical practitioners to nurses; secondly, the decentralisation of ART care delivery from hospitals to more peripheral health facilities.

Task shifting is the process whereby specific tasks are transferred to different cadres of health workers who have had less training and have fewer qualifications. Task shifting aims to make efficient use of existing health care workers in order to ease delays in service delivery (WHO 2008). Task shifting may also include the delegation of clearly-outlined duties to various levels of health workers who receive specific, skills-based training. Task-shifting should result in an equivalent standard of care to that provided by higher cadres of health workers. There are trials and systematic reviews and reports that nurses can provide care that is at least as good as that provided by physicians (Laurant 2004; Sanne 2010).

Decentralisation of care is key for efficient service delivery, including increasing access to care for large numbers of patients not yet in care, and facilitating treatment closer to the homes of patients, thereby improving convenience and reducing travel costs. The overall aim is to improve retention in care, which is a critical outcome for successful and sustained HIV/ADS treatment. This review primarily interrogates the value of decentralisation of care, and the related programmatic indicator of success, retention in care. Task shifting is being addressed by a separate Cochrane review (Araoyinbo 2008).

How the intervention might work

The benefits of decentralisation include increased access to care, which, in turn, may improve health outcomes: it may increase the individual patient attention by nurses and counsellors, as there may be lower staff to patient ratios; and the point of care may be closer to the community, and the increased access may reduce defaulting and treatment failure (Fatti 2010).

On the other hand, there is legitimate concern that the provision of care at lower levels of the health service may result in decreased quality of care and poorer clinical outcomes (Decroo 2009). Given these uncertainties, the extent to which HIV/AIDS treatment is available via decentralised services varies considerably between and within countries. There is a need for clarity around the risks and benefits of decentralising ART service in order to inform future operational guidance.

One of the problems in cross-national comparisons of HIV care is in terminology. First, with terminology of health services, and secondly with models of decentralisation. For health services, the problem is that "community," "health post," "health centre" and "hospital services" vary in meaning and in what they represent between countries. For example, a health centre in Tanzania has paramedical staff, and is equivalent to a district hospital in Thailand.

In this review, we define each "tier" in the health system by the staffing configuration they have (Table 1). Thus, for community, the care is provided by someone with only a few months training; for a health centre, this is led by a paramedic or nurse; for a hospital, it is led by a doctor; and for an advanced hospital, there are specialist doctors present. In the table we also define community in three categories: family member, village volunteer, or a primary health care clinic with a nurse aide or community health worker. At community care level, systems may thus be established to deliver treatment at household level. This framework is to help describe different programmes, but it may be modified in the light of models identified in the literature.

For HIV care, the emerging models are giving rise to a variety of terms, such as "decentralised," "down referral," and "delocalised." To help classify models and allow cross study comparisons, we have developed a nomenclature (Table 2). This is not meant to be definitive and may need to be modified as the models of care develop, but provides a working framework for this review.

OBJECTIVES

To evaluate retention, and quality of initiation and maintenance of HIV/AIDS care, in HIV treatment care models that decentralise from hospitals to more basic levels of care.

METHODS

Criteria for considering studies for this review

Types of studies

- Randomised, non-randomised and controlled before-and-after studies.
- Prospective and retrospective cohort studies with a comparison between standard delivery of HIV treatment and one where components of HIV treatment and care are delegated to a lower level in the health care delivery system.
- Comparators need to be contemporary (delivered at the same time), in the same country, and geographically adjacent (such as adjacent districts within a province).

Types of participants

- HIV-infected patients at the point of initiating treatment.
- HIV-infected patients on treatment requiring maintenance and follow up.

Types of interventions

Intervention

- Any form of care delivery that is decentralised out of the hospital, for initiating treatment, continuing treatment, or both.
- Decentralised is defined as provision of treatment at a more basic level in the health system than the control site (Table 1).

Control

- Care delivered at the usual site.

Types of outcome measures

Primary outcomes

- Retention: Any measure of comparative retention between study populations at set time points after the intervention as defined by the study authors.
- Death after being considered eligible for treatment, or during treatment.

Secondary outcomes

- Time to initiation of antiretroviral treatment.
- Patients diagnosed with tuberculosis after entry into HIV care.
- Virologic response to ART. This is the proportion of participants that reach or maintain a pre-defined level of viral load suppression, as defined by the study authors.
- Immunologic response to ART. This is the mean change in the concentration of CD4+ lymphocytes from baseline, as expressed in cells/μL.
- Occurrence of a new AIDS-defining illness. This is a newly diagnosed WHO clinical stage 4 illness.
- Patient satisfaction with care, as defined by the study authors. We will include qualitative analysis if available.
- Cost to the provider.
- Cost to the patient and family.
- Any negative impact on other programme and health care delivery reported by the authors.

Search methods for identification of studies

See the Cochrane HIV/AIDS Group search strategy.

Electronic searches

In collaboration with the Trial Search coordinator of the Cochrane HIV Review Group, we will develop a comprehensive search strategy to identify all relevant studies regardless of language or publication status (published, unpublished, in press, and in progress). We will search from 1 January 1996 because triple-drug ART was not used before this year. We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE
- EMBASE
- LILACS
- Web of Science

Key words will include MeSH terms and free-text terms relevant to decentralisation, down referral, delivery of health care, health services accessibility, and other relevant terms.

Searching other resources

Researchers and relevant organisations. We will contact individual researchers working in the field and policymakers based in inter-governmental organizations, including the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) to identify studies either completed or ongoing.

Reference lists. We will check the reference lists of all studies identified by the above methods and examine the bibliographies

of any systematic reviews, meta-analyses, or current guidelines we identify during the search process.

Ongoing studies. We will search the WHO International Clinical Trials Registry Platform search portal for information on unpublished and on-going trials.

Data collection and analysis

The methodology for data collection and analysis is based on the guidance of Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2008). Abstracts of all trials identified by electronic or bibliographic scanning will be examined by two authors working independently. Where necessary, the full text will be obtained to determine the eligibility of studies for inclusion.

Selection of studies

We will aim to remove duplicate references using a reference management software. Following this, a Cochrane research specialist will do a broad review of results, excluding those that are clearly irrelevant. Two authors will independently select potentially relevant studies by scanning the titles, abstracts, and descriptor terms of the remaining references and apply the inclusion criteria. Irrelevant reports will be discarded, and the full article or abstract obtained for all potentially relevant or uncertain reports. The two authors will independently apply the inclusion criteria. Studies will be reviewed for relevance, based on study design, types of participants, exposures and outcomes measures. A neutral third party will adjudicate any disagreements that could not have been resolved by discussion.

Data extraction and management

After initial search and article screening, two reviewers will independently double-code and enter information from each selected study onto standardised data extraction forms. Extracted information will include:

- Study details: citation, start and end dates, location, study design and details.
- Participant details: study population eligibility (inclusion and exclusion) criteria, ages, population size, attrition rate, details of HIV care and disease progression and any clinical, immunologic or virologic staging, tuberculosis or laboratory information.
- Interventions details: level of health service, cadre of health worker and other forms of patient support, including diagnosis of tuberculosis.
- Outcome details: retention in care, mortality, tuberculosis case finding, AIDS-related progression of disease, virological and immunological outcomes, patient satisfaction, cost of care.

The interventions will be carefully and systematically described, to ensure that all of the interventions and co-interventions that are reported are captured.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias within the included studies against key criteria described below in accordance with methods recommended by the Cochrane Effective Practice and Organisation of Care (EPOC) Group and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). The following judgments will be used: low risk of bias, high risk of bias or unclear risk of bias (either due to lack of information or uncertainty over the potential for bias). We will resolve disagreements by consensus, or involve an arbitrator when necessary.

Risk of bias for studies with a separate control group

Randomised controlled trials (RCTs); Non-randomised controlled trials (NRCTs) and Controlled before-after (CBA) studies:

Nine standard criteria are suggested for all RCTs, NRCTs and CBA studies from the EPOC. Further information can be obtained from the *Cochrane Handbook* section on risk of bias (Higgins 2008a).

1. Adequate generation of the allocation sequence
2. Adequate allocation concealment
3. Baseline outcome measurements were similar
4. Baseline characteristics were similar
5. Incomplete outcome data were adequately addressed
6. Knowledge of the allocated interventions was adequately prevented during the study (where applicable)
7. The study was adequately protected against contamination
8. The study was free from selective outcome reporting
9. The study was free from other risks of bias

Cohort studies:

We will use the Newcastle-Ottawa Scale (Newcastle-Ottawa Scale) to assess the quality and risk of bias in non-randomised studies. Specifically, the scale uses a star system to judge three general areas: selection of study groups, comparability of groups, and ascertainment of outcomes (in the case of cohort studies). As a result, this instrument can assess the quality of non-randomised studies so that they can be used in a meta-analysis or systematic review.

Assessment of Quality of Evidence Across Studies

We will assess the quality of evidence across a body of evidence (i.e., multiple studies with similar interventions and outcomes) with the GRADE approach (Guyatt 2011), defining the quality of evidence for each outcome as "the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest" (Higgins 2008). The quality rating across studies has four levels: high, moderate, low or very low. Randomised controlled trials are initially categorised as providing high quality evidence, but the quality can be downgraded; similarly, other types of controlled trials and observational studies are initially categorised as providing low quality evidence, but the quality can be upgraded. Factors that decrease the quality of evidence include limitations in design, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results or high probability of publication bias. Factors that can increase the quality level of a body of evidence include a large

magnitude of effect, if all plausible confounding would lead to an underestimation of effect and if there is a dose-response gradient.

Measures of treatment effect

We will use Review Manager software (Review Manager 2011) provided by the Cochrane Collaboration for statistical analysis and GRADEpro software (GRADEpro 2008) to produce GRADE Summary of Findings tables and GRADE Evidence Profiles. We will summarise dichotomous outcomes for effect in terms of risk ratio (RR) with their 95% confidence intervals. We will calculate summary statistics using meta-analytic methods and present findings in GRADE Summary of Findings tables and GRADE Evidence Profiles for all outcomes of interest.

Dealing with missing data

Study authors will be contacted when missing data is an issue.

Assessment of heterogeneity

It is possible for some outcomes that meta-analysis may be conducted. If it is, we will examine heterogeneity by using the χ^2 statistic with a significance level of 0.10, and the I^2 statistic. We will interpret an I^2 estimate greater than 50% as indicating moderate or high levels of heterogeneity and will investigate its causes (Deeks 2008).

Data synthesis

Data will be grouped by the tiers of service and care configurations outlined in tables 1-2 (Table 1; Table 2). When interventions and study populations are sufficiently similar across the different studies, we will pool the data across studies and estimate summary effect sizes using random-effects models. We will use the inverse variance method for analysis of cluster randomised designs.The inverse variance method assumes that the variance for each study is inversely proportional to its importance, therefore more weight is given to studies with less variance than studies with greater variance.We will use the inverse variance method for analysis of cluster randomised designs.

We will summarise the quality of evidence for the studies separately for each outcome for which data is available in GRADE Summary of Findings tables and GRADE evidence profiles (Guyatt 2011).

Subgroup analysis and investigation of heterogeneity

Data will be grouped by the tiers of service and care configurations outlined in tables 1-2.

Sensitivity analysis

We will explore the pattern of results when non-randomised comparisons are excluded.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Health service nomenclature in middle and low income countries

Tier	Highest cadre	Terms often used	Facility and staff	Equipment facilities
Community	Individual with maximum of few months training; paid or unpaid	1a. Family led care	Family member	
		1b. Village volunteer	Trained volunteer; health assistants	HIV tests, counselling, replenish drugs
		1c. Primary care clinic	Nurse aide or community health worker with a few months training	

Table 1. Health service nomenclature in middle and low income countries (*Continued*)

Health centre	Paramedic or nurse (2+ years training)	Health centres; district hospitals	Purpose built with at least one paramedic or nurse with some health assistants	HIV tests; antiretrovirals; opportunistic infections medicines; point of care laboratories
Hospital	Doctor	Health centres; district hospitals	Purpose built with at least one medical doctor with nurses / paramedics and assistants	CD4 count Medicines Not viral load
Advanced hospital	Specialist doctor	District hospital; referral hospital	Purpose built with at least 2 specialist doctors with nurses / paramedics and assistants	Viral load and full investigations

Table 2. Models of HIV care

Our term	Initiation	Follow up
Standard hospital model	Hospital	Hospital
Down referral (partial)	Hospital	Health centre
Down referral (full)	Health centre	Health centre
Delocalised	Health centre (weekly clinics with hospital staff)	Health centre (weekly clinics with hospital staff)
Radical community	Primary (tier 1c) Health centre	Primary (tier 1c) (monitor six monthly by health centre)

WHAT'S NEW

Date	Event	Description
8 June 2012	New citation required and major changes	New authors taking forward this review.

HISTORY

Protocol first published: Issue 7, 2012

Date	Event	Description
13 March 2009	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

NF, TK, FA and PG developed the protocol. PG developed the framework for the nomenclature and models of health care delivery.

DECLARATIONS OF INTEREST

None declared.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- World Health Organization, Department of HIV/AIDS, Switzerland.