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An economic evaluation of task-shifting approaches to the dispensing of anti-retroviral treatment in the Western Cape, South Africa

Thesis presented in partial fulfilment of the requirements for the degree of
MASTERS IN PUBLIC HEALTH (Health Economics)

In the
Health Economics Unit
School of Public Health and Family Medicine
Faculty of Health Sciences
University of Cape Town
July 2011

Candidate
Nicola Foster

Supervised by
Prof Di McIntyre (Health Economics Unit, University of Cape Town, South Africa)
This dissertation is dedicated to

My son, Michael Louis Foster because you inspire me to make
the world a better place

and to

My husband, Clint Foster for being so supportive and for complementing
my English language skills
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Abstract

Human Resources for Health (HRH) have been identified as one of the primary constraints to achieving universal Anti-retroviral Treatment (ART) coverage in South Africa. This scarcity is exacerbated by the focus on decentralised, primary health care ART delivery that necessitates a rapid scale up and strengthening of pharmacy services in terms of supply, infrastructure requirements and HRH to ensure a safe and efficient pharmaceutical service. The shortage of pharmacists has led to the use of alternative pharmaceutical care models including indirectly supervised pharmacists assistants (ISPA) and nurses; however evidence on the costs, benefits and challenges faced in the implementation of these models are lacking. This study therefore aims to critically evaluate the ISPA and nurse-based pharmaceutical care models against the standard of care that involves a pharmacist dispensing ART, on the basis of cost, and patient preference.

A cost analysis was conducted from the societal perspective and informed by patient exit interviews (240 respondents), expert interviews, and time and motion studies to calculate waiting time. The study was set in a peri-urban district of the Western Cape of South Africa.

While both of the decentralised pharmaceutical care models (ISPA and nurse-driven) were found to minimise the costs incurred by patients, in travel costs and time, the nurse-driven pharmaceutical care model was found to be significantly more costly (per patient visit) from the provider’s perspective than the ISPA model. However, many patients had a preference for nurse dispensing, generally linked to stigma concerns when collecting medicines in the pharmacy.

The study highlights the importance of considering the cost of task-shifting on nurses and the inherent value of their time. Patient preferences and challenges in the implementation of the pharmaceutical care models are also explored.
Acknowledgements

The original idea and inspiration for the study came from the Indirectly Supervised Pharmacist Assistant (ISPA) model developed and supported by Ms Lindsay Wilson. I further acknowledge the assistance of the facility staff and management of the Infectious Diseases Unit in the Cape Winelands, under the leadership of Dr Dirk Hagemeister. I am indebted to the ANOVA staff, Dr Nelis Grobelaar, Dr Mea van Huyssteen and Mr Theunis Hurter for their assistance, comments and suggestions on earlier drafts and providing me with the platform to present the study to clinical staff and receive feedback.

Ms Vanessa Daries, from the Health Economics Unit was an invaluable source of information and wisdom on the mechanics of conducting and managing field research and I owe her a great deal of thanks. In addition, I could not have interviewed and conducted the fieldwork without the assistance of Ms Sibongile Bovana.

I would also like to thank A/Prof Susan Cleary for helpful comments on earlier drafts, and Ms Sheetal Silal for advice on the statistical aspects of the study.

Finally, I would like to thank my excellent supervisor Prof Di McIntyre who contributed to the initial conceptualisation of the study, supervised the analysis and provided many helpful suggestions, while trying to keep me focused on the issue at hand. The study was made possible by the support of the National Research Fund (NRF): Health and Wealth chair.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
</tr>
<tr>
<td>DOH</td>
<td>Department Of Health</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-Time Equivalent</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HRH</td>
<td>Human Resources for Health</td>
</tr>
<tr>
<td>IMCI</td>
<td>Integrated Management of Childhood Illness</td>
</tr>
<tr>
<td>ISPA</td>
<td>Indirectly Supervised Pharmacists Assistant</td>
</tr>
<tr>
<td>LMIC</td>
<td>Low- and Middle Income Countries</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-Governmental Organisation</td>
</tr>
<tr>
<td>OSD</td>
<td>Occupation Specific Dispensation</td>
</tr>
<tr>
<td>PA</td>
<td>Pharmacists Assistant</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
</tr>
<tr>
<td>SAPC</td>
<td>South African Pharmacy Council</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
Index of key terms

Dispensing related activities is defined, for the purposes of this analysis, as activities relating to stock control, administrative tasks (incl. collecting medication from a central dispensing unit where applicable), the interpretation and evaluation of the prescription, the preparation and labelling of the prescribed medicine as well as counselling of the patient on the safe and effective use of the medication (adapted from the Pharmacy Act).

Pharmacists Assistant (PA): While there are different levels of PAs employed by the Department of Health, dependent on their level of completed in-service training, where the term is used in this dissertation we are referring to PAs who are fully qualified as Post-basic PAs and are therefore under the Pharmacy Act, able to work under indirect supervision. The training of a PA from Learner Basic PA to Post-basic PA takes a minimum of two-years of in-service training under the guidance of a pharmacist.
Part A: Research protocol

1. INTRODUCTION

Due to the worsening scarcity of health care workers in Sub-Saharan Africa there has been an increased focus on task-shifting of the duties of doctors and nurses, but there is a lack of research on similar strategies to address the shortage of pharmacists.

Task-shifting is not a novel concept in resource-poor settings but has organically developed out of necessity. It relates to the allocation of tasks in health service delivery to the least costly health worker capable of doing that task reliably (McPake and Mensah 2008). In South Africa, the urgency of care needed in the context of the HIV epidemic has resulted in a lack of standardised pharmaceutical service staffing norms but rather different approaches have been adopted at individual ART sites in line with the available resources. Some clinics have pharmacists dispensing ART. Another option has been where pharmacists prepare medication from a prescription for a specific patient at a central dispensing unit or hospital pharmacy from where it is distributed to the ART clinics and the medication is issued by nurses or counsellors. A third option currently being piloted in districts in the Western Cape has a Pharmacists Assistant (PA), working under the indirect supervision of a pharmacist, dispensing ART as well as managing the drug supply of the clinic (Heli Moeng, personal communication). These approaches will be referred to as Pharmacist, Indirectly Supervised Pharmacists Assistant (ISPA), and Nurse-led pharmaceutical care models respectively.

Pharmaceutical service provision is key to a successful ART service and a limiting factor if the scale-up of services is to include Primary Health Care (PHC) facilities. Van Damme et al. (2008) in their article on how the South African health system can adapt to the need for scaling-up ART, name three constraints to meaningful scale-up: the ever increasing case load of people who will need long-term ART, shortage and skewed distribution of Human Resources for Health (HRH) towards the private health sector, and thirdly the heavy workload inherent in the current ART service provision models. They further comment that there are really only two options; either there are
no fundamental health system changes and ART gets priority status and a greater proportion of (already scarce) resources thereby crowding out other services, or the ART scale-up strengthens the overall health system by stimulating a reform of the health system towards greater efficiency (Van Damme, Kober et al. 2008). It is therefore evident that there is a need for implementing less resource intensive models of ART service delivery while strengthening the health system. Task-shifting and integrating primary health care and ART service delivery is an attractive solution, but evidence on this approach is lacking.

1.1. PROBLEM STATEMENT

If South Africa is going to achieve universal access to ART, alternative pharmaceutical staffing models will be required to address the HRH scarcity which is limiting the scale-up of ART and therefore people’s access to the healthcare that they need. Research is required to explore the impact of task-shifting models used.

1.2. JUSTIFICATION OF THE STUDY

Transportation costs and therefore geographical availability has been identified as a key barrier in access to Antiretroviral Treatment (ART) in Sub-Saharan African countries (Tuller, Bangsberg et al. 2009). Likewise there is a relationship between barriers in access to treatment and a lack of sustained adherence to ART (Melese, Alemayehu et al. 2004; Hardon, Davey et al. 2006; Uzochukwu, Onwujekwe et al. 2009). Adherence to ART is crucial for viral suppression, delaying resistance to treatment regimens and therefore favourable outcomes. It has furthermore been found that high ART adherence was associated with lower mean direct health care costs over time as poor adherence promotes resistance to first line regimens leading to earlier switching to costly second line ART (Leisegang, Cleary et al. 2009; Nachega, Leisegang et al. 2010). Improving adherence by increasing availability of ART is therefore a priority with limited health resources and an increasing burden of need. A lack of HRH is constraining efforts to expand or roll-out the provision of ART to lower levels of health care service, which would greatly improve physical availability. Although, there has been much research into alternative staffing norms for doctors
and nurses to improve the geographical availability of ART, there is a need for similar research and policy recommendations for pharmaceutical services.

1.3. AIMS AND OBJECTIVES

The aim of the study is to evaluate the annual cost per patient treated associated with two task-shifting pharmaceutical care models, ISPA and nurse driven, against the standard of care which involves dispensing by a pharmacist. Patient preferences for different pharmaceutical care models will also be evaluated.

The objectives of the study are to:

- compare the annual cost per patient treated of the task-shifting pharmaceutical care models (ISPA and Nurse) with the reference (Pharmacist) model;
- evaluate the impact of the different pharmaceutical care models on access to ART using an access evaluation framework;
- estimate the initial start-up costs associated with the implementation of the ISPA model;
- formulate policy recommendations based on the findings.

2. LITERATURE SUMMARY

There are many demand and supply side factors which influence individuals’ ability to access health services (Ensor and Cooper 2004). Access to health services refers to the “degree of fit” between health systems or health programmes and the individuals or households that constitutes a society. More specifically, it relates to an individual’s ability to derive benefits from health care services, and not simply a health system’s capacity to fund and provide services (McIntyre, Thiede et al. 2009). This definition of access therefore implies that there are more factors than simply utilisation to consider when evaluating health programmes (Thiede, Akweongo et al. 2007). These factors can be evaluated in three dimensions, including acceptability, affordability and availability. Acceptability relates to the “degree of fit” between provider and patient attitudes towards and expectations of one another. Patient attitudes towards provider characteristics such as the gender, race, age and language may influence the patient’s
ability to receive care (McIntyre, Thiede et al. 2009). Cultural practices, beliefs and preferences also influence acceptability and are a much-neglected aspect of policy and intervention formulation. Even though ART is currently provided free of charge in South Africa, it is widely recognised that accessing treatment comes at a cost to patients (McIntyre, Thiede et al. 2006). Patients incur economic costs in the form of the cost of transport to and from the facility, resources spent on additional medical treatments and home care, as well as opportunity costs in time spent at the facility (McIntyre, Thiede et al. 2009). Research conducted in South Africa has suggested that non-drug costs incurred by patients may act as a barrier to patients in accessing treatment (Rosen, Ketlhapile et al. 2007). This has been supported by research from South-western Uganda (Tuller, Bangsberg et al. 2009). The final dimension of the access framework, availability, relates to the staff mix as well as their scope of practice, the range of services offered relative to the needs of the community. The location of health care facilities and health services relative to the location of those who need the services and their transportation opportunities impact on individuals’ ability to access treatment (Ensor and Cooper 2004; McIntyre, Thiede et al. 2009; Tuller, Bangsberg et al. 2009). This is seen in South Africa where the ART programme was designed to be pro-equity with respect to the urban and rural parts of the country and sites were deliberately established in all districts and sub-districts of the country. However the ART roll-out was initially centralised to hospital services in these districts, which seriously disadvantaged rural areas. 

1 This led to a barrier in access to treatment for those who had to travel far to receive treatment. Cross cutting factors such as knowledge, power relations, training and professionalism issues impacts on the expectations of providers in relation to patients and vice versa and affects all dimensions of access (Goudge, Gilson et al. 2009; McIntyre, Thiede et al. 2009). These dimensions provide a framework within which access can be evaluated.

These dimensions of access and the associated factors impacting on these dimensions are important to consider in the scaling-up of ART services. The integration of ART into primary health care services, as opposed to a specialised hospital-based service, has been proposed. It could be argued that providing ART closer to communities

1 Many thanks to Prof. Helen Schneider for pointing out the difference between the rural-urban bias versus barriers to access due to services being offered in a centralised manner.
would improve the ability of those in need to access treatment. Evidence from a Medicines Sans Frontiers (MSF) clinic in Lusikisiki, South Africa has shown that decentralised HIV/AIDS care, due to greater proximity and acceptability of services, has led to faster enrolment and better retention compared to a centralised hospital based approach (Bedelu, Ford et al. 2007). However, providing ART at primary health care clinic level would require a scale-up of services and resources while straining an already over-burdened health service and if not addressed could result in the crowding out of patients with other needs. The current model for the provision of ART is very resource intensive and does not lend itself to universal access to treatment as ART services are provided in the form of a vertical program with pharmacists, doctors, nurses and administration dedicated exclusively to ART provision. This approach has elements of inefficiency as factors such as economies of scale, economies based on learning by doing and economies of scope influences the amount of resources (including HRH) required for the provision of ART (Cleary, Boulle et al. 2008).

In South Africa there has been a move towards a nurse-based, doctor-supported ART service to be integrated into the district health system (Provincial Government of the Western Cape 2007). Task shifting could be a possible solution for reducing the cost of health care and optimising human resources as it involves the delegation of certain activities to less qualified, specifically trained, health care personnel. Examples of the use of lay workers in South Africa include the community health worker and community-based volunteers for giving directly observed treatment for tuberculosis during home visits (Philips, Zachariah et al. 2008). In a multi-country study Huicho et al. (2008) found that in underserved rural areas where health care needs are the greatest, health workers with longer pre-service training (i.e. doctors) are less available than those with shorter pre-service training (i.e. nurses). Furthermore, a study performed in Mozambique found that there was less migration by mid-level workers trained in the country than physicians. They found that 90% of mid-level workers recruited from rural areas, returned and stayed in rural areas for a minimum of seven years after graduation compared to 0% of physicians. This is thought to be due to the ease with which physicians’ skills are transferable to other countries as
training is based on European standards (Kruk, Pereira et al. 2007). Task-shifting could therefore assist in the retention of skills where they are most needed.

Critics of the concept of task-shifting have urged caution and more operational research in order to ensure that quality of care for patients on ART is not compromised, amid growing concern around adherence and detection of treatment failure (Philips, Zachariah et al. 2008). Inferior quality of care is often mentioned as an argument against task-shifting. Research has however found evidence to the contrary. A comprehensive multi-country study by Huicho et al. (2008) comparing the performance of different categories of health workers trained in the Integrated Management of Childhood Illness (IMCI) and child mortality has fuelled the task shifting debate. Huicho et al. found that the quality of care (defined as compliance with IMCI guidelines for assessment and treatment of sick children) did not differ between those with longer and shorter duration of pre-service training. The IMCI treatment was delivered in primary health care facilities. One of the explanations offered is that health workers with shorter duration of training might be more willing to comply with standard clinical guidelines than health workers with more training who might be accustomed to taking short cuts or delegating some tasks such as counselling to clerks dispensing medication at the end-point of service delivery (Huicho, Scherpber et al. 2008).

There has also been resistance to task shifting from professional bodies, which are seen as promoting narrow economic interests of specific professional groups. In Brazil, pressure from professional bodies led to the discontinuation of IMCI training for nurses in 2002 (Huicho, Scherpber et al. 2008). In Uganda, the Professional Council of Pharmacists opposed the introduction of training for pharmacy assistants. The Nurses Council furthermore opposed the accelerated training of nurse assistants (McPake and Mensah 2008). Conversely, in Ghana, Malawi, Tanzania, and Zambia nurses were trained and allowed to perform tasks traditionally restricted to physicians, providing support for task shifting practices long before the practice was accepted (Huicho, Scherpber et al. 2008).
South Africa has policies and regulations in place that could enable the task-shifting of pharmaceutical services to professional nurses or PAs where pharmaceutical services are lacking in order to ensure access to essential care. The National Service Plan (NSP 2007 to 2011) provides guidelines and targets for a comprehensive response plan to the HIV epidemic. Targets include that 80% of new patients should be initiated and managed by nurses, and that 70% of people on ART would be managed outside of the hospital setting by 2011. The NSP further acknowledges that the development and implementation of new innovative staffing norms that are sustainable and have the potential for growth in order to scale-up ART is required. National treatment protocols for HIV as well as the scheduling of ART medication as Schedule four substances enable nurses to safely dispense ART. Section 33 of the Nursing Act allows for professional nurses to dispense medication if in possession of a dispensing license. Section 56 (6) of the act provides for the Director General, head of the Provincial DOH or the doctor in charge of a municipality to authorise nurses in service of the DOH, or municipality to assess, diagnose and treat patients where no doctor or pharmaceutical service is available, but this applies only for medication up to Schedule four. The National Drug Policy of 1996 states that prescribing should be competency not occupation based, and that doctors and nurses should dispense where no pharmaceutical service is available, provided that the health professional has a dispensing license from the Medicines Control Council.

It can therefore be seen that there is a great deal of policy and legislative provision for dispensing by clinicians where pharmaceutical services are not available. This enables nurses to provide a complete service of managing and dispensing ART in a PHC setting. These practices would however take time away from the clinical duties of the health professional and could restrict scale-up of services (Schulman, Makani et al. 2009). In light of the severe shortage of nurses in South Africa, this may not be a viable solution. The South African Pharmacy Council allows for the registration of PAs, a category of mid-level worker who are trained and employed in pharmacies to perform administrative or repetitive tasks essential in the operation of a pharmacy (South African National Department of Health 2007).
The Pharmacy Act 53 of 1974 deals with the scope of practice, training as well as registration of PAs. It also allows for PAs working under the indirect supervision of a pharmacist in government facilities. Regulations GN1158 and GG21754 of the Act (20 November 2000) specifies that a PA working under indirect supervision must be visited once a month by the designated supervisory pharmacist and that such visits should be documented (Honermann 2009). An enabling regulatory framework for the task-shifting of pharmaceutical services is therefore available in South Africa but further work is required to develop a standardised pharmaceutical staffing norm that would be sustainable.

3. METHODS

3.1. LITERATURE REVIEW

A more detailed literature review will be conducted, exploring the issues around access to health care, HRH concerns, and task shifting. Electronic databases such as PubMed, EBSCOhost, South African National Health Research Database, Google Scholar and grey literature will be used.

3.2. STUDY DESIGN

A cost analysis will be conducted from a modified societal perspective and the impact on patients will be critically evaluated using the access evaluation framework.

3.3. STUDY POPULATION AND SAMPLING

Data collection will take place within the Cape Winelands district of the Western Cape, in the Stellenbosch and Drakenstein (Paarl) subdistricts. Within the subdistricts, facilities providing ART services will be stratified on the basis of the pharmaceutical service staffing model that is currently used to dispense ART. The strata are defined as follows:
Group A   Facilities where pharmacists are dispensing ART medication directly to patients.

Group B   Facilities where PAs work under the indirect supervision of a pharmacist and dispense ART medication directly to the patients (pilot sites).

Group C   Facilities where patient-ready packs are dispensed by pharmacists at a central facility (e.g. district level hospital or central dispensing unit) and then transported to the ART clinic where the medication is issued by nurses.

Within the strata, purposive sampling has been used to select facilities based on the advice of the NGO partner’s project manager in Paarl (Dr Nelis Grobbelaar, personal communication). This sampling strategy is used partly due to the limited extent to which these services are available and in order to ensure that samples are geographically representative. Six facilities will be sampled with two facilities from each stratum. Idas Valley clinic and TC Newman CDC will provide information on the pharmacist pharmaceutical care model, Mbekweni and Kyamandi CDCs will represent facilities where indirectly supervised PAs are dispensing, and Dalvale and Franschoek clinics will provide the sample for nurse-driven pharmaceutical models.

Equal numbers of patients will be selected from each stratum in order to have a sufficient sample to inform the costing component of the study. Within the strata (groups), the number of individuals to be selected from each facility has been calculated to be proportional to the size of the facility in the strata (proportional stratified sampling).

Table 1
Participant inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons older than 18 years.</td>
<td>Persons younger than 18 years</td>
</tr>
<tr>
<td>Patients who have already started receiving ART.</td>
<td>Patients being worked up to receive ART.</td>
</tr>
</tbody>
</table>
3.4. SAMPLE SIZE CALCULATION

Patient exit interviews will be conducted, the results of which will be used to inform the costing. In addition differences in access to ART between the specified groups will be explored. In order to make statistically significant inferences regarding these differences, the sample size required were calculated using a one-way ANOVA power analysis.

An estimate of the anticipated outputs in the groups is required when calculating the appropriate sample size. The anticipated outputs of interest were identified as patient travelling and waiting times, used in the cost analysis to estimate indirect patient costs. Data from a recent study, Researching Equity in Access to Health care (REACH) was used to estimate the output with the smallest mean, therefore requiring the largest sample size to detect differences. One could therefore assume that if the sample size calculated is large enough to show statistically significant differences in the most sensitive outcome it would be adequate to show differences in other outputs measured. A one-way ANOVA power analysis was then conducted using PASS® software. The power of the test and standard deviation was varied to determine the optimum combination, considering resource limitations. The power of the test refers to the probability of rejecting a false hypothesis, which should be close to one (or 100%). For the test to have a power of 85% and a standard deviation of 80 a minimum sample size of 105 respondents (66 from Group A, 18 from Group B, and 21 from Group C) are required. In order to provide adequate information for the costing, equal numbers of interviews will be conducted from each group of patients. Therefore 70 interviews will be conducted within each group, with a total sample of 210 respondents. Within the groups, facilities will be sampled proportional to size.
Table 2
Summary of Sampling Strategy

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample size required</th>
<th>Facility name</th>
<th>Approximate number of patients</th>
<th>Final sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>70</td>
<td>Pharm clinic 1</td>
<td>1,200</td>
<td>42</td>
</tr>
<tr>
<td>Pharmacist</td>
<td></td>
<td>Pharm clinic 2</td>
<td>800</td>
<td>28</td>
</tr>
<tr>
<td>Group B</td>
<td>70</td>
<td>ISPA clinic 1</td>
<td>300</td>
<td>35</td>
</tr>
<tr>
<td>ISPA model</td>
<td></td>
<td>ISPA clinic 2</td>
<td>300</td>
<td>35</td>
</tr>
<tr>
<td>Group C</td>
<td>70</td>
<td>Nurse clinic 1</td>
<td>300</td>
<td>50</td>
</tr>
<tr>
<td>Nurse</td>
<td></td>
<td>Nurse clinic 2</td>
<td>120</td>
<td>20</td>
</tr>
</tbody>
</table>

| Total     | 210                  | 3,520          | 210                            |

The ART clinics use an appointment system for patients to collect their medication; however patients do not arrive at a predetermined time, which makes random sampling from the appointment book impractical, as all selected patients may be ready to leave at the same time. Therefore systematic sampling will be used to select the patients to be interviewed. A list of patients at each clinic will be obtained; the total number of patients on ART at each clinic will then be divided by the target sample size for the clinic. The output will represent the interval of sampling. The first patient to be interviewed will be selected at random and each clinic will be sampled on multiple days. This would limit the introduction of biases related to respondents who have systematic differences in for example employment accessing the clinic at different times of the day as well as different days of the week.

3.5. MEASUREMENT TOOLS

A range of collection tools will be used to inform the cost analysis and are summarised in Table 3.
### Table 3
Data collection tools and sources

<table>
<thead>
<tr>
<th>Tool (Sources)</th>
<th>Aiming to measure</th>
<th>To inform…</th>
<th>Target sample size per strata</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exit interviews (patients leaving clinics)</td>
<td>Costs incurred by patients in accessing service.</td>
<td>Costing</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Dimensions of patient access, including direct and indirect costs, as well as patient preference.</td>
<td>Access component of the evaluation</td>
<td></td>
</tr>
<tr>
<td>Waiting and consultation times (timing patients in clinics)</td>
<td>Duration of consultation, Patient time, and Staff time.</td>
<td>Costs of staff time, Costs of patient’s time</td>
<td>70</td>
</tr>
<tr>
<td>Interviews with clinicians and timing of tasks (clinical staff, facility observation)</td>
<td>Portion of time spent on dispensing related duties.</td>
<td>Allocation of staff time to dispensing.</td>
<td>All relevant personnel</td>
</tr>
<tr>
<td>Costing (facility records, facility observations)</td>
<td>Cost per visit, Total cost, and Cost per patient treated.</td>
<td>Resource use</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

3.5.1. Facility Observation

Patient waiting time and the amount of time clinical staff spend on dispensing related duties will be determined by observation within the facilities. To determine patient time, each patient attending the clinic on a given day will be supplied with the designed observation tool upon entering the facility. The time of entry of the facility, time in and out of nurse’s rooms, time in and out of doctor’s rooms, time of arrival at dispensary and time of exit of facility will be recorded (see Appendices). The amount of time clinical staff spends on dispensing duties/medication management duties will be determined by interviewing clinical staff. In order to validate their responses, the researcher will time the amount of time spent on dispensing duties.
3.5.2. Patient Exit Interviews

Exit interviews will be conducted with patients selected in line with the inclusion criteria (see Table 1). The interview guide is attached in the appendices (see Appendix 3). Fieldworkers will administer the interview guide in English, Afrikaans or Xhosa as appropriate, and the patients’ responses will be recorded on a paper-based interview guide form. The interview guide has been designed to elicit responses that can be used in calculating the costs related to accessing ART, for patients receiving care from facilities using different methods of dispensing and managing ART drugs. It includes questions on demographic information, frequency of ART service utilisation, direct and indirect costs incurred during service utilisation, transport to the facility, affordability of accessing treatment, and patient preferences.

3.6. PILOT STUDY

The interview guide and observation tool will be piloted to ensure that questions are easily understandable and aimed at the correct level. Furthermore, piloting will help to determine the nature of potential responses, difficulties in the administration of the interview guide and observation tool as well as to estimate the ease with which potential respondents will be recruited relating to the potential for achieving the required sample size. It will also be useful to determine the approximate time taken to conduct an interview. The interview guide will be piloted on 10 patients who comply with the inclusion criteria for sampling. They will be interviewed using the interview guide. Following the interview, respondents will be asked about the clarity of the questions, and their understanding and comprehension of the questions. The pilot study will be conducted in the same population to be studied but not selected into the sample and responses will not be included in the analysis.

3.7. FIELD MANAGEMENT

Prior to commencement of fieldwork, fieldworkers will be trained and familiarised with the use of the interview guide. Two fieldworkers (including the principal investigator) will visit facilities on a predetermined schedule, negotiated with the
facility staff. One of the fieldworkers will manage the collection of time data while the other conducts interviews, based on the predominant language spoken at the facility. Fieldworkers will spend a full day at the clinics in order to sample all required patients attending the ART clinic at different times of the day, as there may be systematic differences in patients attending the clinic during different times of the day. Each patient exit interview will take approximately 15 minutes and an expected minimum of 8 interviews will be conducted per clinic day. The location where the interview will be conducted will depend on the individual clinic. This will be discussed with the facility manager on day one of data collection and a room decided on that would ensure privacy, and minimal disruptions and inconvenience caused to the smooth running of the facility and staff members.

3.8. QUALITY CONTROL

Each aspect of the study poses unique problems in maximizing validity and reliability. The following approaches will be used to maximise validity and reliability:

*Improvement of validity*

- Fieldworkers will be required to have excellent communication skills, verbal and literate fluency in English and either Afrikaans or Xhosa. Fieldworkers will be trained on the terms used in the study, foundations of the subject matter and in the application of the interview guide.
- Fieldworkers will be encouraged to document any problems or concerns raised during interviews, and these will be addressed and corrected for during weekly team meetings and more informal daily report backs to the principal fieldworker.
- Details of interviews, including name of interviewer, time started and time completed will be recorded on the interview guide and stored, should there be a need to address quality control concerns.
- The data from interviews will be captured concurrently with data collection, so that problems can be identified and relayed to the interviewers instantly for improvements in further data collection.
- Pilot study: the interview guides and observation tool will be piloted on a group of patients from a facility in the sampling frame. Data from the pilot study will not
be analysed but used to correct problems with the interview guide as well as further training for the fieldworkers. It is an opportunity to correct any problems related to comprehension, understanding or ambiguity. The wording, timing, presentation and flow of the interview guide will also be tested during the pilot study.

- Attempts will be made to correct for potential sources of social desirability bias, i.e. patients providing responses they believe to be more acceptable and in line with societal norms. These issues will be kept in mind while conducting the interviews and as well as during the training of fieldworkers.
- Respondents will furthermore be assured of the privacy of interviews and that health workers will be not able to access their responses.
- Researchers will measure patient time spent waiting in the facilities for treatment rather than relying on respondents’ estimates.

**Improvement of reliability**

- Fieldworkers will be trained on how to administer interview guides and irregularities will be identified during questionnaire quality control review and data capturing. Any concerns will be addressed and corrected.
- Double entry of data will also minimise errors introduced during the capturing of data.
- The quality of completed interviews will be checked daily. Missing values will be identified and fieldworkers requested to provide feedback. This will improve the quality of the data, as fieldworkers are likely to be able to recall the interview accurately.
4. LOGISTICS AND TIME SCHEDULE

Figure 1
Proposed time schedule

<table>
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<tr>
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<tbody>
<tr>
<td>Proposal development</td>
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<tr>
<td>Submission for ethics &amp; pgwc approval</td>
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<td></td>
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<tr>
<td>Pilot Study</td>
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<tr>
<td>Data Collection</td>
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<tr>
<td>Data Analysis</td>
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<tr>
<td>Report write-up</td>
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<tr>
<td>Submission of report</td>
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<tr>
<td>Dissemination</td>
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</tbody>
</table>

Assuming that 8 patient exit interviews will be conducted per clinic day per fieldworker, and taking into consideration that ART clinics are offered between one and five days per week, data collection would take approximately six weeks. One afternoon per week will be reserved for administration, planning and team meetings to discuss progress.

5. DATA MANAGEMENT AND ANALYSIS

5.1. ACCESS EVALUATION FRAMEWORK

The results of the study will be used to critically assess and evaluate the impact of the different pharmaceutical care models on access to ART using the Access Evaluation Framework.
As discussed previously, access is defined as the “degree of fit” between health services and the individuals or households that constitute a society (McIntyre, Thiede et al. 2009). To evaluate the impact that the different pharmaceutical care models have on access to ART, factors relating to the three dimensions of access (availability, affordability and acceptability) as well as their root causes will be explored.

5.2. ANALYSIS OF PRIMARY DATA

The interview guide has been pre-coded for ease of data entry (see Appendix C for coding used for variables). Data will be double-entered using the Epidata® programme, which allows for the cross-checking of errors during the second-entry to ensure that data is entered correctly and will greatly reduce errors introduced during data capturing. A data-capturing guide will also be compiled for data capturers to ensure that data capturers capture data in a similar fashion. Furthermore, data capturers will be trained on the use of the Epidata® software as well as the interview tools. Following data entry, the data will be exported from Epidata into STATA 10®, cleaned and prepared for analysis. Any strange or missing values will be identified during data checking and investigated by going back to the raw data. Estimation/hypothesis testing will be done at a 5% significance level and 95% confidence limits.
5.2.1. Univariate distributions

Numerical data will be explored using histograms, the generation of frequency tables and box plots. This includes respondent characteristics such as age. Numerical data will be summarised using measures of central location such as the mean and the variability of data.

Categorical variables will be explored using frequency tables showing proportions for each category. These include the age and sex distribution, utilisation of ART services, adherence to treatment, availability, mode of transport, and acceptability of treatment. Data will be summarised using pie charts and bar graphs.

5.3. COST ANALYSIS

5.3.1. Costing conceptual framework

A marginal analysis approach will be taken to the costing of alternative dispensing approaches, whereby only costs that differ will be focused on. Costs that are common to all three approaches (such as the cost of ARTs) will be excluded (Drummond, Sculpher et al. 2005). The costs associated with the different dispensing systems will be sourced from expenditure data, primary data collection, and expert opinions. All costs (except for the policy brief which is targeted at local managers and policy makers) will be presented in US Dollars, expressed in 2009/2010 prices and inflation adjustments will be made using CPIX, the Consumer Price Index.

Perspective

In order to make inferences regarding the impact of the different pharmaceutical care models on the availability of ART, non-health care costs incurred by those accessing treatment such as cost of transport and other possible barriers would also need to be considered. Costing therefore takes a societal perspective in defining costs (Luce, Manning et al. 1996).
Unit Costs

Unit cost refers to the total economic cost per patient visit, and includes both variable and fixed costs i.e. costs that do and do not vary with the scale of provision. The economic definition of cost is based on the concept of “opportunity cost” referring to the benefits lost because the next-best alternative was not selected and implies that all resources consumed by an intervention are valued and not only those that could be represented in a budget (Gold, Siegel et al. 1996; Clewer and Perkins 1998; Johns, Baltussen et al. 2003). Costs will be categorised into provider (staff time), direct non-health care (cost of transport) and indirect (patient-time) costs components.

5.3.2. Provider costs

As the costing takes a societal perspective, costs incurred by the patient, the health system and other relevant individuals are considered. Cost definitions and allocation basis to be used is summarised in Table 4.

The primary cost difference from the health service perspective relates to the cost of HRH. Salary costs will be calculated from gross (pre-tax) salary and contributions to pension and medical funds plus other benefits will be taken into account. Capital costs are defined as resources that last for more than a year, and under this definition, training costs should also be included as capital costs. However, in line with the methodology used in the WHO-CHOICE project, the current level of education of health professionals is excluded since a reallocation of health system resources does not affect these costs (Johns, Baltussen et al. 2003). A proxy for the additional cost relating to level of education would be the salary of the professional, as salary level in the public sector is directly related to years of experience and level of education. In the final analysis, the time required to train the respective professionals will be included in the discussion.
Table 4
Costs and sources of cost data

<table>
<thead>
<tr>
<th>Recurrent (health system) costs</th>
<th>Allocation basis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical staff time involved in dispensing related activities (interviews, facility observation, and payroll data)</td>
<td>Percentage of time</td>
<td>This will include all staff involved in dispensing (nurse, PA and/or pharmacist). It will be assessed through timing staff to determine the percentage of their total time spent on dispensing duties as defined.</td>
</tr>
<tr>
<td>Supervisory staff time (interviews, facility observation, and payroll data)</td>
<td>Percentage of time</td>
<td>In the PA model, in accordance with the Pharmacy Act a designated supervisory pharmacist will supervise the PA under indirect supervision and scheduled supervisory visits. Time spent at the facility will be calculated as percentage of total work time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direct non-healthcare costs</th>
<th>Allocation basis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Costs: Costs borne by patients, households and communities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport (patient exit interviews)</td>
<td>Direct</td>
<td>Patients’ mode of transport and cost of the transport will be calculated from patient exit interviews.</td>
</tr>
<tr>
<td>Clinic fees (patient exit interviews)</td>
<td>Direct</td>
<td>ART is provided free of charge, however at some facilities (such as hospitals) user fees whether formal or informal may apply.</td>
</tr>
<tr>
<td>Cost of treatment (patient exit interviews)</td>
<td>Direct</td>
<td>These costs refer to costs incurred by patients when having to purchase medication not provided by facilities but required due to known side-effects of ART.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indirect costs</th>
<th>Allocation basis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payment of substitute labour (patient exit interviews)</td>
<td>Direct</td>
<td>These costs include the payment of another person to perform tasks the patient would ordinarily perform but is unable to do so as is accessing treatment at the facility; this would include the cost of a childminder.</td>
</tr>
<tr>
<td>Income loss on the day of clinic visit (patient exit interviews)</td>
<td>Direct</td>
<td>Income loss would refer to the loss of earnings from having to forgo work to spend a day at the clinic.</td>
</tr>
</tbody>
</table>

Since the cost of ART drugs per patient does not vary across programme models, these costs will be excluded from the analysis. Furthermore, some of the costs of central administration relating to the overall planning and management of the health system and not directly related to the health system programmes evaluated will be excluded (Johns, Baltussen et al. 2003).

Where costs/ expenses are funded by donor funding, these will be specified and included as at some point these functions will be taken over by a government department (Creese and Parker 1994).
5.3.3. Patient Costs

A key characteristic of the societal perspective is the inclusion of time costs, the use of opportunity costs and community preference (Meltzer and Johannesson 1999; Garrison, Mansley et al. 2010). The inclusion of productivity losses related to the time spent by patients travelling to and from the clinic as well as waiting time, is very contentious in the economic evaluation literature (Drummond, Sculpher et al. 2005). Previous studies on the cost to patients accessing ART in SA has found that most of the patients were not employed, few (4 – 16%) indicated any loss of income because of time spent at the facility or reported paying for substitute labour (4 – 13%) while visiting the clinic, and for those who are employed, SA labour law enables employees to have access to paid sick leave which would minimise a loss in income (Rosen, Kethylapile et al. 2007). Furthermore, Drummond et al. (2005) point out that during short-term absences, losses in production could be compensated for by the worker on their return to work, or by colleagues. Also, for many categories of workers the value of productivity lost at the margin is likely to be lower than the average wage as all jobs contain tasks that are less important that are usually forgone as a result of a short period of absence. However given the lack of paid sick leave in the informal job market, and in order to include differences in waiting and travelling times between facility, for the purpose of this analysis, opportunity cost will be reported separately in the cost analysis, leaving it up to the decision maker as to whether or not to take them into consideration.

5.3.4. Start-up Costs

Calculating the costs required in upgrading current “medicine rooms” in PHC facilities to comply with SAPC regulations for dispensing ART will be performed as a separate costing exercise to avoid double counting of certain categories of costs. The results will be used to comment on the feasibility of a scale-up of this service at a PHC level given the resources required. The need for a decentralised ART service in an effort to provide universal access to treatment is well established. Structural improvements to PHC facilities to enable accurate dispensing and the safe storage of medication is essential if the SA DOH is to provide comprehensive care packages at a
Primary Health Care clinic level. However, in terms of this analysis, adequate dispensing areas are only essential for the ISPA or pharmacist pharmaceutical care models, as when nurses dispense pre-packed ART medication, designated SAPC approved pharmacies within PHC facilities are not required as pharmaceutical services are provided from a hospital or day-hospital. The costs associated with setting up a dispensary in a PHC clinic to the standards required for registration with the SAPC are included in this study as these costs could conceivably be a barrier to the scale-up of an ISPA pharmaceutical care model. Section 22A of the Medicines and Related Substances Act 101 of 1965 as well as Regulation(s) 1.2 and 1.3 of the Regulations pertaining to the Pharmacy Act 53 of 1974 specifically relates to the handling, storage and minimum standards for pharmacy premises, facilities and equipment (PSSA Pharmacy Law Compendium: PRE 174 – 185).

Expenditure data relating to the start-up cost of setting up a SAPC approved dispensary in a PHC clinic will be sourced from expenditure reports and suppliers.

5.3.5. Costing Assumptions

Where applicable, it is assumed that a working day has 8 working hours and that a month has 22 working days.

5.4. UNCERTAINTY

In conducting an economic evaluation, certain costing assumptions are made, which could have important implications for the decision making process. The analysis is subject to uncertainty relating to data requirements, the choice of analytic method as well as the generalisability of the results (Briggs, O'Brien et al. 2002).

The percentage of time and types of staff involved in dispensing related activities will be determined by observation in the facilities (timing) and the percentage time allocated will then be varied in order to test the assumption of time spent on dispensing duties and its impact on total costs.
6. BUDGET

The proposed budget for the study is summarised in Table 5. This study will be funded by the National Research Fund (NRF) South African Research Chair: Health and Wealth program. Unit costs were derived from the *UCT planning and budget guidelines* (version 05/10), available from [www.uct.ac.za/usr/finance/notices/budgui10.xls](http://www.uct.ac.za/usr/finance/notices/budgui10.xls) (Accessed 24 November 2009).

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Qty required</th>
<th>Unit cost</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translation</td>
<td>Translation of interview guide training guide into Xhosa and back translation.</td>
<td>8 pages</td>
<td>R150 per page</td>
<td>R1 200 x 2 R2 400</td>
</tr>
<tr>
<td>Printing</td>
<td>Printing of Research information sheet, consent form, interview guide and observation tool.</td>
<td>Interview tools: 8 pages x 220 1,760 pages Observation tool: 1 page x 220 220 pages</td>
<td>R0.40 per page</td>
<td>R792</td>
</tr>
<tr>
<td>Labels</td>
<td>Printing of patient number labels.</td>
<td>440 labels (2 labels per participant)</td>
<td>R0.45 per label</td>
<td>R198</td>
</tr>
<tr>
<td>Travel</td>
<td>Travel to and from facilities during data collection (fieldwork co-ordinator).</td>
<td>145 km (average daily travel) x 20 days = 2,900 km</td>
<td>R2.92 per km</td>
<td>R8 468</td>
</tr>
<tr>
<td>Fieldworkers</td>
<td>A fieldworker to be employed to assist in conducting patient exit interviews.</td>
<td>One full-time fieldworker employed for 6 weeks.</td>
<td>R8,500 per month (includes travelling costs and food)</td>
<td>R8 500</td>
</tr>
<tr>
<td>Stationery</td>
<td>Pens and pencils</td>
<td></td>
<td>R100</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>R20 458</strong></td>
<td></td>
</tr>
</tbody>
</table>

An interview training guide will be developed and translated into both Xhosa and Afrikaans, which are the dominant languages spoken in the Western Cape. Professional translation will only be required for the Xhosa translation, as the researcher will perform the translation into Afrikaans. Following the initial translation, the training guide will then be back-translated from Xhosa into English to ensure the quality and the correct interpretation of the translation. Numerical labels will be printed to represent the patient number. There will be two labels of each patient number, and one will be attached to the signed consent form and the other to...
the patient exit interview guide. Travel costs of the fieldwork co-ordinator were calculated by averaging the distances to be travelled to and from the respective facilities per day, and the average distance (measured in kilometres) per day was then multiplied by an estimated number of days of supervision visits.

7. ETHICS

Potential Benefits
There are no personal benefits to participation in the study; however it could benefit the community through the future planning and efficient delivery of health care services. This study will directly benefit the communities in which the research is conducted as it informs methods of decentralising ART and improving the availability of treatment.

Potential Harms
While the study does not involve invasive procedures, potential harms to participants of the patient exit interviews involve the loss of anonymity in the process of interviewing. These harms are most acute in communities where HIV infection is stigmatised and people who are HIV positive are reluctant to reveal their status for fear of discrimination and stigmatisation. Taking care in ensuring confidentiality during the interviewing of patients will minimise these harms. In each facility selected, private rooms will be used for conducting patient exit interviews.

Accountability
Permission will be obtained from the relevant health authorities and facility managers for the interviews and data collection. A patient information sheet will be designed to provide participants with a background to the study, emphasising their role in the study, measures employed to protect their confidentiality as well as their right to opt out of the interview/survey at any point (see Appendix 1). Signed informed consent will be collected during the patient exit interviews (see Appendix 2). Consent forms as well as patient exit interviews will be translated and conducted in any of the three most prevalent languages spoken in the Western Cape, English, Xhosa and Afrikaans. The contact information of the researchers as well as the ethics committee will be
stated in the patient information form, which will be given to participants to keep. This will improve the accountability of the researchers.

Incentives
There will be no monetary compensation for participants of the patient exit interviews.

8. DISSEMINATION OF FINDINGS

This study will be submitted towards fulfilment of the requirements set for a Masters in Public Health (MPH), specialising in Health Economics. A journal article and policy brief will be written on the findings and a research report submitted to the Western Cape Provincial Department of Health. Findings will be presented at regional conferences attended by public health sector staff. A summary report will also be made available to the facilities participating in the study.
REFERENCES


Part B: Literature review

9. INTRODUCTION AND METHODOLOGY

The objectives of the literature review are to identify studies measuring the costs and outcomes of pharmaceutical service delivery models, to understand some of the reasons for the scarcity of Human Resources for Health (HRH) in Sub-Saharan Africa, the theory and empirical research around task-shifting and the impact on patients’ access to health care.

Databases used in searching for and identifying research studies included MedLine, PubMed, Google Scholar, conference abstracts and presentations, as well as the South African National Health Research database and the Cochrane Library. Resources were included from published sources and grey literature, opinion or policy reviews, literature reviews as well as primary research. As studies on health human resources in developed nations lacked generalisability to the South African setting, there was an emphasis on research conducted in Low- and Middle- Income Countries (LMIC), although research from developed countries was not excluded. In addition to the database searches, a snowball approach was used to identify potential articles from the reference lists of relevant articles.

10. DRUG SUPPLY MANAGEMENT

Access to essential medicines is often constrained in less developed or impoverished countries, and the availability of essential medicines is considered to be a proxy for the quality of care in a country. There are many country and region specific reasons for a lack of access to essential medicines, but the reasons can broadly be summarised into the following categories:

- a lack of sustainable funding,
- poor planning and management of drug procurement and distribution processes,
- and a shortage of pharmaceutically trained HRH.
These issues are becoming even more urgent and the battleground for access to essential medicine now also includes ART due to the high economic costs of treatment failure (Vogel and Stephens 1989; Quick, Boohene et al. 2005; Harries, Schouten et al. 2007; Waako, Odoi-adome et al. 2010).

Many studies commenting on problems with drug stock outs or lack of essential medicines in countries focus on the financing and procurement aspects of drug supply. However, Windisch and others argue that in reality, many other components of service delivery, not directly related to supply chain management, may impact on the availability of medicine such as the adequacy of infrastructure and HRH (Windisch, Waiswa et al. 2011). External funders supporting ARV services might attempt to mitigate these conditions by implementing parallel systems of drug distribution. In Malawi, for example, it was found that a focus on a single first-line regimen for ART simplified the process of drug ordering, drugs were then packaged into easy to use “starter packs” and “continuation packs” to assist in distribution at facility level. In addition drug level “ceilings” were decided on and quarterly data on patient outcomes were used to calculate future drug needs. In addition, a parallel procurement agency (i.e outside of government structures) was used where the government procurement system was weak (Harries, Schouten et al. 2007). While these initiatives worked initially, it did not strengthen the countries’ drug procurement and distribution systems and the parallel system started failing as the ART service grew and new drug regimens were added to the requirements (Schouten, Jahn et al. 2011). The study concluded that a more systemic approach needs to be taken.

One of the needs of a functioning drug procurement and distribution system is pharmaceutically trained HRH. A survey of HRH found that in Malawi the vast majority of mission facilities were severely understaffed with as few as 20% having any pharmaceutically trained staff, and Uganda fared only marginally better at 22% (Waako, Odoi-adome et al. 2010).
11. **HUMAN RESOURCES FOR HEALTH**

Human resources to treat HIV/AIDS is considered to be one of the main constraints to achieving universal Anti-Retroviral Treatment (ART) coverage (Kober and Van Damme 2004; Hirschhorn, Oguda et al. 2006; Barnighausen, Bloom et al. 2007; Van Rensburg, Steyn et al. 2008). Current ART coverage for LMIC is estimated to be 28% to 32% and according to Barnighausen et al. (2007) will drop to between 16% and 19% by 2017, if human resources for health (HRH) production rates are kept constant, considering the inflow of people needing treatment (Barnighausen, Bloom et al. 2007).

HRH can be broadly defined as “the stock of all individuals engaged in the promotion, protection or improvement of population health” and, according to the World Health Organisation (WHO), includes those working in the public and private sectors, in clinical, research as well as public health interventions (World Health Organization 2000). Globally it has been found that there is a close correlation between the number of qualified health workers and key health outcomes related to the quality of health care, such as the infant mortality rate, immunization coverage and maternal survival. This is thought to be because, within a health system, qualified health workers function as gatekeepers for the efficient or wasteful use of all other resources such as drugs, vaccines and supplies (World Health Organization 2006). Given the importance of HRH to a country, it is not surprising that there is a heated debate on the best method of calculating the need for HRH, which impacts on planning and capacity building. HRH planning attempts to match the available supply of trained health workers with the demand for the resources, and is not only a technical process, but also a political one. Decisions related to the number, types and distribution of health workers depend on political, and economic choices as well as the social values that underlie a particular health system and country (Fulop and Roemer 1987; Birch, O'Brien-Pallas et al. 2003; Dreesch 2005). While there are several different technical approaches used in estimating HRH needs in a country, a production function which looks at the factors influencing the inputs and outputs is useful.
11.1. **INTRODUCTION TO THE HRH PRODUCTION FUNCTION**

If one were to consider the need for HRH as a production function (see Fig. 1) representing the relationship between the quantity of inputs used (human resources) and the quantity of outputs produced from those inputs (for example, the number of patients receiving ART), the output produced from a given number of providers can be said to depend on a number of production factors (O'Brien-Pallas, Birch et al. 2001; Birch, O'Brien-Pallas et al. 2003).

**Figure 1: Human Resources for Health (HRH) production function**

Provider level production factors include, the quality of training that staff receive, their level of experience, productivity, morale and attitude towards patients, in this case people living with HIV/AIDS. These individual provider related production factors will influence staff’s efficiency and thus ultimately the number of staff that need to be employed. Productivity, defined as the ability to render a service, is further impacted by HIV in that health workers can contract HIV themselves and in addition, absenteeism can be high due to workers needing to attend to family members who are ill (Hirschhorn, Oguda et al. 2006).

The determinants of service outputs in the HRH production function are not restricted to the characteristics of the HRH workforce. Human resources do not provide care in
isolation, but use their skills and knowledge in combination with other human and non-human resources to provide health services to meet the needs of the population. Therefore system factors that may influence the extent of the need for HRH include the range of care offered, staffing models, visit frequency, facility characteristics, the type of facility or sector, the current facility resources, facility ART experience, characteristics of the patient population as well as local and national support for the implementation of HIV/ART programmes (Hirschhorn, Oguda et al. 2006). On a more global level, the scarcity of HRH as well as the push and pull factors impacting on the migration of HRH away from developing countries towards more developed countries also impact on the availability of HRH. These factors in turn influences national policy towards a shifting or reallocation of tasks (task-shifting) towards less internationally mobile health workers (these concepts are discussed in more detail in chapters 10.2 and 10.3). At a local level, the frequency and intensity of patient visits is dictated by the severity of the patient’s condition, maturity of the programme, national guidelines and intensity of the management of adherence and side effects, which influence the demand for health care and therefore HRH. The more experienced staff are in HIV management, the more productive they will be and the lower the staff requirement is (Cleary 2010). At a new site, the number of patients on ART will tend to increase slowly as staff and site experience increases and patients are initiating treatment but after some time, more and more patients will be coming for follow-up treatment and therefore the patients in care will grow rapidly for a period of time even without additional staff. However, as the site nears full capacity, more patients will experience treatment failure or toxicities and the site’s ability to manage patients and enrol new patients will decrease unless additional resources are added (Hirschhorn, Oguda et al. 2006).

In theory, we would want the combination of inputs that minimises the cost of producing the required services while maximising the outputs. However, the availability of certain inputs (such as HRH) may constrain the range and type of production processes that can be used (O’Brien-Pallas, Birch et al. 2001).
11.1.1. Skills mix

In 2006 the *World Health Report* concluded that “in many countries the skills of limited yet experienced professionals are not well matched to the local profile of health needs” (World Health Organization 2006). Where the skills mix is not matched to local need, health care services become less available, and where available they become less affordable (Fulton, Scheffler et al. 2011).

If we consider the production function from a different perspective (see Figure 2), we see that the optimal staff mix would be the combination of HRH provided at a particular quality for the lowest cost, and this is considered productively efficient. The number and mix of staff required can be depicted in a production function graph, represented in Figure 2 below.

*Figure 2:* Graphical representation of the Human Resources for Health (HRH) production function
Source: Fulton et al. (2011)

Figure 2 represents the nurse to physician staff mix in a particular health service. The horizontal axis represents the number of physicians and the vertical axis represents the number of nurses. The straight line that intersects the axes represents a fixed budget constraint along which total staffing costs are equal. Where the budget constraint line intersects the horizontal axis, the entire budget is used for physicians and where it intersects the vertical axis, the entire budget is used for nurses. The curve $Q_2$ represents a particular quantity of health services produced by a mix of physicians and
nurses, while \( Q_1 \) represents a different quantity that is greater than \( Q_2 \). The figure shows a productively inefficient skills mix (point A) and a productively efficient skill mix (point B). Point A is not productively efficient as the service provider could decrease the number of physicians from \( P_A \) to \( P_B \) and increase the number of nurses from \( N_A \) to \( N_B \) – this change would not increase costs but would produce a greater quantity of health service (\( Q_1 > Q_2 \)). The productively efficient point is where the quantity of services at a given quality is maximised subject to the available budget (Fulton, Scheffer et al. 2011).

One can therefore see that if a country were to employ too many expensive physicians, it would exponentially decrease the amount of nurses that they’ll be able to employ, which significantly decreases the availability of services. Conversely, if a country only employs nurses, this could conceivably decrease the quality of service patients experience as specialist medical services may not be available. Skills mix decisions for a health service are influenced by health care worker associations, licensure requirements and scope of practice and will impact on the availability of a service as well as the affordability of scaling-up to universal access.

11.2. SCARCITY OF HUMAN RESOURCES FOR HEALTH

Sub-Saharan Africa, which has the greatest burden of health need, has some of the lowest health worker to population ratios (World Health Organization 2006). There are several factors that contribute towards a scarcity of HRH, including lower economic incentives, poor working conditions and a straining education system. This maldistribution of resources relative to need is often referred to as Hart’s inverse care law, which was described by Julian Tudor Hart in 1971 and relates to the effects of market forces in health care (Watt 2002).

*The availability of good medical care tends to vary inversely with the need for it in the population served.*

*JH Hart, 1971*
Hart further argued that ‘no market will ever shift corporate investment from where it is most profitable to where it is most needed’ (Watt 2002). This can also be said to be true of HRH, for which an international market has developed.

The maldistribution of HRH according to need is evident at multiple levels; at an international level with the international migration of health workers from developing countries to more developed countries, and within countries HRH distribution is often skewed towards the urban areas and private sector health care. On average, about one third of a country’s stock of HRH works in the private sector serving only a fraction of the population (World Health Organization 2006).

In recent years high-income countries such as Australia, Canada, Saudi-Arabia, the USA, the United Arab Emirates and the UK have been using their buying power in the form of better salaries, living conditions and a more stable economy to purchase scarce, trained health care workers from developing nations (Chen, Evans et al. 2004). On the one hand, one could argue that the migration of health workers may have economic benefits for both countries as capital-rich countries gain an influx of scarce skilled labour and labour-rich countries are compensated in remittances (formal and informal) which go directly to households, contributing to broad based income growth in migrant sending areas and promoting poverty alleviation and development (Taylor 1999; Record and Mohiddin 2006).

However, where migration outstrips training, a shortage of staff would make it extremely difficult for the ‘exporting’ country to deliver essential health services and keep up the training output required. In the United Kingdom, almost one in ten doctors were trained in Africa (Mills, Schabas et al. 2008). In terms of the impact of large scale HRH migration on the delivery of essential health services, it has been shown that as the density of health-care workers in a country decreases, the mortality rate increases. Based on the effect on the health of the ‘exporting’ country, Mills et al (2008) call for the active recruitment of health workers from developing countries by developed countries to be considered unethical and should be prosecuted by the International Criminal Court (Mills, Schabas et al. 2008).
The problem with Mills and colleagues’ argument is that it assumes that people have no influence over their environment or circumstances, but as Robinson and Carey suggest, migration decisions are ultimately not made in isolation but are influenced by the wider political, social and economic context of a country (Robinson and Carey 2000). This viewpoint is echoed in Siegfried and Pienaar’s comment on Mills’ article, which argues that it is important to consider the migration “push factors” of a country such as South Africa, where it is not only health professionals who are migrating but that they are part of a bigger wave of migration of skilled professionals. Siegfried and Pienaar further quote the results of a survey conducted by the South African Migration project which found that health professionals who emigrated said that the general conditions in the country (including a lack of security, personal safety and concern for their children’s futures) were a bigger “push factor” than poor working conditions. Siegfried and Pienaar therefore concluded that the increasing of regulations to stem the migration of health workers would undermine human rights at an individual level (Siegfried and Pienaar 2008). The approach of Yassi et al., which suggests that instead of well resourced countries having an ethical obligation to stop migration, they have an obligation to improve the working conditions and knowledge base in resource poor countries, seems more balanced and achievable (Chen, Evans et al. 2004; Yassi, Bryce et al. 2009). Similarly Mackintosh argues that there should be a form of restitution from countries accepting health professionals trained in Sub-Saharan African countries towards the country training health professionals, in order to compensate for the benefit from skills not created through investment in training (Mackintosh 2007; McIntyre and Mooney 2007).

Similar to international migration, scarcity is often experienced within countries in terms of a rural/urban bias with a greater concentration of health care professionals practicing in urban settings, which leads to people living in rural communities having less access to health care, crowded clinics and lower quality of care (Reuter and Couper 2007; Thiede, Akweongo et al. 2007; Hawthorne and Anderson 2009). Strategies that have been used to improve the distribution of HRH include direct financial incentives, benefits derived from training opportunities, or financial assistance in exchange for a commitment to work in rural areas (Lagarde and Blaauw 2009).
A review of discrete choice experiment studies to analyse health care providers’ preferences for different job characteristics in both developed and developing countries, showed that non-financial incentives are often more powerful than financial incentives. Non-financial strategies that are used to retain HRH include; encouraging the recruitment of students who appear more likely to work in rural areas after graduation, increasing the sensitization of health students to rural areas, the improvement of working conditions in remote areas, more flexible working arrangements and improving access to communication (Reuter and Couper 2007; Lagarde and Blaauw 2009). A qualitative study conducted in South Africa which examined different options for encouraging health care professionals to work in rural practice, found that health care professionals with a rural origin, or having been exposed to rural practice during training, as well as exposure to rural role models were more likely to continue working in rural settings (Reuter and Couper 2007).

In conjunction with international migration, and a preference for urban over rural posts, South Africa also experiences a strong pull of health workers away from the public service and into the private sector, with approximately 43% of professional nurses being employed in the public sector which serves more than 80% of the population (Van Rensburg, Steyn et al. 2008). The reasons for this exodus relates to low pay and poor working conditions (Hirschhorn, Oguda et al. 2006). In an effort to mediate this effect on the health system, the South African government has mandated a 3 year compulsory in-service training for doctors, two years of which is called internship and 1 year of community service. Other health care professionals similarly have to complete a year of community service working in a public institution after completion of graduate studies. This provides some reprieve and there is the hope that health professionals would choose to stay on in the public sector after internship and community service. Another important strategy that has been used in South Africa to retain health professionals in the public sector and to draw them back from the private sector is the Occupation Specific Dispensation (OSD) which is a financial reward structure aimed at improving the compensation of all health professionals in a fair manner for their skills. Unfortunately due to the manner of the negotiations, the OSD has left some doctors (especially mid-level doctors with some experience) feeling unappreciated and not compensated to the same extent as their peers in private practice (Parkes, Abratt et al. 2009).
It can therefore be concluded that where health professionals are severely underpaid compared to their counterparts in private practice, financial incentives will present an enticing carrot to leave the public sector. Therefore, a combination of financial strategies as well as an improvement in working conditions for health workers may assist in retaining health workers in the public sector.

11.3. TASK-SHIFTING

Apart from staff-retention and improved production strategies, a common response to HRH shortages in poor-resourced settings is the use of substitute health workers, such as mid-level workers or lay workers for non-technical tasks, to relieve pressures on health professionals (Van Rensburg, Steyn et al. 2008). Task-shifting can be defined as the delegation of tasks from highly skilled workers to cadres with either less training (but still capable of doing the work) or more narrowly tailored training (Callaghan and Schneider 2009). The primary aim of task-shifting is to increase productive efficiency and that the efficiency gain may lead to improvements such as increased patient access, lower health worker training and wage bill costs, and a decrease in the health workforce shortage relative to need. Another objective of task-shifting is to decrease the time needed to mobilise a scale-up in the workforce according to the health needs of the population, as the cadres require shorter training times (Fulton, Scheffer et al. 2011).

Different types of task-shifting have been described: (1) indirect substitution or delegation of tasks to an existing but different profession (e.g. delegation of tasks from a doctor to a nurse); (2) direct substitution to a less-trained/ mid-level worker within the same profession (e.g delegation of tasks from a professional nurse to a nurses assistant); (3) the delegation of non-technical tasks to lower trained or lay cadres of staff (e.g. employing administrative staff or community health workers to take over some of the roles and duties of nurses); and (4) the creation of a new level of health worker (e.g. pharmacists assistant) (Dovlo 2004; Van Rensburg, Steyn et al. 2008).
While task-shifting has been occurring for decades, it is seen as becoming more urgent, because of the health care needs of HIV/AIDS patients and needing to prevent people with other conditions from being squeezed out of the health services (Fleischer, Kevany et al. 2010). Until recently, much emphasis had been placed on the assumption that staff needs for HIV care differ dramatically from primary care services and are more “doctor intensive”. However, there have been proposals to simplify treatment regimens and move towards task-shifting, together with an emphasis on the involvement of local communities (Stevens and Lehman 2009). In South Africa there has been a move towards a nurse-based, doctor-supported ART service to be integrated into the District Health System (SANDH 2007; South African National Department of Health 2007; Colvin, Fairall et al. 2010).

Task-shifting can have many benefits. In a multi-country study, Huicho et al. (2008) found that in underserved rural areas where health care needs are the greatest, health workers with longer pre-service training (i.e. doctors) are less available than those with shorter pre-service training (i.e. nurses) (Huicho, Scherpber et al. 2008). A study performed in Mozambique found that there was less out-migration by mid-level workers trained in the country than physicians. They found that 90% of mid-level workers recruited from rural areas, returned and stayed in rural areas for a minimum of seven years after graduation compared to 0% of physicians. This is thought to be due to the ease with which physicians’ skills are transferable to other countries as training is based on European standards (Dovlo 2004; Kruk, Pereira et al. 2007). Task-shifting whereby people are trained on an in-service basis, could therefore assist in the retention of skills where they are most needed.

Quality of care has been mentioned as an argument against task-shifting (Philips, Zachariah et al. 2008). Research has however found evidence to the contrary. A comprehensive multi-country study by Huicho and others, comparing the performance of different categories of health workers trained in Integrated Management of Childhood Illness (IMCI) and child mortality, found that the quality of care (defined as compliance with IMCI guidelines for assessment and treatment of sick children) did not differ between those with longer and shorter duration of pre-service training. The IMCI treatment was delivered in primary health care facilities. One of the explanations offered is that health workers with shorter duration of training might be
more willing to comply with standard clinical guidelines than health workers with
more training who might be accustomed to taking short cuts or delegating some tasks
to clerks, such as counselling and dispensing medication (Huicho, Scherpbier et al.
2008).

The use of task-shifting in poorly-resourced areas could therefore alleviate the most
urgent needs by providing a health worker who is skilled, works according to standard
operating procedures and is less likely to migrate.

12. PHARMACEUTICAL CARE: THE ROLE OF THE PHARMACIST

Pharmaceutical services experience the same workload pressures and staff shortages
that plague other HRH. In fact, during the initial roll-out of ART in South Africa the
focus was on increasing access to drug supply, by for example lowering the cost of
ART drugs and negotiating for the production of generic drugs. However, limited
effort has been directed towards ensuring that the systems, processes and human
resources associated with the safe provision of drug therapy are available (King and
Fomundam 2009). This is becoming more crucial as the ART programme is being
scaled-up and adherence to treatment over the long term is becoming a concern.

Studies in developed countries have found that support from pharmacists can
positively affect adherence and has a strong impact on promoting good clinical
outcomes in patients on ART (Horberg, Hurley et al. 2007). In developing countries,
the role of pharmacy staff in supporting the ART program varies considerably and
pharmacists’ skills are often underutilized (Walkowiak and Keene 2004).

Pharmacy as a profession, has in recent years reoriented its practice from a clinical
service model to a pharmaceutical care model (Blantyre 2007). Pharmaceutical care
refers to the direct, responsible provision of medicine-related care designed to achieve
definite outcomes that improve a patient’s quality of life. Beyond simply handing out
medicine, the concept of pharmaceutical care refers to a far more responsible role of
promoting adherence to therapeutic regimens, investigating and addressing problems
such as over dosage, sub-therapeutic dosage, adverse drug reactions, medication
errors and untreated indications. The lack of trained pharmacists therefore creates severe disease management challenges in a country, despite the fact this extended role of pharmacists are often not possible in a resource-limited setting (King and Fomundam 2009).

12.1. PHARMACISTS IN PRIMARY HEALTH CARE

In 2005, the UK National Health Service (NHS) launched an initiative called “Choosing Health through Pharmacy”, aimed at enhancing the pharmacist’s contribution to improving public health and reducing health inequalities through pharmaceutical care (United Kingdom department of health 2005). The initiative presumes that on the basis of their knowledge, skills and proximity to the public, pharmacists are an untapped resource for health in the United Kingdom.

Studies examining the benefits of pharmacists in primary health care had mixed results. Evidence suggests that pharmacist-led medication reviews, focused on high-risk patients with conditions that alter drug handling by the body and where patients receive multi-medication regimens, improves patient outcomes compared to no comparable service (Nkansah, Mostovetsky et al. 2010). However, there is a paucity of evidence on the impact of pharmacist-led medication reviews when the service is provided by another health care professional, such as in nurse-led dispensing. The difficulty in assigning a value to the service provided by pharmacists often lies in the outcome measure used. Notably Holland et al. (2008) in their systematic review excluded patients’ improvements in knowledge and adherence and focused on more measurable effects such as hospital admissions and deaths in older people (Holland, Desborough et al. 2008; Silcock and Petty 2008). It could be argued that the value of pharmacist intervention lies in imparting knowledge and the changing of prescribing practices. Monroe et al. (1997) and Dooley et al. (2003) concluded that pharmacists are cost saving when one considers total monthly medical costs, as pharmacists put measures in place to promote rational prescribing (Munroe, Kunz et al. 1997; Dooley, Allen et al. 2003). There is however a lack of similar evidence in resource-poor outpatient settings, where the service is provided by another health care professional.
12.2. TASK-SHIFTING: THE PHARMACISTS ASSISTANT DEBATE

The World Health Organization’s (WHO) guidelines recommend a minimum country average of 1 pharmacist per population of 2,300 people. An overview of the state of a selection of developed and developing countries shows the range of population to pharmacist ratios with developed countries (and countries who often actively recruit health care workers from other countries) falling well under the WHO recommendation of 2,300 people per pharmacist (see Table 1). Conversely, as can be expected, developing countries, with less pharmacy schools have higher population to pharmacist ratios.

Table 1: Pharmacy health human resources (King and Fomundam 2009; Sanchez 2010)

<table>
<thead>
<tr>
<th>Name of Country</th>
<th>Nr of pharmacy schools‡</th>
<th>Nr of pharmacists</th>
<th>Population/ pharmacist*</th>
<th>Population† urban/rural*</th>
<th>Formal pharmacy tech/assistant training</th>
<th>Nr of assistants</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>114</td>
<td>249,642</td>
<td>1,193</td>
<td>2,878,422,000</td>
<td>/</td>
<td>yes</td>
</tr>
<tr>
<td>CANADA</td>
<td>10</td>
<td>27,078</td>
<td>1,193</td>
<td>3,239,700,000</td>
<td>/</td>
<td>yes</td>
</tr>
<tr>
<td>UK</td>
<td>27</td>
<td>29,726</td>
<td>1,952</td>
<td>58,042,000</td>
<td>/</td>
<td>yes</td>
</tr>
<tr>
<td>CUBA</td>
<td>3</td>
<td>2,962</td>
<td>3,779</td>
<td>11,193,000</td>
<td>/</td>
<td>yes 7047†</td>
</tr>
<tr>
<td>SA</td>
<td>9</td>
<td>11,097</td>
<td>4,332</td>
<td>11,071,000</td>
<td>/</td>
<td>yes 1,424</td>
</tr>
<tr>
<td>BOTSWANA</td>
<td>0</td>
<td>140</td>
<td>13,136</td>
<td>1,839,000</td>
<td>/</td>
<td>yes 163</td>
</tr>
<tr>
<td>SWAZILAND</td>
<td>0</td>
<td>46</td>
<td>34,435</td>
<td>1,124,000</td>
<td>46/0</td>
<td>/</td>
</tr>
<tr>
<td>LESOTHO</td>
<td>0</td>
<td>17</td>
<td>317,353</td>
<td>1,995,000</td>
<td>/</td>
<td>yes</td>
</tr>
<tr>
<td>UGANDA</td>
<td>4</td>
<td>215</td>
<td>133,484</td>
<td>28,699,000</td>
<td>209/9</td>
<td>/</td>
</tr>
<tr>
<td>ZAMBIA</td>
<td>0</td>
<td>68</td>
<td>172,688</td>
<td>11,738,000</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>MALAWI</td>
<td>1</td>
<td>37</td>
<td>124,109</td>
<td>15,692,000</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

†WHO guidelines recommend 1 pharmacist per population of 2,300 (public + private)
‡academic_institutional_membership.fip.org/world-list-of-pharmacy-schools/
*apps.who.int/globalatlas/docs/HRH/html/Geo_ctry.htm
†population estimates: esa.un.org/unpp/index.asp

From Table 1, one can see that there is a severe shortage of pharmacists to provide pharmaceutical care in South Africa (and many other developing countries). With the overwhelming increase in demand for ART, it is no surprise that pharmacies and pharmacists are unable to cope. This is aggravated by regulatory authorities which might not have the funding or resources available to enforce applicable laws or to carry out research to amend policies (King and Fomundam 2009). Therefore, an array of health care professionals is known to dispense medication. In South Africa,
provision is made in the law for nurses themselves to prescribe and dispense medication.

Pharmacists Assistants (PA) are used in many countries as a form of mid-level worker, who is practically skilled to perform a specific function but is not as highly trained as the pharmacist. The PAs are therefore used to perform the so-called “lick and stick” pharmacy operation, which frees the pharmacist up to check for medication errors, spend time on counselling patients during dispensing and providing a more patient-centred service (Canadian Pharmacists Association 2008).

South Africa has policies and regulations in place that could enable the task-shifting of pharmaceutical services to professional nurses or PAs where pharmaceutical services are lacking in order to ensure access to essential care. This enables professional nurses to provide a complete service of managing and dispensing ART in a Primary Health Care (PHC) setting. These practices would however take time away from the clinical duties of the health professional and could restrict scale-up of services. In light of the severe shortage of nurses in South Africa, this may not be a viable solution (Schulman, Makani et al. 2009). The South African Pharmacy Council allows for the registration of PAs, a category of mid-level worker who are trained and employed in pharmacies, to perform administrative or repetitive tasks essential in the operation of a pharmacy (South African National Department of Health 2007).

The Pharmacy Act 53 of 1974 deals with the scope of practice, training as well as registration of PAs. It also allows for PAs working under the indirect supervision of a pharmacist in government facilities. The provisions under which a PA can dispense under indirect supervision, include that medication is provided in patient-ready packs or re-packaged for this purpose at the hospital or provincial depot. It is further specified that a PA working under indirect supervision must be visited once a month by the Designated Supervisory Pharmacist (DSP) and that such visits should be documented (Medecins Sans Frontieres 2007; Honermann 2009).

In South Africa’s PHC system, the PA is a crucial team member in the nurse-driven service with only visiting doctor’s support (Du Preez 2009). However, many pharmacists are still concerned about delegating tasks for which they feel accountable
and therefore see PAs as a threat as opposed to an opportunity (Gray, Gengiah et al. 2006). In conjunction with this, PAs are currently trained through a form of in-service learnership with a pharmacist acting as tutor and responsible for their training. This can be an onerous task in an already resource-limited pharmacy.

Following the release in 2006 of the SA Department of Health’s human resource plan for health, there has been an increased push to develop mid-level workers for all health professions. This has resulted in increased pressure on the SAPC to use the lessons learnt from the PA programme and revamp the pharmaceutical care mid-level worker (White 2007). The intention is to replace the concept of PAs, and to change the training to include more academic content. The new grade of mid-level worker is to be called a Pharmacy Technician and the intention is to give them more responsibility but still under supervision (whether direct or indirect), with the authority to supervise and train more junior assistants (Dring 2007; Osman 2010). This will certainly assist pharmacists in improving pharmaceutical services in the public sector and improve patients’ access to treatment.

12.3. MODELS OF ART DELIVERY

In Working Together for Health: The World Health Report 2006, the WHO highlights that in many countries the skills of scarce and expensive health professionals are not well matched to the local profile of need (WHO 2006). Therefore, even where methods of task-shifting are used but not used appropriately or efficiently, instead of improving access it would make health services less available, and where available less affordable (Fulton, Scheffer et al. 2011).

The model of ART service delivery will influence the number and mix of staff required to provide an ART service and this depends on several factors (see Figure 1). These include the spectrum of care provided by sites, the level of integration into the primary health care system, and the frequency and level of skills required per patient visit. When it comes to the spectrum of care, a specialist, hospital based ART service maximizes the use of specialists trained in ART care and support, resulting in higher ART patient-to-staff ratios and can play an important role in the management of
complicated ART patients from other sites, but due to the scarcity of ART specialists this system limits patient access to treatment or greatly increases travel and time costs. Conversely, the primary care service provision model allows providers to develop expertise in ART, will require more staff per patient but allows for a more integrated and decentralized approach, which ultimately facilitates access to ART. The integration of ART service into the primary health care service will change staff requirements and needs to be accompanied by the supply of additional HRH to prevent the crowding out of other services and to decrease the risk that expansion of a well-funded programme will weaken other health services by competing for the same HRH (Hirschhorn, Oguda et al. 2006; Van Rensburg, Steyn et al. 2008; Hanefeld and Musheke 2009).

With the need for the expansion of ART services in South Africa, the South African government in conjunction with partners and stakeholders have authorised the down-referral of patients stabilized on ART from hospitals to PHC clinics. This will alleviate the patient load on the hospital pharmaceutical service as well as decrease the cost of transportation to collect medication for patients. The shortage of pharmacists at primary health care clinics has led to the deployment of pharmacists’ assistants and nurses to support the expansion of the ART programme and to ensure that patients get their medication. In different provinces and districts of South Africa, different approaches have been explored, but evidence on the effectiveness of these measures in improving access to treatment is still lacking (Walkowiak and Keene 2004; Colvin, Fairall et al. 2010).

One option is that prescriptions are prepared at a nearby hospital and delivered to the clinic closest to the patient’s home or place of work. The prescription is packaged with the needed information and delivered for nurses to dispense (Colvin, Fairall et al. 2010). The nurse will then review the patient’s progress, and returns the progress report and any uncollected medication to the hospital.

A recent development which is currently under scrutiny, involves the amendment of the antiretroviral therapy guidelines to allow primary care nurses to “place their patients on ART using predetermined national guidelines, re-prescribe using those regimens and manage stable patients”, subject to completing the national training
programme for nurses (NIM-ART), access to experienced physicians to provide support, referral measures in place and ongoing clinical mentoring (Househam 2010). This option has become feasible as the criteria for starting patients on ART has changed and relatively healthier patients with better projected outcomes are now starting treatment, who are easier to manage, although little evidence exists that this will be a safe and effective method of ART service provision.

An option used in the Western Cape involves PAs dispensing ART in PHC clinics under the indirect supervision of a pharmacist. Additional training is provided for assistants, along with a clear description, standard operating procedures and monitoring tools implemented to set standards for practice and to facilitate effective oversight. An adaptation of the above scenario is where pharmacists visit the PHC clinic once a week to dispense ART or check scripts prepared by a PA and the medication is then handed to the patients by either the pharmacists or nurses working in the PHC clinic (Walkowiak and Keene 2004; Monteith, Grimwood et al. 2010). An outline of three models of ART service delivery is summarized in Table 2.
### Table 2: Pharmaceutical care service delivery models (Von Zeil 2008)

<table>
<thead>
<tr>
<th>Pharmaceutical care provider</th>
<th>Full-time Pharmacist available</th>
<th>Pharmacists Assistant under indirect supervision</th>
<th>Nurse-led service provision</th>
</tr>
</thead>
</table>
| Overview                     | Full-time pharmacist dispensing medication from a prescription written by doctor, directly to the patient. | The PA works under the indirect supervision of an offsite pharmacist who conducts monthly visits and provides telephonic support.  
Dispenses directly to the patients and is responsible for stock control.  
One pharmacist is allowed to supervise up to 5 pharmacists’ assistants. | This service is often provided in conjunction with an outreach service from a larger centre or in small satellite clinics.  
Medication is pre-packed by a pharmacist for each patient (patient ready packs) and delivered to the clinic from which the nurse hands out the medication and monitors the patients’ condition. |
| Requirements                  | Service is available at larger facilities, for example at a community health centre (CHC).  
Dispensing is conducted from a pharmacy, operated under the personal supervision of a responsible pharmacist, licensed by the NDOH and recorded with the South African Pharmacy Council (SAPC). | Dispensary has to be secure, organised, temperature controlled.  
Pharmaceuticals and related products are ordered, stored and dispensed directly to clients by the PA and issued to staff for treatment areas. Dispensary design and layout is similar to that of a pharmacy but with smaller floor size. | Storage of medication in a medicine room. The medicine room is intended as a secure, organised, temperature controlled room with limited access, for the bulk storage of pharmaceuticals, for refilling trolleys or cupboards in treatment rooms.  
No direct patient dispensing, only from patient-ready packs or according to standard operating procedures. |
| Benefits                      | Highly skilled and trained health professional, skilled in working under pressure and in a team.  
Promotes rational prescribing and is therefore cost-saving | More cost-effective in salary and training costs (Dovlo 2004)  
Onsite to assist in stock management and if patient come outside of appointment dates.  
Increases access to ART | Increases access to ART for patient  
Patients have established rapport with clinician.  
There is a perception of time saved if clinician dispenses, though each consultation will take longer. |
| Problems                      | Limit trained professionals  
Would limit scale-up of ART service  
Expensive training  
Higher salary level | Insufficient training (operational management, dealing with the public/providers)  
Does not have the authority/skill to promote rational prescribing.  
Limited pharmacology training  
Lack of career path (Osman 2005) | Prescriber and dispenser is the same person – potential for mistakes.  
Nurses might not be aware of drug interactions between drug classes.  
Service is likely to reach saturation point sooner. |
Birch et al. (2003) suggests that the use of new HRH staffing models, may change the HRH requirements associated with a given service (Birch, O'Brien-Pallas et al. 2003). For example, the shift in ART service provision from a centralized doctor-driven service to a decentralized service incorporated in the primary health care package would conceivably reduce the number of highly specialized HRH needed but will certainly increase the number of nurses and community health workers required (Colvin, Fairall et al. 2010). Consequently, HRH monitoring and evaluation in addition to evaluations of the impact of different mixes of HRH would be very useful to assess human resource strategies in countries and sensitise political stakeholders to the importance of addressing labour issues (Diallo, Zurn et al. 2003).

13. METHODOLOGICAL CONSIDERATIONS

The difficulty with staff mix comparative studies is that external validity of the study, by the very nature of the subject matter, should be considered low (Buchan and Calman 2005; Fulton, Scheffer et al. 2011). This is because the factors of production of HRH vary so considerably between countries and even between districts in the same country. In addition it is the very differences in factors of HRH production and the unique circumstances in the country’s health system (including health care financing) that gave rise to specific task-shifting measures in the first place.

There is little consensus on the appropriate methodology to use in comparing HRH mix (also called “staff mix”) in a health system, although Fulton et al. (2011) has suggested that cost-effectiveness analyses would be useful in ensuring that the correct comparisons are made (Fulton, Scheffer et al. 2011). Until recently, the focus of staff mix evaluations have been on the delegation of tasks from doctors to physician assistants (Chilopora, Pereira et al. 2007; Herbertson, Blundell et al. 2007; Kruk, Pereira et al. 2007; Pereira, Cumbi et al. 2007; De Brouwere, Dieng et al. 2009; Hounton, Newlands et al. 2009; McCord, Mbaruku et al. 2009; Brentlinger, Assan et al. 2010); from doctors to nurses (Kinersley, Anderson et al. 2000; Buchan and Calman 2005; Barber, Gertler et al. 2007; Huicho, Scherpbie et al. 2008; Shumbusho, van Griensven et al. 2009; Vasan, Kenya-Mugisha et al. 2009; Sanne,
Orrell et al. 2010); and from nurses to community health workers (Rowe, Kelly et al. 2007; Rahman, Malik et al. 2008; Gary, Batts-Turner et al. 2009; Wools-Kaloustian, Sidle et al. 2009; Lewin, Munabi-Babigumira et al. 2010; Selke, Kimaiyo et al. 2010), with a paucity of studies referring to pharmaceutical care staff (Monteith, Grimwood et al. 2010).

Key economic evaluation methodological considerations include deciding on the comparators to contrast and defining the outcome measures to be evaluated (Drummond, Sculpher et al. 2005). Concerns raised by Verteuil (2007) and Fulton (2011) in relation to Kruk et al.’s Mozambique study comparing the cost and productivity of surgically trained assistant medical officers and specialist physicians related to the importance of including a ‘do nothing’ comparator when comparing different task-shifting scenarios (Fulton, Scheffer et al. 2011). They argue that … “a more realistic alternative for patients treated by tecnicos de cirurgia (surgically trained assistant medical officers) would be no formal treatment at all, which would, it is presumed, result in far worse outcomes for the patients” (Kruk, Pereira et al. 2007; Fulton, Scheffer et al. 2011). While Verteuil is correct in that a “do nothing” comparator would be useful, given that the political and social intent for a country’s health system is to provide access to care, the question to be answered by task-shifting evaluations really is only which approach is more likely to improve access to care at the lowest cost and at a certain quality of care. The use of an incremental or marginal analysis approach would help to ensure appropriate comparisons as costs which are common to all options are excluded (Drummond, Sculpher et al. 2005).

Another key methodological consideration for economic evaluations is the outcome measure to be evaluated. These have differed between studies and interventions. For example, in their evaluation of diabetes primary care provided by nurses and community health workers as opposed to standard care, Gary et al. (2009) used a clinical measure of blood sugar control (HbA1c levels) and emergency room utilization as the outcome measure (Gary, Batts-Turner et al. 2009). In contrast, a study conducted by Babigumira et al. (2009) focused on determining the impact of task-shifting on the costs of ART supply, and concluded that task-shifting was cost-saving when delegating follow-up visit tasks from doctors to nurses and pharmacy workers (Babigumira, Casteluovo et al. 2009). Interestingly, while Babigumira et al.
(2009) took into account the potential saving of Full-Time Equivalent (FTE) doctors due to task-shifting, their study did not include the opportunity cost of task-shifting to nurses and pharmacy staff. This is because a cadre that has taken on additional tasks shifted from other cadres will no longer be able to perform its original tasks and an increase in workload will be experienced by these cadres. The study may therefore be overestimating the cost-saving benefits of task-shifting (Van Rensburg, Steyn et al. 2008; Fulton, Scheffer et al. 2011). In addition, Callaghan et al. (2010) made an important point when saying that while task-shifting/ different staff mixes may be cost-effective, it may not necessarily be cost-saving because a greater number of people will be able to access health services which places an additional burden on the health services and it is important to consider these factors when recommending a combination of HRH (Callaghan, Ford et al. 2010).

14. ACCESS TO ART SERVICES

The importance of task-shifting is that it improves access to care insofar as it enables health services to rapidly scale-up an intervention and to provide health care in close geographical proximity to people’s homes (Fulton, Scheffer et al. 2011).

While utilization of health services has often been used as a proxy for access to health care, and certainly skewed utilization of a service may be the first indicator that there are problems in access to the service, the reverse is not true - what is considered to be “good” utilization of a service does not tell us whether people have access to a service (Thiede, Akweongo et al. 2007). For acceptable reasons, those with equal need and equal access to health care may not make equal use of services, with individual preferences being a key factor. Essentially, the concept of access is not the same as service use. A useful definition of access is that it refers to interactions between health services and the individuals or households that make up the community (Thiede, Akweongo et al. 2007; McIntyre, Thiede et al. 2009). More specifically, it relates to an individual’s ability to derive benefits from health care services, and not simply a health system’s capacity to provide the services (McIntyre, Thiede et al. 2009). Access, as opposed to use of services recognises that a service may be available but not suitable to the needs of the community and therefore not accessible. In addition, if
the service is available but the community does not have the necessary knowledge on how to make use of the service or that the service exists, the community cannot be said to have access to the health service.

The demand and supply side factors which influence individuals’ ability to access health services can be evaluated in terms of three dimensions; acceptability, affordability and availability (Ensor and Cooper 2004; Thiede, Akweongo et al. 2007). Demand side factors refer to patient-level factors as opposed to supply side factors relating to the service provider, the health system and the social and political landscape of a country.

14.1. AVAILABILITY

Availability is defined, within the context of the access framework, as having the appropriate health service available in the right place when needed and of good quality. It includes issues such as the relationship between the location of a service relative to location of the community and the range and type of services relative to burden of disease; the availability and need for transport and includes the ability of health care providers to provide mobile services or home visits; the hours of opening of health care facilities and whether or not an appointment system is being used; the drug supply system used in a service in so far as whether the appropriate medication is available for the patient when needed; as well as the appropriate or sufficient staff mix relative to the health needs of the population (Thiede, Akweongo et al. 2007).

14.1.1. Transport as a barrier to access

The location of health care facilities and health services relative to the location of those who need the services and their transportation opportunities impacts on individuals’ ability to access treatment and therefore it’s availability (Ensor and Cooper 2004; McIntyre, Thiede et al. 2006; Weidle, Wamai et al. 2006; Tuller, Bangsberg et al. 2009; Wasti, Simkhada et al. 2009). This is of concern in South Africa where there is an urban-rural bias in ART services, as the initial roll-out of
ART was concentrated around hospitals and the urban areas, which leads to a barrier to treatment for those who have to travel far to receive treatment. In Uganda, the concern around transportation constraints was addressed by providing a home-based AIDS care service in the rural Tororo and Busia districts, with measurable success (Weidle, Wamai et al. 2006). Similarly, evidence from a Medicines Sans Frontiers (MSF) clinic in Lusikisiki, South Africa has shown that decentralized HIV/AIDS care, due to greater proximity and acceptability of services, has led to faster enrolment and better retention compared to a centralized hospital based approach (Bedelu, Ford et al. 2007).

14.1.2. Drug “stock-outs” as a potential barrier to access

Drug “stock-out” refers to the unexpected lack of availability of certain essential drugs at a facility. This has a serious impact on the availability of health care, as even if the drugs are expected to be in stock in a week’s time, this would result in a second trip for the patient to the clinic with all the monetary costs and time lost associated with it. Furthermore, a “drug stock-out” could indicate a break in treatment for the patient, which has disastrous effects in the case of ART where adherence is vital to preventing viral mutation and treatment failure.

“Drug stock-out” is seldom caused by a single factor but it’s rather due to a combination of circumstances. In a comprehensive situational analysis of a district in Limpopo South Africa, Matse (2005) found the following the factors to be associated with drug shortages in primary health care (PHC) facilities:

- Pharmacy staff often did not know how to use formulas associated with the quantification of drugs to be ordered. They therefore often guessed or estimated how much drugs were to be ordered.
- The drug procurement and distribution company was directly contributing to drug shortages by themselves having multiple “stock-outs” of essential drugs.
- The facilities often did not have a stock control system in place, while it has been found that if stock cards are used correctly it could be used to accurately calculate consumption and therefore quantify the order.
- The researcher further found that irrational drug prescribing as well as the use of multiple drugs for the same condition (poly-pharmacy) was a key reason for drug stock-outs. Irrational drug prescribing is often the result of poorly trained prescribing staff as well as the lack of supervision by a pharmacist.

- Lastly, while storage and security is in many other countries a contributing factor to drug stock-outs, the researcher could find no evidence of such factors in South Africa (Matse 2005).

The result of the study therefore underscores the importance of the supervision by a pharmacist, in conjunction with adequately trained prescribers to prevent “drug stock-outs”, thereby improving patient outcomes as well as being cost saving if one considers that medication is the second greatest item on the medical facility budget after staff costs. For patients, regular drug stock-outs at the clinics can lead to ‘shopping around, non-consultation and self-treatment rather than wasting funds on transport for a fruitless trip to the local clinic’ (Goudge, Gilson et al. 2009).

14.2. AFFORDABILITY

Even when health care is provided free of charge, it is widely recognised that accessing treatment comes at a cost to patients (McIntyre, Thiede et al. 2006; Tuller, Bangsberg et al. 2009). Patients incur economic costs in the form of the cost of transport to and from the facility, resources spent on additional medical treatments, healthy food and home care, as well as the opportunity costs of productive time spent away from work (McIntyre, Thiede et al. 2006). Research conducted in South Africa has suggested that non-drug costs incurred by patients may act as a significant barrier to accessing treatment (Rosen, Ketlhapile et al. 2007). This has been substantiated by research from South-western Uganda (Tuller, Bangsberg et al. 2009).

It is important to distinguish between willingness and ability to pay. Assuming that a service is affordable because people are utilizing it does not take into account that households will often prioritise health care and healthy food for those members who are critically ill, and forgo other essential needs such as education, with serious consequences for the household (Russell 1996; Goudge, Gilson et al. 2009).
Affordability can therefore be defined as the degree of fit between the cost of using a health care service and the individual/household/society’s ability to pay for it. The direct and indirect costs associated with health care may not be a barrier to treatment if people are receiving government subsidies, they have access to credit or if they have a regular income and therefore receive paid sick-leave. Often though, the expenses related to health care, in conjunction with people’s inability to earn due to being ill and working in an informal sector, cuts into household savings and pushes household into what has been termed the “medical poverty trap” which refers to the cycle of being sick, needing money for treatment but being unable to earn money due to the illness (McIntyre, Thiede et al. 2006).

14.3. ACCEPTABILITY

Even when a service is geographically available and is affordable, it may not necessarily be acceptable and therefore not accessible. Acceptability relates to the degree of fit between provider and patient attitudes towards and expectations of one another. Patient attitudes towards provider characteristics such as gender, race, age and language may influence the patient’s ability to receive care (McIntyre, Thiede et al. 2006). Respect and trust between patients and providers along with power relationships are often the underlying root causes of acceptability barriers to access. Gilson et al. (2005) in their study exploring user and provider views on public and private health services in South Africa found that respect was linked to provider attitudes and interlinked with the perceived competence of the provider. The authors further concluded that respectful treatment is the central demand of primary care service users in South Africa (Gilson, Palmer et al. 2005). Evidence from Tanzania suggests that community perceptions on the quality of local health care provided influences women’s decisions on where to give birth (Kruk, Rockers et al. 2010). Akin et al. (1999) found similar results in Sri Lanka which suggests that patients are willing to bypass one facility, to travel further to use another facility which offers a better perceived quality of care. In addition, the Sri Lankan study suggests that patients are more likely to travel further for good quality care the more ill they are (Akin and Hutchinson 1999). While the perceived quality of care of a health service is often influenced by staff workload, the cleanliness of facilities, productivity, staff
training and motivation, the underlying factor relates to respect for patients and co-workers and presence of good leadership in the health management team.

Acceptability of health services also differs between males and females. In Southern Africa, it has been found that there are more females on ART than males which cannot solely be explained by the higher HIV prevalence among females compared to males (Muula, Ngulube et al. 2007). It has been suggested that the emphasis on HIV testing among women attending antenatal care means that women are diagnosed much earlier than their male counterparts. This has resulted in a pattern whereby women are the ones bringing home the diagnosis of HIV, and anecdotally it has been suggested that men test by proxy i.e. if their girlfriends are negative they must be too. These circumstances in conjunction with a very female-centred approach at primary health care clinics in South Africa creates barriers for men to testing and receiving HIV care at the local clinic (Braitstein, Boulle et al. 2008; Kipp, Alibhai et al. 2010).

14.3.1. Stigma

Stigma, discrimination and avoidance of stigma is a recurrent theme and struggle in ART programmes, based on evidence from Nepal (Wasti, Simkhada et al. 2009), Uganda (Muhamadi, Nsabagasani et al. 2010), and Tanzania (Parkes-Ratanshi, Bufumbo et al. 2010). It is often mentioned as a factor that delays testing and results in poor adherence to treatment (Seidel 1996; Weidle, Wamai et al. 2006; Wasti, Simkhada et al. 2009; Muhamadi, Nsabagasani et al. 2010; Parkes-Ratanshi, Bufumbo et al. 2010).

Steinberg (2008) in his book wherein he follows a young man through the process of acknowledging the disease in his community, to testing and finally acknowledging that he is HIV positive commented that:

*When people die en masse within walking distance of treatment, my inclination is to believe that there must be a mistake somewhere, a miscalibration between institutions and people.*

(Steinberg 2008)
Stigma relates to the way in which we present health care services and can be defined as a social process whereby a discredited attribute is used to devalue a person. The process is rooted in power. The legitimate identity is acknowledged by cultural norms introduced by the dominant groups or institutions of a society, and the spoiled identity by its nature does not conform or has in some way broken the norms. There seems to be disagreement in the literature as to the inevitability of discrimination as an outcome. Goudge and others (2009) suggested that the marginalised daily resists the negative labelling of HIV identities and negotiates the creation of new positive HIV identities (Goudge, Ngoma et al. 2009). They further suggest that it is in the individual finding meaning through social roles that they have the strength to resist stigma.

Other studies highlight the importance of support and counselling in promoting adherence to treatment, as well as highlighting the damage of secrecy around people’s HIV status (Seidel 1996), with reports of patients not taking their medication at home for fear of being discovered to be HIV positive (Wasti, Simkhada et al. 2009). A limitation of many of these studies, that are seeking information on why people don’t access treatment, is that they seldom interview people who don’t access treatment, as they are often in denial of their status and difficult to identify.

A common perception among ART service funders and clinical managers is that stigma would decrease where treatment is available, perhaps due to the control of symptoms leading to less outwardly visible signs of the disease, or perhaps the counselling and awareness of communities where treatment is available (Steinberg 2008; Goudge, Ngoma et al. 2009). However, Maughan-Brown (2010) found a significant rise in stigma in the Western Cape between 2003 and 2006 (which was a period of ART roll-out) when measured on the basis of questions related to behavioural intentions, instrumental stigma (negative judgement based on inflated fears) and symbolic stigma (negative moral judgement). They further found that while fear of infection increased for everyone, the increase was greater among men, and the increase in negative moral judgements was the greatest among women. Considering that the underlying cause of stigma is fear, Maughan-Brown (2010) concluded that it is imperative to weaken associations between HIV and death, which could be achieved by educating people on how to avoid HIV infection and on the potential
people living with HIV and AIDS have to live long and healthy lives on HAART (Maughan-Brown 2010).

There are still significant barriers for people in accessing ART, and it is important that these are identified, discussed and addressed within communities to promote the cost-effective use of funding for ART programmes and work towards equal access to ART for those who need it.

15. SUMMARY

Access to essential medicine is often constrained in developing countries. These reasons are context specific and include the lack of sustainable funding, poor planning and management of drug procurement and distribution processes as well as the shortage of pharmaceutically trained HRH. More broadly, a lack of sufficient HRH has been identified as one of the main constraints to achieving universal ART coverage. Some of the provider and system factors impacting on HRH production are graphically summarised in Figure 1. The maldistribution of HRH according to need has been shown to be on an international basis whereby internationally mobile HRH from developing countries are attracted to developed countries where salaries are higher. However, nationally there is often an additional maldistribution of HRH between urban and rural settings as well as between the private and public health sectors.

Given the scarcity of HRH, various models of pharmaceutical care delivery have been debated globally, however little evidence has been found of evaluations of these different models. One approach includes different task-shifting arrangements. Task-shifting refers to the delegation of tasks from the more highly qualified health worker to a narrowly trained worker. While quality has been discussed as a concern, the studies seem to indicate that the quality of care delivered by mid-level workers is at least comparable to that of the internationally mobile HRH. In addition, mid-level workers are more likely to work in more rural facilities where the need is greatest (this is especially true if recruited from those areas).
The major benefit of task-shifting is that it can improve patients’ access to treatment. Access has been defined across three dimensions including availability, affordability and acceptability. Availability relates to the relationship between the physical availability of drugs, human resources and the needed infrastructure relative to the needs of the community (the burden of disease). Affordability relates to the degree of fit between the economic costs incurred by patients in accessing treatment or the costs incurred by the health system in providing the service and society or the household’s ability to pay. Finally, Acceptability refers to the appropriateness of a service provided, as well as the expectations of both HRH and patients. The literature review provides in-depth information on the concept of Access.

In the literature review, key methodological issues relating to economic evaluations of HRH interventions as highlighted by other papers and experiences are discussed. Most of the studies available discuss the shifting of tasks from the doctor towards the nurse, while no studies was found that considers pharmacy HRH.

The urgency of addressing the lack of HRH in high disease burden countries, the contributing reasons as well as possible policy recommendations have been highlighted in the literature review. While task-shifting has been recommended as an effective option for limiting the impact of the scarcity of HRH, there are few published accounts of evaluations of task-shifting approaches (specifically in pharmaceutical care).
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Part C: Journal article manuscript

This manuscript has been prepared in accordance with the requirements set out for publishing in the open access journal, Human Resources for Health. The Instructions for authors are attached as Appendix 7. Given the international readership of the journal, all costs are presented in United States (US) Dollars. The manuscript below differs from the one to be submitted to the journal in format. For ease of reading and facilitating the flow of the dissertation, tables and figures are included in the text, 1.5 spacing is used, text is justified and page numbers follow on previous sections. A cover letter will be added prior to submission to the journal, which will include a motivation for publication, any comments on editorial policies (if applicable), a declaration of competing interest and the contact details of potential peer reviewers for the manuscript, in line with the requirements for publication set by the journal’s editorial board.
An economic evaluation of pharmaceutical care models for anti-retroviral therapy delivery in the Western Cape, South Africa

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Abstract

Background
A scarcity of human resources for health has been identified as one of the primary constraints to the scale-up of the provision of Anti-Retroviral Treatment (ART). In South Africa there is a particularly severe lack of pharmacists. The study aims to compare two task-shifting approaches to the dispensing of ART, Indirectly Supervised Pharmacists Assistants (ISPA) and Nurse-based pharmaceutical care models against the standard of care which involves a pharmacist dispensing ART.

Methods
A cross-sectional mixed methods study design was used. Patient exit interviews, time and motion studies, expert interviews and staff costs were used to conduct a costing from the societal perspective. Six facilities were sampled in the Western Cape province of South Africa, and 230 patient interviews conducted.

Results
The ISPA model was found to be the least costly task-shifting pharmaceutical model. However, patients preferred receiving medication from the nurse. This related to a fear of stigma and being identified by virtue of receiving ART at the pharmacy.

Conclusions
While these models are not mutually exclusive, and a variety of pharmaceutical care models will be necessary for scale up, it’s useful to consider the impact of implementing these models on the provider, patient access to treatment and difficulties in implementation.

Key words Task-shifting, pharmaceutical care models, skills mix, anti-retroviral therapy
Background

The scarcity of Human Resources for Health (HRH) has been identified as one of the primary constraints to the provision of Anti-retroviral Treatment (ART) to all who need it [1-3]. Pharmaceutical services experience similar workload pressures and staff shortages to those that plague other HRH. While the World Health Organisation’s (WHO) guidelines recommend a minimum country average of 1 pharmacist per 2,300 people, many Low- and Middle-Income Countries (LMIC) have averages far above that level. South Africa has 1 pharmacist per 4,332 people [4]. In conjunction with international migration, and a preference for urban over rural posts, South Africa also experiences a strong pull of pharmacists away from the public health service and into the private sector, with approximately 24% of registered pharmacists employed in the public sector which serves more than 80% of the population [5]. This has led to a gap in the systems and processes associated with the safe provision of chronic (and specifically ART) drug treatment which is crucial as adherence is becoming of greater concern [4].

The substitution of scarce health workers with purpose trained mid-level workers (termed task-shifting) is a logical strategy to address the scarcity of HRH [6]. The primary aim of task-shifting is to facilitate increased patient access to health services, through enabling a rapid scale-up of much needed health care interventions, and lower HRH training and salary costs [7]. In addition to the cost and efficiency benefits, mid-level workers have been found to be more likely to remain and work in rural areas and follow treatment guidelines. While quality of care has been cited as a concern by critics, studies suggest that the quality of care provided by mid-level workers is at least comparable to that of their more highly qualified colleagues [8-11]. A randomised non-inferiority trial conducted in primary health care clinics in SA, which compared doctor- versus nurse-monitored ART care found that nurse-monitored care was comparable to doctor monitored ART care and therefore supported task-shifting [11].

The shortage of pharmacists in the public health sector of South Africa (SA) has led to the use of pharmacists assistants and nurses to support the expansion of the ART
programme and to ensure that patients receive medication. For the purposes of this study we specifically considered activities relating to stock control, administrative tasks such as collecting medication from a central dispensing unit where applicable, the interpretation and evaluation of the prescription, the preparation and labelling of the prescribed medicine as well as counselling of the patient on the safe and effective use of the medication (adapted from the Pharmacy Act) as duties pertaining to pharmacy staff. In different provinces and districts of SA, different models of pharmaceutical care have been explored, but evidence of the costs and benefits of these models is lacking. In addition, there is little consensus in the literature on the appropriate methodology to use in comparing HRH staff mix in a health system, although Fulton et al. (2011) have suggested that cost-effectiveness analyses would be useful in ensuring that the correct comparisons are made [7]. Thus far, the focus of staff mix evaluations has been on the delegation of tasks from doctors to physician assistants [9, 12-18], from doctors to nurses [11, 19-24], and from nurses to community health workers [25-30], with a paucity of studies referring to pharmaceutical care staff [31]. This study therefore aims to critically evaluate the indirectly supervised pharmacists assistant (ISPA) and nurse-based pharmaceutical care models against the standard of care which involves a pharmacist dispensing ART, on the basis of cost, waiting and travel time and patient preference.

**Methods**

**Study design and setting**

A cross-sectional, mixed method study design was used. Data was collected using patient exit interviews, time and motion studies, and expert interviews. The study was conducted in a district in the Western Cape Province of South Africa with a combination of small-town and rural areas.

**Sampling**

Within the district, health care facilities were grouped based on the pharmaceutical care model they used, with two facilities sampled per group. For each group an equal
number of respondents were sampled, and the desired sample size per facility was proportional to the number of patients on treatment at the facility. Systematic sampling was used to select adult respondents on ART to interview while waiting for medication. The sample size required to detect statistically significant differences between the groups were calculated using a one-way ANOVA power analysis.

Data collection

A questionnaire was developed, piloted and interviewer-administered, to collect data regarding the direct and indirect costs incurred in accessing treatment as well as the acceptability of the service provided. The questionnaire was based on the questionnaire used in a multi-centre collaborative study, Researching Equity in Access to Health Care (REACH). Direct costs included the cost of transport, any facility fees incurred, the cost of employing someone to take over tasks (such as childminding), accommodation if sleeping over, and the cost of food, and telecommunication while waiting at the facility. Indirect costs were estimated by asking respondents about income lost from taking time to come to the facility, as well as the cost of time spent travelling to the facility. Patient waiting time was estimated by attaching a printed form to each patient’s folder, noting the time at which they entered the facility and pharmacy or nurse dispensers were asked to note the time at which respondents received their medicine. Collecting medication was considered to be the last contact point in the service chain. The difference in time was aggregated per facility and added to the average travel time to estimate the indirect cost per respondent per visit.

Health service expenditure and staffing data was obtained through facility observation and expert interviews with service managers. In order to determine the time spent by nurses on dispensing related activities, the researcher observed practice and asked nurses to estimate time spent dispensing if a total of 100% represents one work day. In the analysis, the observed time was used and the nurse-estimates on time were used in the sensitivity analysis. The cost of HRH was estimated from Department of Health (DOH) advertisements for posts and discussed with service managers to ensure accuracy.
The potential cost of upgrading a medicine room to a dispensary, as required by the Pharmacy Act for a pharmacists assistant to work in, was determined from a case study of a facility within the same district that the research was conducted, and sourced from the non-governmental organisation (NGO) which paid for the upgrade.

Respondent preferences were explored by asking whether they would prefer collecting medication from a local clinic or hospital, in addition to asking whether a nurse or pharmacist/pharmacists assistant dispensing was preferable. Respondents were also asked to explain their preferences.

Data analysis

Statistical analysis of data was conducted using STATA 10® [32]. For examining health care costs, Microsoft Excel® was used. All costs are presented in 2009/2010 prices and estimated costs were converted to US Dollars at the average exchange rate of the US Dollar to South African Rand for the 2010 financial year of $1 = R7.80 [33].

The cost analysis was conducted from a societal perspective, and includes health service and patient costs. Given that the nature of the study is comparative, a marginal approach to costing was adopted and costs that are common across pharmaceutical care models were excluded [34]. For example, given that the cost of ARV drugs per patient does not vary between models, these costs were excluded [35]. Costs covered by donor funding as well as the cost of staff employed by donors were included, in line with donor mandate that these functions are to be taken over by the Department of Health in the future [36]. A key characteristic of the societal perspective in economic evaluation is the inclusion of time – and opportunity cost and community preference, but its inclusion is debated in literature [37-39]. Drummond et al. (2005) argue that during short-term absences, losses in production could be compensated for by staff on their return to work or by colleagues [39]. However, in order to account for patients’ waiting and transport time, which differed significantly between facilities, and could be seen as a measure of efficiency of service provision, opportunity cost was calculated using the minimum hourly rate for a domestic worker.
in South Africa, $0.94 per hour [40]. The total cost at the patient level per visit was then calculated by adding the average direct and indirect costs, and the cost incurred by society was calculated by adding the health service costs and the total cost to the patient. Preliminary results of the analysis were discussed with service managers to confirm assumptions and validate results.

The open-ended or discussion questions of the exit interview responses were analysed using domain analysis during which topics were identified, assigned a code, and domains and sub-categories explored. A list of codes was generated and used to explore the common (and different) perspectives of the respondents [41].

*Ethics*

The research was approved by the University of Cape Town Health Science Faculty Human Research Ethics Committee as well as by the Western Cape Department of Health. The study was conducted in adherence to the Declaration of Helsinki of the 25th World Medical Assembly and all respondents participated on the basis of written informed consent [42].

*Results*

Only 19 patients refused to be interviewed. Of the 230 patient exit interviews conducted, 6 were excluded from the analysis as respondents were either not on ART yet or were collecting medication for someone else.
Respondent characteristics

The characteristics of respondents are summarized in Table 1.

Table 1
Profile of respondents

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number (n = 224)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>62</td>
<td>27.7%</td>
</tr>
<tr>
<td>Female</td>
<td>162</td>
<td>72.3%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean age ± standard deviation</td>
<td>36.2 ± 9.2 years</td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>unemployed</td>
<td>140</td>
<td>62.8%</td>
</tr>
<tr>
<td>employed full-time</td>
<td>41</td>
<td>18.4%</td>
</tr>
<tr>
<td>employed part time</td>
<td>42</td>
<td>18.8%</td>
</tr>
</tbody>
</table>

The unequal gender distribution of people who access ART in public health facilities has been well documented [43-45]. The age distribution of respondents, with a mean age of 36 years, is in line with the national profile of those on ART [46]. The unemployment rate of respondents is significantly higher at 62.8% than the overall Western Cape provincial estimate of 20.3% of the working age people [47]. This can partly be attributed to the organisation of the SA health system whereby those employed are more likely to use private health care paid for by medical insurance.

Facility characteristics

The study was conducted in a district with a combination of small-town and rural areas. Table 2 summarizes some of the key aspects of the service provided by the facilities sampled.
<table>
<thead>
<tr>
<th>Group A: full-time pharmacist</th>
<th>Group B: pharmacist assistant under indirect supervision</th>
<th>Group C: nurse-driven</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharm clinic 1</strong></td>
<td><strong>ISPA clinic 1</strong></td>
<td><strong>Nurse clinic 1</strong></td>
</tr>
<tr>
<td><strong>Pharm clinic 2</strong></td>
<td><strong>ISPA clinic 2</strong></td>
<td><strong>Nurse clinic 2</strong></td>
</tr>
<tr>
<td><strong>Level of service</strong></td>
<td>CDC</td>
<td>CDC</td>
</tr>
<tr>
<td><strong>Pharmaceutical care delivery system</strong></td>
<td>A full-time pharmacist and pharmacists assistant dispenses medication on request, and sends the patient-ready packs to nurses to dispense to patients.</td>
<td>Full-time pharmacist dispenses directly to patients, gives adherence and side-effects counselling.</td>
</tr>
<tr>
<td><strong>Staff assisting in pharmaceutical care related activities</strong></td>
<td>1 Pharm</td>
<td>0.66 Pharm</td>
</tr>
<tr>
<td></td>
<td>1 PA</td>
<td>0.66 PA</td>
</tr>
<tr>
<td><strong>Number of patients on ART</strong></td>
<td>1874</td>
<td>829</td>
</tr>
<tr>
<td><strong>Ratio of FTE staff to patients enrolled in care</strong></td>
<td>1 : 586</td>
<td>1 : 419</td>
</tr>
<tr>
<td><strong>Average number of months on ART (SD)</strong></td>
<td>38 (12-52) months</td>
<td>28 (15-49) months</td>
</tr>
</tbody>
</table>

* Community day centre (CDC): a facility which is not open 24 hours a day, 7 days a week, but at which a broad range of primary health care services are provided. It also offers accident and emergency services but not midwifery or surgery under general anaesthesia. Also have access to x-rays, full-time pharmacist and full-time dentist (vd Merwe, personal communication)

** SPharm = supervisory pharmacist who supervises a maximum of 5 Pharmacists assistants
Pharm clinic 1 represents a relatively well resourced health centre, and had one full-time Pharmacist (Pharm), and a Pharmacists Assistant (PA) exclusively dispensing ART, with two nurses using an estimated 60% of their working day in dispensing related activities. This included, taking prescriptions to the pharmacy to be filled, collecting medication and counselling patients on drug use. This arrangement came after patients expressed their discomfort at waiting at the general pharmacy window to collect their medication. Pharm clinic 1 had the greatest proportion of Full-Time Equivalent (FTE) dispensing staff at 3.2 FTE compared to Pharm clinic 2 with 1.98 FTE. However, the ratio of patients on ART to FTE staff at Pharm clinic 1 was at 586:1 far greater than 419:1 at Pharm clinic 2.

The Indirectly Supervised Pharmacists assistant (ISPA) facilities had similar absolute FTEs (1.2 versus 1.8) and ratios of patients on ART to FTE at 378:1 and 345:1 respectively. This does not explain the high average waiting time at ISPA clinic 1 of four hours and seventeen minutes (see Figure 1). This facility was struggling under the lack of a full-time ART physician, which slowed down the renewal of prescriptions and ultimately the dispensing process. ISPA clinic 2 also had significant assistance in the dispensing process by the nurse; this included the ordering of medication for patients, and ensuring that the prescription is in order for patients only coming for repeat medication.

The nurse-driven group had the fewest number of FTE dispensers as nurses often only providing a once or twice weekly outreach service to the site. Notably the ratio of patients on ART to FTE dispenser was considerably lower in the pharmacist model than in either of the other pharmaceutical care models at 300:1 and 308:1 respectively. This may be due to, increased efficiency of “learning through doing” as the pharmacist model facilities have been operational for longer, have the largest patient numbers and therefore achieve elements of economies of scale, and have more stable patients on treatment requiring less input time in terms of counselling, which could all contribute to less FTE staff members needed. Another factor may be that staff trained in dispensing (i.e. pharmacists and pharmacists assistants) could bring greater productive efficiency to the dispensing process and the service therefore takes longer to reach “saturation point” where new dispensing staff members are needed. It is difficult to determine how much each of these factors contributes to efficiency gains.
Staff costs

Given that the main difference between the pharmaceutical care models relates to the cost of HRH, it was the primary focus in the cost analysis from the provider perspective. The provider (or staff) cost per patient visit (summarised in Table 3) for the nurse-driven pharmaceutical care model was at $10.16 almost double that of the pharmacist- or ISPA- models ($6.55 and $5.74). This can be attributed largely to the difference in salaries between a pharmacists assistant and a nurse. In some of the facilities, the boundaries of the dispensing team were blurred, and observation and interviews with staff members was therefore used to identify time spent on dispensing-related activities. Where there was a pharmacist provided services but nurses were still involved in medicine related counselling, the time of nurses was also included (see Pharm clinic 1 and ISPA clinic 2 in Table 2). The time cost of a PA pre-packaging the medicine into patient-ready packets as well as the time spent by a Pharmacist on supervising the dispensing was accounted for in all non-pharmacist models (see ISPA and nurse clinics in Table 2). Specifically, the time spent by the PA and Supervisory Pharmacist (SPharm) preparing patient-ready packets for nurses to dispense was included in the cost analysis.

In the ART programme, nurses working on outreach services are generally more experienced and compensated at a higher salary level. It is therefore important to consider the trade-off involved in shifting dispensing related tasks from pharmacists to nurses given the scarcity of nurses. One could argue that the nurse’s time may better spent performing clinical duties for which s/he is trained.

As would be expected, the direct costs incurred by patients accessing treatment, reflected the level of decentralization of the service. Patients paid the most at the pharmacist-led model facilities, where they spent almost four times more on transport than at the more decentralized ISPA- and nurse-driven facilities.
Table 3
Average cost per patient visit (n=244)

<table>
<thead>
<tr>
<th></th>
<th>Group A: full-time pharmacist</th>
<th>Group B: pharmacist assistant</th>
<th>Group C: nurse-driven</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharm clinic 1</td>
<td>Pharm clinic 2</td>
<td>ISPA clinic 1</td>
</tr>
<tr>
<td><strong>Average provider cost</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff costs</td>
<td>$6.08</td>
<td>$7.01</td>
<td>$5.09</td>
</tr>
<tr>
<td><strong>Total cost to provider per patient visit</strong></td>
<td>$6.08</td>
<td>$7.01</td>
<td>$5.09</td>
</tr>
<tr>
<td><strong>Average patient costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct costs</td>
<td>$6.20</td>
<td>$3.35</td>
<td>$1.59</td>
</tr>
<tr>
<td>Indirect costs</td>
<td>$5.42</td>
<td>$5.09</td>
<td>$7.47</td>
</tr>
<tr>
<td><strong>Total cost to patient per visit</strong></td>
<td>$11.62</td>
<td>$8.45</td>
<td>$9.06</td>
</tr>
<tr>
<td><strong>Total societal costs for ART care per visit</strong></td>
<td>$17.70</td>
<td>$15.46</td>
<td>$14.16</td>
</tr>
<tr>
<td>Percentage of respondents who incurred direct costs, and found it unaffordable (n)</td>
<td>90% (36)</td>
<td>70% (14)</td>
<td>77.78% (21)</td>
</tr>
</tbody>
</table>

*The average opportunity costs to those unemployed were estimated from the minimum daily rate for a domestic worker in South Africa (SA Department of Labour, 2010)*
The cost of transport has been found to be a significant barrier to patient access to ART in other studies [48, 49]. Similarly, when asked about the affordability of direct costs incurred in attending the clinic, 90% of respondents at pharmacist-led, and 67% at nurse-driven pharmaceutical care model facilities indicated that the costs incurred are unaffordable. This is certainly not surprising, given the high level of unemployment among respondents.

The average travel time is slightly less than reported by other studies. Rosen et al. (2007) documented travel times (round trip) of between 83 and 158 minutes [50]. In this study, travel time was between 45 and 127 minutes per round trip (shown in Figure 1). However, it is interesting to note that respondents in Rosen’s study were unlikely to walk to the facility while we found that up to 97% of patients from the more decentralised sites walked to the facility. This would also impact on the transport (direct) costs reported.

**Figure 1**
Respondent travel- and waiting time

![Graph showing respondent travel and waiting time](image)

The costs per patient visit is summarised by pharmaceutical care model in Table 4. The annual cost per patient was calculated by multiplying the cost to provider and patient per visit with the average number of visits per year reported in the patient exit interviews. There was less of a difference between the ISPA and nurse pharmaceutical care models; this is partly because the high cost to the provider in the nurse model is offset by the relatively low cost to the patient due to the decentralised nature of the service.
Table 4
Cost of ART service use, compared between different levels of service

<table>
<thead>
<tr>
<th>Level of service</th>
<th>Average number of patient visits per year</th>
<th>Cost to provider</th>
<th>Cost to patient</th>
<th>Societal cost</th>
<th>Average annual cost per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-time pharmacist</td>
<td>7.78</td>
<td>$6.55</td>
<td>$10.04</td>
<td>$16.58</td>
<td>$128.99</td>
</tr>
<tr>
<td>ISPA</td>
<td>10.74</td>
<td>$5.74</td>
<td>$7.44</td>
<td>$13.18</td>
<td>$141.55</td>
</tr>
<tr>
<td>Nurse</td>
<td>9.78</td>
<td>$10.16</td>
<td>$6.29</td>
<td>$16.45</td>
<td>$160.89</td>
</tr>
</tbody>
</table>

While the annual cost per patient for the pharmacist model is lower than for the ISPA model, the average cost per visit is higher. This relates to the difference in the average number of patient visits per year. Patients who are stable and adherent on treatment are given enough medication for two months and would therefore, on average, only visit the facility six times per annum. Given that the pharmacist model at more centralised facilities, has been available for longer, their patients have been on treatment longer (see Table 2) and are therefore more likely to visit the clinic less often. This decreases the burden of care on the clinic and more patients can be seen using similar resources, while minimising the cost to the patient.

The cost of upgrading a medicine room to a dispensary

While the ISPA model is the cost saving option to the provider, there is an infrastructure upgrade required when moving from the nurse- to the ISPA model. For the nurse model there is no need for a pharmacy or dispensary as medication is prepared for the patient at a central dispensary and merely handed out by the nurse in patient ready packs. However, the ISPA model requires a dispensary to be registered with the South African Pharmacy Council (SAPC). A case study from the district sampled was selected and expenditure costs obtained to provide an idea of the approximate costs of an upgrade (Table 5).

A total cost of $11 479.88 was spent in the upgrading of the facility. In the case study, the cost for the upgrade was paid for by a non-governmental organisation and the Department of Health is responsible for maintenance. The costs for the upgrade
included enlarging of the medicine room, the installation of concrete beams in the room to improve security, installation of a security gate, shelving and the purchasing of a vaccine refrigerator as well as a backup household fridge.

Table 5
The cost of upgrading a medicine room to a dispensary

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost (Rand)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The modification and enlarging of medicine room to dispensary</td>
<td>$2 402.18</td>
</tr>
<tr>
<td>Security</td>
<td>$1 089.74</td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
</tr>
<tr>
<td>Shelving</td>
<td>$1 137.77</td>
</tr>
<tr>
<td>Signage</td>
<td>$10.90</td>
</tr>
<tr>
<td>Electronic &amp; electrical</td>
<td>$5 463.72</td>
</tr>
<tr>
<td>Reference sources</td>
<td>$166.35</td>
</tr>
<tr>
<td>Dispensing</td>
<td>$807.25</td>
</tr>
<tr>
<td>General</td>
<td>$401.97</td>
</tr>
<tr>
<td>Total</td>
<td>$11 479.88</td>
</tr>
</tbody>
</table>

Data sources: Lizette Monteith, Keth'Impilo; Lindsay Wilson, PGWC HIV directorate and Margaret von Zeil, City of Cape Town

Sensitivity analysis

A sensitivity analysis was conducted to test what the impact on the results would be if one were to vary some of the assumptions. Key assumptions that could detract from the robustness of the results include variations in the time spent by nurses on dispensing-related activities, as well as the number of clinic visits per year. Both of these assumptions are likely to differ depending on the facility and particular characteristics of the service provided. In the sensitivity analysis, the baseline represents the current practice at the facilities, where the amount of time nurses spend on dispensing related activities was observed and averages about 60% of their time. A "best case" scenario was considered, where it was assumed that nurses were not involved in dispensing activities at all in the pharmacist and ISPA models and at the observed average of 60% of their time in the nurse model. This scenario also assumed that visits occurred every two months. The ratio of the cost for the ISPA to nurse models was similar for the baseline scenario (see Table 6). A “worst case” scenario was also set up, which assumed that nurses spent 90% of their time on dispensing-
related activities, which was based on the maximum time estimated by nurses interviewed. This scenario also assumed that patients attended the clinic monthly. For scenario 2, the original results held and the ISPA model was still less costly than the nurse model.”

### Table 6
Sensitivity analyses of provider costs

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Assumptions</th>
<th>Number of patient visits per year</th>
<th>Average provider cost/visit</th>
<th>Annual provider cost per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Full-time pharmacist</td>
<td>Based on exit interview</td>
<td>$6.55</td>
<td>$50.95</td>
</tr>
<tr>
<td></td>
<td>ISPA</td>
<td></td>
<td>$5.74</td>
<td>$61.63</td>
</tr>
<tr>
<td></td>
<td>Nurse-driven</td>
<td></td>
<td>$10.16</td>
<td>$99.38</td>
</tr>
<tr>
<td>1</td>
<td>Full-time pharmacist</td>
<td>One pharmacist and one pharmacists assistant</td>
<td>$4.61</td>
<td>$27.64</td>
</tr>
<tr>
<td></td>
<td>ISPA</td>
<td>One supervisory pharmacist and one pharmacists assistant</td>
<td>$4.46</td>
<td>$26.77</td>
</tr>
<tr>
<td></td>
<td>Nurse-driven</td>
<td>One supervisory pharmacist and one nurse</td>
<td>$11.11</td>
<td>$66.65</td>
</tr>
<tr>
<td>2</td>
<td>Full-time pharmacist</td>
<td>One pharmacist, one pharmacists assistant and maximum nurse time estimate</td>
<td>$8.81</td>
<td>$105.72</td>
</tr>
<tr>
<td></td>
<td>ISPA</td>
<td>Supervisory pharmacist, pharmacists assistants and maximum nurse time estimate</td>
<td>$8.92</td>
<td>$107.08</td>
</tr>
<tr>
<td></td>
<td>Nurse-driven</td>
<td>Supervisory pharmacist, pharmacists assistants and maximum nurse time estimate</td>
<td>$18.80</td>
<td>$225.62</td>
</tr>
</tbody>
</table>

**Patient preferences**

The results of the cost analysis suggest that while both of the decentralized approaches, the ISPA- and nurse-driven pharmaceutical care models, significantly decreases direct and indirect costs to patients when accessing treatment, the ISPA model once implemented would also be the least costly to the provider per patient visit (see Table 4). However, only considering the costs does not give us the full picture of the benefits or limitations of the specific models of care.
During the patient exit interviews, respondents were also questioned about whether they would prefer to receive their medication from the nurse or from the pharmacy. The response was most surprising from facilities where the ISPA model had already been implemented. At these facilities, the ISPA model had provided an opportunity for the integration of HIV and other chronic diseases management with all patients receiving medication from the same pharmacy in the facility and waiting in the same waiting room. However, the majority of respondents from these facilities indicated that they would prefer to receive their medication directly from the nurses. Here are some of their responses:

“I have to walk past people to get the pharmacy and they might recognise me. Also for the time saved” (Respondent, Pharm clinic 2)

“The people ask us so many questions that are not pleasant. I don’t find it easy to collect them [her medication] at the pharmacy ‘coz it is like automatic disclosure of my status to everyone” (Respondent, ISPA clinic 1)

Many of the responses reflected a spatial component to the stigma of HIV, related to being identified when seen by other community members collecting medication (visually known as ART) from the pharmacy. At one of the ISPA model facilities, the identification of people who are HIV positive was facilitated by the use of a different coloured folder for those who are not on ART.

The fear of stigma and the value of anonymity also played a central role in patients’ choice of health facility. As some explained:

“I feel safer here; the people do not know me here. [It] would’ve been cheaper to go to [facility name] but [I] still rather come here.” (Respondent, Pharm clinic 1)

“There are too many people in [facility name] and a lot of people there talk badly about HIV people.” (Respondent, Pharm clinic 1)
“My child gets ARV’s from [facility name] but I don’t like it there. There are a lot of people there. If you go that side everyone knows you are positive. Here [current facility] we are not separate.” (Respondent, Nurse clinic 1)

While respondents preferred receiving their medication directly from the nurse as opposed to the pharmacy as they felt that their anonymity was protected, there was a trade-off. A challenge of the nurse-driven pharmaceutical care model revolved around the logistics of ordering medication for each patient based on their latest prescription in advance of their appointment, and that patients sometimes arrived out of appointment dates, requesting medication. In an attempt to ensure that patient care continues, nurses would then open the pre-packed medication and dispense medication to patients from that source. This is how respondents described it:

“They give you “bietjie bietjie” [little, little] tablets with other people’s names on. It confuses us.” (Respondent, Nurse clinic 2)

“Last month I came and they gave me treatment for another person. Even now they gave me treatment for a week and it’s not in my name.” (Respondent, Nurse clinic 2)

“I don’t like the fact that I would come on my date and leave the clinic without getting my pills, I have to take time away from work and my boss is not happy with it.” (Respondent, Nurse clinic 2)

At one of the facilities, there were also concerns that medication ordered but not collected, were stored in a drawer. This left the stock open to be stolen, and is not stored in the correct conditions and could compromise patient safety.

**Discussion**

Each of the pharmaceutical care models has a unique set of benefits and challenges, as summarised in Table 7. Health services are provided in a team, and an inappropriate mix of staff can be inefficient and limit patient’s ability to get the treatment that they need. The full-time pharmacist model is presented as the standard of care that would be the ideal at every facility and that has been found to promote rational prescribing
<table>
<thead>
<tr>
<th>Table 7</th>
<th>Comparison of Pharmaceutical Care models</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmaceutical care provider</strong></td>
<td>Full-time Pharmacist available</td>
</tr>
<tr>
<td><strong>Overview</strong></td>
<td>Full-time pharmacist dispensing medication from a prescription written by doctor, directly to the patient.</td>
</tr>
<tr>
<td><strong>Requirements</strong></td>
<td>Service is available at larger facilities, for example at a community health centre. Dispensing is conducted from a pharmacy, operated under the personal supervision of a responsible pharmacist, licensed by the DOH and recorded with SAPC.</td>
</tr>
<tr>
<td><strong>Benefits</strong></td>
<td>Highly skilled and trained health professional, experienced in working under pressure and in a team. Promote rational prescribing and is therefore cost-saving</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Problems</strong></td>
<td>Scarce</td>
</tr>
<tr>
<td></td>
<td>Would limit scale-up of ART service</td>
</tr>
<tr>
<td></td>
<td>Expensive training</td>
</tr>
<tr>
<td></td>
<td>Higher salary level</td>
</tr>
</tbody>
</table>
and therefore been cost saving [52]. However, with the shortage of pharmacists, and an expensive 4 year training program, this approach would limit the scale-up of ART service provision. The benefits of the ISPA model are that pharmacists assistants undergo only a 2 year in-service training course supervised by a pharmacist. The PA dispenses directly to the patient and is responsible for stock control. In terms of supervision, one pharmacist can supervise up to five PAs simultaneously. Some concerns are that a PA might not be getting sufficient training, they have limited pharmacology training and do not have the authority to promote rational prescribing. Osman (2005) makes the point that PAs also lack a career path.

The nurse model is very useful in that it provides an option for the rapid scale-up of ART services, although it also reaches saturation point sooner due to the difficulties of ordering medication per patient appointment. Medication is not dispensed directly to patients but only from patient-ready packs with the help of standard operating procedures. While there is a perception that waiting time will be reduced when nurses dispense medication, it is more likely that consultation times will be longer and waiting times will increase.

Where there was a lack of doctors to renew prescriptions, this also resulted in increased waiting times and more time spent by nurses being involved in the dispensing process. While nurse prescribing and dispensing was not a model evaluated in this study, it has been proposed and might conceivably decrease waiting times. However, it does raise concerns when the prescriber and dispenser is the same person, as there is a lack of quality control.

The generalisability of this single district evaluation could be seen as a limiting factor given that the functioning of a facility is dependent on many facility-specific characteristics such as the level of skilled staff, skill mix, the infrastructure available and staff motivation [53]. More specifically, the role(s) of staff members in pharmaceutical care could be considered as endogenous to the broader arrangement of HRH within these facilities and may partly account for variations within these models. However, the study does provide a framework within which to evaluate other facilities and some experiences will be common to many facilities. An additional limiting factor to the study is the lack of the facility staff members’ opinions on issues
such as the importance of the different colour folders and influence on patients access to treatment. Further research to explore health professionals’ opinions is recommended.

Conclusions

In reality, these pharmaceutical care models are not mutually exclusive options and a variety of systems will no doubt be required to achieve scale-up. While the ISPA model is the least costly to the provider and to the patient, the concerns of patients in terms of confidentiality and the avoidance of stigma needs to be addressed as it could negatively impact on patients’ health seeking behaviour. In contrast, the nurse-driven pharmaceutical care model is useful in rapidly scaling-up pharmaceutical care and indeed rolling-out ART service provision to new sites as capital outlay and the recruitment of dispensing personnel is not needed. It does however place a burden on nurses, uses more costly staff and reports suggest that pharmaceutical care may be compromised with patients needing to return to the health facility out of scheduled appointments to collect medication due to them. Both of these pharmaceutical care models have a place in service provision, but it is imperative to address quality of care and confidentiality concerns from patients. This could be achieved by removing ART service identifiers from patient folders, by putting up screens next to the pharmacy dispensing window to limit the view from the waiting area, and dispensing all medication (not just ARTs) into brown paper bags.
List of abbreviations used

HRH        Human Resources for Health
ART        Anti-retroviral Therapy
WHO        World Health Organisation
LMIC       Low and Middle-Income Countries
SA         South Africa
ISPA       Indirectly Supervised Pharmacists Assistants
DOH        South African national Department Of Health
NGO        Non-Governmental Organisation
PA         Pharmacists Assistant
Pharm      Pharmacist
SPharm     Supervisory Pharmacist
FTE        Full-time Equivalent
SAPC       South African Pharmacy Council
PGWC       Provincial Government of the Western Cape
HIV        Human Immunodeficiency Virus
NRF        National Research Fund

Competing interests

The authors declare that they have no conflicts of interest.

Acknowledgements

Financial support for this study was received from the National Research Foundation (NRF). The NRF had no further role in study design; in data collection, analysis and interpretation of data; in the writing of the report or in the decision to submit a paper for publication. Furthermore, I would like to thank Sibongile Bovana and Vanessa Daries for their assistance and advice on fieldwork. I also acknowledge the assistance of Dr Nelis Grobbelaar from Anova Health Cape Winelands, and Dr Dirk Hagemeister at TC Newman Hospital in facilitating access to respondents.
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Part D: Policy brief

The impact of pharmaceutical care models on access to antiretroviral therapy

Summary

Two alternative pharmaceutical care models, dispensing by a nurse and by a pharmacists assistant were compared against the standard practice of pharmacist dispensing. The models were evaluated on the basis of cost from the health service perspective as well as patients’ access to antiretroviral treatment (ART). The task-shifting models were shown to improve patients’ geographical and financial access to treatment through lower travel costs. The results further suggested that while the pharmacists assistant model was less costly than the nurse-driven model and would strengthen and support a more integrated primary health care service, patients preferred receiving their medication directly from the nurse. The reasons related to trust and the fear of stigma. Measures to improve patient confidentiality when receiving medication from the pharmacy, such as removing ART service identifiers from patient folders, and dispensing all medication in brown paper bags, is likely to positively impact on patients’ access to ART.

Introduction

This policy brief discusses results from a study conducted in the Western Cape, evaluating different models for the dispensing of antiretroviral treatment (ART) and their impact on patients’ access to healthcare. The burden of need for ART and the resultant need for the decentralisation and integration of ART services into the primary health care system is well documented. This will require a scale-up of pharmacy services in terms of supply systems, infrastructure and staff to ensure a safe and efficient pharmaceutical service within an environment of scarce Human Resources for Health (HRH).

Models of pharmaceutical care

Task-shifting has been shown to be an effective and safe option for addressing the need created by insufficient health professional staff. It refers to the delegation of
tasks from highly skilled workers to those with either less training or task specific training. In South Africa, the shortage of pharmacists in the public sector has led to the use of Pharmacists Assistants (PA) and nurses to support the expansion of the ART programme. Different models of pharmaceutical care have been used, and include variations of:

- Pharmacist model (the standard of care) where medication is dispensed by a pharmacist directly to patients.
- Indirectly supervised pharmacists assistant (ISPA) model where a PA working under the indirect supervision of an offsite pharmacist, dispenses medication directly to patients and is responsible for stock control.
- Nurse model where prescriptions are sent to a nearby hospital pharmacy, where they are prepared before the patient’s expected appointment date and delivered to the primary health care clinic in patient-ready packs. The nurse then provides the patient with medication, reviews the patient’s progress, and returns uncollected medication to the pharmacy.

How were the different pharmaceutical care models evaluated?

The study was conducted in a peri-urban district in the Western Cape of South Africa. Within the district, six health facilities were sampled based on the model of pharmaceutical care used. A total of 224 patient exit interviews were conducted, patients’ waiting times were documented and staff time spent on pharmacy related tasks were observed. In order to get a complete picture of which model is most appropriate, the cost implications for the health system was calculated and the impact of the service offered on patients’ access to health care was assessed.

Is it an efficient use of nurses’ time to dispense medication?

The aim of economic evaluations is to highlight the differences in cost between health care interventions, and to compare it with a gain or loss in outputs. The primary cost differences between the pharmaceutical care models relates to the staff providing the service. Table 1 summarises the staff cost per patient treated, by model.
Table 1
Staff cost of ART service use, compared between different service models

<table>
<thead>
<tr>
<th>Level of service</th>
<th>Average number of visits per patient per year</th>
<th>Average staff cost to provider per visit</th>
<th>Average annual staff cost per patient treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-time pharmacist</td>
<td>7.78</td>
<td>R 50.78</td>
<td>R 395.07</td>
</tr>
<tr>
<td>Pharm assistant under indirect supervision</td>
<td>10.74</td>
<td>R 44.76</td>
<td>R 480.72</td>
</tr>
<tr>
<td>Nurse-driven dispensing</td>
<td>9.78</td>
<td>R 79.26</td>
<td>R 775.16</td>
</tr>
</tbody>
</table>

While from the results in Table 1 it seems as if the least expensive model would be to have a pharmacist driven service. This is partly due to economies of scale, whereby in the pharmacist model more patients can be helped by a pharmacist working with pharmacists assistants. As well as due to fewer visits per annum in the pharmacist model because the service has been running for longer, patients are more stable on treatment and are therefore receiving their medication every two months as opposed to monthly. The scale-up of a pharmacist driven service is not necessarily an option given the scarcity of pharmacists and the impact of a centralised pharmacist driven pharmaceutical care model on patients’ access to treatment. The results further indicate that between the task-shifting models, the ISPA model is less costly to the service provider per patient visit. In fact, the costs per visit for the nurse model is almost double that of the ISPA model. This relates to the value of nurses’ time, and it is important to consider whether it is an efficient use of nurses’ time to dispense medication.

What is the cost of upgrading a medicine room?

An additional cost that comes with the implementation of the ISPA model is that it requires a dispensary registered with the South African Pharmacy Council. Smaller primary health care clinics often only have a medicine room designed for the bulk storage of patient-ready packs for the refilling of trolleys or a cupboard in treatment rooms. The medicine room is often not big enough to support the dispensing of products directly to patients. An estimate of the cost of the infrastructure upgrade is given in Table 2.
Table 2

The cost of upgrading a medicine room to a dispensary

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost (Rand)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The modification and enlargement of medicine room to dispensary</td>
<td>R 18 737.00</td>
</tr>
<tr>
<td>Security</td>
<td>R 8 500.00</td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
</tr>
<tr>
<td>Shelving</td>
<td>R 8 874.64</td>
</tr>
<tr>
<td>Signage</td>
<td>R 85.00</td>
</tr>
<tr>
<td>Electronic &amp; electrical</td>
<td>R 42 617.00</td>
</tr>
<tr>
<td>Reference sources</td>
<td>R 1 297.50</td>
</tr>
<tr>
<td>Dispensing equipment</td>
<td>R 6 296.57</td>
</tr>
<tr>
<td>General</td>
<td>R 3 135.34</td>
</tr>
<tr>
<td>Total</td>
<td>R 89 543.05</td>
</tr>
</tbody>
</table>

Data sources: Lizette Monteith, Keth’Impilo; Lindsay Wilson, PGWC HIV directorate and Margaret von Zeil, City of Cape Town

The costs were sourced from expenditure documents related to a facility in the district studied which had recently invested in this infrastructure. The upgrade of the medicine room does not only benefit the ART service but it enables the dispensing of medication for other chronic and acute conditions treated in the health facility, which supports a more integrated and holistic approach to health services.

**How do decentralised care models affect patient access to care?**

**Availability**

More patients lived within walking distance of the ISPA (95%) and nurse model (87%) facilities than those attending pharmacist model facilities (28%), and patients attending the pharmacist model facilities spent more time travelling.

In spite of the greater geographical availability of the service, patients attending the ISPA and nurse model facilities did not always have access to ART. Drug stock-outs were experienced at two facilities (one a nurse and the other an ISPA model facility).
- At the ISPA facility, 30% of respondents indicated that they did not always receive medication and had to return another day to collect medication due to them. This is compared to 42% of respondents at the nurse clinic.

- The reasons for drug stock-outs are related to difficulties in stock management. At the nurse clinic, patients did not always arrive on their appointment dates, or their prescriptions changed and in order to facilitate care, the nurse would give some medicine prepared for another patient. This resulted in a cycle of insufficient drug supply and was concerning for patients:

  “They give you ‘bietjie bietjie’ [little little] tablets with other people’s names on it. It confuses us.” (Respondent, Nurse clinic 2)

  “I don’t like the fact that I would come on my date and leave the clinic without getting my pills, I have to take time away from work and my boss is not happy with it.”
  (Respondent, Nurse clinic 2)

- At the ISPA facility, drug stock-outs related to the impact of insufficient doctors at the facility to renew prescriptions and resulted in the PA being unable to dispense medication for patients.

**Affordability**

Multiple visits to the clinic due to drug unavailability have cost implications and could impact on sustained adherence to ART. Patients incurred significant costs in attending ART services amounting to an average of R37.18 per visit by patients attending a pharmacist clinic, compared to R12.60 per visits at an ISPA clinic and R16.03 at a nurse-based clinic. Respondents who were employed said that they forfeited an average of approximately R100 per day in missed wages.

**Acceptability**

In spite of the challenges regarding stock management in the nurse model, the majority of respondents indicated that they would prefer receiving medication from the nurse as opposed to at the pharmacy. While there was an element of hope that nurse dispensing will translate into shorter waiting times, the most common themes
for preferring nurse-based dispensing related to trust in confidentiality being maintained. Respondents preferred nurse dispensing in an effort to avoid stigma.

“The people ask us so many questions that are not pleasant. I don’t find it easy to collect them at the pharmacy ‘cause it is like automatic disclosure of my status to everyone.” (Respondent, ISPA clinic 1)

“At the pharmacy there is also a person from my neighbourhood and they’ll ask and wonder why I collect this medication.” (Respondent, Pharm clinic 1)

In addition, respondents at one of the ISPA facilities explained that different coloured folders are used for patients in the ART program than what is used for the patients accessing other services at that facility. The respondents likened having to wait at the pharmacy with these folders to “automatic disclosure”.

“The queue is very long at the chemist and with us ARV clients our folders are different from other people so they can easily see that we are HIV positive”

(Respondent, ISPA clinic 1)

“People say things about us because we have different folders, so if they can change the folder maybe it would be fine to take treatment at the pharmacy”

(Respondent, ISPA clinic 1)

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**Key issues**

- The task-shifting pharmaceutical care model facilities facilitated geographical access to care with more patients being able to walk to the clinic.
- Given the scarcity of pharmacists, the ISPA model is a less costly option than the nurse-driven model in terms of staff costs.
- Both task-shifting models experienced challenges in drug stock management.
- Patients prefer receiving their medication from nurses, in order to avoid the stigma of being identified as HIV positive.
Policy recommendations

The study highlighted that while the ISPA pharmaceutical care model is cost-saving when compared to the nurse model, more efficient in terms of the use of nurses’ time, and supports the integration of ART services into primary health care, it is important to address patients’ concerns around confidentiality and stigma.

Possible approaches would be to:

- Remove any ART service identifiers from patient folders by ensuring that all patients accessing the facility have the same colour and type of folder,
- Improve patient confidentiality at the pharmacy window by putting up screens next to the window, limiting the view from the waiting area, and dispensing all medication (not just ARTs) into brown paper bags.

The research presented in this paper was conducted by Nicola Foster and funded by the National Research Fund (NRF) South African Research Chair: Health and Wealth program.
Part E: Appendices
You have been asked to participate in a research study that is being conducted as part of a Masters degree in Public Health from the University of Cape Town (UCT). Before you agree to participate, I would like you to understand why this research is being done, and what I will be asking of you as a participant.

Why is this research being done?

In South Africa we have a shortage of doctors, nurses and pharmacists. This shortage affects our ability to provide good quality health care for everyone within his or her local community. We are looking for ways in which to make the health service more efficient by perhaps training more people to do jobs that would originally have been done by pharmacists or nurses so that the pharmacists/ nurses would be able to do the work that they are especially good at. In this study we are trying to find out what the costs and the benefits would be of using pharmacist assistants to provide people with their ARVs as opposed to the nurse, doctor or pharmacist providing the medicine at the moment.

What information will be collected and how?

In order to find out how much time you spend waiting at the clinic and where, you will be given a piece of paper on which the health workers will record when you arrive at a certain service and when you leave. The paper is to be given back to me before your interview.

After you have been helped, we would like to ask you some questions on how you get to the clinic, possible costs involved for you in being at the clinic as well as questions regarding how often you take your medicine. These questions will be asked in the form of an interview in a private room. The interviewer will record your answers, but your name will not be used in the reporting of the results.

The questionnaire is three pages long and should take no more than 15 minutes to complete.

What are the benefits of participation?

You will receive no personal benefits to participation in the study. However, this research could in the future benefit your community by changing the way in which health services are delivered.

What are the harms/ risks to you in participating?

There are no foreseen physical harms to your participation in the study, but to protect your anonymity while participating in this study the interview will be conducted in a private room. Please note that non-participation in the study will in no way have an effect on your current or future health care in this clinic, or in any other clinic.
The Consent Form will further explain your rights and responsibilities while participating in the research. The fieldworker will read and explain the consent form to you and if you are willing to participate, we will ask to sign that you agree to participate. You are welcome to take this information form home with you, so that if you later have any questions regarding this research you are welcome to contact me.

Contacts

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e-mail: Nicola.Foster@uct.ac.za

Professor Diane McIntyre
Supervisor (UCT)
Tel: 021 406 6579
e-mail: Diane.McIntyre@uct.ac.za

Questions or concerns for the UCT research ethics committee can be referred to:
Lameez Emjedi
Tel: 021 406 6492
ECONOMIC EVALUATION OF TASK SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL (ARV) TREATMENT

PATIENT EXIT INTERVIEW CONSENT FORM

CONSENT TO PARTICIPATE IN THE INTERVIEW

Facility: [enter name of facility] ______________________________________________

I HAVE BEEN INFORMED ABOUT THE PROJECT ECONOMIC EVALUATION OF TASK SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL (ARV) TREATMENT, AND I UNDERSTAND THAT IT IS UP TO ME WHETHER OR NOT TO BE INTERVIEWED.

I understand that there will be no consequences of any kind through my participation (or non-participation) in this study; in particular, there will be no impact on the care that I receive in this hospital/ clinic or any other hospital/ clinic.

I understand that I can ask the person interviewing me to stop the interview at any time.

I understand that the information that I give will be treated in the strictest confidence and that my name will not be used when the interviews are analysed.

Yes, I give my permission for the interview.

__________________________________________  ________________
Interviewee’s name (please print)  Date

__________________________________________  ________________
Interviewee’s signature  Date

Study sticker  Place sticker here

__________________________________________
Interviewer’s name (please print)

__________________________________________  ________________
Interviewer’s signature  Date
## ECONOMIC EVALUATION OF TASK SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL (ARV) TREATMENT

### PATIENT EXIT INTERVIEW QUESTIONNAIRE

<table>
<thead>
<tr>
<th>0.1</th>
<th>Date of interview</th>
<th>dd</th>
<th>mm</th>
<th>yyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>Interviewer name</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.3</td>
<td>Study sticker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Place sticker here</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.4</td>
<td>Start time of interview</td>
<td>hour</td>
<td>min</td>
<td></td>
</tr>
<tr>
<td>0.5</td>
<td>Site (name of facility)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Instructions for interviewers:

Questions or parts of questions that do not always have to be read out and instructions are in highlighted text.

Unless specifically asked to do so, options do not need to be read out but should rather be used as a guide and as prompts to illicit a response from respondents.

Skips indicating which questions can be left out are represented by arrows.

### SECTION ONE: DEMOGRAPHIC AND BACKGROUND INFORMATION

<table>
<thead>
<tr>
<th>1.1</th>
<th>Sex</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2</th>
<th>What was your age at your last birthday?</th>
<th>Year born</th>
<th>Years</th>
</tr>
</thead>
</table>

### SECTION TWO: UTILISATION AND ADHERENCE

<table>
<thead>
<tr>
<th>2.1</th>
<th>When did you FIRST begin receiving anti-retroviral (ARV) treatment?</th>
<th>Mm</th>
<th>Yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2.2</th>
<th>How often do you collect your ARV treatment here at the clinic?</th>
<th>Monthly or less (weekly/bi-weekly)</th>
<th>Two-monthly</th>
<th>More than two-monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.3</th>
<th>Besides ARVs, are you able to get the other health services you need in this facility?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.4</th>
<th>If NO, what other services do you have to get elsewhere?</th>
</tr>
</thead>
</table>

If YES, Go to 2.5

IF YES, Go to 2.5
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>Did you miss taking any of your ARV tablets YESTERDAY?</td>
<td>Yes 1 No 0</td>
</tr>
<tr>
<td>2.6</td>
<td>Did you miss taking any ARV tablets the day before YESTERDAY?</td>
<td>Yes 1 No 0</td>
</tr>
<tr>
<td>2.7</td>
<td>Did you miss taking any ARV tablets 3 DAYS ago?</td>
<td>Yes 1 No 0</td>
</tr>
<tr>
<td>2.8</td>
<td>Apart from the last three days, have you ever missed taking any ARV tablets?</td>
<td>Yes 1 No 0</td>
</tr>
<tr>
<td>2.9</td>
<td>Have you missed any VISITS to the ARV clinic in the last 6 months?</td>
<td>Yes 1 No 0</td>
</tr>
<tr>
<td>2.10</td>
<td>If YES, how many VISITS did you miss?</td>
<td>No. of visits</td>
</tr>
<tr>
<td></td>
<td>What was the reason(s) for missing the visits?</td>
<td>Yes No</td>
</tr>
<tr>
<td></td>
<td>Do not read the list aloud; probe respondent to give up to three reasons.</td>
<td>Circle up to three yes options and circle all others no.</td>
</tr>
<tr>
<td></td>
<td>Lack of money</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>Lack of time</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>I felt better</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>I could not take time off from work</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>No transport</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>Too ill to travel</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>Other responsibilities</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>The treatment does not make me feel better</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>The queues in the facility are too long</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>The staff are rude or uncaring</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>I have had bad experiences with staff before</td>
<td>1 0</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>If other, please specify</td>
<td></td>
</tr>
</tbody>
</table>

SECTION THREE: AFFORDABILITY

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>In coming to receive treatment today, how much did you pay for:</td>
<td>Rand</td>
</tr>
<tr>
<td></td>
<td>Read out each item, if no money spent, code as “0” for each item.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transport (one way)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinic/ hospital fees</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medicines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Someone to take over your tasks while you are here, including childcare</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Accommodation if you need to stay the night nearby</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Food during visit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phoning or sms’ing</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>If other, please specify</td>
<td>If other, please specify</td>
<td></td>
</tr>
</tbody>
</table>

### 3.2 Did you find it easy or difficult to incur these expenses? (refer to expenses in 3.1)
- **Easy**: 1
- **Difficult**: 2
- **Neither easy or difficult**: 98
- **Don’t know**: 99

### 3.3 Are you currently employed (working or earning money)?
- **Yes, full-time**: 1
- **Yes, part-time**: 2
- **No**: 0
- **Don’t know**: 99

**Type of employment**

**3.3 If NO, go to 3.6**

### 3.4 If YES, did you lose income from the time you took from your job to come here today?
- **Yes**: 1
- **No**: 0

### 3.5 If YES, how much money did you lose? (Rand)

**3.5 If NO, go to 4.1**

### 3.6 Are there extra medicines you need that you are not receiving at the facility?
- **Yes**: 1
- **No**: 0

**3.6 If YES, go to 3.7**

**3.6 If NO, go to 4.1**

### 3.7 If YES, which type of medicines are you buying and how much do you spend per month?
- **Pain medicine (Painblok®)**
- **Vitamins**
- **Cream for itchy skin (Dovate®)**
- **Moisturising cream (Aqueous cream)**
- **Other**

<table>
<thead>
<tr>
<th>Other</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>If other, please specify</td>
<td>If other, please specify</td>
</tr>
</tbody>
</table>

### 3.8 Did you find it easy or difficult to incur these expenses? (refer to expenses in 3.6)
- **Easy**: 1
- **Difficult**: 2
- **Neither easy or difficult**: 98
- **Don’t know**: 99

### SECTION FOUR: AVAILABILITY

#### 4.1 Is this the closest clinic to your home that offers ARV treatment?
- **Yes**: 1
- **No**: 0

**4.1 If YES, go to 4.3**

**4.2 If NO, why do you prefer this facility?**

### 4.3 How did you get here today?
- **By foot**: 1
- **Bicycle**: 1
- **Minibus taxi**: 1
- **Bus/train**: 1
- **Own private car**: 1
- **Other private car (meter taxi, hire car, catching a lift)**: 1
- **Ambulance/hospital transport**: 1
- **Other**: 97

<table>
<thead>
<tr>
<th>Other</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>If other, please specify</td>
<td>If other, please specify</td>
</tr>
</tbody>
</table>
### SECTION FIVE: ACCEPTABILITY

**READ OUT**

Different people have different preferences in how and where they get their medicine, I would like to ask a few questions about what you prefer.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 Since you first started collecting your medicine from this facility,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>have you ever left without ARV tablets?</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>5.2 Have you ever had to come back another day (other than your appointment date) to collect tablets owed to you?</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td><strong>READ OUT:</strong> Where would you prefer to collect your ARV medicines?</td>
<td>At the clinic</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Hospital</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Indifferent</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>99</td>
</tr>
</tbody>
</table>

Note: Insert the respondent’s previous response into the question:

5.4 Why do you prefer the ............ (clinic/hospital)?

5.5 In receiving your ARV medicines, what would you prefer:

(a) For the doctor/nurse to give you the medicine after seeing you; or to

(b) Collect the medicine at the facility’s pharmacy from a pharmacist/assistant.

<table>
<thead>
<tr>
<th>Preference</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor/Nurse</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Pharmacist/assistant</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Indifferent</td>
<td>98</td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td>99</td>
<td></td>
</tr>
</tbody>
</table>

Note: Insert the respondent’s previous response into the question:

5.6 Why do you prefer the ............ (doctor/nurse/pharmacist/assistant)?

5.7 Do you have anything else that you would like to tell us about your experience of seeking or receiving ARV care at this facility?

Note the end time of the interview hour min
Appendix 4

ECONOMIC EVALUATION OF TASK SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL (ARV) TREATMENT

OBSERVATION TOOL

Facility: 

Name of fieldworker: 

Date 

Time of entry of facility 

NURSE 

Time of Entry 

Time of Exit 

DOCTOR 

Time of Entry 

Time of Exit 

PHARMACY (pharmacist/pharmacist-assistant) 

Time of Entry 

Time of Exit 

Time of exiting facility 

ECONOMIC EVALUATION OF TASK SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL (ARV) TREATMENT

OBSERVATION TOOL

Facility: 

Name of fieldworker: 

Date 

Time of entry of facility 

NURSE 

Time of Entry 

Time of Exit 

DOCTOR 

Time of Entry 

Time of Exit 

PHARMACY (pharmacist/pharmacist-assistant) 

Time of Entry 

Time of Exit 

Time of exiting facility
25 February 2010

REC REF: 064/2010

Ms N Foster
Health Economics Unit

Dear Ms Foster,

PROJECT TITLE: AN ECONOMIC EVALUATION OF TASK-SHIFTING APPROACHES TO THE DISPENSING OF ARV TREATMENT IN THE CAPE WINELANDS DISTRICT.

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has formally approved the above-mentioned study.

Approval is granted for one year till the 28th February 2011.

Please submit an annual progress report (FHS016) if the research continues beyond the expiry date. Alternatively please submit a study closure report (FHS 010) if the study is completed within one year so that we can close our file.

Please add the following statement to the informed consent document: non-participation in the study will in no way impact on the patients' current or future health care in the clinic or any other clinic.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely,

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Dear Ms N Foster,

RE: AN ECONOMIC EVALUATION OF TASK-SHIFTING APPROACHES TO THE DISPENSING OF ANTI-RETROVIRAL TREATMENT IN THE CAPE WINELANDS DISTRICT

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research at the following facilities. Please contact the facility managers to assist you with access to the facilities:

1. TC Newman hospital
2. Mbekweni Clinic
3. Kyamandiclinic
4. Franschoek
5. Idasvalley
6. Daalvlei

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@newc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely,

DR J CUP
DEPUTY DIRECTOR-GENERAL
DISTRICT HEALTH SERVICES AND PROGRAMMES

DATE:

CC: Ms L Phillips  Director Cape Winelands
Appendix 7

Instructions for Human Resources for Health authors

General Information

Submission process
Manuscripts must be submitted by one of the authors of the manuscript, and should not be submitted by anyone on their behalf. The submitting author takes responsibility for the article during submission and peer review.

To facilitate rapid publication and to minimize administrative costs, Human Resources for Health accepts only online submission.

Files can be submitted as a batch, or one by one. The submission process can be interrupted at any time – when users return to the site, they can carry on where they left off.

See below for examples of acceptable word processor and graphics file formats. Additional files of any type, such as movies, animations, or original data files, can also be submitted as part of the publication.

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Assistance with the process of manuscript preparation and submission is available from the customer support team

We also provide a collection of links to useful tools and resources for scientific authors, on our Tools for Authors page.

Publication and peer review processes
Human Resources for Health uses online peer review to speed up the publication process. The time taken to reach a final decision depends on whether reviewers request revisions, and how quickly authors are able to respond.

Human Resources for Health has an open peer-review process, aimed at improving the accountability of peer review and giving reviewers credit for the work they do.

Once an article is accepted, it is published in Human Resources for Health immediately as a provisional PDF file. The paper will subsequently be published in both freely browsable web form, and as a formatted PDF. The article will then be available through Human Resources for Health, BioMed Central and PubMed Central, and will also be indexed in PubMed.

The ultimate responsibility for any decision lies with the Editor-in-Chief, to whom any appeals against rejection should be addressed.

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Submission of a manuscript to Human Resources for Health implies that all authors have read and agreed to the content, and that any experimental research that is reported in the manuscript has been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Declaration of Helsinki, and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate. Informed consent must also be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.

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Generic drug names should generally be used. When proprietary brands are used in research, indicate the brand names in parentheses in the Methods section.

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CD DeAngelis, P.B Fontanares, A Rangan, Reporting financial conflicts of interest and relationships between investigators and research sponsors, JAMA 2001, 286:339-3

K Marc, H Rejtanekova, FA Riddick Jr, LJ Morse, JI O'Brien 3rd, MS Geldrich, P. Rev, M Wales, FM Sade, NA Solomon, Managing conflicts of interest in the conduct of clinical trials, JAMA 2002, 287:78-84

For all articles that include information or clinical photographs relating to individual patients, written and signed consent from each patient to publish must also be mailed or faxed to the editorial staff. The manuscript should also include a statement to this effect in the Acknowledgments section, as follows: “Written consent for publication was obtained from the patient or their relative.”

Human Resources for Health supports initiatives to improve the performance and reporting of clinical trials, which include prospective and randomized trials. The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as any research study that prospectively assigns human subjects to one or more health related interventions to evaluate the effects on health outcomes. Authors of protocols or reports of such clinical trials, where the primary purpose of the research is to understand the causes, development and effects of disease, or to improve preventive, diagnostic or therapeutic interventions, must register their trial prior to submission in a suitable publicly accessible registry, which meet the requirements of the ICMJE. Include WHO Primary Registration. The trial registration number should be included as the last line of the abstract of the manuscript.

Human Resources for Health also supports initiatives aimed at improving the reporting of biomedical research. Checklists have been developed for a number of study designs, including randomized controlled trials (CONSORT), systematic reviews (PRISMA), meta-analyses of observational studies (MOOSE), diagnostic accuracy studies (STARD), and qualitative studies (CUBES). We recommend authors refer to the CONSORT network website for further information on the available reporting guidelines for health research, and the MESH Portal for prescriptive checklists for reporting biomedical and biological research where applicable. Authors are requested to make use of these when drafting their manuscript and peer reviewers will also be asked to refer to these checklists when evaluating these studies. For authors of systematic reviews, a supplementary file, either from the Methods section, should reproduce all details concerning the search strategy. For an example of how a systematic review should be presented, see the Cochrane Reviewers’ Handbook.

Authors from pharmaceutical companies, or other commercial organizations that sponsor clinical trials, should adhere to the Good Publication Practice guidelines for pharmaceutical companies, which are designed to ensure that publications are produced in a responsible and ethical manner. The guidelines also apply to any companies or individuals that work on industry-sponsored publications, such as freelance writers, contract research organizations and communications companies.

The involvement of medical writers or anyone else who assisted with the preparation of the manuscript should be acknowledged, along with their source of funding, as described in the European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing research reviews publications. If medical writers are not listed among the authors, it is important that their role be acknowledged explicitly. We suggest wording such as ‘We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.’

Any ‘in press’ articles cited within the references and necessary for the reviewers’ assessment of the manuscript should be made available if requested by the editorial office.

Submission of a manuscript to Human Resources for Health implies that readily reproducible materials described in the manuscript, including all relevant raw data, will be freely available to varied users, such as bioinformatics companies or universities. Nucleic acid sequences, protein sequences, and atomic coordinates should be deposited in an appropriate database in time for the accession number to be included in the published article. In computational studies where the sequence information is unacceptably for inclusion in databases because of lack of experimental validation, the sequences must be published as an additional file with the article.

Nucleotide sequences

Nucleotide sequences can be deposited with the DNA Data Bank of Japan (DDBJ), European Molecular Biology Laboratory (EMBL/EBI), Nucleotide Sequence Database, or GenBank (National Center for Biotechnology Information).

Protein sequences

Protein sequences can be deposited with SwissProt or the Protein Information Resource (PIR).

Chemical structures and assays

Structures of chemical substances can be deposited with PubChem Substance, Bioactivity screens of chemical substances can be deposited with PubChem BioAssay.

Microarray data

Where appropriate, authors should adhere to the standards proposed by the Microarray Gene Expression Data Society and must deposit microarray data in one of the public repositories, such as ArrayExpress, Gene Expression Omnibus (GEO) or the Center for Information Biology Gene Expression Database (CIBMTR).

Computational modeling

We encourage authors to prepare models of biochemical reaction networks using the Systems Biology Markup Language and to deposit the model with the BioModels database, as well as submitting it as an additional file with the manuscript.

Preparation of manuscripts

File formats

The following word processor file formats are acceptable for the main manuscript document:

Preparing main manuscript text
Human Resources for Health

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- Rich text format (RTF)
- Portable document format (PDF)
- TeX/LaTeX (use Biomed Central's TeX template)
- Device independent format (DVI)
- Publimed Document (ND)

Users of other word processing packages should save or convert their files to RTF before uploading. Many free tools are available which ease this process.

TeX/LaTeX users: We recommend using Biomed Central's TeX template and BiMed style file. If you use the standard format, you can submit your manuscript in TeX format (after you submit your TeX file, you will be prompted to submit your BibTeX file). If you have used another template for your manuscript, or if you do not wish to use BibTeX, then please submit your manuscript as a DVI file. We do not recommend converting to RTF.

Note that ROUNDS must be submitted as separate image files, not as part of the submitted DOC/PDF/TeX/DVI file.

Article types

When submitting your manuscript, you will be asked to assign one of the following types to your article:

- Research
- Case study
- Commentary
- Hypothesis
- Methodology
- Review

Please read the descriptions of each of the article types, choose which is appropriate for your article and structure it accordingly. If in doubt, your manuscript should be classified as Research, the structure for which is described below.

Manuscript sections for Research articles

Manuscripts for Research articles submitted to Human Resources for Health should be divided into the following sections:

- Title page
- Abstract
- Background
- Methods
- Results
- Discussion
- Conclusions
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Authors' information (if any)
- Acknowledgements and Funding
- Appendices
- Figure legends (if any)
- Tables and captions (if any)
- Description of additional data files (if any)

You can download a template (compatible with Mac and Windows Word 97/98/2000/2003/2007) for your article. For instructions on use, see below.

The Accession Numbers of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000, DDBJ:AD00812, GenBank:U49845, PDB:1B87, Swiss-Prot:Q96KQ7, PIR:96116] These databases, for which we can provide direct links are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (National Center for Biotechnology Information), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

Title page

This should list the title of the article. The title should include the study design, for example:

A versus B in the treatment of C: a randomized controlled trial

X is a risk factor for Y: a case control study

The full names, institutional addresses, and e-mail addresses for all authors must be included on the title page. The corresponding author should also be indicated.

Abstract

The abstract of the manuscript should not exceed 350 words and must be structured into separate sections: Background, the context and purpose of the study; Methods, how the study was performed and statistical tests used; Results, the main findings; Conclusions, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract; Trial registration, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number, e.g. Trial registration: Current Controlled Trials ISRCTN73634458. Please note that there should be no space between the letters and numbers of your trial registration number.

Background

The background section should be written from the standpoint of researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a very brief statement of what is being reported in the article.

Methods

This should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate.

Results and Discussion

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Human Resources for Health

The Results and Discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text, either they should be defined in the text where first used, or a list of abbreviations can be provided, which should precede the competing interests and authors’ contributions.

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A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors should disclose any financial competing interests but also any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

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Financial competing interests

- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
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Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

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An author is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author’s contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript; CD carried out the immunoeasys. EF participated in the sequence alignment, FG participated in the design of the study and performed the statistical analysis, FH conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

Authors’ information

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Acknowledgements and Funding

Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also acknowledge anyone who contributed materials essential for the study.

The role of a medical writer must be included in the acknowledgements section, including their source(s) of funding.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

References

All references must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Reference citations should not appear in titles or headings. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

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Citations in the reference list should contain all named authors, regardless of how many there are.
Human Resources for Health

Examples of the Human Resources for Health reference style are shown below. Please take care to follow the reference style precisely; references not in the correct style may be rejected, necessitating tedious proofreading.

Links

Web links and URLs should be included in the reference list. They should be provided in full, including both the title of the site and the URL, in the following format: The Mouse Tumor Biology Database [http://tumor.informatics.jax.org/mtbwi/index.do]

Human Resources for Health reference style

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- EndNote style file
- Reference Manager
- Zotero

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Article within a journal supplement


In press article


Published abstract


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Whole issue of journal


Whole conference proceedings


Complete book


Monograph or book in a series


Book with institutional author


PhD thesis


Link / URL


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- If there are sections which you do not need, delete them (but check the rest of the Instructions for Authors to see which sections are compulsory).
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Figures should be provided as separate files and should not be included in the main text of the submitted manuscript. Each figure should comprise only a single file. There is no change for the use of color.

Please read our figure preparation guidelines for detailed instructions on maximizing the quality of your figures.

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- PDF (also especially suitable for diagrams)
- PNG (preferred format for photos or images)
- Microsoft Word (figures must be a single page)
- PowerPoint (figures must be a single page)
- TIFF
- JPEG
- BMP
- CDX (ChemDraw)
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The legends should be included in the main manuscript text file rather than being part of the figure file. For each figure, the following information should be provided: figure number (in sequence, using Arabic numerals – i.e. Figure 1, 2, 3 etc); short title of figure (maximum 16 words); detailed legend, up to 300 words.

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- File format (including name and a URL of an appropriate viewer if format is unusual)
- Title of data
- Description of data

Additional data files should be referenced explicitly by file name within the body of the article, e.g. ‘See additional file 1: Movie1 for...’
the original data used to perform this analysis.

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- Animations
- SWF (Shockwave Flash)
- Movies
  - MOV (QuickTime)
  - MPG (MPEG)
- Tabular data
  - XLS (Excel spreadsheet)
  - CSV (Comma separated values)

As with figure files, files should be given the standard file extensions. This is especially important for Macintosh users, since the Mac OS does not enforce the use of standard extensions. Please also make sure that each additional file is a single table, figure or movie (please do not upload linked worksheets or PDF files larger than one sheet).

**Mini-websites**

Small self-contained websites can be submitted as additional files, in such a way that they will be browsable from within the full text HTML version of the article. In order to do this, please follow these instructions:

1. Create a folder containing a starting file called index.html (or index.htm) in the root
2. Put all files necessary for viewing the mini-website within the folder, or sub-folders
3. Ensure that all links are relative (e.g. "Images/picture.jpg" rather than "Images/picture.jpg"
4. Ensure that the URL file names do not exceed 255 characters
5. Compress the folder into a ZIP, check the file size is under 20 MB, then submit the file online.

**Style and language**

**General**

Currently, Human Resources for Health can only accept manuscripts written in English. Spelling should be British English, but not a mixture.

Gene names should be in italics, but protein products should be in plain type.

There is no explicit limit on the length of articles submitted, but authors are encouraged to be concise. There is no restriction on the number of figures, tables or additional files that can be included with each article online. Figures and tables should be sequentially referenced. Authors should include all relevant supporting data with each article.

**Human Resources for Health** will not edit submitted manuscripts for style or language; reviewers may advise rejection of a manuscript if it is compromised by grammatical errors. Authors are advised to write clearly and simply, and to have their article checked by colleagues before submission. In-house copyediting will be minimal. Non-native speakers of English may choose to make use of a copyediting service.

**Help and advice on scientific writing**

The abstract is one of the most important parts of a manuscript. For guidance, please visit our page on "Writing titles and abstracts for scientific articles".

Tim Albert has produced for BioMed Central a list of tips for writing a scientific manuscript. MedBioWorld also provides a list of resources for science writing.

**Abbreviations**

Abbreviations should be used as sparingly as possible. They can be defined when first used or a list of abbreviations can be provided preceding the acknowledgements and references.

**Typography**

- Please use double line spacing.
- Type the text justified, without hyphenating words at line breaks.
- Use hard returns only to end headings and paragraphs, not to rearrange lines.
- Capitalize only the first word, and proper nouns, in the title.
- All pages should be numbered.
- Use the Human Resources for Health reference format.
- Footnotes to text should not be used.
- Greek and other special characters may be included. If you are unable to reproduce a particular special character, please type out the name of the symbol in full.

Please ensure that all special characters used are embedded in the text, otherwise they will be lost during conversion to PDF.

- Genes, mutations, genotypes, and alleles should be indicated in italics, and authors are required to use approved gene symbols, names, and formatting. Protein products should be in plain type.

**Units**

SI units should be used throughout (liter and molar are permitted, however).