

**ACCESSING ANTIRETROVIRAL TREATMENT IN THE RURAL EASTERN CAPE:
PATIENTS' PERCEPTIONS OF A DECENTRALISED PRE-PACKING MODEL OF CARE
AND THE IMPACT ON DIRECT OUT-OF-POCKET SPENDING**

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ABSTRACT

Background:

With an estimated 5.51 million HIV infected South Africans, HIV/AIDS contributes significantly to the burden of disease in the country, with far-reaching socio-economic implications particularly for poor and vulnerable groups. High out-of-pocket health expenditure associated with HIV/AIDS care has a serious impact on vulnerable individuals and is likely to severely affect the wellbeing of the affected household. Geographic inaccessibility of centralised, hospital-based antiretroviral treatment (ART) services and excessive transportation costs may contribute to patient attrition and these barriers are exacerbated in rural populations.

Aim:

The objectives of this study are to ascertain the out-of-pocket expenses that are incurred by patients travelling to their ART down-referral site, and compare this with the out-of-pocket expenses of those patients from the same catchment area still receiving their ART from the central hospital. The study also aims to determine whether or not the down-referral programme has impacted the patients' economic status and improved their treatment experience.

Methods:

A semi-quantitative cross sectional study design was employed. Zithulele Hospital ARV Clinic and five different PHC collection points within the hospital's catchment area were selected as the study sites. Included in the study were 44 hospital-based patients and 73 clinic-based patients registered on the Zithulele Hospital HIV Programme. Using a standard questionnaire, all socio-economic data and information related to mode of transportation and associated costs, as well as other out-of-pocket spending associated with accessing ART, was collected. Clinical data was recorded from patient medical records during the interview.

Results:

The average monthly household income was R1653 (R301.05 per capita) for hospital-based patients and R1617 (R392.66 per capita) for clinic-based patients. Income was predominantly sourced from either child support or pension grants. Study participants had an overall unemployment rate of 94% and, subsequently, 75% of hospital-based patients and 68.5% of clinic-based patients were living below the food poverty line of R400 per month. A higher proportion of hospital-based patients used taxis (80.5% versus 28.8%) while more clinic-based patients walked to the facility for their treatment

(71.2% versus 14.6%). In terms of monthly transport costs, hospital-based patients spent on average R71.92, significantly more than the R25.81 spent by clinic-based patients. With a point estimate of 1.169, regression analysis indicated that for every one Rand increase on transport, the odds of the patient being hospital-based rather than clinic-based are 16.9% higher. There were higher levels of satisfaction recorded amongst the hospital-based group (95.5% compared to 89%) but despite this, 100% of the clinic-based patients listed their respective clinic as their preferred ART collection point.

Conclusion:

Decentralisation and down-referral of patients to their nearest primary healthcare clinic minimises out-of-pocket spending in rural communities while maintaining good levels of satisfaction with the healthcare service provided. It is important to consider the social, geographical and cultural context of the individuals seeking and utilizing healthcare before interventions are implemented.

DECLARATION

In fulfilment of the requirements of the degree of Masters in Pharmacy in the School of Pharmacy, University of KwaZulu-Natal, Durban, South Africa, I Monique Lines declare that

- (i) The research reported in this dissertation, except where referenced, is my original work.
- (ii) This dissertation has not been submitted for any degree or examination at any other university.
- (iii) This dissertation does not contain other person's data, pictures, graphs or other information, unless specifically acknowledged as being sourced from other persons.
- (iv) This dissertation does not contain other persons' writing, unless specifically acknowledged as being sourced from other researchers. Where other written sources have been quoted, then:
 - a. their words have been re-written but the general information attributed to them has been referenced;
 - b. where their exact words have been used, their writing has been placed inside quotation marks, and referenced.
- (v) Where reference to a publication for which I am a principal author, I have referenced the "In Press" publication.

Student Signature _____

Date _____

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ABBREVIATIONS

AIDS: Acquired Immune Deficiency Syndrome

ART: Antiretroviral treatment

DWF: Donald Woods Foundation

EC DoH: Eastern Cape Department of Health

FPL: Food Poverty Line

HCT: HIV Counselling and Testing

HIV: Human Immunodeficiency Virus

JAL: Jalamba Clinic

KSD: King Sabato Dalindyebo

KOT: Kotyana Clinic

LBPL: Lower Bound Poverty Line

LUT: Lutubeni Clinic

MAP: Mapuzi Clinic

MPM: Mpame Clinic

NGC: Ngcwanguba Community Health Centre

NIMART: Nurse-Initiated and Managed Antiretroviral Treatment

NZU: Nzulwini Clinic

SANAC: South African National AIDS Council

TSH: Tshezi Clinic

UBPL: Upper Bound Poverty Line

USD: United States Dollar

WHO: World Health Organisation

WIL: Wilo Clinic

ZHHP: Zithulele Hospital HIV Programme

ZID: Zidindi Clinic

ZIT: Zithulele Hospital

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CHAPTER 1: INTRODUCTION AND BACKGROUND

1.1 Introduction

With an estimated 5.51 million HIV infected South Africans, HIV/AIDS contributes significantly to the burden of disease in the country, with far reaching socio-economic implications particularly for poor and vulnerable groups (1). In low- and middle-income countries, health service utilisation is often determined by affordability and accessibility (2) but South Africa, although classified as a middle-income country by the World Bank, also has to contend with unique socio-economic challenges due to the “juxtaposition of its first world economic prowess and third world poverty and disrepair” (3).

Many of the advances in HIV treatment and care have taken place in sub-Saharan Africa, but ART services still rely heavily on hospital-based services that are predominantly doctor-supported (4). HIV/AIDS is increasingly affecting the poor and those who already have barriers to access to healthcare (5); these growing healthcare needs have required rapid expansion of the HIV treatment programme, which has placed tremendous pressure on human resources (6).

Since 80% of South Africans, and especially the poorest quintile of the population, rely exclusively on public sector health services (7), the South African government has increased efforts to integrate HIV/AIDS treatment with PHC services. Task shifting and decentralisation of care has reduced the impact of human resource shortages and improved accessibility to ART for many affected populations in Africa (8).

In order to access healthcare services, people have to pay direct and indirect costs, including transportation costs for outpatient services that account for 12% of per-visit treatment charges in South Africa, as indicated by a WHO Report (2010) (7). Adherence, a key determinant of clinical outcomes, remains a challenge for the rural poor due to these unaffordable out-of-pocket costs and the geographical inequity of treatment facilities (8).

Continued strengthening and innovative transformation of the existing health system in South Africa will be required for scaling up of ART in order to achieve universal coverage (9). Health services to the impoverished and vulnerable populace must become more accessible and financially protective, and strategies to improve and monitor retention in care will have to be developed simultaneously to monitor the success of the HIV programme.

Systems changes must be well informed and the social, geographical and cultural context of the population seeking and utilising healthcare should be considered before interventions are implemented (10). From a policy perspective this can partly be achieved through a better understanding of the factors associated with out-of-pocket spending on health (2).

1.2 Background

1.2.1 Socio-economic profile of South Africa and the Eastern Cape

Despite being a middle income nation, universal access to ART has not been achieved in South Africa. A number of factors have contributed to this shortcoming, including, but not limited to, a lack of political commitment, widespread poverty, cultural barriers and the inequalities that still persist as a result of Apartheid (3).

1.2.1.1 Inheriting an inequitable healthcare system

Pre-1994, there was extreme inequity in the health sector of South Africa, with a highly fragmented system based on race and ethnicity. Health professional training was conducted on racial grounds and there were very little training opportunities for black people in disciplines other than nursing and medicine. Public health services for white people were superior to those for black people, and people living in rural areas were significantly worse off in terms of access to services.

The Apartheid government developed Bantustans to which black South Africans were assigned based on their ethnicity. These semi-autonomous homelands were responsible for administering healthcare for the “citizens”. The homelands were poorly organised and incapable of providing public healthcare services. Missionary churches established hospitals and clinics in these neglected areas but in most cases were not able to meet the overwhelming medical needs of the community (11). Zithulele Hospital, first established as a clinic by the Dutch Reformed Church in 1956, was handed over to the government of the “independent” homeland of the Transkei in 1976.

Post 1994, the first democratic government of South Africa entrenched the right to access to healthcare services in Section 27(1) of the Constitution of South Africa. The political commitment to achieve equitable access to health services was seen in the comprehensive transformation of the health system. Initial interventions included free healthcare for pregnant women and children (and later people with disabilities), eradication of racially based services, and a massive clinic building programme to improve access to health services. But despite all of these changes, the economic and

social divides of Apartheid are still, to this day, clearly evident in the inequitable health services and living conditions in the old Transkei area of the Eastern Cape.

1.2.1.2 Population and HIV statistics

According to Statistics South Africa's Mid-Year Population Estimates 2014 Report, South Africa has a total population of 54 million people with 30% aged younger than 15 years. 8.4% of the population is 60 years or older and this proportion of the population is increasing over time. With 6 786 900 people, the Eastern Cape makes up 12.6% of the total population of the country. It is estimated that between 2011 and 2016, there will be a nett migration of 241 000 people from the Eastern Cape, altering the demographic age structure and distribution of the province's population.

South Africa has an HIV prevalence rate of 10.2% putting the total number of people living with the virus at approximately 5.51 million (1). It is estimated that 16.8% of the adult population between 15-49 years is HIV positive. In 2014, life expectancy at birth for female South Africans was 63.1 years while for males it was slightly lower at 59.1 years. Approximately one-fifth of South African females at a reproductive age are HIV positive and just over 31% of deaths in South Africa in 2014 were AIDS related.

1.2.1.3 Poverty

Since 2012, Statistics South Africa has used three national poverty lines to measure poverty in the country: the food poverty line (FPL), the lower-bound poverty line (LBPL) and the upper-bound poverty line (UBPL). The FPL is defined as "the level of consumption below which individuals are unable to purchase sufficient food to provide them with an adequate diet" (1). The LBPL requires that individuals sacrifice food in order to attain non-food items whereas the UBPL sees individuals with sufficient food and non-food items. In 2011, approximately 23 million South Africans and a third of all households were classified as poor (that is, living below the UBPL), while a staggering 10.2 million people (20.2%) lived in extreme poverty (falling below the FPL). In the same year, the level of poverty in the Eastern Cape was the second highest provincially at 60.8%. Females made up the majority of the people living in poverty in South Africa and female-headed households (43.9%) were more likely to be poor than male-headed households (25.7%) (12).

In terms of income, South Africa had one of the highest levels of inequality in the world in 2011. More than two thirds of rural residents and over 55% of rural households were living in poverty. An important factor in decreasing poverty levels in South Africa is the social assistance provided by the government. Over 10 million recipients of child support grants were registered in 2011 but, in that

same year, almost half of all poor people in South Africa were children, warranting further research as to whether or not child support grants are actually reaching their intended targets. In total, almost 15 million individuals are registered for social support grants in South Africa (12).

1.2.1.4 Education

Education undoubtedly plays a vital role in eradicating poverty. Only 5.5% of South Africans with a post-matric qualification were classified as poor compared to the 66% of adults with no formal education. According to the 2011 census conducted by Statistics South Africa, 8.6% of adults over 20 years of age had no formal education, 12.3% had some primary school education and 4.6% had completed primary school. Secondary schooling attainment was markedly higher with 33.9% and 28.9% of adults over the age of 20 years obtaining some secondary schooling or a matric certificate respectively. Only 11.8% of South Africans over the age of 20 years have achieved a higher education.

The proportion of functionally illiterate people in the Eastern Cape (26.5%) is the highest amongst all the provinces. Individuals are deemed functionally illiterate if they are 15 years or older with no schooling or less than a Grade 7 as their highest level of education. By population group and sex, functional illiteracy is the highest in the black population and among female South Africans (13).

1.2.1.5 Household expenditure

In 2011, the average South African household was composed of 3.8 people with a household income at an average of R98 939 per annum, compared to the average expenditure of R95 183. When taking a closer look at expenditure, households spent 12.8% (R12 200) on food and 17.1% (R16 319) on transport annually. In comparison to the above stated averages, poor households recorded an annual household expenditure of R25 348 with transport costs accounting for 10.2% of this. Rural households in South Africa tend to be larger than urban households with an average of 4.3 household members and an annual household income of R47 847, almost two-and-a-half times smaller than urban household income. Rural households spent 15.4% of this income on transport.

1.2.2 The Zithulele Hospital ARV Clinic: A short history and model overview

Zithulele Hospital initiated its first HIV positive patient on ART in November 2006. Since then, patient numbers have grown steadily and by April 2014, 4134 patients were actively receiving their free HIV management and ART through the Zithulele Hospital HIV Programme (ZHHP).

In an attempt to make ART more accessible to the communities served by the hospital, outreach days were introduced at Ngcwanguba Community Health Centre (NGC) and Mapuzi Clinic (MAP) in 2008. It was considered the most logical option to decongest the hospital's ARV clinic days as a large proportion of patients on treatment travelled from these areas. Down-referral of clinically stable ART patients from hospitals to PHC clinics has been suggested as a necessary progression of sustainable ART services (4). Due to the rural locality and inaccessibility of the hospital as a result of the poor condition of the road and pronounced distances from the clinics, the ZHHP team implemented a different form of decentralised ART care and offered treatment initiation and support at primary healthcare (PHC) level. At this time, HIV positive patients were managed exclusively by doctors, and PHC clinics were not registered as ART sites. To circumvent these barriers to treatment, a team from the hospital consisting of a doctor, a pharmacy worker and a lay counsellor would deliver ART services at the two said clinics once a month. Additional medicines to treat co-morbid infections and chronic diseases were also included due to the unreliable medicine supply at the PHC clinics. In March 2008, ZHHP had 242 patients on ART (0 down-referred) and by March 2009, the number had increased to 738 patients on ART (of whom 120 were down-referred).

In September 2009, Cell-Life donated the Intelligent Dispensing for Antiretroviral Treatment (iDART) software, in collaboration with the Desmond Tutu HIV Foundation, in order to support dispensing in the Zithulele ARV Clinic. The iDART down-referral functionality allowed for pre-packing of ART and enabled the potential expansion of ZHHP outreach efforts. Implementation of pre-packing commenced with existing down-referred patients at NGC and MAP. A hospital team visited the clinics on designated ARV days: a doctor would consult patients needing clinical reviews, the clinic nurse was responsible for drawing the necessary bloods and a lay counsellor/clinic staff dispensed the pre-packed ART to those patients requiring a treatment refill. To reduce clinic numbers and depending on the patients' clinical status and time on ART, patients received up to three months' supply of treatment.

The South African HIV treatment guidelines were revised and released in 2010 with two distinct alterations: nurses were permitted to initiate HIV positive patients on ART, and PHC facilities could be registered as ARV treatment sites allowing PHC staff to initiate, manage, monitor and refer HIV positive patients. A South African study found that, when treated by doctors at both levels, patients managed at PHC facilities achieved better outcomes than patients managed at hospitals (14). The new South African HIV treatment guidelines clearly focused on decentralisation of care and task shifting through the integration of stable, adult ART patients into existing PHC services using a nurse-initiated and managed ART (NIMART) strategy. These decentralisation efforts were driven by

the need to increase the capacity of the South African public sector to initiate and retain patients on ART despite resource challenges (4).

Due to increasing patient numbers and the relative shortages of human and infrastructural resources at Zithulele Hospital, it became imperative for the ZHHP to expand the pre-packing and down-referral model to additional PHC clinics within the catchment area. By December 2010, 40% of patients registered on the ZHHP were collecting their ART at their nearest PHC clinic by extending down-referral to a total of 5 clinics: NGC, MAP, Wilo (WIL), Jalamba (JAL) and Nzulwini (NZU).

The ZHHP had, until then, been exclusively funded by the Eastern Cape Department of Health (EC DoH) and relied solely on departmental employees to provide ART services. It was in December 2010 that the Donald Woods Foundation (DWF) offered additional support in terms of human resources, funding for programme expansion and infrastructure. The aim of DWF support was to supplement existing EC DoH staff in order to fill the human resource gaps so that systems and processes within the programme could be strengthened.

DWF employed an ART Programme Project Manager, an HCT Outreach Coordinator and a team of 4 HCT Outreach Peer Educators to implement education, counselling and testing in the community. A Data Capturer, a PMTCT Coordinator, a Default Tracer, a Nurse Mentor, a Pharmacy Assistant and 15 clinic-based Peer Educators were also integrated into the programme. Two vehicles were purchased to facilitate default tracing and allow for HIV counselling and testing (HCT) outreach and support visits to the clinics. DWF provided infrastructural improvements by renovating the Zithulele Hospital ARV Clinic building; renovations included the construction of a waiting room and the provision of office equipment. Wellness centres were also built at JAL and WIL clinics.

DWF invested significant time and money to strengthen the ART service provided by the ZHHP. Both DWF and the EC DoH staff involved in the ZHHP were trained and mentored e.g. breastfeeding training, peer educator training; counselling skills, group facilitation training and four bursaries were awarded to four nurses to do their advanced certificate in HIV Management through the University of Fort Hare. The EC DoH was still responsible for providing all the necessary ART and all clinicians remained government employed.

From January 2011, the ZHHP services were systematically introduced at the remaining PHC clinics in the Zithulele Hospital catchment area i.e. Lutubeni (LUT), Kotyana (KOT), Mpame (MPM), Zidindi (ZID) and Tshezi (TSH) clinics. Although NIMART and PHC level ART provision had been introduced by the 2010 South African HIV Treatment Guidelines, the clinics supported by Zithulele Hospital faced many challenges including but not limited to inconsistent and unreliable availability

of ART, a lack of adequately trained and experienced NIMART trained nurses and a high level of staff turnover. As a result, the pre-packing system persisted and clinic outreach days continued so as to support the NIMART trained nurses and improve their ability to confidently provide a quality service to patients consulted. By April 2014, 4134 patients were receiving their ART through the ZHHP and 3764 (91%) of these patients were receiving their ART pre-packed at a clinic of their choice.

Table 1: Zithulele Hospital and associated PHC facilities in the catchment area

Clinic name	# ART pts	Driving distance from Zithulele Hospital	Approximate drive time from Zithulele Hospital	Road type
Jalamba	266	43km	1hr5min	Dirt
Kotyana	200	9.5km	16min	Dirt
Lutubeni	374	32km	49min	Tarred
Mapuzi	448	42km	1hr10min	Tarred
Mpame	180	33km	55min	Dirt
Ngcwanguba CHC	846	28km	45min	Tarred
Nzulwini	118	18km	30min	Dirt/tarred
Tshezi	117	16km	27min	Dirt
Wilo	389	28km	46min	Tarred
Zidindi	301	16km	27min	Dirt
Zithulele Gateway Clinic	525	n/a	n/a	n/a
Zithulele Hospital	370	n/a	n/a	n/a

1.3 Problem statement

It has been shown that high out-of-pocket health expenditure associated with HIV/AIDS care has a serious impact on vulnerable individuals and is likely to severely affect the wellbeing of the affected household (2). There is also evidence to suggest that geographic inaccessibility of centralised hospital-based ART services and excessive transportation costs may contribute to patient attrition (4) and these barriers are exacerbated in rural populations (15).

Studies have shown the significant protective effect that decentralisation of HIV care has on the socio-economic status of households and how this facilitates access to healthcare (16). Thus a study was conducted to evaluate to what extent the ZHHP and related decentralisation of HIV/AIDS care has had an effect on the out-of-pocket costs and poverty status of patients accessing their treatment in this deeply rural Eastern Cape community.

1.4 Objectives

The objectives of this study are to ascertain the out-of-pocket expenses incurred by patients travelling to their ART down-referral site, and compare this with the out-of-pocket expenses of those patients from the same catchment area still receiving their ART from the referring hospital. The study also aims to determine whether or not the down-referral programme has impacted the patients' economic status and improved their treatment experience.

1.5 Significance of the study

The results of this research could contribute to the knowledge of how accessing ART impacts the financial status and poverty levels of South Africans in resource-limited settings. The results will potentially highlight specific barriers to treatment encountered by some of the most vulnerable HIV positive patients in the country.

It is estimated that there are 6.4 million South Africans living with HIV, accounting for 17% of the global HIV burden (17). By better understanding barriers to uptake and retention in care, specific approaches could be developed to ensure South Africa achieves universal access to ART. This study may provide policy makers with a key step towards identifying possible strategies to mitigate the impact of specific socio-economic barriers to accessing HIV services in rural communities.

1.6 Research questions

1. What is the economic status of patients accessing ART through the ZHHP?
2. How does accessing ART impact on the economic status of rural HIV positive patients on ART?
3. Does decentralisation of care aid in relieving the financial burden of accessing ART in a rural setting?
4. What mode of transport do rural patients use to access ART and how does this impact on their out-of-pocket spending?
5. Are ART patients accessing treatment in a rural setting satisfied with the HIV services provided by their PHC clinics or District Hospital?

1.7 Hypothesis

- H_0 : Down referral of HIV positive patients to their nearest clinic makes no difference to direct out-of-pocket expenses or their healthcare experience
- H_A : Down referral of HIV positive patients to their nearest clinic minimises direct out-of-pocket expenses and improves their healthcare experience

CHAPTER 2: LITERATURE REVIEW

The HIV epidemic has caused global economic and social instability, suffering and death, especially tangible in developing countries most affected by the virus (18). Political commitment to address HIV in South Africa is undeniable. Despite the many socio-economic and infrastructural challenges, the South African government has made remarkable efforts to develop and broaden HIV treatment and care. But despite all of these efforts, the country still has a long way to go before it is able to reach universal ART coverage, especially as more South Africans will qualify for ART in 2015 as a result of the lowered eligibility criteria (19).

Due to the continued focus on delivering adequate HIV treatment and care in South Africa, HIV has evolved into a chronic condition that can be effectively managed (10). As the life expectancy of HIV positive patients on ART continues to improve, there has been increased focus on the long-term economic consequences of HIV for individuals and households affected (20).

2.1 Access barriers to ART

Research was conducted in Haiti to assess methods of decreasing barriers to ART access in resource-poor settings to promote adherence (21). As in the Zithulele context, most of the individuals accessing treatment at the clinics were poor subsistence farmers or associated with migrant labour. From earlier implementation phases of the HIV Equity Initiative in Haiti, it was observed that factors associated with poverty posed a greater barrier to treatment adherence than an individual's behaviour. Food insecurity and lack of access to transport presented a unique challenge to ART adherence. Through the HIV Equity Initiative, ART services including medication and monitoring, were integrated into PHC services and offered free of charge. Patients were given transport stipends and community health workers were incorporated into the service to promote adherence and provide a link between the community and the clinic. It was established that integrating HIV services into a PHC context and improving access to PHC are critical for the scale-up of HIV programmes, especially in resource-poor settings. It was also suggested that if unaddressed, food insecurity would threaten HIV programmes and the health and survival of vulnerable populations despite the financial investment in scaling up ART.

Despite having the largest HIV-infected population in sub-Saharan Africa, South Africa was very slow to provide treatment in the public sector due to the lack of political will (22). During this time, South Africa's HIV programme received much criticism and the number of South Africans that lost their lives due to these missed opportunities was evidence of the country's failure to adequately

address the HIV crisis. Ojikutu, Makadzange and Gaolathe (2008) assessed experiences from South Africa, Zimbabwe and Botswana to address scaling up of ART and the capacity to do so. Challenges that were identified included health system infrastructure deficits such as inadequate clinic and laboratory facilities particularly in remote, rural areas; human resource deficits; and poor integration of HIV services into PHC services. It was stated that failure to address these challenges would result in HIV services becoming saturated in the future, limiting expansion of the ART programme (3).

Ojikutu, Jack and Ramjee (2007) did a case study in South Africa exploring infrastructural deficits, poverty and traditional medicine as unique challenges to providing ART in South Africa. A disparity in access to ART among South Africa's nine provinces was identified, evidently seen in infrastructural deficits inherited through a legacy of healthcare inequity. As a result, the poorest and often the most vulnerable communities were left without adequate access to HIV services. Low-income, rural residents described the public healthcare system as being of low quality, difficult to access and overcrowded. Efforts to decentralise HIV services and initiate ART at PHC facilities was hindered by inadequate space and overworked and undercompensated healthcare workers. The large discrepancy between hospitals and clinics in terms of laboratory facilities and availability of adequately trained and experienced healthcare workers still persists, particularly in rural areas. 72% of South Africans are poor rural residents suffering from these inequalities in access to care. Long distances from healthcare facilities and transportation costs were identified as significant barriers to ART for rural, unemployed patients. To a limited degree, social welfare grants including child care, old age pension and disability grants mitigated the effects of high rates of unemployment within rural communities but a call for welfare transformation was stressed in order to remove the risk of patients trading their health or financial means to support larger households in order to access social grants (23).

Bartlett *et al.* (2011) conducted a systematic literature review to identify barriers and potential solutions to effective ART in resource-limited settings. Eleven peer-reviewed journal articles and 19 International AIDS Society Conference abstracts were included in the review. A number of economic, sociocultural and behavioural issues were identified as barriers to ART. Strengthening medicine procurement and supply chain management was listed as a priority since access to ART and the success of HIV programmes was threatened by inconsistent and unreliable availability of ART at healthcare facilities. Inclusion of transportation in HIV programmes or providing patients on ART with monetary supplements were suggested solutions to the significant transport costs that patients incurred. Over and above the cost of transport, patients also travelled long distances to access ART and experienced long waiting times at healthcare facilities. This was a significant barrier

for employed patients and women with children, as it resulted in lost wages and time away from household responsibilities. In addition to economic barriers to care, rural populations were often faced with geographic and natural barriers such as poor roads, rivers and forests. Decentralisation of HIV care and integration into PHC services was necessary to improve coverage and access to ART at a community level (18).

Tuller, *et al.* (2010) conducted 41 open-ended interviews with patients attending a clinic in Mbarara, Uganda to understand structural barriers to ARV adherence and clinical care. A constant source of stress and anxiety for the patients was the need to locate funds for monthly clinic visits. There were competing demands between transport costs and other necessities (food, housing and school fees) but patients generally expressed their determination to sustain treatment and reported that saving money for transportation came above all else. Adherence to ART was being compromised by transport costs (24)

Another study in the rural Thyolo district in south Malawi investigated the low uptake of HIV positive TB patients onto ART despite eligibility for treatment (15). Once diagnosed with TB, patients received their first two weeks of treatment as in-patients at Thyolo district hospital during which they were offered HCT. The remainder of their TB treatment was collected at decentralised health centres in the district. TB patients diagnosed with HIV were requested to return to the district hospital two months after TB treatment was initiated to prepare for initiation of ART. ART had not been decentralised and once initiated, patients had to return to the hospital on a monthly basis to collect their ART. Only 13.6% of the 742 TB patients found to be HIV positive were initiated on ART. The geographic location of these 101 patients was mapped and the road distances and cost of transport calculated accordingly. The average distance travelled to the Thyolo district hospital was 22km and the cost of transport ranged from 30 to 270 Malawi Kwacha. Considering that over three quarters of the study population were poor subsistence farmers earning less than USD 4 per week, it was not surprising to find that the cost of transport was identified as the reason for the low uptake of TB patients onto ART. The cost of transportation associated with accessing healthcare has been cited as a significant barrier to accessing ART for poor, rural and unemployed patients (21) (23).

Decentralisation of HIV services, as was done with TB, was identified as a potential strategy to reduce the cost of transport for patients and improve access to ART.

Ware *et al.* (2009) interviewed 414 patients, treatment partners and healthcare workers to determine what influenced adherence to ART. The semi structured interviews took place in three sub-Saharan countries (Nigeria, Tanzania and Uganda) and included rural and urban settings. A number of clinic

activities such as patient consultations, ART dispensing and counselling and education sessions were also observed. Money needed for transport was identified as a factor that hindered adherence to ART. Patients prioritised ART adherence which necessitated borrowing money or selling possessions in order to attend scheduled clinic appointments. Patients sacrificed other basic commodities in order to maintain good adherence levels, often at the expense of family members. In those situations where there were no means to pay for transportation, patients were committed to walking long distances for several hours to ensure their treatment was uninterrupted. Destigmatisation and keeping patients motivated resulted from positive social relationships with treatment partners at a community level. As HIV evolves into a chronic disease and normalisation occurs, adherence dynamics are likely to evolve too (25). And as such, strategies to assist HIV positive patients to overcome economic and social barriers to adherence will have to be adapted accordingly.

2.2 Task shifting and decentralization of HIV services

Bemelmans *et al.* conducted a study to describe how a model of care based on task shifting and decentralisation of care was used to achieve and maintain district-wide access to HIV care in the rural district of Thyolo, Malawi (2010). Thyolo District was one of the poorest districts with one of the highest rates of HIV infection in Malawi. In order to rapidly scale up ART, a number of innovative strategies were employed (26). Human resource deficits due to employment opportunities abroad and the toll of HIV on healthcare workers drove the introduction of task shifting to increase the number of healthcare workers engaged in HIV care. Community health workers were tasked with the responsibility of HIV preventive activities as well as HIV testing and counselling. HIV services were decentralised to health centres and sites in the community, aiding to spread the workload and improve access to care at a community level. Nurses were trained to consult with stable patients, freeing up clinicians' time to see complicated patients and ultimately enabling more HIV positive patients on ART to access care every month. HIV positive people in communities established support groups, improving adherence and health-seeking behaviour at a community level. By moving HIV services closer to patients' homes in the Thyolo District, the HIV programme saw better coverage and earlier initiation of ART, improved retention in care and decongestion of health centres. These simple interventions helped Malawi to achieve and sustain universal access targets since 2007 at an average annual cost of only €2.6 per individual. A number of factors needing further investigation were identified, including appropriate remuneration of community health workers and ensuring long term support as patients face new challenges related to long-term adherence.

Moshabela, *et al.* (2011) evaluated healthcare accessibility among patients taking ART after they were down-referred from hospital-based programmes to PHC clinics in Bushbuckridge. Participants were asked about availability, affordability and acceptability of their HIV care in a cross sectional study. The down referred patients had fewer access barriers to ART and saved time and money as they were more likely to walk to collect ART. Evidence suggests that long travel times, unaffordable and even unavailable transportation and long waiting times are barriers associated with hospital-based HIV services and may negatively impact on retention in care, leading to patient attrition and increased mortality (4). After controlling for confounders, down-referred patients were found to be eight times more likely to adhere to ART than hospital-based users. Interestingly, the down-referred patients preferred to be seen by a doctor and were more likely to seek additional healthcare through private doctors and self-care, suggesting possible inadequacies regarding the perceived quality of care at clinics. Down-referral was an equitable model of care that provided a response to the need to increase the capacity to initiate ART and retain HIV patients on ART, but the system was still threatened by the human resource deficits and lacking healthcare capacity (3).

Decroo *et al.* conducted a case study in Tete, Mozambique, to identify consequences of poorly planned large-scale down referral of ART services that had resulted in a loss to follow-up of over 100 patients (loss to follow-up rate of 30%). Tete Provincial Hospital had to down refer 61% of their ART patients to four urban PHC clinics due to major reconstruction work at the hospital. The PHC clinics faced a number of challenges following the influx of down-referred patients: clinic staff were inexperienced and could not manage the increased patient load, waiting times increased and waiting areas became overcrowded, laboratory services could not process all the additional bloods collected and inadequate forecasting resulted in the clinics running out of ARVs. A number of interventions were implemented in an attempt to improve services at the four PHC clinics. Monthly quotas of down-referred patients were established to guide ARV supply forecasting, coordinate laboratory services and better utilize clinic space. Task shifting to nurses and receptionists also took place. The case study showed that improving the proximity of patients to their ART services did not necessarily represent improved access to healthcare (27). This indicates that proper planning and phased implementation is critical if the full benefits of down-referral are to be realised.

Using a systematic review, Wouters *et al.* evaluated publications from November 2003 to December 2011 to identify the contributory role and function of community-based support services and how these impact on delivery and outcomes of HIV programmes in resource-limited settings. The severe shortage and poor retention of skilled health professionals is a serious obstacle undermining the implementation of HIV treatment plans in many under resourced countries. The critical shortage of

nurses has also hindered decentralisation of care to PHC facilities as well as task shifting of HIV management from doctors to nurses. Community support initiatives were found to positively address a number of challenges to ART coverage, namely the human resource deficit, defaulter tracing, empowering patients towards self-management and integrating HIV treatment services into existing PHC programmes (9). The review recommends that policy makers and managers recognise and strengthen the role of community support as it provides a critical link between patients and the health system.

Task shifting has been defined as “a process of delegation of tasks to health workers with lower qualifications” (28). In a viewpoint written by the authors, they describe a number of challenges associated with task shifting within the HIV programme in South Africa. The implementation and expansion of the HIV programme has highlighted the critical shortage of healthcare workers, especially in rural areas. Maintaining quality of care when task shifting is utilised, especially from trained healthcare professionals to lay health workers, was identified as a cause for concern. Adequate training and supervision as well as limiting the complexity and amount of work allocated to lay and community health workers was essential for maintaining good quality care. Adequate remuneration of community health workers for their valuable contribution to improving treatment coverage and adherence must be addressed if the work of such cadres is to be sustained. The viewpoint suggested that task shifting was not associated with a need for fewer staff and as such, it should not be viewed as the only solution to the shortage of human resources. Focus should be placed on strategies to increase, retain and sustain the number of healthcare workers employed (28).

The outcomes of a cohort of 1041 HIV positive adults initiated on ART in a community-based ART programme in rural Rwanda were reviewed (29). The study participants were identified at six ART sites in eastern Rwanda. The programme operated within the Rwandan national HIV health system and, as such, HIV services and treatment were offered free of charge. Through collaboration with Partners in Health, additional community level support was included to address socio-economic barriers to care. Community health workers provided ongoing HIV education and psychosocial support, patients were provided with a travel allowance for routine visits and a monthly food package was supplied for their first 10 months in the ART programme. After two years the community-based ART programme had retained 92.3% of the enrolled patients in care with a median increase in CD4 count of 336 cells/microliter. In the study, men with advanced HIV were identified as having a higher rate of attrition from care and, as such, it was suggested that new interventions should be more appealing and culturally appropriate to specifically target men. In addition, the negative impact of food insecurity, transportation costs and healthcare fees on treatment adherence and retention in

care needs to be addressed for the future success of HIV programmes in resource-limited countries (29).

From a provider's perspective, Long *et al.* (2011) evaluated the cost effectiveness of down-referring stable ART patients from a hospital-based doctor-centred ART clinic to PHC facilities that were nurse run. Down-referred patients were matched with patients eligible for down-referral but not down-referred. Clinical outcomes and the cost of treatment with down-referral were compared to hospital-based patients after twelve months. Cost reductions of approximately 11% per patient-year in care were observed with task shifting from doctors located at hospitals to PHC nurses. Due to the scale of the South African HIV programme, the saving potential is significant. By moving HIV care of stable patients from hospitals to PHC facilities, not only did doctors have more time to focus on patients with complications but the well-equipped hospital facilities were better utilised. There were fewer recorded deaths and loss to follow up among the down-referred patients and it was noted that in order to avoid poor patient outcomes, down-referral sites should not exceed their service delivery capacity. Given South Africa's resource constraints, the study identifies task shifting and decentralisation of HIV care as an essential step needed to increase treatment coverage and meet HIV programme targets without compromising patient outcomes (6).

Babigumira *et al.* (2009) studied the impact of task-shifting from doctors to nurses and pharmacy workers in a large urban HIV clinic in Uganda. An aggregate cost minimisation model was developed from a societal and provider perspective, taking into account task shifting, healthcare worker and patient time use and the associated cost of healthcare staff. The cost data was also used to make national cost projections based on the number of HIV positive patients needing ART in Uganda. Although the model did not measure quality of care, treatment adherence or patient satisfaction, the study results showed that annual cost per patient from a societal perspective was less for nurse and pharmacy worker follow up (USD 44.58 and USD 18.66 respectively) than for doctor follow-up (USD 59.88). Uganda could potentially save USD 4.59 million using nurse follow-up and USD 12.37 million using pharmacy follow-up from a societal perspective at 100% ART access. Although the study notes that task shifting comes with its own unique challenges, it can save sub-Saharan Africa up to USD 2.769 billion and free up to 5.9% full time equivalent doctors. The study suggested that appropriate HIV management training and adequate supervision of lower cadres will be essential to ensure that quality of care is not compromised (30).

There were 84 articles that were assessed in a systematic review to identify the impact of task shifting in Africa. Task shifting allowed various cadres of health staff to use their time more

efficiently, often reducing patient waiting times. An increase in the number of patients initiated on ART as well as more accessible HIV counselling and testing associated with task shifting has improved treatment coverage and adherence in many under-resourced settings. The review recommended that in terms of human resources, the healthcare system should continue to be capacitated, as task-shifting was an inadequate strategy to deal with shortages of all levels of health staff in isolation. Task-shifting has seemingly influenced the social environment within healthcare facilities; the limits to what tasks can be delegated and the roles and responsibilities of each cadre must be clearly defined. In conclusion, the research indicated that task-shifting was a cost effective intervention that played a positive role in expanding access to treatment, particularly in resource-poor settings (8).

Babigumira *et al.* (2011) used a retrospective cohort analysis in an urban HIV clinic in Uganda to compare the cost effectiveness of a pharmacy refill programme compared to a doctor-centred approach. The study was done from a limited societal perspective with 251 patients in the doctor-centred group and 578 in the pharmacy refill group. Stable HIV positive patients who had been on ART for at least 12 months with good self-reported adherence and a CD4 cell count of over 200 cells per microliter were included in the study. The patients allocated to the pharmacy refill arm collected their ART from the pharmacy every month and were reviewed by a doctor every six months. A nurse based at the pharmacy asked each patient a series of screening questions to establish adherence and identify any clinical signs or symptoms that would warrant being reallocated to the doctor-centred standard of care. The costs of the pharmacy refill programme were calculated based on the cost of treatment and tests done, healthcare staff and costs incurred by patients, looking specifically at transportation and loss of time. From a societal perspective, the study found that the pharmacy refill programme (USD 520) cost less than the existing doctor-centred programme (USD 655), and the same was found from a provider perspective. The study provided an alternative form of task shifting that could potentially provide a cost-effective way of allowing under-resourced facilities to deal with increasing patient numbers (31).

2.3 The economic impact of accessing ART

A cross-sectional survey in Cameroon sought to assess whether or not decentralisation of HIV services had a protective effect against catastrophic health expenditure (16). The study population was made up of 2412 respondents who had all been on ART for at least one month. Almost three quarters of the households were living below the poverty line. Over half of the respondents spent 17% of total household income on health, with most of the expenditure being on ART and

transportation. Although the risk of catastrophic spending on health was reduced by providing free access to ART, it did not financially protect the poorest households. Decentralisation, however, appeared to have a significant protective effect. The cost associated with transportation had a stronger impact on catastrophic health expenditure at lower income levels and poor households had a lower risk of catastrophic spending if they were from urban or semi-urban areas. Decentralisation reduced waiting times and patients recorded higher levels of trust in clinic staff but the study shows that, although decentralisation enhanced equitable access to ART, in isolation, it was insufficient in fully removing the risk of catastrophic health expenditure. Recommendations were made to investigate innovative mechanisms of enhancing ART coverage while limiting healthcare expenses.

In another study, 2381 HIV positive patients on ART were followed up in 27 treatment centres across six of the ten provinces of Cameroon (16). Data was collected by using a face-to-face questionnaire and retrospectively collecting clinical data from medical records. Socio-economic and behavioural characteristics such as financial difficulties, food insecurity, binge drinking and discrimination due to HIV status had an impact on adherence levels. In facilities experiencing ARV stock outs, a significantly higher proportion of patients reported financial difficulties and treatment interruptions. Guaranteeing a reliable supply of ARVs is essential for the success of any HIV programme. The study found that in low-income households and/or households living below the poverty line, treatment interruptions were most significantly driven by financial factors. Patients accessing care at larger hospitals had a significantly higher risk of treatment interruption and non-adherence to treatment than those patients followed up at small sized hospitals because the smaller treatment centres provided better financial and geographical accessibility to HIV services (16). A number of studies have been done to estimate the total cost to patients of accessing care for HIV/AIDS. The cost of transportation relative to income has been shown to be substantial, especially for those living in rural areas. Apanga, Punguyire and Adjei (2012) did a cross-sectional retrospective study of 80 patients receiving ART at an outpatient ARV clinic in the centre of Ghana. Using data obtained from patient medical records as well as a pre tested questionnaire, direct costs (monthly fee, additional medication), indirect costs (labour productivity losses) and other costs (transport) were estimated. It was found that the patients spent an extra 38% more than their median annual income to obtain their HIV/AIDS treatment (32).

A cross-sectional survey of 280 households (average of 5 people per household) was done in a rural setting in Mpumalanga, South Africa by Goudge *et al.* (2009). Household expenditure was used to define socio-economic status and the study found that 80% of these households were living below the minimum poverty line as defined by the WHO (below 1 USD per day). 34% of these households

incurred a catastrophic direct cost burden as a result of healthcare expenditure. A visit to a district hospital outpatient department incurred considerably higher cost burdens than clinic visits, equivalent to the cost of a month's supply of the staple starch for an average family. According to national policy, exemptions were available at hospitals for the unemployed or those with social grants, but only 58% of those eligible did not pay a fee at the time of the visit. On average, transport costs accounted for 42% of health expenditure (rising to 51% in the poorest households). The extent of not seeking care suggested that distance to the nearest clinic was a barrier to the sick, elderly and the young, who were unable to cover the distance on foot (33).

Ataguba *et al.* (2009) conducted household surveys and used existing national data to investigate out-of-pocket spending in Ghana, South Africa and Tanzania. The study defined catastrophic health expenditure as "spending more than 10% of total household expenditure on out-of-pocket payments for healthcare". Household spending on healthcare was also used to determine the impoverishing effect of out-of-pocket spending. The research found that in all three countries, compared to urban dwellers, poor and rural households were most likely to experience catastrophic health expenditure and a greater extent of impoverishment as a result. It is interesting to note that of the three countries, South African's out-of-pocket healthcare expenditure had the least impoverishing effect on households (34).

Two studies were conducted in India that looked at the economic impact on households when HIV positive patients accessed treatment and care. In South India, Duraisamy *et al.* (2006) interviewed a cohort of 153 people living with HIV/AIDS. Using a standard questionnaire, out-of-pocket spending on HIV care as well as coping mechanisms employed by households to mitigate these expenses were determined. Direct medical and non-medical costs as well as indirect costs were evaluated. 16% of the cohort was found to be living below the poverty line, with an average household income of 8294 Rupees per month. 49% of total household income was used to cover the cost of HIV care and 67% of the cohort admitted to borrowing money in order to access treatment. The data showed that patients on ART spent five times more on healthcare than non-HIV patients, and the economic burden of HIV care weighed heavily on low income households. Although not significant, uneducated patients spent more on treatment than their educated counterparts (35). In India, many interventions deemed cost-effective by policy makers have remained unaffordable for poor patients in the absence of financial assistance (36).

Causes of out-of-pocket spending on healthcare and consequent catastrophic health expenditure were analysed in Tanzania using data from the Tanzanian National Panel Survey (2). Using logistics

regression models, it was found that for the adult population, being female and having a functional disability significantly increased out-of-pocket spending on health. Average out-of-pocket spending, mostly on service fees and hospital admissions, was USD 2.2 for adults and USD 0.7 for adults over the age of sixty. About one fifth of households in the study experienced catastrophic health spending, significantly associated with living in a household with more than five members and having a household member with a chronic disease. Development and expansion of social welfare services is essential for the reduction of the financial burden of healthcare in low and middle income countries and to improve health seeking behaviour.

HIV/AIDS has established itself as a chronic, treatable disease but has socio-economic consequences unlike any other, necessitating a need to take a closer look at the associated financial implications on households (36). As out-of-pocket healthcare spending increases, access to essential health services becomes less attainable to impoverished households and subsequently results in inadequate health seeking behaviour. Poor households are unlikely to have savings available to cover out-of-pocket health expenditure and are less likely to have the financial capacity to pay back debt if money is borrowed from friends or family. As a result, these households often sacrifice on food and schooling for their children in order to access ongoing healthcare, perpetuating the vicious cycle of poverty and inequity (20).

There is a continuing need to better understand the interactions of poor households with health systems in different contexts. Existing policy interventions, such as free public PHC services and income related exemptions from public hospital fees offer social protection against illness-related impoverishment. Access to ART needs to be expanded without compromising quality of follow-up and care for those people already on treatment and without adding to the financial burden of already impoverished individuals (37). Patients cannot be expected to travel great distances and incur exorbitant costs when receiving life-long treatment. ART needs to be delivered as close as possible to where people live in order to maintain good adherence and encourage good health-seeking behaviour.

*This literature review was conducted accessing a number of databases, including but not limited to Google Scholar and PubMed. Search terms included: HIV, ART, decentralization, task shifting, out-of-pocket spending, direct costs, transport costs, catastrophic costs, etc. Case reports, cohort studies and a number of systematic reviews were included in the literature review.

CHAPTER 3: PAPER 1

Preface:

This article has been submitted to the African Journal of Primary Healthcare and Family Medicine for publication.

Summary:

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ARTICLE TITLE

Patients' perceptions of a rural ART model and its impact on direct out-of-pocket spending

ABSTRACT

Background:

Understaffed PHC facilities are incapable of meeting the populations' healthcare needs in the Eastern Cape, South Africa. Geographical and financial barriers further hamper accessibility to HIV services for rural communities.

Aim:

To ascertain the impact of a decentralised pre-packing model of care on the direct out-of-pocket expenses of patients accessing ART in a rural setting, transport costs of patients travelling to their nearest PHC clinic and those patients from the same geographical area collecting ART from the referral hospital were compared.

Setting:

Zithulele Hospital, the only District Hospital in the KSD municipality, served approximately 130 000 people in the rural Eastern Cape. Of the 4134 patients receiving ART through the hospital's HIV programme, 91% collected their ART pre-packed at their nearest clinic.

Method:

Using a semi-quantitative cross sectional study design, 117 patients from five different PHC collection points and Zithulele Hospital ARV Clinic were interviewed using a standard questionnaire.

Results:

More clinic patients walked to their clinic (71.2% versus 14.6%), leaving hospital patients spending more than clinic patients on monthly transport costs (R71.92 versus R25.81, Anova $F=12.42$, $p=0.0009$). All clinic patients listed their respective clinic as their preferred ART collection point despite recording lower levels of satisfaction with HIV services (89% compared to 95.5%).

Conclusion:

Despite decentralisation and task-shifting to improve accessibility to HIV care, socio-economic and geographical barriers impact healthcare utilisation. For South Africa to achieve universal ART coverage, inequitable healthcare and poverty in rural communities has to be addressed.

INTRODUCTION

With an estimated 5.51 million HIV (Human Immunodeficiency Virus) infected South Africans, HIV/AIDS (Acquired Immune Deficiency Syndrome) contributes significantly to the burden of disease in the country, with far reaching socio-economic implications particularly for poor and vulnerable groups (1). In low- and middle-income countries, health service utilisation is often determined by affordability and accessibility (2) but South Africa, although classified as a middle-income country by the World Bank, also has to contend with unique socio-economic challenges due to the ‘juxtaposition of its first world economic prowess and third world poverty and disrepair’ (3).

The first democratically elected government of South Africa inherited an inequitable healthcare system instigated by the former Apartheid government. Despite a number of changes and implementation of various interventions and new policies, social and economic disparities still persist today, evident in the inequitable health services and living conditions seen in rural, previous Bantustan areas across the country.

Since 80% of South Africans, and especially the poorest quintile of the population, rely exclusively on public sector health services (4), the South African government has increased efforts to integrate HIV/AIDS treatment into primary healthcare (PHC) services. Rural communities account for 46% of South Africa’s population but only 12% of South Africa’s doctors and 19% of the country’s nurses serve in rural healthcare facilities (5). Task shifting and decentralisation of care have reduced the impact of human resource shortages and improved accessibility to ARTs for many affected populations in Africa (6).

According to the World Health Organisation (WHO), successful implementation of PHC services is reliant on geographical accessibility of healthcare facilities. For rural communities, geographical location of healthcare facilities still remains an access barrier to much needed care. Due to poor service availability in rural areas, rural communities often have to travel long distances, exacerbated by poor road infrastructure and unavailability of public transport (7). Rural clinics are situated far from main roads and most rural roads are not tarred and full of potholes, becoming unnavigable during the rainy season. A general absence of affordable and available transportation significantly impacts on continuity of care for many rural households and increases the cost associated with accessing ART.

Socio-economic status remains the main predictor of access to healthcare in South Africa (8) and rural households in the country generally have a lower socio-economic status than those in urban

areas. Based on income, South Africa has one of the highest levels of inequality in the world, with more than two thirds of rural residents and over 55% of rural households living in poverty (9). Rural households in South Africa tend to be larger than urban households with an average of 4.3 household members and an annual household income of R47 847, almost two-and-a-half times smaller than urban household income. Rural households also spend 15.4% of this income on transport (10).

It has been shown that high out-of-pocket health expenditure associated with HIV/AIDS care has a serious impact on vulnerable individuals and is likely to severely affect the wellbeing of the associated household (2). There is also evidence to suggest that geographic inaccessibility of centralised hospital-based ART services and excessive transportation costs may contribute to patient attrition (11) and these barriers are exacerbated in rural populations (12).

Studies have shown the significant protective effect that decentralisation of HIV care has on the socio-economic status of households and how this facilitates access to healthcare (13). As such, the aim of the study was to evaluate to what extent the Zithulele Hospital HIV Programme (ZHHP) had an effect on the out-of-pocket spending and economic status of patients accessing their treatment in this deeply rural Eastern Cape community. Levels of satisfaction with HIV-related healthcare services were also investigated.

RESEARCH METHODS AND DESIGN

Study Design:

A semi-quantitative cross sectional study design was employed.

Setting:

The Eastern Cape Province is the third most populated province in South Africa, accounting for over 6.7 million (12.6%) of the country's population (1). The province is divided into two metropolitan municipalities and six district municipalities. The district municipalities are in turn divided into 37 local municipalities.

The King Sabata Dalindyebo Local Municipality (KSD) lies within the OR Tambo District and is predominantly rural in character. KSD has a population of 451 710 living in 105 240 households. The households have on average four members and 57.3% are female headed (14). Compared to South Africa's national average of 25.5%, unemployment in KSD is high (38.3%, with a youth unemployment rate of 48.3%). Education in the area also leaves much to be desired, with only 18.9%

of the local population over the age of 20 years having achieved a matric qualification while 14% have had no schooling at all, compared to the national averages of 28.9% and 8.6% respectively (10).

Zithulele Hospital is the only District Hospital in the KSD municipality and serves a rural catchment area of approximately 130 000 people. Zithulele Village is roughly 90 km South East of Mthatha and 5 km inland from the northern part of the Eastern Cape's coastline. The hospital serves as a referral centre for 11 PHC Clinics. At the time of the study, 4134 patients were receiving ART through the ZHHP. ART was pre-packed and sent to the clinics for 91% of the enrolled patients.

Study population and sampling strategy:

A group of hospital-based patients was compared to patients accessing ART at a PHC level with regards to accessibility of the facility and associated direct costs and satisfaction with services provided.

Five out of the 11 down-referral clinics were selected as study sites: Jalamba Clinic (266 ART patients – furthest clinic from ZIT along a very bad dirt road), Mpame Clinic (180 ART patients – its geographic location makes it the most difficult to access by road and/or foot), Ngewanguba Community Health Centre (864 ART patients – the largest of the down-referral clinics and more easily accessible due to the tarred road), Wilo Clinic (389 ART patients – one of the more accessible clinics along the tarred road) and Zidindi Clinic (301 ART patients – situated closer to ZIT than most clinics, accessed either by a dirt road or tarred road with a section of dirt road). The clinics were chosen based on their various sizes and accessibility to and from the hospital, providing an adequate mix of dirt versus tarred road accessibility as well as varied distances from ZIT.

The data collected at the clinics was compared to data collected from patients receiving treatment at Zithulele Hospital (895 ART patients of which 525 were on the prepacking system) who were from the same geographical area as one of the five down-referral clinics selected for the study.

In order to be sufficiently powered, a total study sample size of 94 was computed using an online calculator (<http://www.surveysystem.com/sscalc.htm>). This was based on a population of 4134 (total number of patients registered for ART at the ZHHP), confidence level of 0.95 and a confidence interval of 10.

At all the study sites, individuals were excluded from interviews if they:

- were less than 18 years of age
- had been on ART for less than a month

- were not prepared to give informed consent to participate in the study

The ZHHP clinic-based visits are done by the outreach team from Monday to Thursday and all 11 clinics are visited in a two week cycle. Hospital-based patients are seen on the ZIT ARV clinic days every Wednesday (for adult patients) and Thursday (for paediatric patients and pregnant women). Study sites were visited according to this standard two week cycle.

Participants were selected on the day of the interview while sitting in the clinic's waiting room. Selection took place as follows: (i) patients would register their attendance to the clinic for the day where they would be checked for conformity to the eligibility criteria (ii) if eligible, the patient would be taken to a private consulting room where the aim of the study and the purpose of the interview was clearly explained (Appendix 2 & 3) and participation in the study was proposed (iii) signed informed consent was obtained (Appendix 2 & 3) (iv) the patient was then interviewed face-to-face by a research assistant in the language of their choice, using a structured questionnaire (Appendix 1) (v) on completion of the interview, the patient resumed his/her position in the queue to be seen by the medical team, as per normal. For the sample size to be sufficiently large, 15 patients at each down-referral study site were interviewed to make up the clinic-based group. Patients from those same geographic areas who were still accessing their ART at ZIT were identified for the hospital-based group. Attempts were made to include the same number of participants in the clinic-based and hospital-based groups from each geographical area.

The research assistants received specific training on the questionnaire by the principal investigator in order to achieve inter-reviewer reliability. Face validation of the questionnaire was performed by experts and staff at the University of KwaZulu-Natal.

Data collection:

Data collection took place between 01 April 2014 and 18 April 2014. A total selection of 123 participants was done and all 123 individuals provided informed consent to be interviewed for the study.

Patient demographic data such as age, gender and race was recorded. Additional patient characteristics identified included the level of education obtained, employment status, ART collection site and, for those patients collecting their ART at Zithulele Hospital, the clinic located nearest to their home.

Clinic records were reviewed to retrieve data on the patients' date of ART initiation, CD4 cell count at ART initiation and most recent CD4 cell count and viral load. These record reviews were conducted at the same time as the interview since patients collected their medical records on arrival when registering for the clinic.

Individuals socio-economic characteristics collected through the interview included: size of the household, number of known HIV positive individuals in the household and the number of these on ART, total monthly household income and sources thereof, mode of transportation to the hospital/clinic, transportation time to the hospital/clinic and any expenses incurred on the day, specifically for transportation and meals purchased.

The questionnaire explored transportation costs based on patient reported outpatient visits in the 30 days preceding the interview. The public transport from the road-stop closest to the patients' home to the clinic/hospital was assessed. In order to better understand the factor of the distances covered by foot, walking times were also noted.

Enquiries were made regarding the level of satisfaction with the service provided at the ART collection site. The participants were asked to identify areas of dissatisfaction and to make suggestions for service improvements at their respective facilities.

Interviews were conducted in one of the consulting rooms in the clinic, creating a private space to facilitate an open and confidential encounter. The structured questionnaire was used by the research assistants to conduct the interviews. The interviews took between ten and fifteen minutes per participant. The principal investigator was not present at all of the interviews, but data collection forms were reviewed every day after completion of the field work to ensure data quality.

Data analysis:

Data was coded, entered and verified using a Microsoft Excel Workbook. Descriptive statistics including means, medians, standard deviations and inter-quartile ranges were automatically calculated and summary tables generated for demographic and clinical characteristics of the sample groups.

In order to analyse data pertaining to age, gender, education and employment, the one-way Anova (F-test) was used to test differences in means between hospital-based and clinic-based patients while Chi-square tests were done to analyse the relationship between categorical variables.

In order to assess the economic status of each household, income per household member per month was calculated. This was done by dividing the total household income per month by the number of members in that household. Based on these figures, an additional categorical variable was created, which indicated whether income per household member per month was

- (i) below the food poverty line of R400
- (ii) between the food poverty line and lower-bound poverty line of R544
- (iii) between the lower-bound poverty line and the upper-bound poverty line of R753 or;
- (iv) above the upper-bound poverty line

These values were based on the March 2014 figures published by Statistics South Africa. (9).

Total expenditure incurred to access ART was calculated by adding the transport costs with additional costs incurred and multiplying this by the number of patient-reported facility visits in the 30 days preceding the interview. This amount and the total household income was then used to calculate the percentage of total household income utilised to access ART.

The monthly per capita household income was recalculated after subtracting total expenditure incurred and results were then analysed again to determine if the individual's economic status according to the 4 categories had changed. Regression analysis was used to determine if expenditure incurred to access ART was significantly different for hospital and down-referred patients.

The regression framework is characterized by having a dependent variable of interest that can be better understood or modelled by making use of other independent variables to predict the value of the dependent variable. Regression analysis was therefore used to better understand monthly transport costs between hospital and clinic patients by modelling the relationship between the transport costs and hospital versus clinic ART collection sites. Odds ratios were adjusted using multi-variate logistic regression, and the related p-value was based on the Wald test. The level of significance was set at $p < 0.05$ and a 95% confidence interval. All data was analysed using the SAS System.

Ethical considerations:

The study and questionnaire was reviewed and received full ethics approval from the Biomedical Research Ethics Committee, University of KwaZulu-Natal (BE277/13). To conduct the interviews and collect patient data at the healthcare facilities, permission was sought and granted by the Zithulele Hospital HIV Programme Manager and the Zithulele Hospital Manager.

Written informed consent was obtained separately for the interview from each participant and anonymity of the participants was maintained during the data collection, analysis and reporting of results.

RESULTS

Out of 123 eligible patients who were randomly selected, all 123 agreed to participate in the study. The sample size was finalised at 117 participants as six of the questionnaires had to be rejected due to missing/incomplete data, giving a global response rate of 95.1%. There were 73 clinic-based and 44 hospital-based participants.

All of the study participants were isiXhosa speaking Black Africans. As indicated in Table 1, of the 117 participants, 31 (26.5%) were male and 86 (73.5%) were female. There was no significant difference between hospital-based and clinic-based patients in terms of gender (chi-square = 0.0219, $p=0.8825$). There was a significant difference between the hospital-based and clinic-based patients in terms of their actual age (37.1 years versus 42.2 years respectively, Anova $F=4.81$, $p=0.0303$) but when categorised into age bands there was no reported significant difference (chi-square=5.112, $p=0.4024$).

In terms of the level of education attained, there were significant differences between hospital and clinic patients (chi-square=6.47, $p=0.004$). Just over 30% of the clinic-based patients had no schooling compared to 7% of the hospital-based patients. Significantly more hospital-based patients had secondary schooling compared to the clinic-based patients, 60.5% versus 26.4% respectively.

Clinic-based patients achieved slightly better clinical outcomes than the hospital-based patients, although none of these differences were significant. The mean CD4 cell count at initiation of ART was slightly higher among clinic-based patients (167 cells/mm³ versus 156 cells/mm³). Although the clinic-based patients had a shorter mean duration on ART (33.23 months compared to 37.73 months for hospital-based patients), the mean CD4 increase was higher in the clinic-based group, although not significantly so (t-test $F=0.23$, $p=0.6329$). 91% of the clinic-based patients were virally suppressed while only 84% of the hospital-based patients had achieved an undetectable viral load.

The average household was comprised of 5.5 members with 2.2 being below 12 years of age. 1.5 members per household were HIV positive and on ART. Only seven out of the total study sample of 117 patients had some form of employment. The average monthly household income was R1653 (R301.05 per capita) for hospital-based patients and R1617 (R392.66 per capita) for clinic-based patients, predominantly sourced from either child support or pension grants (98 households and 50

households respectively). Monthly per capita income was not significantly different between the two study groups (Anova $F=0.8$, $p=0.3734$).

75% of hospital-based patients and 68.5% of clinic-based patients were living below the food poverty line of R400 per month. 93% of the study participants were classified as poor i.e. living below the upper bound poverty line of R753 per month. The economic status of the hospital-based patients was not significantly different to that of the clinic-based patients (chi-square=0.6822, $p=0.8774$).

Mode of transport to access ART was significantly different between hospital- and clinic-based patients (chi-square=34.9183, $p=0.0001$). A higher proportion of hospital-based patients used taxis (80.5% versus 28.8%) while more clinic-based patients walked to the facility for their treatment (71.2% versus 14.6%). When asked why they walk to their respective healthcare facilities, just under half of the clinic-based patients answered that it was because taxi fare was unaffordable and a fifth of the patients lived close enough to the clinic for walking to be a viable mode of transport. Clinic-based patients did, on average, walk for longer periods of time than hospital-based patients although this was not significantly different (Anova $F=1.67$, $p=0.2026$).

In terms of monthly transport costs, hospital-based patients spent on average R71.92, significantly more than the R25.81 spent by clinic-based patients (Anova $F=12.42$, $p=0.0009$). This was specifically as a result of the transport costs associated with Ngcwanguba CHC and Wilo Clinic being significantly different to those of Zithulele Hospital patients ($p=0.0175$ and $p=0.0072$ respectively). With a point estimate of 1.169, regression analysis indicated that for every one Rand increase in transport costs, the odds of the patient being hospital-based rather than clinic-based is 16.9% higher.

When considering all direct out-of-pocket expenditure related to accessing ART (transportation and meals while waiting), clinic-based users had a lower mean cost per month compared with hospital-based patients and this saving was statistically different for all down-referral clinic sites included in the study (Anova $F=13.27$, $p<0.0001$).

There were higher levels of satisfaction recorded amongst the hospital-based group (95.5% compared to 89%) but despite this, 100% of the clinic-based patients listed their respective clinic as their preferred ART collection point. Despite being satisfied with the level of care at the hospital, just over a fifth of the hospital-based patients would prefer to collect their ART and receive HIV care at their nearest clinic.

	All participants	Hospital patients	Clinic patients	Test value	p-value
Male	31 (26.5%)	12	19	Chi-square = 0.0219	0.8825
Female	86 (73.5%)	32	54		
Age		37.1 years (sd 11.24)	42.2 (sd 12.73)	Anova (F=4.81)	0.0303
<20 years	7	4	3	Chi-square = 5.112	0.4024
20 – 30 years	22	10	12		
30 – 40 years	41	16	25		
40 – 50 years	28	10	18		
50– 60 years	10	1	9		
>60 years	9	3	6		
Education				Chi-square = 6.47	0.0004
None	25	3	22		
Primary school	37	10	27		
Secondary school	45	26	19		
Matric and higher	8	4	4		
Employed	7 (5.9%)	4 (9.1%)	3 (4.1%)	Chi-square = 1.211	0.2711
Unemployed	110 (94.1%)	40 (90.9%)	70 (95.9%)		
Duration on ART		37.73 months	33.23 months	Anova (F=0.97)	0.3262
Baseline CD4	163.09	156.30	167.33	t-test (F=0.3)	0.5875
Most recent CD4	464.41	453.70	470.99	t-test (F=0.15)	0.6985
CD4 increase	351.88	339.56	359.03	t-test (F=0.23)	0.6329
Undetectable viral load	88%	84%	91%	Chi-square = 1.1694	0.2795
Household size: Total	5.5	5.9	5.3		
12 years and older	3.3	3.6	3.1		
Under 12 years	2.2	2.3	2.2		
Total monthly household income	R1630	R1653	R1617		
Monthly income per capita	R358.21	R301.05	R392.66	Anova (F=0.8)	0.3734
Economic status				Chi-square = 0.6822	0.8774
Below the FPL	83 (70.9%)	33 (75%)	50 (68.5%)		
Between the FPL and LBPL	18 (15.4%)	5 (11.4%)	13 (17.8%)		
Between the LBPL and UBPL	8 (6.8%)	5 (11.4%)	3 (4.1%)		
Above the UBPL	8 (6.8%)	1 (2.2%)	7 (9.6%)		

Table 1: Data collected comparing the hospital-based and clinic-based sample groups

DISCUSSION

The gender make-up of the hospital-based and clinic-based participants was not significantly different, with 27.3% and 26% males and 72.3% and 74% females, respectively. This was a good representation of the ZHHP who have 27.6% males and 72.4% females registered for treatment. Given the lack of resources, the hospital provides excellent antenatal care with a high uptake of HIV counselling and testing within the female population. This together with the literature showing that men identify health seeking behaviour as a sign of weakness (15) explains the large proportion of females on treatment, comparable to the national average of 68% females on ART. The majority of the participants were between the ages of 30 and 40 years for both hospital-based and clinic-based groups. Although there was no significant difference between the hospital-based and clinic-based groups when analysing age categories, analysis of the actual ages of study participants indicated that the mean age of 42 years for clinic-based patients was significantly older than the average 37.1 years recorded for the hospital-based patients ($p=0.0303$). Well over two-thirds of the hospital-based group was female and as such, the difference in age between the hospital- and clinic-based groups can be explained by the HIV positive mothers who are not down-referred since the vast majority of paediatric patients on ART are managed at the Zithulele hospital ARV clinic.

Despite clinic-based patients recording slightly better clinical data, there were no significant differences between the two groups with regard to the most recent CD4 cell count or that at initiation, and since the respective means and medians are similar, any outliers had minimal impact on these results. The clinic-based patients were initiated on ART at a higher CD4 cell count (167 cells/mm³ compared to 156 cells/mm³ of hospital-based patients) and also showed a slightly better increase in CD4 cell count since initiation on ART despite being on treatment for a shorter duration than hospital-based participants (33.2 months versus 37.7 months). This supports the idea that earlier initiation of ART at higher CD4 cell counts facilitates a better immune response (16). Only 84% of the hospital-based patients were virally suppressed compared to 91% of the clinic-based group. Complicated cases that need ongoing management by a doctor are usually up-referred, back to the Zithulele Hospital ARV clinic. This practice is confirmed by the higher number of virally suppressed participants seen in the clinic-based group.

Both hospital-based (90.9%) and clinic-based (95.9%) groups had unemployment rates far exceeding the 38.3% average listed for the KSD Municipality (14). The deeply rural nature of

the area does not lend itself to employment opportunities and most households rely on subsistence farming and social welfare support to get by. The extreme unemployment rates are perpetuated by the low levels of education that have been identified. The clinic-based participants had significantly lower levels of education and 59.7% were functionally illiterate. Three fifths of the hospital-based patients had achieved some level of secondary schooling. The literature shows that rural residents and individuals with low levels of educations find it more difficult to access HIV services (17) and are less likely to utilise these services, increasing out-of-pocket spending in the long run (2).

According to Statistics South Africa, the KSD municipal households have a mean of four people per household (14). With 5.5 members, the households accounted for in the study that fall within the Zithulele catchment area are slightly larger. On average the households comprise of 3.3 adults over the age of 12 years and 2.2 children under the age of 12 years.

There was no significant difference between hospital-based patients and clinic-based patients with regards to total monthly household income and monthly per capita income. With monthly per capita income of R301.05 and R392.66 respectively, the average hospital-based and clinic-based patient is living below the food poverty line of R400 per month. Where employment opportunities are scarce, levels of education low and inequity high, it is not surprising that over 70% of the study sample lived below the food poverty line and 93% are poor by definition. Only eight participants (one hospital-based and seven clinic-based) lived above the upper bound food poverty line of R753 per month. Although subsistence farming as a non-monetary source of income was not investigated, research has shown that it reduces vulnerability of rural populations and helps to mitigate the growing cost of food (18). Social grants play a tangible role in improving poverty levels and have become a source of income that the vast majority of this rural population depends on to survive. Reportedly, 98 of the households were receiving at least one child support grant and 50 households had one elderly member collecting pension money every month. Additionally, free PHC and free access to ART and HIV services as part of the South African government's social welfare 'package', further financially protects vulnerable individuals and households from the economic impact of HIV. With very little employment opportunity, absence of household members due to temporary migration for employment reasons is very common in the rural Eastern Cape. According to South Africa's 2011 Census, 436 466 people migrated out of the Eastern Cape, predominantly to the Western Cape and Gauteng (10). While remittance of wage earnings as

a source of income for rural households is a positive result, migration has the negative impact of driving HIV transmission.

For rural communities, access to essential health services such as ART, are often dependent on the geographical location of healthcare facilities and availability/presence of public transport (12). The mode of transport used to access ART was significantly different in the two study groups: while over 80% of hospital-based patients used local taxis, over 70% of clinic-based patients walked to their respective clinics on appointment days. For hospital-based patients, the distance that needed to be covered in order to reach the HIV clinic was too far to go by foot, so at an average monthly transport cost of R71.92, taxi transport was used. The road to Zithulele Hospital is tarred and this improved infrastructure has remarkably increased accessibility to the hospital. Hospital-based patients that walked every month stated that taxi fare was unaffordable and that they lived close enough to the hospital to travel on foot within a day. The average walking time for hospital-based patients was two hours. Clinic-based patients spent an average amount of R25.81 on transportation costs per month, significantly less than hospital-based patients ($p=0.0009$). By decentralising HIV services and pre-packing ART for patients at all the clinics, treatment sites have been moved closer to patient homes within the communities. The overall burden of accessing ART and particularly the related cost of transport has been minimised. Poor conditions of the roads to the clinics remain an access barrier and over 30% of clinic-based patients reported that public transport was not available between their homes and their healthcare facility. As indicated by the clinical data, patients demonstrate ongoing commitment to treatment adherence despite the geographical and transportation barriers identified.

The total monthly direct out-of-pocket expenditure of R21.35 for clinic-based patients was significantly lower than the R98.50 calculated for hospital-based patients. The reduction in direct out-of-pocket spending seen in the clinic-based group is associated with decentralisation and the pre-packing model. By moving HIV services closer to patients' homes, accessibility and associated cost of accessing ART is significantly reduced since the distance to the facility is shorter, taxi fares are cheaper and the waiting times are reduced. The lowered costs may contribute to the economic protection of the households in this rural area. Hospital-based patients were more satisfied with the level of care provided than clinic-based patients. Positive themes consistent in both groups included the fact that patients were receiving excellent counselling and being taught a lot about HIV and their treatment. Patients

were satisfied with the amount of time they were spending at their respective facility on appointment days and hospital-based patients in particular were complimentary of the queuing system, which they felt facilitated good patient flow. Hospital-based patients felt they were always informed of where they were meant to go and what they had to do on their appointment days. Hospital-based patients were largely dissatisfied with the infrastructure of the Zithulele Hospital HIV clinic, complaining that the toilets were not usable and that the building was too small and too old for all of the patients to use.

Hospital-based patients commented on the more private nature of their treatment collection and consultations and they were generally more positive with regards to their experiences with healthcare workers. Despite the many compliments for the Zithulele Hospital HIV clinic staff, patients felt the facility was understaffed and criticised the nurses' handling of administrative tasks, such as providing the paperwork required for patients to transfer to another province/facility. In the Eastern Cape where the nurse vacancy rate is 67%, task shifting of HIV management from doctors to nurses has not relieved the effects of healthcare worker shortages. Clinic-based patients were also unhappy with the number of staff employed at the facilities and there were remarkably more complaints about the attitudes and poor treatment of patients by clinic nurses. Between one and three nurses were employed at the five down-referral sites included in the study, highlighting the critical shortage of qualified staff at PHC level. Since a large number of the clinic-based patients have received some care at Zithulele Hospital since initiating ART, their expectations may have been raised by the availability of doctors and more experienced nurses (11).

Availability of treatment was praised by both hospital- and clinic-based groups and a number of participants went as far as saying that they had never been turned away without their ART. The literature shows that inconsistent and unreliable supply of ART as a result of insufficient qualified staff capable of managing stock, has been known to cause treatment interruptions (17). Guaranteeing reliable availability of ART promotes positive health seeking behaviour, improves equity in access to HIV care and also minimises out-of-pocket spending on multiple, avoidable trips to healthcare facilities. As such, continued reliable availability of treatment will be critical for successful scaling up of the ART programme, both at Zithulele Hospital and nationally.

The challenge that the geographical location of the rural healthcare facilities pose for patients has been confirmed. Patients criticised the poor condition of dirt roads, especially at Jalamba

and Zidindi Clinics; and also voiced their concern for their safety when having to cross rivers and pass through “dangerous” forests to access their treatment. These factors played an important role in determining which facility was used. Asymptomatic patients inevitably preferred to continue collecting their ART at a healthcare facility close to their home.

Limitations

Due to time constraints, the study had a small sample size. The potential bearing of participant selection bias is relatively limited given the 100% participation rate. The study did not, however, take into account those individuals who did not seek care and, as such, there may be selection bias towards more motivated patients. Additionally, only five out of eleven of the down-referral clinics were included in the study. Those facilities that were not included could possibly have impacted the study results. The way in which participants and the study sites were selected may also potentially contribute to selection bias.

Although the hospital-based and clinic-based group characteristics were tested for any significant difference, there is the risk that the two groups also differed with respect to some unmeasured factor. No distinction between the different stages of HIV was made and this could have affected out-of-pocket expenditure and the number of clinic and/or hospital visits in the preceding month.

Participant self-reporting may be subject to recall and social desirability bias. These have the potential to result in under-reporting and possible underestimation of negative factors.

Administration of the questionnaire by interviewers who were independent of hospital staff may have reduced the risk of social desirability.

CONCLUSION

A large proportion of the South African population lives in rural areas, and for these rural residents, the geographical location and unavailability of public transport are persisting barriers to utilisation of healthcare services. Decentralisation of HIV care to PHC level improves accessibility to ART to a limited extent and has been shown to minimise out-of-pocket spending. In order to scale up existing ART programmes, healthcare worker deficits must be addressed through implementation of rural retention policies that will encourage more clinical staff to live and work in rural areas. Additionally, PHC services and infrastructure must be resuscitated to a level that is acceptable to healthcare users and patients alike.

Since 1994, health-related legislation and policy changes in South Africa have been commendable but inadequate in fully addressing the inequitable access to healthcare services experienced by many vulnerable communities. Despite social grants and free PHC and HIV services, most South Africans remain severely impoverished with significant socio-economic barriers to accessing healthcare. South Africa has the largest ART programme in the world yet has only managed to provide ART to less than 40% of HIV positive individuals who are eligible for treatment (19).

Since affordability, more so than the need for healthcare services determines out-of-pocket spending (2), measures must be taken to improve the capacity of households to generate income so as to mitigate the financial burden of HIV. Furthermore, in depth analysis focusing on the economic impact of HIV on rural, impoverished communities must be done as these resource limited settings present unique challenges to patients and the health system alike.

Systems changes must be well informed and the social, geographical and cultural context of the population seeking and utilising healthcare should be considered before interventions are implemented (20). From a policy perspective this can partly be achieved through a better understanding of the factors associated with out-of-pocket spending on health (2).

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Competing interests

The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.

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CHAPTER 4: RECOMMENDATIONS AND CONCLUSION

The results of this study suggests that there is a need to better understand the socio-economic background of various communities and how subsequent barriers impact on their interaction with the health system. Despite decentralisation of ART to PHC facilities, the study suggests that long travel times and poor or sometimes absent public transportation as a result of the geographic location of healthcare facilities are persistent barriers to HIV care for poor rural residents.

In January 2015, South African HIV programme changes will be implemented reducing the eligibility criteria for initiation of ART to a CD4 cell count of 500 cells/mm³. As the number of ART eligible individuals increases and the longevity of the HIV program is realised, preserving the quality of care provided and ensuring the necessary support for the healthcare system will need to be a key focus area for the South African government. Strategies to sustain long-term adherence to treatment will need to be developed, requiring both psychosocial support for HIV positive individuals on ART as well as general health system strengthening.

For rural populations specifically, there is an obvious need for more equitable healthcare financing, improved accessibility to healthcare facilities and urgent improvements in the critical human resource deficits. Task shifting remains a useful intervention that improves utilization of the various healthcare workers' skills and time but it is important to outline clear roles and responsibilities of each cadre and ensure that lower cadres such as lay counsellors and community health workers are appropriately remunerated for their services. It will also become vital to address issues related to human resource retention in rural healthcare facilities if the long term success of the HIV programme is to be achieved.

The levels of poverty and unemployment witnessed in this study were astounding and far exceeded the statistics recorded in the literature (12). As much as social grants have aided rural and poor households and provided a certain level of financial protection, on the basis of the findings of this study, there is still a clear need for social welfare reform. Sustainable interventions to improve the poverty levels of rural households must be investigated.

Education levels need to be addressed and employment opportunities created to ensure that rural communities do not remain victims of the poverty trap.

Due to their consistent, long-term use of healthcare services, people with chronic conditions

are recognised as a vulnerable group in terms of out-of-pocket spending. For poor patients the accumulated expenditure on accessing healthcare services on an ongoing basis can easily become an unbearable financial burden. In order to encourage and improve the health seeking behavior of poor communities, methods to financially protect poor households from the financial impact of out-of-pocket spending need to be explored. The South African government has taken reasonable steps to remove economic obstacles that can lead to ART interruptions by providing free PHC and HIV services in the public sector, but further economic analysis is necessary to determine the additional financial challenges faced by rural HIV positive patients when accessing ART.

The study highlights the challenge households face of financing long-term ART in cases of extreme poverty and identifies the need to investigate how poor South African households cope with the financial burden of accessing healthcare services. Obstacles to increasing the number of ART sites in rural areas must be determined and allocation of resources to healthcare facilities should address the inequities in access to healthcare and be based on population need. Further research should be done to determine the total out-of-pocket expenditure incurred by deeply rural populations including payment for traditional healers and private healthcare services. There seems to be a growing need to advocate for financial support of unemployed and impoverished patients to improve adherence and ensure the future success of the South African HIV programme.

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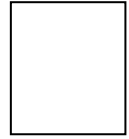
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APPENDIX 1: DATA COLLECTION FORM

Questionnaire

Demographic characteristics:



- Age _____
- Gender
 - Male Female
- Race
 - White African Indian Other
- Educational qualification
 - Never went to school Primary school (Grade _____)
 - High school (Grade _____) Tertiary education
- Employment
 - Unemployed Employed

Clinical characteristics

- ART start date: _____
- Baseline CD4 _____
- Most recent CD4 _____
- Most recent VL _____

ART collection point

- Zithulele Hospital Jalamba Mpame Wilo Zidindi NGC

Nearest clinic

- Jalamba Mpame Wilo Zidindi NGC

1. How many people live in your household? _____

● Adults & children over the age of 12 _____

● Children under the age of 12 _____

2. How many of the people living in your household are HIV positive?

● _____

3. How many of the people living in your household are taking ARVs?

● _____

4. What is the household's total monthly income?

● _____

5. What is the source of this income?

Grant (R _____) Pension (R _____) Local employment (R _____)

Migrant labour (R _____) Other _____ (R _____)

6. How do you get to the ARV clinic/hospital every month?

Walk Taxi Own car Lift Other _____

7. If you walk, is it because

You live close enough to the clinic (It takes _____ to walk to the clinic)

You can't afford to pay the taxi fare

There is no public transport available

8. If you travel by taxi/own car/lift, what does your transport cost per visit (return trip)?

R _____

9. In the past month, how often have you travelled to the clinic/hospital for ART purposes?

Clinic _____ Hospital _____

10. Are there any other costs that you have incurred as a result of:

Coming to the **clinic**: Yes (R _____) No

Coming to the **hospital**: Yes (R _____) No

11. How much of your day do you spend for collection of your medicines at:

The **clinic**: _____ The **hospital**: _____

12. Are you happy with the service provided?

- 1 Dissatisfied
- 2 Neutral
- 3 Satisfied

13. What about the service are you satisfied with?

14. What about the service are you dissatisfied with? Suggestions for improvement?

**15. Do you prefer getting your ART from the clinic or the hospital?
Why?**

END

APPENDIX 2: INFORMED CONSENT FORM



ZITHULELE HOSPITAL

Province of the Eastern Cape • Iphondo leMpuma-Koloni

Department of Health • Isebe leZempilo

This informed consent form is for users of the Zithulele Hospital ARV clinic and its down-referral sites who we are inviting to participate in research, titled “Out-of-pocket spending of HIV positive patients receiving ART in the rural Eastern Cape – The impact of a down referral model”

The principle investigator is Monique Lines who is working towards a Master in Pharmacy (Pharmacoeconomics) through the University of Kwazulu Natal. Professor Fatima Suleman is the project supervisor.

This Informed Consent Form has two parts:

1. Information Sheet (to share information about the study with you)
2. Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form.

Part I: Information Sheet

Introduction

I am Monique Lines, working as the pharmacist at Zithulele Hospital. I am doing research on the ARV down-referral system and trying to establish if it has reduced the amount of money that patients spend on transport when they collect ARVs or see the doctor. I also want to see if patients are happy with the service provided. This consent form may contain words that you don't understand. Please ask me to stop as we go through the information and I will take time to explain. If you have any questions later, you can ask them of me.

Purpose of the research

Although ARV treatment is provided free of charge, you still spend money in order to remain compliant with treatment. I want to learn how much money you spend on transport and other costs every month to collect your treatment and I also want to establish whether or not down-referral to your nearest clinic is reducing the amount of money you spend.

I also want to learn whether or not you are happy with the service provided at the ARV clinic i.e. what you like about the service and what you don't like about the service and would like to see improve. This information will help us to improve the ARV clinic and your experience in it.

Type of Research Intervention

This research will involve you answering a questionnaire which I will go through with you. It will take about thirty minutes of your time.

Participant Selection

You have been randomly selected to take part in this research. Participants are being selected from Zithulele Hospital, Wilo clinic, Zidindi clinic and Jalamba clinic.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all services you receive at the ARV clinic will continue and nothing will change. If you agree to participate, you are free to withdraw from the research at any time and there will be no negative consequences if you do withdraw.

Procedures

I am asking you to help me learn more about patient spending on transport to access ARV treatment. I am inviting you to take part in this research project. If you accept, you will be asked to complete a questionnaire which I will read out to you. You can say out loud the answer you want me to write down. The questionnaire will be done on the day that you are scheduled to come to the clinic. If you do not wish to answer any of the questions during the interview, you may say so and I will move on to the next question. No one else but I and the translator will be present unless you would like someone else to be there. The information recorded is confidential and your name is not being recorded on the forms. Only a number will identify you, and no one else except me and my supervisor will have access to your answered questionnaire.

Duration

The research will take place over 2 months in total. During this time you will only have to complete the one questionnaire that will take approximately thirty minutes.

Risks

I am going to ask you to share some very personal and confidential information and you may feel uncomfortable talking about some of the topics. You do not have to answer any question if you do not wish to do so. You do not need to give me any reason for not responding to any question or for refusing to take part in the questionnaire.

Benefits

There will be no direct benefit to you, but your participation is likely to help me find out more about the extent of out of pocket spending and if the ARV down-referral system has had a positive or negative impact on this. It will also help to highlight what about the ARV service is good and what needs to be improved in order to improve patients' experience.

Reimbursements

You will not be provided any incentive to take part in the research.

Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from the research project will be kept private and any information about you will have a number on it instead of a name. Only I will know what your number is and that information will be kept under lock and key. It will not be shared with or given to anyone except Prof Fatima Suleman, the research project supervisor.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and choosing to participate will not affect your clinical treatment in any way. You may stop participating in the questionnaire at any time that you wish without your treatment being affected. I will give you an opportunity at the end of the questionnaire to review your answers and you can ask to modify or remove portions of these as you see fit.

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact

Monique Lines at the Zithulele Hospital Pharmacy (contact number 074 7572260).

This proposal has been reviewed and approved by the University of Kwazulu Natal's Humanities and Social Sciences Research Ethics Committee whose task it is to make sure that research participants are protected from harm.

Part II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print name of participant _____

Signature of participant _____

Date (day/month/year) _____

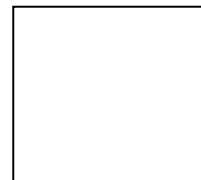
If illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ Thumb print of participant

Signature of witness _____

Date (day/month/year) _____



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands what will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Print name of researcher/person taking the consent _____

Date (day/month/year) _____

APPENDIX 3: TRANSLATED INFORMED CONSENT FORM IN isiXhosa



ZITHULELE HOSPITAL Province of the Eastern Cape • Iphondo leMpuma-Koloni Department of Health • Isebe leZempilo

Le fomu yodliwano ndlebe yeyabantu abathatha izithomalalisi zabo kwisibhedlele sase zithulele kunye neekilini ezingqongileyo apho izithulele ibathumela khona abantu ukuba bafumene izithomalalisi zabo kufutshane neendawo abahlala kuzo, abamenywayo ukuba bathathe inxaxheba kolu phando, olubizwa ngokuba “ Isibonelelo kubantu abanentsholongwane kagawulayo abafumana izithomalalisi kwiphondo Lempuma Koloni-
Indima okanye injongo yosondezwa kunyango.”

Umqulunqi woluphando ngu Monique Lines ofunda ngezifundo zengcali kwicandelo lwamachiza kwi Dyunivesi yakwa Zulu Natala. Unjingalwazi Fatima Sueman ngumkhokeli wale project.

Le fomu yodliwano ndlebe inezigaba ezibini:

1. Iphepha elinenkcukacha ngolu phando (apho sokwabelana ngenkcukacha malunga nesisifundo).
2. Isatifiketi sodliwano ndlebe (oyothi usisayine ukuba ukhethe ukuthatha inxaxheba kudliwano ndlebe.

Uyawukinikezwa ifomu epheleleyo yoludliwano ndlebe.

Isigaba sokuqala: Ifomu enenkcukacha

Ukuzazisa

Ndingu Monique Lines, kwaye ndenza uphando ngenqubo yokuthunyelwa kwabantu abufumana izithomalalisi zentsholongwane kagawulayo ezikilini ezikufutshane kubo, kwaye ndizama nokufumanisa ukuba ngaba ukuthunyelwa kwabantu ezikilini kulinciphisile na ixabiso lemali ebelichitha kwizithuthi besiza esibhedlele bezothatha izithomalalisi babone nogqirha. Ndifuna nokuqonda ukuba ngaba izigulane ziyakuvuyela na okokuthunyelwa ezikilini. Lefomu yodliwano ndlebe isenoba namagama ongangawaqondi. Nceda ucele ukuba ndime xa ungaqondi, ndawuzinika ixesha lokuba ndikucacisele. Ukuba uphinde wanemibuzo ekuhambeni kwexesha ungaphinda undibuze ngayo.

Injongo yoluphando

Njengokuba siyazi ukuba amachiza kagawulayo akakhutshelwa mali afumaneka simahla, kodwa ukuze uqhubekele nokufumana unyango lwakho kufuneka uchithe imali. Ndifuna ukwazi ukuba yimalini na oyichitha kwizithuthi zikawonke wonke nakwezinye inkcitho ngenyanga nganye uzothatha izithomalalisi zakho. Kwaye ndifuna ukwazi ukuba ngaba ukuziselwa kwakho amayeza kufutshane nalapho uhlala khona okanye kwikilini ekufutshane kuwe kuyayinciphisa na imali oyichithayo.

Kwaye ndifuna ukwazi ukuba uyalonwabela na uncedo olufumana kwikilini yezithomalalisi, uthanda ntoni ngoluncedo, zintoni ozithandayo, sifuna ukwazi ukuba singaphucula ndawoni na. Olulwazi luyakusinceda ukuba siphucule ikilini kunye namava akho ngayo.

Uhlobo longenelelo phando

Oluphando lwenza ukuba uphendule imibuzo endizakuncedisana nawe kuyo ukuyiphendula. Ndiza kuthatha kangangemizuzu egamashumi amathathu yexesha lakho.

Ukhethe lwabathathi nxaxheba

Ukhethwa nje ukuba uthathe inxaxheba koluphando. Abathatha inxaxheba bakhethwa kwisibhedlele sase Zithulele, Wilo kiliniki, Zidindi kiliniki, nase Jalamba kiliniki.

Ukuthatha inxaxheba ngokuzinikela

Inxaxheba yakho koluphando iyawuba yebonelelayo (awujonge ntlawulo). Uyawuzikhethele ukuthatha inxaxheba okanye hayi. Nokuba awuthathanga nxaxheba uhoyo olufumana e ARV kiliniki luzoqhubeka akukho nto izotshintsha. Ukuba uvumile ukuthatha inxaxheba uvumelekile ukuba ungarhoxa koluphando naninina kwaye awuyi kufumana zinkathazo ngokurhoxa.

Imigaqo

Ndicela nindifundise malunga neendleko zezigulana ekukhweleni izithuthi zikawonke wonke ukuzakufumana izithomalalisi (ARV's).

Ndiyanimema ukuba nithathe inxaxheba kulenkqubo yoluphando. Ukuba uyakwamnkela oku, uyakucelwa ukuba uzalise ifomu enemibuzo endiyawuthi ndikufundele yona. Ungaphendula ngomlomo impendulo ofuna ukuba ndiyibhale phantsi. Uphendulo mibuzo luyakwenziwa ngosuku olubekelweyo ukuba uze ngalo ekilini, ukuba uthanda ukuba ungaphenduli mibuzo ngethuba lovavanyo, ungatsho ndawudlulela kumbuzo olandelayo. Akusoyi kubakho omnye umntu iyawukuba ndim kuphela notoliki oyawubakho kunye nomnye umntu ongathanda wena ukuba abekhona. Inkukacha ezithe zashicilelwa ziyimfihlelo negama lakho aliyikubhalwa kwifomu. Yinombolo yakho eyakuchaza ukuba ungubani, akekho omnye umntu oyakuwaphatha lomaphetha aneempendulo zakho ngaphandle kwam nomphathi wam.

Ixesha olithathayo

Oluphando luyakuthatha isithuba esingangenyanga ezimbini. Ngelixesha kuyakufuneka uphendule ifomu enemibuzo eyakuthatha ixesha elingange mizuzu engamashumi amathathu.

Isixwayiso

Ndizakucela ukuba wabelane nam ngezinye zeenkukacha ezimalunga nawe nezinye zazo eziyimfihlelo yakho, ezinye zazo uyawuziva ungaphathekanga kakuhle ukuba ungathetha ngazo, awunyanzelekanga ukuba mawuphendule nawuphi na umbuzo ukuba uthanda ukungaphenduli. Awunyanzelekanga ukuba undinike isizathu sokuba kutheni ungafuni ukuphendula umbuzo okanye sokuba ungavumi ukuthatha inxaxheba kuvavanyo lwemibuzo.

Inzuzo

Akukho nzuzo okanye ntlawulo oyakuyifumana, kodwa ukuthatha kwakho inxaxheba kuyawunceda mna ndazi ngakumbi ngobungakanani benkcitho eniyenzayo nangokuba ukuthunyelwa kwenu ezikilini kunandima intle koku okanye hayi. Iyawunceda kananjalo ukuba siqaphele ukuba yintoni na ncedayo kwinkqubo yethu yonyango lwezithomalalisi okanye singaphucula ndawoni ukuze.

Intlawulo/ Isibonelelo

Awuyikunikwa sibonelelo samalji ngokuthatha inxaxheba kolu phando.

Ukugcina imfihlelo

Asisayikwabelana naye nabani na ogekho kwiqela lophando malunga nencoko yethu. Iinkukacha esiziqokelelayo sileliqumrhu lophando ziyakugcinwa ziyimfihlo, kwaye naziphi na inkukacha malunga nawe ziyakubane nombolo endaweni yokuba zibenegama lakho. Uyakuba mnye qha umntu oyakuyazi inombolo yakho kwaye ezonkukacha zakho ziyakugcinwa endaweni etshixwayo. Akuyikwabelwana okanye inikezwe komnye umntu ngaphandle ko Njingalwazi Fatima Suleman ongumphathi walenkqubo yoluphando.

Ilungelo lokwala ukuthatha inxaxheba okanye elokurhoxa

Awunyanzelekanga ukuba uthathe inxaxheba nokuba awuthandi, kwaye ukukhetha uku thatha inxaxheba akuyi kuchaphazela unyango lwakho nangayiphi na indlela. Unganqumama ukuthatha inxaxheba kolu dliwanondlebe nanini na ufuna kwaye oko akuyi kuchaphazela unyango olufumanayo. Ekupheleni kodliwano ndlebe ndiyakunika ithuba lokuba uphinde uhlole iimpendulo zakho kwayo ungakwazi ukucela ukuba zisuswe ezo xa ubona kuyimfuneko.

Unganxulumana nabani

Ukuba unemibuzo, ungayibuza ngoku okanye ngelinye ixesha. Ukuba unqwenela ukubuza imibuzo ethubeni unganxulumana no Monique Lines esibhedlele eZithulele kwicandelo elikhupha amayeza (inombolo 074 757 2260). Esi sicelo sihloliwe saza saphunyezwa yi Dyunivesi yaKwazulu Natala engobuntu nezentlalo emsebenzi wayo ikukuqinisekisa ukuba abathathi nxaxheba koluphando bakhuselekile ekwenzakaleni.

Isigaba sesibini: Isatifiketi sokuzibophelela

Ndifundile ngenkqubo yeenkcukacha, okanye ndiyifundelwe. Ndibenalo ithuba lokubuza imibuzo malunga noluphando, kwaye nemibuzo endiyibuzileyo iphenduleke ngokundanelisayo. Niyazibophelela ngokuzinikela ukuba ndibenenxaxheba kwesisifundo.

Igama lomthathi nxaxheba _____

Sayina mthathi nxaxheba _____

Umhla (usuku,inyanga,unyaka) _____

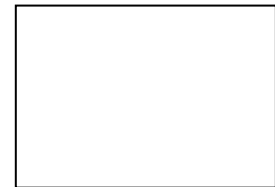
Ukuba awufundanga

Ndikungqinile ukufundela ngokucacileyo ifomu yesivumelwano kumthathi nxaxheba, kwaye nomntu lowo ubenethuba lokuzibuzela imibuzo. Ndiyaqinisekisa ukuba umthathi nxaxheba unikezele ngenkcukacha ngokukhululekileyo.

Igama lengqina _____ Isithupha

Ukusiyina kwengqina _____

Umhla (usuku/inyanga/unyaka) _____



Ingxelo okanye inkcukacha ngomphando / Umntu ongumququzeleli woluphando

Ndifundile imphepha ezineenkukacha ngomthathi nxaxheba ozinikeleyo, kwaye ngako konke endinako ndizamile ukuqinisekisa ukuba umthathi nxaxheba uyakuqonda konke okuzoqhubeka.

Ndiyinqina ukuba umthathi nxaxheba ulinikeziwe ithuba lokubuza imibuzo malunga nesisifundo, kwaye yonke imibuzo ebuziweyo ngumthathi nxaxheba iphendulwe ngokwanelisayo nangako konke okusemandleni wam. Ndiyaqinisekisa ukuba umthathi nxaxheba akakhohliswanga ukuba anikeze inkcukacha, kwaye neenkukacha leyo inikezelwe ngokukhululekileyo nokuzinikezela.

Ikopi yezinkcukacha zesivumelwano inikeziwe kumthathi nxaxheba.

Igama lomphandi/ umntu othatha iinkcukacha _____

Umhla (usuku/inyanga/unyaka) _____

APPENDIX 4: PERMISSION TO CONDUCT THE STUDY



ZITHULELE HOSPITAL

Province of the Eastern Cape • Iphondo leMpuma-Koloni
Department of Health • Isebe leZempilo

Miss Monique Lines
Responsible Pharmacist, Zithulele Hospital
Mqanduli
5080
Mobile: 074 757 2260
Email: montylines@gmail.com
26 August 2013

RE: Permission to Conduct Research at the Zithulele ARV Clinic

To the Zithulele Hospital HIV Programme Manager

I am writing to request permission to conduct a research study at Zithulele Hospital. I am currently enrolled in the Masters in Pharmacy (Pharmacoeconomics) programme at the University of Kwazulu-Natal, Westville Campus and am in the process of writing my master's thesis. The study is entitled "Out-of-pocket spending of HIV positive patients receiving ART in the rural Eastern Cape – The impact of a down referral model".

I hope that Zithulele Hospital and ARV clinic management will allow me to recruit patients from the ARV programme to complete an interview questionnaire (copy enclosed). Interested patients, who volunteer to participate, will be given a consent form to sign at the beginning of the interview process.

If approval is granted, the patients will complete the interview questionnaire at the ARV clinic on their treatment review day so as not to inconvenience anybody or disrupt the usual running of the ARV clinic. The interview process should take no longer than thirty minutes. The questionnaire results will be pooled for the thesis project and individual results of this study will remain absolutely confidential and anonymous. Should this study be published, only pooled results will be documented. No costs will be incurred by either Zithulele Hospital or the individual patients. Patients will not be remunerated for their

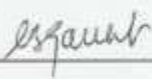
participation. Other demographic data will also be collected from the Zithulele ARV clinic database. It is important to note that I am not requesting access to information/data that I don't already have access to.

Your approval to conduct this study will be greatly appreciated. I will be happy to answer any questions or concerns that you may have. If approved, kindly sign below and return the signed form in the enclosed self-addressed envelope. Alternatively, kindly submit a signed letter of permission acknowledging your consent and permission for me to conduct this study at Zithulele Hospital.

I have attached a copy of my research proposal as well as the Ethical Clearance confirmation from the University of Kwazulu-Natal Humanities and Social Sciences Research Ethics Committee for your perusal.

Regards,


Monique Lines

Approved by: <u>Dr CB GANI, CLINICAL MANAGER</u> (Please print your name and title)
Signature: <u></u>
Date: <u>28/8/2013</u>





ZITHULELE HOSPITAL

Province of the Eastern Cape • Iphondo leMpuma-Koloni
Department of Health • Isebe leZempilo

Miss Monique Lines

Responsible Pharmacist, Zithulele Hospital

Mqanduli

5080

Mobile: 074 757 2260

Email: montylines@gmail.com

26 August 2013

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I am writing to request permission to conduct a research study at Zithulele Hospital. I am currently enrolled in the Masters in Pharmacy (Pharmacoeconomics) programme at the University of Kwazulu-Natal, Westville Campus and am in the process of writing my master's thesis. The study is entitled "Out-of-pocket spending of HIV positive patients receiving ART in the rural Eastern Cape – The impact of a down referral model".

I hope that Zithulele Hospital and ARV clinic management will allow me to recruit patients from the ARV programme to complete an interview questionnaire (copy enclosed). Interested patients, who volunteer to participate, will be given a consent form to sign at the beginning of the interview process.

If approval is granted, the patients will complete the interview questionnaire at the ARV clinic on their treatment review day so as not to inconvenience anybody or disrupt the usual running of the ARV clinic. The interview process should take no longer than thirty minutes. The questionnaire results will be pooled for the thesis project and individual results of this study will remain absolutely confidential and anonymous. Should this study be published, only pooled results will be documented. No costs will be incurred by either Zithulele Hospital or the individual patients. Patients will not be remunerated for their

participation. Other demographic data will also be collected from the Zithulele ARV clinic database. It is important to note that I am not requesting access to information/data that I don't already have access to.


Your approval to conduct this study will be greatly appreciated. I will be happy to answer any questions or concerns that you may have. If approved, kindly sign below and return the signed form in the enclosed self-addressed envelope. Alternatively, kindly submit a signed letter of permission acknowledging your consent and permission for me to conduct this study at Zithulele Hospital.

I have attached a copy of my research proposal as well as the Ethical Clearance confirmation from the University of Kwazulu-Natal Humanities and Social Sciences Research Ethics Committee for your perusal.

Regards,

Monique Lines

Approved by: N. E. MATEBESG (Please print your name and title)

Signature: 

Date: 2013. 09. 03.



APPENDIX 5: ETHICAL CLEARANCE



18 February 2014

Ms M Lines
P.O Box 226
Winklespruit
4145
montylines@yahoo.com

PROTOCOL: Out-of-pocket spending of HIV positive patients receiving ART in the rural Eastern Cape - The impact of a down referral model. REF: BE277/13.

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 18 July 2013.

Your responses received by BREC on 11 February 2014 to queries raised on 07 February 2014 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 18 February 2014.

This approval is valid for one year from 18 February 2014. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

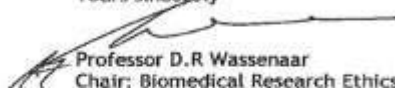
Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its next meeting taking place on 11 March 2014.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely



Professor D.R. Wassenaar
Chair: Biomedical Research Ethics Committee

Professor D Wassenaar (Chair)
Biomedical Research Ethics Committee
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Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>
Founding Campuses: ■ Edgewood ■ Howard College ■ Medical School ■ Pietermaritzburg ■ Westville

