



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

**Factors associated with concurrent consultation of primary health care clinics
and other providers by TB patients and HIV patients.**

by

Don Lawrence Mudzengi

University student number: 13204204

**Submitted in partial fulfilment of the requirements for the
Master of Science in Epidemiology**

**University of Pretoria
School of Health Systems & Public Health
Faculty of Health Sciences**

October 2015

DECLARATION

I, Mr Don Lawrence Mudzengi, hereby declare that the dissertation which I hereby submit for the Master of Science in Epidemiology at the University of Pretoria is my own work and has not been submitted previously by me for a degree at another university.



12 OCTOBER 2015

Mr Don Lawrence Mudzengi

ACKNOWLEDGEMENTS

First I thank the Lord for the unceasing blessings, the life and family which is always on my side.

I would also like to express my sincere gratitude to my supervisor Professor Brendan Girdler-Brown for the constant support and guidance in writing this dissertation.

I also want to express my gratitude to the Aurum Institute for the opportunity to study for this Master of Science. Foremost I thank Dr Salome Charalambous for her, Dr Tendesayi Kufa for her advice and many thanks to Dr Violet Chihota for helping me maintain balance between work and school.

Acknowledgements are also due to the MERGE team which was responsible for collecting the data used for this dissertation.

CONTACT DETAILS

MSc candidate and researcher: Mr Don Lawrence Mudzengi
The Aurum Institute
Aurum House, The Ridge, 29 Queens Road,
Parktown, Johannesburg, 2193
Postnet Suite 300, Private Bag X30500,
Houghton, 2041
South Africa

Supervisor: Professor BV Girdler-Brown
University of Pretoria
Faculty of Health Sciences
School of Health Systems and Public Health
5th Floor, HW Snyman Building North
31 Bophelo road
Gezina, 0031
Pretoria

Table of Contents

1. INTRODUCTION	1
2. LITERATURE REVIEW	2
2.1. Background	2
2.2. Study setting	3
2.3. Health system of South Africa	4
2.4. Ambulatory PHC services	5
2.5. Ambulatory non-PHC services	6
2.6. Choice of service	7
2.7. Data analyses	9
3. AIMS and OBJECTIVES	11
3.1. Study aim	11
3.2. Study objectives	11
4. METHODS	12
4.1. Study design	12
4.2. Clinic selection	12
4.3. Sampling and data collection	13
4.4. Inclusion and exclusion criteria	14
4.5. Measurements	14
4.6. Treatment of confounders	15
4.7. Statistical analyses	16
4.7.1. Post-regression diagnostics	17
4.7.1.1. Hosmer and Lemeshow`s Goodness of fit tests	17
4.7.1.2. Design effects	18
4.7.1.3. ROC curves	18
4.8. Assessing linearity of numerical variables with the logit	18
4.9. Principal component analysis	19
4.10. Data Management	22
4.10.1. Data capturing	22
4.10.2. Data storage and confidentiality	22
4.11. Ethical and Legal considerations	23
4.11.1. Good clinical practice	23
4.11.2. Approvals for the primary study	23
4.11.3. Approvals for the secondary analysis	23
4.11.4. Clinical trial registration	23
4.11.5. Data and Safety Monitoring Board	23
4.12. Logistics, Time Schedule and Action Plan	24

4.13. Budget/Resources	24
5. FINDINGS	25
5.1. Overview	25
5.2. Study flow	25
5.3. Descriptive analysis and patient demographics	27
5.4. Logistic regression results	28
5.4.1. Survey design logistic regression results	30
5.4.2. Logistic regression results using the “cluster” option in Stata’s regular logistic regression	31
5.4.3. Regular logistic regression results	32
5.5. Comparison of results	33
5.5.1. Comparison of unadjusted results	33
5.5.2. Comparison of adjusted results	34
5.6. Post-regression diagnostics	34
5.6.1. Significance of logistic regression models	34
5.6.2. Hosmer and Lemeshow goodness of fit tests	34
5.6.3. Design effects	35
5.6.4. Receiver Operating Characteristic (ROC) curves	35
5.7. Additional analyses	36
6. DISCUSSION	37
6.1. Comparisons with previously published study results	38
6.2. Factors not associated with concurrent PHC & non-PHC use	40
6.3. Effects of analysing the data using the survey adjustment module in Stata	43
6.4. Limitations of the study	44
6.5. Public health implications	45
7. CONCLUSION	47
8. REFERENCES	49
9. LIST OF APPENDICES	54
9.1. Appendix 1: Participant information sheet and informed consent form	54
9.2. Appendix 2: Screening, eligibility and enrolment	59
9.3. Appendix 3: Baseline demographics	61
9.4. Appendix 4: Data extraction template	63
9.5. Appendix 5: GCP Certificate	64
9.6. Appendix 6 : WITS ethics letter	65
9.7. Appendix 7 : London school ethics	66
9.8. Appendix 8 : Ekurhuleni approval	67
9.9. Appendix 9 : AURUM approval	68
9.10. Appendix 10: UP ethics	69
9.11. Appendix 11: DECLARATION OF HELSINKI	70

10.	ANNEXURE	71
10.1.	Annexe 1 : Normality graphs for numerical variables	71
10.2.	Annexe 2 : Eigen vectors for principal components	72
10.3.	Annexe 3 : Scoring coefficients for principal components	73

LIST OF TABLES

TABLE 1 : SUMMARY OF ENROLMENTS PER SITE.....	13
TABLE 2 : VARIABLE USED IN THE STUDY	15
TABLE 3 : PRINCIPAL COMPONENT ANALYSIS STATA OUTPUT	21
TABLE 4 : LOGISTIC REGRESSION BOX-TIDWELL RESULTS FOR NUMERICAL CO-VARIABLES: TEST P-VALUES.....	25
TABLE 5 : DESCRIPTIVE STATISTICS	27
TABLE 6 : DESCRIPTIVE SUMMARY OF NUMERICAL CO-VARIABLES	28
TABLE 7 : LOGISTIC REGRESSION RESULTS FOLLOWING ADJUSTMENT FOR SURVEY DESIGN.....	30
TABLE 8 : LOGISTIC REGRESSION RESULTS USING THE “CLUSTER” OPTION IN STATA	31
TABLE 9 : REGULAR LOGISTIC REGRESSION RESULTS WITH NO ALLOWANCE MADE FOR THE CLUSTER DESIGN	32
TABLE 10 : COMPARISON OF UNADJUSTED LOGISTIC REGRESSION RESULTS	33
TABLE 11 : COMPARISON OF ADJUSTED LOGISTIC REGRESSION RESULTS	34
TABLE 12 : HOSMER AND LEMESHOW GOODNESS OF FIT TESTS	34
TABLE 13 : DESIGN EFFECTS	35
TABLE 14 : RESULTS EXCLUDING MEDICAL AID BENEFICIARIES	36

LIST OF FIGURES

FIGURE 1 : STRUCTURE OF INTERVENTION	12
FIGURE 2 : SCREE PLOT OF EIGENVALUES AFTER PCA.....	22
FIGURE 3 : STUDY FLOW DIAGRAM	26
FIGURE 4 : ROC CURVES FOR CLUSTER AND SURVEY DESIGN	35

LIST OF ABBREVIATIONS

ART	Anti-retroviral Therapy
ARV	Anti-retroviral
CDC	Centers for Disease Control
DHIS	District Health Information System
DSMB	Data Safety and Management Board
GCP	Good Clinical Practice
HBC	High Burden Country
HIV	Human Immunodeficiency Virus
IQR	inter-quartile range
NHI	National Health Insurance
PCA	Principal Component Analysis
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
RA	Research Assistant
SES	Socio-Economic Status
STI	Sexually Transmitted Infection
TB	Tuberculosis
WHO	World Health Organization

Abstract

Introduction. Concurrent use of public sector and other healthcare facilities by adult persons seeking treatment for human immunodeficiency virus (HIV) and/ or tuberculosis (TB) has been shown to lead to poorer health outcomes for such patients. Apart from structural factors (e.g. service standards), demographic and personal factors may also influence patients to use private health services concurrently with public sector services for these two diseases.

Aim. The Aim of this analysis was to explore demographic and personal factors associated with concurrent use of public and private health services by TB and/or HIV patients, attending public sector primary health care clinics.

Methods. This was a secondary analysis of data collected during a cluster randomised controlled trial. In that trial, structured interviews were conducted with 486 patients with HIV and or TB aged between 18 and 71 years in 18 primary health care clinics in Ekurhuleni North, Gauteng South Africa. Descriptive analyses were followed by multiple logistic regression using Stata Version 12 to analyse associations between independent variables and concurrent use of public and private health services. The analyses were repeated with adjustment for the complex survey sampling design and also with regular logistic regression but using the “cluster” option available in Stata, for comparison.

Results. It was found that two factors associated with concurrent use of public and private health services were shown to be statistically significant: having access to medical scheme funding and being accompanied by at least one other adult when attending the public sector clinic.

Conclusions and recommendations. As the factors associated with co-consultation may be beyond the control of policy makers it is recommended that emphasis be placed on improving standards of care in both the public and private sectors; and encouraging private providers to comply with national diagnostic, treatment and reporting guidelines for these two conditions.

Key words

public and private health facilities; concurrent TB and HIV; primary health care choices; medical scheme membership

1. INTRODUCTION

This paper reports the findings from a secondary data analysis. The analysis explored factors associated with the concurrent use of primary health clinics in the public sector (PHC) and any other provider (non-PHC) by Tuberculosis (TB) and by Human Immunodeficiency Virus (HIV) infected patients in the Ekurhuleni North district of Gauteng in South Africa. The primary data used for this study were collected by the Aurum Institute for Health Research in a separate study of TB and HIV patient costs. The patient costs study was nested in a cluster randomised trial that was conducted at 18 clinics in Ekurhuleni north sub-district, Gauteng, South Africa.¹ The cluster randomised trial was a TB/HIV integration study known as MERGE.¹

In the current report, public sector clinics that belong to the Ekurhuleni Metropolitan Municipality are referred to as PHC clinics and all other health providers are called non-PHC providers. The non-PHC providers in this study were facilities where patients voluntarily made co-consultations and these include private doctors, private pharmacies and traditional healers.² Only ambulatory services in both sectors were considered.

Public hospitals were not considered as non-PHC facilities because they were regarded as part of the PHC sector clinic referral chain; consulted consecutively rather than concurrently.

Three types of data analysis were conducted using Statacorp`s statistical software Stata (Version 12). First was a survey-adjusted analysis followed by two analyses where the complex sampling was ignored; one with, and one without the use of Stata`s “cluster” option for the logistic regression analyses. Adjusted and unadjusted descriptive summaries were produced for participants who made concurrent use of PHC and non-PHC services; and those who did not. The descriptive summaries were followed by logistic regression models with the outcome (dependant) variable being concurrent use of PHC and non-PHC services. This outcome was defined as making at least one visit to any of the non-PHC providers mentioned above while also (concurrently) making use of the PHC services.

The paper will present a detailed account of the methods used in primary data collection and the secondary data analyses. These will be followed by a presentation of the findings of the secondary analyses, a discussion and conclusion. Lists of references, appendices and an annexure are provided last. The phrase “concurrent consultation” will be used throughout the paper to refer to the concurrent use of PHC and non-PHC services.

2. LITERATURE REVIEW

2.1. Background

TB and HIV are still the leading causes of morbidity and mortality in the world. In 2012, TB caused deaths of 1.3 million of the 8.6 million people who had developed the disease.³ In the same year, Acquired Immune deficiency Syndrome (HIV/AIDS) claimed 1.6 million lives out of 35.3 million people who were living with HIV⁴, and a fifth of these HIV deaths were believed to be due to TB.³

TB and HIV are disproportionately concentrated in low and middle income countries and unduly affect the poorer strata of society.⁵⁻⁸ Only low and middle income countries form the 22 TB high burden countries (HBC).³ South Africa is among these HBCs and has the highest TB incidence rate of 1 000 per 100 000 population. The prevalence rate is also the highest at 857 per 100 000 population and the second highest TB mortality of 59 per 100 000 population.³ TB mortality in South Africa is 2.3 times higher than Africa's region's overall and also 4.5 times higher than for the overall global TB mortality rates.³ South Africa also ranks fourth globally in HIV prevalence among adults with a 2012 prevalence of 17.6%.⁴ In 2012 6.1 million adults were living with HIV making South Africa the country with the highest HIV burden in the world.⁴ Since 2011, the adult HIV prevalence has risen from 18.5% in 2011 to 18.9 in 2014.⁹ It is believed that 60% of TB patients in South Africa are infected with HIV.¹⁰ The World Health Organization (WHO) recommends the integrated management of TB and HIV in health facilities.^{11,12} This is due to diseases' dependence on each other, that is, HIV infection increasing the risk of acquiring and activating latent TB infection due to a weakened immune system and the presence of TB worsening morbidity and delaying initiation of Anti-retroviral therapy (ART).¹³

In South Africa, TB and HIV are mainly managed in PHC clinics where these services are provided free.¹⁴⁻²⁰ In the non-PHC sector services are not free; patients make out-of-pocket payments or use medical schemes.^{14-16,18,19} Despite free services offered in PHC clinics, sometimes patients co-consult with non-PHC service providers. Although concurrent consultation has not been explicitly studied in South Africa, it is believed that poor quality of services common in PHC facilities such as bad staff attitudes, lack of confidentiality, long waiting times, shortages of essential medicines and autonomy, among others; attracted patients to non-PHC providers where such challenges are not present.^{2,19,21-31}

In South Africa, the majority of TB and HIV is managed in PHC clinics which, with a few local adaptations in the national programmes, follow the recommendations of the

WHO.^{14,15,19,32} On the other hand are non-PHC providers who also provide TB and HIV in South Africa but are believed to exist outside the National TB programmes and their HIV services also lack regulation.^{14,15} Regulation of non-PHC sectors, mainly in terms of standards of care has been widely reported and criticised in South Africa^{26,33} and also in other parts of the world^{2,25}. Such poor regulation has the potential for dire consequences on health outcomes. For instance, in the Khayelitsha suburb of Cape Town South Africa, it was found that TB patients who consulted non-PHC providers experienced treatment delays.¹⁵ Evidence from Basu et al.³⁴ also suggests that, contrary to popular view, PHC providers in low and middle income countries are usually more efficient than non-PHC providers for all services although it is not clear whether this general finding specifically applies to South Africa. In fact, one study claims that non-PHC TB services are substandard.²⁵ Other studies which have evaluated the quality of services offered in non-PHC facilities have found them to fall short of the standard of quality despite their high costs.^{2,14,23,26,31,33,35-37} Many of these studies have, however, only described patients' perspectives but did not establish empirical associations of such factors with choice of health provider.^{15,20-23,26,38} Only in Vietnam and also in India have these empirical associations between personal and demographic factors; and use of non-PHC over PHC, been investigated.^{28,37}

Gaps thus exist in South Africa on the explanations for patients' choices of healthcare. This knowledge may help align these choices to national programmes such as TB programmes and reduce apathy to these regulated programmes.²⁵ Currently available information mainly found in descriptive studies may not be adequate to explain the reasons for concurrent consultation. Such factors are mainly service related and almost entirely exclude personal and demographic factors which may also be responsible for patients' use of non-PHC services. In Vietnam and in India such studies have been conducted and these demographic and personal factors were identified.^{28,37} There is therefore need to explore further and provide empirical evidence on these and other factors that are responsible for concurrent consultation. Using the hypothesis that not only service related factors cause TB and HIV patients to use PHC and non-PHC services concurrently, this study will explore the association of demographic and personal factors with concurrent consultation of PHC and non-PHC services.

2.2. Study setting

The TB/HIV integration study which nested the patient costs was conducted in Ekurhuleni North; a sub-district in Eastern Gauteng, South Africa. It is a densely populated district with a density of 1 609 people per square kilometre in 2011.³⁹⁻⁴¹ In general, overcrowded societies such these with a high population density are believed

to be breeding grounds for TB and especially among HIV patients who are usually poor.⁴²⁻⁴⁴ The sub-district includes Kempton Park, parts of Edenvale, Germiston (including Bedfordview and Primrose) and Tembisa (the most populous with approximately 463 110 people in 2013)⁴¹. The population density is expected to have increased due to a 2.47% 2011 annual population growth rate which saw the 2013 Ekurhuleni population reach 3 178 470 inhabitants.^{39,40-45}

At the time of implementation of the randomised controlled trial, there were twenty-two community level primary care clinics that offered a wide range of services such as primary health care, maternal and child health, HIV counselling and testing, treatment of Sexually Transmitted Infections (STIs), TB treatment services and ART.¹ Clinics in Ekurhuleni North referred patients to three secondary level hospitals with the majority of those being referred going to Tembisa Hospital.¹ Nineteen of the 22 primary care clinics offered TB services and varying extents of HIV care and treatment services. All clinics offered HIV counselling and testing; and CD4 testing. The clinics differ in size, catchment area population and TB caseloads.¹ Two clinics out of the nineteen were satellite clinics which operated for three days per week.¹ Two out of nineteen clinics initiated ART while an additional two functioned as ART down-referral sites. ART referral sites provided follow up care for ART patients initiated elsewhere.¹ TB care was provided at all the nineteen clinics by TB nurses.¹ Nineteen clinics had informal settlements characterised by overcrowding and poor living conditions in their catchment areas.¹

2.3. Health system of South Africa

South Africa has twin health systems made up of a government-funded public health sector and a non-PHC sector where patients or their medical schemes are charged for health services offered.^{33,46,47} In the public sector, there are PHC clinics and referral hospitals. The public sector serves 84% of the population where a majority of the services are not charged for; while the private sector caters for only 16% of the population (and who pay for services).⁴⁸ This population consulting non-PHC providers includes TB and HIV patients who make out-of-pocket payments if they are not beneficiaries of medical aid schemes.^{17,19,27,49-51} The majority of the members of medical aid schemes are in higher income bracket²⁶ and their contributions account for 47% of total health expenditure in the country; mainly spent in the non-PHC sector sector⁴⁶. Given the higher incomes among beneficiaries or members of medical aid schemes²⁶, it is likely that the majority of TB and HIV patients, who are often poor⁵, make out-of-pocket payments for non-PHC services.

Despite the small population served by the non-PHC providers, the expenditures in the non-PHC sector equal the 100 billion rands that are spent by government each year in the PHC sector.^{47,48} This skewed funding might have contributed to the much publicised PHC sector system constraints which are characterised by long waiting time, bad staff attitudes and shortage of essential medicines in PHC sector; leading patients to seek “quality” care from private providers.^{20,52}

2.4. Ambulatory PHC services

The curative component of the PHC sector health services in South Africa is made up of government funded clinics and hospitals. PHC clinics offer ambulatory medical services and refer patients with complicated conditions to referral hospitals. Ambulatory TB and HIV care regimens in PHC clinics follow guidelines based on those recommended by the WHO.^{14,15,19,32} Although guided by the WHO, maximum efficiency in the PHC facilities in South Africa and outside is thwarted by several system problems such as: lack of patient confidentiality, long waiting hours, staff shortages, drugs shortages and poor staff attitudes.^{2,19-31} As mentioned above, in South Africa these problems are believed, at least in part, to be caused by imbalances in funding that favour the non-PHC sector, leaving the PHC sector with fewer resources to cater for majority of about 84% of the population.⁴⁸ As these problems in the PHC sector persist, patients become dissatisfied and opt for non-PHC sector providers with the hope of better services. Chimbindi et al. also believe that long clinic waiting times are the major cause for lack the of ART adherence among HIV patients²¹ while Harrison also cites waiting time at PHC facilities a common indicator for quality of services¹⁹. A study in rural Limpopo South Africa which also found patient dissatisfaction with long waiting time reported some patients spending more than 60 minutes waiting for services.³²

It may be inaccurate to conclude that factors such as long waiting times cause patients to use non-PHC over PHC without testing this relationship empirically. Honda et al. in a recent study in South Africa found that patients in the PHC sector may be prepared to tolerate perceived poor service such as long waiting times provided that they “receive the medicine they need, a thorough examination and a clear explanation of the diagnosis and prescribed treatment from health professionals”.³⁰ This may therefore suggest that many of the problems that have been reported in descriptive studies could be weak predictors of the patient’s choice to use PHC clinics and/or non-PHC sector services. Therefore, there is need for more accurate empirical studies such these to clarify more factors that influence choice of health provider other than the factors highlighted in the descriptive studies.

In spite of these service-related problems, PHC clinics may nevertheless provide more equitable and more efficient TB/HIV services than the non-PHC sector providers.¹⁴ Regulation and adherence to recommended standards, which may not be common practice in the non-PHC sector, may contribute to the improved efficiencies even under strained resources in the PHC sector.^{14,32}

2.5. Ambulatory non-PHC services

The non-PHC sector serves about 16% of the population and has approximately the same financial resources as allocated to the care of the rest of the population.^{47,48} It is estimated that 79% of the doctors in South Africa work in the non-PHC sector and the remaining 21% in the PHC health sector.⁴⁸ This structure in the twin health system thus favours the non-PHC sector and hence the likely superior efficacy over the PHC sector. The new National Health Insurance scheme currently under development has the prime mandate to address these financial and resource imbalances in health.⁴⁸

Non-PHC sector health services are believed to be easily accessible by people of higher income status, mainly through membership of medical aid schemes.^{15,50} However, poorer patients who cannot afford membership of medical aid schemes also consult with non-PHC sector providers and may also make out-of-pocket payments.^{17,19,23,25,27,33,49,50,52} In fact, it is believed that about 25% of patients, including TB and HIV patients, in South Africa make out-of-pocket payments.⁵¹ For poor patients, consulting with non-PHC providers causes catastrophic costs and consequently poor health outcomes.^{5,6} Van Wyk suggests that if poor patients consult with non-PHC providers they may exhaust their money and revert back to the PHC services with even poorer outcomes.¹⁵ TB and HIV disproportionately affect the poor who may not be able to afford to be members of medical aid schemes.⁵ Poor people who still pay for medical aid schemes utilise more of their income than those in high income groups. As for those making out-of-pocket payments, non-PHC sector costs often immerse them into catastrophic expenditure for health and further poverty, much to the detriment of preferred positive TB outcomes.⁵ Some TB patients consulting non-PHC sector providers are believed to have interrupted care and revert back to the PHC sector after exhausting their money.¹⁵ Some of these patients also “get lost in the system” due to consulting with different providers.⁵³

Despite being relatively well-resourced, non-PHC sector services may not be the best providers of quality TB and HIV care; indeed, some authors have deemed their services “substandard”.²⁵ A combination of poor case management¹⁷ and treatment delays.¹⁵ for TB patients form some of the reasons for the discrediting of non-PHC sector services. For HIV, private providers are sometimes accused of managing patients in such a way

that multiple providers become involved in the treatment of a single patient, resulting in poor integration and discontinuity of care as the patient moves from one provider to the other.¹⁴ Chabikuli et al. also reported typical findings; in the non-PHC sector sexually transmitted diseases were poorly managed because providers lacked sufficient knowledge and also used non-membership of a medical aid scheme to discriminate against the poor by giving them inferior services.²⁶ For these reasons, therefore, it can be said that despite the huge source of funds available for non-PHC sector services these services may not always yield optimal outcomes for TB and HIV patients, unless regulated¹⁷.

The inability to regulate services in the non-PHC sector is themed in different studies as the major causal factor for paradoxically poor TB and HIV services despite adequate resources.^{2,14,15,17,19,23,25,27,33,34,50,52} To the contrary, the under-resourced PHC facilities which abide by the recommendations such those by the WHO often perform better for TB and HIV outcomes.^{15,34,37} For TB, Uplekar warns against the weakening of epidemiological outcomes due to the unregulated nature and poor management in the non-PHC sector.¹⁷ In South Africa, Sinanovic and Kumaranayake also report that the positive aspects of service experience in non-PHC sector are often easily diminished by private practitioners' disregard for recommended drugs, defaulters and record keeping.²³ Furthermore, private hospitals have been identified in particular as being reluctant to provide data that could be essential for monitoring quality of services.⁵⁴

2.6. Choice of service

Patients' preferences for the type of health provider are believed to be based on their perception of the quality of care in the specific health sector, PHC or non-PHC. Poor quality services have the potential of driving patients from either health sector. In South Africa^{20, 21,23,24,26} and elsewhere^{2,25,28,31,34,52}, poor services in the PHC sectors are believed to drive patients away from the PHC in favour of the non-PHC services. Non-PHC services are more attractive because of shorter waiting times, available medicines and respect of persons; among other factors that define quality of service.^{20,25} These reasons can be attractive for patients but may not directly however translate to better TB and HIV outcomes in the non-PHC sector. Literature has however informed that TB and HIV services are no more superior in non-PHC than PHC facilities.^{14,15,23,25,26,34} Therefore these patients who are attracted to non-PHC services may be oblivious of the poorer TB and HIV outcomes there.

The factors believed to influence patients' choices of healthcare also neglect the influence of personal and demographics factors. Although the forces of the system such as long waiting times are significant in use of non-PHC services, personal factor can

also have a role. Therefore, patients' behaviours or responsiveness to health systems may be incomplete without the understanding of the influence of the personal factors. These factors have not been studied in South Africa but in Vietnam^{31,37} and in India²⁸ by Lönnroth et al. and Hazarika respectively. The Vietnamese study that aimed at understanding non-PHC sector use from patient's perspective found that socio-economic factors such as income, education and socio-economic status are weak predictors of use of non-PHC services by TB patients.³⁷ This contrasts with other published information that higher income is associated with use of non-PHC services.¹⁵ The Indian study by Hazarika investigating measures to increase participation of non-PHC providers in national TB programmes found that being older, being male and higher socio-economic status increase the likelihood of using non-PHC services.²⁸ With these findings however, the author acknowledges the role poor quality services have on use of non-PHC facilities.²⁸ Lönnroth et al. in a different study also found significant influences by friends and family on the choices made in healthcare and this further strengthens the view that ascribing concurrent consultation to systems problems can be misleading.³¹

In South Africa, being a member or beneficiary of a medical aid scheme has been associated with use of non-PHC.^{15,26} It is also believed that increasing income is associated with non-PHC use because those patients afford more.^{15,26} This is, however, disputable because even poor patients, especially TB patients, still use non-PHC services regardless of their poverty.^{17,25} Harding also alludes to the fact that poor patients will go where they want to go regardless of those system factors hence she advises policy makers to devise means of reaching such patients who consult with non-PHC services.⁴⁹ Poor patients who are neither members nor beneficiaries of medical aid make out-of-pocket payments for their healthcare and this can cause catastrophic spending for health which has a detrimental effect on the household and on the patients' TB and HIV outcomes.¹⁵ Van Wyk et al., in fact, write that poor patients consulting in the non-PHC sector may run out of funds and revert back to the PHC sector.¹⁵ Not all poor patients will return to the PHC sector, however, because some will "get lost in the system"⁵³ while those that successfully return may do it with poorer outcomes because of the evidence of poor TB and HIV outcomes in non-PHC settings^{14,15,23,25,26,34}.

The current study also includes traditional healers as non-PHC practitioners who have been estimated to number 200 000 in South Africa in 2004¹⁶. A further study reported that these traditional healers were consulted by an estimated 1.2% of the population.⁵⁵ Traditional practitioners are also reportedly held in high regard and trust by most

patients in South Africa due to their perceived effectiveness in patient care as well as continuity of care.⁵⁵ In the public-private mix for TB and HIV in South Africa, traditional healers are identified as key partners in instances where they are incorporated; TB outcomes have been shown to improve.^{30,56,57} However, consulting traditional healers has been seen to delay treatment for TB patients like other non-PHC practitioners.^{30,56}

In South Africa, there is little information on the proportion of TB and HIV patients who consult non-PHC practitioners and whether patients entirely leave the PHC sector clinics to receive exclusive care from private practitioners or if they consult concurrently in PHC sector clinics and private practitioners. There is also no further information about personal and other factors other than service factors such as poor services and bad staff attitudes that are alleged to cause patients to co-consult non-PHC services for TB and HIV. The general assumption, without empirical proof, that non-PHC facilities offer better services than PHC clinics might have influenced patients' co-consultation with non-PHC facilities for TB and HIV. It is therefore important that these personal factors are investigated in order to understand the full spectrum of patients' responses to health systems as well as assist in the management of TB and HIV patients who use multiple providers.

2.7. Data analyses

Data from samples that are stratified, and/ or clustered, at the data collection stage, may need to be analysed with this sampling strategy taken into account. When Stata statistical software is used to perform the analyses the commands are preceded by "svy:" after first setting the survey sampling parameters.⁵⁸ Stata then recognises the data as coming from a survey with such a complex sampling design and remembers survey features for all commands that are prefixed with the syntax "svy :".⁵⁸ Survey data are believed to lose precision that would have been achieved by simple random sampling if clustering was used for the sampling. On the other hand, stratification would be expected to result in increased precision. Due to affordability and feasibility challenges, complex survey designs are commonly used to collect data, especially where the study population is widely geographically dispersed and/ or there is no readily accessible sampling frame. In order therefore to infer the results from a survey which are assumed to have lost precision, design effects are produced as factors which inform the magnitude of random sample needed to produce a variance equal to that of a survey. This stems from the principle that survey samples are usually homogenous and hence variance is small, however with homogeneity stems less information than would be in a heterogeneous sample. Thus a homogenous survey sample has less precision

than a simple random sample. However, conclusions the design effects are better if accompanied by design effects.

Clustering and stratifying which are common in survey samples have different effects on precision and design effects. Lohr writes that clustering increases design effects to values greater than one while stratifying decreases the design effects to below unity.⁵⁹

Design effects below unity indicate higher precision and they are unusual, however if data is from strata as Lohr suggests, it is possible to get such.⁵⁹

3. AIMS and OBJECTIVES

3.1. Study aim

To identify the factors that are associated with the concurrent use of PHC and non-PHC services by TB, HIV, and TB/HIV co-infected patients attending PHC clinics in the Ekurhuleni North sub-district of Gauteng between April and October 2013.

3.2. Study objectives

1. To determine the proportion of PHC patients also using non-PHC services.
2. To describe the demographic characteristics of patients who do and who do not make concurrent use of non-PHC services.
3. To determine factors (from among those collected) associated with the concurrent use of non-PHC services.
4. To compare the use of non-PHC services by treatment group (i.e. TB; HIV; TB and HIV co-infection).

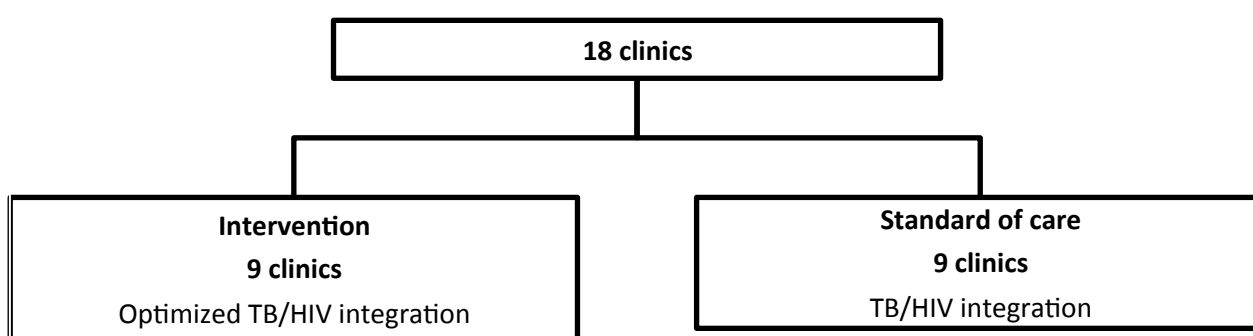
4. METHODS

4.1. Study design

This study was a secondary analysis of data obtained from a sub-study of a two-armed (intervention and control) cluster randomized controlled trial. The sub-study was on costs that patients incur as they visit intervention and control clinics.

The cluster randomised trial had 18 clinics with 9 clinics in each arm. The intervention arm offered an optimized TB/HIV integration model where a TB/HIV integration officer and a TB screening officer were introduced in a supported environment; and the control offered standard care.

Figure 1 : Structure of intervention



4.2. Clinic selection

Eighteen (18) clinics were selected from the 32 Ekurhuleni North district clinics using the following initial exclusion criteria:

- *No other research study in progress (6 excluded)*
- *At least 40 TB cases per year (4 excluded)*
- *TB data available for the clinic (1 excluded)*
- *Clinic is still operating (1 excluded)*
- *Clinic is not a mobile clinic (1 excluded)*

Data from 2010 were used to calculate TB fatality rates for the remaining 18 clinics. These data were used because they were the most complete recent data available. The calculated TB mortality rates ranged between 0 and 9.6 per 100 000 population per year.

The TB mortality rates were then used to allocate the clinics into high and low case fatality, high representing rates from 4 and above while low represent all the rates below 4. This resulted in 10 allocated to low and 8 to high fatality rate.

The Aurum Institute then convened a workshop with clinic managers of the 18 clinics to allocate the clinics into intervention and control arms. Two bowls were filled with balls labelled with the clinic name and TB fatality category (high or low).

The high TB fatality bowl had 8 balls and the low TB case fatality bowl had 10 balls. The 18 clinic managers were asked to randomly pick one ball each from one bowl first, alternately allocating a picked ball to either the intervention or the control arm, until all the balls in both bowls were exhausted. This process yielded 9 clinics in each arm; composed of 5 with low TB fatality and 4 with high TB fatality rate.

4.3. Sampling and data collection

The sample size of 486 for the study was predetermined by the design of the primary study and data were collected in one cluster comprised of 18 eligible clinics which were considered strata. Table 1 below summarises the enrolment figures per stratum.

Table 1 : Summary of enrolments per site

Study site	Co-infected	TB only	HIV only	Total
006	2	1	4	7
030	3	0	6	9
003	2	0	11	13
012	3	0	10	13
022	3	1	9	13
031	8	1	11	20
014	3	0	18	21
024	9	8	4	21
029	7	3	11	21
008	0	3	26	29
011	1	3	25	29
016	2	0	29	31
005	5	1	26	32
027	6	1	28	35
004	8	2	27	37
009	25	6	18	49
015	12	13	24	49
017	26	6	25	57
Total	125	49	312	486

Software package G*Power 3.1.6 showed that if a sample size of 486 is selected, then the power of this analysis to detect a statistically significant OR of 2 ($\alpha=0.05$) is at least 87.75% ($\beta=0.122$).^{60,61} If a design effect (due to clustering) of 2 is assumed, the power for the same sample size would be at least 70.94% ($\beta=0.2906$)

A pilot study was conducted between December 2012 and February 2013 to evaluate the questionnaires. Data from the pilot study were not included in the analysis and the respective patients were not eligible for recruitment in the main study.

After the pilot study, data were collected through consecutive screening of all patients identified, and, if eligible and if they gave consent by signing a consent form, they were

enrolled. Enrolment of participants lasted for 7 months from April until October 2013 when enrolment at the sites was required to stop. Trained Research Assistants (RAs) collected the data using the following questionnaires:

- screening form to assess eligibility,
- patient demographics,
- Data extraction template

The questionnaires are attached in appendices 2 to 3 respectively and the data extraction template is in appendix respectively. screening and demographics are attached as full questionnaires whereas the TB and the HIV questionnaires presented include only the questions extracted for this study. Research assistants were trained to ensure that they collect the complex patient cost data accurately.

4.4. Inclusion and exclusion criteria

The following criteria were used to assess patients` eligibility for the study.

- ***Co-infected TB/HIV***
- ***TB-only (negative HIV test within three months of TB diagnosis) and;***
- ***HIV-only;***

all of whom were patients diagnosed with the respective diseases within 3 to 5 months prior to enrolment into the study. Through experience from past studies, the investigators of the primary study believed that patients would, within 3 to 5 months, be able to recall sufficient information about the questions asked and thus minimise the threat of recall bias.

All patients who were approached were asked to go through a screening process that the trained research assistant documented. Information from the screening process was used to evaluate patients` eligibility and those who did not meet the criteria were excluded from further questioning.

4.5. Measurements

The following variables in table 2, which were found in previous studies, were used in the study. The following variables found in a similar study in India²⁸ about factors that influence TB patients to make use of private practitioners were adapted for this study; sex, age, residence (rural or urban), education, socio-economic status and religion.

Table 2 : Variable used in the study

Time spent travelling to clinic	Accompanied by at least one other adult
Age of patient at last clinic visit	Assisted by someone at home
Last recorded CD4 result	On ART
Socio-economic status	Had a CD4 count
Currently partnered	Beneficiary of a medical aid scheme
Sex	Employment at diagnosis
Intervention arm	Total visits made to this clinic
Country of origin	Primary home language
TB/HIV co-infection	Time spent at the clinic
Infection with TB only	Level of education
Infection with HIV only	

Urban/rural residence and religion were excluded from the analysis because for the former, all patients were from urban areas; and the latter was not captured in the study questionnaire.

Other variables included in the analysis were: being a beneficiary of a medical aid scheme, employment status at diagnosis, current marital status, country of origin, stage of treatment (defined as whether the patient was ART or not), time from symptom onset to treatment-start, type of treatment group (TB & HIV, TB only or HIV only) and family or social support (patient assisted at home and/or is accompanied to clinic by someone).

Data for time from symptom onset to treatment-start was not sufficient due to large numbers of missing responses hence the variable was excluded. However, income and other socio-economic variables were used in a study in Vietnam hence their inclusion in the current study.³⁷

Association between the outcome (concurrent use of PHC and non-PHC services) and the predictors (non-system factors) was modelled in a logistic regression model adjusted for survey design. Additional analysis was also conducted while adjusting for clustering in order to assess the differences in results between the two analysis methods.

4.6. Treatment of confounders

The demographic variables that were identified in the study in India and Vietnam were considered as the primary co-variables. However, other variables which were believed to confound the relationship between the outcome and primary predictor variables were included in the logistic regression model to adjust for their independent effect on the outcome.

These were: beneficiaries of medical aid schemes, employment status at diagnosis, socio-economic status, current marital status, country of origin, stage of treatment defined as whether the patient was on ART or not, treatment group (TB & HIV, TB only or HIV only) and family or social support (patient assisted at home and/or is accompanied to clinic by someone).

It was also believed after assessing the data that the variables about membership to medical aid would potentially confound the relationship with the outcome. Therefore, data analysis was repeated without participants who were members of medical aid schemes by the time of TB or HIV diagnosis.

4.7. Statistical analyses

The main data analysis modelled the data using logistic regression and the survey data commands in version 12 of Stata by Statacorp. The data were set for survey analysis using the Stata syntax below:

```
svyset site, vce(linearized) singleunit(missing)
svyset _n, strata(site) vce(linearized) singleunit(missing)

pweight: <none>
VCE: linearized
Single unit: missing
Strata 1: site
SU 1: <observations>
FPC 1: <zero>
```

From this it is clear that the clinics were regarded as strata. The reason is that all the eligible clinics were included. Sample size at each clinic was deemed proportional to the clinic load due to the fact that recruiting was carried out over a fixed, constant, time period (rather than quota sampling).

Hence there was no element of oversampling at any clinic. The data were first analysed by univariate analysis calculating univariate odds ratios and afterwards all variables with coefficient p-values greater than 0.25 were excluded from further modelling.⁶² The full logistic regression model thus included variables whose coefficient p-values were less than 0.25.

Two additional analyses, regular logistic regression (without the survey adjustment), sometimes referred to later as “SRS”, meaning the assumption of simple random sampling; and SRS followed by Stata’s “cluster” option, were also performed in Stata using non-survey commands.

SRS with the “cluster” option is used in Stata when data are collected assuming SRS but there may be subsequent clustering within the data; this differs from the situation where the data were collected using cluster sampling.

This third method of analysis is included, not because it is appropriate, but purely out of interest. Although the data were collected as part of a “cluster randomised trial”, they were not collected using “cluster sampling”. Rather, the data were collected in strata (since all eligible clinics were included).

This this third type of analysis is of interest because it takes into account any clustering within the sample due to the clinics variable. Unfortunately this “cluster” option (not a function of the sampling design” is not available concurrently with the svy: module in Stata.

These additional types of analyses will be referred as regular and cluster analysis respectively throughout the paper. These analyses were performed to compare the effect of adjusting for either survey or cluster design and not adjusting; on the results of the logistic regression. A table comparing 95% confidence intervals, p-values and standard deviation is included in the results section of this mini-dissertation.

4.7.1. Post-regression diagnostics

4.7.1.1. Hosmer and Lemeshow`s Goodness of fit tests

The Hosmer and Lemeshow`s Goodness of fit test which assesses the extent of the similarity between the results predicted by the model and the true population results was used for post-regression diagnostics for all the three types of analyses.⁶²⁻⁶⁴

The Hosmer and Lemeshow goodness of fit test is based on the following logic:

H_0	:	<i>results predicted by the model and the true population are not similar</i>
H_1	:	<i>results predicted by the model and the true population are similar</i>
Test	:	<i>Hosmer and Lemeshow goodness of fit</i>
α	:	<i>0.05</i>
Decision rule	:	<i>reject H_0 if $p \geq \alpha$</i>

A sensitivity analysis of the goodness of fit test results was performed with groupings of 8, 10 and 12 (based on octiles, deciles etc.. of the estimated probabilities). The good fit for the model was anticipated if the p-value for each of the groups was greater than 0.05. Table 10 in the results section shows the p-values for the Hosmer and Lemeshow test.

4.7.1.2. Design effects

Design effects were further produced for the survey adjusted analysis. Design effects measure the efficiency of the survey design.⁵⁹ by calculating the ratio of variance from the survey sample with that expected if assuming a hypothetical simple random sample.⁶⁵ This ratio gives a measure of the precision “gained or lost” by not using simple random sampling.⁵⁹

Lohr suggests the possibility of having design effects less than 1 in stratified samples, unless these strata have equal means.⁵⁹ Lohr further postulates decreased precision in cluster samples hence the expectation of design effects greater than 1 in such cases. If there is stratification, precision is likely to increase and hence yield design effects closer to 1.⁵⁹

In samples with both stratification and clustering therefore, there is no guarantee that the design effects will be less or greater than 1.^{59,65}

4.7.1.3. ROC curves

For analysis assuming a stratified design, as well as for a simple random sampling assumption, Receiver Operating Characteristic (ROC) curves were plotted. ROC curves depict the proportion of covariate group outcome predictions that tally with the observed outcomes.⁶²⁻⁶⁴

4.8. Assessing linearity of numerical variables with the logit

All numerical explanatory variables were assessed for linearity of their relationships with the logit by use of an application of the Box-Tidwell test described by Hilbe.⁶⁶

Non-linearity of this relationship would lead to biased estimates (odds ratios in this study) and biased standard errors as well as incorrect predictions from the model.⁶⁶

Non-linearity may also increase Type II errors.⁶⁶

The Box-Tidwell test runs a logistic regression of the outcome with the numerical variable and an interaction term.

The interaction term is generated as the product of the numerical variable and its log.

In Stata, the syntax to test linearity will be developed is shown below

Generating an interaction term

*gen varbt = var * ln(var)*

where var is the numerical variable being assessed for linearity with the logit.

Running the model with the interaction term

svy: logistic outcome var varbt

If the resulting p-value of the interaction term “varbt” is greater than 0.05, the relationship between the numerical variable “var” and the outcome with the logit will be assumed linear. In cases where the relationship is not linear the variable will be recoded as categorical. The Box-Tidwell assessments were performed prior to the Wald test following the hypothesis test presented below:

H_o	:	<i>Numerical variable not linear with the logit</i>
H_i	:	<i>Numerical variable linear with the logit</i>
Test	:	<i>Box-Tidwell test</i>
α	:	<i>0.05</i>
Decision rule	:	<i>reject H_o if $p \geq \alpha$ (for the coefficient of varbt)</i>

Table 4 in the results section shows Wald test (for survey adjusted) and t-test (for cluster and regular analyses) p-values of the interaction terms that have been modelled with the original numerical variable when testing linearity with the logit.

4.9. Principal component analysis

Principal Component Analysis (PCA) was conducted to create a socio-economic status (SES) variable. PCA was used because assets indices are believed to be more valid and reliable (for quantifying socio-economic status) than actual income data, especially among the poor.⁶⁷ In addition, assets may reflect some form of economic status that is not normally captured by income.⁶⁸ The variables used to create SES in this study are in in Appendix 3 and were consistent with those recommended in previous studies.⁶⁷

Since PCA normally deals with variables with large numbers of data that are not easy to interpret, PCA reduces this data into simpler linear combinations.⁶⁹ PCA produces new variables called principal components whose magnitude is measure by the variance from the variables under consideration.

Variance in this case can be construed as popularity of a particular asset among the dataset. For instance, in this study very few people owned a working electric stove hence this finite number of stoves would give high variability to the components. In a similar fashion, owning a bicycle would translate to lower socio-economic status also

because more people might own them. Variance is assigned to each component created using this popularity.

The first principal component can be thought of as the measure of the highest SES and it derived from plotting a straight line in a particular direction known as the eigen vector across all the variables.⁶⁹ In this first component, measures of variance known as eigen values are developed and they inform the amount of variance in the direction of the eigenvector. The total of the maximum variances from each variable are plotted on a straight line that can also be called a linear combination that becomes the first principal component. The second component is plotted if all the variance is not captured in the first component.

This component is made up of a vector that is plotted perpendicular to the first because it has to search for the residual variance in a different direction.^{67,69} Being perpendicular thus make components 1 and 2 unrelated and also because component 2 searches for residual variances, it is always lower than the component 1 in its eigen value. The subsequent components continue searching for any additional variances in completely different directions but all with smaller eigen values.

The reason for multiple components is because the variance cannot be explained in a single vector, hence more vectors are created if variability still remains in the data. In practice, it has been shown that variables that are interrelated have fewer components because the vectors created are able to capture and extract all the variability in fewer permutations.⁶⁷ A higher eigen value means higher SES.⁶⁷

After creating the principal components, the first components is usually chosen as the measure of SES.^{67,68,70} Following these recommendations, component 1 was chosen as the measure of SES for this study, this variable was split into a binary variable of high (1) and low (0) SES using the Stata syntax shown below:

```
predict f1  
hist f1  
egen pcacomp= cut(f1), group(2)
```

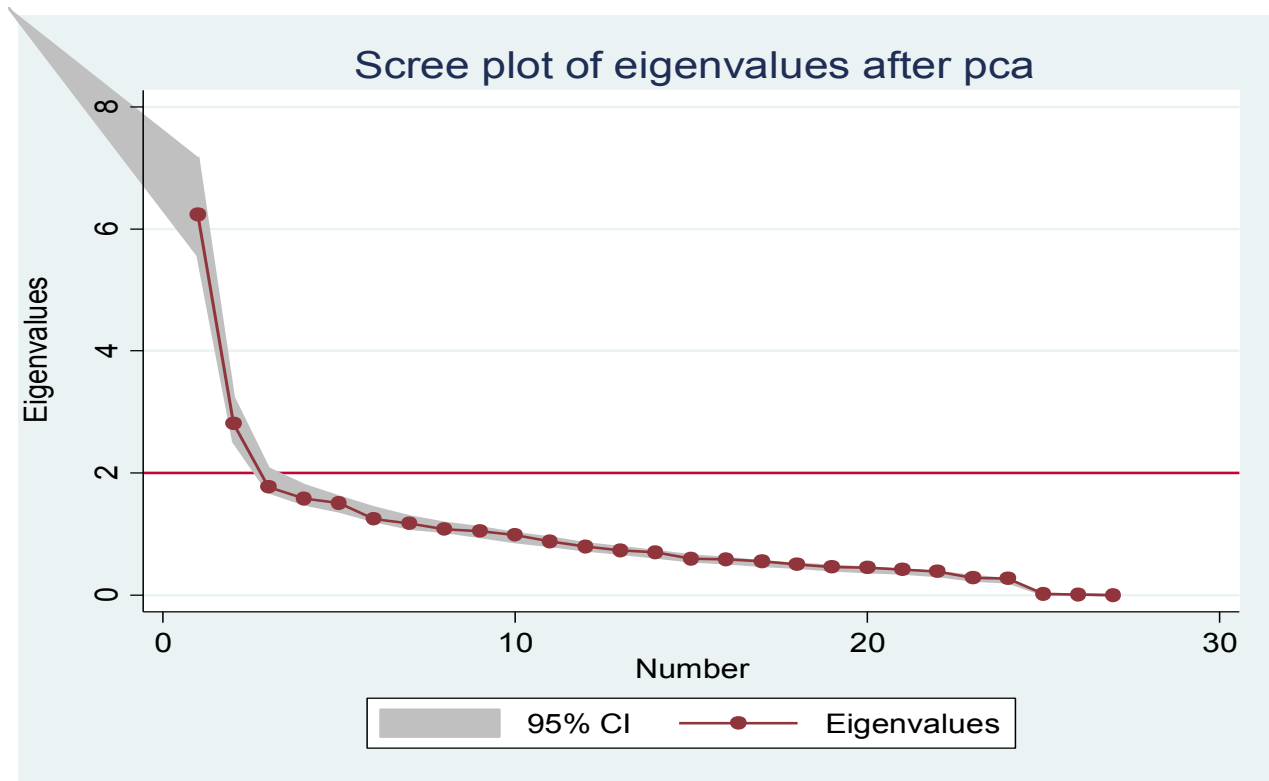
Table 3 below shows the components and their respective variances. Component 1 account for 23% of the total variable in its vector. This proportion of variance was observed in other studies referenced by Vyas and Kumaranayake where it ranged between 11% and 27%.⁶⁷

Table 3 : Principal component analysis Stata output

COMPONENT	EIGENVALUE	PROPORTION OF VARIANCE	CUMULATIVE VARIANCE
Component 1	6.24	0.23	0.23
Component 2	2.81	0.10	0.34
Component 3	1.77	0.07	0.40
Component 4	1.58	0.06	0.46
Component 5	1.51	0.06	0.52
Component 6	1.24	0.05	0.56
Component 7	1.17	0.04	0.60
Component 8	1.08	0.04	0.64
Component 9	1.05	0.04	0.68
Component 10	0.98	0.04	0.72
Component 11	0.88	0.03	0.75
Component 12	0.80	0.03	0.78
Component 13	0.73	0.03	0.81
Component 14	0.70	0.03	0.83
Component 15	0.59	0.02	0.86
Component 16	0.58	0.02	0.88
Component 17	0.55	0.02	0.90
Component 18	0.50	0.02	0.92
Component 19	0.45	0.02	0.93
Component 20	0.45	0.02	0.95
Component 21	0.42	0.02	0.97
Component 22	0.38	0.01	0.98
Component 23	0.28	0.01	0.99
Component 24	0.27	0.01	1.00
Component 25	0.01	0.00	1.00
Component 26	0.00	0.00	1.00
Component 27	0.00	0.00	1.00

In addition to table 3 above, a scree plot is of eigen values with a confidence interval is provided in figure 2 below. Figure 2 shows a narrow confidence interval for all the components. It also shows component 1 with the highest eigen value, the following component has at least less than half the eigen value of component 1. The subsequent components in the dots down the line represent other components in decreasing variance and hence less information to explain SES.

Figure 2 : Scree plot of eigenvalues after PCA



4.10. Data Management

4.10.1. Data capturing

Data from the questionnaires were captured by trained Aurum Institute’s data capturers in a double-password-protected database developed by Bytes Technologies for the Aurum Institute’s data management department. Access to the database was restricted to designated research staff. Due to capacity constraints data capturers captured by single entry. However, this researcher further verified the captured data for all observations using the original questionnaires against the data in the database to ensure data accuracy and completeness.

4.10.2. Data storage and confidentiality

During data collection, all questionnaires were stored at clinics in locked cupboards that only research staff could access. Questionnaires that were used to collect individual patient data did not contain patient names. However, informed consent forms which contained patient names and signatures were locked away in a pedestal affixed inside the locked study cupboard. This was done for further security and confidentiality of patients` private information. Research staff included the following people; research assistants, study coordinators, research managers, principal investigators, quality assurance officers, statistician and external monitors appointed

by the Centers for Disease Control and Prevention (CDC) which sponsored the cluster randomised controlled trial.

At the end of the study, all documents used for the study were moved from the clinics to a secure archiving facility at the Aurum Institute`s head office.

4.11. Ethical and Legal considerations

4.11.1. Good clinical practice

All staff involved in the study were trained for good clinical practice (GCP) using the latest standards. GCP was regarded as necessary for all project staff in order to align their skills with global standards of confidentiality, privacy and respect of persons when collecting trial data from patients.

A sample of a GCP certificate is included in the list of appendices.

4.11.2. Approvals for the primary study

The primary study was approved by the Human Subjects Research Ethics Committee at Witwatersrand University in South Africa (Appendix 4), and the London School of Hygiene and Tropical Medicine in the United Kingdom (Appendix 5). Relevant approvals were also sought (and approved) from the Ekurhuleni Municipality, Gauteng (Appendix 6).

4.11.3. Approvals for the secondary analysis

The researcher was given permission to use the secondary data by the Aurum Institute`s Principal Investigator of the primary study (Appendix 7). Additional ethical approval was obtained from the Faculty of Health Sciences Research Ethics Committee of the University of Pretoria (Appendix 8).

4.11.4. Clinical trial registration

The study was registered as a clinical trial on the South Africa Register of clinical trials with trial number DOH-27-1011-3846.

4.11.5. Data and Safety Monitoring Board

The principal investigators and co-investigators invited three experts in the field of TB and HIV integration and operational research to function as a Data Safety and Management Board for the trial (DSMB). The DSMB was constituted and functioned according the DSMB charter.

4.12. Logistics, Time Schedule and Action Plan

The data for this sub-study were collected over 28 weeks spanning from April 2013 to October 2013. Data were analysed from November 2014 to January 2015 after receipt of ethics approval from the University of Pretoria's Faculty of Health Sciences Research Ethics Committee. All study participants presenting to the clinics during the study period were enrolled provided informed consent was obtained. Hence enrollements per clinic were taken to be proportional to patient loads at the clinics.

4.13. Budget/Resources

The randomised controlled trial project was funded through a PHC sector health evaluation grant from the President's Emergency Plan for AIDS Relief (PEPFAR) through CDC, South Africa. This budget covered the costs of the implementation of interventions, enrolment and data collection. The budget did not include the cost of TB investigations. TB and HIV investigations were carried out through the routine DOH structures and facilities.

5. FINDINGS

5.1. Overview

The first section of the results presents details of the response rate and a flow diagram of the study, with a table of reasons for non-response. The second section provides the descriptive summary statistics by group (the first group are those who make use of concurrent providers; the second group are those who do not). Means and standard deviations are used to summarise normally distributed numerical variables and percentages for binary and categorical variables.

Medians and inter-quartile ranges (IQR) would have been used if the variables were not normally distributed. Descriptive analyses are then followed by logistic regression models using three different approaches to analysis accompanied by appropriate post-regression diagnostics.

In the logistic regression models, none of the numerical variables violated the assumption of linearity with the logit when assessed using the Box-Tidwell test and hence the variables were all modelled as numerical variables.⁶⁶ Results of the Box-Tidwell tests (given in table 4 below) produced p-values of more than 0.05 which translate to evidence for linearity of the continuous variables with the logit.

Table 4 : Logistic regression Box-Tidwell results for numerical co-variables: test p-values

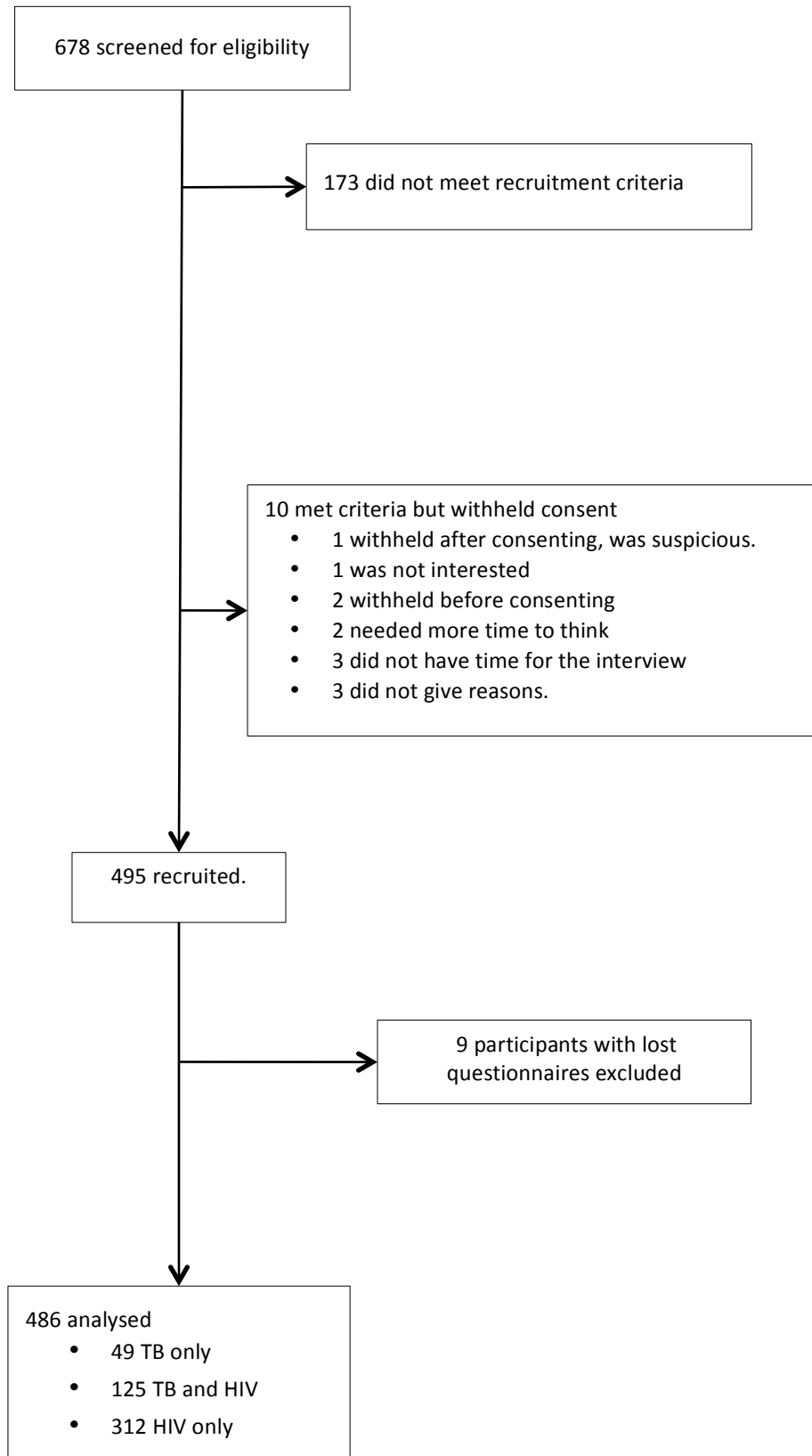
VARIABLE	Svy: design-adjusted	SRS with cluster option	SRS*
Age at last visit	0.312	0.310	0.321
Time spent at the clinic	0.079	0.073	0.074
Time spent travelling to the clinic	0.226	0.305	0.343
Last recorded CD4 result	0.461	0.446	0.462
Number of clinic visits	0.945	0.962	0.951

Svy: is the Stata command invoking analysis taking the sampling design into consideration; SRS is simple random sampling (i.e. analysis under such an assumption)

5.2. Study flow

A total of 486 participants were enrolled in the study. The sample was composed of 49 with only TB, 125 co-infected with TB and HIV and 312 with HIV only. From the 505 who were screened and met the inclusion and exclusion criteria, 495 agreed to participate thus yield a response rate of 98.02%. The reasons for non-response are presented in figure 3 below.

Figure 3 : Study flow diagram



5.3. Descriptive analysis and patient demographics

Table 5 below shows the descriptive summaries for categorical variables from the sample.

Table 5 : Descriptive statistics

VARIABLE	Concurrent users		Non-concurrent users	
	N	**%	N	**%
Proportion	74	(15.23)	412	(84.77)
Gender				
Female	41	(55.41)	261	(63.35)
Male	31	(41.89)	144	(34.95)
Unknown	2	(2.70)	7	(1.70)
Disease group				
TB/HIV co-infection	22	(29.73)	104	(25.24)
TB only	6	(8.11)	43	(10.44)
HIV only	46	(62.16)	265	(64.32)
CD4 count (yes/no)	66	(89.19)	355	(86.17)
On ART (yes/no)	43	(58.11)	269	(65.29)
Medical schemes beneficiary (yes/no)	5	(6.76)	1	(0.24)
Assisted at home (yes/no)	28	(37.84)	173	(41.99)
SA citizen (yes/no)	63	(85.14)	342	(83.01)
Grade 8 or above (yes/no)	63	(85.14)	359	(87.14)
Employed at diagnosis (yes/no)	44	(59.46)	220	(53.40)
Currently married (yes/no)	11	(14.86)	85	(20.63)
*Socio-economic status	36	(50.70)	198	(49.87)
Has adult/s accompanying (yes/no)	10	(13.51)	22	(5.34)
RCT Intervention arm (yes/no)	38	(51.35)	238	(57.77)
Ethnicity (black/non-black)	71	(95.95)	399	(96.84)
Primary language (Zulu/others)	32	(43.24)	140	(33.98)

**estimated by principal component analysis*

***adjusted for survey design*

About 15.23% of the sampled population used PHC clinics and non-PHC services concurrently. The sample was predominantly female and almost all patients who made concurrent use PHC and non-PHC services and those who did not were infected with HIV. Participants who visited non-PHC providers were however older, with lower CD4 counts and had spent more time travelling to and waiting to be served at the clinic.

Descriptive summaries for numeric variables are presented in Table 6 below. Means were used as the default measure of central tendency after histograms testing for normality found them to be unimodal and not skewed. The histograms are attached in Annexe 1. The means for the adjusted and unadjusted analysis did not differ, however the standard deviations for the adjusted analysis tended to be higher for most variables.

Table 6 : Descriptive summary of numerical co-variables

VARIABLE	UNADJUSTED FOR SURVEY DESIGN						SURVEY-ADJUSTED			
	Concurrent users			Non-concurrent users			Concurrent users		Non-concurrent users	
	N	Mean	SD	N	Mean	SD	Mean	SD*	Mean	SD
Age at last visit (years)	71	35.48	0.98	401	35.11	0.44	35.48		35.11	0.44
Time spent at the clinic (minutes)	69	163.20	11.36	397	171.22	5.68	163.20		171.22	17.06
Time spent travelling to the clinic (minutes)	28	32.79	4.61	146	34.99	2.65	32.79		34.99	3.83
Last recorded CD4 result	74	209.51	24.41	412	201.98	9.72	209.51		201.98	14.34
Number of clinic visits	74	7.20	0.82	412	8.03	0.48	7.20		8.03	1.32

* Standard deviations are not estimated due to the fact that there were several strata with 1 or zero concurrent users.

Patients who made concurrent use spent an average of 163 minutes at the clinic; 8 minutes less than the average time spent by patients who did not make concurrent use. Further analysis among the same group of concurrent users showed that HIV patients spent the most time, 188 minutes at the clinic; followed by patients co-infected with TB and HIV and those with TB only who spent 137 and 88 minutes respectively. Additional analysis between ages of concurrent and non-concurrent users showed no statistically significant differences. All patients had an average age of 35 years for both the survey adjusted and unadjusted analyses with standard deviations below 1. Table 6 gives the rest of summaries of the other continuous variables among concurrent and non-concurrent users of PHC and non-PHC users.

5.4. Logistic regression results

Univariate and multivariate analyses were conducted using three different forms of analyses namely; survey design-adjusted for strata; and two analyses where SRS was assumed, one with Stata's "cluster" adjustment and the other without. Table 7 below presents the results from these analyses. The full models only had variables with Wald test p-value of less than 0.25 for their coefficients. From these adjusted results from the three different analyses, it was found that patients who were beneficiaries of medical schemes had 26.6 times higher odds of making concurrent use of PHC and non-PHC services than those who were not. Patients who were accompanied by at least one other adult had 2.4 times higher odds of being concurrent users than those who were not.

These two variables were the only ones found to be statistically significant with p-values of less than 0.05 and odds ratio confidence intervals which did not include the null value of 1. Patients who were taking ART at the PHC clinic and also those who were partnered at the time of interview were found to have lower odds (0.686 and 0.659 respectively) of concurrent PHC/ non-PHC use.

However, with p-values higher than 0.05, the relationships were not statistically significant. Being a male and also speaking Zulu as the first language both had higher odds of concurrent PHC/ non-PHC use than their opposite counterparts but also did not yield statistically significant results.

Logistic regression without sampling design adjustment also found that neither time spent at the clinic while waiting for service nor time spent travelling to the clinic had any effect on concurrent use of PHC and non-PHC services. The odds ratios for these variables were all approximately 1 but there was no statistical significance found due to p-values being greater than 0.05 and confidence intervals including the null value of 1.

Both these explanatory variables were continuous and so Odds ratios close to 1 may simply be an effect of the scaling of the variable; however due to the lack of statistical significance rescaling and re-analysis was not done, as scaling would not have affected the p-values. Table 7 below presents the rest of the survey design-adjusted logistic regression results.

The rest of the results are given in the tables 7 to 11.

5.4.1. Survey design logistic regression results

Table 7 : Logistic regression results following adjustment for survey sampling design

VARIABLE	UNIVARIATE LOGISTIC REGRESSION RESULTS					ADJUSTED MULTIVARIATE LOGISTIC REGRESSION RESULTS				
	Odds ratio	*p-value	**Linearised SD	95% CI		Odds ratio	*p-value	**Linearised SD	95% CI	
Beneficiary of a medical aid scheme	29.78	0.002	33.01	3.37	262.92	26.58	0.008	32.68	2.37	297.77
Accompanied by at least an adult to the clinic (Yes/No)	2.77	0.013	1.13	1.24	6.19	2.41	0.046	1.06	1.02	5.72
On ART (yes/no)	0.74	0.239	0.19	0.44	1.23	0.69	0.172	0.19	0.40	1.18
Primary language (Zulu/others)	1.48	0.127	0.38	0.90	2.45	1.43	0.203	0.40	0.83	2.46
Currently partnered (yes/no)	0.67	0.255	0.24	0.34	1.33	0.66	0.267	0.25	0.32	1.38
Sex (Male/Female)	1.30	0.180	0.25	0.89	1.89	1.31	0.193	0.27	0.87	1.98
Employment at diagnosis (yes/no)	1.28	0.332	0.33	0.78	2.11					
Had a CD4 count (µL)	1.33	0.484	0.53	0.60	2.92					
Assisted by someone at home (yes/no)	0.84	0.505	0.22	0.50	1.40					
Country of origin (SA/Not)	1.17	0.655	0.42	0.58	2.36					
Intervention arm (Intervention/control)	0.77	0.293	0.19	0.48	1.25					
†Time travelling to the clinic (hours)	1.00	0.688	0.01	0.98	1.03					
†Total visits made to this clinic	1.00	0.435	0.01	0.96	1.02					
†Time at clinic (hours)	1.00	0.525	<0.01	1.00	1.00					
†Last recorded CD4 result	1.00	0.771	<0.01	1.00	1.00					
†Age at last visit (years)	1.01	0.727	0.01	0.98	1.03					
Level of education	0.85	0.630	0.30	0.43	1676					
Socio-economic status	1.03	0.897	0.27	0.62	1.71					
Disease group	TB/HIV co-infection	1.00	Referenc							
	TB only	0.66	0.403	0.33	0.25	1.75				
	HIV only	0.82	0.486	0.23	0.47	1.43				

*Wald test p-value **Linearised standard deviation †numerical variable

5.4.2. Logistic regression results using the “cluster” option in Stata’s regular (SRS) logistic regression

Table 8 : Logistic regression results using the “cluster” option in Stata

VARIABLES	UNADJUSTED					ADJUSTED				
	OR	*p-value	**Robust SD	95% CI		OR	*p-value	**Robust SD	95% CI	
Beneficiary of a medical aid scheme	29.78	<0001	25.25	5.65	156.89	26.58	0	20.53	5.85	120.78
Accompanied by at least an adult to the clinic (Yes/No)	2.77	<0.001	0.74	1.65	4.66	2.41	0.001	0.66	1.41	4.12
On ART (yes/no)	0.74	0.107	0.14	0.51	1.07	0.69	0.074	0.15	0.45	1.04
Primary language (Zulu/others)	1.48	0.134	0.39	0.89	2.47	1.43	0.172	0.37	0.86	2.37
Currently partnered (yes/no)	0.67	0.211	0.21	0.36	1.25	0.66	0.211	0.22	0.34	1.27
Sex (Male/Female)	1.30	0.233	0.28	0.85	1.98	1.31	0.290	0.34	0.79	2.17
Employment at diagnosis (yes/no)	1.28	0.425	0.40	0.70	2.35					
Had a CD4 count (µL)	1.33	0.451	0.49	0.64	2.75					
Assisted by someone at home (yes/no)	0.84	0.49	0.21	0.51	1.38					
Country of origin (SA/Not)	1.17	0.514	0.29	0.73	1.89					
Intervention arm (Intervention/control)	0.77	0.525	0.32	0.35	1.72					
†Time travelling to the clinic (hours)	1.00	0.625	0.01	1.00	1.01					
†Total visits made to this clinic	1.00	0.652	0.02	0.94	1.04					
†Time at clinic (hours)	1.00	0.669	<0.01	1.00	1.00					
†Last recorded CD4 result	1.00	0.707	<0.01	1.00	1.00					
†Age at last visit (years)	1.01	0.753	0.02	1.00	1.04					
Level of education	0.85	0.785	0.52	0.25	2.82					
Socio-economic status	1.03	0.909	0.30	0.59	1.83					
TB/HIV co-infection	1.00									
Disease group										
TB only	0.66	0.366	0.30	0.27	1.63					
HIV only	0.82	0.559	0.28	0.42	1.59					

*Wald test p-value **Robust standard deviation †numerical variable

5.4.3. Regular logistic regression results

Table 9 : Regular (SRS) logistic regression results with no allowance made for clustering

VARIABLES	UNADJUSTED					ADJUSTED				
	OR	p-value	Linearised	95% CI	Odds ratio	p-value	Linearised	95% CI		
Beneficiary of a medical aid scheme	29.78	0.002	32.85	3.43	258.80	26.58	0.004	30.30	2.85	248.30
Accompanied by at least an adult to the clinic (Yes/No)	2.77	0.012	1.12	1.25	6.12	2.41	0.051	1.09	1.00	5.83
Primary language (Zulu/others)	1.48	0.126	0.38	0.90	2.45	1.43	0.187	0.38	0.84	2.41
Sex (Male/Female)	1.30	0.188	0.25	0.88	1.90	1.31	0.185	0.27	0.88	1.97
On ART (yes/no)	0.74	0.236	0.19	0.45	1.22	0.69	0.161	0.19	0.41	1.16
Currently partnered (yes/no)	0.67	0.254	0.23	0.34	1.33	0.66	0.264	0.25	0.32	1.37
Intervention arm (Intervention/control)	0.77	0.306	0.20	0.47	1.27					
Employment at diagnosis (yes/no)	1.28	0.336	0.33	0.77	2.12					
Had a CD4 count (μ L)	1.33	0.483	0.53	0.60	2.91					
†Total visits made to this clinic	1.00	0.490	0.02	0.96	1.02					
Assisted by someone at home (yes/no)	0.84	0.505	0.22	0.51	1.40					
†Time at clinic (hours)	1.00	0.578	<0.01	1.00	1.00					
Level of education	0.85	0.640	0.30	0.42	1.71					
Country of origin (SA/Not)	1.17	0.652	0.41	0.59	2.34					
†Time travelling to the clinic (hours)	1.00	0.729	0.01	0.98	1.01					
†Age at last visit (years)	1.01	0.745	0.02	0.98	1.03					
†Last recorded CD4 result	1.00	0.764	<0.01	1.00	1.00					
Socio-economic status	1.03	0.897	0.27	0.62	1.71					
	TB/HIV co-infection	1								
Disease group	TB only	0.66	0.401	0.33	0.25	1.74				
	HIV only	0.82	0.486	0.23	0.47	1.43				

*Wald test p-value

**Robust standard deviation

†numerical variable

5.5. Comparison of results

5.5.1. Comparison of unadjusted results

Table 10 : Comparison of unadjusted logistic regression results

Variable	Odds ratio	p-value			Standard deviation			95% CI						
		* svy	¶ cluster	¶ regular	¥ svy	∫ cluster	¥ regular	svy		cluster		regular		
Beneficiary medical scheme	29.78	0.002	<0.001	0.002	33.00	25.25	32.85	3.37	262.92	5.65	156.89	3.43	258.80	
Accompanied by an adult	2.77	0.013	<0.001	0.012	1.13	0.74	1.12	1.24	6.19	1.65	4.66	1.25	6.12	
On ART	0.74	0.239	0.107	0.236	0.19	0.14	0.19	0.44	1.23	0.51	1.07	0.45	1.22	
Primary language (Zulu/other)	1.48	0.127	0.134	0.126	0.38	0.39	0.38	0.90	2.45	0.89	2.47	0.90	2.45	
Currently partnered (yes/no)	0.67	0.255	0.211	0.254	0.24	0.21	0.23	0.34	1.33	0.36	1.25	0.34	1.33	
Sex (Male/Female)	1.30	0.180	0.233	0.188	0.25	0.28	0.25	0.89	1.89	0.85	1.98	0.88	1.90	
Employment at diagnosis	1.28	0.332	0.425	0.336	0.33	0.40	0.33	0.78	2.11	0.70	2.35	0.77	2.12	
Had a CD4 count (µL)	1.33	0.484	0.451	0.483	0.53	0.49	0.53	0.60	2.92	0.64	2.75	0.60	2.91	
Assisted by someone at home	0.84	0.505	0.49	0.505	0.22	0.21	0.22	0.51	1.40	0.51	1.38	0.51	1.40	
Country of origin (SA/Not)	1.17	0.655	0.514	0.652	0.42	0.29	0.41	0.58	2.36	0.73	1.90	0.59	2.34	
Intervention arm	0.77	0.293	0.525	0.306	0.19	0.32	0.20	0.48	1.25	0.35	1.72	0.47	1.27	
†Time to the clinic (hours)	1.00	0.688	0.625	0.729	0.01	0.01	0.01	0.98	1.03	1.00	1.01	0.98	1.01	
†Total visits made to this clinic	1.00	0.435	0.652	0.49	0.01	0.02	0.02	0.96	1.02	0.94	1.04	0.96	1.02	
†Time at clinic (hours)	1.00	0.525	0.669	0.578	<0.01	<0.01	<0.01	1.00	1.00	1.00	1.00	1.00	1.00	
†Last recorded CD4 result	1.00	0.771	0.707	0.764	<0.01	0.00	<0.01	1.00	1.00	1.00	1.00	1.00	1.00	
†Age at last visit (years)	1.01	0.727	0.753	0.745	0.01	0.02	0.02	0.98	1.03	0.98	1.04	0.98	1.03	
Level of education	0.85	0.630	0.785	0.64	0.30	0.52	0.30	0.43	168	0.25	2.82	0.42	1.71	
Socio-economic status	1.03	0.897	0.909	0.897	0.27	0.30	0.27	0.62	1.71	0.59	1.83	0.62	1.71	
TB & HIV	1	Ref												
Disease group	TB only	0.66	0.403	0.366	0.401	0.33	0.30	0.33	0.25	1.75	0.27	1.63	0.25	1.74
	HIV only	0.82	0.486	0.559	0.486	0.23	0.28	0.23	0.47	1.43	0.42	1.59	0.47	1.43

Svy = adjusted for survey design; cluster = assuming SRS but including the cluster option in Stata to allow for clustering within the data; regular = assuming SRS and without allowing for clustering within the sample.

* wald test p-value ¶ t-test p-value ¥ linearised SD ∫ robust standard deviations

5.5.2. Comparison of adjusted results

Table 11 : Comparison of adjusted logistic regression results

Variable	Odds ratio	p-value			Linearised			95% CI					
		* svy	¶ cluster	¶ regular	¥ svy	∫ cluster	¥ regular	svy	cluster	regular	svy	cluster	regular
Beneficiary of a medical aid scheme	26.58	0.008	<0.001	0.004	32.68	20.53	30.30	2.37	297.77	5.85	120.78	2.85	248.30
Accompanied by at least an adult	2.41	0.046	0.001	0.051	1.06	0.66	1.09	1.02	5.72	1.41	4.12	01.00	5.83
On ART (yes/no)	0.69	0.172	0.074	0.161	0.19	0.15	0.19	0.40	1.18	0.45	1.04	0.41	1.16
Primary language (Zulu/others)	1.43	0.203	0.172	0.187	0.40	0.37	0.38	0.83	2.46	0.86	2.37	0.84	2.41
Currently partnered (yes/no)	0.66	0.267	0.211	0.264	0.25	0.22	0.25	0.32	1.38	0.34	1.27	0.32	1.37
Sex (Male/Female)	1.31	0.193	0.290	0.185	0.27	0.34	0.27	0.87	1.98	0.79	2.17	0.88	1.97

Svy = adjusted for survey design (strata); cluster = routine logistic regression assuming SRS with the cluster option included; regular = assuming SRS with no allowance for clustering within the sample.

* wald test p-value ¶ t-test p-value ¥ linearised SD ∫ robust standard deviation s

5.6. Post-regression diagnostics

5.6.1. Significance of logistic regression models

The Chi-square p-values for survey sampling-adjusted, SRS with the cluster option and SRS without the cluster option were all less than 0.001 (0.0004, 0.0000, 0.0004 respectively). Therefore, all the three models were statistically significant.

5.6.2. Hosmer and Lemeshow goodness of fit tests

Post regression diagnostics for the three types of regression models were conducted using the Hosmer and Lemeshow goodness of fit tests. Table 10 below shows the results from the diagnostics of the three types of analyses. The results show that with the p-values greater than 0.05, the logistic regression models for all groups and analyses fit well with the true values that the sample is inferring to.

Table 12 : Hosmer and Lemeshow goodness of fit tests p-values

Groups	Survey adjusted	Cluster adjusted	Regular
8	0.944	0.882	0.882
10	0.940	0.879	0.879
12	0.957	0.706	0.706

5.6.3. Design effects

Design effects were calculated for the survey sampling design logistic regression model. The results are presented in tables 11 below. All design effects were approximately equal to 1 which suggests comparability between the precision of this sample selected in 18 clinic strata and a hypothetical simple random sampling.

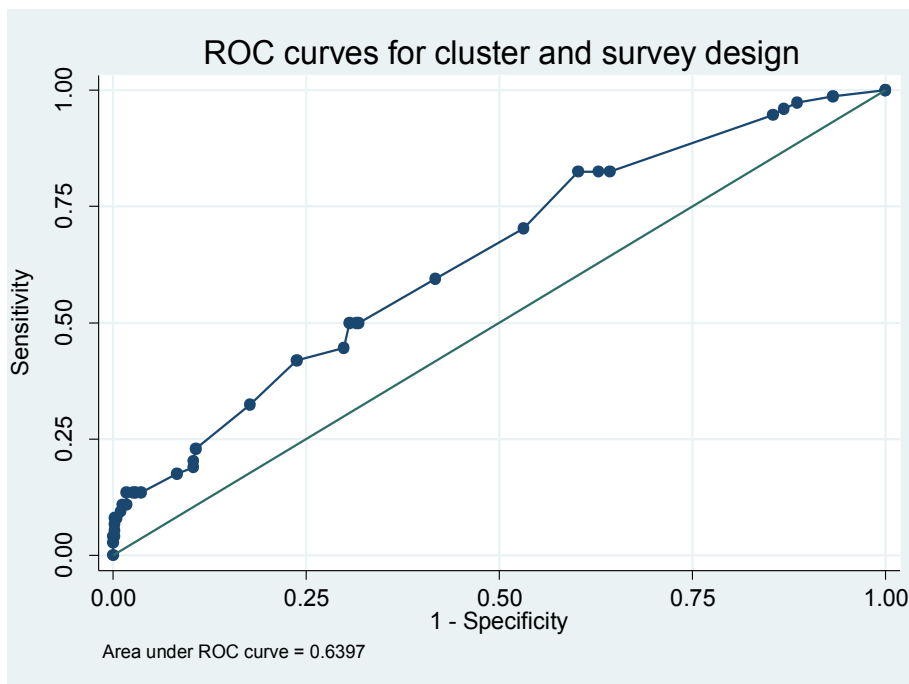
Table 13 : Design effects

Variable	Odds ratio	Linearised SD	*DEFF
Beneficiary of a medical aid scheme	26.579	1.230	1.011
Accompanied by at least an adult to the clinic (Yes/No)	2.411	0.430	1.022
Sex (Male/Female)	1.313	0.209	0.999
Primary language (Zulu/others)	1.425	0.277	1.000
On ART (yes/no)	0.686	0.276	1.008
Currently partnered (yes/no)	0.659	0.375	1.003

5.6.4. Receiver Operating Characteristic (ROC) curves

ROC curves were further plotted for SRS with the cluster option and SRS analyses (not available after the svy: model). The two graphs were however the same; hence only one graph is shown below. The graph shows that at approximately 63% of the outcome was explained by the logistic regression models.

Figure 4 : ROC curves for cluster and survey design



5.7. Additional analyses

Data analysis was repeated for all the three types of logistic regression; but excluding patients who were either members or beneficiaries of medical aid schemes. This repeat analysis was motivated by the wide confidence intervals for the Odds ratios for those who were scheme beneficiaries. These wide confidence intervals were caused by the small number of scheme beneficiaries in this sample. The results from the repeat analysis are presented in Table 14 below and show marginal differences between the two sets of analyses.

Table 14 : Results excluding medical aid beneficiaries

Variable	with beneficiaries of medical aids schemes				without beneficiaries of medical aids schemes			
	Odds ratio	* svy	¶ cluster	¶ normal	Odds ratio	* svy	¶ cluster	¶ normal
Beneficiary of a medical aid scheme	26.58	0.001	<0.001	0.004	-	-	-	-
Accompanied by at least one adult	2.41	0.005	0.001	0.051	3.13	0.006	0.003	0.078
On ART (yes/no)	0.69	0.092	0.074	0.161	.075	0.294	0.076	0.174
Primary language (Zulu/others)	1.43	0.190	0.172	0.187	1.49	0.136	0.124	0.141
Currently partnered (yes/no)	0.66	0.228	0.211	0.264	0.72	0.357	0.167	0.216
Sex (Male/Female)	1.31	0.304	0.290	0.185	1.34	0.152	0.259	0.154

Svy = adjusted for survey design; cluster = routine logistic regression with the cluster option included; normal = assuming a simple random sample.

* wald test p-value ¶ t-test p-value

6. DISCUSSION

This study investigated the factors associated with TB and HIV patients' concurrent use of PHC and non-PHC services. Data were obtained through stratified sampling (clinics were the strata) and enrollments per clinic were deemed to be proportional to clinic loads as enrollment went ahead for the same time interval at all clinics; and all new patients were enrolled provided they were eligible and gave consent to participate.

The data were then analysed using logistic regression adjusted for survey sampling design (Strata) and two comparison logistic regression approaches; first assuming SRS but using the Stata "cluster" option for clustering within the selected sample; and second without the "cluster" option. Statistical significance was determined by p-values and 95% confidence intervals. All variables with odds ratio p-values of less than 0.05 in the multivariate analysis and 95% confidence intervals values excluding 1 were regarded as being statistically significant. Those with p-values close to the critical p-value of 0.05 were considered marginally significant.

The three analysis approaches produced identical odds ratios since the sampling was deemed to be proportional to probability of inclusion, thereby removing the need to use weighting adjustments for the strata. However different predictor variable p-values, standard errors and 95% confidence intervals were obtained for the estimated odds ratios due to the different ways in which the Standard deviations are calculated in the three different approaches.

The similarity of the results obtained from the SRS model and SRS plus cluster model suggest that the study population was homogenous with little difference between the variability between and within clinics. This is born out by the fact that the design effects, following regression adjusted for sampling design, were all found to be very close to unity.

In all the three analyses, it was found that only those patients who were either members or beneficiaries of medical schemes and also those who were accompanied by at least one other adult to the clinic had higher odds for concurrent PHC and non-PHC use than their opposite counterparts. Patients who were on ART had lower odds of making concurrent PHC and non-PHC use; however, this relationship was only marginally statistically significant.

6.1. Comparisons with previously published study results

In this study, it was found that as many as 15.23% of the sampled population made concurrent use of PHC and non-PHC services, and this confirms the importance of non-PHC providers in TB and HIV control in South Africa. This proportion is also identical to an equally important 16% of the general population serviced by the non-PHC sector in South Africa, but that 16% is of higher income and is believed to include those able to afford using non-PHC services.^{47,48}

This study is the first of its kind in South Africa because it focused explicitly on TB and/or HIV patients and on concurrent use of services. Previous studies have instead only reported population level proportions on use of non-PHC sector facilities without inquiring about concurrent use. For instance, in 2004 Harrison estimated that up to 32% and 15% of the South African population consulted private doctors and private hospitals respectively.¹⁹ A household survey in 2013 was to also estimate 28.9% of households in the entire country making use of non-PHC sector services (doctors, clinics and hospitals) while traditional healers' consultation ranged between 0.1%²⁴ and 1.2%⁵⁵. While this study did not analyse non-PHC sector use by type of provider (numbers were too small for such an analysis), it was able to estimate the likelihood of this cohort of TB and/or HIV patients using PHC and non-PHC services concurrently. It may be useful to initiate further research into studies that, in this same cohort of patients, stratify concurrent use by type of provider. This current information estimated in this study is also important in informing vital estimates of vulnerable patients who make concurrent consultations and in turn increase their chances of poorer TB and HIV outcomes. These patients may need to be traced in order to ascertain if they received quality, guideline-compliant, services in the non-PHC sector.

The most significant factor associated with concurrent use was being a beneficiary of a medical aid scheme at the time of diagnosis with either TB or HIV. Patients who were beneficiaries of medical aid schemes had 36.36 significantly higher odds of consulting PHC and non-PHC services concurrently. These results agree with those from studies that associated use of non-PHC sector services with being a member or beneficiary of medical aid schemes.^{15,19,26} The majority of the members of medical aid schemes are of higher income levels²⁶ and the contributions they make account for 47% of total health expenditure which is mainly spent in the non-PHC sector sector⁴⁶. Despite this observed association between medical aid beneficiary status and concurrent use, it should be noted that there were extremely small numbers of participants (only 5; 1/412 of those who did not make use on non-PHC providers and 5/74 of those who did) of participants who had access to medical scheme benefits. This explains the very wide

95% CIs that were observed for the odds ratio for medical scheme benefits and it is also a reason to interpret the finding of statistical significance with caution. Du Prel et al. describe small samples, as a cause for wide confidence intervals and hence reduced precision of the odds ratio.⁷¹ However, in spite of the wide confidence interval, the estimate was highly statistically significant with a p-value of <0.001. The suggestion is that as more people obtain access to non-PHC providers (perhaps as a result of greater formal employment and medical scheme membership) more TB and HIV patients might be expected to make concurrent use of providers for their care. This would imply that the need to educate monitor and evaluate the non-PHC providers is likely to become more important in the future.

Although evidence from this study shows that patients consulting concurrently with PHC and non-PHC services are more likely to be beneficiaries of medical aid schemes, it may be misleading to conclude without exploring the structure of the sample further. Among those that made concurrent use, only 5 were beneficiaries of medical aid schemes therefore the rest of those making concurrent use made out-of-pocket payments. The small number of people who were members of medical aid schemes is to be expected in this cohort of poor patients.

Chabikuli et al. stated that people of higher income can normally afford to be members of these medical schemes therefore the low number with access in this study is in keeping with a predominantly poor demographic status. This also confirms other previous studies' findings again that the choices of poor patients can be independent of their poverty, resulting in consultation of non-PHC providers.^{17,26,50}

In fact, since the majority of patients who made concurrent use in this study were neither members nor beneficiaries of medical aid schemes, it is possible to assume that among poor patients, there are other forces stronger than medical aid that determine concurrent use. This opinion was supported in repeat analyses which excluded beneficiaries of medical aid schemes and found very little difference to the adjusted odds ratios of the remaining variables in the model. The results of the repeat analysis indicate that the results for other variables were not unduly influenced or distorted by the inclusion of small numbers of members of medical aid schemes. Therefore, with or without membership to any medical aid scheme, concurrent consultation will occur but with out-of-pocket payments which cause catastrophic costs. The results of the repeat analysis were presented in table 14.

The only other factor found to significantly increase concurrent use of PHC and non-PHC services by TB and/or HIV patients was having the patient accompanied to the

clinic by at least one other adult person. Such accompanied patients had 2.4 times higher odds of concurrently consulting than patients those who were not accompanied; this means double the likelihood of concurrent consultation. While there was no other South African study found to support this finding, two Vietnamese studies found that patients' choices for healthcare were strongly based on external influence. In the first study³¹, relatives and friends were central to the patient's decision making process and in the second study³⁷ patients' use of private services for TB were partly a result of the advice received from health staff at the public sector clinic.

Although people who accompanied patients were not interviewed in this study, it would seem from the consistency with previous studies' findings and the current study that TB and HIV patients' health seeking behaviours may well be influenced by people close to them. It could also be that accompanying persons are easily dissatisfied with PHC services which are roundly considered poor and since they may not be sick are thus likely to influence the patients to use PHC and non-PHC concurrently. While the implications of this finding are new in South Africa and among TB and HIV patients, it may be possible, and perhaps warrants further study, that adults who accompany patients also assist in other health decisions such as adherence to treatment given their influence on the patient.

Patients who were HIV positive and were taking ART were also found to be less inclined to making concurrent use of PHC and non-PHC services. With odds ratios of 0.7 in both the unadjusted and adjusted analyses it would seem being on ART discourages concurrent usage; however, this association was only marginally significant in the adjusted analysis with a p-value of 0.074 in the cluster sampling design analysis. This was also consistent with the odds ratios of 0.8 for HIV only in the unadjusted analysis (when compared to co-infected patients) which was the reference variable for TB only and HIV only patient as shown in tables 7 to 11.

6.2. Factors not associated with concurrent PHC & non-PHC use

The following variables were assessed in the univariate analysis and were not associated with the concurrent use of the PHC and non-PHC services; last recorded CD4 count, total time spent at the clinic, total time spent travelling to the clinic and total visits made to the clinic. Long clinic waiting time; which previous studies such as one by Chimbindi et al. regarded as the strongest factor for patient dissatisfaction at the clinic had odds ratio p-values of 0.5 and greater (depending on the approach used) and so were clearly statistically non-significant in this study.²¹ This contradicts available knowledge because dissatisfaction due to long clinic waiting times would make PHC

services less attractive and might be expected to influence concurrent use with non-PHC where patients would be more satisfied. However, long waiting times might also be expected to encourage the abandonment of the PHC clinic (completely) in favour of exclusive non-PHC use, rather than concurrent use. Furthermore the high costs of TB and HIV treatment in the private sector may make it non-feasible for patients to switch. Concurrent usage would be expected to add to the costs for the patient.

One study in Limpopo reported waiting times ranging from 30 minutes to beyond 60 minutes and these were regarded as long, and having an influence on use or non-use of non-PHC services. In the present study, average waiting times for both concurrent and non-concurrent users were 163 and 171 minutes respectively. Surprisingly, concurrent users had spent less time waiting for service at the clinic. This has the potential to strengthen this finding that waiting times are not associated with concurrent use in this study population because it would have been concurrent users spending more time and hence opting for non-PHC care and those who spend less time remaining at the PHC facility.

Therefore, the suggestion by Honda et al. that poor quality of services, especially waiting times, have a conditional effect on concurrent use can be consistent with the findings here. In that study, it was found that in PHC clinics patients may tolerate the poor services such as long clinic waiting times and bad staff attitudes if they receive their appropriate care and medication.³⁰ Although this justification is conditional, if it is valid it may suggest that these PHC clinics in Ekurhuleni north provide relatively satisfactory services such that patients are not actively motivated to make use of concurrent PHC and non-PHC services.

The reasons behind concurrent use, therefore, may not be service-related but, rather, personal and demographic factors such as being accompanied to the clinic as found above. The PHC clinic health system has no influence of these factors. A different explanation however could be that patients who use only PHC services were mainly poor people as reported in previous study, even in Ekurhuleni there is generalised poverty.^{5,6,41,72} Therefore, their only option for TB and HIV care were the PHC clinics while the (few) wealthier patients, who were more likely to be members of medical schemes, and others who made out-of-pocket payments, consulted with non-PHC providers. While it may not seem problematic for wealthier patients to avoid the use of PHC clinics, Chandra et al. in Buso's study¹⁶ found that poorer patients remaining in the PHC clinics may not be able to raise concerns on quality of services (as compared to their richer counterparts who have options for non-PHC services). Therefore, PHC services may continue to deteriorate while poorer patients remaining in these settings

endure poor service since that is their only source of healthcare. This therefore reinforces the need to improve the services in PHC services, regardless of the users, because, although waiting times and bad staff attitudes may not cause concurrent use, it could also be a result of fear of reprisals for raising quality concerns among the patients rather than clinics offering adequate medicines (as Honda et al. suggest).

Further analyses of clinic waiting time found that HIV patients had the highest waiting time and the lowest was among patient with TB only; this was also similar to the findings in Chimbindi et al. While this was not explained in the current study, Chimbindi et al. postulate that HIV patients would spend more time because the TB patients are seen by a single health provider whereas HIV patients are assisted by multiple care-givers. This could also be assumed for this study since belonging to either the intervention or control arm of the cluster randomised trial did not impact on concurrent consultation. The justification could have been more accurate however if further analysis had been conducted comparing waiting times by study arm, but this was not considered significant since belonging to either arms did not significantly affect increase concurrent use.

Speaking isiZulu as first language, being a male, employment at diagnosis, having a CD4 count done, being a South African and being of an older age and socio-economic status were all found to increase concurrent PHC and non-PHC use, but not with statistical significance. Although speaking isiZulu as first language and being a male were included in the multivariate analysis, they were included only on the basis of an initial p-value of below 0.25 during the screening stage.

These variables remained not statistically significant in the multivariate analysis; speaking isiZulu was included in both models in order to test if it had any influence, however, as there was previous justification for its inclusion. The weakest associations were for older age and higher socio-economic status.

For variables such as employment at time of diagnosis and socio-economic status which attempt to proxy the patient's income level, there was no significant association with concurrently using PHC and non-PHC services. This, like the non-significance of long waiting time, contradicts findings from descriptive studies which suggested patients with higher income are more likely to use non-PHC services (but not necessarily concurrent use as was investigated in this study). This was expected after the descriptive analysis found that 96% of concurrent users were not part of the highest income quintile that had access to medical aid schemes. However, a scientific justification of these findings was reported by Lönnroth et al. who report that these

social class factors such as employment and socio-economic status were weak predictors of use of non-PHC services by TB patients.³⁷ Instead, circles of friends and relatives are were found to play a major role in the choice of type of facility that a patient will attend for TB care.³¹ In this study, this finding may also hold because most patients were relatively poor and income would not have been a major determinant. Van Wyk found that patients who consult with non-PHC providers may sometimes revert back to PHC because of depleted funds. This therefore suggests that most poor patients using non-PHC may not afford to use these services in the first place hence income may not so much influence concurrent use.

6.3. Effects of analysing the data using the survey adjustment module in Stata

This study used three different analysis approaches; adjustment for survey sampling design, assumed SRS sampling with Stata 12 “cluster” option to allow for clustering within a SRS, and another SRS approach with no consideration of the clustering in the sample. The results from the three different analyses are shown respectively in tables 7, 8 and 9. Table 10 and 11. There the tables compare p-values, standard deviations and confidence intervals for the three approaches. With stratification as the only sampling design issue in these data, and clinic-level sample sizes deemed to reflect clinic patient loads, the incorporation of sampling design adjustments did not affect the point estimates as shown in tables 10 and 11. Only their variances and confidence intervals changed, due to the fact that the Standard deviations are estimated differently in the three approaches. On the one hand the analysis with adjustment for the stratified sampling design is theoreticllay the more corrcet, perhaps. However, the fact that there was clustering within the selected sample should ideally also be taken into account. The analysis of the data as if it were part of a SRS is the least appropriate.

The design effects following the sampling design adjusted logistic regression were all approximately equal to one. This may be due to the fact that the only design influence present was due to stratified sampling which would result in a reduced design effect in many instances. As there was no sampling design involving cluster sampling there would be no expected countering increase in the design effect due to the sampling design.⁵⁹ Stratification usually reduces the design effect to less than one, and might cancel out any increase due to clustering. However, in this study the entire study population was treated as 18 clinic strata; hence the low design effects. The fact that these effects were all close to unity suggests that there was fairly homogeneous distribution of patient predictor variables between the clinics with similar variances both within and between the clinics. In other words the results were similar to what would have been obtained if a simple random sample had been used.

6.4. Limitations of the study

This analysis was a secondary analysis of data that were collected with a different purpose in mind. Therefore, the initial design was not informed primarily by the needs of the current analysis. The result was that sample size was too small for some rare variables of interest such as benefitting from medical scheme access or the type of non-PHC practitioner consulted.

In addition, oversampling in clinics where the outcome (concurrent use) was rare or absent was not done, resulting in an inability to estimate clinic level standard deviations.

Finally, the questionnaire did not include additional items of interest such as interviews with those adults who accompanied some patients to the clinic.

Actual incomes were not included in the analysis because the data were too patchy with a very large number of missing entries. As a result SES was used as a proxy for income. One problem might have been, too, that the study population was very homogeneous with regard to SES, making it difficult to determine whether SES influenced concurrent use (apart from the variable for medical scheme access).

A further limitation was the inability of the analysis to breakdown the outcome to study concurrent use per specific provider, as mentioned earlier. Instead all providers who were not PHC clinics were considered non-PHC. This, however, might be less accurate because not all patients have a homogeneous preference for non-PHC providers. For instance, traditional healers were consulted by less than 5% of patients in previous studies but in this study their preference was equated to private doctors where most non-PHC ambulatory services are obtained. A study which stratifies concurrent use by type of provider will therefore provide more accurate estimates than the generalised ones produced here. Such stratification was not possible due to inadequate numbers in the pre-determined sample.

Another limitation relates to the lack of comparison data from the non-PHC sector hence the need to engage more with this sector for purposes of data collection. Although this was a result of working with secondary data, it is imperative that more data about quality of service and nature of outcomes are collected for the private sector because this study suggests that 15% of users make concurrent use of the non-PHC sector, and the indication is that this proportion might increase as access to medical scheme membership improves. There may also be some resistance in this (non-PHC) sector to provision of data.⁵⁴ However, without accurate scientific evidence of the nature of services in non-PHC services, all the comparisons risk being based on anecdotes and perceptions/ opinions.

6.5. Public health implications

The implications of the findings from this study are important. The evidence that at least 15% of TB and HIV patients made concurrent use of PHC and non-PHC services, and that this proportion might be expected to increase in the future, puts non-PHC services on the agenda for TB and HIV control and research in South Africa. It also shows that the two sectors are not independent of each other.

Although it is believed that consulting non-PHC providers may pose a risk of poorer TB and HIV outcomes for these patients than PHC providers, the capacity of the latter may limit its ability to cater for all TB and HIV patients. Concurrent consultation may cause discontinuity of care due to patients obtaining care from different providers with varying levels of expertise. We do not know whether the non-PHC sector is compliant with national treatment guidelines. This may pose a risk for increasing drug resistance and treatment failure.

Literature has suggested that PHC providers are more experienced in providing TB and HIV services and despite system problems such as lack of staff, they follow recommendations from the WHO and National programmes; while it is possible that the non-PHC providers do not always do so. It has also been shown that TB and HIV outcomes in PHC clinics are often better than those in non-PHCs, therefore it is imperative that services are standardised in both PHC and non-PHC facilities in order to preserve the quality of care for patients who either cross over or make concurrent use of PHC and non-PHC services.

This standardisation of services has been discussed already in the past where the concept of public-private mix is recommended. In the public-private mix, there is need to export the TB and HIV management process from the PHC sector and import the health financing models as is in the non-PHC sectors. However, the slow pace of the effective implementation of this mix remains unhelpful to the cohort of such patients who make use of both sectors' services.

The two most significant factors associated with concurrent use of PHC and non-PHC services are independent of the PHC health system. This indicates that while it is important to focus on improving PHC sector services which are sometimes criticised, and attributed to patients' use on non-PHC services, it is also important to understand the dynamics which influence effective use of services at patient level. Health providers both in the public and non-PHC sector therefore need to expand their scope of care to include not only the patients' symptoms or disease but also social factors in the patients' profile. For instance, if it is known that patients' decisions on health choices

are also influenced by friends and family, who often accompany patients to the health centres, their influence may as well be tapped to encourage positive health behaviours among patients such as adherence to clinic visits and treatment. This patient circle can therefore be a useful tool to help health workers, both in PHC and non-PHC settings, manage patients better.

The findings from this analysis also lend extra support for the implementation of the National Health Insurance, a policy aimed at establishing equity, financial equity, in a health system that is skewed in favour of the non-PHC sector. In lending support, it is also advisable to the NHI that it also establishes measures of standards of care across private and PHC sectors because, as found in this study, people's choices of concurrent use may be in spite of the fact that services which they pay more to access are not necessarily the best. Therefore, focusing on establishing financial equity alone, or purporting that PHC services are worse off than non-PHC may not achieve desirable outcomes for TB and HIV patients who will continue the use PHC and non-PHC services concurrently. Public-private partnerships which seek to standardise quality of care may thus be implemented alongside the NHI with goals of creating homogenous systems both on the financial and quality of care platforms.

The fact that the majority of the patients who made out-of-pocket payments were poor means that they may have made large sacrifices for expenditure on non-PHC. This is because only a few poor patients might be able to afford to pay for medical aid schemes hence any out-of-pocket payments they make can increase the burden of costs on their families and also negatively affect TB and HIV outcomes.

It is therefore necessary to protect these patients from catastrophic spending on health care in order to safeguard their progression to good health. Therefore, the NHI is a policy that needs to be promoted more aggressively for its prompt implementation because it will bring equitable health care where all patients will afford healthcare without catastrophic spending. This will also move the country towards WHO's 2035 goal to reduce catastrophic spending by households for TB to zero.¹⁰

7. CONCLUSION

Factors influencing co-consultation may be beyond the control of policy makers. It is recommended that emphasis be placed on improving standards of care in both the public and private sectors. Private providers also need to be encouraged to comply with national diagnostic, treatment and reporting guidelines for these two conditions, and may need to be monitored in that regard.

TB and HIV patients will continue to consult with non-PHC providers concurrently with the PHC clinics, with poorer outcomes as a result; and this is beyond the control of health systems. The reasons for such consultation cannot be addressed by improving the PHC health system alone, as proposed by the NHI. There is therefore need to engage these non-PHC sector providers more in order to standardise quality of services so that the cohort of TB and HIV patients, who are normally poor, get uniform services across both service providers.

Standards are also more important because for TB and HIV patients, vast resources in the non-PHC sector do not translate to better outcomes; hence patients who consult in both sectors at the same time face risk if services are not regulated. There is also a (parallel) need to discourage unnecessary use of non-PHC providers and to come up with innovative measures to curb the possible catastrophic costs that might be incurred by an uninsured majority of poor TB and HIV patients when they consult with non-PHC providers where services are paid for out of pocket. This is in order to meet the goal by the WHO of eliminating catastrophic costs by 2035.

Health priorities aimed at addressing system problems in the PHC sector health sector must also engage the non-PHC sector where 15.23% of TB and HIV consult for reasons not related to current system problems. This and other studies in other countries have shown that patients' choice of health care may not be entirely influenced by system and financial factors; instead in cohorts of generally poor patients, non-PHC facilities will still be a source of healthcare at costs that patients can ill-afford.

There is therefore a need to improve strategies for engaging the non-PHC sector for standardising TB and HIV practices, including standard reporting of treatment and investigation and patient outcomes, in line with recommended guidelines. This is in order to cater for the 12% of patients identified in this study who may receive poorer services in the non-PHC sector at additional personal costs. The PHC sector also needs to address the current service delivery problems which most patients and other affected parties continue to raise.

The NHI therefore needs to widen their scope from focusing on financial equity to service adjustment and regulation also for the non-PHC sector especially for TB and HIV services (as these are leading causes of morbidity and also leading cost drivers for the health services). Patients who use PHC and non-PHC services concurrently will benefit if services in both sectors are standardised and co-ordinated.

8. REFERENCES

1. Kufa T, Hippner P, Charalambous S, Kielmann K, Vassall A, Churchyard G, et al. A cluster randomised trial to evaluate the effect of optimising TB/HIV integration on patient level outcomes: The “merge” trial protocol. *Contemporary clinical trials* 2014;39(2):280-287.
2. Malmborg R, Mann G, Thomson R, Squire SB. Can public-private collaboration promote tuberculosis case detection among the poor and vulnerable? *Bull.World Health Organ.* 2006;84(9):752-758.
3. World Health Organization. *Global tuberculosis report 2013.* : World Health Organization; 2013.
4. Joint United Nations Programme on HIV/AIDS. *Global report: UNAIDS report on the global AIDS epidemic: 2012.* : UNAIDS; 2012.
5. Barter DM, Agboola SO, Murray MB, Barnighausen T. Tuberculosis and poverty: the contribution of patient costs in sub-Saharan Africa--a systematic review. *BMC Public Health* 2012 Nov 14;12:980-2458-12-980.
6. Foster N, Vassall A, Cleary S, Cunnama L, Churchyard G, Sinanovic E. The economic burden of TB diagnosis and treatment in South Africa. *Soc.Sci.Med.* 2015;130:42-50.
7. Mashologu-Kuse T. The relationship between HIV/AIDS and poverty: The case of three administrative areas in the Transkei. *Social Work/Maatskaplike Werk* 2014;41(4).
8. Mbirimtengerenji ND. Is HIV/AIDS Epidemic Outcome of Poverty in Sub-Saharan Africa? *Croat Med J.* 2007;48(5):605.
9. UNAIDS. *HIV PREVALENCE AMONG ADULTS (15-49).* 2015; Available at: <http://aidsinfo.unaids.org/#>. Accessed September/2015, 2015.
10. WHO. *Global Tuberculosis Report 2014.* : World Health Organization; 2014.
11. WHO. *WHO policy on collaborative TB/HIV activities : guidelines for national programmes and other stakeholders.* 2012;9789241503006.
12. World Health Organization. *Tuberculosis care with TB-HIV Co-management. Integrated management of adolescent and adult illness (IMAI).* Geneva 2007.
13. TBFacts.org. *TB and HIV | Co-infection, diagnosis & treatment.* 2015; Available at: <http://www.tbfacts.org/tb-hiv/>. Accessed October/2015, 2015.
14. Stevens M, Sinanovic E, Regensberg L, Hislop M. HIV and AIDS, STI and TB in the private sector: health care delivery. *South African health review* 2007:201-211.
15. Van Wyk S, Enarson D, Beyers N, Lombard C, Hesselning A. Consulting private health care providers aggravates treatment delay in urban South African tuberculosis patients. *The International Journal of Tuberculosis and Lung Disease* 2011;15(8):1069-1076.
16. Buso D. Public-private health sector mix-way forward: open forum. *South African Family Practice* 2004;46(9):p. 5-8.
17. Uplekar M. Involving private health care providers in delivery of TB care: global strategy. *Tuberculosis* 2003;83(1):156-164.

18. Rosen S, Ketlhapile M, Sanne I, DeSilva MB. Cost to patients of obtaining treatment for HIV/AIDS in South Africa. *South African Medical Journal* 2007;97(7):524-529.
19. Harrison D. An overview of health and health care in South Africa 1994–2010: Priorities, progress and prospects for new gains. Washington, DC: Henry J Kaiser Family Foundation 2009.
20. Peltzer K. Patient experiences and health system responsiveness in South Africa. *BMC Health Serv.Res.* 2009 Jul 14;9:117-6963-9-117.
21. Chimbindi N, Barnighausen T, Newell ML. Patient satisfaction with HIV and TB treatment in a public programme in rural KwaZulu-Natal: evidence from patient-exit interviews. *BMC Health Serv.Res.* 2014 Jan 23;14:32-6963-14-32.
22. Mukora R, Charalambous S, Dahab M, Hamilton R, Karstaedt A. A study of patient attitudes towards decentralisation of HIV care in an urban clinic in South Africa. *BMC Health Serv.Res.* 2011 Aug 26;11:205-6963-11-205.
23. Sinanovic E, Kumaranayake L. Quality of tuberculosis care provided in different models of public-private partnerships in South Africa. *The International Journal of Tuberculosis and Lung Disease* 2006;10(7):795-801.
24. Statistics South Africa. General household survey 2013 : Statistical release P0318. Statistics South Africa: Statistics South Africa; 2014.
25. Sykes M, Tolhurst R, Squire SB. Vulnerable patients and the Public-Private Mix in tuberculosis. Background paper for the Report on Tuberculosis of the Task Force on HIV/AIDS, Malaria, Tuberculosis, and Access to Essential Medicines. UN Millennium Project, New York 2003.
26. Chabikuli N, Schneider H, Blaauw D, Zwi AB, Brugha R. Quality and equity of private sector care for sexually transmitted diseases in South Africa. *Health Policy Plan.* 2002 Dec;17 Suppl:40-46.
27. Kula N, Fryatt RJ. Public-private interactions on health in South Africa: opportunities for scaling up. *Health Policy Plan.* 2014 Aug;29(5):560-569.
28. Hazarika I. Role of Private Sector in Providing Tuberculosis Care: Evidence from a Population-based Survey in India. *J.Glob.Infect.Dis.* 2011 Jan;3(1):19-24.
29. Gebrekidan G, Tesfaye G, Hambisa MT, Deyessa N. Quality of tuberculosis care in private health facilities of Addis Ababa, Ethiopia. *Tuberculosis research and treatment* 2014;2014.
30. Honda A, Ryan M, van Niekerk R, McIntyre D. Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment. *Health Policy Plan.* 2015 Jun;30(5):600-611.
31. Lönnroth K, Tran T, Quy HT, Diwan V. Can I afford free treatment?: Perceived consequences of health care provider choices among people with tuberculosis in Ho Chi Minh City, Vietnam. *Soc.Sci.Med.* 2001;52(6):935-948.
32. Edginton ME, Sekatane CS, Goldstein SJ. Patients' beliefs: do they affect tuberculosis control? A study in a rural district of South Africa. *Int.J.Tuberc.Lung Dis.* 2002 Dec;6(12):1075-1082.

33. van den Heever AM. The role of insurance in the achievement of universal coverage within a developing country context: South Africa as a case study. *BMC Public Health* 2012;12 Suppl 1:S5-2458-12-S1-S5. Epub 2012 Jun 22.
34. Basu S, Andrews J, Kishore S, Panjabi R, Stuckler D. Comparative performance of private and public healthcare systems in low-and middle-income countries: a systematic review. *PLoS medicine* 2012;9(6):e1001244.
35. Lönnroth K, Thuong L, Lambregts K, Quy H, Diwan V. Private tuberculosis care provision associated with poor treatment outcome: comparative study of a semi-private lung clinic and the NTP in two urban districts in Ho Chi Minh City, Vietnam. *The International Journal of Tuberculosis and Lung Disease* 2003;7(2):165-171.
36. Quy H, Lönnroth K, Lan N, Buu T. Treatment results among tuberculosis patients treated by private lung specialists involved in a public-private mix project in Vietnam. *The International Journal of Tuberculosis and Lung Disease* 2003;7(12):1139-1146.
37. Lonroth K, Thuong LM, Linh PD, Diwan VK. Utilization of private and public health-care providers for tuberculosis symptoms in Ho Chi Minh City, Vietnam. *Health Policy Plan.* 2001 Mar;16(1):47-54.
38. Nshuti L, Neuhauser D, Johnson JL, Adatu F, Whalen CC. Public and private providers' quality of care for tuberculosis patients in Kampala, Uganda. *Int.J.Tuberc.Lung Dis.* 2001 Nov;5(11):1006-1012.
39. Statistics South Africa. **Ekurhuleni**. 2011; Available at: http://www.statssa.gov.za/?page_id=1021&id=ekurhuleni-municipality. Accessed September/29, 2015.
40. City of Ekurhuleni. *Ekurhuleni Annual Report 2012-2013*. 2013.
41. City of Ekurhuleni. *Ekurhuleni Annual Report 2013-2014*. 2014.
42. Narasimhan P, Wood J, MacIntyre CR, Mathai D. Risk factors for tuberculosis. *Pulmonary medicine* 2013;2013.
43. Figueroa-Munoz JI, Ramon-Pardo P. Tuberculosis control in vulnerable groups. *Bull.World Health Organ.* 2008;86(9):733-735.
44. Schmidt CW. Linking TB and the environment: an overlooked mitigation strategy. *Environ.Health Perspect.* 2008;116(11):A478-85.
45. Statistics South Africa. *Mid-year population estimates 2013*. 2013(P0302).
46. McIntyre D, Thiede M. Health care financing and expenditure: pooling of resources and purchasing of health care. *South African health review* 2007:35-46.
47. McIntyre D, Goudge J, Harris B, Nxumalo N, Nkos M. Prerequisites for national health insurance in South Africa: results of a national household survey. *SAMJ: South African Medical Journal* 2009;99(10):725-729.
48. Naidoo S. The South African national health insurance: a revolution in health-care delivery! *J.Public.Health.(Oxf)* 2012 Mar;34(1):149-150.
49. April Harding. Oxfam — This Is Not How to Help the Poor. 2009; Available at: <http://www.cgdev.org/blog/oxfam-%E2%80%94-not-how-help-poor>. Accessed September/2015, 2015.

50. Saksena P, Xu K, Elovainio R, Perrot J. Utilization and expenditure at public and private facilities in 39 low-income countries. *Tropical Medicine & International Health* 2012;17(1):23-35.
51. Mayosi BM, Benatar SR. Health and Health Care in South Africa—20 Years after Mandela. *N.Engl.J.Med.* 2014;371(14):1344-1353.
52. Montagu D, Anglemeyer A, Tiwari M, Drasser K, Rutherford GW, Horvath TH, et al. Private versus public strategies for health service provision for improving health outcomes in resource limited settings: a systematic review. Published by EPPI-Centre, UK DFID, and Institute of Education (University of London) 2011.
53. The Presidency of the Republic of South Africa. DELIVERY AGREEMENT FOR OUTCOME 2: A Long and Healthy Life for All South Africans. 2013.
54. Matsebula T, Willie M. Private hospitals: Health care delivery. 2007.
55. Nxumalo N, Alaba O, Harris B, Chersich M, Goudge J. Utilization of traditional healers in South Africa and costs to patients: findings from a national household survey. *J.Public Health Policy* 2011:S124-S136.
56. Barker R, Millard F, Malatsi J, Mkoana L, Ngoatwana T, Agarawal S, et al. Traditional healers, treatment delay, performance status and death from TB in rural South Africa. *The International Journal of Tuberculosis and Lung Disease* 2006;10(6):670-675.
57. Colvin M, Gumede L, Grimwade K, Maher D, Wilkinson D. Contribution of traditional healers to a rural tuberculosis control programme in Hlabisa, South Africa. *The International Journal of Tuberculosis and Lung Disease* 2003;7(9s1):S86-S91.
58. Hamilton L. *Statistics with Stata: version 12.* : Cengage Learning; 2012.
59. Lohr S. *Sampling: design and analysis.* : Cengage Learning; 2009.
60. Faul F, Erdfelder E, Lang A, Buchner A. G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior research methods* 2007;39(2):175-191.
61. Faul F, Erdfelder E, Buchner A, Lang A. Statistical power analyses using G* Power 3.1: Tests for correlation and regression analyses. *Behavior research methods* 2009;41(4):1149-1160.
62. Hosmer Jr DW, Lemeshow S. *Applied logistic regression.* : John Wiley & Sons; 2004.
63. Archer KJ, Lemeshow S, Hosmer DW. Goodness-of-fit tests for logistic regression models when data are collected using a complex sampling design. *Comput.Stat.Data Anal.* 2007;51(9):4450-4464.
64. Archer KJ, Lemeshow S. Goodness-of-fit test for a logistic regression model fitted using survey sample data. *Stata Journal* 2006;6(1):97-105.
65. Institute for Digital Research and Education. 2015; Available at: http://www.ats.ucla.edu/stat/stata/seminars/applied_svy_stata13/. Accessed July/19, 2015.
66. Hilbe JM. *Logistic regression models.* : CRC Press Boca Raton; 2009.
67. Vyas S, Kumaranayake L. Constructing socio-economic status indices: how to use principal components analysis. *Health Policy Plan.* 2006 Nov;21(6):459-468.

68. McKenzie DJ. Measuring inequality with asset indicators. *Journal of Population Economics* 2005;18(2):229-260.
69. George Dallas. Principal Component Analysis 4 Dummies: Eigenvectors, Eigenvalues and Dimension Reduction. 2015; Available at:
<https://georgemdallas.wordpress.com/2013/10/30/principal-component-analysis-4-dummies-eigenvectors-eigenvalues-and-dimension-reduction/>. Accessed October/05, 2015.
70. Houweling TA, Kunst AE, Mackenbach JP. Measuring health inequality among children in developing countries: does the choice of the indicator of economic status matter? *Int.J.Equity Health*. 2003 Oct 9;2(1):8.
71. du Prel J, Röhrig B, Hommel G, Blettner M. Auswahl statistischer Testverfahren. *Dtsch Arztebl* 2010;107(19):343-348.
72. Statistics South Africa. Ekurhuleni. 2015; Available at:
http://www.statssa.gov.za/?page_id=1021&id=ekurhuleni-municipality. Accessed August/13, 2015.

9. LIST OF APPENDICES

9.1. Appendix 1: Participant information sheet and informed consent form

PARTICIPANT INFORMATION SHEET FORM- PATIENT COSTS INTERVIEW

PROTOCOL NUMBER: **M110116**
ZA.09.0256/ ZA.09.0262
AUR-2-6-099

**STUDY TITLE: IMPLEMENTATION AND EVALUATION OF AN OPTIMISED
MODEL FOR SCALING UP TB/HIV INTEGRATION AT PRIMARY CARE CLINICS IN
EKURHULENI NORTH SUB-DISTRICT, SOUTH AFRICA**

SPONSOR: PEPFAR

PRINCIPAL INVESTIGATOR: Dr. Tendesayi Kufa

INSTITUTION: THE AURUM INSTITUTE

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

- **Dr Tendesayi Kufa (Principal Investigator)**
 - **Office (011) 484-8844 ext. 1397**
 - **Cell (071) 513 7826**

- **Study Coordinator: Don Mudzengi**
 - **Office (010) 590 1300 ext. 1388**
 - **Cell (073) 218 9444**

To the potential Study Participant: *This form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not understand.*

Protocol: Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa
Patient information sheet/ informed consent for - Patient costs interview
Wits HREC Protocol number M110116
Aurum Protocol #: AUR-2-6-099
Version 2.0 _ 01.10.2012
Principal Investigator: Dr Tendesayi Kufa
Site: Ekurhuleni North sub-district, Ekurhuleni Metropolitan Municipality

Participant ID _____

Participant Initials _____

Page 1 of 5

STUDY PARTICIPANT INFORMATION SHEET AND CONSENT FORM FOR THE:

Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa

Good day my name is _____. I am from the Aurum Institute for Health Research, and I am speaking to you today on behalf of Dr. Tendesayi Kufa, the Principal Investigator on this research study.

I am going to tell you about a research study concerning the time and money you spend as a patient receiving care at this clinic. After that I will invite you to be part of this study. We are asking patients who attend at this clinic and are 18 years or older to answer some questions about their illness, clinic visits and money spent during care.

Before agreeing to be a part of this study, it is important that you are fully informed of the study. It is also important that you understand that you do not have to take part in the study if you do not want to. You also need to know that you are allowed to stop answering questions at any time during the interview.

This document is to help you decide if you would like to participate.

If you have any questions, please do not hesitate to ask me.

If you agree to be a part of the study, I will ask you to sign this document to show that you understand the study and you will be given a copy to keep.

Why are we doing this study?

We would like to know how much money you spend or have spent as you seek health care due to your current or past symptoms and/or illness. These include your transport costs; costs of buying medication from pharmacies, consultation fees and other related costs incurred when you visit or visited private doctors or traditional healers. We are also looking to find information on other indirect costs such as the money that you may lose due to the illness.

Protocol: Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa
Patient Information sheet/ Informed consent for - Patient costs interview
Wits HREC Protocol number M110116
Aurum Protocol #: AJR-2-6-099
Version 2.0 01.10.2012
Principal Investigator: Dr Tendesayi Kufa
Site: Ekurhuleni North sub-district, Ekurhuleni Metropolitan Municipality

Participant ID _____

Participant Initials _____

Why are you being asked to be in this study?

You are being asked to participate in this study because you are attending the clinic today.

What will happen during the study?

If you agree to take part in this study, I will ask you some questions about your education, employment, where you live, how much money you earn, how much money you spend on transport to get here, how many clinic visits you have had in the last three months, how long they lasted, what services you received and how much time you spent in the clinic. Many of our questions will however be on the money you spend or lose due to your current or past illness and/or symptoms. After answering the questions, participants will have a R20 (or the closest denomination available) airtime voucher given to them as part of compensation for participating in the study.

It will take me about half an hour to finish asking the questions

How long do you have to be part of the study?

I will only ask you these questions today and we will not invite you for another interview for the same research which we are asking about your costs.

What are your rights as a participant in this study?

Your participation in this study is voluntary and entirely up to you. You can refuse to be a part of this study or stop answering questions at any time without giving us a reason for your decision. You can also refuse to answer any questions which you are not comfortable answering. Refusing to answer questions or to participate in this study will not affect in any way how your TB or HIV treatment is provided at this clinic or anywhere else you choose to seek care from.

What are the benefits of being in the study?

By participating in the study, you will get an airtime voucher of R20 (or the closest denomination available) for completing the study questions. There may be no direct benefit to you from being a part of this study. Your participation in this study will contribute to medical knowledge that may help other people that have HIV and TB disease.

Protocol: Implementation and evaluation of an optimised model for scaling up TB/HIV Integration at primary care clinics in Ekurhuleni North Sub-District, South Africa
Patient Information sheet/ informed consent for - Patient costs interview
Wits HREC Protocol number M110116
Aurum Protocol #: AUR-2-6-099
Version 2.0_01.10.2012
Principal Investigator: Dr Tendesayi Kufa
Site: Ekurhuleni North sub-district, Ekurhuleni Metropolitan Municipality

Participant ID _____

Participant Initials _____

Page 3 of 5

What are the dangers and discomforts of being in this study?

There are no anticipated dangers or discomforts from being a part of this study

Will my information be kept private?

Yes, all study information will be kept confidential.

Study staff will be the only people who are allowed come in contact with study records and documents. The records for the study documents will be kept locked away and separate from your medical records. We will NOT record your name or contact details in our questionnaires, just your date of birth and whether you are male or female. There may be accidental disclosure of this information you are providing us with. However, we will do everything we can to protect this information and to ensure that no one outside this study team is able to see this information. However,

Will I be paid to be a part of this study?

You will **NOT** be paid to be in this study. However, by taking part in the study and answering the study questions you will be given cell phone airtime vouchers with a value of R20 (or the closest denomination available).

Who can I contact if I have any questions about participating in the study?

If you have any problems or questions about this study or about any research-related queries, you may contact Don Mudzengi (Study Coordinator) 24 hours a day on the cellphone at 0732189444.

You may contact the Principal Investigator of this study Dr. Tendesayi Kufa during working hours at her office at (011) 484-8844.

If you have any problems or questions about your rights as a research subject you may also contact Professor Cleaton-Jones, the Chairperson of the University of the Witwatersrand Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of study participants. His telephone number is (011) 717-2301.

Protocol: Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa
Patient information sheet/ Informed consent for - Patient costs interview
Wits HREC Protocol number M110116
Aurum Protocol #: AJR-2-6-099
Version 2.0 01.10.2012
Principal Investigator: Dr Tendesayi Kufa
Site: Ekurhuleni North sub-district, Ekurhuleni Metropolitan Municipality

Participant ID _____

Participant Initials _____

INFORMED CONSENT

I have been informed by _____ about the goals, procedures, benefits and risks of the "Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa"

I understand the information that I was given about the study.

I am aware that the results of the study, including personal details about my sex, age and diagnosis will be anonymously processed into a study report.

I agree that the information collected during this study can be processed in a computerised system by The Aurum Institute or their research collaborators.

I may leave the study at any time if I so wish

I had enough opportunity to ask questions and, of my own free will, agree to participate in the study.

Participant Name (printed)	Signature/mark/thumbprint	Date & Time

Person conducting Informed Consent:

Name (printed)	Signature/mark/thumbprint	Date & Time

Translator assisting with Informed Consent:

Name (printed)	Signature/mark/thumbprint	Date & Time

Witness who was present for the entire Informed Consent procedure (if the study participant cannot read or write):

Name (printed)	Signature/mark/thumbprint	Date & Time

Protocol: Implementation and evaluation of an optimised model for scaling up TB/HIV integration at primary care clinics in Ekurhuleni North Sub-District, South Africa
 Patient information sheet/ Informed consent for - Patient costs interview
 Wits HREC Protocol number M110116
 Aurum Protocol #: AJR-2-6-099
 Version 2.0 01.10.2012
 Principal Investigator: Dr Tendesayi Kufa
 Site: Ekurhuleni North sub-district, Ekurhuleni Metropolitan Municipality

Participant ID _____
 Participant Initials _____

9.2. Appendix 2: Screening, eligibility and enrolment

SCREENING NUMBER:

AUR2-6-099--9
Protocol Site code – SCREENING NUMBER

Date of Enrolment:

//
dd/MMM/yyyy



T-E AURUM
INSTITUTE

EL002: ECONOMICS SUB-STUDY SCREENING, ELIGIBILITY & ENROLMENT

Instructions: Complete this CRF for all people who screen for the study, regardless of whether or not they enrol.

1. Is this person enrolled in the MERGE study? 1=Yes, 0=No
If No, go to question 2.

1a. MERGE assigned study ID number: AUR2-6-099--

1b. Date of most recent study visit? dd/MMM/yyyy //

2. Gender: 1=Male, 2=Female

3. Date of birth: dd/MMM/yyyy //

INCLUSION CRITERIA

4. Has this person been diagnosed with TB? 1=Yes, 0=No
If No, go to question 5.

4a. When was this person diagnosed with TB: dd/MMM/yyyy //

5. Has this person had an HIV test? 1=Yes, 0=No
If No, go to question 6.

5a. Date of this person's most recent HIV test: dd/MMM/yyyy //

5b. Result of this person's most recent HIV test: 1=Positive, 2=Negative, 3=Unknown/No result

Instruction: In order to be eligible to complete this sub-study this person must:

- Have been diagnosed with TB (Q4) 3-5 months ago (Q4a) AND had a positive HIV at any time OR,
- Have been diagnosed with TB (Q4) 3-5 months and is HIV negative or status is unknown OR,
- Have tested HIV positive for the first time 3-5 months ago and does not have TB.

6. Based on the answers above, is this person eligible to participate in the Merge economics sub-study?
..... 1=Yes, 0=No

If No, STOP, form is complete.

7. Into which group has this person been assigned to?
1 = TB positive AND HIV positive
2 = TB positive AND HIV negative
3 = HIV positive (no TB)

8. Did this person consent to participate in the study? 1=Yes, 0=No
If Yes, go to question 9.

Completed By:
EL002 v1.1 13MAY2013

Date Entered: //

Page 1 of 2

SCREENING NUMBER:

Date of Enrolment:

AUR2-6-099--9

//



THE AURUM
INSTITUTE

Protocol - Site code - SCREENING NUMBER

dd/MMM/yyyy

8a. Why did this person **not** consent to participate in the study?(primary reason)

.....(secondary reason)

10 = Refused before the consenting process

11 = Refused after the consenting process

12 = Does not have time to participate

13 = Needs time to think about it/may come back later

14 = Not interested

15 = Suspicious

16 = Wants to see a doctor first

17 = Did not want medical records reviewed

18 = Will not be in area for duration of follow-up period

19 = Unable to communicate in required language

20 = Inadequate remuneration for visits/contacts

99 = Other, specify: _____

STOP, form is complete.

9. Date of consent:dd/MMM/yyyy //

10. ECONOMICS SUB-STUDY study identification number:AUR2-6-099--7

Instructions:

- All participants must complete the DM002 Economics Sub-study Demographics questionnaire.
- Use the following table to determine in which group to place this participant, complete the indicated questionnaire.

	TB Positive	TB Negative
HIV Positive	Group 1: SS004	Group 3: SS005
HIV Negative	Group 2: SS004	Not Eligible

9.3. Appendix 3: Baseline demographics

Study Identifier:

Date of Visit:

AUR2-6-099--
Protocol Site code Participant ID dd/MMM/yyyy



DM003: ECONOMICS SUB-STUDY BASELINE DEMOGRAPHICS

Instructions: Complete this CRF for all persons enrolled.

1. Participant country of origin/birth?

- 1 = South Africa
- 2 = Lesotho
- 3 = Swaziland
- 4 = Mozambique
- 5 = Botswana
- 6 = Namibia
- 7 = Zimbabwe
- 8 = Malawi
- 9 = Other, Specify: _____

2. What is your ethnic group?

- 1 = Black/African
- 2 = Coloured
- 3 = Indian/Asian
- 4 = White/European
- 9 = Other, Specify: _____

3. Which two languages do you speak most often in your household? (primary)

- 11 = Tswana
- 12 = Sotho
- 13 = Zulu
- 14 = Xhosa
- 15 = Swati
- 16 = Ndebele
- 17 = Pedi
- 18 = Tsonga
- 19 = Venda
- 20 = English
- 21 = Afrikaans
- 99 = Other, specify: _____

.....(secondary)

4. What is the highest level of education you have completed?

- 1 = Pre-school
- 2 = Grade 1-3
- 3 = Grade 4-7
- 4 = Grade 8-11
- 5 = Grade 12
- 6 = Matric with Technical Qualification or Diploma
- 7 = Associates or Bachelor's Degree
- 8 = Master's or Doctoral Degree
- 9 = Other, specify: _____

5. What is your marital status?

- 1 = Single, never married
- 2 = Married
- 3 = Married and currently separated
- 4 = Cohabiting
- 5 = Divorced
- 6 = Widow/Widower

6. What type of dwelling do you live in?

- 10 = House or brick/concrete block structure on separate stand or yard or on a farm
- 11 = Traditional dwelling/hut/structure made of traditional materials
- 12 = Flat or apartment in a block of flats
- 13 = Cluster house in complex
- 14 = Townhouse (semi-detached house in a complex)
- 15 = Semi-detached house
- 16 = House/flat/room in backyard
- 17 = Informal dwelling (shack in backyard)
- 18 = Informal dwelling e.g. in an informal squatter settlement or on a farm
- 19 = Room/flat let on a property or a larger dwelling, servant's quarters, or granny flat
- 20 = Caravan/tent
- 21 = Homeless
- 99 = Other, specify: _____

Completed By:

Date Entered: //

DM003 v1 12/MAR/2011

Page 1 of 3

Study Identifier:

Date of Visit:

AUR2-6-099- -
Protocol - Site code - Participant ID

/ /
dd/MMM/yyyy



7. What is the main material of your floor?
- 1 = Natural floor (earth/sand/dung)
 - 2 = Rudimentary floor (bare wood planks)
 - 3 = Finished floor (parquet/polished/ceramic tiles/cement/carpet)
8. What is the main material of your walls?
- 1 = Plastic or cardboard
 - 2 = Mud
 - 3 = Mud and cement
 - 4 = Corrugated iron or zinc
 - 5 = Prefab or wood
 - 6 = Bare brick or cement blocks
 - 7 = Plaster or finished
 - 9 = Other, specify: _____
9. What is the main source of drinking water for members in your household?
- 1 = Piped (tap) water inside dwelling
 - 2 = Piped (tap) water inside the yard
 - 3 = Piped (tap) water on community stand
 - 4 = No access to piped water
 - 5 = Borehole
 - 6 = Open source (river or stream)
 - 9 = Other, specify: _____
10. What kind of toilet facilities does your household have?
- 1 = Flush toilet connected to sewage
 - 2 = Flush toilet connected to septic tank
 - 3 = Chemical toilet
 - 4 = Pit toilet/latrine with ventilation (VIP)
 - 5 = Pit toilet without ventilation
 - 6 = Bucket toilet
 - 7 = None
 - 9 = Other, specify: _____

9.4. Appendix 4: Data extraction template

TEMPLATE FOR DATA EXTRACTION FROM THE DATASET				
AT THE TIME OF YOUR DIAGNOSIS, DID OR WERE YOU :		Yes = 1	No = 0	
SECTION 1	Visit any of these providers in addition to your regular clinic	General practitioner		
		Pharmacy		
		Out-patient hospital		
		Traditional healer		
	Employed			
	Beneficiary of a medical aid scheme			
	Accompanied by at least an adult to the clinic			
	On ART (if TB only, answer is "No")			
	Partnered			
	Have a CD4 count done			
Enter CD4 count value here []				
Assisted by someone at home				
SECTION 2	How many visits have you made to your regular clinic since your diagnosis with either TB or HIV, or both?			
	How much time did you spend travelling to you regular clinic on your (hours)?			
	How much time did you spend travelling to you regular clinic on your (hours)?			

9.5. Appendix 5: GCP Certificate

 **BCOMPLIANT cc**

CERTIFICATE OF COMPETENCE

THIS SERVES TO CERTIFY THAT

Don Lawrence Mudzengi

HPCSA Registration No: *n/a*

HAS SUCCESSFULLY PASSED A

GCP REFRESHER COURSE

IN JOHANNESBURG

02 September 2014



FACILITATOR SIGNATURE: RETHA BRITZ

DATE

SUMMATIVE TEST SCORE: **100%**

CPD Accreditation Number: M0B015/007/01/2014

CPD Points allocated: 12 Ethics CPD Points, Level 2

SACRA Registration Number: SACRA/GCP/184/2013

9.6. Appendix 6 : WITS ethics letter

M110116M110116

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Tendesayi Kufa

CLEARANCE CERTIFICATE

M110116

PROJECT

Implementation and Evaluation of an Optimized
Model for Scaling up TB/HIV Integration at Primary

Care

Clinics in Ekurhuleni North Sub-District, South

Africa

INVESTIGATORS

Dr Tendesayi Kufa.

DEPARTMENT

Aurum Institute for Health Research

DATE CONSIDERED

28/01/2011

DECISION OF THE COMMITTEE*

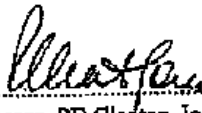
Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE

07/03/2011

CHAIRPERSON


(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor: 

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

9.7. Appendix 7 : London school ethics

**LONDON SCHOOL OF HYGIENE
& TROPICAL MEDICINE**

ETHICS COMMITTEE



APPROVAL FORM

Application number: 5969

Name of Principal Investigator Professor Alison Grant

Faculty Infectious and Tropical Diseases

Head of Faculty Professor Simon Croft

**Title: Implementation and evaluation of an optimized model for scaling up
TB/HIV integration at primary care clinics in Ekurhuleni North sub-
district, South Africa**

This application is approved by the Committee.

Chair of the Ethics Committee

Date3 June 2011.....

Approval is dependent on local ethical approval having been received.

**Any subsequent changes to the application must be submitted to the Committee
via an E2 amendment form.**

9.8. Appendix 8 : Ekurhuleni approval

Memorandum



Ekurhuleni
METROPOLITAN MUNICIPALITY

Southern Service Delivery Region
ALBERTON SERVICE DELIVERY CENTRE

To: Aurum Health Institute Research Team
Cc: Regional Executive Managers: Northern Sub-District
Manager: Clinic Services

Tel: (011) 861-2031

Fax: (011) 861-2410

From: Ms A Botha

Enquiries: Ms T Sibeko

Email: Sibekot@ekurhuleni.com

Date: 15th April 2010

Health Department
Level 7

Civic Centre
Alberton
Alberton
1450

Tel: (011) 861- 2031/2365
Fax: (011) 861-2410
www.ekurhuleni.com

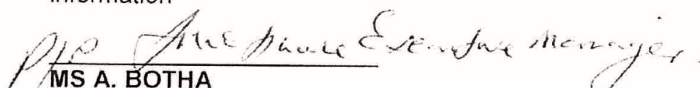
SUBJECT:REQUEST FOR PERMISSION TO CONDUCT TUBERCULOSIS (TB), HIV/AIDS RESEARCH STUDY AT THE PRIMARY HEALTH CARE (PHC) FACILITIES IN THE EKURHULENI METROPOLITAN MUNICIPALITY: NORTHERN SUB-DISTRICT.

The Health Department (Family Health Directorate) of Ekurhuleni Metropolitan Municipality acknowledges receipt of the request from the Aurum Health Institute to conduct the Tuberculosis (TB)/HIV/AIDS study at the PHC facilities in the Ekurhuleni Metropolitan Municipality: Northern Sub-district.

Permission has been granted to Aurum Health Institute to conduct the research study for twenty four (24) months as requested. Please note that the permission has been granted in accordance with the conditions that were agreed upon during discussions held between the Family Health Directorate and the Aurum Health Institute as follows:

- The research study will be conducted at eighteen (18) PHC facilities in the Northern Sub-district.
- Aurum Health Institute will allocate Enrolled Nursing Assistants (ENA's) at twelve (12) facilities for a period of twenty four (24) months for the research study to assist with PHC services should it be necessary.
- The above-mentioned Institute will write and forward quarterly reports on study progress.
- The above Aurum Health Institute will conduct training (workshops) for personnel of the eighteen (18) chosen PHC facilities, in consultation with the Family Health Management.
- The study should not interfere with primary health care delivery.
- The material resources for example stationery and paperwork (forms, registers, reports etc.) for the study will be provided by the Aurum Health Institute.

Your cooperation and assistance in ensuring that the study is a success will be highly appreciated. Should there be any further enquiries, feel free to contact the Director, Family Health for more information


MS A. BOTHA
DIRECTOR: FAMILY HEALTH

9.9. Appendix 9 : AURUM approval



Aurum House, The Ridge
29 Queens Road
Parktown, 2193
South Africa

PostNet Suite # 300
Private Bag X30500
Houghton, 2041
South Africa

Tel: +27 (0) 11 484 8844 / (0) 861 287 861
Fax: +27 (0) 11 484 4682
Website: www.auruminstitute.org

11 August 2014

Faculty of Health Sciences
School of Health Systems and Public Health
5th Floor, HW Snyman Building North
31 Bophelo Road
Gezina
0031

To whom it may concern

Re: Letter of Authorization to use The Aurum Institute's Research Data for dissertation

This letter serves as authorization for Mr. Don Lawrence Mudzengi to use the data that were collected by The Aurum Institute in a patient costing component of the cluster randomized trial for the "IMPLEMENTATION AND EVALUATION OF AN OPTIMIZED MODEL FOR SCALING UP TB/HIV INTEGRATION AT PRIMARY CARE CLINICS IN EKURHULENI NORTH SUB-DISTRICT, SOUTH AFRICA" for his Masters of Science in Epidemiology at the University of Pretoria.

The Aurum Institute acknowledges that it has reviewed the reasons and protocol presented by the researcher, as well as the associated risks to the Institute. The Aurum Institute accepts the protocol and the associated risks to The Aurum Institute, and authorizes the research project to proceed. If you have any concerns or require additional information please contact Dr. Tendesayi Kufa the Principal Investigator for project.

Principal Investigator

11 August 2014

Date

Tendesayi Kufa

Printed Name and Title of Authorized Signatory

9.10. Appendix 10: UP ethics

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria, complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00022957, Approved dd 22 May 2002 and Expires 28 Oct 2016.
- IRB 0020 2335 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

5/11/2014

Approval Certificate New Application

Ethics Reference No.: 427/2014

Title: FACTORS ASSOCIATED WITH CONCURRENT CONSULTATION OF PRIMARY HEALTH CARE CLINICS AND OTHER PROVIDERS BY TB PATIENTS AND HIV PATIENTS.

Dear Mr Don Lawrence Mudzengi

The **New Application** as supported by documents specified in your cover letter for your research received on the 29/09/2014, was approved by the Faculty of Health Sciences Research Ethics Committee on the 5/11/2014.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year.
- Please remember to use your protocol number (427/2014) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:

- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely



Dr R. Souders; MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677 📠 0866516047 ✉ deepaka.bohana@up.ac.za 🌐 <http://www.healthethics-up.ac.za>
📍 Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Strydom South Building, Level 2, Room 2.33, Gezina, Pretoria

9.11. Appendix 11: DECLARATION OF HELSINKI

**COMMITMENTS AND RESPONSIBILITIES OF SUB- INVESTIGATORS
 REQUIRED FOR RESEARCH THROUGH THE FACULTY OF HEALTH SCIENCES RESEARCH
 ETHICS COMMITTEE, UNIVERSITY OF PRETORIA**

DECLARATION BY INVESTIGATOR:

I agree to **personally** conduct or supervise the described investigation.

I understand as sub-investigator that I am **totally responsible** for aspects of the study delegated to me by the Principal Investigator and am legally bound by the contract signed with the sponsor and **will not inappropriately delegate my responsibilities** to the rest of my study team.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments, without relinquishing my total responsibility for the study.

I confirm that I am **suitably qualified and experienced** to perform and/or supervise the study proposed.

I agree to conduct the study in accordance with the relevant, current protocol and will make changes in the protocol only after approval by the sponsor and the Ethics Committee, except when urgently necessary to protect the safety, rights, or welfare of subjects.

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the ICH GCP Guidelines and Ethics Committee requirements relating to obtaining informed consent are met.

I agree to timeously reporting to the sponsor and Ethics Committee adverse experiences that occur in the course of the investigation according to the time requirements adopted by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

I agree to maintain **adequate and accurate** records and to make those records available for inspection by the appropriate authorized agents, be it EC, FDA or sponsor agents.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the Declaration of Helsinki and South African and ICH GCP Guidelines and am conversant with these guidelines.

I agree to inform the Ethics Committee in advance should I go on leave together with an agreed plan of action regarding an alternate principal investigator or sub-investigator to take responsibility in my absence.

I understand that the study may be audited at any time and that deviation from the principles in this declaration will be put before the Ethics Committee for action, which may include disqualification as an investigator and rehabilitation before being accepted as an investigator in other studies.

I confirm that there is no conflict of interest whatsoever in my participation in this study. I have no shares in the sponsoring company and my participation and interests are as defined in the financial agreement.

DON MUDZENSI

NAME (Printed)



SIGNATURE OF PRINCIPAL INVESTIGATOR

17/09/2014

DATE

NAME (Printed)

SIGNATURE OF SUB-INVESTIGATOR

DATE

10. ANNEXURE

10.1. Annexe 1 : Normality graphs for numerical variables

