ACCESS TO CARE IN PEOPLE LIVING WITH HIV

By

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DECLARATION

I, Elizabeth du Toit, hereby declare that he work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work or any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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THESIS ABSTRACT

Background: South Africa has the most people living with HIV (PLWH) in the world. With increased access to HIV Counselling and Testing (HCT) as well as expanded Antiretroviral Therapy (ART) treatment guidelines; there is a large and increasing number of people who need access to HIV care. Limited data and few studies have evaluated access to HIV care.

Methods: A cross sectional survey with stratified random sampling was conducted from January – April 2011 to determine the proportion of PLWH in urban areas in the greater Cape Town area who are accessing appropriate HIV care and factors associated with accessing care. The sampling frame for this study was the Zambia South Africa TB and AIDS Reduction (ZAMSTAR) Study. Self reported HIV positive adults were randomly selected. Self reported HIV negative adults or adults of unknown HIV status were also randomly selected in order to decrease possible stigmatisation. Consenting participants were interviewed and completed a questionnaire detailing their access to HIV testing and care. Participants who disclosed that they were HIV positive were included in the analysis. Access to appropriate HIV care was defined as one of three scenarios: 1. Receiving ART and having attended an ART clinic or collected ART medication within the last three months. 2. Undergoing ART work up and having attended an ART clinic within the last three months. 3. In PreART care having had a CD4 count in the last 6 months.

Results: 1257 participants were interviewed. 627(50%) reported being HIV positive, 487(39%) HIV negative and 143(11%) did not know or wish to disclose their status. Of the 627 HIV positive participants: 392 (63%) reported taking ART of whom 369 (94%) accessed appropriate HIV care. 25 (4 %) were being worked up for ART of whom 16 (64%) accessed appropriate HIV care. 210 (33%) were in PreART care, 81 (39%) having accessed appropriate HIV care. Females were 3.78 times more likely to be in appropriate care than males ($p < 0.001$), and a person in the age category greater than 45 years was 4.63 times more likely to be in appropriate care than someone in the age category 15-24 ($p = 0.002$).

Conclusion: Access to appropriate care was high for those on ART; however for PreART care it was low. A systematic approach to PreART care with attention to client and service factors is needed. The impact on existing resources and the need for additional resources to deliver this care should be investigated.

Table of Contents

Contents

PART A PROTOCOL

ACCESS TO CARE IN PEOPLE LIVING WITH HIV

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Executive Summary

Background

South Africa has the most people living with HIV (PLWH) in the world. With increased access to HIV Counselling and Testing (HCT) as well as expanded Antiretroviral Therapy (ART) treatment guidelines; there are a large and increasing number of people who need access to HIV care. There is little information available on the proportion of PLWH in the Western Cape who are accessing care and the factors that are associated with this. To ensure that PLWH access HIV care, opportunities to target this group must be exploited.

Research Question

To identify factors associated with accessing appropriate HIV care in PLWH

Setting and Population

The study will be conducted in urban areas in the greater Cape Town area where the Zambia South Africa Tuberculosis and AIDS reduction study (ZAMSTAR) TB and HIV prevalence survey has been conducted. These areas have a high prevalence of HIV and Tuberculosis (TB). The population will be individuals who have previously participated in the prevalence survey.

Methods

Self reported HIV positive adults will be randomly selected. Self reported HIV negative adults or adults of unknown HIV status will also be randomly selected in order to decrease possible stigmatisation.Individuals will be revisited and, after giving informed consent, they will be asked to complete a questionnaire which will detail their self reported HIV status, and in those PLWH if they have had a CD4 count and are in care, as well as factors thought to be associated with accessing care for HIV.

Analysis

Univariable and multi-variable analyses will be performed to determine factors associated with being in care for HIV.

Significance

This information may allow for informed suggestions to be made to health structures in the Western Cape to improve services within health care facilities and HCT testing stations to target the very vulnerable group of people who are not in care for HIV.

1. Introduction

1.1. Background to HIV prevalence and the roll out of HCT in South Africa

South Africa has the largest Antiretroviral Therapy (ART) programme in the world with around 1 million people on ART by the end of 2009(1). However, South Africa also has the highest number of people living with HIV (PLWH) in the world with UNAIDS estimating that in 2009 there were 5.7 million people living with HIV in South Africa(1, 2). Access to treatment is thus low(1) and in mid 2008 the number of adults with untreated clinical AIDS or CD4 counts < 200 cells/mm^3 was 760 000(3). There is a large gap between the number of people undergoing HCT and those accessing ART.

The target of the 2011 National Strategic Plan is to initiate 80% of those needing ART onto treatment by 2011(2). Prior to initiation of ART a large number of people will need to access PreART care and continue to access care until they are eligible for ART.

Presently there is a focus on the provision and scale up of HIV Counselling and Testing (HCT), which is seen to be a critical element in the prevention as well as HIV care and treatment pathway(1).

The goal of the HIV Counselling and Testing campaign (HCT), launched in South Africa in April 2010, is to test 15 million people for HIV by June 2011 and to refer them to care as needed(1-4). The campaign also aims to screen and appropriately refer people for TB and other chronic diseases such as diabetes and hypertension. One of the proposed outcomes of the HCT campaign will be that the diagnosis of HIV will take place earlier and may result in earlier initiation of appropriate care and treatment(1, 2).

1.2. Current Standard of Care for people living with HIV in South Africa

The 2010 ART treatment guidelines state that ART should be initiated at a CD4 count of ≤350 cells/mm^3 if the patient is pregnant or co-infected with TB, otherwise initiation of treatment is recommended at a CD4 count <200 cells/mm^3 or stage 4 disease(5). These guidelines also recommend that in people not eligible for ART a six monthly CD4 count should be done at a preART or wellness clinic to determine when ART is indicated(5). Unfortunately there is no further information or guidance given in the guidelines about how to effectively manage this large group of patients who are not yet eligible for ART.

1.3. The need to determine factors that impact on accessing HIV care

It is essential that those that test HIV positive access care and have an initial CD4 count, and thereafter regular monitoring with initiation of ART when needed, otherwise the full benefit of strategies such as the HCT campaign will largely be negated and the treatment gap for those needing ART but not accessing it will widen.

The National TB research priorities for 2010 – 2011 have identified the need to study and evaluate leakages within the existing TB and HIV referral mechanisms in order to determine the extent to which co-infected patients are lost to ongoing care due to weaknesses in the referral system(6). HIV and TB are closely linked in South Africa. Understanding more about the group of people who know their HIV positive status but who are not in care will help to address this national research priority.

It is important to identify not only the gaps, but also the opportunities, in order to target those that have not accessed care. One such opportunity may be to use any exposure that individuals have to health care facilities to target the group of PLWH who are not yet in care. It is important to know if exposure to health care facilities on a regular basis, defined in this proposal as at least once in the last 6 months, for reasons other than those directly related to HIV care is associated with an increased

chance of accessing HIV care. This information could inform and guide decisions and strategies to target HIV positive individuals whenever they are exposed to a health care facility and to provide means to increase their access to HIV care.

1.4 Current literature pertaining to Access to Care in PLWH

Although many studies have looked at ways to increase scale up and uptake of HCT, as well as factors impacting on ART initiation, treatment adherence, and ART loss to follow up, little data is available about the gap between those who test HIV positive and access to HIV care in sub-Saharan Africa.

In 2008 the South African National HIV Prevalence, Incidence, Behaviour and Communication Survey; found that 25% of people aged between 15 and 49 years had tested for HIV within in the last year(1). This rose to 37% in 2009 according to the 2009 National Communication Survey(1). However, there were no data in this report as to how many accessed HIV care.

A small number of published studies reported on loss to care in sub-Saharan Africa in people newly diagnosed with HIV(7, 8). A study by Losina et al(7) in Durban, conducted in 2006-2007, investigated pre treatment loss to care in newly diagnosed HIV positive people in two sites in Durban. Nearly half of the cohort studied resulted in pre treatment loss to care with failure to obtain a CD4 count in 8 weeks following diagnosis. Factors influencing this included a distance from the health centre of greater than 10km, a history of being treated for TB, and referral for HIV testing by a health care provider as opposed to self referral. This would imply that exposure to health care services that result in TB treatment or referral for HIV testing could be negatively associated with accessing appropriate HIV care.

Other factors that have been associated with pre treatment loss to follow up in Uganda were male sex and a low CD4 count(9) while factors for loss to follow up after ART initiation included the cost of transportation and work and child care

responsibilities(10). Male sex, unemployment and a low CD4 count predicted loss to care in patients who had received their CD4 counts and had been given an appointment for ART workup(7).

A study by Ulett et al(11) looked at a retrospective cohort of patients in the United States and described, following HIV diagnosis, the linkage to outpatient treatment, ART initiation, and further retention in care. They found that delayed initial linkage to care was associated with older age and African American race. This study is, however, not generalisable to our population as the cohort comprised a large proportion (51%) of men who have sex with men (MSM), males (75%) and there was a high percentage of reported drug abuse (26%).

The health care provider plays a vital part in ensuring that after HCT a person accesses care. In Cape Town, delay in TB diagnosis was more attributable to health care provider delay than patient delay(12). Given the high TB HIV co-infection rate this serves to highlight the need to look at health care provider related opportunities to channel people into care.

This study seeks to determine factors that impact on PLWH accessing care for HIV across multiple sites in the greater Cape Town area. The population will be those who have undergone HCT and know their HIV status. This will provide an opportunity to determine the proportion of PLWH who are accessing care.

The aim is that by better understanding this population, strategies to prevent missed opportunities can be suggested.

1.5. Research Question

To identify factors associated with accessing appropriate HIV care in PLWH**.**

1.6. Objectives

Primary Objectives

To determine whether the following factors impact on a person accessing care for HIV:

- Attendance at a health care facility within the last six months for reasons other than HIV care
- Self referral or provider initiated referral for HIV testing
- Mode of transport and transport cost to access the clinic
- Clinic waiting times
- Current or previous treatment for TB
- Age and sex
- Education level
- Employment status
- Disclosure of HIV status to a partner or friend
- Knowing a family member or friend who either had HIV, was on ART or who had died with HIV.

Secondary Objectives

To determine the proportion of PLWH who were accessing appropriate care:

- Receiving ART and having attended an ART clinic or collected ART medication within the last three months of being interviewed
- Undergoing work up in order to receive ART, and having attended an ART clinic within the last three months of being interviewed
- Not eligible for ART but in care and having had a CD4 count in the last 6 months

2. Methods

2.1 Study design

The design is a cross sectional study. The study will form an addition to the ZAMSTAR Household TB and HIV Prevalence Survey (Ethics number NO4/10/173) which is summarised below.

The ZAMSTAR TB and HIV Prevalence survey as a platform to study access to HIV care

The Zambia South Africa TB and Aids Reduction (ZAMSTAR) study(13) is a community based study that has implemented innovative ways such as intensified TB case finding and Household contact tracing to decrease the prevalence of TB and HIV. The South African arm of the study is based at eight sites in the greater Cape Town area where there is a high prevalence of TB and HIV. The final outcome of the ZAMSTAR study is a prevalence survey of TB and HIV. In South Africa there is a target to survey 40 000 adults across the eight sites. The sites comprise between one and two primary health care clinics and include a minimum number of 25 000 people in each area according to 2003 Census data.

Electronic maps have been generated for each site and the Census Enumeration Areas have been randomly selected. The ZAMSTAR Prevalence Survey enumerates and enrolls all consenting adults from these randomized Enumeration Areas. An enrolment target of 5000 adults per site has been set.

All participants in the ZAMSTAR survey give written informed consent which includes consent to a repeat visit by the research team. Once enrolled in the survey participants complete a questionnaire that focuses on their demographics, socioeconomic status, and medical history, specifically with regard to TB and HIV. Participants are asked whether they know their HIV status, and whether they are

willing to disclose their status. Participants submit a sputum sample for culture for TB and are offered HCT.

Interim data from the survey indicate that about 50% of participants enrolled know their HIV status, and about 13% of these report that they are HIV positive. It is unknown how many of these are in care for HIV.

This proposal intends to address this knowledge gap and survey those participants who have disclosed that they are HIV positive to determine if they are in care for HIV and the factors associated with this

2.2 Study Setting

The study will take place in the urban areas of the greater Cape Town area where the ZAMSTAR prevalence survey is being conducted. These areas are within Kayamandi, Stellenbosch; Mbekweni, Paarl; Wallacedene; Delft South; Nyanga; Mzamomhle, Philippi; Site C, Khayelitsha; and Kuyasa, Khayelitsha.

2.3 Population and Sampling

2.3.1 Definitions

Access to HIV Care refers to any of the following in PLWH:

1. Receiving ART and having attended an ART clinic or collected ART medication within the last three months of being interviewed
2. Undergoing work up in order to receive ART, and having attended an ART clinic within the last three months of being interviewed
3. In those not on ART or undergoing work up (i.e. PreART), having had a CD4 count in the last 6 months

Adult: An individual 18 years and older.

Known HIV Positive: An individual who says that he/she has previously tested for HIV and knows that his/her status is HIV positive.

Pre treatment loss to care: An individual who has tested positive for HIV and has not accessed HIV care.

Self referral for HCT: A person accessing HCT on their own as an independent initiative (as opposed to being offered or referred for HCT by a health care practitioner).

Provider initiated HCT: HCT offered or recommended by a health care provider.

2.3.2. Inclusion and exclusion criteria

Inclusion criteria

- Age ≥18 years
- Previously enrolled in the ZAMSTAR TB and HIV prevalence survey
- Informed consent given to complete a questionnaire for this study

Exclusion criteria

- Age <18 years
- No consent obtained for the ZAMSTAR prevalence survey
- An Individual that is living in an institutional setting (i.e. prisons, boarding schools, military camps, hostels and lodges)
- Informed consent not able to be obtained due to the influence of alcohol or drugs or mental impairment

2.3.3 Population

The study population will be those who fulfill the inclusion criteria. In summary these are adults who have previously been enrolled in the ZAMSTAR TB and HIV Prevalence Survey and gave consent to be visited again by the research team. They will be revisited in this study, written informed consent will be obtained and consenting participants will be asked to complete a questionnaire. The target population for this

study are participants who, during the ZAMSTAR survey, disclosed that they were HIV positive. However, in order to avoid stigmatization around HIV as well as to maintain confidentiality in the community, a proportion of participants who either disclosed that they were HIV negative, or else did not know or wish to reveal their HIV status will be also be revisited.

2.4 Sampling strategy

A random sample of individuals who participated in the ZAMSTAR TB Prevalence Survey will be revisited by Research Assistants. 75% of this sample will be comprised of participants who disclosed that they were HIV positive, and 25% who disclosed that they were HIV negative or who had not disclosed their HIV status.
Individuals will be allocated a unique barcode that will be different to, but will be able to be linked with the barcode that was allocated in the ZAMSTAR survey.

The following procedure will be followed for determining the random sample:

- Overall lists of participants that were enrolled in the ZAMSTAR survey will be generated per site – only unique bar code numbers will be used (no names).
- Lists of the Enumeration Areas (EAs) surveyed in the ZAMSTAR prevalence survey will be compiled per site. Half of these EA's will be selected randomly and included in the sampling frame.
- Lists of known HIV positive participants (from the ZAMSTAR prevalence survey) living in these randomly selected EAs, will be compiled using only unique bar code numbers (no names).
- Lists of HIV negative participants or those who did not wish to disclose their status (from the ZAMSTAR prevalence survey) living in these randomly selected EAs, will be compiled using only unique bar code numbers (no names).

- Individuals will be randomly selected (using only unique bar code numbers (no names), from these EA's so that for every 3 HIV positive participants there will be 1 HIV negative participant.
- Only after this selection, will the name and address be linked to the bar code to enable the research team to visit the identified participant.
- EA's will be visited in order, and all randomly selected individuals visited, until the required sample size is reached per site.

The details from the ZAMSTAR study for the randomly selected individuals will be unlinked by the senior data manager so that names and addresses are available for each individual. Consent forms will be printed that include a new unique barcode, name and address. The barcodes from the ZAMSTAR study will not be printed on these consent forms. Research Assistants will then be given all the randomized individuals per EA per site to visit and to obtain informed consent to enroll in this study.

Individuals will be enrolled if they give written informed consent and complete a questionnaire on accessing care that the Research Assistant reads out aloud. (Access to Health Care Questionnaire: Appendix 1) This information will be captured on a Personal Digital Assistant (PDA) and the information downloaded on a daily basis at DTTC. The Research Assistant will scan the new bar code into the PDA so that there is no name on the questionnaire. The only place where name will occur will be on the consent form.

2.4.1 Field Management

Correct Identification of individuals in the field:

The consent form that the individuals signed for the ZAMSTAR prevalence survey form indicated that staff from DTTC may visit the individual again at a later date. As described in the sampling section: A new pre barcoded consent form with the

individual's name, unique barcode and address will be printed. The Research Assistant will revisit the individual and confirm that the individual has been identified correctly by asking them to confirm their name and date of birth.

The participant will be provided with an information sheet about this study and asked if they agree to take part in it. The consent form and information sheet will also document that the participant agrees that the study can access information that was recorded about them in the ZAMSTAR survey. If the participant agrees then they will sign the pre-barcoded consent form. (Information sheet and Informed Consent: Appendix 2+3). The RA will ask them the questions on the questionnaire and record the answers on a personal digital assistant (PDA). The questionnaire and data on the PDA will have a unique code and will not have any personal identifiers.

If a participant is not at home, the Research Assistant will make a note on a management form as to the time and date of the visit (Management form: Appendix 4). The Research Assistant will visit the house on two additional occasions at different times to try to locate the person. If after three visits they have not succeeded in finding the person then they will return the consent form having marked that they were unable to locate the person.

All participants who disclose during the questionnaire that they are HIV positive and who are not accessing care for HIV will be given information as to the appropriate clinic to access care. They will also be offered a referral letter to go to the clinic to seek care.

2.5 Sample size

A minimum sample size of 632 PLWH will be needed to detect a 10% risk difference in attendance at a health care facility within the last six months for reasons other than HIV care with 95% significance level, and 80% power. The sample size of PLWH was

calculated using Open Epi , version 2, open source calculator for Cross sectional survey.

The total sample size will include an additional 1 participant who is HIV negative or who has not disclosed their HIV status for every 3 PLWH. This is to avoid stigma related complications and to be able to assess the number of HIV negative individuals who are exposed to health care facilities.

Assuming that 30% of participants are not able to be found or do not consent to take part in the study, and to allow for a design effect of 1.58 due to clustering, an additional 15% has been added to the required total, bringing the sample size to 945 individuals who are known to be HIV positive. The total sample size, which includes 315 individuals who are HIV negative or have not disclosed, will be 1260.

In order to achieve recruitment of the sample size eight research assistants (RA) will need to work in four of the eight sites at any one time, in teams of two RA's per team. Given a conservative estimate that each team can enroll 6 people per day, five days per week in four sites, then the sample size will be reached in three months.

2.6. Data Management

All informed consent forms will be coded with a unique barcode that will be able to be linked to the ZAMSTAR barcode for the individual by the data manager.

If the participant gives informed consent and signs the consent form, the barcode on the consent form will be scanned into the PDA and the answers to the questionnaire captured on the PDA. No name will be linked to the data on the PDA. The information will be downloaded daily from the PDA's onto the DTTC central database designed for this study.

The informed consent forms will be scanned in daily at DTTC. The name of the participant and the barcode will be captured electronically and saved on the DTTC central database. All data is backed up onto a second server on a daily basis. Data from the ZAMSTAR Prevalence survey will to be linked to the data on the PDA via the unique barcode. This will only be able to be done by the data manager. The name of the individual will only appear on the consent form. The senior data manager will be the only person who can link the name from the consent form via the unique barcode to the data. The consent forms will be stored in locked steel cabinets.

2.7 Data dictionary

See appendix 8

2.8. Quality Control

Research Assistants will be trained by the Principal Investigator, the study coordinator and the data team to accurately record the answers to the questionnaire on the PDA. The study coordinator will randomly select 5% of the completed consent forms on a weekly basis for a home visit to ensure that participant was enrolled as per protocol in the survey as an additional quality control measure. During that visit the signature of the participant will be confirmed.

2.9. Potential Strengths and Weaknesses of the study

2.9.1 Weaknesses

There may be a selection bias in that some known HIV positive participants in the ZAMSTAR study will be unwilling to disclose their status to the Research Assistant conducting the ZAMSTAR prevalence questionnaire. These participants may therefore never be interviewed or enrolled in this study. It is possible that these participants are more likely not to be in care if they are unwilling to disclose their status.

There will be recall bias as all the data will be self reported and the answers for some questions may need recall from a long time ago. Where possible the validation of answers from the participants HIV clinic card will be included.

2.9.2 Strengths

A large sample size is required, and it is probable that a wide distribution across sex, age, education and health status will be obtained.

Data from the ZAMSTAR Prevalence survey Household and Individual questionnaires (ZAMSTAR Individual and Household Questionnaire: Appendix 5) will be collated with information collected in this study. This will give additional information that can be used to predict factors influencing access to care.

This study is targeting individuals in the community. Selection bias is minimized, as many other studies focusing on access to care, or loss to follow up care, select their population from a clinic as opposed to the general population.

This study collects data directly from individuals and not from folder reviews, therefore missing data as a result of a folder review design will be negated.

3. Statistical Analysis

All data will be exported into and analyzed in STATA version 11.0. The sample will be described according to the individual's demographics and HIV testing pathways in numbers and percentages. The number and percentage of participants accessing appropriate care, as per the study definition, will be determined. Associations between the HIV positive and negative groups will be described using the chi-square test of independence. Factors that are thought to impact on access to care will be described in numbers and percentages and a untivariable analysis of these factors will be conducted. A multivariable analysis using a logistic regression model will be conducted to determine independent factors associated with access to care.

4. Ethics and communication

4.1 Ethical considerations

Ethics approval will be obtained from the Stellenbosch University Committee for Human Research and the research will be conducted according to the Helsinki Declaration. Ethical clearance will also be obtained from the Ethics advisory group of the International Union against TB and Lung disease (The Union) and the Health Sciences Human Research Ethics Committee at the University of Cape Town.

The autonomy of the participants will be respected by providing information in a written information sheet (Information sheet and Informed Consent: Appendix 2+3) and answering any questions that they have regarding the aims and nature of the study. The participant will be free to decide whether or not to participate in the study without being coerced. Should they decide to participate in the study, their written informed consent will be obtained (Information sheet and Informed Consent: Appendix 2+3)

Participants will be assured that any personal information will be kept confidential. Data will be captured on a PDA using a unique barcode and the database will not contain any personal identifiers. The senior data manager will be the only person who can link the name from the consent form via the unique barcode to the data.

The interview will be conducted in the language (English, Afrikaans or Xhosa) that the participant is most comfortable in. There will be no financial incentives awarded to the participants.

Participants may feel vulnerable about disclosing their HIV status to the RA, even though the majority would already have volunteered this information in the ZAMSTAR prevalence survey. They may feel distressed by recalling their experiences as to when they were first diagnosed with HIV. In order to alleviate distress all participants will be told that they need not answer questions which they are not

comfortable with, and are free to withdraw from the study at any time. The RA's will be trained in Good Clinical Practice and will understand the importance of maintaining confidentiality. Where possible, at least one RA per team will also have been trained in HIV counselling.

After completing the questionnaire, those participants who have not accessed care, will be informed about the importance of accessing care and will receive counselling around issues of HIV, should this need arise. All participants will receive information on HIV, CD4 Counts, and HIV care in the community – as stated in the Information sheet and Informed Consent Form.

All participants will be given the contact details of the study managers, where they can direct questions relating to the study or to their rights as study participants.

4.2 Dissemination of results

The findings from the study will be presented at the annual DTTC dissemination meeting attended by members from the community advisory boards as well as by clinic staff and colleagues from the City and Provincial Health departments.

A summary of the findings of the study will be compiled and given to the facility manager of the clinics to distribute to staff.

Results will be communicated both personally and in a written summary to local stakeholders. These are the City of Cape Town and Provincial Health Department.The results will be written in a scientific article and sent to a peer reviewed journal for publication. Results will also be submitted to the South African TB and HIV conference as well as to the International Union against TB and Lung Disease.

5. Logistics

5.1 Budget See Appendix 6

5.2 Timeline – See Appendix 7

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7. Appendices

Appendix 1: Access to Health Care Questionnaire

Appendix 2: Information sheet

Appendix 3: Informed Consent sheet

Appendix 4: Management form

Appendix 5: ZAMSTAR Individual and Household Questionnaire

Appendix 6: Budget

Appendix 7: Timeline

Appendix 8: Data Dictionary

Appendix 9a: The Union Ethics approval documentation

Appendix 9b: Stellenbosch University Ethics approval documentation

Appendix 9c: University of Cape town Ethics approval documentation

PART B LITERATURE REVIEW

ACCESS TO CARE IN PEOPLE LIVING WITH HIV

1. Introduction and Objectives

The following literature review focused on access to appropriate HIV care for People Living with HIV (PLWH). The burden of HIV, as well as the current standard of care and guidelines for appropriate care in South Africa, is described. Particular attention was paid to recent studies that have been based in South Africa as the extent to which PLWH have access to care and the associated factors will often be influenced by demographic, geographical, cultural and political factors, and so the most value from this study would be to the South African Policy makers, thus the focus on South African literature. The literature presented is categorized according to set time points in the HIV pathway where access to care has been studied. The need for further research in this arena is also addressed.

The concept of Access to care in people living with HIV aims to describe those persons with HIV in different points of their HIV pathway who are accessing the appropriate care, and this encompasses availability, affordability, accessibility as well as utilization of health care services.

2. Search Strategy and Inclusion and Exclusion Criteria

A search for articles in English published between 2000 and 2011 that related to access to care in PLWH was performed by searching PubMed and Google Scholar. Quantitative and Qualitative studies were included. Systematic review articles were included, but case reports and case series were not. In addition to this, the reference lists of applicable studies were scrutinized for additional relevant citations. All the studies that were included were published in peer reviewed journals. Although the initial search strategy included both developed and developing countries, studies pertaining to access to care in PLWH focused on South Africa and sub-Saharan Africa and therefore studies from beyond sub Saharan Africa were excluded. For studies

pertaining to the validity of self reported HIV status both developed and developing countries were included.

For literature pertaining to Access to HIV care the search terms used included: HIV (or Human Immunodeficiency virus) OR CD4 count or CD4 testing or ART (or Antiretroviral therapy) AND" linkage to care" OR "loss to follow up" OR "access to HIV care".

WHO reports, UNAIDS reports and documents from the South African National Department of Health were sourced via their respective websites for information pertaining to the Background and Current Standard of Care sections. Terms that were used to gather additional information about background and current guidelines included HIV, Voluntary Counselling and Testing (VCT), HIV Counselling and Testing (HCT), CD4 testing, ART (or antiretroviral therapy) AND South Africa.

For literature concerning the Validity of self reported HIV status search terms included: "Knowledge of HIV status "OR "CD4 count" OR "Self disclosure" AND "validity" OR "reliability".

3. Study quality and relevance

Of the twelve quantitative studies that dealt with Access to Care, four were prospective cohort studies and eight were retrospective cohort studies. The central theme of the studies was loss to care in the time period before antiretroviral therapy (ART) initiation (PreART). In all the studies there was loss to follow up of participants and it was not possible to ascertain whether a patient truly failed to access care, or rather sought care after the stipulated timeframe, or at another facility. This was a particular problem with retrospective studies but it also depended on the quality of the health information tracking systems that were in place.

One systematic review that investigated PreART retention in care in Africa(1) was included. This review was used to identify additional studies that were of relevance as well as to summarize the results of the studies. It is important to note that the overall

core question of , “What proportion of patients who test positive for HIV are staged, enroll and remain in preART care until eligible for ART, and initiate ART” was not answered by the systematic review(1), and hence the need for this study.

4. Summary of the literature

4.1. Background to the burden of HIV in South Africa and the need for access to HIV care

South Africa has the greatest HIV epidemic in the world with an estimated 5.6 million PLWH in 2009(2). This requires appropriate HIV care for those afflicted. This care needs to be tailored for different time points as indicated by the natural lifecycle of the disease.

The provision of appropriate HIV care depends on a series of steps that incorporate the need for initial diagnosis of HIV, monitoring of the CD4 cell count, treatment of HIV-related illnesses until the stage is reached where ART is indicated, and thereafter initiation and maintenance on ART.

Initial HIV diagnosis should be as early as possible, so that the index case can be empowered to reduce ongoing transmission as well as live positively with HIV(3, 4). Initiation on ART should also be timely as mortality is strongly associated with CD4 cell counts below 50 cells/mm^3, or Stage 4 disease at ART initiation(5). Strategies to reduce HIV related mortality need to include earlier diagnosis of HIV, strengthening of PreART HIV care and prompt initiation of ART(5-7).

The overall goal of treatment programmes that deliver HIV care are: Early diagnosis of HIV infection; prompt enrollment in PreART care, appropriate monitoring and care prior to ART eligibility; timely initiation of ART; ensuring survival through the early years on ART and lastly lifelong retention in the treatment programme(8).

The HIV and AIDS and STI National Strategic Plan for South Africa 2007 – 2011 has been developed to identify interventions to reduce the incidence of HIV, as well as the impact that HIV has on the lives of individuals, as well as their families and communities(9). An important component of the plan is that it sets targets with regard to these interventions. The target was set to reduce the national HIV incidence rate by 50% by 2011, and to provide an appropriate package of treatment, care and support services to 80% of PLWH by 2011(9).

4.2 Current Standard of Care for PLWH in South Africa

1. HIV Counselling and Testing (HCT)

The entry into appropriate HIV care begins with the knowledge of HIV status. As the epidemic progresses and the way in which it is managed changes, there are new opportunities to expand access to HCT(10). Many different strategies are incorporated into the 2007 – 2011 NSP which aims for 70% of South Africans to have tested at least once for HIV, and furthermore 25% of the population to test annually by 2011(9). HCT for HIV has expanded rapidly in the last few years with 7 million adults (aged 15 years and older) having received HCT in 2009(11).

Another initiative that ensures the increase of HCT has been the launch of The HIV Counselling and Testing Campaign in 2011, which aimed to test 15 million people for HIV by June 2011 and to refer them to care as needed. The target for the Western Cape was 1,1 million people over the age of 12 years who were sexually active(12). The campaign aimed to increase the incidence of appropriate health seeking behaviour, as well as access to treatment, care and support. Although the final figures are not yet available, the South African Health Minister, Dr A Motsoaledi, announced in his 2011 health budget policy speech that 11.9 million people had tested for HIV since the launch of the campaign(13).

2. PreART Care

Once the diagnosis of HIV has been established, CD4 cell count monitoring and HIV staging needs to occur at regular intervals in order to establish when the person should commence ART. According to the 2010 ART treatment guidelines CD4 cell count monitoring at a preART or wellness clinic should occur at six monthly intervals if a PLWH is not yet eligible for ART(14). The guidelines fail however to give more insight into how to effectively manage this large group of patients who are not yet eligible for ART.

3. ART

The 2010 ART treatment guidelines stipulated that initiation of ART should occur if the CD4 cell count was «350 cells/mm^3 if the patient was pregnant or co-infected with Tuberculosis (TB), otherwise ART was recommended at a CD4 count of« 200 cells/mm^3, or stage 4 disease(14). These guidelines fell short of the WHO recommendations that all patients initiate treatment at a CD4 cell count of «350 cells/mm^3(15). The guidelines were amended in 2011 to state that all patients with a CD4 count of «350 cells/mm^3 initiate treatment(16).

4.3 Validity of self reported HIV status

Access to appropriate HIV care can either be determined through routine or research orientated monitoring programmes that track patients at any point from the time of initial HIV diagnosis to ART initiation, or it can be self reported by the patients. There is limited data available, especially in developing countries, as to the validity of a person's self reported HIV status and other self reported HIV measures like CD4 count as compared to the clinical records.

In developed countries a study found that amongst IV drug users only 68% of HIV positive participants accurately reported their HIV status, whereas 98% of HIV negative participants accurately reported their status(17). CD4 cell counts have been found

however to be reliably and validly assessed through self reporting in PLWH, especially in those with a higher education level(18).

A study conducted in Cape Town(19) showed that self reported HIV status is likely to be understated as well as the prevalence of unprotected sex amongst married or cohabiting couples.

4.4 Literature review of articles pertaining to Access to Care in PLWH

Studies pertaining to time points at which linkage to care have been reported

The majority of programmes report the number of people initiated on ART(20). Recently there has been limited data reporting on other time points related to linkage to care in Sub-Saharan Africa(21-23). Studies from developed countries were not included as the patient population is very different. In developed countries population groups differ substantially with regard to socioeconomic status and mode of HIV acquisition, with a higher percentage of HIV acquisition linked to IV drug abuse and homosexual sex(24). Factors associated with linkage to care in these contexts would not be generalisable to South Africa.

In a systematic review by Rosen & Fox(1), which looked at retention in HIV care before initiation of ART, the following time points were identified: Stage 1: The patient is staged for referral to either PreART or ART care. This includes CD4 testing after initial HIV diagnosis and collection of results. Stage 2: From enrollment in HIV care until eligibility for ART. Stage 3: From establishment of ART eligibility until ART initiation. They report that these steps were often poorly defined in the literature and vary widely, especially where a certain time is allocated for a step to occur, e.g. collection of CD4 results, or where eligibility is a factor, e.g. eligibility for ART. This wide variation is often the result of different programmes administrating and delivering HIV care, e.g.

different NGO's or government departments which have their own criteria and goals for patients in their care.

For this literature review, studies were categorized according to the three stages as reported by Rosen and Fox(1) in order to standardize definitions of linkage to care, as has been recommended in their systematic review. Some studies looked at only one point whilst others reported a combination. No study looked at linkage to care across all time points.

Studies pertaining to Stage 1: Patients staged for PreART or ART HIV care

Kranzer et al(21) looked at linkage to HIV care in individuals testing at different sites in a community in Cape Town. They looked at clinical and laboratory records for a random sample of HIV positive patients (n=988) and found that 63% (n = 621) went for a CD4 test within 6 months of testing and 26% (n=255) had no record of a CD4 count result. Patients most likely to return for CD4 count testing were those that tested for HIV at antenatal care and sexually transmitted infection (STI) services. It was lowest amongst those that were self referred for HIV testing.

Losina et al(22) looked at pre treatment loss to care (PTLC) in newly diagnosed HIV-positive people in two sites in Durban. They defined PTLC as failure to obtain a CD4 count within 8 weeks following HIV diagnosis. Nearly half of the cohort (45%) (n=206) did not collect their result within 8 weeks. Factors associated with PLTC included a distance from the health care centre of greater than 10km, a history of being treated for TB, and referral for HIV testing by a health care provider as opposed to self referral. Larson et al(25), in a similar study at a public sector HIV clinic in Johannesburg, determined the proportion of HIV-infected persons that had a CD4 cell count taken and returned for their results within 12 weeks (CD4 testing completion) . CD4 testing

completion was 35% (n=122/352). A higher baseline CD4 cell count (>200 cells/mm^3) was associated with a lower odds of CD4 testing completion.

Data from an HCT folder review of 634 positive HCT clients, during a routine annual HIV/TB/STI evaluation in Cape Town, found that 77.5% had a CD4 count taken(26). It is not known how many clients had returned for their results.

These studies showed a wide range (35% - 63%) in the number of clients returning for a CD4 count after initial HIV diagnosis. Associated factors included the type of referral system within the facilities (self referral for HIV testing as opposed to health care provider referral), distance that the patient had to travel to the health centre, a previous history of TB and the progression of HIV disease as indicated by a lower CD4 count.

Studies pertaining to Stage 2: From enrollment in HIV care until eligibility for ART

Retention in HIV care, and associated factors in individuals not yet eligible for ART, was determined by Lessells et al(23) in rural KwaZulu – Natal, South Africa. Participants were older than 16 years and ART naive with an initial CD4 count>200 cells/mm^3. Of the 4223 included in the analysis, the overall retention, defined as returning for a follow up CD4 count within 13 months was 45% (n=1896). In addition 72% (n=1371) returned only once for a follow up CD4 count. Factors associated with higher retention were a lower initial CD4 count, older age and female sex. In a subset analysis where individuals were matched to the Africa Centre Demographic Information system (ACDIS) male sex, higher baseline CD4 count, out migration (patients who were initially resident in the demographic surveillance area but became non-resident during the 13 month study period), full time employment, and a household size of more than 10 members were all associated with a lower likelihood of retention in care.

In Johannesburg at a public sector PreART care programme LTFU was determined between initial enrollment and the first scheduled follow up medical visit(25). They found that 74% of patients (n=169/228) with a CD4 count >350cells/mm^3 who were scheduled to return within 6 months had not returned within one year. Only 6% (n=8/128) of the patients that had a CD4 count between 251 and 350, and who were scheduled to return within 3 months kept their appointment within a 4 month period, and only 41% (n=53/128) had returned within a one year period(25). Employed patients were more likely to return, as were those with a lower CD4 count (CD4 251-350cells/mm^3).

These two studies indicate a high proportion (55%-74%) of LTFU after an initial CD4 count. Associated factors include the progression of HIV disease as determined by a lower CD4 count as well as gender, age and employment status.

Studies pertaining to Stage 3: From establishment of ART eligibility until ART initiation

Kranzer et al(21), reported that only 67% (n=147) of those who returned for a CD4 count within 6 months of HIV diagnosis and who were eligible for ART (defined as a count of 200 cells/mm^3 or less), were initiated on ART within 6 months of their HIV diagnosis. Linkage to care in this group was highest amongst those testing through antenatal care.

A study in Durban examined the loss to care and mortality rates before starting ART in ART eligible HIV-infected patients(27). They found that 16% (n=82) were lost before ART initiation with 34% (n=28) having been confirmed as having died. Loss to care was associated with lower baseline CD4 counts as well as unemployment. The study population differed from other programmes in South Africa as the patients had to pay a small monthly fee in order to be initiated and continue on ART.

In a large prospective cohort study in the Free State, South Africa, differences in access and patient outcomes across ART treatment clinics were assessed(28). 45000 ART naïve patients were enrolled in the study between May 2004 and December 2007. The odds of starting ART improved over calendar time. Overall they found that by the end of 2008, 34% of eligible patients had started ART within 1 year of enrollment. Factors associated with not initiating treatment included male sex, CD4 count below 50 cells/mm^3, weight below 50kg, and distance to the clinic of greater than 15km. PreART mortality was high with the majority of deaths in the cohort (83%) occurring in patients not yet on ART.

In an prospective study in Uganda where patients who were eligible for ART were followed up to see if they completed three screening visits required prior to initiating ART(29), they found that 26% (n=637) did not complete screening and did not start ART. Associated factors included male sex and a low CD4 count. Pre treatment mortality was high with 28% (n=181) having died at a median follow up of 351 days. The high cost of transport was a reason given by many who later returned for follow up (n=70/158).

These findings are corroborated by provisional data by Togun et al(30) in a study from the Gambia which found that a third of people eligible to start ART (n=254/790) did not do so, and of these 15% (n=118/790) were confirmed as having died. Predictors of pre-treatment mortality were a low CD4 count (<100 cells/mm^3) and WHO stage 3 or 4 disease. A barrier to ART initiation that was cited by 40% of those lost to follow up who were traced by the research team was the requirement to disclose their HIV status prior to ART initiation.

A study in Malawi looked at LTFU up after initial screening for ART eligibility(31), and found that 13.9% of eligible patients (n=88/633) defaulted before starting ART. There was a high mortality amongst this group with 58% of those who defaulted and who were followed up at their homes (n=35/60) having died. Of these 21 had died before

their scheduled follow up ART appointment. Factors associated with defaulting included lower education, difficulties in dressing, and a follow up ART appointment of more than one week.

In Ethiopia the effect of improved availability of HIV services on PreART and on ART outcomes was studied by Mulissa et al(32). In the cohort 25% were lost to care before ART initiation (n=549/2191). Factors associated with LTFU included a less advanced WHO HIV staging as well as living in a rural area.

High rates of TB HIV co-infection is a particular concern in South Africa with 58% of TB patients who tested for HIV in 2009 being HIV positive(33). Pepper et al looked at barriers to initiation of ART in HIV infected TB patients in an integrated TB HIV health care service in Cape Town. Of the 100 patients eligible to be assessed 66% initiated ART treatment during TB treatment. Factors that were found to be associated with failure to initiate ART included male sex, and younger age.

Qualitative studies explored factors associated with linkage to and retention in HIV care. In a study in Rural Tanzania, where in depth interviews and focus group discussions with PLWH who had been referred to an ART clinic were conducted, health related beliefs and perceived barriers and benefits associated with regular clinic attendance were explored(34). They found that perceptions of susceptibility to HIV related illnesses as well as the presence of physical symptoms that reinforced this perception of susceptibility were important in determining who attended clinic appointments. Barriers included health system factors like distance to the clinic, as well as long journey times and long waiting times to be seen by the clinic staff. These findings largely corroborate the findings of factors in the quantitative studies.

There was a wide range of loss to follow up prior to initiation of ART, and timeframes and definitions varied widely across the studies. A factor common, however, to the

majority of the above studies is that PreART mortality was high and that a lower baseline CD4 count was associated with not initiating treatment.

4.5 Limitation of studies included in the literature review

Few studies have been completed that look specifically at access to HIV care in PLWH. There has also been no longitudinal study that spans the time from HIV diagnosis until initiation onto ART.

Although the studies have been summarized according to stages 1-3, as defined by Rosen & Fox(1), there was a wide variation in the time points that pertained to specific outcomes. E.g. the time frame from when a patient tests HIV positive and goes to collect their result (stage 1) differed across all three studies(21, 22, 25). Some studies looked at only one time point(22, 35), whilst other studies looked at more than one time point(21, 28). No study, however, looked comprehensively at all time points from testing for HIV until initiation on ART. There were also different definitions for Linkage to Care or Loss to Follow Up, depending on what organization was managing and providing the HIV services.

The majority of the quantitative studies (eight out of twelve) were from patient populations in South Africa. Although this forms a solid research base from South Africa, which is also the country of interest to the researcher, it means that results will not be fully generalisable to Sub Saharan Africa. In addition to this, the majority of studies, even in South Africa, reported on different HIV programmes, many supported by different Non Governmental Organizations or academic units which further led to non generalisabilty of results.

Factors that impacted on access to care differed widely across the studies, and their definitions lacked consistency. There were a range of factors described which included

patient employment status, gender, CD4 count, to factors from the individual health programmes, like referral patterns leading to referral for HIV testing and time between follow up appointments.

5. Conclusion

The above literature review has given an account of findings from studies that have evaluated access to HIV care prior to the initiation of ART.
Gaps in the literature include the need for a longitudinal study to be done spanning the time from HIV diagnosis until initiation onto ART as well as a need for ongoing identification and analysis of factors that are associated with accessing appropriate HIV care, both from within the health care system and on an individual patient level

A challenge for many studies has been the absence of established patient data tracking systems to determine which patients are successfully accessing care. Future studies may benefit from utilising other methods of determining access to care, such as self reported health seeking behaviour.

Future studies will add to the current knowledge and may facilitate strategies to be tailored to target those who currently fall through the gaps or experience unnecessary delay from the time of HIV diagnosis to lifelong maintenance on ART.

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PART C JOURNAL MANUSCRIPT

ACCESS TO CARE IN PEOPLE LIVING WITH HIV

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This will be formatted for submission to JAIDS.

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Abstract

Introduction: Limited data and few studies have evaluated access to appropriate HIV care (AHC).

Methods: A cross sectional survey with stratified random sampling was conducted from January – April 2011 to determine the proportion of People Living with HIV (PLWH) in urban areas in Cape Town who are accessing AHC and associated factors. Self reported HIV positive, negative or participants of unknown status completed a questionnaire around access to HIV care. Participants who disclosed that they were HIV positive were included in the analysis. Access to AHC was defined as one of three scenarios: 1. Receiving ART and having attended an ART clinic or collected ART medication within the last three months. 2. Undergoing ART work up and having attended an ART clinic within the last three months. 3. In PreART care having had a CD4 count in the last 6 months.

Results: 1257 participants were interviewed. 627(50%) were HIV positive, 487(39%) HIV negative and 143(11%) did not know or disclose their status. Of the 627 HIV positive participants: 392 (63%) reported taking ART, 369 (94%) accessed AHC.25 (4 %) were being worked up for ART, 16 (64%) accessed AHC. 210 (33%) were in PreART care, 81 (39%) accessed AHC. Females were 3.78 times more likely to access AHC than males ($p < 0.001$), and a person in the age category greater than 45 years was 4.63 times more likely to access AHC than someone in the age category 15-24 ($p = 0.002$).

Conclusion: Access to AHC was high for those on ART; however for PreART care it was low. A systematic approach to PreART care with attention to client and service factors is needed.

Keywords: Access to HIV care, PreART, ART, HIV

Introduction

South Africa has the largest HIV epidemic in the world with an estimated 5.6 million people living with HIV (PLWH) in 2009(1). This necessitates care for a large and growing number of people. This care needs to be tailored for different time points as indicated by the natural lifecycle of the disease, and includes monitoring the CD4 cell count, treatment of HIV-related illnesses and initiation and maintenance on Antiretroviral Therapy (ART). There has been a strong drive to increase the numbers of people testing for HIV and to provide the appropriate package of treatment, care and support to PLWH(2). Mortality however remains high in patients known to be HIV positive but not yet having accessed ART(3) and there is evidence that the level at which people initiate treatment is well below the recommended threshold(4, 5). Improvement in access to appropriate HIV care is essential if a lowering in mortality prior to ART initiation is to be achieved.

The current standard of care for PLWH in South Africa includes: 1. HIV Counselling and Testing (HCT): The2007-2011 HIV, AIDS and STI National Strategic Plan (NSP) aims for 70% of South Africans to have tested at least once for HIV, and for 25% of the population to test annually by 2011. 2. PreART care: CD4 cell count monitoring at a PreART clinic should occur at six monthly intervals in those not yet eligible for ART(6). 3. ART care: The South African National Department of Health's 2010 clinical guidelines (amended September 2011)(7) stipulate that all patients with a CD4 count «350cells/mm^3 are eligible to initiate ART.

Many programmes providing care for PLWH report the number of people initiated on ART and the retention in care on ART(8) but there is limited data reporting on other time points related to HIV care in Sub-Saharan Africa(9-11). In this study we aimed to describe the proportion of PLWH who were accessing appropriate care and to determine the factors associated with this.

Methods

Setting and population

This study was conducted in eight communities in the greater Cape Town area. All the participants had previously taken part in a TB and HIV prevalence survey in 2010 as part of the Zambia South Africa TB and AIDS Reduction (ZAMSTAR) study(12). In the TB and HIV prevalence survey the participants had completed a questionnaire, been offered HIV testing and had tested for TB through sputum culture. About 33000 people living in randomly selected Census Enumeration Areas in each of the 8 communities were enrolled. All communities had a high burden of HIV and TB. The self disclosed HIV prevalence from the ZAMSTAR Prevalence survey ranged from 12-19% across the communities (Mr Rory Dunbar, personal communication). All communities are served by at least one public sector primary health care facility within a 5km radius of the homes of the participants, which offers HIV testing, PreART and ART care.

For this study a random group of participants (≥18 years old) whose self reported HIV status from the TB and HIV prevalence survey was positive, negative or unknown, were revisited and asked to complete a questionnaire that focused on access to appropriate HIV care. Participants who had disclosed that they were HIV negative or did not know their status were included in the revisit in order to decrease stigmatization that may have resulted from only enrolling self disclosed HIV positive people. Participants who disclosed that they were HIV positive were included in the analysis.

Study design and data collection

All data is self reported. Data were collected from two sources. Firstly, variables were used from the ZAMSTAR questionnaire which had been completed at the time of the TB prevalence survey. These were age, sex, race, years lived in the area, and history of previous TB treatment. Secondly, data were collected from the cross sectional household study described here and conducted between February and April 2011. In the cross sectional study a questionnaire was completed that pertained to accessing

HIV care. Trained research field-workers visited participants in their homes where they interviewed them in their home language and completed the access to care questionnaire. The research field workers were unaware of the participants HIV status. They attempted to locate a person at least three times, once being after 4pm or over the weekend. Data were recorded on an electronic personal data assistant (PDA) and downloaded on a daily basis onto a server at the Desmond Tutu TB Centre (DTTC). Data from these two sources (the ZAMSTAR and Access to Care questionnaires) were merged for the same individual based on unique barcode identifiers in order to identify variables associated with appropriate HIV care.

As many participants as possible were enrolled during the same time period. A minimum sample of 632 PLWH was required to detect a 10% risk difference in attendance at a health care facility within the last six months for reasons other than HIV care with 95% significance level and 80% power.

Definitions

Access to appropriate HIV care was defined, according to our own study definition, as one of three scenarios. 1. Receiving ART and having attended an ART clinic or collected ART medication within the last three months of being interviewed. 2. Undergoing work up in order to initiate ART, and having attended an ART clinic within the last three months of being interviewed.3. In those not on ART or undergoing work up (i.e. PreART), having had a CD4 count in the last 6 months.

Ethics

All participants had given written informed consent when enrolled in the ZAMSTAR Prevalence survey which included consent to be visited again for follow up studies. All participants gave written informed consent for the Access to Care Study. The study was approved by the Stellenbosch University Committee for Human Research, the Ethics advisory group of the International Union against TB and Lung disease (The Union) and the Health Sciences Human Research Ethics Committee at the University of Cape Town.

Statistical analysis

Stata version 12 (Stata Corp.LP, College Station, TX, United States of America) was used for all analyses. Standardization was used to account for the sex ratio of HIV prevalence in the Western Cape according to the ASSA model(13). Logistic regression with robust standard errors to control parameter estimates for clustering at a community level was used to explore factors associated with receiving appropriate HIV care. This was used for univariable and multivariable analyses. Factors that were explored using univariable regression to see if they impacted on the likelihood of a person accessing appropriate HIV care were: sex; age; employment status; highest education level; years living in the same area; referral mechanism of last HIV test; history of previous TB treatment; mode of transport and cost to access the clinic at their last visit, overall waiting time at the clinic; and knowing someone close to them who either had HIV, was on ART or had died with HIV. Significantly associated risk factors that were identified were then introduced into a respective multivariable model with variables being retained in the final model if associated likelihood-ratio test showed a *P* value<0.052

Results

1547 participants were selected from the ZAMSTAR prevalence survey. These comprised randomly selected self reported HIV positive participants (n=969), randomly selected self reported HIV negative participants (n=503) and randomly selected participants of unknown HIV status (n=75). There was a response rate of 81% (n=1257) (Figure 1). Of those who consented and were enrolled 627(50%) self reported that they were HIV positive, 487(39%) that they were HIV negative and the remaining 143(11%) either did not know or wish to disclose their status.

Table 1 presents the demographic and HIV testing characteristics of the HIV negative and positive participants. 72% of the HIV negative participants were female compared

to 86% of the HIV positive participants (p<0.000). 54% of the HIV negative participants were unemployed as compared to 63% of the HIV positive participants (p=0.002).

CD4 counts:

Of the 627 participants who were HIV positive 97% (n= 608) had had a CD4 count (Table 2). 83% (n=506) of participants knew the value of their CD4 count, and when asked if their recollection was precise or an estimate, 70% (n=353) reported it to be precise. 84%of participants (n=510) said that they had had more than one CD4 count.

Access to appropriate HIV care:

Of the 627 HIV positive participants 63% (n=392) said that they were taking ART of which 94% (n=369) reported that they had attended a clinic within the last three months for treatment (Table 3). 4% (n=25) of participants reported that they were being worked up for ART, with 64% (n=16) having attended an ART clinic as part of this work up process in the last three months. 33% (n=210) of participants were in PreART care of which 39% (n=81) had had a CD4 count in the last 6 months. In total 74% (n=466) of participants were in appropriate care according to our study definition.

Factors associated with access to appropriate care

In a multivariable regression analysis (Table 4) sex and age were associated with being in appropriate care. Females were 3.78 times more likely to be in appropriate care than males (p <0.001; 95% CI: 2.07- 6.90), and those in the age category greater than 45 years were 4.63 times more likely to be in appropriate care than those in the age category 15-24 years (p= 0.002; 95% CI: 1.78-12.01).

Clinic attendance:

Of the 627 PLWH 1% (n= 9) reported not having attended a clinic in the last 2 years, 2% (n=14) in the last year, and 5% (n=29) in the last six months. 77% waited for less than four hours at the clinic at their last visit, and 80% did not pay any transport costs

to get to the clinic. Where a transport cost was incurred, 65% (n=82) reported that this was less than R10.

Discussion

According to our definition 94% of participants who were on ART, 64% who were being investigated in preparation for ART, and 39% of PreART participants were in appropriate care. Of the 627 HIV positive participants 63% reported that they were on ART. Thus it appears that in the areas surveyed a high proportion of self reported HIV positive people are accessing ART and that access is good with 94% of participants being in appropriate care. The ASSA model estimated that in 2011 there were 296 746 HIV positive people in the Western Cape and 90 179 (30%) were on ART(14). This was, however, a projection that included all PLWH, irrespective of whether they knew their HIV status or not. In this study the true HIV prevalence was not known.

Only 64% of participants who were being investigated in preparation for ART had attended an ART clinic in the preceding three months. Other studies have also showed high rates of attrition in this group. A study in Cape Town reported that only 67% (n=147) of those who returned for a CD4 count within 6 months of HIV diagnosis and who were eligible for ART, were initiated on ART within 6 months of their HIV diagnosis(9). A study in Durban examined the loss to care and mortality rates before starting ART in ART eligible HIV-infected patients(15). They found that 16% (n=82) were lost before ART initiation with 34% (n=28) having died. A large prospective cohort study in the Free State, South Africa found that only 34% of eligible patients had started ART within 1 year of enrolment(3).

In the PreART group only 39% had had a CD4 count in the preceding six months. South Africa has the most PLWH and the largest ART programme in the world(1, 18). The group eligible for ART is large and increased when the South African ART treatment guidelines were expanded to include the initiation of ART in PLWH with a CD4 count «350 cells/mm^3(7, 16). It is essential that PreART patients have regular CD4 counts and initiate ART as soon as it is indicated to decrease mortality associated with low CD4 counts(17). In South Africa there has been poor implementation of a comprehensive

care package from HCT through to initiation on ART, specifically with regard to PreART care(18, 19). In Cape Town, the policies for PreART care are defined but this has not translated into practice with weaknesses in the continuity and quality of the services rendered (18). Attention needs to be paid to the PreART programmes to continue to strengthen them.

Our study showed that utilisation of local clinics is good. Only 5% of HIV positive participants had not attended a clinic in the last 6 months. Waiting times and transport costs do not appear to limit access, with 77% of people waiting less than 4 hours at the clinic, and 80% not paying any transport costs. The low proportion of PreART participants in appropriate care may be due to both patient and provider factors. Patient factors may be related to stigma or denial and prevent PLWH from accessing care in the earlier stages of their disease, prior to their becoming ill. Provider factors may be a lack of trained staff and the absence of a dedicated implementation program for PreART care. Clinic attendance, irrespective of the reason, provides an opportunity to target PLWH who are not in appropriate care. A systematic approach to PreART care in the clinics is needed and in order to achieve this additional resources need to be made available(18).

Men and young adults were less likely to be accessing appropriate care for HIV. This finding is also reflected in other studies(3, 11, 20). In a study in rural KwaZulu – Natal, retention in HIV care in individuals not yet eligible for ART was associated with a lower initial CD4 count, older age and female sex(11). In a large prospective cohort study in the Free State, differences in access and patient outcomes across ART treatment clinics were assessed(3). Factors associated with not initiating ART included male sex, a CD4 count below 50cells/mm^3, weight below 50kg, and distance to the clinic of greater than 15km. Factors associated with failure to initiate ART in HIV infected TB patients in an integrated TB HIV health care service in Cape Town included male sex, and younger age(20). Ongoing targeting of vulnerable groups such as men and the youth with initiatives such as youth clinics; non medical sites in the community that offer HCT and

CD4 testing; and HIV education and awareness campaigns may contribute to improved access and retention in care.

There are several strengths to the study. Firstly, the study design allowed us to source participants in their homes as opposed to a health care facility. To our knowledge no other study determining access to HIV care has sampled in this manner. Access to appropriate HIV care could thus be from any health care facility and across any time period as opposed to being restricted to clinical records from a specific health care facility within a certain timeframe.

Secondly, 94%of the participants (n=1182) had had an HIV test, and 86% (n=1115) were willing to disclose their status. Thus, of the group interviewed, a large proportion was able to complete the study questionnaire.

There are limitations to this study. An objective of the study had been to determine if attendance at a health care facility within the last six months for reasons other than HIV care was associated with access to appropriate HIV care. During the study it became evident that there was often uncertainty as to whether a clinic visit had been related to HIV care. This factor was therefore not analysed or reported on. Data was however collected regarding a person's last clinic attendance. Other factors thought to impact on access to appropriate HIV care, as detailed under the statistical analysis section, were analysed.

Secondly, it was a self reported study and results that pertain to records such as CD4 counts and health care facility attendance dates, were not validated. Recall as well as reporting bias may influence the results. 97% of the HIV positive group said that they had had a CD4 count and 83% knew the value of their first CD4 count. This may be a result of reporting bias as other studies have shown much lower proportions. A study in Cape Town showed that only 74% of participants had a recorded CD4 count measurement in their primary care clinic or hospital records at any time point from 2004 – 2009(9). Data from a folder review of 634 positive HCT clients, during a routine annual HIV/TB/STI evaluation in Cape Town, found that 77.5% had a CD4 count

taken(18), although it is not known how many clients returned for their results. In addition participants were asked if they had ever had a CD4 count as opposed to other studies where participants were asked if they had had a CD4 count within a certain time period.

There is limited data available, especially in developing countries, as to the validity of self reported HIV status and knowledge of CD4 count as compared to clinical record reviews. A study in a developed country found that amongst IV drug users only 68% of HIV positive participants accurately reported their HIV status, whereas 98% of HIV negative participants accurately reported their status(21). CD4 cell counts were found in another study to be reliably assessed through self reporting in PLWH, especially in those with a higher education level(22). In our study we found that most people were receptive to talking about their HIV testing and treatment pathway and were knowledgeable about their test results.

A third limitation relates to the sampling frame which was comprised of participants from the ZAMSTAR Prevalence survey. Participants may have been more likely to be in appropriate care due to their increased awareness of TB and HIV as a result of their exposure to ZAMSTAR.

A further limitation was the response rate. 16% (n=250) of the randomly selected sample were not found. It is possible that some of these people may have been ill or had died from HIV-related illnesses and may have been more likely not to have been in appropriate care. Additionally 6% (n=76) of participants who knew their HIV status were unwilling to disclose it. These participants may have been reluctant to disclose their status to the researchers because they were HIV positive and not in appropriate care. The selection biases may affect generalisability of results to PLWH in the rest of South Africa.

Conclusion

In our study access to appropriate HIV care was high for ART care, however PreART care was low. These findings contribute to the growing literature in this field. Clinics providing HIV care appear to be accessible but this did not result in the utilisation of

their services to access PreART care. In order for this to occur a systematic approach to PreART care with attention to client and service factors is needed. The impact on existing resources and the need for additional resources to deliver this care should be investigated.

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Figure 1 Breakdown of Participants enrolled in the study

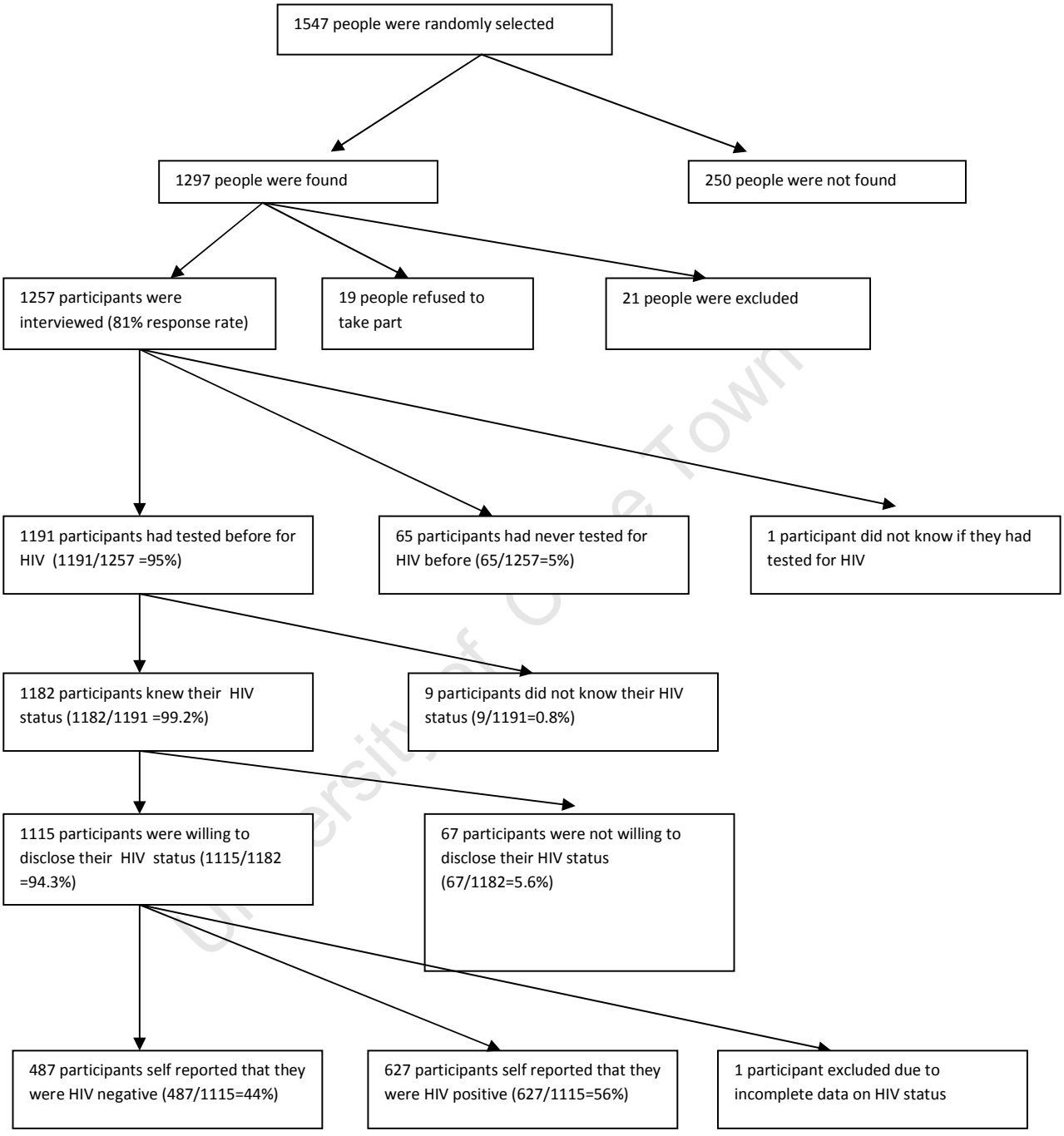

Table 1: Demographic and HIV testing characteristics of HIV negative and positive groups

	HIV Negative (n=487) % (N)	HIV positive (n=627) % (N)	
Sex			p = 0.000
Female	72 (350)	86 (538)	
Male	28(137)	14 (89)	
Age categories in years			p= 0.000
18-24	23 (113)	8 (52)	
25-34	34 (167)	39 (244)	
35-44	27 (131)	37 (234)	
>45	15 (76)	15 (97)	
Mean age in years	34	36	P=004
Age range in years	19 - 71	19-66	
Employment status			p = 0.002
Unemployed	54 (265)	63 (400)	
Employed part time	17 (84)	16 (103)	
Employed Full time	28 (138)	20 (124)	
Years in community			p = 0.822
<5 years	22 (105)	21 (129)	
5-10 years	22 (107)	20 (128)	
>10 years	56 (275)	59 (370)	
Number of times participants had tested for HIV			p=0.000
1	43 (210)	31 (193)	
2	31(150)	41 (257)	
3	15 (73)	20 (124)	
4	5 (25)	5 (31)	
>4	6 (27)	3 (16)	
unknown	0 (2)	1 (6)	
Testing place at time of last HIV test			**p=0.000**
ZAMSTAR	41 (200)	47 (292)	
Clinic	40 (193)	36 (227)	
Community non medical site	6 (28)	0 (2)	
Antenatal	5 (22)	9 (57)	
Hospital	4 (20)	7 (43)	
Private Dr	3 (15)	1 (6)	
Workplace	1 (6)	0 (0)	
Other	1 (3)	0 (0)	
Referral mechanism at time of last HIV test (excluding participants who tested at ZAMSTAR)	N=287	N=335	
Self referred	80 (230)	56 (186)	
Referred by health care worker	20 (57)	44 (149)	

Table 2: CD4 count testing characteristics

HIV positive group N=627	**% (N)**
Participants reporting to have had a CD4 count.	97 (608)
Participants reporting to have had a CD4 count the same day as testing HIV positive	95 (598)
Participants reporting to have had collected their CD4 result	99 (601)
Participants knowing the value(either precisely or as an estimate) of their first CD4 count	83 (506)
Participants knowing the value of their first CD4 count precisely	70 (353)
Number Participants reporting to have had more than 1 CD4 count	84 (510)

Table 3: Access to appropriate HIV care

HIV positive group (n=627)	
Number on ART	392 (63%)
• On ART & Accessing Care • On ART & Not Accessing Care	94% n=369 6% n=23
Being investigated for ART	25 (4%)
• Being investigated for ART & Accessing care • Being investigated for ART & Not Accessing care	64% n=16 36% n=9
Not on ART or being investigated for ART	210 (33%)
• Not on ART or being investigated for ART & Accessing Care • Not on ART or being investigated for ART & Not Accessing Care	39% n=81 61% n=129

Table4: Factors associated with access to appropriate care

			UNIVARIABLE		MULTIVARIABLE	
	N (%)	Accessing appropriate care N (%)	OR	95% CI	OR	95% CI
Total	627	466				
Sex			p=0.001		p=0.000	
male	89 (14.2%)	52 (58.4%)	1			
female	538 (85.8%)	414 (77.0%)	2.376	(1.428 - 3.951)	3.783	(2.075 - 6.897)
Agecat			p=0.005		p=0.000	
15-24	52 (8.3%)	36 (69.2%)	1			
25-34	244 (38.9%)	169 (69.3%)	0.946	(0.43 - 2.08)	1.073	(0.579-1.988)
35-44	234 (37.3%)	178 (76.1%)	1.136	(0.475 - 2.714)	1.637	(0.745-3.597)
45+	97 (15.5%)	83 (85.6%)	2.636	(0.905-7.678)	4.627	(1.784-12.005)
Referral			p=0.056			
self reffered	187 (29.8%)	134 (71.7%)	1			
referred by health care worker	149 (23.8%)	115 (77.2%)	1.934	(1.041-3.594)		
referred by ZAMSTAR	291 (46.4%)	217 (74.6%)	1.134	(0.682-1.884)		
education			p=0.242			
primary or none	114 (18.2%)	90 (78.9%)	1			
secondary ro tertiary	513 (81.8%)	376 (73.3%)	0.681	(0.358-1.295)		
employed			p=0.238			
un-employed	400 (63.8%)	306 (76.5%)	1			
part time	103 (16.4%)	71 (68.9%)	0.706	(0.434-1.149)		
full time	124 (19.8%)	89 (71.8%)	0.631	(0.311-1.278)		
transport			p=0.743			
other transport	117 (18.7%)	93 (79.5%)	1			
walk	501 (79.9%)	372 (74.3%)	0.868	(0.372-2.126)		
missing	9 (1.4%)	1 (11.1%)				
transport cost			p=0.728			
no cost (walkers)	501 (79.9%)	372 (74.3%)				
R1-10	82 (13.1%)	62 (75.6%)	0.819	(0.38-1.764)		

>R10	29 (4.6%)	25 (86.2%)	1.841	(0.315-10.748)		
missing	15 (2.4%)	7 (46.7%)				
traveltime			p=0.115			
0-14mins	81 (12.9%)	62 (76.5%)				
15-29mins	194 (30.9%)	135 (69.6%)	0.663	(0.381-1.156)		
30-44mins	200 (31.9%)	149 (74.5%)	0.748	(0.394-1.42)		
>45mins	143 (22.8%)	119 (83.2%)	1.266	(0.666-2.409)		
missing	9 (1.4%)	1 (11.1%)				
waitingtime			p=0.426			
0-2hr	213 (34.0%)	155 (72.8%)	1			
2-4hrs	271 (43.2%)	209 (77.1%)	1.326	(0.837-2.1)		
>4hrs	133 (21.2%)	101 (75.9%)	1.292	(0.5-3.336)		
missing	10 (1.6%)	1 (10.0%)				
know HIV+ person			p=0.082			
no one	141 (22.5%)	104 (73.8%)				
someone	483 (77.0%)	362 (74.9%)	0.704	(0.475-1.045)		
missing	3 (0.5%)	0 (0.0%)				
know someone on ART			p=0.362			
no one	209 (33.3%)	146 (69.9%)	1			
someone	416 (66.3%)	319 (76.7%)	1.194	(0.815-1.75)		
missing	2 (0.3%)	1 (50.0%)				
know someone who died of HIV			p=0.757			
no one	311 (49.6%)	226 (72.7%)	1			
someone	315 (50.2%)	240 (76.2%)	1.097	(0.61-1.974)		
missing	1 (0.2%)	0 (0.0%)				
previous TB treatment			p=0.129		p=0.052	
no	330 (52.6%)	227 (68.8%)	1		1	
yes	297 (47.4%)	239 (80.5%)	1.524	(0.885-2.624)	1.761	(0.995-3.116)
years in community			p=0.731			
<5 years	129 (20.6%)	104 (80.6%)	1			
5-10 years	117 (18.7%)	81 (69.2%)	0.799	(0.331-1.924)		
>10years	370 (59.0%)	275 (74.3%)	0.722	(0.323-1.617)		
missing	11 (1.8%)	6 (54.5%)				

Appendices

Appendix 1: Access to Health Care Questionnaire

Please complete for all Participants who give consent to complete this questionnaire.

Q1 Did you take part in the ZAMSTAR Prevalence Survey in 2010? | No | Yes |

If no then probe to be certain that they did not take part, and if they did not then thank participant and finish interview. If yes continue.

Q2 What tests or procedures did you take part in for the ZAMSTAR Prevalence Survey? **(Mark all that apply.)**

2.1	Completed a questionnaire	No	Yes
2.2	Gave a sputum sample for TB testing	No	Yes
2.3	Tested for HIV	No	Yes
2.4	Had a glucose test	No	Yes
2.5	Was weighed	No	Yes
2.6	Had height measured	No	Yes

The following questions relate to how you access health care.

Q3.1 In the last two years have you attended a clinic or community health centre (CHC) for:
(Read aloud each option and mark all that applies. If they have attended MARK WHETHER PUBLIC or PRIVATE).

	No	Public	Private
1. Antenatal Care	0	2	3
2. For a chronic disease	0	2	3
3. To test for TB	0	2	3
4. TB treatment	0	2	3
5. HIV care	0	2	3
6. Feeling unwell	0	2	3
7. Trauma	0	2	3
8. Family planning	0	2	3
9. For your child	0	2	3
10. Accompanied someone	0	2	3
11. Other	0	2	3

If Public or Private to any of the above continue. If No to all go to Q7

Q3.2 How many months ago did you last attend for any of the following?
(Indicate exact number of months on PDA)

1.	Antenatal Care	1 – 60; 99
2.	For a chronic disease	1 – 60; 99
3.	To test for TB	1 – 60; 99
4.	TB treatment	1 – 60; 99
5.	HIV care	1 – 60; 99
6.	Feeling unwell	1 – 60; 99
7.	Trauma	1 – 60; 99
8.	Family planning	1 – 60; 99
9.	For your child	1 – 60; 99
10.	Accompanied someone	1 – 60; 99
11.	Other	1 – 60; 99

Q4 The last time you went to the clinic – how did you get there?
Mark only one option

1.	Walk	1
2.	Taxi	2
3.	Bus	3
4.	Own Transport	4
5.	Train	5
6.	Other	6

If Taxi or Bus or Train option marked continue. Otherwise go to Q5.

Q4.1 What is the cost of a return journey? **(999 if unknown)**
(Indicate exact amount on PDA. Round to the nearest rand.) Ammt in Rands

Q5 The last time you went to the clinic how long (in minutes) did it take in travelling time.(both **there and back)** (include time spent walking to where the bus/taxi/train is, waiting for the taxi/bus/train, time used on the taxi/bus/train to get to the clinic)? **(999 if unknown)** Time in min

Q6 The last time you went to the clinic how long (in minutes) did you spend at the clinic (include time spent waiting to get your folder, waiting to be seen and waiting for and receiving treatment)?
(999 if unknown) Time in min

Q7 Which of the following would best describe your employment situation currently? **(Mark only one that applies)**

1 .Not working at all	1
2. Employed full-time	2
3. Employed part-time	3
4. Self-employed full-time	4
5. Self-employed part-time	5
6. Pensioner	6

Q8 Which one of the following would best describe your current occupation? **(Mark only one that applies)**

1. Working in formal, salaried employment	1
2. Working for yourself	2
3. Casual labour	3
4. Caring for children or relatives	4
5. Unemployed	5
6. General domestic work in your home	6
7. At school or a student	7

Q 9	The last time you attended the clinic – did you need to take time off from work or your studies?	No	Yes
Q10	Do you know someone close to you that has told you that they are HIV positive? **If Yes continue. If No go to Q11.**	No	Yes

Q10.1 Who was that person? **(Mark all that applies)**

1. Partner	No	Yes
2. Child	No	Yes
3. Parent	No	Yes
4. Sibling	No	Yes
5. Another family member	No	Yes
6. Close friend	No	Yes
7. Other	No	Yes

Q11	Do you know someone close to you that is on ARV's? **If Yes continue. If No go to Q12**	No	Yes

Q11.1 Who was that person? **(Mark all that applies)**

1. Partner	No	Yes
2. Child	No	Yes
3. Parent	No	Yes
4. Sibling	No	Yes
5. Another family member	No	Yes
6. Close friend	No	Yes
7. Other	No	Yes

Q12 Did you know someone that you were close to that died from HIV?

If Yes continue. If No go to Q13

	No	Yes

Q12.1 Who was that person? **(Mark all that applies)**

1. Partner	No	Yes
2. Child	No	Yes
3. Parent	No	Yes
4. Sibling	No	Yes
5. Another family member	No	Yes
6. Close friend	No	Yes
7. Other	No	Yes

The following questions relate to testing for HIV.

Q13 Have you ever been tested for HIV?

IF No or Unknown continue. If YES go to question Q14.

N	Y	U

Q13. Have you ever been offered an HIV test?
1

If No or Unknown, then go to question Q13.3, else continue.

N	Y	U

Q13.2 If you have been offered a test, but did not test, what was the reason for not testing? **(Mark all that apply)**

1. Inconvenient.(Did not have time or want to wait to be tested)	No	Yes
2. Did not think that I had HIV	No	Yes
3. Was scared to know the result	No	Yes
4. Did not wish to test because I was worried about the confidentiality of the results	No	Yes
5. Did not want it to be known that I had tested for HIV	No	Yes
6. Did not understand why it is important to test for HIV	No	Yes
7. Other	No	Yes

Q13. Do you think that you might be at risk for having HIV?
3

N	Y	RTA

Q13. Do you think that you have HIV?
4

N	Y	RTA

Thank Participant and finish the interview.

Q14 What was the date you **FIRST** tested for HIV? (01/01/1800 if unknown)

D	D	M	M	Y	Y	Y	Y

Q15 How many times have you tested for HIV? **(Indicate exact number of times on PDA) (99 if unknown)**

NUMBER

Q16 What was the date that you **LAST** tested for HIV? (01/01/1800 if unknown)

D	D	M	M	Y	Y	Y	Y

Q17 Where did you last test for HIV? (**Mark only one option)**

1. Clinic/CHC	1
2. Hospital as an outpatient	2
3. Hospital as an inpatient	3
4. Community non medical site	4
5. Private medical doctor (private general practitioner)	5
6. Work place	6
7. Antenatal	7
8. Zamstar	8
9. Other	9

Q18 When you **last tested** for HIV were you: **(Mark only ONE OPTION)**
(Note: Self referred means that you decided by yourself to go to test, rather than a health care worker asking you to do so.)

1. Self referred	1
2. Referred by health care worker	2
3. Referred by ZAMSTAR	3
4. Unknown	-5

If Self Referred, answer only 18.1 and then go to Q19, if referred by HCW then only answer 18.2 and then go to Q 19. If ZAMSTAR or UNK go directly to Q19.

Q18.1 Why did you self refer to test? **(Read aloud and mark all that applies)**

1. Wanted to know status	No	Yes
2. Partner encouraged me	No	Yes
3. Partner was HIV Positive	No	Yes
4. Family or friends encouraged me	No	Yes
5. Was ill	No	Yes
6. Insurance	No	Yes
7. Other	No	Yes

Q18.2 If referred by Health care worker, why were you referred? **(Read aloud and mark all that applies)**

1. Was ill	No	Yes
2. Pregnant	No	Yes
3. Diagnosed with Tuberculosis	No	Yes
4. Partner was HIV Positive	No	Yes
5. Sexually Transmitted Disease (STD)	No	Yes
6. Other	No	Yes

The following questions relate to the ZAMSTAR Prevalence Survey.

Did you get tested again for HIV at the mobile caravan for the ZAMSTAR Prevalence Survey? **If Yes continue If No go to Q20**	No	Yes
Was this the first time that you tested for HIV? **If No continue, If Yes go to Q19.3**	No	Yes
Was your HIV result different to the last time that you tested?	No	Yes

Did you receive a referral letter for HIV care from the ZAMSTAR VCT staff? **If Yes continue. If No go to Q20**	No	Yes	Unknown	N/A
Did you keep that appointment?	No	Yes		

The following questions relate to knowing your HIV status.

Do you know your HIV status?	No	Yes

Are you willing to disclose your HIV status? | No | Yes |

If YES continue. IF NO FINISH INTERVIEW. THANK PARTICIPANT.

Q22 What is your HIV status? | NEG | POS |

If Positive continue. IF NEGATIVE FINISH INTERVIEW. THANK PARTICIPANT.

Q23 What was the date when you were first tested as positive for HIV? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown) **Refer to Timeline to help complete dates**

Q24 How many times did you test Negative before you tested Positive? **(999 if unknown)** | NUMBER |

(Indicate exact number of times on PDA.)

Q25 Where did you test when you were first tested as positive for HIV? **(Mark only One Option)**

1. Clinic/CHC	1
2. Hospital as an outpatient	2
3. Hospital as an inpatient	3
4. Community non medical site	4
5. Private medical doctor (private general practitioner)	5
6. Work place	6
7. Antenatal	7
8. Other	8

Q26 Have you been tested for HIV again after you knew you were HIV Positive? | No | Yes |

If Yes continue. If No go to Q27

Q26.1 What was the date when you were tested again for HIV? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown)

Q26.2 Why did you test again? **(Mark only One Option)**

1. Referred by health care worker	1
2. To reconfirm the results	2
3. ZAMSTAR study	3
4. Other	4

Q27 When you first tested positive for HIV did you receive counselling on the same day? | No | Yes |

Q27.1 Did you receive additional sessions of counselling at a later date? | No | Yes |

Q28	When you first tested positive for HIV was a CD4 count taken the same day that you tested positive? **If No continue, if Yes go to Q29**	No / Yes
Q28.1	Were you given a referral letter to go and have a CD4 count taken? **If No continue, if Yes go to Q29**	No / Yes
Q28.2	Were you told verbally to go to have a CD4 count taken? **If Yes continue, if No go to Q29**	No / Yes
Q28.3	Did you go to have the CD4 test done?	No / Yes

Please ask the Participant if they have an HIV treatment card available or any other patient card or documentation that details their HIV care and fill in the timeline and answer the following questions which relate to CD4 counts.

Q29	Is a Patient Treatment card that relates to HIV care available?	No / Yes
Q30	**RA ask participant:** Have you ever had a CD4 count done?	No / Yes / Unk
Q30.1	**RA look at card:** Is CD4 count documented on card?	No / Yes / N/A
Q30.2	**RA ask participant:** What was the date of your first CD4 count? **(01/01/1800 if unknown)**	D D M M Y Y Y Y
Q30.3	**RA look at card:** Date of first CD4 count documented on card **(01/01/1800 if unknown)**	D D M M Y Y Y Y
Q30.4	Were you given a follow up appointment to collect your results?	No / Yes / Unk
Q30.5	Did you ever go to collect your results?	No / Yes / Unk

Q30.6 Who gave you your results? **(Mark only One Option)**

1. Nurse	1
2. Counselor	2
3. Doctor	3
4. Other	4
5. Unknown	-5

Q30.7 **RA ask participant:** What was your first CD4 count? Enter the number. **(9999 if unknown)**

Q30.8 Is this a fact or an estimate? F | E | N/A

Q30.9 **RA look at card:** What was the number of the first CD4 count on the card? **(9999 if unknown)**

Q30.10 When you collected your first CD4 results were you given another appointment for a follow up visit? No | Yes

If Yes continue directly below, If No go to Q31

Q30.10.1 If YES, did you keep that appointment? No | Yes

Q30.10.2 Was the follow up visit? **(Read aloud and mark all that applies)**

1. In order to be worked up for ARV's — No | Yes
2. In order to have a repeat CD4 test — No | Yes
3. In order to be seen by a Doctor or Health Care practitioner — No | Yes
4. Other — No | Yes

Q31 Have you had more than one CD4 count done? No | Yes

If Yes continue directly below, If No go to Q32

Q31.1 **RA ask participant:** What was the date of your most recent CD4 count? **(01/01/1800 if unknown)** D D M M Y Y Y Y

Q31.2 **RA look at card:** Date of most recent CD4 count confirmed on treatment card **(01/01/1800 if unknown)** D D M M Y Y Y Y

Q31.3 **RA ask participant:** What was your most recent CD4 count? **(9999 if unknown)**

Q31.4 **RA ask participant:** Is this a Fact or Estimate or is it Unknown? F | E | UNK

Q31.5 **RA look at card:** What was the number of the most recent CD4 count on the treatment card?

(9999 if unknown)

Q32 Are you currently taking ARV's? | No | Yes |

If Yes continue, If No go to Section B (Question 38)

Q32.1 Are ARV's documented on card? | No | Yes |

Section A: The following questions relate to participants who are taking ARV's.

Q32.2 **RA ask participant:** What date did you start ARV's? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown)

Q32.3 **RA look at card:** Date ARV treatment started on treatment card? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown)

Q32.4 **RA ask participant:** What date did you last go to the clinic for ARV's? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown)

Q32.5 **RA look at card:** Date of last visit on treatment card? | D | D | M | M | Y | Y | Y | Y |

(01/01/1800 if unknown)

Q33 How do you normally get to the clinic to collect your ARV's? **(Mark only One Option)**

1. Walk	1
2. Taxi	2
3. Bus	3
4. Own transport	4
5. Train	5
6. Other	6

If Taxi or Bus or Train continue, else go to Q34

Q33.1 If Taxi or Bus or Train, what is the cost of a return journey? **(999 if unknown)**
(Indicate exact amount on PDA. Round to the nearest rand.) | Ammt in Rands |

Q34 The last time you went to the clinic how long (in minutes) did it take in travelling time (both **there and back)** (include time spent walking to where the bus/taxi/train is, waiting for the taxi/bus/train, time used on the taxi/bus/train to get to the clinic)? **(999 if unknown)** | Time in min |

Q35 How long (in minutes) did you spend at the clinic (include time spent waiting to get your folder, waiting to be seen and waiting for and receiving treatment)? **(999 if unknown)**

Time in min

Q36 The last time you attended the clinic – did you need to take time off from work?

No	Yes

Q37 Where are you taking your ARV's? **(Mark only One Option)**

1. ARV clinic/community health centre (CHC)	1
2. Hospital	2
3. Work place	3
4. Private clinic/private doctor	4
5. Other	5

Continue to Q51 (if Section A completed)

Section B: The following questions relate to being worked up for ARV's.

Q38 If you are NOT TAKING ARV's are you in the process of being worked up in order to take ARV's?

No	Yes	Unk

(RA explains to Participant that being worked up for ARV's means that the Participant is being prepared to start ARV's.

They are attending counselling sessions and may be having investigations done)

If Yes continue, if No or Unknown go to Q44

Q38.1 Date you last attended the clinic for a reason that was related to being worked-up for ARV's?

(01/01/1800 if unknown)

D	D	M	M	Y	Y	Y	Y

Q39 How do you normally get to the clinic? **(Mark only One Option)**

1. Walk	1
2. Taxi	2
3. Bus	3
4. Own transport	4
5. Train	5
6. Other	6

If Taxi or Bus or Train continue, else go to Q40

Q39.1 If Taxi or Bus or Train, what is the cost of a one way journey? **(999 if unknown)**

(Indicate exact amount on PDA. Round to the nearest rand.)

Ammt in Rands

Q40 The last time you attended the clinic – did you need to take time off from work or studies?

No	Yes

Q41 The last time you went to the clinic how long (in minutes) did it take in travelling time? (Both **there and back)** (Include time spent walking to where the bus/taxi/train is, waiting for the taxi/bus/train, time used on the taxi/bus/train to get to the clinic)? **(999 if unknown)**

Time in min

Q42 How long (in minutes) did you spend at the clinic (include time spent waiting to get your folder, waiting to be seen and waiting for and receiving treatment)? **(999 if unknown)**

Time in min

Q43 What kind of Health Facility are you going to for your ARV work-up? **(Mark only One Option)**

1. ARV clinic/community health centre (CHC)	1
2. Hospital	2
3. Work place	3
4. Private clinic/private doctor	4
5. Other	5

Go to Question 51

Q44 If you know your CD4 count to be below 250 then why are you not taking ARV's? **(Read aloud and mark all that applies)**

1. Did not know that I needed to	No	Yes
2. Have been on ARV's before but have stopped	No	Yes
3. Don't think ARV's work	No	Yes
4. Don't want family or friends to know	No	Yes
5. Can't take time off from work to go to clinic	No	Yes
6. Don't have the time to go to the clinic	No	Yes
7. I intend to but have not yet done so	No	Yes
8. Don't Know	No	Yes
9. Other	No	Yes
10. Not applicable	No	Yes

Continue to Question 45

Section C: The following questions relate to preHAART or Wellness Clinic.

Q45 Are you attending a preHAART or Wellness Clinic?

No	Yes

(RA explain to Participant that preHAART or Wellness Clinic means that they are going for HIV care and regular CD4 testing and checkups as they do not yet qualify for ARV's).

If Yes continue, if No go to Q51

Q45.1 Date that you last attended the clinic for a preHAART or Wellness Clinic?

D	D	M	M	Y	Y	Y	Y

(01/01/1800 if unknown)

Q46 How do you normally get to the clinic to go to the PreHAART or Wellness clinic? **(Mark only One Option)**

1. Walk | 1
2. Taxi | 2
3. Bus | 3
4. Own transport | 4
5. Train | 5
6. Other | 6

If Taxi or Bus or Train continue, else go to Q47

Q46.1 If Taxi or Bus or Train, what is the cost of a return journey? **(999 if unknown)**
(Indicate exact amount on PDA. Round to the nearest rand.) | Ammt in Rands

Q47 The last time you went to the clinic how long (in minutes) did it take in travelling time (both **there and back)** (include time spent walking to where the bus/taxi/train is, waiting for the taxi/bus/train, time used on the taxi/bus/train to get to the clinic)? **(999 if unknown)** | Time in min

Q48 How long (in minutes) did you spend at the clinic (include time spent waiting to get your folder, waiting to be seen and waiting for and receiving treatment)? **(999 if unknown)** | Time in min

Q49 The last time you attended the clinic – did you need to take time off from work or studies? | No | Yes

Q50 Where are you going for preHAART/Wellness Clinic? **(Mark only One Option)**

1. ARV clinic/community health centre (CHC) | 1
2. Hospital | 2
3. Work place | 3
4. Private clinic/private doctor | 4
5. Other | 5

The following questions relate to disclosure.

Q51 Have you ever disclosed your status to your **(Read aloud and mark all that applies)**

1. Partner	No	Yes
2. Family	No	Yes
3. Friends	No	Yes
4. Community	No	Yes
5. Other	No	Yes

6. No One

No	Yes

Q52 Have you ever attended a support group for HIV?

No	Yes	Unk

If Yes continue. IF NO OR UNKNOWN FINISH INTERVIEW. THANK PARTICIPANT.

Q52.1 Were you referred to a support group: **(Read aloud and mark all that applies)**

1. When you tested positive for HIV	No	Yes	Unk
2. When you collected your CD4 results	No	Yes	Unk
3. When you were referred to an ARV clinic	No	Yes	Unk

Q52.2 What date did you last attend the support group? **(01/01/1800 if unknown)**

D	D	M	M	Y	Y	Y	Y

Thank the Participant for their time. RA to ensure that if the Participant is not accessing care that they are given information as to which clinic they can visit and given a Referral Letter if they would like one.

	Interviewer's Code	Date								Signature
		d	d	m	m	y	y	y	y	
Interviewer										
Study coordinator										
1st data entry										
2nd data entry										

Appendix 2: Information Sheet

PARTICIPANT INFORMATION SHEET

TITLE OF RESEARCH PROJECT: Access to Care Study

REFERENCE NUMBER: N10/09/291

PRINCIPAL INVESTIGATOR: Dr. Elizabeth Du Toit

ADDRESS: Access to Care Study, DTTC, Department Paediatric and Child Health, Faculty of Health Sciences, Stellenbosch University, Tygerberg Campus.

CONTACT NUMBER DTTC: Phone 021-9389062; Fax: 021-9389719

CONTACT NAME AND NUMBER: STUDY MANAGER: Mr David Nikani ; 021 9389062; Fax: 021-9389719

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part. If you decide to take part, you will be asked to give written consent before you take part.

This study has been approved by the Health Research Ethics Committee (HREC) at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is the purpose of the study?

You are invited to take part in a study to determine the factors associated with accessing health care. About 170 people who were past participants in the ZAMSTAR project will take part from your community. These people have been chosen at random from all the people who participated in the ZAMSTAR survey. The ZAMSTAR project was conducted from January to December 2010 to determine the amount of TB, HIV, and Chronic Disease in people living

within your community. This is a follow up study to determine if people are accessing health care. The study is being carried out in all 8 former ZAMSTAR communities and about 1360 people will take part in the whole study. The main aim of the Access to Care Study is to determine the possible factors associated with accessing health care, specifically with regard to HIV care. This will help us to explore improving access to health care within our country, and to present the findings to the relevant health care managers.

Information on HIV

The human immunodeficiency virus (HIV) affects the immune system, destroying or impairing its function. The immune system fights infection and disease so that you do not get ill. HIV is mainly spread through unprotected sex with an infected person. It can also be spread if people share contaminated needles, syringes or other sharp instruments. It can also be transmitted between a mother and her baby during pregnancy, childbirth and breastfeeding. Infection with HIV is easy to test for and can be diagnosed with a blood sample from a finger prick at your local clinic or hospital. People with HIV normally get ill when they get an opportunistic infection. The most common opportunistic infection affecting people living with HIV and AIDS is Tuberculosis (TB). TB is an infectious disease caused by bacteria (germs), which are spread through droplets (coughing). If you are not diagnosed quickly, you can go on infecting other people without knowing it. TB can be detected with a sputum (phlegm) examination at your local clinic or hospital.

CD4 Count Values

CD4 cells are a type of white blood cell that fights infection such as bacteria and viruses within your body. CD4 cells are made in the thymus gland, spleen, and lymph nodes, which are the infection-fighting system within your body.CD4 cells are destroyed by HIV.

Your CD4 Count measures the number of CD4 cells in your body. It is measured by taking a sample of your blood from a vein in your arm by using a needle. The CD4 count indicates how strong your immune system is and indicates which stage of HIV disease you are in and guides when to start ARV treatment for HIV. Keeping your CD4 count high can reduce infections associated with HIV disease and extend your life.

Antiretroviral treatment (ART)

Antiretroviral drugs are referred to as ARV's. The drugs do not kill HIV, instead they decrease the amount of virus in your body until it is very low and does not multiply anymore. In order for this to happen you need to take ARV's everyday at the same time. Currently there are no drugs that can kill HIV. Slowing down the virus slows down the HIV disease. You need to begin ARV treatment when your CD4 count is below 200. If you are pregnant or have TB, then you need to start ARV's when your CD4 count is below 350. If a person does not yet need ARV's then every six months a CD4 Count should be done at a preHAART or Wellness Clinic to determine when ARV's should be started.

Treatment and Care

HIV Counseling and Testing is offered at your local clinic and hospital and in most facilities a preHAART (which means pre treatment) or a Wellness Clinic is available for HIV Testing, CD4 Count Testing, and counselling. Access to ARV's is free at your local government clinic and local government hospital. If you seek care at a private clinic or private hospital then there will be a cost which is set by that particular institution.

More about this study

We will ask you questions to get more details about how you access health care. This information will help us better understand the possible factors associated with accessing care, especially for HIV. We will record your answers to the questionnaires electronically on a Personal Digital Assistant (PDA).

Taking part in this study is voluntary. You will also be given information about HIV, CD4 Count Values, and Accessing Care within your community. You are free to withdraw from this study at any stage, without any consequences for you. No financial reward will be given to any persons taking part in this study. About 1360 are taking part in the whole study, and about 170 people from your community are taking part.

Are there any risks for people who take part in this survey?

Taking part in this study does not pose any risks to you or your family. However, you may feel worried if you need care for HIV and you are currently not in care. If you need a referral for HIV care then we will refer you to your local clinic for care.

The following will be required by those taking part:

1) You will be asked to sign a consent form after you have read and understood this information leaflet. You will be given an original copy of this leaflet and the consent form to keep.

2) You will be asked to complete (with the help of a trained interviewer) a questionnaire about how you access care.

The questionnaire will take about twenty to thirty minutes to complete

What is the benefit to you by taking part in this study?

By taking part in this study you will be given health information/education leaflets concerning HIV, CD4 Count Values, and Accessing Care within your community. If you are not in care and would like a referral, you will be referred for treatment so that you can keep healthy.

The information gained from this study will be used to provide suggestions for improving health services.

Quality assurance

As part of the process of collecting data, we will perform quality assurance on some of the data that will be collected. You may be revisited by other members of the study team who will check and confirm that you have been visited by the field study team.

Confidentiality of information and privacy of the participant

All personal information obtained during this study will remain strictly confidential. The answers will be transferred to a computer, but your name will not be included, and you will be identified by a coded number only. No information about any of the other results will be released to any other parties but the research team, without your further consent. Completed questionnaires will be stored in a safe place. No information regarding personal details which could identify individuals or individual households will be disclosed. Sponsors of the study, study monitors or auditors or Research Ethics Committee members may need to inspect research records.

The study is funded by the International Union Against Tuberculosis and Lung Disease. There is no conflict of interest between the Principal Investigator and the funders.

There may, however, be follow-up studies to this study. In this case personal details may be obtained only after further ethics approval and the name may only be made available to the principal investigator of the new study.

The results of this study will be given to the City and Provincial Health departments and also published in a medical journal. No names of participants taking part in this study will be published or in any way made known.

Thank you for reading this information sheet. If you have any questions, please ask them now. The interviewer will be pleased to answer them. If you wish to take part, please read and sign the consent form. Please keep this information sheet in a safe place. You can contact the Project Manager as documented at the top of this information sheet if you have any further queries or encounter any problems.

You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed.

Appendix 3: Informed consent sheet

Every breath counts

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Individual Barcode

Name:

Address:

ACCESS TO CARE STUDY: INFORMED CONSENT FORM

Declaration by participant

I confirm that I have read the information sheet, and that the information and procedures involved in my taking part in this study have been explained to me.

1. I understand that I am being followed up from the ZAMSTAR study (Zambia South Africa TB & AIDS Reduction Study) which ran from January thru December 2010 for this new study called Access to Care.
2. I give permission for my information from the ZAMSTAR study to be used in the Access to Care Study.
3. I confirm that I have had the opportunity to ask questions about the study and that I am satisfied with the answers provided.
4. I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this study.
5. I understand that if it is necessary and should I want one I will be given a referral to the nearest clinic for appropriate HIV care, if I am currently not in care.
6. I understand that I will be given information about HIV, CD4 Count Values, and available HIV related access to care in the community.
7. I understand that the researchers will keep all my personal information confidential.
8. I understand that at any point I can withdraw from the study without any consequences.
9. I understand that I will not get any financial reward for taking part in this survey.
10. I understand that the results of this study will be published in scientific journals but that my name will never be used.
11. I understand that I may in future be requested to participate in follow-up studies but that I may decline at a later stage to take part in future studies.
12. I agree to take part in the survey.

Declaration by Participant

By signing below, I (Please Print)

(First Name)_____ (Surname) _____

agree to take part in a research study entitled Access to Care.

Signed on (*date (dd/mm/yyyy)*) _____/_____/2011

_____ _____
Signature of participant/(Thumbprint) Signature of witness if needed

Declaration by Research Assistant

I (First Name)_____(Surname) _____ (RA Code) _____

declare that:

- I explained the information in this document to (*name of participant*)_____ and encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below*)

Signed on (*date (dd/mm/yyyy)*) _____/_____/2011

_____
Signature of Research Assistant

Declaration by interpreter

I (First Name)_____(Surname) _____

declare that:

I assisted the Research Assistant (*name*) _____ to explain the information in this document

to (*name of participant*) _____ using the language medium of _____.

- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed on (*date (dd/mm/yyyy)*) _____/_____/2011

_____
Signature of interpreter

Appendix 4: Management form

Access to Care 2011 - Management Form

BARCODE	

Participant Details:

EA:		**Participant Details (change) :**
Name		N Y
Address		N y
DOB		N y

	Date	Participant Found Y/N	Consent Y/R/E/N/P	Outcome	Date next visit	Comments
Visit 1						
Visit 2						
Visit 3						

Appendix 5: ZAMSTAR Individual and Household questionnaire

ZAMSTAR PREVALENCE SURVEY: INDIVIDUAL QUESTIONNAIRE

HOUSEHOLD BARCODE	**INDIVIDUAL BARCODE**

SECTION 1

ALL QUESTIONS IN THIS SECTION MUST BE ANSWERED

Q01_INC **Interviewer's (RA) code** | | | |

Q02_DAT **Date today**

D	D	M	M	Y	Y	Y	Y

Q03_SEN **Serial Number (on HH Management Form)** | | |

Q04_HOH **Are you the Head of Household?**

No	Yes
0	**1**

Q05_SEX **Sex**

M	F
1	**2**

Q06_AGE **Age (-1 if unknown)** | | | |

Q07_MAR **Married to (Only women to answer – use serial no on HH Management Form)** | |

Q08_DIS **Disability?**

No Disability	1
Sight(blind/ severe visual impairment)	2
Hearing (deaf/ profoundly hard of hearing)	3
Communication(speech impairment)	4
Physical(needs wheelchair/ crutches)	5
Mental disability	6

Q09_CON **Consent**

No	Yes	Absent	Excluded	Pending
0	1	2	3	4

ONLY CONTINUE IF CONSENT IS GIVEN

SECTION 2A – FILL THIS AND SUBSEQUENT SECTIONS IN ONLY IF PERSON HAS GIVEN

I would like to ask you some questions

Q11_DOB **Date of Birth** (01/01/1800 if unknown)
If not known, what was your age in Q11_1_DOB years at **your last birthday?** (-1 if unknown)

D	D	M	M	Y	Y	Y	Y

Q12_YLC How many years have you lived in this community?

Write down actual number, zero if less than one year, (-1 if unknown)

Q13_RAC What is your race?
Select only one option

Black	1
Coloured	2
Indian/Asian	3
White	4
Other	5

Q14_COB What is your country of birth?
(Drop down menu with SADC countries and few other Africa countries)

SA		Nigeria	
Zambia		Congo (DRC)	
Zimbabwe		Somalia	
Malawi		Other. If other, specify_____	
Mozambique			

Q15_HZS Before this survey, have you heard of or been involved with DTTC/ ZAMSTAR Desmond Tutu TB Center / Zambia South Africa TB & Aids Reduction Study)

No	Yes
0	1

Q16_CMS What is your current marital Status?

Never married	1
Currently married or living as married	2
Divorced or Separated	3
Widowed	4

If never married go to Q18, else continue

Q17_AFM Age at first marriage? (years, -1 if unknown) _____

18_MOY What has been your main occupation during the past year?

Unemployed/working on own land	1
Occasional/seasonal employment	2
Employed (Formal employment or self employed making money)	3
Unable to work	4
Student	5
Housewife/ home-maker	6

Individual Barcode

I would like to ask you about smoking

Q19_HES Have you ever smoked
If yes continue, if no go to Q20_CDH

No	Yes
0	1

Q19_1_HES How old were you when you first started regular cigarette smoking?
(Age in years; -1 if unknown)

Q19_2_ HES If you have stopped smoking, how old were you when you stopped?
(If the participant has **not** stopped smoking, current age in years; -1 if unknown)

Q19_3_HES per
On average over the entire time that you smoke(d), about how many cigarettes

week do (did) you smoke? (-1 if unknown)

Q19_4_HES On average over the entire time that you smoke(d), do (did) you primarily smoke manufactured or hand rolled cigarettes

Manufactured	Hand Rolled
1	2

I would like to ask you about your current drinking habits

Q20_CDH How would you describe your drinking habits?

Have never drunk	1
Daily drinker	2
Occasional drinker	3
Ex-drinker	4

Now I will ask questions about your education

Q21_HEA What is the highest level of education you have attained?

No formal education	0	Grade 8 /Std 6	
Grade 1 / Sub A		Grade 9 / Std 7	
Grade 2 / Sub B		Grade 10 / Std 8	
Grade 3 / Std 1		Grade 11 / Std 9	
Grade 4 / Std 2		Grade 12 / Std 10	
Grade 5 / Std 3		College	20
Grade 6 / Std 4		University	30
Grade 7 / Std 5			

If has attended school, continue, if No formal education go to Q23_OCC

		No	Yes	Unknown
Q21_1_FBS	Have you ever attended a faith-based school	0	1	-5

Q22_YES When was the last year you were enrolled in School/College/University? (-1 if unknown)

Y	Y	Y	Y

Q23_OCC Please state main occupation at age 15 years?

Unemployed/ working on own land	1
Seasonal/Occasional employment	2
Employed (formal employment or self employed making money)	3
Unable to work	4
Student	5
Housewife/home-maker	6
Can't remember	-5

I would like to ask you about your health. (Current TB questions)

		No	Yes
Q24_CTB	Are you currently on TB treatment? Probe and be sure only conventional treatment (on ATT)	0	1

(If yes continue, If No go to **Q35**)

Q25_FPS Where did you first present for your symptoms? (Mark only 1 option)

Government/Community clinic	1
Private Clinic/hospital	2

Government Provincial/District hospital	3
Pharmacy/Chemist	4
Private Doctor	5
Traditional Healer	6
ZAMSTAR/DTTC Sputum collection point	7

Q26_TCA Is TB treatment card available? (confirm by seeing the card)
If yes continue, If No go to Q31 (Record Q27 to 30 from TB Treatment Card)

No	Yes
0	1

Q27_DTS **Date treatment started**
01/01/1800 if not recorded on card

D	D	M	M	Y	Y	Y	Y

Q28_TTN **TB treatment Number (from treatment card, Type in UNKNOWN if not recorded on card)**

					/		

Q29_CAT **Category of TB as recorded on card?**

Sputum smear Positive	1
Sputum smear Negative	2
Extrapulmonary	3
Unknown/not recorded	-5

Q30_TTC **TB treatment Centre(as written on card)**

Individual Barcode

IF TB TREATMENT CARD NOT AVAILABLE ASK QUESTIONS 31 TO 34, ELSE GO TO QUESTION 35
ASK QUESTIONS 31 TO 34

Q31_MST Which month did you start treatment

January	1
February	2
March	3
April	4
May	5
June	6
July	7
August	8
September	9
October	10
November	11
December	12
Unknown	-5

	No	Yes	Unk
Q32_SPT Was the sputum smear positive for TB?	0	1	-5

Q33_RTF Where are you receiving your TB treatment from?

Government/Community clinic	1
Private Clinic/hospital	2
Government Provincial/District hospital	3
Pharmacy/Chemist	4
Private Doctor	5

Q34_TTC **TB treatment Centre**
(if not known, type in UNKNOWN)

Questions about previous TB treatment

Previous TB treatment

	No	Yes	Unk
Q35_TTB Have you ever been on TB treatment before? **If yes continue, if no go to Q37**	0	1	-5

Q36_HMT How many times?

Once	1
Twice	2
Three	3
More than three times	4
Unknown	-5

I would like to ask about your current state of health

	No	Yes
Q37_CHC Do you currently have a cough? **If yes continue, if no go to Q47**	0	1

Q38_WBC How many weeks have you been coughing?

< 1 week	0	6 weeks	6
1 week	1	7 weeks	7
2 weeks	2	8 weeks (2 months)	8
3 weeks	3	3 – 6 months	9
4 weeks	4	>6 months	10
5 weeks	5	Unknown	-5

Q39_CPS Do you currently produce sputum?

No	Yes
0	1

Q40_CCB Do you currently cough up blood?

No	Yes
0	1

Q41_CAC Did you consult anybody for this cough?
If yes continue, if no go Q47

No	Yes
0	1

Q42_GHF Where did you go for help first? (Mark one only)

Government /Community clinic	1
Private clinic/hospital	2
Government Provincial/ District hospital	3
Pharmacy/Chemist	4
Private Doctor	5
Traditional healer	6
ZAMSTAR/DTTC Sputum collection point	7

If checked 1 or 2 or 3 above go to Question 44.

Q43_GCP If pharmacy/private/tradition healer, did you ever go to a government/community/sputum collection point

No	Yes
0	1

Q44_ASS Did anyone ask for sputum samples?
If yes continue, if no go to Q 47

No	Yes
0	1

Q45_DGS If yes, did you give sputum?

If yes continue, if no go to Q47

No	Yes
0	1

Q46_RES What was the result?

Negative for TB	0
Positive for TB	1
Unknown/can't remember	-5

Other symptoms

Q47_CCP Do you currently have chest pains?

No	Yes
0	1

Q48_CHF Do you currently have fever?

No	Yes
0	1

Q49_DNS Do you currently have drenching night sweats?

No	Yes
0	1

		No	Yes
Q50_LWU	In the last month have you lost weight unintentionally?	0	1
Q51_DBB	Do you currently have difficulty breathing or shortness of breath?	0	1

Individual Barcode

Now I will ask questions about Diabetes and HIV

		No	Yes
Q52_THD	Have you ever been told you have diabetes **If Yes continue, if No go to Q55**	0	1
Q53_CAT	If yes, are you currently on any treatment for diabetes? **If yes continue If no go to Q55**	0	1

Q54_TON What treatment are you on?

Dietary only	1
Tablets	2
Insulin injections	3

		No	Yes
Q55_KHS	Do you know your HIV status? **If No and Male, go to Q60.** **If No and Female – thank participant and FINISH interview.**	0	1
Q56_DHS	Are you willing to disclose your HIV status? **If Yes continue, if not willing to discuss and Male go to Q60.** **If Yes continue, if not willing to discuss and Female – thank participant and FINISH interview.**	0	1

Q57_HIV What is your HIV status?

Negative	0
Positive	1

If HIV status is Positive, continue, if Negative and Male go to Q60.
If HIV status is Positive, continue, if Negative and Female – thank participant and FINISH interview.

		No	Yes
Q58_ART	Are you on Antiretroviral treatment(ART) **If Yes continue, if No and Male go to Q60.** **If Yes continue, if No and Female – thank participant and FINISH interview.**	0	1

Q59_LAR	How long have you been on ART? Write down actual number of months, -1 if unknown	

Ask question 60 and 61 only to males

		No	Yes	Unk
Q60_CIR	Are you circumcised? **If yes continue, if no go to Q62**	0	1	-5

Q61_WCI At what age were you circumcised?

0-10 years	1
10-15 years	2
15 – 20 years	3
>20 years	4
Unknown/can't remember	-5

Thank participant and FINISH interview

INTERVIEWER AND TEAM LEADER TO SIGN OFF QUESTIONNAIRE OVER THE PAGE

THANK YOU FOR YOUR HELP

	RA Code	Date								Signature
		d	d	m	m	y	y	y	y	
Interviewer										
Team Leader										
1st data entry										
2nd data entry										

Appendix 6: Budget

OPERATIONAL RESEARCH PROJECT October 2010 to November 2011								
Name of Project: Access to Care in Peolple living with HIV								
Name of Researcher: Elizabeth du Toit								
	Categories	**Item**	**No of Units**	**% per 12 months**	**Unit Cost**	**Amount**	**Total**	**Total in dollars**
Personnel								
	Study Coordinator	FTE	1 (4months)	33%	200 000	84 000	66 666	8888.8
	Research Assistant	FTE	8 (4 months)	33%	40 000	13 333	106 667	14222.27
	driver	FTE	1 (4 months)	33%	75 000	25 000	25 000	3333.333
	Data mananger	FTE	1	13%	300 000	40 000	40 000	5333.333
	Data Capturer	FTE	1 (50% 0f 4 months)	17%	60 000	10 200	10 200	1360
Total of Personnel Cost							**248 533**	**33137.73**
Travel and Transportation								0
	Vehicle running costs		1		-	20 000	20 000	2666.667
	Domestic travel *	trips	0					0
	International travel*	trips	0					0
	District Travel	trips	0		-	-	-	0
Total of Travel and Transportation						**20 000**	**20 000**	**2666.667**
Equipment								0
	Vehicles*	unit	0			-	-	0
	PDA*							0
	Computers*	unit	0					0

						-	-	
Total of Equipment						**-**	**-**	**0**
Materials								0
	stationery	unit	0			2 000	2 000	266.6667
	refreshments for participants	unit	0			-	10 000	1333.333
	Dissemination meetings	unit	0			1 000	1 000	133.3333
Total of Materials						**3 000**	**13 000**	**1733.333**
Other Costs								0
	Printing	lumpsum	0			2 000	2 000	266.6667
	IT Costs*	lumpsum	0		-	-	-	0
	Training					2 000	2 000	266.6667
	Ethics submission						3 500	466.6667
	Statistical support	lumpsum					10 000	1333.333
	Telephone(cell phone allowance)	lumpsum	0		3 160	2 000	3 000	400
Total of Other Costs						**6 000**	**20 500**	**2733.333**
Total Cost							**302 033**	**40271.07**
* Costs to be covered by DTTC								

Appendix 7: Timeline

Phase:	Months																
	10-Jul	10-Aug	10-Sep	10-Oct	10-Nov	10-Dec	11-Jan	11-Feb	10-Mar	11-Apr	11-May	11-Jun	11-Jul	11-Aug	11-Sep	11-Oct	11-Nov
Preplanning for field work																	
Finalisation of research protocol																	
Submit documentation for ethics approval																	
Adgudication for review panel																	
Project commences																	
Advertise and Hire staff																	
Train Staff																	
Pilot questionnaires																	
To develop the tools for analysis																	
Design, develop and maintain database for data																	
Field Work																	
Conduct visits and complete Questionnaires																	
To analyse the data																	
Enter and collate data																	
Quarterly progress reports to mentors																	
Submit abstract to IUATLD																	
Do data-analysis and statistical calculations																	

Write report on findings, discuss with stakeholders																	
Write article based on findings for peer-reviewed journal																	
Finalization of paper and presentation at IUATLC conference																	
Dissemination of findings																	
Dissemination meetings with stake holders, icluding NDOH and PDOH																	

Appendix 8: Data Dictionary

Appendix Data dictionary

Variable name	Variable description	Type	Values/Format/Range
ACC	Attended clinic or CHC for any of the following	Discrete	1 = Antenatal care 2 = For your child 3 = For a chronic disease (High blood sugar, Epilepsy, Diabetes) 4 = Accompanied someone 5 = TB treatment 6 = HIV Care 7 = Acute Illness 8 = Trauma 9 = Family Planning 10 = Other (if so list)
NTC	Normally to clinic method	Discrete	1 = Walk 2 = Taxi 3 = Bus 4 = Own transport 5 = Other
COJ	Cost of one way journey	Continuous	1 = 1 rand 2 = 2 rand 3 = 3 rand 4 = 4 rand 5 = 5 rand 6 = 6 rand 7 = 7 rand 8 = 8 rand 9 = 9 rand 10 = 10 rand To indicate exact amount on PDA (round to the nearest rand)
DHS	Someone close disclosed HIV status	Discrete	0 = No 1 = Yes
DHS.1	Which of the following	Discrete	1 = Partner 2 = Child 3 = Parent 4 = Sibling 5 = Another family member

			6 = Close friend 7 = Other (if so list)
SAR	Someone closed on ARV's	Discrete	0 = No 1 = Yes
SAR.1	Which of the following	Discrete	1 = Partner 2 = Child 3 = Parent 4 = Sibling 5 = Another family member 6 = Close friend 7 = Other (if so list)
SHI	Someone close that died of HIV	Discrete	0 = No 1 = Yes
TFH	Tested for HIV	Discrete	0 = No 1 = Yes
DFH	Date first tested for HIV	Continuous	Day, Month, Year
HMT	How many times tested for HIV	Discrete	1 = 1 time 2 = 2 times 3 = 3 times 4 = 4 times 5 = 5 times 6 = 6 times 7 = 7 times To indicate exact number of times on PDA
DLH	Date last tested for HIV	Continuous	Day, Month, Year
WTH	Where test for HIV	Discrete	1 = Clinic 2 = Hospital as Outpatient 3 = Hospital as Inpatient 4 = Community HCT 5 = Private GP 6 = Work place 7 = Other (if so list)
SRH	Self referred	Discrete	1 = Self referred 2 = Referred by Health care worker

	or health care worker referred		3 = Unknown
SRH.1	If self referred why test	Discrete	1 = Wanted to know status 2 = Partner encouraged me 3 = Partner was HIV Positive 4 = Family or friends encouraged me 5 = Was ill 6 = Insurance 7 = Other (if so list)
SRH.2	If referred by Health Care Worker why referred	Discrete	1 = Was ill 2 = Pregnant 3 = Diagnosed with Tuberculosis 4 = Partner was HIV Positive 5 = Sexually Transmitted Disease (STD) 6 = Other (if so list)
ZPS	Test for HIV for ZAMSTAR Prevalenc e Survey	Discrete	0 = No 1 = Yes
ZPS.1	If yes received referral for HIV Care	Discrete	0 = No 1 = Yes -5 = Unknown
ZPS.2	Clinic to be seen for HIV Care	Discrete	0 = No 1 = Yes
KHS	Know HIV Status	Discrete	0 = No 1 = Yes
DHS	Disclose HIV Status	Discrete	0 = No 1 = Yes
HIV	HIV Status	Discrete	0 = Negative 1 = Positive
DTP	Date tested Positive for HIV	Continuous	Day, Month, Year

WTP	Where first tested Positive for HIV	Discrete	1 = Clinic 2 = Hospital as Outpatient 3= Hospital as Inpatient 4 = Community HCT 5 = Private GP 6 = Work place 7 = Other (if so list)
MTO	More than once tested for HIV after known HIV Positive	Discrete	0 = No 1 = Yes
MTO.1	Date first tested again	Continuous	Day, Month, Year
MTO.2	Why test again	Discrete	1 = Referred by Health care Practitioner 2 = To reconfirm the results 3 = ZAMSTAR Study 4 = Other (if so list)
HCA	HIV treatment card available	Discrete	0 = No 1 = Yes
CDC	CD4 count done	Discrete	0 = No 1 = Yes -5 = Unknown
CDC.1	Date of first CD4 count	Continuous	Day, Month, Year
CDC.2	Given follow up appointment	Discrete	0 = No 1 = Yes -5 = Unknowns
CDC.3	Collected results	Discrete	0 = No 1 = Yes -5 = Unknown
CDC.4	Who gave results	Discrete	1 = Nurse 2 = Counselor 3 = Doctor

			4 = Unknown 5 = Other (if so list)
CDC.5	First CD4 count	Continuous	Numbers
CDC.6	Given appointment for follow up visit at same clinic	Discrete	0 = No 1 = Yes -5 = Unknown
CDC.6.1	Did you keep the appointment	Discrete	0 = No 1 = Yes
RAC	Referral to an ARV clinic	Discrete	0 = No 1 = Yes -5 = Unknown
RAC.1	Did you keep the appointment	Discrete	0 = No 1 = Yes
MCD	More than one CD4 count done	Discrete	0 = No 1 = Yes -5 = Unknown
MCD.1	Date of most recent CD4 count	Continuous	Day, Month, Year
MCD.2	Most recent CD4 count	Continuous	Numbers
CAR	Currently taking ARV's	Discrete	0 = No 1 = Yes
CAR.1	Date treatment started	Continuous	Day, Month, Year
CAR.2	When last gone to	Continuous	1 = 1 month 2 = 2 months

	the clinic for ARV's		3 = 3 months 4 = 4 months 5 = 5 months 6 = 6 months 7 = 7 months 8 = 8 months 9 = 9 months 10 = 10 months 11 = 11 months 12 = 12 months To indicate exact months on PDA
NTA	Not taking ARV's being worked up for ARV's	Discrete	0 = No 1 = Yes -5 = Unknown
NTA.1	When last did you go to the clinic as part of work up	Continuous	1 = 1 month 2 = 2 months 3 = 3 months 4 = 4 months 5 = 5 months 6 = 6 months 7 = 7 months 8 = 8 months 9 = 9 months 10 = 10 months 11 = 11 months 12 = 12 months To indicate exact amount of months on PDA
PHW	Attending preHAART or Wellness clinic	Discrete	0 = No 1 = Yes -5 = Unknown
PHW.1	When last did you go to the clinic to attend preHAART	Continuous	1 = 1 month 2 = 2 months 3 = 3 months 4 = 4 months 5 = 5 months 6 = 6 months

	or Wellness clinic		7 = 7 months 8 = 8 months 9 = 9 months 10 = 10 months 11 = 11 months 12 = 12 months To indicate exact amount of months on PDA
WAC	Where accessing HIV care	Discrete	1 = ARV clinic/CHC 2 = Hospital 3 = Work place 4 = Private clinic/Private Doctor 5 = Other (if so list)
DYS	Disclosed status to:	Discrete	1 = Partner 2 = Family 3 = Friends 4 = Community 5 = Other
SGH	Attended support group for HIV	Discrete	0 = No 1 = Yes
SGH.1	Referred to support group for any of the following:	Discrete	1 = When tested positive for HIV 2 = When collected CD4 results 3 = When referred to ARV clinic
SGH.2	When last did you go to support group	Continuous	1 = 0 – 1 month ago 2 = 2 – 3 months ago 3 = 4 – 5 months ago 4 = 6 – 12 months ago 5 = >1 year ago

Appendix 9a: The Union Ethics approval

Ethics Advisory Group Date: 3rd November 2010

To: Dr Elizabeth du Toit

Title of research project:

Access to Care in People Living with HIV

Investigators:

Dr Elizabeth du Toit, Desmond Tutu TB Centre, Stellenbosch University

Blia Yang, DTTC,

Karen Jennings City of Cape Town Health Department

Donald A. Enarson The Union

EAG number : 53/10

Thank you for your application to the Ethics Advisory Group of the Union.

Your study has our formal approval.

We trust that your study proceeds well and that it will be productive.

With best wishes,

Prof. Mary Edginton

Chairperson

signature removed

Appendix 9C: University of Cape Town Ethics approval

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6626 • **Facsimile** [021] 406 6411
e-mail: shuretta.thomas@uct.ac.za

07 July 2011

Dr E Du Toit
Desmond Tutu TB Centre (DTTC)
Stellenbosch University
Tygerberg
7505

Dear Dr Du Toit

Re: Waiver of HREC Approval

The University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee note that you already have research ethics approval from the Human Research Ethics Committee in the Faculty of Health Sciences at Stellenbosch University and the International Union against Tuberculosis and Lung Disease.

Accordingly, it is not necessary to obtain further research ethics approval from the Human Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town.

Yours sincerely

signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

pp

S Thomas