Chapter 1: INTRODUCTION

1.1 Definition:

Food security is a flexible concept as reflected in the many attempts at definition in research and policy usage. Whenever the concept is introduced in the title of a study or its objectives, it is necessary to look closely to establish the explicit or implied definition (Maxwell 1996). The following definition is used by the food and agricultural organization (FAO) of the United Nations. "*Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food, which meets their dietary needs and food preferences for an active and healthy life*" (FAO 2001). Therefore, severely food insecure people are those individuals whose food intake falls below their minimum calorie, or energy requirements, and those who exhibit physical symptoms caused by energy and nutrient deficiencies resulting from an inadequate or unbalanced diet, or from inability of the body to utilise food effectively due to infection or disease (FAO 1998).

1.2 Food Security and HIV

Often neglected, food security and nutrition are critical for individuals, households and communities affected by HIV. Lack of food security and poor nutritional status may hasten progression to AIDS-related illnesses and undermine adherence and response to antiretroviral therapy (Gillespie & Kadiyala 2005). Addressing food security and nutrition in all settings is vital to achieving the goal of universal access to HIV prevention, treatment, care and support by 2010, to which all member states of the United Nations have committed themselves (Political Declaration on HIV/AIDS 2006).

Malnutrition associated with HIV infection has far reaching ramifications not only for the patient, but also for the health care system and society in general. Many patients become too debilitated to work steadily and come to rely on public or other assistance. Weight

loss often is the initiating event in a vicious cycle of increased fatigue and decreased physical activity, including the ability to prepare and consume food (Babameto & Kotler 1997). The main factors associated with malnutrition are reduced calorie intake, increasing resting energy expenditure (REE), chronic diarrhoea and opportunistic infections (Babameto & Kotler 1997;Melchior et al. 1999).

The significance of food insecurity on management of HIV patients using highly active antiretroviral therapy (HAART) cannot be overstated since some of the combinations of HAART have to be taken after food and insufficient food can be the sole reason to affect adherence. In a study conducted in an HIV clinic in Kigali Rwanda, the fear of developing too much appetite but not having enough to eat was one of the major obstacles to adherence to HAART (Au Joyce et al. 2006).

1.3 EFFECTS OF HIV ON FOOD SECURITY

The effects of HIV on food security have been shown by researchers to occur at four different levels; individual, household, institutional and country.

1.3.1 Individual level

Many people who have been affected or afflicted by HIV/AIDS develop a short term outlook. In terms of economic activities, they often prefer to invest in petty trading, rather than agricultural enterprises whose returns take longer to accrue (Michael & Stuart 2003). As a result, food production decreases. HIV/AIDS further threatens food security by eroding social security networks, an important component of social capital. The burdens of caring for the sick and for orphans are customarily spread within communities (Shah et

al. 2001). As prevalence rises, these burdens may overwhelm the ability or willingness of other households to take in further dependants, further dividing their economic entitlements (Mtika 2001).

1.3.2 Household level

Insecurity in rural areas, particularly as a result of the theft of crops and livestock, is another major problem resulting in reduced production and unwillingness to invest further in vulnerable agricultural enterprises (Malawi Government 2001). The AIDS epidemic contributes to this problem because adults who are absent from house for long periods to nurse sick relatives in hospital cannot properly care for and guard their own fields and animals (Ngwira, Bota, & Loevinsohn 2001).

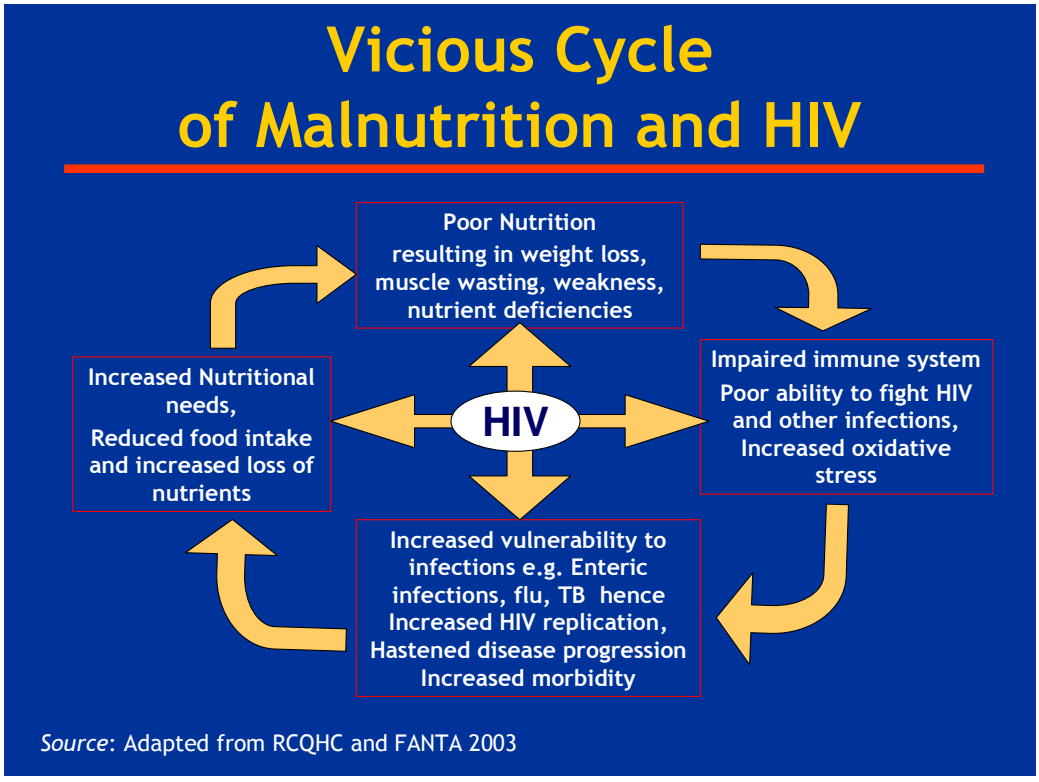
1.3.3 Institutional level

AIDS affects the ability of the agricultural and allied institutions to provide services by depleting their human resources. First, there is attrition of staff in agricultural administration, extension and research, due to death. Second, the quality of human resources declines due to morbidity and disorientation of those left behind. It is reported that in 1998, nearly 66% of staff that died in the Ministry of Agriculture in Malawi died from AIDS related illness based on UNAIDS estimates of AIDS related mortality in urban areas (Bota, Malindi, & Nyekanyeka 1999)

1.3.4 Country level

Several rigorous studies have detailed the drops in net household production associated with AIDS- related adult mortality. In Kenya, (Yamano & Jayne 2002) found a 68% decline in net household production. In Zimbabwe, (Kwaramba 1997) found output declines of 37-61% for different crops, and in Swaziland, Muwanga (2002) found a reduction of 54% in maize production following the death of the household head. In a study reported by the Southern African Development Community (SADC) on the impacts of HIV/AIDS on food insecurity in Southern Africa it was noted that food consumption dropped by as much as 40% in households affected by HIV/AIDS (SADC 2008).

FIGURE 1.1: INTERACTION OF MALNUTRITION AND HIV



At an individual level, HIV infection essentially accelerates the vicious circle of inadequate dietary intake and disease that leads to malnutrition (see Figure above) while malnutrition increases the risk of HIV transmission from mothers to babies and the progression of HIV infection (Piwoz & Preble 2000). HIV-infected individuals have higher nutritional requirements than normal, particularly with regard to protein (up to 50% increased) and energy (up to 15%). They are also more likely to suffer a loss of appetite, even anorexia, thus reducing dietary intake at the very time when requirements are higher. More over, such interactions are thrown into starker contrast for the poor, who are more likely to be malnourished prior to becoming infected.

In 1999, the National Food Consumption Survey was conducted in South Africa to determine the nutrient intakes and anthropometric status of children 1-9 years old and results of the survey showed that a majority of households were food-insecure and that energy deficit and micronutrient deficiencies were common, resulting in a high prevalence of stunting (Labadarios D. et al. 2005). The likelihood that similar levels of food insecurity affect adult South Africans are very high, especially in households where an adult member is suffering from HIV/AIDS.

1.4 FOOD SECURITY IN SOUTH AFRICA

In the year 2000, the South African government released an "Integrated food security strategy" with four primary objectives. First, this was done to overcome rural food insecurity by increasing the participation of food insecure households in productive agriculture sector activities, since roughly 70% of the country's poorest live in rural

areas; Second, to match incomes of people to prices; Third, to ensure that there are adequate safety nets and food emergency management systems to provide people that are unable to meet their food needs from their own effort and lastly to ensure that enough food is available to all, now and in the future (Department of Agriculture 2002).

Despite these policies, a section of the South African population is said to be food insecure. The alarming food insecurity is attributed to the government's strong ideological commitment to free market economies and not primarily to agricultural failure as it might be in other South African states (Katja Schmidt 2005).

1.5 SOCIAL SUPPORT

The concept of social support and its potential impact on health has been widely studied since the 1970s. Social support and its relationship to health has been examined in diverse age groups, populations and conditions such as cancer, pregnancy, heart disease and depression (Kadushin G. 1996;Langford C.P.H. et al. 1997;McGough KN 1990). Research to date suggests that social support may promote positive physical and psychological health outcomes during serious illness and even reduce mortality in adults (Blancy N.T. et al. 1990;Kadushin G. 1996;Schwarzer, Dunkel - Schetter, & Kemeny 1994;Stewart & Tilden V.P. 1995)

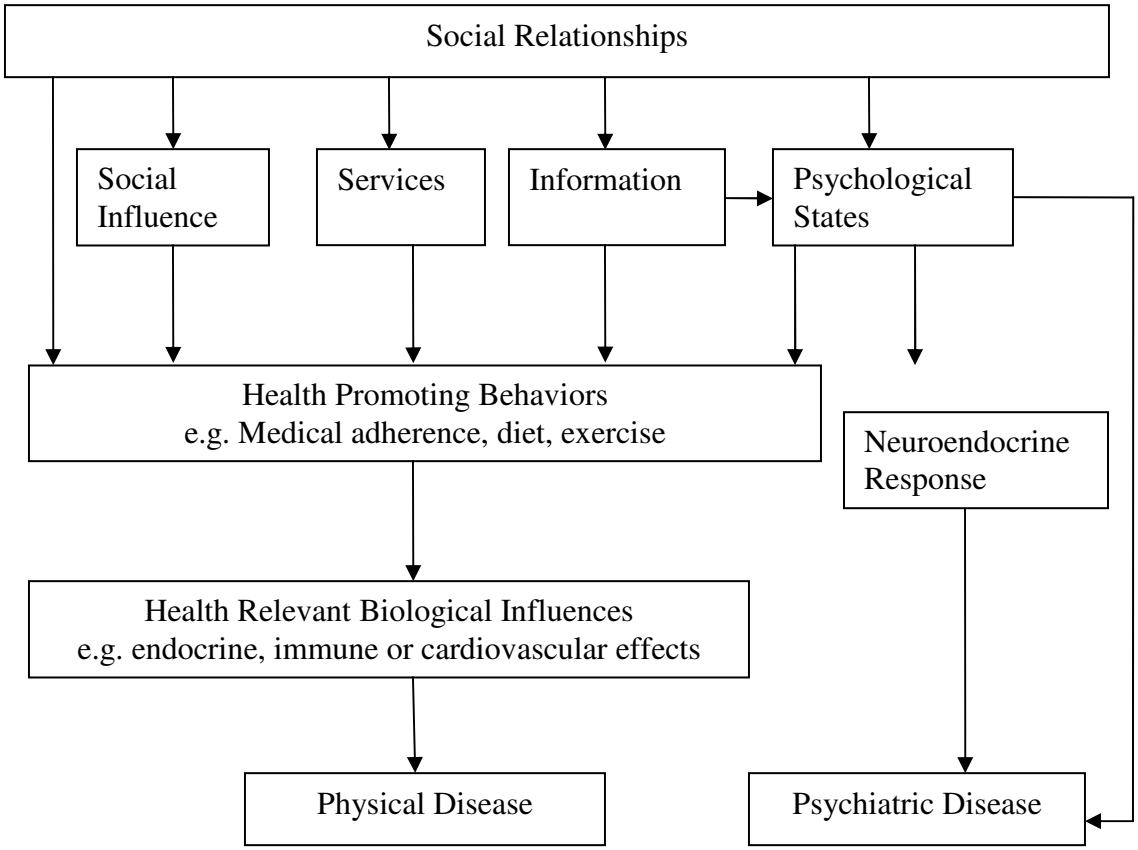
There is general consensus that social support mediates health related behaviour and outcomes. Two widely accepted models by which social support may influence outcomes have been proposed: a *main effect model* and *a buffering model* (Cohen 1985).

The main effect model postulates that social support has a beneficial effect on health or well-being regardless of whether individuals are under stress. The buffering model

proposes that social support lessens the impact of stress on well-being when high levels of stress are experienced but does not affect health/ well-being in the absence of stress (Irving B. Weiner, Handbook of psychology).

1.6 MAIN EFFECT MODEL

FIGURE 1.2: Main Effect Model



Adopted from Social Support Measurement and Intervention by (Sheldon Cohen, Lynn Underwood Gordon, & Benjamin H.Gottlieb 2000).

The figure above shows the mechanisms through which social relationships can have main effects on psychological and physical health. The social networks might influence

whether they take medications, eat a balanced diet and adhere to the clinic schedule. Having a wide range of network ties also provides multiple sources of information and thereby increases the probability of having access to an appropriate information source. Information could help one to avoid or minimize stressful or other high-risk situations for example, serious opportunistic infections associated with HIV and how to deal with the side effects of ART. A network may operate to prevent disease by providing tangible and economic services that result in better health like food, clothing and housing that operate to prevent disease and limit exposure to risk factors.

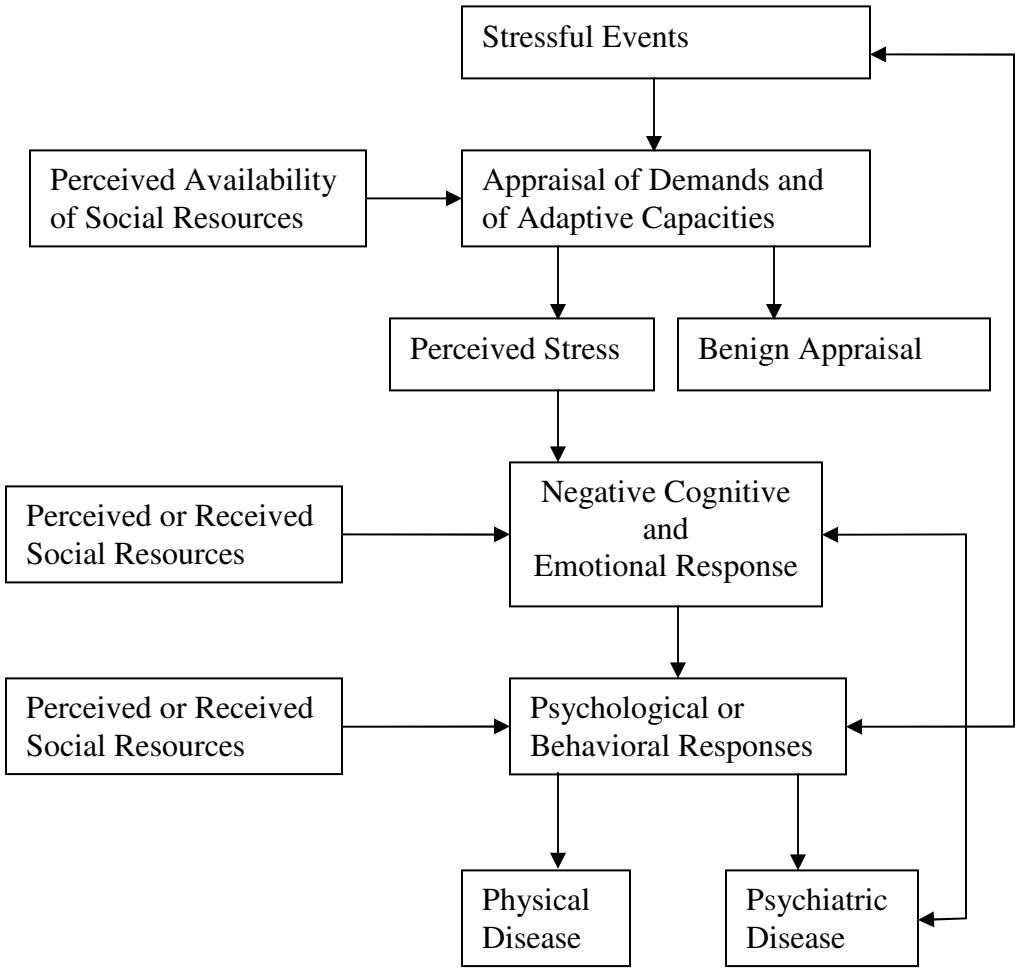
Integration in a social network is also presumed to provide a positive affect, which include senses of predictability and stability of purpose, of belonging and security, and recognition of "self-worth" because of demonstrated ability to meet normative role expectations (Cassel 1976;Hammer 1981;Thoits 1983;Wills 1985). These positive psychological states are presumed to be beneficial because they reduce psychological despair and result in greater motivation to care for oneself, suppressed neuroendocrine response and enhanced immune function (Bovard 1959;Cassel 1976;Cohen S. 1988;Uchino, Cacioppo, & Kiecolt-Glaser 1996).

1.7 STRESS-BUFFERING HYPOTHESIS

The stress-buffering hypothesis was formally proposed in 1976 by physician and epidemiologist John Cassel and psychiatrist Sidney Cobb. Both argued that those with strong ties were protected from the potential pathogenic effects of stressful events. (Cassel 1976) thought that stressors that placed persons at risk of disease were often characterized by confusing or absent feedback from the social environment. In contrast,

the impact of the stressors was mitigated among individuals whose networks provided them with consistent communication of what is expected of them, assistance with tasks, evaluation of their performance, and appropriate rewards (Cassel 1976).

FIGURE 1.3: Stress Buffering Model



Adopted from Social Support Measurement and Intervention by (Cohen, Gordon Underwood, & Gottlieb Benjamin 2000).

The figure above shows how social support may play a role at several different points in the causal chain linking stressors to illness.

First, the belief that others will provide necessary resources may redefine the potential for harm posed by a situation and bolster ones perceived ability to cope with imposed demands, thereby preventing a particular situation from being appraised as highly stressful (Thoits 1986). Second, support beliefs may reduce or eliminate the affective reaction to a stressful event, dampen physiologic responses to the event or prevent maladaptive behavioral responses. Third, support may alleviate the impact of stress appraisal by providing a solution to the problem, by reducing the perceived importance of the problem, or by providing a distraction from the problem.

1.8 Measurement of Social support

The Social Support Inventory for People with AIDS (SSIPWA) (Renwick, Friedland, & Rudman 1995) is a multidimensional and phenomenological measure which explores type, source and satisfaction with social support in relation to stressors commonly experienced by people with HIV or AIDS. It attempts to measure actual (rather than perceived) availability of social support by asking questions such as whether or not there are people who help to get things done on a day-to-day basis, for example preparing meals and doing laundry etc. The SSIPWA also asks whether the respondent wants each type of support (irrespective of whether he/she has it), who provides the support, and how satisfied the respondent is with the support provided. Higher scores on the SSIPWA indicate higher levels of support (Friedland, Renwick, & McColl 1996).

Social support is categorized into three types: instrumental, informational and emotional support. Instrumental support is tangible help in managing practical concerns such as assistance with household chores. Informational support is provision of advice, feedback

or other information which helps the individual appraise his situation. Emotional support consists of behaviours such as listening, caring, or providing companionship, that contribute to making an individual feel loved and comforted (Renwick R 1999).

The inventory includes both closed and open-ended items permitting collection of both quantitative and qualitative data. It may be self-administered or administered via a telephone or personal interview. It assesses four dimensions of received support: whether or not support is received; whether or not the individual wants the support; how satisfied the individual is with the support received; and who provides the support. These four dimensions are measured for three subscales, each for 1 type of support: instrumental, informational, and emotional (Renwick R 1999).

1.9 SOCIAL SUPPORT AND HIV

Social support for people living with HIV is described as assistance offered by one's social network, rather than by a professional (Burgoyne & Saunders 2000) and is often linked with improved health outcomes. Lack of social support is identified as one of the barriers known to influence care outcomes and adherence to Antiretroviral (ART) medications (Battagliori-DeNero 2007).

Social support is a critical for those living with chronic illness. Numerous studies suggest that social support may improve the quality of life in chronic illness, particularly for those living with HIV/AIDS (Ichikawa & Natpratan 2006;Malcolm et al. 2003;Nicholas et al. 2003;Nokes, Chew, & Altman 2003;Plach, Stevens, & Heidrich 2006;Singh et al. 1999).

(Reilly & Woo 2004) investigated social support and safer sex practices in a sample of HIV-positive individuals and found that medical professionals, friends and siblings were reported as the most frequent sources for assistance, whereas regular sexual partners, medical professionals and community organizations were found to be most helpful. Positive social networks were found to significantly influence safer sexual practices. (Nicholas, Corless, Webster A., McGibbon C.A., Davis S., Dolan S., & Paul-Simon A. 2003) found that social support was significantly correlated with a greater quality of life in HIV-positive individuals who attended a behavioural medicine program (Ncama et al. 2008).

Social support has been hypothesized to serve as a buffer against stressful life events by enhancing coping effectiveness, self-esteem, or motivation, and through engagement in health-promoting behaviour (Lazarus & Folkman 1984;Wortman C.B 1984). Its absence has been reported to result in increased stress levels and lowered immune function (Lynch 1992)

1.10 STATEMENT OF THE PROBLEM

There is inadequate information regarding food security and social support and how they affect HIV patients who are attending treatment at Tintswalo Hospital and many other hospitals in South Africa.

1.11 RATIONALE OF THE STUDY

Information on how food security and social support affect HIV patients attending treatment at Tintswalo Hospital will contribute to improvement of HIV management and

health of people in Sub-Saharan Africa. It will guide researchers, the government and other stakeholders like community and faith based organisations on how to maximize the benefits of the Wellness package; making recommendations for improving the existing package especially with regard to nutritional management and social support for People living with HIV/AIDS (PLWHA).

1.12 STUDY OBJECTIVES

1.12.1 Broad Objectives

To determine the influence of food security and social support on the health outcomes of HIV patients attending Rixile Clinic in Tintswalo Hospital from March 2003-May 2008.

1.12.2 Specific Objectives

- To describe the distribution of food security and social support among HIV patients attended between March 2003 and May 2008.
- To determine the health outcomes of HIV patients attended between March 2003 and May 2008.
- To investigate predictors of health outcomes among selected factors that affected patients attended at Rixile Clinic between March 2003 and May 2008.

CHAPTER 2: METHODOLOGY

2.0 STUDY SITE

The study was conducted from March 2003 to May 2008 at the Rixile Clinic in Tintswalo hospital as part of the Adult Wellness programme. The Wellness Programme provided comprehensive care and support for HIV-positive clients before they require antiretroviral therapy (ART). It was first piloted in Soweto and has subsequently been rolled out to two rural sites in Limpopo and Mpumalanga Province.

Tintswalo hospital is the largest of the three hospitals that serve approximately 500,000 inhabitants of the Bushbuckridge Sub-District (formerly part of Bohlabela District) with a bed capacity of 450. The other hospitals are Mapulaneng (350 beds) and a public-private Life Healthcare facility, Matikwana (150 beds).

It is situated in Acornhoek and is approximately 140 km from Nelspruit, the capital of Mpumalanga Province. The hospital is located in a rural, environmentally degraded area where the main source of income comes from migrant remittances, social grants and the informal sector. It serves a population of about 300,000 with an antenatal (ANC) HIVseroprevalence of 30%.

2.1 RADAR

The Rural Aids and Development Action Research Programme (RADAR) comprises clinical and social intervention research on HIV/AIDS, with an emphasis on developing model approaches that are appropriate and relevant to the rural African context. It is a collaboration between the School of Public Health at the University of the Witwatersrand and the London School of Hygiene and Tropical Medicine.

RADAR's portfolio of clinical interventions for TB/HIV includes the following:

1. National TB/HIV pilot programme
2. HIV/ AIDS Wellness service
3. Addressing the TB epidemic in Rural South Africa
4. Anti-Retroviral in the developing country context.

The HIV/AIDS wellness service constitutes a package of interventions that have been shown to be both effective and inexpensive; they include:

- Screening for sexually transmitted infections at every visit
- Screening for tuberculosis at every visit
- Asking about safer sexual behaviour and condom use
- Offering family planning services to those who need it
- Annual Papanicolau (PAP) smears for women
- Basic nutrition, psychosocial and peer support.

This study utilizes a secondary analysis methodology to examine data derived from the Adult Wellness study in Rural South Africa.

2.2 STUDY POPULATION

The study population consisted of all HIV patients who attended Rixile Clinic in Tintswalo Hospital from March 2003 to May 2008. About half of the total number of patients were on ART. The total study population was 2216.

2.3 STUDY SAMPLE

The study sample constituted 1367 HIV patients who were using ART in the study population. It was the total number of patients who were started on ART at different points in time during the follow-up period.

2.4 STUDY DESIGN

The study design was a clinical cohort of HIV positive patients in which information on food security and social support was collected at recruitment into the study and followed up over time. The outcome variables in the study were changes in CD4 count, changes in BMI and survival from starting ART until the end of the study. Food security and social support factors were also collected during follow-up visits apart from the baseline but for the purposes of the current secondary analysis of data, the information obtained on the first clinic attendance was used to classify participants into different categories of the two exposure variables.

It was appropriate to use longitudinal data analysis in a cohort of HIV patients who were involved in the study period because several observations were taken from the same participant at different times of follow up.

2.5 MEASUREMENT OF EXPOSURE VARIABLES

2.5.1 FOOD SECURITY

The frequency of missed meals in the week preceding recruitment into the study was used as a proxy measure of the level of food security. Participants who missed between one and two meals were classified as moderately food insecure, three or more meals (severely food insecure). Participants who never missed a meal were identified as food secure and used as a reference group.

2.5.2 SOCIAL SUPPORT

Participants in the study were interviewed on the number of activities that they required support for from relatives, siblings or other social support networks. The activities include cooking, cleaning, washing and dressing, eating, taking medicines and walking around the house. This section of the questionnaire was similar to the model used by Renwick and colleagues to measure the actual rather than the perceived availability of social support known as the Social Support Inventory for People with AIDS (SSIPWA). The cumulative score obtained by each participant was later used for classification purposes into the following categories: one to two (minimum social support required), three or more (maximum social support required). Patients who scored a zero in all activities in question (no social support required) were used as a reference group.

The following tables summarize the scoring system used to classify the two exposure variables in the study:

2.5.2.1 FOOD INSECURITY

In the past week, how many times did you miss a meal because no food was available?

Number of meals missed	Level of food insecurity
Nil	Food Secure
1-2	Moderate insecurity
3+	Severe insecurity

2.5.2.2 SOCIAL SUPPORT

Do you need help with your daily activities from someone else? If yes which activities;

Activity	Yes=1	No=0
Cooking		
Cleaning		
Washing and dressing		
Eating		
Taking medicine		
Walking around house		

Scoring system;

0= No social support required

1-2= Minimum support required

3+ = Maximum support required.

Data on the exposure variables was likely to change in the subsequent visits to the Wellness study. However, for the purposes of the current secondary analysis of data, the information obtained on the first clinic attendance was used to classify participants into different categories of exposure variables.

2.6 DATA COLLECTION

2.6.1 Clinic Site

Participants attending Rixile Clinic were referred from the peripheral clinics in the catchment population of Tintswalo hospital with their HIV test and CD4 count results. They were required to complete a minimum of three visits to the clinic site before enrolment into the Wellness study. During the clinic visits, information about HIV and how to live positively with the disease was provided either on a one-on-one basis or in group sessions. These sessions were conducted by trained support group facilitators.

A consent form used for the study was translated into local languages for easy understanding of the content into Tsonga, Sotho, Zulu, Shangaan and Swati. Participants were allowed to go through the consent form with their families before agreeing to participate in the Wellness study.

2.6.2 Research Site

The rural Wellness Clinic is based at Tintswalo Hospital in Acornhoek. The rural Clinic sees approximately 1200 patients per month. Although 75% of patients came from an area within a 10 to 20 km radius from the rural site, approximately 25% are from as far as 50km away.

Patients are referred to the HIV Clinics from hospital wards and voluntary counseling and testing programs within the hospital and from surrounding primary health care clinics.

HIV-positive status was confirmed by a laboratory-based enzyme-linked immunosorbent assay (ELISA) and 2 blood-based rapid tests at the rural site. The methodology of the Wellness study has been published in the Journal of AIDS. The article authored by Lurie and colleagues is titled "Sexual Behavior and Reproductive Health Among HIV-infected patients in Urban and Rural South Africa (Lurie, M et al, 2008).

The clinical care form was used to capture information in the research site. It was divided into socio-demographic information, clinical information, anthropometric measurements and laboratory investigations.

Socio-demographic information included: name, sex, address, marital status, source of income, level of education, cigarette smoking, and alcohol consumption. Information regarding hospitalization, the need for social support and levels of food security were also included in this part of the clinical care form.

Clinical Information included: Concurrent or past tuberculosis, sexually transmitted infections, use of family planning methods, sexual behavior, eye disease, opportunistic infections and clinical staging of HIV using WHO guidelines.

Anthropometric measurements: measurements of weight, waist and hip circumference.

ART treatment: date of starting, type of drug and reported adverse effects of the drugs.

Special investigations that included the following: Rapid plasma reagin (RPR) test for screening syphilis, Papanicolau (PAP) smear for cervical cancer screening and Chest X-ray.

Laboratory results: CD4 count, viral load, random blood sugar, cholesterol, and liver and kidney function tests. Sputum culture and smear for Acid fast bacilli (AFB) were also included as part of the routine tests in the study.

The above information was collected every three to six months for follow up.

2.6.3 Data Quality

The information collected in clinical care forms (CCF) was later transferred to case report forms (CRF) by data capturers before undergoing quality checks in two different stages. The first stage was done by the study coordinator and it involved the comparison of information contained in CCF and CRF. The second stage involved double entry into the database by two different data clerks. In the event of queries in the information entered by the two data clerks generated during data comparison, the data manager would recall the CCF and CRF concerned, and send them back to the study coordinator for clarification. Once the mistakes were rectified and edited, the data manager would verify that there were no more mistakes and save the information in the Back-end database.

2.7 MEASUREMENT OF OUTCOME VARIABLES

The absolute numbers of the CD4 count were used in this secondary analysis of data. It should be noted that the CD4 count levels were not checked in every visit to the clinic and occasionally, participants would attend the clinic to take the drugs but decline to go for blood testing to avoid prolonged waiting periods. Hence the numbers of absolute CD4 records in the laboratory dataset did not always correspond with clinic visits.

Measurements of body weight were recorded in every visit to the Wellness study. The ratio of body weight in kilograms divided by the square of the height in meters was used to construct the body mass index (BMI) variable in the dataset. The BMI was recorded in all the subsequent visits to the clinic.

The third outcome variable was HIV related death and it was confirmed using death certificates for those who died in a hospital setting. A verbal autopsy was used for deaths that occurred outside the hospital. Participants who missed three consecutive visits were considered as lost to follow up.

The follow up time was taken to be the difference between the date of starting ART and date of death, loss to follow-up or end of study (31/5/2008). The dataset had a large number of HIV related deaths without the actual date of death, which necessitated the use of a termination date as a proxy for the date of death. It was done to allow the use of survival analysis from starting ART to the end of study participation.

2.8 SOCIOECONOMIC STATUS

The socioeconomic index was constructed using principal component analysis (PCA) method. PCA is a multivariate statistical technique used to reduce the number of variables in a dataset into a smaller number of dimensions. In mathematical terms, from an initial set of n correlated variables, PCA creates uncorrelated indices of components, where each component is a linear weighted combination of the initial variables. For example, from a set of variables X_1 through to Xn,

$PC_1 = a_{11}X_1 + a_{12}X_2 + \ldots\ldots\ldots\ldots a_{1n}X_n$

$PC_m = a_{m1}X_1 + a_{12}X_2 + \ldots\ldots\ldots\ldots a_{mn}X_n$ where

a_{mn} represents the weight for the m^{th} principal component and the n^{th} variable (Vyas S, Kumaranayake L, 2006).

The following variables in the Wellness study were available for the construction of the socioeconomic index: household characteristics (type of house and main material used to make house walls, number of rooms in the house), literacy or education level of the participant, access to utilities (source of drinking water) and individual monthly income in South African Rands. Information on the ownership of durable assets was not collected in the Wellness study. The education level, source of water and type of housing were categorical variables. They were re-coded into binary variables before using the principal component analysis method. The individual monthly income was categorized into the following groups: G1 (no income), G2 (R40-600), G3 (R600-2000), G4 (R2000-4000), G5 (R4000-6000), G6 (>R6000).

The pca command in STATA 9 was used to obtain eigenvectors (weights) for different variables in the STATA output. The education level was the principal component with the highest eigenvalue of 2.525, and it explained 11% of the variability in original data. It was associated with higher socioeconomic status. The eigenvectors of the first component were used as scoring weights for each of the variables. The variable scores were then used to construct a wealth index value for each patient, which in turn formed the basis of assigning participants into the 3 categories of socioeconomic index (low, medium and high).

2.9 DATA ANALYSIS

2.9.1 DESCRIPTIVE ANALYSIS

In the descriptive analysis of data, frequencies and percentages were used to describe demographic, confounders, exposure and outcome variables. They were all categorical variables. SPSS 14.0 was used in the statistical analysis section.

2.9.2 INFERENTIAL ANALYSIS

In the inferential analysis the effect of clustering was taken into consideration. In the context of Wellness study repeated and multiple measures were taken from the same participant during the follow up period. The clusters were different categories of food insecurity and social support.

2.9.2.1 Random Effects (Multilevel) Models

Random-effects models are analytical methods used in longitudinal studies when there is variation among study participants in the number and timing of observations. This variation results in unbalanced data sets that cannot be analyzed using a general multivariate model (Laird NM, Ware JH, 1982).

Random-effects models consist of two stages:

First stage: it is assumed that the probability distribution for the multiple measurements has the same form for each individual, but the parameters of that distribution vary over each individual (random effect).

Second stage: the distribution of these parameters or “random effects” in the population constitutes the second stage of the model.

The Random-effects model is used to test hypotheses about the equality of group means, similar to the analysis of variance (ANOVA). Using the mathematical representation of the model for one-way ANOVA:

$X_{ij}=\mu+ \alpha_j + e_{ij}$

Where;

X_{ij} = Is the i^{th} observation in the j^{th} group

μ = Grand mean

α_j = The effect associated with group j may be thought of as the difference between the mean of group j and the grand mean.

e_{ij} = an error (residual)

The size of an effect is related to the size of the difference between a given group mean and the grand mean. When inferences involve only specific levels of the factor included in the study, the model is called a fixed-effect model. For example when investigators wish to draw conclusions about specified dosage levels of a drug.

On the other hand, if the dosage levels are viewed as being randomly selected from all different possible dosage levels of the drug, the model is called a random-effects model.

The random effects model can be used to make inferences to other levels of the factor not represented in the study. It has the following advantages:

- No requirement for balance in data (good for longitudinal study)
- It allows explicit analysis of between/within individual variation.

2.9.2.1.1 Univariate analysis for Changes in CD4 and BMI

Linear regression model was used to identify factors that significantly predict changes in CD4 count using the following variables: social support, food security, gender, age group, alcohol use, education level, presence/absence of Tuberculosis, WHO clinical staging of HIV, marital status and socioeconomic status. The exposure variables were collected at baseline only. The same factors were used to predict changes in BMI as an outcome variable

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2.9.2.1.2 Multivariate Analysis for Changes in CD4 and BMI

Variables which were shown to be significant at univariate analysis were used in multivariate models investigating the relation between food security, social support and changes in CD4 cell count and BMI.

2.9.2.2 SURVIVAL ANALYSIS

The analysis of survival experience from the beginning of ART until death from HIV, loss to follow up or termination of the study were conducted using Cox proportional hazards regression model. It is the most commonly used approach to the regression analysis of survival data. It assumes that the ratio of the hazards comparing different exposure groups remains constant over time. Mathematical representation of the model is:

$$\text{Log}[h(t)] = \log[h_o(t)] + \beta_1 X_1 + \beta_2 X_2 + \ldots\ldots\ldots \beta_n X_n$$

Where h(t) is the hazard at time t, $h_o(t)$ is the baseline hazard (the hazard for an individual in whom all exposure variables=0) at time t, and X_1 to X_n are the n exposure variables.

The regression coefficient β is the estimated log hazard ratio comparing exposed with unexposed individuals. In this study, the exposure groups were participants with:

1. Food insecurity at baseline (moderate, severe), whereas participants who never missed a meal were considered unexposed.
2. who needed support with activities like cooking, cleaning and washing, whereas those who required no support from their social network were considered unexposed.

It should be noted that baseline CD4 count and BMI were considered to be independent predictors in the model explaining survival from the beginning of ART. The baseline values of repeated measured variables were used in the model.

Potential confounding variables were controlled for in the multivariate analysis.

2.9.2.2.1 Univariate Survival Analysis

The univariate analysis was carried out to identify factors that predict survival from the beginning of ART to death from HIV or termination of the study. The following variables were used: social support, food insecurity, gender, age group, alcohol use, education level, history of Tuberculosis, WHO clinical staging of HIV, marital status, socioeconomic status, baseline CD4 count and baseline BMI.

2.9.2.2.2 Multivariate Model

Factors shown to be univariately significantly associated with survival from starting ART to HIV related death or termination of the study were included in multivariate models. .

2.10 ETHICAL CONSIDERATIONS

Ethical approval for the Adult Wellness study was given by the committee for research on Human subjects (Medical) of the University of Witwatersrand to RADAR/PHRU in 2003. The project title was "Developing Comprehensive Services for People living with HIV/AIDS in the Bohlabela District of the Limpopo Province". (See Appendix B)

The Protocol number is M03-05-26 and informed consent was obtained from participants before recruitment into the study.

The same committee issued an ethical clearance certificate for secondary analysis of data; protocol number M080981. All participants in the study were identified using unique identifiers (study identification number) and all personal identifiers were removed before starting secondary data analysis. (See Appendix C)

CHAPTER 3: RESULTS

3.1 DESCRIPTION OF STUDY PARTICIPANTS

The study was conducted from March 2003 to May 2008 at the Rixile Clinic in Tintswalo Hospital as part of the Adult Wellness program. During the study period a total of 1367 participants began ART at different time points and followed up until the 31st May 2008. They constituted half of the total number of participants who attended the clinic. There were 943 female (69.19%) and 420 male (30.81%) in the study. The total number of HIV related deaths at the end of the study was 74 (5.4%) of which 51 were females (71.83%) and 20 were males (28.17%).The most common causes of death due to HIV were tuberculosis (44.3%) and diarrhea diseases (24.5%).

Table 1.Background characteristics of study participants

Variable	**Frequency** (n)	**Percentage** (%)
Age(n=1275)		
15-24	40	3.14
25-34	426	33.41
35-44	484	37.96
45-54	238	18.67
55+	87	6.82
Gender(n=1363)		
Male	420	30.81
Female	943	69.19
Marital status(n=1328)		
Never married	476	35.84
Divorced/separated	244	18.37
Widowed	193	14.53
Married (Legal+Traditional)	357	26.88
Co-habiting	58	4.37
Education Level(n=1345)		
No formal education	243	18.07
Grade 1-12	1054	78.36

Tertiary	48	3.57
Wealth index(n=1135)		
High	373	32.86
Medium	381	33.57
Low	381	33.57
Previous alcohol(n=1313)		
Yes	259	19.73
No	1054	80.27
Previous TB(n=1347)	373	27.69
Yes	974	72.31
No		
WHO staging(n=1350)	50	3.70
1	371	27.48
2	802	59.41
3	127	9.41
4		
Food insecurity(n=1270)	1252	98.58
None(food secure)	14	1.10
Moderate	4	0.31
Severe		
Social Support(n=1367)	1210	88.51
None required	132	9.66
Minimal	25	1.83
Maximum		

3.2 Socio-demographic characteristics

The age-group of most participants fell between 35-44 years (n=484, 37.96%), followed in descending order by 25-34 years (n=426, 33.41%) and 45-54 years (n=238, 18.67%). The age of participants ranged between 19 and 75 years, with the median age of 37 years (interquartile range [IQR]: 32 to 45 years). . Among those participants whose marital status was documented, more than a third were single/never married (n=476, 35.84%)

followed by traditional marriage (n=357, 26.88%). The proportions of participants who were divorced and widowed were 244 (18.37%) and 193 (14.53%) respectively.

A total of 243 (18.07%) study participants had no formal education. Among those with formal education only 48 (3.57%) had tertiary education and the remaining 1054 (78.36%) had attained varying levels of education but not beyond grade 12.

Unemployment was very high at a proportion of 86% among the study participants. A small proportion of participants were salaried workers (n=153, 11.4%). The remaining participants were either self employed (n=24, 1.8%) or still students (n=8, 0.6%).

3.3 Clinical characteristics

The majority of participants were referred to Rixile Clinic with very low CD4 counts of less than 50/cc. They constituted 65% (n=890) of all the referrals to the Wellness clinic. The histogram below shows the distribution of participants according to their CD4 groups at baseline and gender.

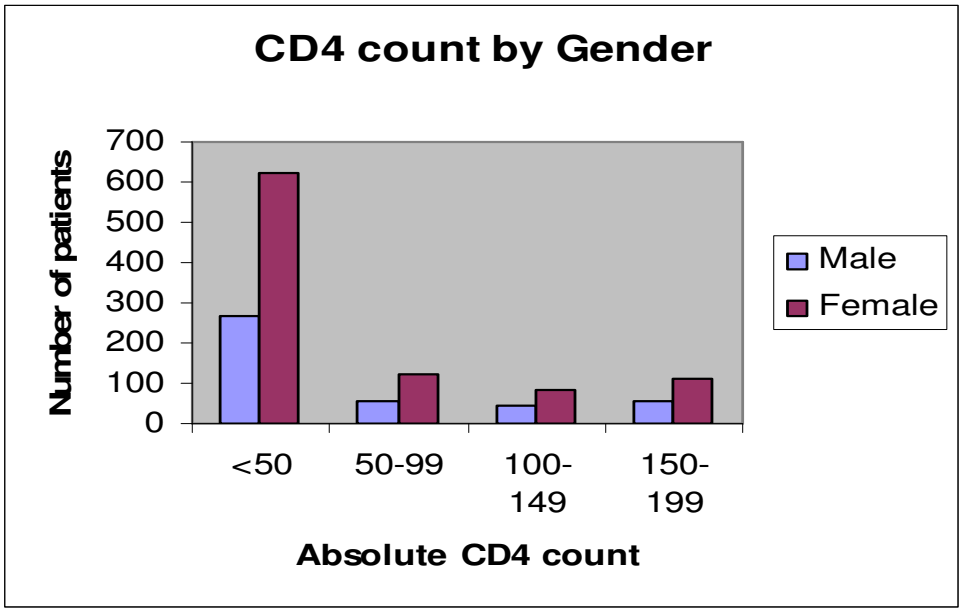

FIGURE 3.1: Distribution of participants in the Wellness study by baseline CD4 count and Gender

The BMI was also calculated. The BMI of more than half of the participants fell within the normal range of 18.5-24.9 kg/m2 (n=773, 65.18%). The remaining participants were equally distributed in the underweight (n=208, 17.54%) and overweight categories (n=205, 17.28%). The histogram below shows the distribution of participants according to their BMI at recruitment and gender.

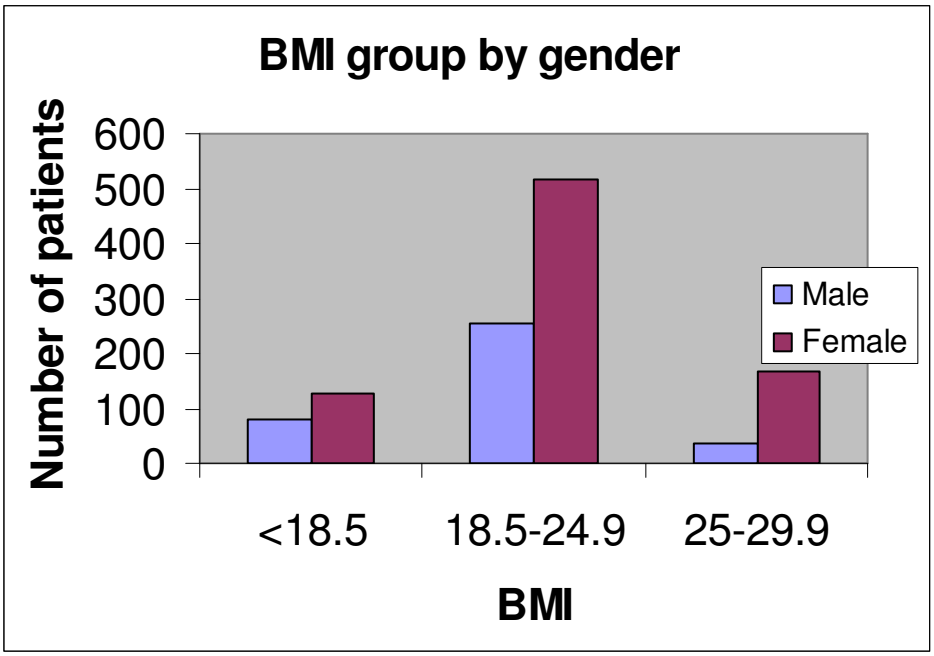

FIGURE 3.2: Distribution of participants in the Wellness study by baseline BMI and Gender

The WHO clinical staging of HIV was determined at baseline using a constellation of clinical symptoms and signs including percentage loss of body weight. More than half of participants (n=802, 59.41%) were recruited at stage 3 of the disease i.e. relatively advanced stage of the disease, followed by stage 2 (n=371, 27.48%). The histogram below shows the distribution of participants who attended the Wellness study according to their baseline HIV staging and gender.

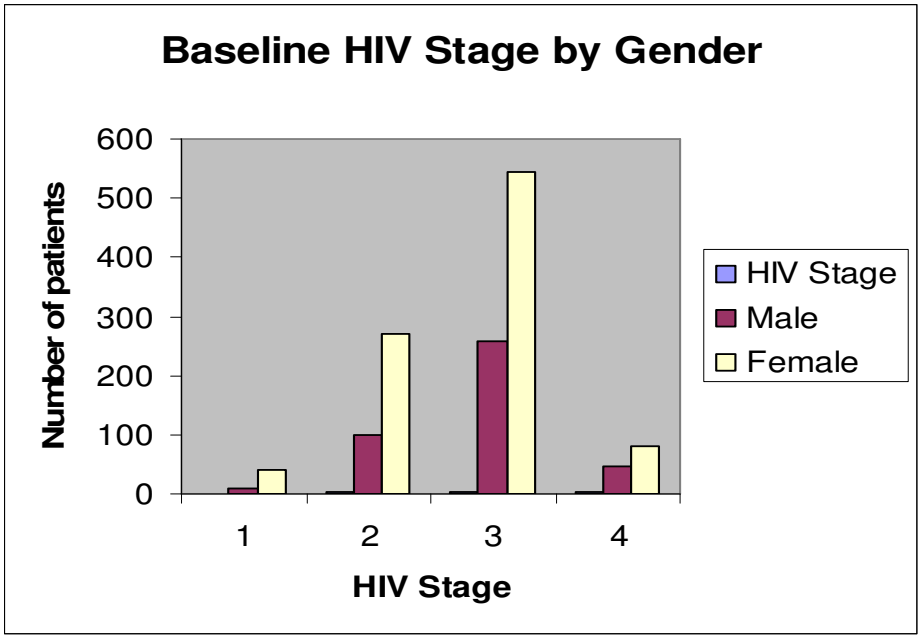

FIGURE 3.3: Distribution of participants in the Wellness study by baseline HIV staging and Gender

A quarter of study participants (n=373, 27.69%) presented a history of TB diagnosis and treatment before enrolment into the Wellness study. Approximately one fifth of participants (n=259, 19.73%) were consuming alcohol before starting the Wellness Clinic.

3.5 Food insecurity and Social Support

Information regarding food insecurity was recorded in 1270 participants out of the total 1367. The majority of them were food secure (n=1252, 91.6%), followed by moderate food insecurity (n=14, 1.02%) and severe food insecurity (n=4, 0.29%). The information on food security was missing in 97 (7.1%) participants.

Information concerning the level of social support was obtained from all participants at the recruitment stage. The majority of them (n=1210, 88.51%) did not require support with activities such as cooking, washing, cleaning, eating and walking around the house.

The remaining 132 (9.66%) required minimal support from their social networks and only 25 (1.83%) reported the need for maximum support.

Table 2.Variations in BMI using Random Effects Model

Variable		Univariate			Multivariate (n=1071)		
	n	Coeff	95%CI	P-value	Coeff	95%CI	P-value
Food insecurity							
None (food secure)	1111	**ref**			**ref**		
Moderate		-4.3	-7.6,-0.96	0.012	-3.2	-6.5,0.08	0.056
Severe		-6.9	-16.2,2.5	0.152	-7.6	-16,0.99	0.083
Social support							
Not required	1174	**ref**			**ref**		
Minimal		-1.8	-2.8,-0.84	0.000	-2.1	-3,-1.2	0.000
Maximum		-3.2	-5.4,-1.1	0.004	-3.4	-5.3,-1.5	0.000
Gender							
Female	1174	**ref**			**ref**		
Male		-1.9	-2.5,-1.25	0.000	-1.63	-2.3,-0.94	0.000
Age							
15-24		**ref**					
25-34	1156	-0.62	-2.34,1.1	0.480			
35-44		-0.49	-2.20,1.22	0.575			
45-54		0.04	-1.74,1.83	0.961			
55+		-0.76	-2.74,1.23	0.455			
Marital status							
Never married		**ref**					
Divorced/separated	1163	0.55	-0.3,1.4	0.201			
Widowed		0.28	-0.63,1.18	0.549			
Married (L + T)		0.32	-0.43,1.06	0.410			
Co-habiting		0.93	-0.50,2.34	0.197			
Previous TB							
No	1160	**ref**			**ref**		
Yes		-1.2	-1.9,-0.55	0.000	-0.27	-0.9,0.37	0.406
Previous alcohol							
No	1154	**ref**			**ref**		
Yes		-1.4	-2.14,-0.66	0.000	-0.5	-1.3,0.28	0.208
Education Level							

No formal		**ref**					
Grade 1-12	1171	-0.24	-1.0,0.5	0.530			
Tertiary		0.496	-1.1,2.18	0.559			
Wealth index							
High	1028	**ref**					
Medium		0.14	-0.58,0.87	0.697			
Low		0.27	-0.45,1.00	0.463			
WHO stage							
1	1161	**ref**			**ref**		
2		-1.7	-3.2,-0.2	0.025	-0.76	-2.2,0.68	0.300
3		-2.96	-4.4,-1.4	0.000	-1.89	-3.3,-0.47	0.009
4		-3.98	-5.6,-2.2	0.000	-2.59	-4.2,-0.93	0.002

3.6 UNIVARIATE ANALYSIS FOR CHANGES IN BODY MASS INDEX

The variation of BMI at baseline was significantly associated at 5% level of significance with the following variables: food insecurity (P=0.011), level of social support (P<0.001), gender (P<0.001), history of TB infection (P=0.0004), previous consumption of alcohol (P=0.0003) and the HIV stage (P<0.001). The age at recruitment, marital status, education level and socioeconomic group were not significantly associated with variation in BMI (P>0.05).

3.7 MULTIVARIATE ANALYSIS FOR CHANGES IN BODY MASS INDEX

The level of social support, gender and HIV stage were shown to be significant predictors of the variation in BMI (P<0.001) after considering other potential confounding variables. The level of food insecurity, history of past TB infection and alcohol use were not significant at multivariate analysis.

Table 3.Variations in CD4 counts using Random Effects Model

Variable		Univariate			Multivariate (n=794)		
	n	Coeff	95%CI	P-value	Coeff	95%CI	P-value
Food insecurity							
None (food secure)	801	**ref**			**ref**		
Moderate		-144	-250,-38	0.008	-117	-221,-12.5	0.028
Severe		-121	-296,52.9	0.172	-110	-282,61	0.208
Social support							
Not required	864	**ref**			**ref**		
Minimal		-23.4	-62.5,15.7	0.240	-37.5	-77.4,2.4	0.065
Maximum		-99	-186.5,-11.6	0.026	-83.6	-173,6.2	0.068
Gender							
Female	863	**ref**			**ref**		
Male		-55	-80.2,-29.8	0.000	-58.7	-85.4,-32	0.000
Age							
15-24		**ref**					
25-34	801	-7.7	-93,77.9	0.861			
35-44		-33.7	-118,51.2	0.436			
45-54		-29.3	-116,58.3	0.512			
55+		-30.3	-124,63.5	0.526			
Marital status							
Never married		**ref**					
Divorced/separated	832	-28.5	-63,5.9	0.105			
Widowed		-0.9	-39.6,37.9	0.964			
Married (L + T)		-29.4	-60,1.1	0.058			
Co-habiting		24.2	-41.8,90.1	0.473			
Previous TB							
No	849	**ref**					
Yes		-0.8	-25.8,27.4	0.952			
Previous alcohol							
No	816	**ref**					
Yes		-16	-46,14	0.294			
Education Level							
No formal		**ref**					
Grade 1-12	847	-22.7	-54,8.5	0.153			
Tertiary		22.5	-45.9,91	0.519			
Wealth index							
High		**ref**					
Medium	679	-2.1	-34,29	0.896			

Low		0.52	-31.6,32.7	0.975			
WHO stage							
1		**ref**			**ref**		
2	853	-66	-143,11.5	0.095	-57	-135,21.5	0.155
3		-100	-176,-25	0.009	-79.3	-156,-3	0.042
4		-129	-212,-47	0.002	-92.5	-178,-7.6	0.033

3.8 UNIVARIATE ANALYSIS FOR CHANGES IN CD4 COUNTS

The variation of the absolute CD4 count at baseline was significantly associated at 5% level of significance with the following variables: Food insecurity (P<0.001), level of social support required (P<0.001), gender (P<0.001) and stage of HIV (P<0.001).

The following variables were not significantly associated with the variations in CD4 count: age at recruitment, marital status, previous TB infection, previous use of alcohol, education level and socioeconomic group.

3.9 MULTIVARIATE ANALYSIS FOR CHANGES IN CD4 COUNT

The level of food insecurity, gender and HIV stage at recruitment were shown to be significant predictors of variations in CD4 count at univariate analysis (P<0.001) and would be considered in the multivariate regression model. The level of social support required was not a significant predictor in multivariate analysis.

Table 4. Cox hazards model for risk of death among participants in the Tintswalo cohort

Variable		Univariate			Multivariate (n=1218)		
	n	HR	95%CI	P-value	HR	95%CI	P-value
Food insecurity							
None (food secure)	1244	**ref**			**ref**		
Moderate		14	5.76,34	0.000	15.7	5.3,46	0.000
Severe		45	15.76,129	0.000	30.9	9,105	0.000
Social support							
Not required	1339	**ref**			**ref**		
Minimal		1.2	0.55,2.62	0.652	2	0.76,5.4	0.155
Maximum		2.4	0.74,7.57	0.144	5.6	1.5,21.6	0.012
Gender							
Female	1336	**ref**			**ref**		
Male		0.86	0.51,1.45	0.574	1.6	0.75,3.4	0.222
Age		**ref**					
	1268	1.00	0.94,1.06	0.980			
Marital status							
Never married		**ref**			**ref**		
Divorced/separated	1303	2.4	1.26,4.54	0.008	1.4	0.6,3.4	0.436
Widowed		1.2	0.5,2.7	0.727	0.6	0.18,1.9	0.389
Married (L + T)		1.0	0.5,2.1	0.977	0.45	0.16,1.3	0.129
Co-habiting		1.1	0.24,4.55	0.946	0.19	0.02,2.1	0.179
Previous TB							
No	1320	**ref**					
Yes		0.6	0.33,1.1	0.095			
Previous alcohol							
No	1287	**ref**					
Yes		0.71	0.35,1.45	0.352			
Education Level							
No formal		**ref**					
Grade 1-12	1319	1.9	0.86,4.13	0.111			
Tertiary		2	0.50,7.55	0.333			
Wealth index							
High		**ref**					
Medium	1111	2.8	0.7,10.6	0.129			
Low		1.1	0.2,5.5	0.899			

WHO stage					
1		**ref**			
2	1323	0.43	0.05,3.85	0.451	
3		2.04	0.28,14.8	0.480	
4		5.27	0.7,39.5	0.106	
Baseline CD4					
<50		**ref**			
50-99	1337	0.92	0.48,1.75	0.804	
100-149		0.67	0.29,1.58	0.362	
150-199		0.97	0.50,1.89	0.934	
Baseline BMI					
<18.5		Ref			
18.5-24.9	1163	0.14	0.05,0.35	0.000	
25-29.9		0	_	_	

Participants in the study were followed up for a total of 25732 person-months. Individual follow up time varied between 14 days and 60 months. The recorded number of HIV related deaths at the end of the follow up period was 74 representing 5.4% of study participants on ART.

In the univariate analysis, the following variables were significantly associated at 5% level of significance with risk of HIV related mortality: food insecurity (P<0.001) and HIV stage (P<0.001). However in the multivariate analysis, the model with food insecurity, social support, gender and marital status was statistically significant (overall P<0.001).

CHAPTER 4: DISCUSSION

The results of Tintswalo (Wellness) study indicated that more women than men were attending HIV clinics in the Mpumalanga Province. In the current study, women were more than two-thirds of the total number of participants. The observed difference in gender could be due to HIV surveillance methods and the health seeking behavior of the participants. The antenatal HIV surveillance is commonly used to determine the prevalence of HIV in South Africa. It identifies more HIV positive women than men. Men are reluctant to attend antenatal clinics despite the advocacy for couple counseling and HIV testing, because they feel out of place and believe these services are primarily for pregnant women. The difference in the health seeking behavior of men and women was studied by Johansson and colleagues in Vietnam (Johansson, Long, & Winkvist A. 2000). Men were found to neglect symptoms until the disease reached a serious stage (Johansson, Long, & Winkvist A. 2000). Male dominance in relationships made women's efforts to convince spouses to attend ART clinics unfruitful. A cross sectional study of 1366 women presented for antenatal care at four health centers in Soweto, South Africa found that intimate partner violence and high levels of male control were associated with an increased risk of HIV (Dunkle et al. 2004). Similar findings have been reported by Maman and colleagues in their study on HIV screening for women attending the Voluntary Counseling and Testing (VCT) clinic in Dar-es-Salaam, Tanzania. HIV positive women reported more lifetime partner violence than HIV negative women (Maman et al, 2002). Indeed, gender inequalities have been recognized to drive the HIV pandemic (UNAIDS 2006).

The proportion of unemployed participants was high (86 %) in this community. The majority of the people rely on remittances from their families in the cities. Incapacitation resulting from HIV-related infections and diseases may have rendered some participants incapable to work. The percentage reported is higher than that reported by Collinson and colleagues in 2007 which was 60%. It was published in the report on illness-related impoverishment in Rural South Africa by Goudge and others in 2009.(Goudge et al. 2009)). Clients could cope with illness-related shocks and impoverishments through free health services, cash transfers and social protection like disability grants, credit and gifts from social networks (Goudge, Russell, Gilson, Molyneux, & Hanson 2009).

The majority of participants in the study were recruited at HIV stage 3 or 4, mostly with CD4 counts of less than 50/cc. This finding highlights the need for social mobilization to increase the uptake of voluntary counseling and confidential testing (VCCT) services for HIV, for early detection of the infection.

The mortality due to HIV was relatively low (5.4%), considering that the majority of participants were recruited at an advanced stage of HIV. This is either due to strict adherence to treatment schedules by participants or loss to follow up and therefore underreporting of deaths. In addition, disease misclassification (which cannot be avoided completely in verbal autopsies) could partly explain the small number of HIV related deaths. Finally, the duration of follow up of 5 years may be not long enough to capture all the HIV related deaths, especially in a cohort of participants on ART. Antiretroviral therapies have consistently been shown to prolong survival in HIV infected individuals (Pallela F.J.Jr. et al. 2003).

In this study, the proportion of underweight participants was 15.7% for females and 21.6% for males. The proportion of overweight participants was 20.6% for females and 10.1% for males. The proportion of underweight participants was higher than the general adult South African population of 6% for females and 13% for males according to the South African Demographic and Health Surveillance of 2003 (SADHS 2003). The proportion of overweight participants was lower than the general adult distribution of 28% for females and 21% for males (SADHS 2003). The observed difference in the proportions of under-and over-weight between study participants and the general adult South African population could in part be explained by the wasting syndrome associated with HIV.

In this analysis, the BMI of male participants was lower on average in comparison to female participants. Men are more likely to be involved with strenuous activities than women hence exerting more physical pressure on their weakened bodies. On the other hand women are likely to be involved with domestic activities, with minimal physical strain exerted on their bodies.

A comparative analysis of activities on which participants required assistance showed more men required assistance with cooking (89%) than women (86%), eating(8.7% men vs. 2.3% women), medication (10.87% men vs 2.3% women) and washing (41.3% men vs. 17.9% women). This may be because men were recruited into the study at an advanced stage and therefore required assistance more often than women. An alternative explanation is the gender role in a rural African setting whereby most of the domestic activities are carried out by women.

This study found an association between BMI and previous consumption of alcohol, in which the BMI was relatively lower among participants who previously took alcohol than those who had never taken alcohol. A history of alcohol consumption could explain faster progression of the disease due to reduced adherence to medication. An assessment of the relationship between alcohol consumption and HIV disease progression was done in a cohort of 349 HIV infected individuals by Jeffrey Samet and colleagues. Among patients with a history of alcohol problems receiving ART, alcohol consumption was associated with higher HIV RNA levels and lower CD4 counts (Samet J.H et al. 2003).The dietary habits of participants who previously took alcohol are more likely to be poor in comparison to those who had never taken alcohol. This may result in a rapid decline in their BMI.

Participants with a previous history of TB infection are at greater risk of social stigmatization and discrimination, than those without previous TB infection. Discrimination can result in physical and emotional isolation, depression and poor dietary habits, which may facilitate a further decrease in BMI. The effect of stigma on TB patients was examined by Jaggarajamma and colleagues among patients attending rural and urban TB clinics in India. They found that perceived (felt) stigma was more than enacted (actual) discrimination or unacceptability in the context of personal, family, community and workplace interactions (Jaggarajamma et al. 2008).

The effects of food insecurity are likely to be mediated through deficiencies in anti-oxidant vitamins (E, C, beta-carotene) and minerals (zinc, selenium, iron). Insufficient anti-oxidants due to increased utilization by the body tissues causes oxidative stress, tissue damage, increased HIV replication, higher viral loads and drops in the CD4 count.

The beneficial effect of antioxidant vitamins has been reviewed by Garland and Fawzi using data collected from several epidemiological studies. They found a protective effect of multivitamin (or multivitamin-mineral) supplements to slow the progression of HIV (Garland & Fawzi 1999).

The absolute CD4 count was on average lower in males compared to females even after adjusting for food insecurity, baseline WHO stage and level of social support required by participants. Findings similar to this were reported by Hubert and colleagues in the SEROCO study cohort on gender, disease progression and response to HAART (Hubert JB et al. 2002). Progression to AIDS was lower in women (RR=0.4, P<0.01) and the difference persisted after adjusting for age, baseline CD4 and viral load. This is contrary to the findings reported by Prins and colleagues who found that a decline in CD4 lymphocyte counts was not significantly affected by gender (Prins M, Robertson J.R., & Brettle R.P 1999). In their study, the absolute differences in CD4 lymphocytes count between men and women were stable, with the exception for the trajectory close to AIDS when the decline became steeper for men than women (Prins M, Robertson J.R., & Brettle R.P 1999).

Participants who are recruited at an advanced stage of disease are more likely to experience faster disease progression compared with those in early stages as reported by MacPherson and colleagues on the causes and predictors of mortality among HAART initiators in rural South Africa. They found that WHO stage 3 or 4 disease and CD4 count less than 50 at baseline were significantly associated with death. (MacPherson et al. 2008)

The risk of HIV related mortality was found to be higher in male than female participants (HR=1.6, 95% CI 0.75-3.4) which is also consistent with the findings reported by MacPherson and colleagues. They found that male gender was significantly associated with death (HR=1.626).

Moderate and severe food insecurity are highly significant predictors of death in this study. Similar findings were obtained by Paton and colleagues in a study on the impact of malnutrition on survival and the CD4 count response in HIV-infected patients starting ART in Singapore (Paton N.I et al. 2006). They found that moderate to severe malnutrition was a significant independent predictor of death (HR=2.19).

The level of social support required by the participant was found to be a significant predictor of death (HR= 5.6 95% CI 1.5-21.6) for those requiring maximum support when compared to participants who required no social support) after controlling for food security. Participants requiring maximum social support were more likely to be at an advanced stage of the disease and poor physical functioning. McInerney and colleagues also reported significant relationship between physical functioning and social support among HIV infected individuals receiving ART in KwaZulu-Natal (McInerney et al. 2008).

The strength of this secondary data analysis lies in the use of multiple regression techniques that can control for multiple confounders. Also, the adoption of questions from the Social support inventory for people with HIV/AIDS (SSIPWA) was important for assessment of its role in the Wellness study. The social support inventory differs from other measures of social support because it assesses received support, which is a better

predictor of outcomes of health-related interventions than perceived support (Collins et al. 1993;Schwarzer, Dunkel - Schetter, & Kemeny 1994).

The Adult Wellness study could assess only two dimensions of received support i.e. *want* (whether the individual wants the support) or *source* (who provides the support). It did not assess the other two dimensions of received support i.e. *have* (whether support is received) or *satisfaction* (how satisfied the individual is with the support received). This secondary analysis of data focused more on instrumental support with household activities and hence results should be interpreted within the specified limits. They should not be generalized to include emotional and informational support.

There are several limitations to this study. The information on food security could only be obtained using numbers of missed meals and not the composition or quality of the food consumed. The small numbers of participants who were classified as severe and moderate food insecure could distort the outcome of the study. However the results have shown a tendency in the outcome variables according to different levels of exposure variables. Social support could only assess instrumental support and not emotional and informational support, since they were not part of primary study. The inclusion of emotional and informational support would have made a better assessment of social support.

The exclusion of patients not on ART may introduce selection bias because they may differ from those receiving ART especially on health outcomes. The generalisability of the study to other populations is affected by the fact that, it was hospital-based. Hence results may not be generalized to the entire population of HIV patients in Bushbuckridge.

Missing data was observed for some participants. To minimize this effect analysis was only done on participants with complete information. The clinical characteristics at the baseline of participants with missing information on food security were explored. The results were following the same pattern as for those without missing data, with the majority shown to have CD4 counts below 50 (59.5%), underweight (50.7%) and HIV stage 3 (60.8%). Therefore, results which were obtained using participants with the complete information on food security can be considered representative of the whole cohort of participants attended during the study period.

4.1 CONCLUSION

The following variables were significant predictors of variation in BMI: food security, social support, gender and WHO stage (HIV). The predictors of the variation in absolute CD4 count were food security, gender and HIV stage. Food security and social support were predictive of death. The two exposure variables have been shown to determine the selected outcomes in this cohort of participants attended between March 2003 and May 2008. The results of this study are focused on food security and social support at the level of an individual participant and not on household-level. Gender difference has been found to be an important determinant of all the three outcome variables in the study, with females fairing much better than male participants.

4.2 RECOMMENDATIONS

The HIV/Wellness service in rural South Africa should put more emphasis on its package for basic nutrition, psychosocial and peer support by:

- Individualizing the nutritional management of HIV infected participants attending ART clinics after a thorough assessment by a qualified dietitian
- Using computerized nutritional software to assess nutritional requirements of HIV infected individuals.
- In order to understand how gender influences the health outcomes of participants in rural South Africa, qualitative methods should be integrated into the Wellness program to supplement information obtained through the use of quantitative questionnaires. For example, focus group discussions (FGD) should be arranged differently for male and female participants to identify possible socio-cultural determinants of HIV progression in rural South Africa.
- Social mobilization to increase the uptake of Voluntary Confidential Counseling and Testing services (VCCT).
- Early reporting to HIV clinics after confirmation of the disease in its early stages.
- A comparative study on adherence to HAART between patients attending urban and rural Wellness clinics.
- The government should provide more support to institutions providing Home Based Care (HBC) so as to attend to the needs of people living with HIV/AIDS and little or no social support.

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APPENDIX A: CLINICAL CARE FORM

Clinical care form **Rixile #:**_____

Rixile clinic: Tintswalo hospital **Hosp #:** _____

Personal information

Name: _____ Male/Female DOB: _____

Race: African / Coloured / White / Indian / Asian / Other

Address:_____ Contact tel nr: _____

Name known by:_____ Contact person: _____

Attending PHC: _____

Next of kin:_____

Next of kin contacts:_____

Consent wellness study **Cohort: Jan/ Jul; Feb/ Aug; Mar/ Sep; Apr/ Oct; May/ Nov; Jun/ Dec**				
Version number	**Date signed**		**Counselor**	
Study visit date	**Interview counselor**	**Health care worker**	**Bloods**	**Checked administr and F/U date given**

We would like to know how people with HIV are really doing. Please tell us what you are **actually** doing as we would like to know what is really happening, not what you think we want to hear. How you answer these questions will not affect your care or participation in this study. If you are unsure about a question, please give the best answer you can.

Main material walls of house are made off?		Main source of drinking water?		
Highest level of education. 0. No education; 1-12 Highest grade; 13. Tertiary education				
Occupational status *Mention all types of income*	1. Self employed 2. Student 3. Salaried worker	4. Unemployed and able/willing to work 5. Unemployed and unable/ not willing to work 6. Other, specify		
Income from non-work sources *(Ho usehold and personal)*	0. None 1. Old age pension 2. Disability grant 3. Child support grant 4. Private pension	5. Financial or non-financial gifts from household member 6. Financial or non-financial gifts from non-HH member 7. Receiving dividends from investments 8. Receiving money from a business 9. Other, specify	Household	Personal

How many people in your household?					
How many rooms are there in your house?					
House hold head: 6 = Self, If not self:	0. Female (18 – 60) 1. Male (18 – 60) 2. Female child less than 18		3. Male child less than 18 4. Female > 60 years 5. Male > 60 year		
Marital status	0. Never married 1. Divorced 2. Separated 3. Widowed		4. Married: Legal 5. Married: Traditional 6. Living together 7. Same sex partner		
Counselling and Testing:	Date of diagnosis: ____/____/_____				
Smoke	**Y N**	Cigarettes per day	Start (yr)	Stop (yr)	
Alcohol	**Y N**	Drinks per week	Start (yr)	Stop (yr)	
Dagga	**Y N**	In past OR Current: occasional/ Once per week/ > once per week/ every day			
Height without shoes (cm)				cm	

First visit; Date: ____/____/_____	**WHO Clinical Stage: _____** *(Underline appropriate conditions)*
I = Asymptomatic, Persistent generalized Lymphadenopathy **II** = Weight loss <10%, Minor skin changes or Prurigo, Uncomplicated Herpes Zoster, Recurrent sinusitis **III** = Weight loss >10%, Unexplained fever >1 month, Oral candidiasis, Vulvo-Vaginal Candidiasis > 1month, Oral hairy leukoplakia, Pulmonary TB within the past year, Pneumonia or Severe bacterial infections. Diarrhoea >1 month, Bedridden > 50% of day most days	**IV** = Extra Pulmonary TB, Esophageal Candidiasis, Mucocutanous Herpes Simplex Lesions > 1 Month, Pneumocystis Pneumonia, Kaposi Sarcoma, HIV wasting syndrome, Meningitis, HIV Encephalopathy/Dementia, Bedridden > 50% of day most days Cryptococcosis, Toxoplasmosis of brain, Cryptosporidiosis with diarrhoea > 1 month, Lmphoma, Atypical mycobacteriosis, Non-typhoid Salmonella septicaemia, Disseminated mycosis, Progressive Multifocal Leucoencephalopathy

Date:								
Whom of the following did the patient visit for healthcare? (Indicate all and number (#) of visits)								
Nearest clinic	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Another clinic	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Doctor (GP)	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Traditional healer	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
This hospital	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Another hospital	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Faith Healer	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Homeopath	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Chiropractitioner	Yes – No	#	Yes – No	#	Yes – No	#	Yes – No	#
Other,specify		#		#		#		#
Have you been hospitalised in the past 6 months? Indicate number of times and Complete Admission form								
Admissions	Yes – No	#=	Yes – No	#=	Yes – No	#=	Yes – No	#=
Do you need help with your daily activities from someone else?								
If yes, which activities:	Yes – No		Yes – No		Yes – No		Yes – No	
Cooking	Yes – No		Yes – No		Yes – No		Yes – No	
Cleaning	Yes – No		Yes – No		Yes – No		Yes – No	
Washing and dressing	Yes – No		Yes – No		Yes – No		Yes – No	
Eating	Yes – No		Yes – No		Yes – No		Yes – No	
Taking medicine	Yes – No		Yes – No		Yes – No		Yes – No	
Walking around house	Yes – No		Yes – No		Yes – No		Yes – No	
Toilet	Yes – No		Yes – No		Yes – No		Yes – No	
Go other places	Yes – No		Yes – No		Yes – No		Yes – No	
Other, specify								
Who helps you with these activities?								
Mother	Yes – No		Yes – No		Yes – No		Yes – No	
Father	Yes – No		Yes – No		Yes – No		Yes – No	
Partner	Yes – No		Yes – No		Yes – No		Yes – No	
Sibling	Yes – No		Yes – No		Yes – No		Yes – No	
Child	Yes – No		Yes – No		Yes – No		Yes – No	
Other family member	Yes – No		Yes – No		Yes – No		Yes – No	
Friend	Yes – No		Yes – No		Yes – No		Yes – No	
Health worker	Yes – No		Yes – No		Yes – No		Yes – No	
NGO/CBO/Church	Yes – No		Yes – No		Yes – No		Yes – No	
Community volunteer	Yes – No		Yes – No		Yes – No		Yes – No	
Other, specify								
How many hours per day do people help you?								
Did any of the following change since the previous study visit?								
Education/ Employment	Yes – No		Yes – No		Yes – No		Yes – No	
Household head/ Marital status	Yes – No		Yes – No		Yes – No		Yes – No	
Housing	Yes – No		Yes – No		Yes – No		Yes – No	
Water source	Yes – No		Yes – No		Yes – No		Yes – No	
How many drinks of alcohol do you take per week?								
How many cigarettes/ pipes do you smoke per day?								
Personal monthly earnings:	R		R		R		R	
Household earnings:	R		R		R		R	
In past week, how many times miss a meal because no food?								
Did you disclose your HIV status to anyone? (New disclosures since previous visit)								
If yes, date of disclosure (mm/yyyy)								
To whom: Sex partner	Yes – No		Yes – No		Yes – No		Yes – No	
Family	Yes – No		Yes – No		Yes – No		Yes – No	
Friend	Yes – No		Yes – No		Yes – No		Yes – No	
Other, specify								

Does this patient qualify for a disability grant? If yes give date applied (mm/yyyy)	Yes – No Date:	Yes – No Date:	Yes – No Date:	Yes – No Date:

TB and TB PREVENTIVE THERAPY			
First visit:	**Previous TB?** Yes – No	If yes: How many times? # = Start date (mm/yyyy) ___/_____ End date (mm/yyyy) ___/_____	**Previous TB PT?** Yes – No

Date:				
TB Symptoms, If Yes, specify: 1. Productive cough 2. Haemoptysis 3. Night sweats or fever 4. Weight loss 5. Other, specify	Yes – No	Yes – No	Yes – No	Yes – No
TB diagnosed, if Yes complete TB section on next page	Yes – No	Yes – No	Yes – No	Yes – No
Is patient on TBPT (INH), if yes complete TB PT section	Yes – No	Yes – No	Yes – No	Yes – No
CPT PREVENTIVE THERAPY:		**START DATE: ____ /____ _/_____**		
Currently on CPT PT	Yes – No	Yes – No	Yes – No	Yes – No
If yes, how many doses did you miss in past 3 days (0-3)				
Progress:				
Code: 1. Ongoing, 2. Stopped due to side effects, 3. Treatment interrupter, 4. Death, 5. Stopped due to clinical improvement, 6. Other				
Side effects:	Yes – No	Yes – No	Yes – No	Yes – No
If yes, Code: 1. Skin rash, 2. Nausea, 3. Allergic reaction, 4. Jaundice, 5. Peripheral neuropathy, 6. Other, specify				
FAMILY PLANNING				
Female patients: Pregnant?	Yes – No	Yes – No	Yes – No	Yes – No
Family planning: Mention all 1. Injectables 2. Pills 3. Barrier (Condom) 4. Intra-uterine device 5. Traditional methods 6. Other, specify				
SEXUALLY TRANSMITTED INFECTIONS				
FIRST VISIT ONLY Have you been treated for an STI in the past?	Circle Yes – No	If yes, on how many times?		# =
Have you had STI symp that resolved and started again with / without being treated?	Circle Yes-No #			
Was family planning discussed?	Yes-No	Yes-No	Yes-No	Yes-No
ALL VISITS Were you treated for an STI since the last study visit?		Circle Yes – No	Circle Yes – No	Circle Yes – No
If yes, how many times?	# =	# =	# =	# =
If yes, what were the symptoms?	Code	Code	Code	Code
Do you currently have STI symptoms?	Circle Yes – No	Circle Yes – No	Circle Yes – No	Circle Yes – No
If yes, what are the symptoms?	Code	Code	Code	Code
Codes: 1. Genital discharge, 2. Genital rash/blisters, 3. Genital sores, 4. Lower abdominal pain (females), 5. Public lice, 6. Other				
SEXUAL BEHAVIOUR				
How many sexual partners have you had in the **past 6 months**?	# =	# =	# =	# =
With each partner - how would you categorize the **pattern of condom use?** ***Code:*** *1. Always; 2. Occasionally; 3. Never; 4. No partner*				
Partner 1 (more regular /spousal)				

Partner 2				
Partner 3				
Partner 4				
Think of each partner you mentioned - did you use a condom at the **last sexual encounter** with this person (circle)				
Partner 1 (more regular /spousal)	Yes – No	Yes – No	Yes – No	Yes – No
Partner 2	Yes – No	Yes – No	Yes – No	Yes – No
Partner 3	Yes – No	Yes – No	Yes – No	Yes – No
Partner 4	Yes – No	Yes – No	Yes – No	Yes – No

EYE SYMPTOMS	Visit 1		FU		FU		FU	
Please complete all (Yes – No)	Left	Right	Left	Right	Left	Right	Left	Right
1.1. Itchy eye	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.2 Dryness	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.3 Sense of foreign body in eye	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.4 Visual deterioration	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.5 Blurring of vision	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.6 Cosmetic redness	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
1.7 Other eye symptoms								
1.8 Duration of symptoms								

EYE SIGNS *(Health care worker)*	Visit 1		FU		FU		FU	
Please complete all (Yes – No)	Left	Right	Left	Right	Left	Right	Left	Right
Distinct triangular shaped vascular in growth with apex toward the cornea but **NOT on the cornea**. (Yes – No)	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
Extent of involvement Nasal side = 1 Temporal side = 2 Both sides = 4								
Raised pearly white mass NOT on cornea (Yes – No)	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
Distinct triangular shaped vascular in growth with apex toward the cornea **On cornea**. (Yes – No)	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
Raised white mass ON cornea (Yes – No)	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
Other eye signs present (Yes – No)	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N	Y – N
Other eye signs								
If Yes, specify								
If any signs are present: Visual acuity without glasses or contact lenses	20	20	20	20	20	20	20	20
Date referred for biopsy	Yes-No __/__/200_		Yes-No __/__/200_		Yes-No __/__/200_		Yes-No __/__/200_	

ANTHROMORPHIC MEASUREMENTS				
Waist	cm	cm	cm	cm
Hip	cm	cm	cm	cm
Blood pressure (last of three seated)	____/_____	____/____	____/____	____/____
Urine dipstix: Protein (0-3+)				
Urine dipstix: Blood (0-3+)				

Form completed by:				
Sign:				

Date:				
Checked by HCW:				
Sign:				
Date:				

Date				
Weight (kg)				
WHO stage If progresses, state reason				
Main complaint				
Assessment				
Indicate ICD 10 for main diagnosis				
First visit: Previous ART?	Yes – No If yes, specify	NVP single dose Mono therapy	Dual therapy HAART	Start: ____/_____ End: ____/_____
On ART at present?	Yes – No	Yes – No	Yes – No	Yes – No
Estimate how much of your ART taken in the last month?				
Code: All = 100%; All most all = 90%; Most = 80%;; About half = 50%;; Sometimes = 20%; None = 0%				
Check ART CCF - How many doses did you miss in the last three days?				
Adverse events? Complete adverse event form	Yes – No	Yes – No	Yes – No	Yes – No
Facial lipo atrophy (Grade 0-4)				
Special investigations **Circle tests done** (Record results on lab sheet) (See ART CCF for patients on ART)	CD4, FBC, RPR Cholesterol, Creatinine, PAP smear, Sputum AFB/Culture CXR	CD4, FBC, RPR Fasting LDL, Creatinine PAP smear Sputum AFB/Culture CXR	CD4, FBC, RPR Fasting LDL, Creatinine PAP smear Sputum AFB/Culture CXR	CD4, FBC, RPR Fasting LDL, Creatinine PAP smear Sputum AFB/Culture CXR
Other instructions to patient.				
Treatment issued Specify amount of tablets!!	**Complete last page if patient on TB treatment or TBPT**			
	TBPT/ TB	Y / N	Y / N	Y / N	Y / N
	Bactrim	Y / N	Y / N	Y / N	Y / N
	MVT	Y / N	Y / N	Y / N	Y / N
	Family Planning on this Visit?	Y / N	Y / N	Y / N	Y / N
	Other				
Admitted to hosp in past 6 months		Yes – No	Yes – No	Yes – No	Yes – No
If Yes, Date of admission					
Facility (Tins/ Other)					
Date of Discharge					
Outcome					
Final diagnosis 1. TB, pulmonary 2. TB, extra pulm 3. Pneumonia, PCP 4. Pneumonia, other 5. Meningitis, Cryptococcal 6. Meningitis, Bacterial 7. Sepsis/ Bacterial infection 8. ARV related 9. Other, specify				

Name of person consulting				
Follow up study date				

TB: Diagnosis, treatment or TBPT

Episode 1

TB diagnosed		**TB Preventive Therapy**		
Date of diagnosis		Start date: Month 1	____/_____/_____	In the past three days, how many doses of TPBT did you miss?
How was the diagnosis made	*Mark all that apply* 1. Sputum AFB 2. Sputum Culture 3. CXR 4. Biopsy or FNA 5. Clinical history 6. Other, Specify	Month 2	____/_____/_____	
		Month 3	____/_____/_____	
		Month 4	____/_____/_____	
		Month 5	____/_____/_____	
		Month 6	____/_____/_____	
		Stop date	____/_____/_____	
Date treatment started		Reason stopped	1. Completed 6 months of TBPT 2. Side effects 3. Treatment interrupter 4. Developed TB symptoms 5. Other, specify	
Date treatment stopped				
Treatment outcome	1. Completed Treat 2. Interrupted Treat 3. Died 4. Other			
Fill in admission form with details and tick if completed				

Episode 2

TB diagnosed		**TB Preventive Therapy**		
Date of diagnosis		Start date: Month 1	____/_____/_____	In the past three days, how many doses of TPBT did you miss?
How was the diagnosis made	*Mark all that apply* 1. Sputum AFB 2. Sputum Culture 3. CXR 4. Biopsy or FNA 5. Clinical history 6. Other, Specify	Month 2	____/_____/_____	
		Month 3	____/_____/_____	
		Month 4	____/_____/_____	
		Month 5	____/_____/_____	
		Month 6	____/_____/_____	
		Stop date	____/_____/_____	
Date treatment started		Reason stopped	6. Completed 6 months of TBPT 7. Side effects 8. Treatment interrupter 9. Developed TB symptoms 10. Other, specify	
Date treatment stopped				
Treatment outcome	5. Completed Treat 6. Interrupted Treat 7. Died 8. Other			
Fill in admission form with details and tick if completed				

Death

Name of informant		Date of death (DD/MM/YYYY)	
Relationship to the deceased		Was the death HIV related?	0. No 1. Yes
Cause of death as on death certificate:	Available/ Not Available	Confirmed TB at time of death?	0. No 1. Yes 2. Unknown
Cause		Where did the patient die?	
Contributing		Admitted since prev visit? *(Complete admission forms)*	0. No 1. Yes 2. Not known
Underlying			
Date completed:	_____/_____/_____	Name of person completing form	

Special investigations flow sheet

Test	Date done	Results
RPR		
PAP Smear		
CXR		
Other tests:		

Test	Result	Result	Result	Result	Result	Result
Date						
CD4						
Viral load						
WCC						
Hb						
Total lymphs						
Plt						
Total Bili						
ALT						
Creatinine						
Cholesterol						
Glucose						
U-dipstix						

Sputum	Results	Results	Results	Results	Results	Results
Date sent:						
AFB 1						
Culture						
AFB2						
Culture						

APPENDIX B: ETHICAL APPROVAL FOR PRIMARY STUDY

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Pronyk/Martinson

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M03-05-26

PROJECT Developing Comprehensive Services for People Living with HIV/AIDS in the Bohlabela District of the Limpopo Province

INVESTIGATORS Drs P/N Pronyk/Martinson

DEPARTMENT RADAR/PHRU, CH Baragwanath Hospital

DATE CONSIDERED 03-05-09

DECISION OF THE COMMITTEE Approved unconditionally

Unles otherwise specified the ethical clearance is valid for 5 years but may be renewed upon application This ethical clearance will expire on 1 January 2008.

DATE 03-06-02 CHAIRMAN.....(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Dr A Heyer
Dept of RADAR· HSDU
Works2\\lain0015\HumEth97.wdb\M 03-05-26

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DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

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

DATE July 21/03 SIGNATURE .....

PLEASE QUOTE THE PROTOCOL NO IN ALL QUERIES : M 03-05-26

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX C: ETHICAL APPROVAL FOR SECONDARY STUDY

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Lweno

CLEARANCE CERTIFICATE	PROTOCOL NUMBER M080981
PROJECT	Food Insufficiency and Social Support as Determinants Health Outcomes among Patients Needing Rural HIV Clinic in Hushbuckridge, South Africa
INVESTIGATORS	Dr D Lweno
DEPARTMENT	School of Public Health
DATE CONSIDERED	08.09.26
DECISION OF THE COMMITTEE*	

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

DATE CHAIRPERSON .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

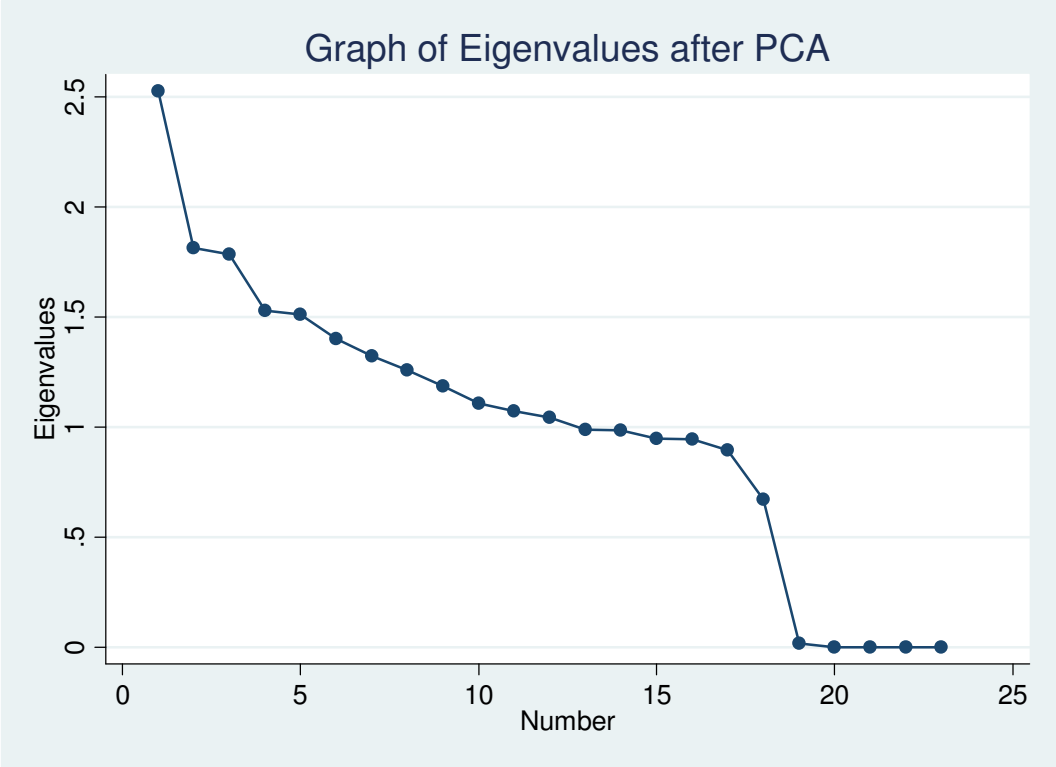
cc: Supervisor: Dr M Mashabela

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

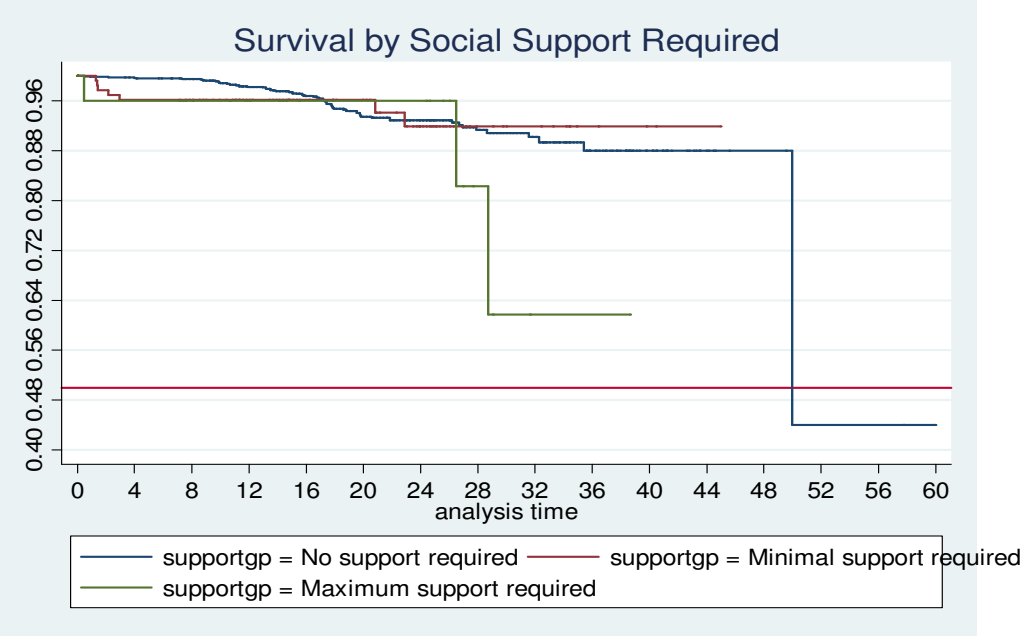
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX D: GRAPH OF EIGENVALUES:

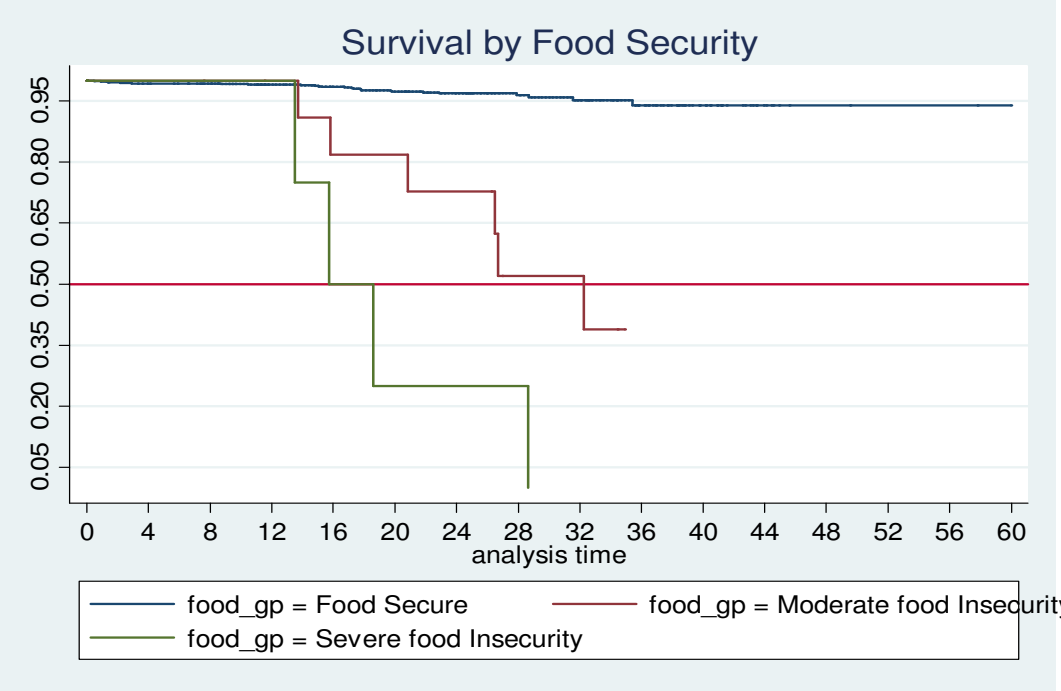


APPENDIX E: KAPLAN MEIER SURVIVAL CURVES

1. Social Support required by Participant



2. Level of Food Insecurity



APPENDIX F: WHO STAGING OF HIV

REVISED WHO Clinical Staging of HIV/AIDS FOR ADULTS AND ADOLESCENTS

Primary HIV infection
Asymptomatic
Acute retroviral syndrome

Clinical Stage 1
Asymptomatic
Persistent generalized lymphadenopathy (PGL)

Clinical Stage 2
Moderate unexplained weight loss (<10% of presumed or measured body weight)
Recurrent respiratory tract infections (RTIs, bronchitis, sinusitis, otitis media, pharyngitis)
Herpes zoster
Angular chelitis
Recurrent oral ulcerations
Papular pruritic eruptions
Seborrhoeic dermatitis
Fungal nail infections of fingers

Clinical Stage 3
Conditions where a presumptive diagnosis can be made based on the basis of clinical signs or simple investigations
Severe weight loss (>10% of presumed or measured body weight)
Unexplained chronic diarrhea for longer than one month
Unexplained persistent fever (intermittent or constant for longer than one month)
Oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis (TB) diagnosed in last two years
Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Conditions where confirmatory diagnostic testing is necessary
Unexplained anaemia (< 8gm/dl),and or neutropenia (<500/cc) and or thrombocytopenia (< 50,000/cc) for more than one month.

Clinical Stage 4
Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations
HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe or radiological bacterial pneumonia

Chronic herpes simplex infection
Oesophageal candidiasis
Extrapulmonary TB
Kaposi's sarcoma
Central nervous system (CNS) toxoplasmosis
HIV encephalopathy

Conditions where confirmatory diagnostic testing is necessary:
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacterial infection
Progressive multifocal leukoencephalopathy (PML)
Candida of trachea, bronchi or lungs
Cryptosporidiosis
Isosporiasis
Visceral herpes simplex infection
Cytomegalovirus (CMV) infection (retinitis, or of organ other than the liver, spleen or lymph nodes)
Any disseminated mycosis (histoplasmosis, coccidiomycosis, penicilliosis)
Recurrent non-typhoidal salmonella septicemia
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Visceral leishmaniasis