

Prevalence of Depression and Its Relationship to Care Engagement among Men Living with HIV

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**Definition of Terms**

Care engagement:

A patient can be termed to have good care engagement in HIV care when they have: consistent clinic attendance, and good adherence to medication (taking medication consistently, as prescribed, and not skipping doses), which together result in suppressed viral load (Gardner et al., 2011; Watt et al., 2019) .

Depression:

Nanni and college (2015), characterized depression as “lack of interest and pleasure in daily activities, significant weight loss or gain, insomnia or excessive sleeping, lack of energy, inability to concentrate, feelings of worthlessness or excessive guilt, and recurrent thoughts of death or suicide” (Nanni et al., 2015, p. 5).

## **Abstract**

**Background:** The study was focused on the prevalence of depression among men living with HIV, who are in HIV care, and assessed the relationship between depression and care engagement. Several factors have been associated with care engagement among people living with HIV, including depression, but also lack disclosure due to stigmatization, poor social support, high pill burden, poor knowledge of ART, as well as young or old age. However, little is known about how these risk factors play out in men, as most of literature have been directed on women.

**Objectives:** To understand the prevalence of depression in men living with HIV, attending Mawenzi Care and Treatment Clinic, and the effect of depression on care engagement.

**Method:** A cross-sectional survey was conducted in the Mawenzi CTClinic, in Moshi, Kilimanjaro, Tanzania. Adult men living with HIV, 18 years and above, were invited to participate. A composite, continuous scale was developed to measure care engagement. At the clinic participants were asked about their medication adherence, their clinic cards were also checked for their viral load. Self-reported medication adherence and viral load were combined to form the outcome variable or as an indicator of patient care engagement. A total of 203 participants were enrolled in the study, with a mean age of 48 years.

**Results:** The prevalence of depression among men living with HIV was 47.8 %: 35.0 % had mild symptoms, 8.9% moderate symptoms, and 3.9% severe symptoms. There was an indirect relationship between predictors: stigma was associated with depression and depression was associated with care engagement.

**Conclusion:** HIV-related stigma and depression should not be underestimated because of their association with each other. Symptoms of depression need to be treated early, to reduce their effects on care engagement and hence disease progression.

## Chapter 1: Introduction

Globally the total number of people living with HIV in 2019 was 38.0 million, and one million of these were living in Tanzania (United Nations Programme on HIV/AIDS, 2020). The use of antiretroviral drugs has significantly prolonged the lives of individuals living with HIV and changed the course of the disease, transforming HIV from a life-threatening illness to a chronic condition (Colvin, 2011; Sule et al., 2018). Yet, despite these significant advances, people are still not engaging sufficiently in treatment to achieve minimal HIV-related morbidity and mortality (Ware et al., 2013).

According to the Tanzania National Guideline for Management of HIV and AIDS (2019), people living with HIV are recommended to be enrolled with a clinic for HIV care. Patients are required to engage with and utilize HIV care which means consistently visiting clinics and keeping antiretroviral treatment (ART) adherence high (Burchell et al., 2015). Consistent clinic visits and ART adherence promote low undetectable viral load levels, and CD4 counts above 350cell/mm<sup>3</sup> which are indicators for good HIV care (United Republic of Tanzania, 2019).

The current literature suggests that there are several factors associated with poor care engagement in HIV care among people living with HIV, including lack of disclosure due to stigmatization, poor social support, high pill burden, poor knowledge of ART, and depression, as well as young or old age (Kaplan et al., 2017). Other associated factors include low education levels, longer distance to a clinic, alcohol consumption, unemployment, and low wage employment (Marwick & Kaaya, 2010; Ramadhani et al., 2007; Sikkema et al., 2010; van der Kop et al., 2010). This literature review will discuss how different levels of these factors contribute to engagement in HIV care and adherence to medication in people living with HIV.

Social support from people close to oneself is an important issue to patients because of its role in coping with a new HIV diagnosis. A new HIV diagnosis is often accompanied by psychological distress and the need for new care routines. A treatment supporter can be a reminder of medications, provide emotional support, lessen stress, provide care, and therefore promote good care engagement (Anderson et al., 2018). By contrast, lack of social support can lead to poor adherence which can cause viral resistance, then treatment failure (Huynh et al., 2013). One reason for the association between a lack of social support and treatment failure could be depression (Castaño & Maurer, 2015). The more social support for HIV management

that a patient has, the more likely to be retained in HIV care and the more the ART adherence rate improved (Anderson et al., 2018; Hill, Huff, & Chumbler, 2018).

However, social support from partners, friends, or relatives is only possible if patients share their HIV status. Yet, disclosing one's HIV status is not a simple thing to do. There are risks associated with a disclosure: it can lead to rejection, being stigmatized, isolation and discrimination (Hoffmann et al., 2017; Kumar et al., 2015). Therefore, disclosure of HIV status must be done carefully with assistance and selectively to family members and friends (Gaskins et al., 2012).

Insufficient knowledge of ART initiation can be a primary barrier to engagement in HIV care and ART uptake (Gwadz et al., 2015). Misunderstandings about the illness, such as not understanding that one can feel well and yet need treatment, can also lead to a lack of commitment to taking ART. Not only is poor knowledge a barrier, but negative beliefs about HIV disease and treatment effectiveness also play a role. In traditional African society, beliefs that people who get infected may be bewitched are prevalent, so patients may turn to prayer rather than medication (Britzke et al., 2003; Kisenyi et al., 2013; Maman et al., 2009). Relatedly, another issue is illiteracy and thus an inability to comprehend medication instructions; this is particularly important for ART as consistency in daily medication therapy is key as if violated may result in poor treatment outcomes (Adam et al., 2003; Bhatti et al., 2016).

Pill burden has been reported as one of the reasons for non-adherence in HIV care. According to patients there are many tablets to take, the taste is unpalatable, and the size may cause distress, and so a patient may be tempted to miss some doses (Adhikari et al., 2019; Nabukeera-Barungi et al., 2015). This makes adopting the new routine and sticking to it consistently more difficult. Added to this, ART does not result in a cure, which may reduce patient motivation to take up this difficult routine (Letta, Demissie, Oljira, & Dessie, 2015).

Previous studies have reported long distances as one of the causes of missed clinic appointments for patients who are from remote areas in low-income countries (Hardon et al., 2007). Public transport may not be available, or the patient may spend a whole day at the facility because there may be a long wait for a drug refill, which can be very exhausting and discouraging. These problems can be associated with a patient being lost to follow-up care (Nabukeera-Barungi et al., 2015).

In terms of socio-demographic factors, being aged less than 30 or older than 45 is positively associated with loss to follow-up (Alvarez-Uria et al., 2013). Young women or adolescents sometimes ignore the importance of medication adherence and clinic appointments, probably because of poor counseling, because they feel physically normal, or because they don't know their HIV status (Knettel et al., 2018). On the other hand, it can be a challenge to get patients aged over 45 with little or no formal education to engage in care, because they show lack of awareness in the importance of treatment as well as negligence in ART adherence and clinic appointments (Alvarez-Uria et al., 2013).

Unemployment or occupations with low wages affect the way an individual meets their basic needs and HIV care. In a study done in Atlanta, Georgia (Ehman et al., 2017), patients who were not retained in care had higher rates of unmet needs related to food and inability in being able to pay for rent. Patients who do not earn enough to cover their basic needs understandably find it difficult to attend clinic appointments and adhere to medications. To unemployed patients, adherence is difficult since they are advised not to take pills on an empty stomach: some may take their pills once a day in the evening instead of twice because that is the only time they have food (Hardon et al., 2007).

Another risk factor for poor adherence is hazardous levels of alcohol use (Kader et al., 2014). Studies show this is associated with minimal antiretroviral utilization and poor viral suppression which are the consequences of high level of alcohol consumption. Drinkers with moderate, heavy, and frequent heavy drinkers were more likely to be non-adherent compared to non-drinkers (Chander et al., 2006).

Among people living with HIV in sub-Saharan Africa, men have a lower HIV prevalence compared to women, but HIV-related deaths are more prevalent in men (Baisley et al., 2018; DiCarlo et al., 2014). There are specific factors that may relate to poor care engagement in men with HIV, such as some forms of masculinity (Kaplan et al., 2017; Sileo et al., 2018). For instance, in a study in KwaZulu Natal, South Africa, it was difficult for men to express their needs or emotions particularly when they are sick. It is perceived as a sign of weakness and femininity, and so it is hard to share with family members about illness (Zissette et al., 2016). According to Zissette et al constructions of masculinity tend to suggest that a man's role is to take care of family, not have his support needs met, and therefore he cannot talk about his health status, especially his HIV status. In one study done in Dar es Salaam, Tanzania, men were more

non-adherent to care than women, which might impact the treatment outcome for men (Hawkins et al., 2011). Men in this cohort had significantly higher rates of loss to follow-up and non-adherence to clinic visits, which can be a risk factor for mortality and immunological failure. One of the barriers to HIV care in men is perceived loss of masculine characteristics after HIV diagnosis, such as being in control of their lives and of their ability to serve as role models and providers for their families (Conserve et al., 2019; Yamanis et al., 2017). These observations suggest that men may not be accessing care, may not be adhering to care, or may not be retained in care as well as women are (Bor et al., 2015; Naidoo et al., 2017).

Studies have addressed the role of psychosocial factors in care engagement in men having sex with men, but relatively little is known about heterosexual men living with HIV in low- and middle-income countries. In heterosexual men living with HIV in high-income countries, depression and suicidal thoughts have been found to be factors for poor care engagement (Dang et al., 2012; Pecoraro et al., 2015). In homosexual men living with HIV, several reasons were associated with poor care engagement: perceived health status, fear of being seen in HIV related care settings, negative self-image (perceived stigma), economic difficulties, and health system challenges (Li et al., 2017; Young et al., 2015).

Studies on other populations, such as men who have sex with men, have shown that common mental disorders (CMD), especially depression, can be a major barrier to antiretroviral therapy adherence for PLHIV. The negative impact of depression in concentration, memory, problem-solving, and motivation can interfere with medication adherence (Kidia et al., 2015). Once an HIV patient is depressed, they struggle to adhere to medication regimes and clinic appointment schedules. More generally, depression can adversely affect quality of life in PLHIV, can influence the disease outcome, and can influence high-risk behaviors that lead to the risk of transmission (Amare et al., 2018). Aside from disengagement in treatment, mental health disorders have been related with HIV infection because they can be risk factors for acquiring the infection, they can be co-morbidities or complications of the infection, or they can be a mediator for the disease progression (Colvin, 2011). Mental health disorders can negatively impact HIV treatment, adherence to treatment, and the prognosis of HIV infection (Velloza et al., 2017).

Depression in particular is relatively common in HIV-positive adults (Chan et al., 2016). PLHIV often suffer from depression as they adjust to the diagnosis and treatment at the same time, face the difficulties of living with a chronic life-threatening illness. For example, a

patient may face some difficulties such as serostatus disclosure, shortened life expectancy, pills burden, stigma from friends or the family, and lack of social support (Blashill et al., 2011; Kagee, 2012; Kiene et al., 2018). People who are living with HIV/AIDS apart from having a disease, nevertheless they are impacted by psychosocial problems such as stress, financial difficulties, and discrimination from a society which is caused by the disease (stigma), which later can influence mental health disorders (Fawzi et al., 2017; Mayston et al., 2012).

### **Statement of the Problem**

Most studies that have been done on depression concerning care engagement with HIV treatment have been done within PLHIV in general, women, and men who have sex with men, but not much is known specifically about heterosexual men's engagement in HIV care (Ren et al., 2018). There is limited information on the role of depression in care engagement in heterosexual men living with HIV. Yet, in previous studies in Tanzania, depression prevalence was found to range from 15.5% to 21% to PLHIV in Moshi (Ramadhani et al., 2007).

This study therefore sought to answer the following two questions:

1. What is the prevalence of depression among men living with HIV attending care at Mawenzi CTC?
2. Is there a relationship between HIV care engagement and depression? It was hypothesized that depression would be associated with poorer care engagement.

## Chapter 2: Method

### Study Setting and Design

The study was conducted at the Mawenzi Regional Hospital, Tanzania. It is the only regional referral hospital in the Kilimanjaro region and treats many HIV-positive patients in its Care and Treatment Clinic (CTC). The cross-sectional survey investigated the relationship between depression and care engagement at Mawenzi CTC Regional Hospital in Moshi.

### Sample Size Calculation

The G\*power calculator was used in the sample size calculation (Kang, 2021). The sample size calculation was based on the effect size obtained from a previous study (Ramadhani et al., 2007) where 16% were non-adherent, and an odds ratio of 2.1 was found for the relationship between depression and non-adherence. Setting alpha at 0.05 and the F statistic at 0.11, this study would need 200 participants to detect a similar effect.

### Sample

The sample was randomly selected from the population of men living with HIV who were in care at the Mawenzi CTC Regional Hospital, aged 18 and above. They were invited to participate if they were scheduled to come to the clinic during the data collection period and were enrolled in the study if they gave consent to participation. All patients are required to attend clinic once a month or once in three months depending on the current viral load test results.

The participants were recruited from the CTC, which is open Monday-Friday. All patients, once registered for the day, have their height, weight, and blood pressure briefly assessed by a triage nurse. This occurs in a large waiting room. The triage nurse introduced me to all patients who were in the waiting room, and she explained the study and the process of sampling. At most, 50-70 patients attended clinic per day. After introductions, every  $n^{\text{th}}$  patient was systematically selected from the list which was provided by the clinic data office a day before. The participants were selected according to the number available in that list, as we aimed to interview between five and six patients per day (thus  $n$  varied from day to day). On a typical day, we would have close to 25 patients who have clinic due dates, and then we would select every fifth person in the list for the interview. There were very few patients who refused to participate in the study. Reasons given were: wasting time by participating in the study; and internalized stigma (worrying how others will think of him after consenting to participate). In

cases of refusal, the next patient on the list was selected. The total of 203 participants included in the final analysis included three patients who were approached during the pilot, since no changes were made to the method or questionnaires after the pilot.

To ensure as representative a sample as possible, clinic staff phoned those patients who were late for their appointments and confirmed that they would come that day. If they confirmed that they were coming, they were retained in the study. In the case of a refusal or missed appointment we replaced the immediately next patient on the list. That procedure was to ensure that the selection of patients was truly random and that the randomness of the selection was visible to patients, thus eliminating any potential for stigma. The Primary Investigator (MM) then introduced selected patients to research assistants, who were stationed in private rooms and who took patients through the informed consent procedure and interviewed them, if they consented to participation.

## **Measures**

### ***Depression***

Symptoms of depression were assessed using the PHQ-9 (Patient Health Questionnaire), a tool adapted from the PRIME-MD which addresses several mental health diagnoses and designed as a self-administered questionnaire by Drs. R.L. Spitzer, J.B. Williams, and K. Kroenke (de Man-van Ginkel et al., 2012; Kroenke et al., 2001). The instrument asked how often a patient had been bothered by various symptoms, such as loss of pleasure, or insomnia, or hypersomnia. Answers were given on a 4-point Likert scale, ranging from “not at all” to “nearly every day”. To assess depression, the item scores were summed. According to US norms (Kroenke et al., 2001), scores of 0-4 points can be interpreted as no or minimal depression, 5-9 as mild depression, 10-14 as moderate depression, 15-19 as moderately severe depression, and 20-27 as severe depression. This tool had also been used in other studies in Tanzania and Kenya, in which Cronbach’s alpha was 0.78 (Ahaneku et al., 2016; Dow et al., 2016).

### ***Anxiety***

The Brief Symptom Inventory (BSI) was developed by Derogatis in 1975 and it was used in this study for assessing anxiety symptoms (Derogatis & Melisaratos, 1983; Lang et al., 2009). The tool had a list of 6 problems that the patient may encounter in their daily life because of their HIV status, for the past week. The tool asked the patient if he had felt any of these symptoms: nervousness, feeling tense, scared, panic, or restless. The patient had to rate the severity of the

problems with answers given on a 5-point Likert scale, ranging from “not at all” to “extremely”. In a previous study in Tanzania, Cronbach's alpha was 0.92 (Knettel et al., 2018).

### ***HIV Related Stigma***

The HASI (HIV/AIDS Stigma Instrument) was used to assess the HIV-related stigma experienced by the participant. The scale captures two broad types of stigma, internalized and enacted, experienced in the last month (Maluccio et al., 2017). Internalized or perceived stigma is when one feels or imagines that he or she was treated badly or isolated from others once they knew his or her HIV status. Enacted or external stigma referred to the actual experience of stigma (Hasan et al., 2012). The questions ask a patient to say if he had experienced any stigmatizing acts like being avoided, blamed, or called bad names because of his HIV status. The responses were given on a 4-point Likert scale, ranging from “never” to “most of the time”. This tool has been previously used in a multi-national study, which collected data in Lesotho, Malawi, South Africa, Swaziland, and Tanzania, where Cronbach’s alpha ranged from 0.76-0.89 (Holzemer et al., 2007).

### ***Alcohol Use***

The Alcohol Use Disorders Identification Test (AUDIT) was used to assess alcohol use and it was developed by World Health Organization (Babor et al., 2001). This tool had 10 questions on the use of alcoholic beverages for the past 3 months, and among them, 3 questions talked about the monthly experience (Reinert et al., 2002). That tool asked a patient about his experience in taking alcohol, how often he had a drink that contained alcohol, and the amount of alcohol he used on a normal day. Answers ranged on a 5-point Likert scale from “never” to “daily or almost daily”, while the two last questions were yes or no which asked a patient if he had been injured or whether other people were concerned about his drinking. The tool had been used in a previous study done in Tanzania in which Cronbach's alpha was  $>0.85$  (Zhao et al., 2018).

### ***Medication Specific Social Support***

This tool assessed medication social support through 4 questions, with a fifth question that asked about the particular person who provided that support (Denison et al., 2015; Lehavot et al., 2011). The questions explored things that other people do to help patients manage their HIV medication, such as reminding the patient to take medication or encouraging the patient to take medication. Scores on a 5-point Likert scale include answers ranging from “never” to “very

often”. This tool was used before in Tanzania, and Cronbach's alpha in this setting was 0.92 (Lehavot et al., 2011).

### ***HIV Disclosure***

This tool assessed HIV disclosure with 5 yes/no questions. Patients were asked about their HIV status disclosure, and if they had disclosed it to their sexual partner or wife or a family member or a friend. There were also two additional disclosure-related questions, which asked about the year the diagnosis to when a patient did his/her first sero status disclosure, and if there was anybody who had ever disclosed participant’s HIV status without his consent. This tool had been successfully used in a study on women living with HIV in Tanzania (Knettel et al., 2018).

### ***Socio-Economic Status (SES)***

SES was assessed through four socio-economic questions, which included variables like monthly income earning, owning a house, owning a mobile phone, or having an electric appliance in a house. The mentioned variables were used to measure the position of an individual in a household in a particular society. Participants were asked about their monthly income, and if they owned a house or rented, if they owned a mobile phone and if they owned any electric appliance in their households. This composite variable representing the socio-economic status of the participants was constructed as part of the data analysis process.

### ***Treatment Adherence Assessment***

Self-reported adherence was measured by the Treatment Adherence Assessment (TAA) which is comprised of 9 questions derived from two previous studies (Phillips et al., 2016; Reynolds et al., 2007). The tool asked a patient the number of pills prescribed; how many pills they had taken in the last 4 days; how many pills had been taken for the last 30 days and two self-report Likert type scale items asking if participants had taken their medication as prescribed (Phillips et al., 2016; Reynolds et al., 2007). This tool had been used in previous studies in Tanzania, though reliability statistics were not available (Boogaard et al., 2011).

### ***Clinical Information***

The current ART regimen and the most recent viral load were recorded from the patient’s record.

### ***Care Engagement***

While clinic visits are an indicator of care engagement, they were not used as such in this study due to their complicated scheduling. According to the Tanzania National Guideline for the

Management of HIV and AIDS (2019), a stable patient may come to the clinic once or twice in 6 months, while an unstable patient needs to come every month. The past 3 months' clinic visits were thus not thought to be a good indicator, since stable and unstable patients have different clinic schedules, and unstable patients with poor care engagement would have similar levels of visit recorded.

Similarly, CD4 counts were not included in this study as a measure of adherence because, CD4 counts are only checked in the initial stages of HIV care, while viral load tests are done after every 6 months (United Republic of Tanzania, 2019).

A composite, continuous scale was developed to measure care engagement, based on the TAA and viral load, and using the imputed data that were to be used in later models. Patients' clinic cards were checked for their most recent viral load. Self-reported medication adherence (the TAA) and viral load were combined to form the outcome variable or as an indicator of patient care engagement.

While some studies have noted that with infrequent testing, measures of high viral load are not always reliable predictors of adherence it is a widely used and recommended measure for patient care (Lecher et al., 2015). High viral load in patients undergoing treatment is indicative of treatment failure. While this may be not only a result of non-adherence, poor adherence does lead to higher viral counts, also known as 'viral blips' (Lecher et al., 2015). However, the definition of concentration of viral load that constitutes a 'viral blip' differs between studies. Lower bounds of <20 or <50 copies per ml are often used to indicate minimal viral load, based on equipment sensitivity (Verhofstede et al., 2010). High viral load is sometimes indicated by concentrations of >50 copies per ml, >500 copies per ml, or >1000 copies per ml (Fung et al., 2012). Some studies have also used <400 or >400 copies per ml (Childs et al., 2015) or <400, between 400-999 or >1000 copies per ml (Taiwo et al., 2011). Beyond the inconsistencies between studies, there may be significant differences within the middle category between upper and lower bounds of the chosen range (Taiwo et al., 2011).

In this study, a 3-level split was used for viral load, consistent with what is used in clinics, where the levels were <20/Target not detected for a low load (coded as 1), 20-900 copies/ml for a moderate load (coded as 0.5), and >900 copies/ml as high viral load (coded as 0; (Sire et al., 2011). The coding of 1, 0.5, and 0 was used to avoid a binary split on viral load, as that would provide only a low-resolution solution. Although a further split was considered to

divide the 20-900 group into 20-400 and 401-900, this would have left the upper end of this division with only 2 data points, and these readings were judged to be more similar to the moderate rather than the high adherence group. The composite adherence variable using the 3 categories of viral load (< 20 copies, >20- 900 copies, and >1000 copies) was highly correlated on average with its individual components (see Table 1).

A ratio between 0 and 1 was calculated for each of the self-report measures included in the TAA for pills taken over the last 4 days, 30 days, and self-reported adherence fidelity. The values for the self-report and viral load measures of adherence were then summed, resulting in a new adherence scale ranging between 0-4, with 4 indicating good adherence. Table 1 shows that the components of this scale correlate highly with each other.

**Table 1: Association between adherence subscale measures.**

	1	2	3	4	5	6	7	8	9	10
1. Viral load	1.00									
2. Treatment Adherence Assessment 4 days	0.01	1.00								
3. Treatment Adherence Assessment 30 days	0.18 ***	0.03 ***	1.00							
4. Treatment Adherence Assessment Likert Rating	0.24 ***	0.15 ***	0.47 **	1.00						
5. Adherence combined self-reports	0.23 ***	0.38 ***	0.57 **	0.96 *	1.00					
6. Viral load 3-imputed	1.00 *	0.01 ***	0.18 ***	0.24 **	0.23 ***	1.00				
10. Total care engagement	0.88 *	0.20 ***	0.43 **	0.66 *	0.68 *	0.69 *	0.87 *	0.85 *	0.86 *	1.00

\* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$

\*0.05 marginal significant

\*\* 0.01 significant

\*\*\* very significant

**Translation**

Kiswahili is the most widely spoken language in the Kilimanjaro region, and all instruments were already available in Kiswahili, and all the interviews were done in Kiswahili. No further translation was carried out.

**Data Management and Analysis**

Data were collected and stored on a password-protected computer so that only members of the research team were able to access the data. No names or other identifying details were collected, and thus the data were anonymous. Data were collected using hardcopy questionnaires which were then entered into Redcap. The data were stored in a password-protected Redcap file. Hardcopy questionnaires were stored in a locked file cabinet to which only the research team had access.

Summary statistics for the various measures were created as appropriate. Descriptive statistics (proportion, mean, median, interquartile range, as appropriate) were used to describe the sample.

The first analysis estimated the prevalence of depression. Patients with symptoms of mild depression who scored 5-9 were treated as depressed, together with those with more serious levels of depression.

Once all summary variables had been calculated, correlations between variables were assessed to explore binary relationships between variables. Regressions were then used to explore the multivariate relationships between variables thought to be associated with adherence. It was hypothesized that some variance would be explained by control variables such as SES and age, which might affect access, and that psycho-social factors such as depression and stigma would also predict care engagement.

An Ordinary Least Squares (OLS) regression was planned to model these relationships. However, the distribution of the composite care engagement variables, and its adherences subscales were skew, which meant the results of a linear regression analysis may be biased: an OLS regression assumes a normal distribution, and the regression equation passes through the mean of the data. When data is this skewed, the mean is no longer an accurate measure of central tendency and a trend line is likely to have more error with residuals that are not normally

distributed. As such, the results of the OLS were compared to other regression analyses as a sensitivity analysis to assess the robustness of the OLS.

Poisson regression (using 15 discrete levels of adherence) and logistic regression were thus also conducted as sensitivity analyses. The Poisson regression assumed a distribution that better matched the data but used counts rather than a continuous outcome variable. This has some negative implications for statistical power (Sedlmeier & Gigerenzer, 1992). Similarly, logistic regression does not require a normally distributed outcome variable, as the outcome variable is binary. The care engagement variable was recoded where 1 indicated perfect care engagement and 0 imperfect care engagement. While these models could run without assumptions being violated, recoding or transforming the care engagement variable reduced the resolution in the data of a complex phenomenon. Yet, together the results of the three models should provide a more accurate description of the predictors of adherence than any one model.

Multiple regression models were used to assess the predictors of adherence. The set of potential predictors that were entered into the model were: stigma, anxiety, medication-specific social support, alcohol use, socioeconomic status, HIV disclosure, and depression.

Due to the complexity of the predictors and the probability of indirect relationships between them, Structural Equation Modelling (SEM) was used in the final analysis (Cacioppo et al., 2006; Khazanov & Ruscio, 2016). As stigma and SES were considered as possible predictors of adherence and may result in exclusion, loneliness, and low instances of positive affect, these variables were considered in the SEM as possible predictors of depression (Rao et al., 2012).

### **Ethical considerations**

Ethical approval of the study was first obtained from the University of Cape Town Institutional Review Board. Ethical clearance was then obtained from the National Institute for Medical Research (NIMR) in Tanzania and the KCMC College Research Ethics and Review Committee (CRERC). The data were collected at Mawenzi CTC, and we also got approval from Moshi Urban Regional Medical Officer (RMO). Please see appendices 1-4 for copies of these approval letters. A data transfer agreement was also signed between the University of Cape Town and the NIMR (Appendix 5).

### ***Informed Consent***

Participants were informed about the study objectives and their roles in participation. Information about the study was explained by the PI at the clinic (after being introduced by a nurse), while patients are waiting to see the doctor. Patients who were systematically selected to participate, and who were interested in taking part in the study, were presented with more detailed information in a private room (in the same clinic building) before being invited to give their consent to the study team. All the details about the study were provided in the information sheet, and participants were given a chance to read it before signing it. For those participants who were illiterate, the researcher read the information sheet and then invited the participant to provide a thumbprint instead of a signature. The research team emphasized the voluntariness of participation, and that those who decided not to participate would get their care as usual. See Appendix 6 for the informed consent.

### ***Risks and benefits***

Some questions might cause discomfort to the participants during an interview, for instance, questions about HIV status or socio-economic information. Participants were reminded that all the information they provided was treated with confidentiality. If a patient became emotional or uncomfortable, as happened in 4 cases, the interview was stopped for a while and continued later.

Participants were informed that there were no benefits in their participation. However, the findings of the study were potentially an indirect benefit to them, via benefits to the health service and improved treatment. Patients with depression were referred to the Department of Psychiatry at Mawenzi Hospital.

### ***Confidentiality***

The participants were assured of the protection of the information they provide. They were given numbers instead of their identity, and no names were collected. Reports would use aggregated data, and therefore no one would be able to identify participants.

The data was stored on a password-protected computer that only the study team could access. Any hard copies were stored in a locked filing cabinet that again only the research team could access.

## Chapter 3: Results

### Demographic Characteristics of the Participants

A total of 203 patients were enrolled in the study, over two months from February to April 2021. Participants were on average 48 years of age (standard deviation of 12.8) with a minimum of 18 and a maximum of 75. The majority were married and almost all participants had at least a primary level of education. With regards to occupation, more than 90% of the participants were unemployed. In the case of income-earning per month, the majority earned less than 21.7\$ which is on the poverty line, only 1.6% were above the poverty line. More than half of the participants spent between 1,100 to 5,000 Tanzania shillings (around USD2) to get to the clinic. Most of the participants spent half an hour covering the distance to the clinic (Table 2).

**Table 2: Demographic characteristics of the participants (n=203)**

Characteristics	Total n (%) <sup>1</sup> or Mean (SD) <sup>2</sup>	Symptoms of depression	
		No or Mild n (%)	Moderate or Severe n (%)
<b>Marital status</b>			
Age: Mean (SD <sup>2</sup> ) Years	48 (12.8)		
<b>Marital status: n (%)</b>			
Married	100 (49.3)	90 (50.8)	10 (38.5)
Single	23 (11.3)	21(11.9)	2 (7.7)
In relationship	13 (6.4)	11 (6.2)	2 (7.7)
Divorced	43 (21.2)	34 (19.2)	9(34.6)
Widow/widower	24 (11.8)	21 (11.9)	3(11.5)
<b>Level of education</b>			
No schooling	5 (2.5)	4 (2.3)	1 (3.8)
Primary	141 (69.5)	120 (67.8)	21 (80.8)
Secondary	45 (22.2)	43 (24.3)	2 (7.7)
Higher	12 (5.9)	10 (5.6)	2 (7.7)

<sup>1</sup> Percentages are column percentages, e.g., 50.8% of those with no or mild depressive symptoms are married.

<sup>2</sup> Standard Deviation

<b>Occupational status</b>			
Unemployed	189 (93.1)	166 (93.8)	23 (88.5)
Employed	14 (6.9)	11 (6.2)	3 (11.5)
<b>Income earning per month in Tsh<sup>3</sup> (n=191)</b>			
10,000-50,000	74 (38.7)	62 (37.1)	12 (50.0)
51,000-100,000	71 (37.2)	63 (37.7)	8 (33.3)
110,000-500,000	43 (22.5)	40 (24.0)	3 (12.5)
>500,000	3 (1.6)	2 (1.2)	1 (4.2)
<b>Cost to get to the clinic in TSh: n (%)</b>			
≤1000	80 (39.4)	70 (39.5)	10 (38.5)
1100-5000	121 (59.6)	106 (59.9)	15 (57.7)
6000-50000	2 (1.0)	1 (0.6)	1 (3.8)
<b>Time taken to get to the clinic</b>			
Within half an hour	103 (50.7)	96 (54.2)	7 (26.9)
Within an hour	65 (32)	57 (32.2)	8 (30.8)
More than an hour	35 (17.2)	24 (13.6)	11 (42.3)

### Health characteristics

Table 3 shows the health characteristics of the study sample. Of the 203 participants involved, 47.8 % had symptoms of depression, and using the PHQ-9 categories (de Man-van Ginkel et al., 2012), 35.0% could be classified as having mild, 8.9% moderate and 3.9% with severe symptoms. Almost all of the participants had good ART adherence ( $\geq 95\%$ ). The majority of the participants by contrast reported experiencing an intermediate level of anxiety. All of the participants had experienced some HIV stigma. Half of the participants had risky levels of alcohol consumption, and among them 31.1% were regarded as highly likely to be alcohol dependent. The majority of the participants had viral suppression, although, for 23 participants, viral load data were not available. All most all of them had social support on their medication use. Almost all of the participants had disclosed to another person, and most had disclosed on the day of diagnosis.

<sup>3</sup> 1USD = 2303.7 TSh

**Table 3: Health Characteristics**

Characteristics	n (%) or mean (SD)	Symptoms of depression	
		No or Mild n (%)	Moderate or Severe n (%)
<b>Depression: n (%)</b>			
None	106 (52.2)		
Mild	71 (35.0)		
Moderate	18 (8.9)		
Severe	8 (3.9)		
<b>Treatment adherence: n (%)</b>			
Poor adherence (0-95%)	34 (16.7)	29 (16.4)	5 (19.2)
Good adherence (≥95%)	169 (83.3)	148 (83.6)	21 (80.8)
<b>HIV viral load: n (%)</b>			
Target not detected (<20)	153 (75.4)	138 (90.8)	14 (9.2)
Target detected (>20)	22 (10.8)	15 (68.2)	7 (31.8)
>900 mil/ copies	5 (2.5)	5 (100.0)	0 (0.0)
Missing	23 (11.3)		
<b>BSI Anxiety scores: mean (SD)</b>			
Intermediate (5-8)	157 (77.3)	150 (84.7)	7 (26.9)
A high score (≥9)	46 (22.7)	27 (15.3)	19 (73.1)
<b>HIV stigma scores: mean (SD)</b>	6.9 (6.7)		
<b>AUDIT scores</b>			
Low-risk consumption (1-7)	101 (49.8)	92 (52.0)	9 (34.6)
Harmful alcohol consumption (8-14)	34 (16.7)	30 (16.9)	4 (15.4)
Alcohol dependence (>15)	68 (33.5)	55 (31.1)	13 (50.0)
<b>Medication Specific Social Support: mean (SD)</b>	7 (6.5)		
<b>HIV disclosure n (%)</b>			
Disclosure to another person	173 (85.2)	151 (85.3)	22 (84.6)
Disclosure to partner	119 (58.6)	105 (59.3)	14 (53.8)
Disclosure to family	140 (69.0)	123 (69.5)	17 (65.4)
<b>Disclose Duration of HIV status: n (%)</b>			
Disclosed same day	154 (79.8)	138 (81.7)	16 (66.7)
Disclosed not on the same day	39 (20.2)	31 (18.3)	8 (33.3)

HIV disclosure was treated as multiple response analysis

#### *Association between adherence and other predictors*

Table 4 shows correlations between scales of interest including the PHQ-9 (depression), Brief Symptoms Inventory (anxiety), HIV Disclosure, Medication Specific Social Support, HIV/AIDS Stigma Instrument, Social Economic Status, and Medication adherence. The

following variables were significantly correlated: education correlated with age ( $p < 0.001$ ), depression correlated with stigma ( $p < 0.001$ ), alcohol use correlated with depression ( $p = 0.015$ ), and stigma ( $p = 0.050$ ). Also, medication support correlated with cost to clinic ( $p = 0.011$ ), depression ( $p = 0.045$ ), anxiety ( $p = 0.029$ ), and HIV disclosure ( $p = 0.015$ ). Stigma was correlated also correlated with depression ( $p < 0.001$ ), anxiety ( $p < 0.001$ ), and HIV disclosure ( $p = 0.042$ ). The participants' social-economic status correlated with age ( $p < 0.001$ ), depression ( $p = 0.037$ ), anxiety ( $p = 0.047$ ), medication support ( $p = 0.009$ ) and stigma ( $p < 0.001$ ). Adherence correlated with age ( $p < 0.001$ ), depression ( $p < 0.001$ ) and social-economic status ( $p = 0.034$ ). The strength and direction of the correlations are reported in Table 4.

**Table 4: Pairwise correlation of different predictors of adherence measures**

	1	2	3	4	5	6	7	8	9	10	11
1. Age (years)	1.00										
2. Education	-0.27***	1.00									
3. CC	0.11	0.03	1.00								
4. Depression	0.01	-0.07	0.07	1.00							
5. Anxiety	0.04	-0.1	0.07	0.60**	1.00						
6. Disclosure	0.013	-0.09	0.01	0.04	0.02	1.00					
7. Alcohol use	0.08	-0.08	-0.02	0.17*	0.16*	0.04	1.00				
8. Medication social support	-0.07	0.08	0.18*	0.14*	0.15*	0.17*	0.01	1.00			
9. Stigma	-0.05	-0.07	-0.04	0.35***	0.28***	0.14*	0.14	-0.02	1.00		
10. SES	0.32***	0.15*	0.14	-0.15*	-0.14*	0.08	-0.08	0.18**	-0.24***	1.00	
11. Care engagement	0.25***	-0.06	0.06	-0.26***	-0.11	0.003	-0.13	0.04	-0.06	0.15*	1.00

\*\*\*p&lt;0.001

\*\*p&lt;0.01

\* p&lt;0.0

### Regressions Assumption

An ordinary least squares regression model was run with all variables of interest; Participant age, HIV disclosure, anxiety, Alcohol, HIV stigma, medication specific social support, and socio-economic status to create a base model without depression. Certain assumptions are made about the data in when running a linear regression including linear relationship of the variables, independence, and homoscedasticity of residuals. However, the outcome variable was not normally distributed which is an underlying assumption of regression. Several other variables including depression were also skew, meaning the assumption of linearity was also not met. While regression analysis is robust enough to produce results despite the violation of these assumptions, it can reduce the prediction accuracy. In this analysis, the skewness of the data also affected the distribution of the residuals which were not normally distributed. This indicates that some portions of the model are less accurate than others. To account for potential inaccuracy from these effects, a sensitivity analysis was conducted, by running a logistic regression on a binary adherence variable and a Poisson regression on a version of the adherence variable with discreet values. There were no issues of multi-collinearity.

Only Participant age, AUDIT (alcohol) and HASI (stigma) significantly predicted adherence. When depression was added to the model, which was a significant predictor of adherence, HASI was no longer a significant predictor. The variable coefficients and significance values are reported in Table 5. The overall model was significant ( $F(3,184) = 9.77, p < 0.001$ ) but only explained approximately 12% of the variance in adherence scores.

**Table 5: Adherence predictors OLS regression**

<b>Variable</b>	<b>Estimate</b>	<b>Std.Error</b>	<b>P-value</b>
<b>Participant's Age</b>	0.27	0.07	<0.001
<b>AUDIT</b>	-0.14	0.07	0.049
<b>Depression</b>	-0.22	0.07	0.0036

Poisson regression and logistic regression were considered to account for the skewness. For the logistic regression, adherence was dichotomized with patients either showing good or poor adherence. For the Poisson regression, the continuous adherence variable was made discrete by rounding the continuous score to 1 decimal place and using each unique value as a separate

level of adherence. This produced 15 categories of adherence, some with only small number of data points. Both of these methods reduce the overall statistical power compared to an OLS regression. However, the results of these additional models as a sensitivity analysis show the robustness of the findings from the OLS model as depression remained a significant predictor in all the models considered. For the logistic regression, only depression remained significant ( $B = -0.75$ ,  $SE = 0.25$ ,  $p = 0.003$ ) while participant age ( $B = 0.32$ ,  $SE = 0.16$ ,  $p = 0.052$ ) and AUDIT ( $B = -0.347$ ,  $SE = 0.18$ ,  $p = 0.050$ ) were just not significant. This is particularly clear for the AUDIT variable where the  $p$  values changes from 0.049 to 0.050 which is a minute change, despite  $p$  no longer being  $< 0.05$ . This is likely due to the loss of power when using a binary outcome variable. For the Poisson regression, Depression ( $B = -0.68$ ,  $SE = 0.225$ ,  $p = 0.003$ ) and participant age ( $B = 0.822$ ,  $SE = 0.214$ ,  $p < 0.001$ ) were significant predictors of adherence while AUDIT score ( $B = -0.440$ ,  $SE = 0.225$ ,  $p = 0.052$ ) was just beyond the threshold value for significance.

The results of this sensitivity analysis suggest that depression is the most robust predictor of adherence. They also suggest that participant age as well as alcohol and drug use are useful factors for predicting adherence, if not as robust as depression.

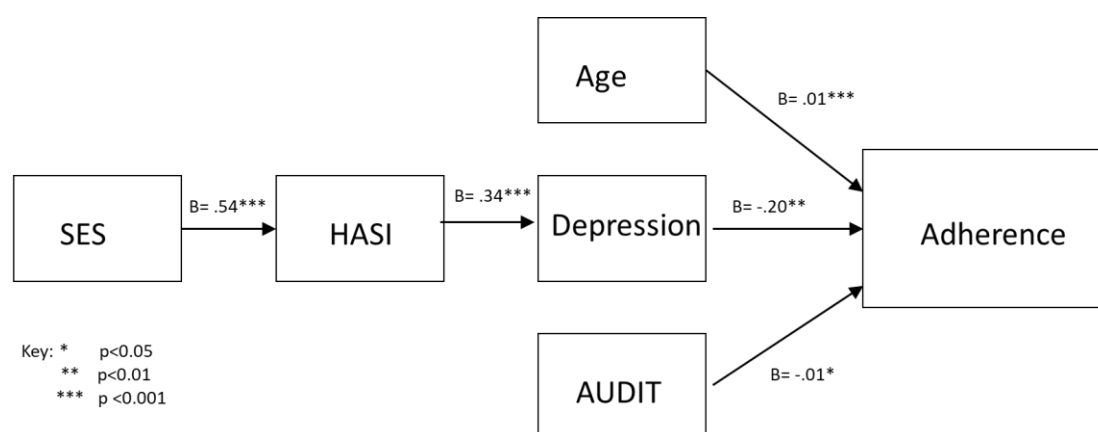
### **Structural Equation Modeling**

As several of the variables considered in the OLS regression were not significant but showed strong correlations with each other; some indirect links to engagement with care were considered. Stigma was strongly correlated with depression and was considered as a plausible predictor of depression. Table 6 shows that depression was predicted by stigma measured with the HASI and that this predicts depression which then predicts care engagement, despite stigma not predicting care engagement directly. However, the indirect effect of HIV related stigma through depression is worth considering. As depression is a robust predictor of adherence, and predictors of depression among HIV-positive people, including HIV related stigma, are worth addressing. As such predictors of stigma were also considered. SES was the only predictor of HIV related stigma, with higher SES predicting greater stigma. It should be noted that as only 1.6 % of the sample lived above the poverty line, the sample only represents those of low SES. In this sample, no indirect effects were found through alcohol and drug use (for the HASI ( $B = 0.29$ ,  $SE = 0.222$ ,  $p = 0.189$ ) for SES ( $B = -0.445$ ,  $SE = 0.449$ ,  $p = 0.321$ ) which both had a significant direct effect on depression in this model. Indirect effects through age were not considered as age was a control variable. Figure 1 shows the path of the indirect effects on care

engagement through depression as well as the direct effects of depression, age and alcohol and drug use.

**Table 6: Structural equation modeling of direct and indirect predictors of care engagement to HIV medication**

Predictor	Estimate	SE	<i>p</i> -value
HASI~ SES	0.539	0.142	0.000
Depression~ HASI	0.342	0.084	0.000
Adherence ~ Depression	-0.200	0.007	0.002
AUDIT	-0.005	0.003	0.042
participant age	0.007	0.002	0.000



**Figure 1: Path Diagram of direct and indirect predictors of adherence to HIV medication**

## Chapter 4: Discussion

The results indicated the prevalence of depression to be 47.8% among men living with HIV attending the HIV care clinic in Mawenzi. Moreover, this study found that HIV-related stigma had a direct association with depressive symptoms, whilst depression was associated with care engagement. There was no direct association between stigma and adherence as we hypothesized, however stigma was mediated by depression which then predicted adherence.

The prevalence of any symptoms of depression among men living with HIV was 47.8%, whereas patients with mild, moderate, and severe depressive symptoms were 35.0%, 8.9%, 3.9% respectively. These findings are in line with the previously reported prevalence of nearly 49.8% from a study which was done in Dar es Salaam, Tanzania, among people living with HIV (PLHIV); however, this high prevalence was observed during initiation of Antiretroviral Therapy but dropped to 20% after one year in care (Regan et al., 2021). The pattern of results of the current study also contrasts with a study in Nigeria and Brazil, where there were more patients with moderate symptoms compared to mild symptoms of depression. (Aguocha et al., 2015; Betancur et al., 2017). The sample in this study had been in care for varied periods (in years) with median (IQR) = 6(3-11), meaning the current study focused on the post-treatment while the other study looked on pre-and post-treatment. Despite this, the current study reported a high prevalence of depression in post-treatment HIV patients. However, the definition of the symptoms of depression was not consistent across studies.

Moreover, these findings are higher when compared to findings from Sub-Saharan Africa and East Africa where studies have reported depression prevalence ranging from 9% to 38% among PLHIV (Ayano et al., 2018; Bernard et al., 2017; Lofgren et al., 2019; Zewudie et al., 2021). The observed prevalence of depression in this study is evidently higher than in those in other African countries. This could be explained by the differences tools or different cut off that were used to measure depression. Another possible explanation could be that this study focuses on men living with HIV only, whereas other studies generally looked into both men and women living with HIV (Rezaei et al., 2019).

However, in Pakistan, the prevalence of depression was higher - 89.9% among PLHIV, which is twice what was found in the current study (Ahmed et al., 2021). Other reasons for high levels of depression can be explained due to sociocultural and socio-demographic differences. Most PLHIV in Pakistan has deported migrants and intravenous drug users, so a belief that these

PLHIV have been punished for their bad behavior may have driven stigma to PLWH in that context (Ahmed et al., 2021).

In the current study, HIV-related stigma was associated with depression. High levels of HIV-related stigma associated with symptoms of depression observed were consistent with other studies from Pakistan, Washington, and India (Ahmed et al., 2021; Chan et al., 2017; Rao et al., 2012). HIV-related stigma can indirectly affect ART adherence through depressive symptoms. A review in Ethiopia reported that combined HIV stigma (enacted, internalized and anticipated stigma) were also found to be associated with non-adherence (Endeshaw et al., 2014). Being stigmatized because of HIV status can influence depressive symptoms like social isolation, reducing self-efficacy/self-esteem, and delayed care-seeking. Through a series of these episodes, a patient can have poor clinical outcomes such as poor adherence, missed clinic visit, detectable viral load and thus these negative outcomes will elicit disease progression (Sweeney & Vanable, 2016; Yigit et al., 2020).

The current study hypothesized that depression would impact HIV care engagement negatively. Depressive symptoms indeed predicted poor adherence in the current study, similarly to other studies in Tanzania (Belenky et al., 2014) and in South Africa (Nel & Kagee, 2013). This is most likely because depressive symptoms such as loss of interest, loss of appetite, fatigue, sleep disturbance feeling worthlessness, or suicidal thoughts would affect the patient capacity to carry out an individual activities to adhere to HIV treatment (Gonzalez et al., 2011). Untreated depressive symptoms can cause inconsistent medication adherence, this in turn can cause unsuppressed viral load which intensifies the possibility of antiretroviral treatment failure, developing antiretroviral resistance, and continued HIV transmission. Most likely for these reasons, depression is associated with faster progression of HIV disease and increase the risk of death among PLHIV (Uthman et al., 2014).

This current investigation explored the prevalence of depression in men living with HIV, which is rare in the body of literature. Depression is prevalent among men like any other population, and as this is a common mental disorder which can impact care engagement, screening depressive symptoms should be done on men too helping them to engage fully in care.

This study suggests that a focus on mental health screening for people living with HIV is vital during care. Such a screening should include checking for stigma, depression, anxiety, and other mental disorders as the findings suggest that if left unchecked, poor mental health can lead

to reduced HIV care engagement. Early screening will help to reduce poor clinic outcomes hence retainment of the patient before it goes to severity. Mental health disorders like depression are not given serious attention compared to a physical or clinical problem, but it is one of the predictors of poor care engagement (Parcesepe et al., 2018; Remien et al., 2019). Depressed patients are likely to have viral suppression, inconstancy adherence, or loss of care.

#### Study limitations

As this was a cross-sectional study; the findings cannot be generalized to the population, and the causal relationship cannot be assumed. Secondly, the COVID-19 pandemic could have triggered depressive symptoms among patients during the study period. Social desirability bias is also a possible limitation of this study. Self-report of HIV medication adherence was reported to be 95%, but this could have been over-reported. Self-report of anxiety and depression symptoms, rather than clinical interviews, means that patients may have been over-identified as depressed or anxious: self-report alone cannot be enough to establish diagnosis (Coyne et al., 2000).

In future studies, diagnostic instruments can be used to measure depression consistently due to its high specificity, compared to screening instruments that focused on high sensitivity.

#### Conclusion

HIV-related stigma should not be underestimated because of the association it has with depressive symptoms. As depression is associated with poor care engagement, PLHIV should receive care that prevents or reduces the impact of depression. Mental health disorders need to be screened routinely in HIV clinics like any other opportunistic infections. Using short instruments, such as the PHQ-9, would make screening and referral easy, even in resource-poor environments. HIV-related stigma should be addressed as well, perhaps through community outreach, to reduce the depressive symptoms to boost engagement in HIV care.

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## Appendix 5: Data Transfer Agreement (DTA)



**NATIONAL INSTITUTE FOR MEDICAL RESEARCH**

**DATA TRANSFER AGREEMENT FOR  
RESEARCHERS/ORGANIZATIONS**

**(FOR RESEARCH USE ONLY)**

**THIS DATA TRANSFER AGREEMENT FOR Researchers/Organizations** (here-in-after **referred to as the "Agreement"**) is made this...10..... Day of **Sep**....., 2020....

Between

Kilimanjaro Christian Medical Centre .....of P.O Box **3010 Moshi, Tanzania**.....

(here-in-after referred to as the "**PROVIDER**");

and

**University of Cape Town** .....of P.O Box Private bag X3, University of Cape Town, Rondebosch 7701, South Africa.....

(here-in-after referred to as "a person" or the "**RECIPIENT**").

PROVIDER and RECIPIENT may each be referred to as a "Party" or collectively as "Parties" to this Agreement.

This preamble shall be a definitive part of this Agreement

**WHEREAS** under this Agreement it is agreed that DATA of medical research may be transferred between Parties to this Agreement only through the conditions stipulated in this Agreement;

**WHEREAS** the PROVIDER retains all ownership rights on DATA procured from the study;

**WHEREAS** under this Agreement it is agreed that the DATA to be transferred pursuant to this Agreement are only those to be used for academic or research purposes;

**WHEREAS** it is hereby agreed that no transfer to third parties is allowed, except for academic or research purposes where RECIPIENT has secured the written consent of the PROVIDER;

**WHEREAS** it is hereby agreed that the RECIPIENT shall cooperate with the PROVIDER to facilitate capacity building in DATA management and analysis;

**AND WHEREAS** the parties to the Agreement undertake to be bound by any lawful order or instruction, as they will be from time to time be obliged to do by the Permit-Issuing Organization.

**NOW THEREFORE** in consideration of the mutual benefits to be derived and the representations, conditions and promises herein contained,

the **PARTIES HEREBY AGREE AS FOLLOWS:**

## **ARTICLE I**

### **DEFINITIONS AND RULES OF INTERPRETATION**

#### **1.1 Definitions**

“**Agreement**” means this “DATA Transfer Agreement for Researchers/Organizations” between the Parties.

“**DATA**” in this context refers to facts, observations, or any information generated and documented (numerical, descriptive or visual) as specified in *Annex I*, which forms part of this agreement.

“**Medical Research Coordinating Committee**” means a committee of the NIMR Council which reviews, monitors and coordinates health research in the United Republic of Tanzania.

“**Permit-Issuing Organization**” means the entities with the legal authority under the law to issue permits and/or to conduct scientific research or to do any activity collateral to that scientific research or matters connected thereto.

“**Permit**” means all consents, approvals, authorization, notifications, concessions, acknowledgements, licenses, permits or similar items required to be obtained from any Permit-Issuing Organization.

“**PROVIDER**” means a person or organization providing the original DATA.

“**RECIPIENT**” means a person or organization to which the original DATA is transferred.

“**The Law**” means any applicable laws of the United Republic of Tanzania or the RECIPIENT country when there is a *lacuna* in the laws of Tanzania.

**CONFIDENTIAL MATTER** means information that is PROVIDER’s proprietary and confidential information. Such CONFIDENTIAL MATTER shall not include any item of information, data, that: (a) is within the public domain prior to the time of the disclosure by the PROVIDER to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the RECIPIENT or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the possession of the RECIPIENT; (c) is acquired by the RECIPIENT from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the RECIPIENT, without reference to the information received from the PROVIDER; or (e) the PROVIDER expressly authorizes the RECIPIENT to disclose.

#### **1.2 Rules of Interpretation**

In this Agreement:

- a) The headings are for convenience only and shall not be considered in interpreting this

- Agreement;
- b) The singular includes the plural and vice versa;
  - c) The obligations on part of the PROVIDER or RECIPIENT shall be interpreted to apply to the conduct and responsibilities of the PROVIDER Investigator or RECIPIENT Investigator, respectively.

## **ARTICLE II**

### **GUIDING PRINCIPLES FOR DATA TRANSFER AGREEMENTS**

1. This Agreement shall be linked to a project that has received ethical clearance from the MRCC under the National Institute for Medical Research. The need to transfer DATA shall be stipulated in an approved proposal or subsequent amendment. Any proposal that has received clearance from a local Institutional Review Board (IRB) will require the Agreement to be processed through the National Institute for Medical Research.
2. Signing of this Agreement shall be mandatory for all research involving foreign researchers, and this shall be declared in a research application for a research permit.
3. This Agreement shall also be mandatory for local researchers collaborating with foreigners, before sending/transferring DATA for research. This Agreement applies also to local researchers when using DATA from communities.
4. Make or cause to be made all necessary prerequisite applications for the consents to the Permit-Issuing Organization and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;
5. In the case of this Agreement involving a foreign counterpart, before signing the Implementing Letter of Agreement (ILA), the concerned research institutions in the PROVIDER country, in this case, the United Republic of Tanzania, should access information from the *National Research Registry* formed under the Tanzania Commission for Science and Technology (COSTECH) Act No 7 of 1986, (and amended in 2000), 3<sup>rd</sup> Schedule, to determine whether the foreign researcher had obtained a research permit.

## **ARTICLE III**

### **TRANSFER OF THE DATA**

#### **3.1 *DATA to be transferred***

Subject to the terms and conditions of this Agreement, the PROVIDER agrees to transfer the DATA and the RECIPIENT agrees to receive the DATA as identified in *Annex I*.

#### **3.2 *Obligation of the RECIPIENT***

It is hereby agreed that the following conditions to the Agreement shall be binding on the RECIPIENT:

- (a) The RECIPIENT agrees to use, store or dispose of the DATA in compliance with all applicable laws including those relating to research involving the use of human and animal subjects.
- (b) The DATA shall remain the property of the PROVIDER and PROVIDER hereby consents to the DATA being made available as a service to the research community.
- (c) The RECIPIENT shall use the DATA for teaching or academic research purposes only.
- (d) Except as previously approved by the Permit-Issuing Organization, and with the written consent of the PROVIDER, the RECIPIENT shall not transfer or distribute the DATA to a third party.
- (e) The RECIPIENT shall acknowledge the source of the DATA in any publications reporting use of it.
- (f) Subject to Article V of this Agreement, the RECIPIENT shall be liable for damages which may arise from RECIPIENT's use, storage and disposal of the DATA.
- (g) The RECIPIENT and the RECIPIENT Investigator shall sign two copies of this Agreement and return one signed copy to the PROVIDER. The PROVIDER shall then transfer the DATA.
- (h) The RECIPIENT shall provide the PROVIDER with a manuscript of any proposed publication or presentation resulting from the study using the DATA at least thirty (30) days prior to submission thereof for publication or presentation. The PROVIDER reserves the right to review any such manuscript and to require the removal of CONFIDENTIAL MATTER in order to protect its proprietary rights and interests. PROVIDER shall notify RECIPIENT in writing within a thirty (30) day period concerning the removal of CONFIDENTIAL MATTER and to suggest editorial modifications in the manuscript.

### **3.3 Obligation of the PROVIDER**

It is hereby agreed that the following conditions to the Agreement shall be binding on the PROVIDER:

- (a) The PROVIDER agrees to transfer, store or dispose of the DATA in compliance with all applicable laws
- (b) The PROVIDER shall transfer immediately the DATA upon receipt of one of the two copies duly signed by the RECIPIENT.

- (c) Subject to availability, the PROVIDER may agree to make the DATA available under a separate agreement with other scientists (at least those at nonprofit organizations or government agencies) who wish to replicate the RECIPIENT Investigator's scientific research).
- (d) Subject to Article V of this agreement, the PROVIDER shall be liable all liabilities for damages which may arise from PROVIDER's use, storage and disposal of the DATA.

#### **ARTICLE IV**

##### **COSTS AND PAYMENT ARRANGEMENTS**

The DATA shall be provided at no cost.

#### **ARTICLE V**

##### **WARRANTIES**

Any DATA transferred pursuant to this Agreement is understood to be experimental in nature. The PROVIDER and RECIPIENT MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

#### **ARTICLE VI**

##### **LEGAL TITLE TO DATA TRANSFERRED AND BENEFIT SHARING**

Legal title to the DATA transferred shall be unaffected by this Agreement or the transfer of any Material hereunder. (i). As between the PROVIDER and the RECIPIENT, the PROVIDER shall be the sole owner of all rights and the title to the DATA transferred including existing intellectual property rights. (ii). The PROVIDER and RECIPIENT shall discuss the sharing of benefits arising from use of the DATA in accordance with the contributions of the Parties.

#### **ARTICLE VII**

##### **PERMITS, LICENCES AND APPROVALS**

**Prior to commencement of this Agreement, PROVIDER and RECIPIENT shall, at their own expense:**

- (a) Make or cause to be made all necessary prerequisite applications for the consents to the Permit-Issuing Organization and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;
- (b) Give all required notices and allow all required inspections under all consents obtained in connection with that transfer. The information supplied in the applications shall be complete and accurate and shall satisfy the substantive and procedural requirements of the applicable laws of the United Republic of Tanzania or of the other country where the DATA is transferred.

#### **ARTICLE VIII**

##### **NON-EXCLUSIVE LICENSE**

The transfer of the DATA constitutes a nonexclusive license to use the DATA solely for academic and research purposes only. The transfer of DATA does not grant the RECIPIENT any additional rights in the DATA other than specifically set forth in this Agreement.

#### **ARTICLE IX**

##### **AMENDMENTS**

This Agreement may be amended by mutual written Agreement of the Parties, which shall enter into force on the date agreed by both Parties.

#### **ARTICLE X**

##### **TERMINATION**

Termination of this Agreement is accomplished:

- a) Immediately upon mutual written consent of both Parties;
- b) Unilaterally by either Party with sixty (60) days' written notice to the other Party; or
- c) Upon 30 days' written notice of a Party's contravention of law; and
- d) As stated in Article XI

#### **ARTICLE XI**

##### **APPLICABLE LAW, SEVERABILITY**

The Parties recognize and agree that this Agreement is a contract and not an International agreement, that

International Law is not applicable to this Agreement, and that International Law does not govern the interpretation of the provisions of this Agreement. Any dispute arising under this Agreement which is not disposed of by agreement between the Investigators shall be submitted jointly to the Authorized signatories of this Agreement. A joint decision of the Authorized signatories or their designees shall be the disposition of such dispute. If the Parties cannot reach a joint decision, either Party may terminate this Agreement immediately.

The Parties hereby consent to the jurisdiction of the Courts of the United Republic of Tanzania for any action, suit or proceeding arising out of or relating to this letter agreement brought against the United Republic of Tanzania or NIMR; and to the jurisdiction of the courts of the RECIPIENT Government for any action brought against the RECIPIENT Government or any of its agencies.

This Agreement is effective when signed by all Parties and countersigned by the Chair of the Medical Research Coordinating Committee (MRCC) for the Government of United Republic of Tanzania. The Authorized Officials executing this Agreement certify that they are the legal representatives of their respective organizations, authorized to sign on behalf of their respective organizations for the purpose of binding the said organizations to the terms of this Agreement, for the transfer specified above.

## **ARTICLE XII**

### **NOTICE**

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

## **ARTICLE XIII**

### **NONAPPLICABILITY OF THIS AGREEMENT TO EXISTING OR FUTURE AGREEMENTS**

The terms of this Agreement are not intended to and do not affect any other existing or future agreements between the Parties.

**IN WITNESS WHEREOF** the **PARTIES** hereto have signed this Agreement in the presence of the witnesses and at the places and on the dates set opposite their respective signatures.

## Appendix 6: Participant Consent Forms

English version

Dear Patient,

You are being invited to participate in a research study.

This study is about depression and its relationship to how men living with HIV/AIDS access the Care and Treatment Clinic (CTC), at Mawenzi Hospital. This study is being conducted as part of a master's degree program in Psychological Research at the University of Cape Town, South Africa.

I am doing this research to find out how many men attending the CTC have depression, and whether their depression affects their HIV care.

Your participation in this study is purely voluntary, and whether you decide to participate or not, your care will not be affected. You can withdraw your participation from this study any time you want, this will not affect your care in the clinic. If you do decide to take part in this study, you will be interviewed in a private room. The interview will ask some questions about who you are, your HIV history, relationship to the people who support your HIV care, about your alcohol use, experience in stigma, anxiety or depression, your experience in disclosure and on your medication adherence. There are no right or wrong answers, it is just how it is to you. In addition to that, you will be asked to show your clinic card to the interviewer, so that we can see the results of your viral load test and the type of antiretroviral medication that has been prescribed for you. The interview will take approximately 30-45 minutes.

There is no compensation for your participation in the study. However, the study will provide 5,000/= Tanzanian Shillings for airtime voucher. And your participation will end after the interview.

The information that you provide will be kept confidential. Paper questionnaires will be stored in a locked file cabinet, and electronic data will be stored on a password-protected computer. After the study is over, anonymous data (no one will be able to tell who you are) may be shared with other researchers.

Please feel free to ask questions or to ask for more information about anything which was not clear to you. You can call these numbers: Martha Oshosen- 0715 860 218 or Prof. Blandina Mmbaga- 0768 435116 or you can write to National Institute for Medical Research (NIMR),

P.O. Box 9653, Dar-es-Salaam. You can email Catherine Ward-[Catherine.Ward@uct.ac.za](mailto:Catherine.Ward@uct.ac.za)  
/[Cathy.Ward.SA@gmail.com](mailto:Cathy.Ward.SA@gmail.com) or Rosalind Adams- [rosalind.adams@uct.ac.za](mailto:rosalind.adams@uct.ac.za).

DECLARATION:

I \_\_\_\_\_ understand all the information  
regarding this study that was provided to me. I have been given time to ask questions and  
clarifications. I agree to give my consent to participate in this study for all the required time.

\_\_\_\_\_ (Signature of the participant consented)

\_\_\_\_\_ (Date)

\_\_\_\_\_ (Signature of the person who ask for the consent)

\_\_\_\_\_ (Date)

I agree that you may record data from my clinic record card.

\_\_\_\_\_ (Signature of the participant consented)

\_\_\_\_\_ (Date)

\_\_\_\_\_ (Signature of the person who ask for the consent)

\_\_\_\_\_ (Date)

Swahili version.

### **Nakala ya ridhaa ya mshiriki**

Mpendwa mgonjwa,

Unaalikwa kushiriki katika utafiti huu.

Utafiti huu unahusiana na sonona (kusoneka) na uhusiano wake katika upatikanaji wa huduma ya VVU, kwa wanaume wanaoishi na VVU, katika hospitali ya Mawenzi. Utafiti huu unafanyika kama sehemu ya masomo ya shahada ya pili ya utafiti wa kisaikolojia kutoka chuo kikuu cha Cape Town, Africa ya kusini.

Ninafanya utafiti huu kubaini ni wanaume wangapi wanaohudhuria au wanaopata huduma ya kliniki ya VVU wana tatizo la sonona, na kama sonona ina athiri upataji huduma ya VVU.

Ushiriki wako kwenye utafiti ni wa hiari kabisa, na kama utapenda kushiriki au la, huduma yako haitaathiriwa. Unaweza kusimamisha ushiriki wako katika utafiti huu muda wowote utakao taka, hii haita athiri huduma yako ya kliniki ya VVU. Kama utamaamua kuwa sehemu ya utafiti huu, utahojiwa katika chumba binafsi. Katika mahojiano utaulizwa maswali kuhusiana na wewe mwenyewe, historia yako ya VVU, uhusiano wako na watu wanaokusaidia kwenye huduma yako ya VVU, matumizi yako ya kilevi, uzoefu wako katika unyanyapaa, wasiwasi au sonona, uzoefu wako katika kuweka wazi hali yako ya maambukizi, na ufuasi wako wa unywaji dawa. Hakuna majibu sahihi au yasiyo sahihi, ni wewe unavyoona au unavyofikiri. Kwa kuongezea, utaombwa kuonyesha kadi yako ya kliniki kwa mhojaji, ili tuweze kuona majibu yako ya kipimo cha wingi wa virusi na aina ya dawa ya kupunguza makali ya VVU ambayo umeandikiwa. Mahojiano yanaweza kuchua kwa makadirio dakika 30- 45.

Hapatakuwa na fidia kwa ajili ya ushiriki wako katika utafiti. Hata hivyo, utafiti utatoa shilingi 5,000/= kama pesa ya mawasiliano. Ushiriki wako utaishia siku hiyo hiyo baada ya mahojiano. Taarifa utakazotupatia zitahifadhiwa kwa usiri. Madodoso yote yatahifadhiwa kwenye kabati la mafaili linalofungwa, na kwa data laini (za kieletronia) zitahifadhiwa kwenye komputa zinazolindwa na neno la siri. Baada ya mradi kuisha, taarifa za mshiriki ambazo hazina utambulisho zitashirikishwa kwa watafiti wengine.

Tafadhali jisikie huru kuulizia maswali au taarifa zaidi kuhusiana na jambo lolote ambalo hujalielewa. Unaweza kupiga simu katika namba zifuatazo; Martha Oshosen-0715 860218 au Prof. Blandina Mmbaga-0768 435116, au ukatuma barua kwa National Institute of Medical

Research (NIMR) S.L.P 9653, Dar es salaam. Barua pepe kwenda [Catherine.Ward@uct.ac.za](mailto:Catherine.Ward@uct.ac.za) /[Cathy.Ward.SA@gmail.com](mailto:Cathy.Ward.SA@gmail.com) au [rosalind.adams@uct.ac.za](mailto:rosalind.adams@uct.ac.za).

TAMKO:

Mimi \_\_\_\_\_ nimeelewa taarifa zote kuhusiana na utafiti huu ambazo zimetolewa kwangu. Nimepewa muda wa kuuliza maswali na ufafanuzi zaidi. Nimekubali kutoa ridhaa yangu ya kushiriki katika utafiti huu kwa muda wote utakao hitajika.

\_\_\_\_\_ (Sahihi ya mshiriki alietoa ridhaa)

\_\_\_\_\_ (Tarehe)

\_\_\_\_\_ (Sahihi ya mtu alieomba ridhaa)

\_\_\_\_\_ (Tarehe)

Ninakubali kwamba unaweza kuchukua rekodi zangu kutoka kwenye kadi yangu ya kliniki.

\_\_\_\_\_ (Sahihi ya mshiriki alietoa ridhaa)

\_\_\_\_\_ (Tarehe)

\_\_\_\_\_ (Sahihi ya mshiriki alieomba ridhaa)

\_\_\_\_\_ (Tarehe)

## Appendix 7: Questionnaire

**STUDY QUESTIONNAIRE**

Date: \_\_\_\_\_

**Demographic Information:**

1. Date of birth (date/month/year): \_\_\_\_\_
2. Where do you live? Town \_\_\_\_\_
3. For how long have you lived in this place? Years \_\_\_\_\_
4. How long does it take to come to the clinic? \_\_\_\_\_
  0. Within an hour
  1. An hour
  2. More than an hour
5. What is the highest level of school that you completed?
  0. No formal education
  1. Primary education (specify level attained) \_\_\_\_\_
  2. Secondary education (specify level attained) \_\_\_\_\_
  3. Higher education (specify field)
6. What best describe your current relationship status?
  1. Married
  2. Single, not in a relationship
  3. In a relationship but not married
  4. Separated from spouse/Divorced
  5. Widower

**Socio-Economic status:**

7. How much does it cost you to come to the clinic? \_\_\_\_\_
  0. No cost
  1. 500- 10,000

2. 11,000-50,000

3. 50,000>

8. Are you working in any sector where you receive a regular monthly salary? (if no skip to number 10)

0.No

1.Yes

9. What type of work do you do? \_\_\_\_\_

10. If you are not formally employed, what do you do to earn you income?

1.No income earning activities

2. I have a big farm and employ other people to work the farm

3. I have a small farm that's just enough for me and my family

4. Business

5. I have a shop or a stall

6. Other, specify \_\_\_\_\_

11. Approximately, how much money do you earn per month from this activity (Tsh)\_\_\_\_\_

0. 10,000-50,000

1. 51000-100,000

2. 110000-500,000

3. 1,000,000>

12. Do you own your own house?

0. No

1. Yes

13. Does the house you live in have electricity?

0. No

1. Yes

14. Do you own a cell phone?

- 0. No
- 1. Yes

15. Does your partner/wife work in a sector where s/he receives a regular monthly salary?

- 0.No
- 1. Yes
- 2. N/A not in relationship

16. If not formally employed, what does s/he do to earn her income?

- 1. No income earn activities
- 2. I have a big farm and employ other people to work the farm
- 3. I have a small farm that's just enough for me and my family
- 4. Business
- 5. I have a shop or a stall
- 6. Other, specify \_\_\_\_\_

17. Approximately, how much money does your partner/wife earn per month from these activities?

\_\_\_\_\_

- 0. 10,000-50,000
- 1. 51000-100,000
- 2. 110000-500,000
- 3. 1,000,000>

18. Who provides the primary financial support in your household?

- 1. Myself
- 2. My wife
- 3. Parents
- 4. Others, specify \_\_\_\_\_

### HIV History

19. When did you first learn that you are HIV positive? (In year) \_\_\_\_\_

20. What motivated you to go for the test?

1. Illness
2. I just wanted to know my status
3. National campaign
4. Others, specify \_\_\_\_\_

21. Has your partner/wife tested for HIV?

0. No
1. Yes
2. I don't know

*The following are the clinical measures, and the information can be obtained from the patient CTC card or in the file*

22. Did you checked your Viral load?

What are your latest Viral load copies \_\_\_\_\_

9. No Viral load test results recorded

23. The date was it measured? \_\_\_\_\_ (dd mm yy)

24. What ARV regimen are you currently using \_\_\_\_\_

8. No information available

And when did you start using that regimen? \_\_\_\_\_ (dd mm yy)

25. When did you started taking ARV's? \_\_\_\_\_ (dd mm yy)

8. No information available

### **Mental disorder**

#### **The patient health questionnaire (PHQ-9)**

#### **Depression**

For the following items, please listen closely and tell me how often you have been bothered by any of these problems over the last 3 months.

PHQ1. Little interest or pleasure in doing things

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
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PHQ2. Feeling down, depressed or hopeless

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ3. Trouble falling asleep, staying awake, or sleeping too much

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ4. Feeling tired or having a little energy

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ5. Poor appetite or overeating

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ6. Feeling bad about yourself - or that you are a failure or have let your family down

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ7. Trouble concentrating on things such as reading the newspaper or watching the television

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ8. Moving or speaking so slowly that other people could have noticed. Or, the opposite-being so fidgety or restless that you have been moving around a lot more than usual

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

PHQ9. Thoughts that you would be better off dead or of hurting yourself in some ways

0. Not at all	1. Several days	2. More than half days	3. Nearly every day
---------------	-----------------	------------------------	---------------------

### Anxiety-BSI

I will ask you about the feelings that you might have felt or encountered in everyday life, specifically, I am going to read for you these emotions and you can tell me if you experience any of them for the last 3 months including today. BSI1. Nervousness or shakiness inside.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

BSI2. Feeling tense or keyed up.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

BSI3. Suddenly scared for no reason.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

BSI4. Spells out terror or panic.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

BSI5. Feeling so restless you couldn't sit still.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

BSI6. Feeling fearful.

0. Not all	1. A little bit	2. Moderately	3. Quite a bit	4. Extremely
------------	-----------------	---------------	----------------	--------------

### HIV Disclosure

I would like to hear your experience talking to people in your life about your HIV status.

HVD1. Have you ever told another person about your HIV status?

0. No

1. Yes

HVD2. Have you told your partner/wife about your HIV status?

0.No

1.Yes

HVD3. Have you told any other sexual partners? Skip to the next question

0.No

1.Yes

HVD4. Have you told any family members?

0.No

1.Yes

HVD5. Have you told any friends?

0.No

1.Yes

HVD6. How soon after learning about your HIV status did you disclose your HIV to someone for the first time?

1. Same day that I learned about my status

2. Not the same day that I learn my status

HVD7. *If not on the same day*, ask how soon after diagnosis did you disclose to someone?

\_\_\_\_\_ (Days/weeks/month)

HVD8. In the last 3 months, has your HIV status ever been told to someone else without your consent?

0. No

1. Yes

HVD9. In the last 3 months, have you experienced any negative changes after someone learned about your HIV status?

0. No

1. Yes

**AUDIT**

Now I am going to ask you some questions about your use of alcoholic beverages during the past 3 months. By alcohol, I am referring to any spirits, beer, wine or local brew.

AUDIT1. How often did you have a drink containing alcohol?

0. Never (*skip to next section*)
1. Monthly or less
2. 2-4 times a month
3. 2-3 times a week
4. 4 or more times a week

AUDIT2. How many standard drinks containing alcohol did you have on a typical day, when you are drinking?

NOTE: *One drink is equal to 1 small can or small bottle of beer, 1 glass of wine, 1 shot of spirits or liquor, or 1 serving of local brew.*

0. 1 or 2
1. 3 or 4
2. 5 or 6
3. 7, 8, or 9
4. 10 or more

AUDIT3. How often did you have 6 or more drinks on one occasion?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT4. How often during last year have you found that you were not able to stop once you have started?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT5. How often during the last year have you failed to do what is normally expected of you because of drinking?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT6. How often during last year have you needed a drink first in the morning to get yourself going things after a heavy drinking session?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT7. How often during the last year have you had a feeling of guilt or remorse after drinking?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT8. How often during the last year have you been unable to remember what happened the night before because of your drinking?

0. Never
1. Less than once in a month
2. Monthly
3. Weekly
4. Daily or almost daily

AUDIT9. Have you or some else been injured because of your drinking?

0. No
1. Yes, but in the last year
2. Yes, during last year

AUDIT10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?

0. No
1. Yes, but last year
2. Yes, last year

b. Is there any other substance that you use apart from alcoholic beverages? \_\_\_\_\_

(Tobacco products, Cannabis (Taiwo et al.), Cocaine, valium, heroin)

c. What is that substance? \_\_\_\_\_

d. How many times are you taking it in a day/week?

### Medication specific social support

Here is a list of some things that other people may do to help you manage your HIV treatment. Please listen to each statement carefully and tell me how often you have gotten this type of support in the past 3months, or since you started taking medication, if less than 3 months ago. How often has someone in the past three months done any of the following things?

MSS1. Reminded you to take your HIV medication?

1. Never	2. Rarely	3. sometimes	4. Often	5. Very often
----------	-----------	--------------	----------	---------------

MSS2.Picked up your medication for you?

1. Never	2. Rarely	3. sometimes	4. Often	5. Very often
----------	-----------	--------------	----------	---------------

MSS3. Checked in with you about your HIV medications?

1. Never	2. Rarely	3. sometimes	4. Often	5. Very often
----------	-----------	--------------	----------	---------------

MSS4. Encouraged you to believe that you can take your HIV medications as prescribed?

1. Never	2. Rarely	3. sometimes	4. Often	5. Very often
----------	-----------	--------------	----------	---------------

*If all the questions above have been answered.*

MSS\_WHO. Who is that person who provides you with the most support with your HIV medications?

1. Partner/husband
2. Mother
3. Mother-in-law
4. Father
5. Father-in-law
6. Sibling
7. Friend
8. Other: \_\_\_\_\_

Enacted Stigma: HIV/AIDS Stigma Instrument (HASI)

I'm going to read a list of events that may have happened to you because you are living with HIV. Please tell me in the past 3 months, how often each of these things happened to you because of your HIV status.

HASI1. I was asked to leave because I was coughing.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI2. Someone stopped being my friend.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
----------	------------------	------------------	---------------------

HASI3. I was called bad names.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
----------	------------------	------------------	---------------------

HASI4. I was made to eat alone.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
----------	------------------	------------------	---------------------

HASI5. Someone insulted me.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
----------	------------------	------------------	---------------------

HASI6. People avoided me.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI7. People cut down visiting me.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI8. People ended their relationship with me.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI9. I was blamed for my HIV status.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI10. My ability to earn money was impacted

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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HASI11. People gossiped about me.

0. Never	1. Once or twice	2. Several Times	3. Most of the time
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### **Treatment Adherence Assessment -TAA**

I am going to ask you some questions about the HIV antiretroviral medications that you were prescribed to treat your HIV.

TAA1. Each day, how many HIV pills are you supposed to take? \_\_\_\_\_ (refers to ARVs only)

For many people, it is difficult to take HIV antiretroviral medications as their doctor or nurse prescribes them. The following questions ask you about your experiences taking HIV antiretroviral medications.

*Interviewer; use days of the weeks to get better recall e.g. Now think about yesterday, which was Tuesday”*

TAA2. Now think about yesterday. Did you take your pills (s)?

0. No

1. Yes

TAA3. Now think about the day before yesterday (2 days ago). Did you take your pills (s)?

0. No

1. Yes

TAA4. Now think about the day before that (3 days ago). Did you take your pill (s)?

0. No

1. Yes

TAA5. Now think about the day before that (4 days ago). Did you take your pill (s)?

0. No

1. Yes

*Now I am going to ask about your experience taking your HIV medication in the past one month, which is 30.*

TAA6. In the last 30 days, on how many days did you miss taking your pill (s)?

*[Write down days: 0-30]* \_\_\_\_\_

TAA7. In the last 30 days, how good a job did you do at taking your HIV pill (s) in the way you were supposed to?

1. Very poor

2. Poor

3. Fair

4. Good

5. Very good

6. Excellent

TAA8. In the last 30 days, how often did you take your HIV pills (s) in the way you were supposed to?

1. Never

2. Rarely

3. Sometimes

4. Usually

5. Almost always

6. Always

TAA9. *If he missed any pills in the past 3 months:* If you missed any pills in the three months, what were your major reason? \_\_\_\_\_