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# **Original Research Paper**

## Medicine

# Determinants of Adherence to Highly Active Antiretroviral Therapy among people attending a Public HIV Clinic in Ghana

Norah Lucky Katende-Kyenda	Walter Sisulu University (WSU), Depart of Medicine & Pharmacology
Ellen Sam	Ghana Public Hospital, Accra, Ghana Depart of Medicine & Pharmacology
Teke Apalata	Department of Pathology and Laboratory Medicine, Mthatha, South Africa.
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**ABSTRACT** Major determinants of survival in HIV-1-infected on HAART are adherence, baseline CD4 count, AIDS-defining illness and drug-resistance. Poor-adherence increases the risk of death in HIV-1-infected. Adherence-rates to HAART and determinants thereof among HIV/AIDS were measured using a cross-sectional study and a standardized-questionnaire using face-to-face interviews. Pill-count was conducted and adherence-rates calculated, considering  $p \ge 95\%$  significant. Data were analysed using SPSS and factors associated with poor-adherence accessed with ANOVA considering  $p \le 0.05$  significant. Of 69 HIV-infected on HAART for 37.48±32.97 months, 48(69.6%) were females and 21(30.4%) males with mean age of 42.41±8.92 years. 53.2% and 40.4% of HIV-infected were on WHO stage 1 and 3 respectively. Of 69 patients, 46(66.7%) had a poor adherence-rate (<95%). Among the assessed variables, sociodemographic factors, duration and knowledge on ART, CD4 count levels, stigma were insignificant. Factors related to treatment-regimens ( $\ge 3$  ART tablets;  $\chi 2=5.08$ , p=0.042) and ( $\ge 4$  other tablets;  $\chi 2=16.03$ , p=0.09) were determinants of poor-adherence to HAART.

KEYWORDS : ARV regimens; drug-resistance, HIV-infected; pill-Count; viral suppression.

## Introduction

The Human immunodeficiency virus (HIV) pandemic continues to spread in the population making HIV infection one of the most important public health crises in the world (United Nations Programme on HIV/AIDS (UNAIDS) 2008). Globally, about 33.3 million persons were estimated to be infected with HIV/AIDS in 2010, of these, 22.5million (68%) were in sub Saharan Africa. According to HIV and AIDS estimates the number of people living with HIV in Ghana in 2014 was 250,000 with adults aged 15 to 49 with the prevalence rate of 1.5%. Women aged 15 and up living with HIV were 140,000. Children aged 0 to 14 living with HIV were 21,000 with deaths due to AIDS being 9,200 and orphans due to AIDS aged 0 to 17 were 120,000 (UNAIDS, 2014) By the end of 2007, the cumulative number of HIV-infected initiated on ART exceeded 13,000. In line with the call for universal access to treatment, care and support for PLHIV, Ghana planned to put 70,000 PLHIV on ART by the year 2010 (Guidelines for antiretroviral therapy in Ghana, 2008).

In 2012, an estimated 5.5 million South Africans were infected with HIV, making South Africa's HIV/AIDS epidemic one of the worst in the world (UNAIDS, 2012). Currently South Africa has the highest prevalence (6.4 million) of HIV/AIDs as compared to other countries in the world with 80% of 20 - 24 yrs of HIV infected being women and 33% of 25 – 29 yrs in men.

Several studies have investigated determinants of ART adherence, particularly in adult populations. The major determinants of survival in HIV-1-infected patients on highly active antiretroviral therapy (HAART) are: HAART adherence, baseline CD4+ T-cell count, AIDs-defining illness and drug-resistance status (Allardice et al., 1998). In one literature review of twenty studies—primarily using data from North American and European patients—determinants most consistently associated with non-adherence included: symptoms and adverse drug side effects, psychological distress, lack of social or family support, complex HAART regimens, low patient self-efficacy, and inconvenience of treatment (Mills et al., 2006).

By contrast, Bikaako-Kajura et al. (2006) in a qualitative study of HIV infected patients in Uganda, found that the main obstacles to optimal adherence were treatment-related costs (transportation, a lost day of work, and registration fees at health facilities), long waiting times at health facilities, stigma, and hunger and side effects during the initial stage of treatment (Hardon et al., 2007). This

exemplifies the wide range of factors associated with adherence and how they may differ according to context.

At the moment there is no cure for HIV/AIDS, therefore antiretroviral therapy (ART) has remained the only available option that offers the possibility of dramatically reducing HIV/AIDS-related morbidity and mortality, while improving the status of People Living With HIV (PLHIV). HAART has proved effective in reducing viral load, improving immune function (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007) and improving the quality of life of PLHIV (Moatti & Spire, 2003). Adherent individuals have been shown to have reduced viral loads and increased CD4 counts, live longer, and have better quality of life (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Moatti & Spire, 2003).

For this long-term treatment of HIV to be successful, strict adherence to the Highly Active Antiretroviral Therapy (HAART) regimen is required (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Moatti & Spire, 2003; Tapper, Flexner, Eron & Molina, 2004). Poor adherences significantly increase the risk of death in HIV-1-infected individuals. According to Samuel et al. (2004), the range for nonadherence to HAART is from 25% to 85%.

Adherence level of at least 95% and above has been considered appropriate to achieve therapeutic success, (Amico, Tor-Alfonso & Fisher, 2005; Remien et al. (2007); Weiser, Wolfe & Bangsberg, 2003) as this maintains optimal viral suppression as demonstrated by Paterson, Swindells & Mohr, 2000. Failure to observe sustained desired adherence threshold has been associated with dire consequences such as treatment failure, disease progression and emergence of drug resistant HIV/IADS strains (Weiser, Wolfe & Bangsberg, 2003; Paterson, Swindells & Mohr, 2000).

With the realization of the central role played by adherence in the success of HIV/AIDS treatment, Reynolds et al. (2004) conducted studies in various parts of the world including reviews, and reported non-adherence rates ranging from 50% to 80% in different contexts. However, in reality adherence as stated by Tapper, Flexner, Eron & Morina (2004), rates are often lower than 95% and rates of adherence from previous studies conducted in Ghana were low. Most of the previous reports were carried out with fewer PLHIV being on treatment restricted access to ARV drugs unavailability and payment for ARV medications being heavily subsidized.

With wide spread awareness of HIV/AIDS, expansion of treatment and prevention programs that have increased ART access to previously un-served and underserved populations in Ghana coupled with provision of free ART services, there is a need for implementation of continuous monitoring and evaluation mechanisms for adherence. This is of great importance especially because the key to the success of ART programmes and prevention of treatment failures is hinged on consistently high adherence levels. Scaling up of ARVs alone is definitely not the answer when adherence inconsistencies are not tackled. Therefore, the first step to solving this problem is to assess the determinants of adherence to HAART which may differ across geopolitical zones of the country with their unique characteristics of culture, religion, educational status and health seeking behaviors.

#### Statement of the research problem

Several studies that have investigated determinants of ART adherence, particularly in adult populations, revealed the major determinants of survival in HIV-1-infected patients on HAART to be HAART adherence, baseline CD4+T-cell count, AIDs-defining illness and drug-resistance status (Allardice et al., 1998).

At the moment there is no cure for HIV/AIDS, therefore ART has remained the only available option that offers the possibility of dramatically reducing HIV/AIDS-related morbidity and mortality, while improving the status of PLHIV. HAART has proven effective in reducing viral load, improving immune function (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007) and improving the quality of life of PLHIV (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Moatti & Spire, 2003).

Adherent individuals have been shown to have reduced viral loads and increased CD4 counts, live longer, and have better quality of life (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Moatti & Spire, 2003). For this long-term treatment of HIV to be successful, strict adherence to HAART regimen is required (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Moatti & Spire, 2003; Tapper, Flexer, Eron & Molina, 2004). Poor adherences significantly increase the risk of death in HIV-1-infected individuals. According to Samuel, Akinola & Joshua (2008), the range for non adherence to HAART is from 25% to 85%.

With wide spread awareness of HIV/AIDS, expansion of treatment and prevention programs that have increased ART access to previously un-served and underserved populations in Ghana coupled with provision of free ART services, there is a need for implementation of continuous monitoring and evaluation mechanisms for adherence. Based on the above information the study assessed the determinants of adherence to HAART which may differ across geopolitical zones of the country with their unique characteristics of culture, religion, educational status and health seeking behaviors.

#### **Research purpose**

The purpose of this study was to measure adherence rates to HAART and determinants thereof among HIV/AIDS clinic attendees during a cross-sectional study.

#### **Research Objectives**

The objectives for this study are to:

- Measure adherence rates to HAART using pill-count method
- Assess determinants of adherence to HAART among HIV/AIDS clinic attendees using a standardized questionnaire and faceto-face exit interviews with participants.

#### **Research Questions**

The study sought to answer the following questions:

- What are the adherence rates of the HIV/AIDS that attend the Ghana AIDS clinic?
- What are the determinants of adherence to HAART thereof among HIV/AIDS clinic attendees?

## Significance of the study

The findings from this study will help specifically in the clinical practice to achieve the following:

- To determine adherence rates to HAART in patients attending the HIV clinic to see if it is the accepted adherence level of at least 95% and above. This value has been considered appropriate to achieve therapeutic success, as demonstrated by Amico, Tor-Alfonso & Fisher, 2005; Remien et al. 2007; Weiser, Wolfe & Bangsberg, 2003) that this maintains optimal viral suppression and also as demonstrated by Paterson, Swindells & Mohr, 2003).
- For other clinics to be able to perform the pill-count method to measure adherence rates.
- Results from this study will serve as a guide to other HIV/AIDS clinics that are not able to measure major determinants of adherence to HAART in terms of HAART adherence, baseline CD4+ T-cell count, AIDS-defining illness to recommend pillcount and Questionnaire as practical tools to use in clinical practice.

#### **Research Design and method**

Research design is defined as the overall plan for obtaining answers to the questions being studied and for handling some of the challenges encountered during the research process. According to Polit & Beck, 2003; Burns & Groove, 2009; a research design is a blueprint for conducting a study that maximizes control over factors that could interfere with the validity of the findings. The researchers in this study used a cross-sectional study which was quantitative, descriptive and prospective in nature to determine adherence rates to HAART and determinants thereof among HIV/AIDS clinic attendees using a convenient sampling method during December 2013.

Quantitative research is a formal, objective, systematic process in which numerical data are used to obtain information about the world (Burns & Grove, 2009). Descriptive research refers to research that has as its main objective the accurate portrayal of the characteristics of persons, situations, or groups, and/or the frequency with which certain phenomena occur (Polit & Beck, 2008). Most importantly, the purpose of descriptive research is to explore and describe phenomena in real-life situations. In addition, this approach is used to generate new knowledge about concepts or topics about which limited or no research has been conducted (Burns & Grove, 2009).

Retrospective design involves collecting data on an outcome occurring in the present, and then linking it retrospectively to antecedents or determinants occurring in the past (Polit & Beck, 2008). Baseline demographic data, medical records on file, HIV CD4 count, viral load measurements as well as pharmacy refill records of HIV-positive patients who were initiated on ART for 37.48  $\pm$  32.97 months were retrieved from the hospital' records. Therefore the data were collected and used to measure the adherence to antiretroviral therapy by HIV-positive patients.

#### **Research setting and Study Population**

The researchers conducted the study at one of the government hospitals in Ghana. The study population comprised of 69 HIV positive patients who were enrolled and had commenced HAART for 37.48  $\pm$  32.97 months. They were 48 (69.6%) females and 21 (30.4%) were males. Participants were consecutively recruited over the study period till the desired sample size was attained. All PLHIV on HAART were eligible to participate except those that satisfied the exclusion criteria. These criteria included PLHIV below 18 years of age, who were attending the clinic but had not commenced HAART, terminally ill patients and pregnant women.

The inclusion criteria adopted for the study included consenting out patients diagnosed and confirmed to be HIV positive, at least 18 years of age and had been on HAART for 3 months. The mean age ( $\pm$  SD) of the patients was 42.41  $\pm$  8.92 years. The study participants were on 53.2% and 40.4% WHO stage 1 and 3 respectively. A

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descriptive prospective cross-sectional study was used to determine adherence rates to HAART and determinants thereof among HIV/AIDS clinic attendees using a convenient sampling method during December 2013.

#### **Research population and sampling**

The population is all the elements (individuals, objects, or substances) that meet certain criteria for inclusion in a given universe (Burns & Grove, 2009). The population for this study was the patients and records of HIV-positive patients who attended the HIV clinic for antiretroviral therapy between January 2011 and December 2012, and that met the eligibility criteria. Sampling is a process of selecting subjects, events, behaviors, or elements for participation in a study (Burns & Grove, 2009).

A sample is a subset of the population that is selected for a particular study, and sampling defines the process for selecting a group of people, events, behaviors, or other elements with which to conduct a study (Burns & Grove, 2009). The sampling plan specifies in advance how the sample will be selected and recruited, and how many subjects there will be (Polit & Beck, 2008).

A convenient sampling design was used to select every patient and their records till the desired sample size was attained. records that meet the following criteria: 18 years and older, had completed at least 12 months of treatment and had at least two viral load measurements recorded after initiation of antiretroviral therapy (Polit & Beck, 2008). The medical records on file, HIV viral load measurements as well as pharmacy refill records were utilised as data sources of information for the study.

#### **Ethical Clearance and Consent**

Ethical clearance had been obtained from the Walter Sisulu University, Faculty of Health Sciences and Research Innovation and Ethics Committees. Ethical Clearance issued was 015/012. This was a collaborative study. Thereafter permission to interview the patients were obtained from the relevant managers in Ghana Hospital. Before the interviews, patients were explained the aim of the study using the Patient Information sheet and thereafter asked to sign a consent form which was optional. No names of patients appeared on the forms.

#### Data Collection and Instrument

In quantitative research, data collection involves obtaining numerical data to address the research objectives, questions, or hypotheses (Burns & Grove, 2009). Data were collected using a standardized questionnaire and face-to-face exit interviews with participants. The questionnaire had been initially tested for validity and reliability. Validity was established by a panel of experts and following a field test that determined whether the questionnaire measured what it intended to measure, whether it represented the appropriate content, whether it was appropriate for the study population and whether it was comprehensive enough to collect the needed information. Reliability was computed after a pilot field test to indicate the accuracy of the measuring questionnaire using test-retest approach.

The questionnaire was divided into sections to collect relevant information on: socio-demographic data, information regarding CD4 count, Viral load and ARV therapy, psychosocial/behavioral characteristics, patient attitudes and beliefs, social relationships/activities, medication characteristics, patient knowledge on the medicines, health-care practitioner-patient communication, pill count, times taken in different places (minutes, hours). Adherence to HAART of the interview was measured by self-report. The questions were adapted from The Brief Medication Questionnaire self-report tool for screening adherence and barriers to adherence (Svarsad, Chewning, Sleath & Claesson, 1998).

The degree of adherence from patient self-reporting was estimated using the following formula: Percentage of adherence = (Tablets dispensed – Tablets returned) / expected to be taken x100

(Olwookere, Fatiregun, Akinyemi & Bamgboye, 2008).

For the purpose of this study a score of 95% and above represented good adherence and less than 95% was rated as having poor/suboptimal adherence.

#### **Data Analysis**

Data analysis is defined as the systematic organisation and synthesis of research data (Polit & Beck, 2008). After data had been collected it was coded and captured in the computer using MS Excel.<sup>®</sup> Analysis of the data was carried out by using the Statistical Package for Social Sciences (SPSS) for Windows (Version 22), and a statistician assisted the researchers in analysing and interpreting collected data and analyzed using SPSS<sup>®</sup> for windows version 22.0 (SPSS Inc; Chicago, II, USA).

Descriptive and inferential statistics were used to describe key research variables and summarizes sample characteristics in terms of frequency distribution, measures of central tendency and measures of variability. Once these features were known, the researchers used bivariate (chi-square) and multivariate (logistic regression) descriptive statistics to describe the relationship between antiretroviral adherence and other variables of interest. These bivariate (chi-square) and multivariate (logistic regression) analysis were used to determine correlates or predictors of adherence.

Descriptive statistics (frequencies, proportions, means and standard deviation were used to summarize variables while Inferential statistics (chi square Test) was used to test the significance of association between categorical variables and level of significance was set at 5%. Logistic regression analysis was used to identify the predictors of adherence to HAART in the study population. Variables entered into the logistic model were those which had earlier been significantly associated on bivariate analysis at 10% significance derived. Predictors were determined at 5% significance. Factors associated with poor adherence to HAART were accessed with ANOVA and; a  $\rho \leq 0.05$  was considered.

#### Results

A total of 69 HIV infected on HAART were enrolled receiving HAART at the public hospital were enrolled in the study. The mean age ( $\pm$  SD) of respondents was 42.41  $\pm$  8.92 years. The largest proportion of the PLHIV were 26 (37.68%) in the age group 35-44 years, followed by 27 (37.68%) in the ≥45 and 15 (21.74%) in the age group 20-34. The majority of those interviewed 48 (69.6%) were females and 12 (30.4%) males.

The majority of the patients were married 36(37.5%). Most patients were on WHO staging one with 25(36.2%), followed by 22(22.9%) on WHO 5. Patients who said had no knowledge about HAART accounted for 64 (92.8%). When it came to CD4 cell count, the majority 35 (50.7%) of the patients had CD4 count < 200 cells/µL The majority of patients taking 3 and 4 antiretroviral tablets accounted for 22 (22.9%) and 22 (22.9%) respectively. It was also established that 11(11.5%) were taking more than 4 total number of tablets in a day.

Prevalence of adherence to HAART in the study population showed that more than half of 69 patients, 46 (66.7%) of the respondents had not attained 95% adherence to prescribed HAART regimen. Among the assessed variables, socio demographic factors, knowledge about HAART, duration on ART, CD4 count levels, stigma were not significantly associated with poor adherence. Factors related to the treatment regimen ( $\geq$  3 combined ART tablets;  $\chi 2 = 5.08$ ,  $\rho = 0.042$ ) and total number of tablets taken by patients ( $\geq$  4 combined tablets;  $\chi 2 = 16.03$ ,  $\rho = 0.09$ ) were determinants of poor adherence to HAART. All results are reported in Table 1 below.

Table 1: Univariate associations between determinants of interest and poor adherence to HAART in HIV-infected (N = 69)

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Variable	Acceptable adherence	Poor adherence	<b>p</b> –
	rate ≥ 95%	rate ≤ 95%	valu
	N (%)	N (%)	e
Age (years)			0.56
20 - 34	4 (17.39)	11 (23.91)	-
35 - 44	11 (47.82)	16 (34.78)	
≥ 45	8 (34.78)	19 (41.30)	
Gender			0.20
Female	18 (37.5)	30 (62.5)	
Male	5 (23.8)	16 (76.2)	
Marital Status			0.62
Married	12 (33.3)	24 (66.7)	
Single	1 (12.5)	7 (87.5)	
Divorced	2 (50.0)	2 (50.0)	
Separated	3 (50.0)	3 (50.0)	
Widowed	3 (50.0)	3 (50.0)	
Cohabiting	2 (50.0)	2 (50.0)	
WHO Stage			0.46
1	11 (47.4)	14 (30.4)	
2	1 (4.3)	2 (4.3)	
3	4 (17.4)	15 (32.6)	
5	7 (30.4)	15 (32.6)	
Knowledge	. (2000)		0.70
about HAART			00
Yes	1 (4.3)	3 (6.5)	
No	22 (95.7)	42 (91.5)	
Duration on ART			
Duration on ART			0.43
Mean duration (months)	32.3	36.4	
Cd4+T – cell			0.58
count (cells/uL)			
< 200	13 (59.1)	22 (52.4)	
200 - 349	4 (18.2)	14 (33.3)	
350 – 499	3 (13.6)	4 (9.5)	
≥ 500	2 (9.1)	2 (4.8)	
Stigma			0.71
Yes	1 (69.6)	2 (5.6)	
No	16 (30.4)	34 (94.4)	
No of ARV			
tablets			
1	9 (39.1)	9 (19.6)	
2	1 (4.3)	3 (4.3)	
3	8 (34.8)	14 (30.4)	
4	5 (21.7)	17 (37.0)	
5	0 (0.00)	3 (6.5)	
Total number of		0 (0.0)	0.09
< 4 combined tablets	5 (21.7)	6 (13.0)	
> 4 combined tablets	2 (8.7)	10 (21.7)	

## Discussion of the results

The present study aimed to measure adherence rates to HAART and determinants thereof among HIV/AIDS clinic attendees during a quantitative, descriptive prospective cross-sectional study among HIV-infected attending a public hospital in Ghana. The self reported adherence in the study was 66.7%. This finding was comparable with other studies done in Nigeria and other African setting (Shaah, Lawoyia & Sangowana, 2008; Agu et al. (2011). The number was slightly higher than earlier as per reports by Iliyasu, Kabir, Abubakar, Habashani & Zubail (2005) in Kano (Northern Nigeria). Katende, Lubbe and Apalata, (2014) in their study done in South Africa, obtained adherence rates of 89.7% in females as opposed to 10.3% in males.

A study performed by Falang, Akubakar and Jimam, (2012) in Nigeria, another study done in Kenya by Shaahu, Lawoyia and Sangowawa, (2008) and in South Africa (Peltzer, Peerez, Ramlagan & Aderson, 2010) reported adherence levels of 54.5%. 49.2% and 43.2% respectively. However adherence level reported in this study was higher than seen in above studies.

Our current findings showed that patients who were interviewed and were on ARV regimens containing 3 and 4 ARVs per day were non adherent giving rise to 30.4% and 37% respectively and these were statistically significant ( $\chi 2 = 5.08$ ,  $\rho = 0.042$ ). Also patients who reported taking  $\geq 4$  combined tablets were non adherent with 21.7% and also statistically significant ( $\chi 2 = 16.03$ ,  $\rho = 0.09$ ). These were determinants of poor adherence to HAART. Emphasis should therefore be placed on adherence to HAART especially during counseling sessions as this is required for optimal clinical response and complete viral suppression.

Most socio-demographic characteristics such as age, gender, marital status, did not significantly affect adherence levels amongst our study population. This corroborates the findings of Talaam, Gatongi and Rotichsome, (2008); Kleeberger et al. (2001); Gifford et al. (2000). On the contrary, a study performed by Ofolabi, Ijadunola, & Fatusi (2009), differed from these results that socio demographic variables were associated with being adherent to HAART.

Pill burden also significantly affected adherence in this study. Respondents on more 4 combined tablets per day were less likely to adhere to their treatment compared to those on at least two pills per day. This finding was also identified as a significant determinant to poor adherence in a study done by Falang, Akubaka & Jimam (2012). Sow, Toure, Coume, Dia and Traore (2012) in Senegal and Katende, Lubbe and Apalat (2014) in South Africa in their studies where the total number of more than 4 combined tablets was reported had a strong impact on adherence. Similarly, in India Cauldbeck et al. (2009) demonstrated that patients who obtained 100% adherence took fewer pills. This could be attributable to the fact that these patients probably because of their busy schedules may have been unable to incorporate their drugs schedule into their daily schedule or may be developing pill fatigue. According to Falang, Akubaka, and Jiman (2012) reducing pill load as well as dosing schedules to once or twice daily has been found to be associated with better adherence.

#### Conclusion

This study showed that medication adherence rate was low among HIV-infected accessing treatment in the public hospital in Ghana. It is also obvious that there are barriers to adherence therefore efforts should be targeted and assessed for each patient so that appropriate adherence enhancing interventions can be undertaken.

The complexity of ARV regimen, in addition to other drugs taken by HIV/AIDS patients, was shown to predict poor adherence. Pharmaceutical companies involved in the manufacture of ARVs should ensure that all recommended ARV regimens should consist of not more than two pills per day.

#### Limitations

There are several limitations to this study. Firstly, it is a retrospective cross-sectional in design and therefore reliance on recording was a major concern. This was due to the fact that some patient files were incomplete, and others did not have patients'CD4 counts, viral loads results. In some records it was also found that viral load measurements after 6 months of antiretroviral therapy initiation were not done due to high expenses of the test.

We had limited sample size because some patients had to be called in though it was their review dates. This led to the usage of a sample of only 69 patients. In addition, all participants were from only one population who lived in rural area. As a result, patients' outcomes in this rural area may not be representative of those in urban areas.

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Moreover, the results of this study do not necessarily reflect practices in other settings and this may limit the generalization of these findings.

Secondly, not all patients brought their left over tablets, so the pill count could not be done. Thirdly the research results are only applicable to one public hospital where the data had been collected. Consequently, these results might not be generalized to other ART services in the province.

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