

1.0 CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Antiretroviral therapy (ART) has managed to turn HIV/AIDS from an acute disease to a chronic disease thus prolonging the lives of those who are infected with the disease (1). Improved outcomes with these agents unfortunately needs strict adherence to treatment. Unlike the management of other chronic diseases, adherence rates of 95% and above are needed to maintain viral suppression (2).

The provision of free ART to HIV positive individuals started in November 2003 when the South African government approved the national “Operational Plan for Comprehensive HIV and AIDS Care Management and Treatment for South Africa” (3). As South Africa (SA) had adopted a district health system as a vehicle to deliver primary health care services (4), it made sense to decentralize HIV/AIDS management and care to the districts. HIV/AIDS, being a chronic condition, would be managed better if ART was accessible to patients at primary health care level (3).

The plan recognised a number of limitations in the health system, infrastructure problems, resource constraints, among others lack of skills, human resource shortages and deficiencies in pharmaceutical services which would impede the roll out of the programme to all facilities. To ensure that quality HIV care is provided, an accreditation tool was developed and implemented before services could be provided in district facilities (3).

The operational plan took into consideration that the success of the HIV program depended on strict adherence to ART and a number of strategies (Table 1.1) were identified to improve adherence. A group of counsellors called “adherence counsellors” were introduced into the program to ensure high adherence rates. Whilst doctors make clinical assessments about when it is appropriate to begin ART, adherence counsellors do “the ART readiness assessment”. The patient attends three sessions with adherence counsellors prior to receiving the first prescription of antiretrovirals (ARVs). The third session includes a treatment supporter. This is a family member or a friend who can support the treatment plan. These sessions provide the patient with the necessary information about ART and its related aspects (i.e. adherence education) as well as assess the patient’s “readiness” to take ART medication. Until patients are prepared to commit themselves to long-term treatment and to maintaining good adherence to the therapy, antiretroviral therapy is deferred (3).

Table 1.1 STRATEGIES TO PROMOTE ADHERENCE
1. Establish “readiness” to take medications before ART initiation. 2. Negotiate a treatment plan that a patient understands to which s/he commits. 3. Explain goals of therapy and need for adherence. 4. Encourage use of alarms, pagers or other available mechanical aids for adherence. 5. Provide adherence tools where available: written calendar of medications, pill boxes etc. 6. Encourage disclosure to family or friends who can support the treatment plan. 7. Develop links with community organizations to support adherence. 8. Include adherence discussions in support groups. 9. Create links with patient advocates.

Strategies to promote adherence. Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (3).

Measures were taken to guarantee that drugs were always available so that the health system should not contribute to non-adherence to treatment. Amongst these was the development of treatment guidelines as well as the strengthening of pharmaceutical

services. To make pharmaceutical services more accessible to patients, ARV sites were equipped with well resourced pharmacies (3). Two standard regimens for adults were recommended by the treatment guidelines (5). Pharmaceutical companies could produce high volumes of ARVs that are on the treatment guidelines rather than many different antiretroviral drugs. While this is good for managing a large group of patients, the need for adherence becomes even more critical as non-adherence also leads to resistance. Resistance to these regimens signifies disaster for the ARV programme. Research however shows that it is possible to conserve future ART options by maintaining the majority of individuals on first line regimens (6).

The operational plan stressed the need for an information system, a standardised, effective and efficient system for data collection, collation, monitoring, and feedback to facilitate programme implementation, ensure good quality care, and achieve good patient/programme outcomes. Some of the specific functions of the patient information system were to monitor adherence as well as follow up and tracking of patients on ART (3). According to the HIV & AIDS and STI National Strategic Plan, accredited facilities must have the capacity to actively trace people on ART who are more than a month late for clinic or pharmacy appointments (7).

The Ekurhuleni district is located in the eastern region of the Gauteng Province. The district has a large urban population of approximately 2.5 million people and the second highest population density in South Africa. The southern part of Ekurhuleni, where the

Lerato HIV clinic is located, serves a middle-lower income urban population with a high unemployment rate (8).

The clinic started operating in April 2007. At the time of the study the Lerato clinic operated with a team consisting of a project manager, two professional nurses, two clerks, one data capturer, two medical officers, a dietician, a social worker, a pharmacist, two pharmacist assistants and two adherence counsellors. Approximately 70 patients visited the clinic on a daily basis to receive their ART. Patients were seen between Monday and Thursday. Friday was reserved for administrative functions. After the first month on ART, patients attended the clinic at four weekly intervals either to consult the doctor or to fetch their supply of antiretroviral medication.

Team members perform different functions in the clinic. The social worker performs among other duties tracing of patients who default on treatment. Defaulters are those patients who stay away for thirty days or more from their clinical appointments. She traces patients (telephonically) who have missed appointments as the institution is not in a position to visit patients because of limited resources. However, there is no system of alerting the social worker as to which patients have missed appointments. The social worker has to go through the pharmacy database to see which patients missed their refill appointments. The pharmacy database contains a record of the dates when the patient last collected their treatment. This is a mammoth task besides the other job functions that need to be performed.

1.2 LITERATURE REVIEW

Non-adherence to ART is an important obstacle to the management of HIV/AIDS (1). This increases the need to measure the prevalence of non-adherence as well as to know and understand the factors that produce non-adherence so as to develop effective interventions to improve adherence. The literature review serves as a study framework that will guide this project. It aims to provide an overview of some key factors associated with non-adherence to ART in South Africa and other parts of the world.

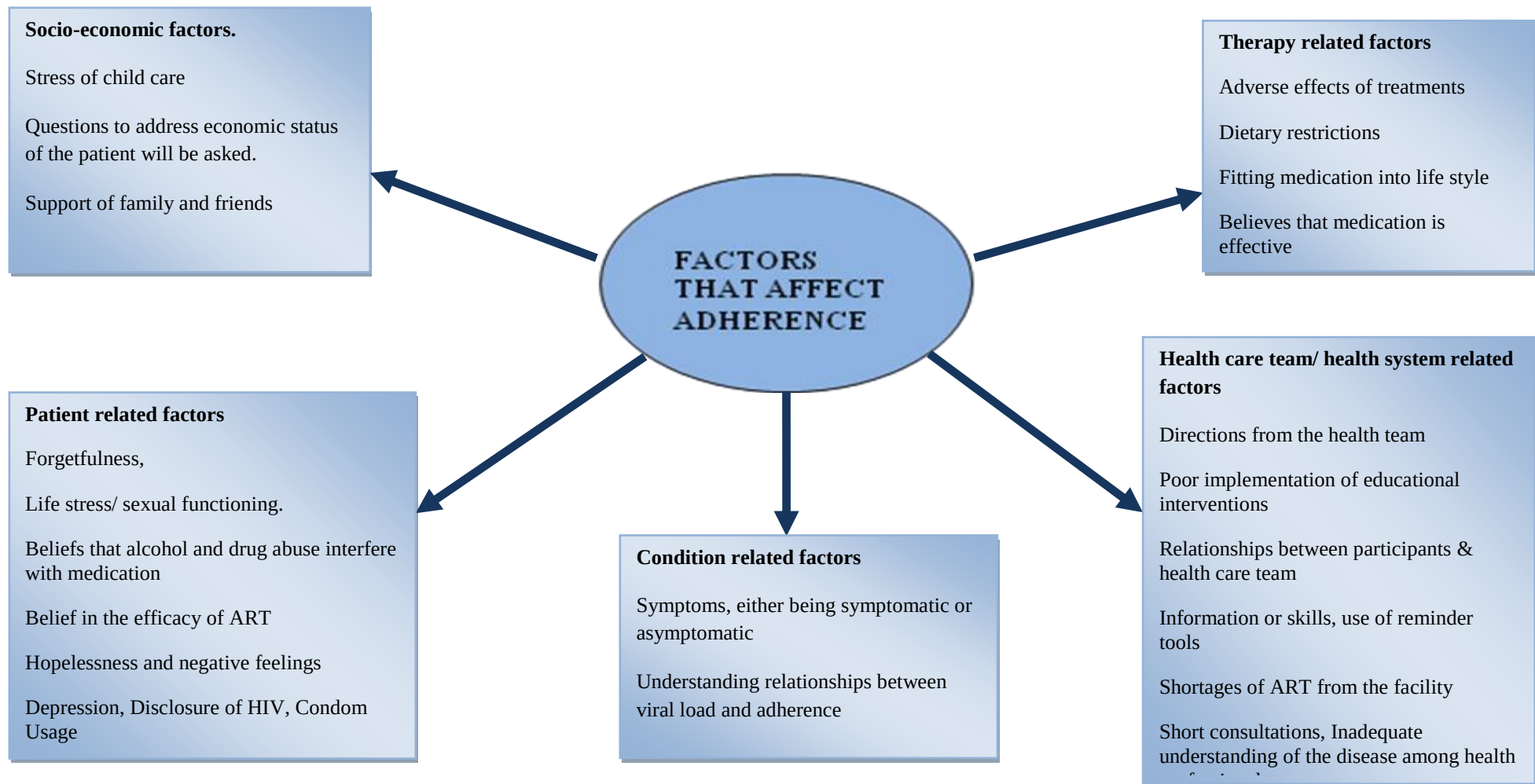
1.2.1 Measurement of adherence

Adherence to treatment can be measured either using direct or indirect methods. “Therapeutic drug monitoring” a direct method of measuring adherence to treatment, involves measuring the amount of drug in the plasma while indirect methods include self-reported adherence, pill-counts monitoring, pharmacy refills and electronic drug monitoring (9). These methods have their advantages and disadvantages as shown in appendix 2. Using a multi-method approach allows the strengths of the one method to compensate for the weaknesses of the other and to more accurately capture the information needed (9, 10).

1.2.2 Factors affecting adherence to ART

WHO (1) classifies factors affecting adherence to ART into five groups as illustrated in figure1. Garcia perceives adherence to be the result of a complex interaction between the patient, prescribed medication and the health system (11). To understand the factors from a health systems perspective, the activities and objectives of the health system are looked at.

The health system seeks to promote, restore or maintain health and its objectives are to improve the health of the population, responding to people's expectations and providing financial protection against the costs of ill-health (12). To achieve these objectives health systems require resources (13). Studies highlight that the challenges that face developing countries in delivering ART lie within the health system itself. These challenges do not only affect access to ART but impact on adherence as well (14, 15). In other words, to improve adherence to ART in developing countries the main barriers to overcome are access barriers. Epping-Jordan (16) argues for the realignment of the health system in accordance with local resources and demands to achieve better outcomes.



1. Figure 1.1. Factors affecting adherence to ART. Adapted From. Adherence to long-term therapies: evidence for action. WHO (1).

Providing ARV's free of charge has not removed financial barriers to access and improved adherence to ART. Studies have highlighted that even under conditions where HIV/AIDS services are free, patients with financial difficulties default on treatment. A study done in one of the Comprehensive Care, Management and Treatment (CCMT) facilities in South Africa showed that the leading cause of failure to follow up was financial (17). In Uganda transportation costs were not only a barrier to ART adherence but also had a huge impact on those who were adhering to treatment as well (18). Other studies also highlighted transport costs as barriers to adherence to ART (19, 20, 21). Binangwalo and Ratnayake (20) in their study showed that patients forfeit buying food for their families, school fees and even medication for their children to ensure that they have transport money to attend the clinic. Adherence cannot be sustained under such conditions.

Besides these costs some poverty stricken patients complained that ART makes them eat more thus making their economic situation even more difficult (21). In Uganda a study demonstrated that access to adequate nutrition is an obstacle to ARV adherence (10). South African HIV/AIDs patients are persuaded by health care workers (HCWs) to purchase high quality foods which are highly priced increasing the financial pressures that they are already experiencing (22). Other studies reported loss of wages due to long waiting times (21) stressing opportunity costs that arise when patients want to adhere to treatment.

In conversations between patients and HCWs in some primary health care clinics in South Africa, patients were more concerned about disability grants than adherence to ART (23). Natrass (24) found that high unemployment rates and poverty contributed not only to high HIV infection levels but also to non-adherence to ART as patients wanted to remain eligible for disability grants. Discontinuing the use of ARVs in order to maintain and, in

some cases, to re-qualify for the disability grant was a common strategy for those who depended on the grant for survival (25).

Time is another resource that both the patient and the health system have to be willing to expend to reach the desired outcomes. Time needs to be invested in the interactions with patients so as to achieve the desired results. Murphy (26) looked at this issue in terms of the time patients spend with their health providers and found that patients who had enough time with their health providers adhered better than those who didn't. Waiting times, the time that patients spend waiting for the HCWs to attend to their needs was found to have an impact on adherence to ART. Waiting times contributed to dissatisfaction with clinic services and caused patients to stop treatment (27). A study looking at both waiting times and time spent with the doctor, however, showed that patients value the time that they spend with the doctor and are willing to overlook waiting times(28).

With increasing numbers of patients joining the programme there are workload challenges. This has a negative impact not only on waiting times, but results in staff burnout and patients not getting the attention that they need. A study conducted in South Africa showed that the major challenges in providing HIV care was coping with workload and insufficient training (23). In Haiti a lack of trained HCWs negatively impacted on patient's continuation with antiretroviral treatment (29).

Poor information on HIV had a negative influence on patients continuing with treatment. Access to information is empowerment to use health care and reflects an individual's capacity to derive benefits from health care services. Access to health care is not inherent

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in an individual. Knowledge about health and health services, perceptions and preferences depend on exchange of information between the health system and the individual. There is a link between access to health services and health information. For patients to benefit from health services, or in this case adhere to treatment, interactive engagement with individuals to increase their capabilities is very important (30).

“Adherence studies support the view that successful adherence to HAART involves provider-patient collaboration and communication to incorporate the therapeutic regimen into the patient’s daily routines successfully” (31). This collaboration takes place in the context of quality patient-provider relationship (32). There is overwhelming evidence that the relationship between the patient and the health care team is important for antiretroviral adherence (33, 34, 35, 36). Several aspects of the patient provider relationship were investigated including information sharing, trust etc. Other ART adherence researchers found that clients who were less engaged with HCWs reported poor adherence compared to those who were more engaged (37).

Evidence has shown that patient trust in HCWs predicts adherence and continued enrolment in health care programs as well as satisfaction does (32). In a review of adherence literature twelve studies showed that lack of trust or dislike of a patient’s health care provider served as an impediment to adherence (33). Kremer and Ironson highlighted that some patients are not open to their HCW about their ART non-adherence because they fear being treated in a judgemental way (38). Patients who felt supported by their HCW’s were more adherent than those who were not (36).

Studies have shown that patient retention is facilitated by decentralised care (39). Hospital based CCMT services had a higher dropout rate as compared to primary health clinics (40). Clinic based care is more effective in dealing with HIV. Similarly access to reliable primary care is related to increased adherence to ART (39, 40). Primary care clinics save patients' time and money thus promoting distributive justice by offering access to treatment close to home (41). Apart from access to clinic sites adherence was found to be influenced by the flexibility of clinic hours (31).

Studies showed that unavailability of drugs at treatment sites (42), migration or travel and forgetfulness constrained patients on ART from sticking to appointments or taking their doses of medication (43).

Chopra highlighted the challenges faced in the introduction of ART in SA among these an environment with a multitude of alternative treatment including traditional African therapies. The study stressed that unless the decision has been made of the choice of therapy patients would vacillate between traditional and antiretroviral therapy. Patients would move from one health provider to the other and not get the full benefit from ARVs (44).

The use of traditional medicines was one of the barriers to adherence (27). Part of the readiness assessment involves ensuring that a patient is ready to use ART exclusively. A qualitative study of homosexual youths showed that primary-care providers exhibited

judgmental behaviour, stereotyping, homophobia, and failure to address cultural issues when administering care (45).

The use of adherence counsellors in the program facilitated a link between the community and health services apart from supplementing the staff in CCMT services in SA (40). They were accepted by the patients as they came from the same community or the same life world as them. They address and engage the patients on their cultural issues making health services not only medically secure, but culturally secure as well (46).

There is no concurrence on the association between demographic characteristics and ART adherence. In one study education status was associated with adherence (47) and another (43) found that demographic factors such as employment, educational status, gender and age are not associated with adherence to ART. A study done in Nigeria found that having a higher educational qualification as well as being female, under 35 and being single was also associated with non-adherence (42).

In conclusion, review of the literature illustrated the complexities of measuring adherence and a need for a multi-method approach for measuring adherence. It also indicated that adherence to treatment is affected by multiple factors. These factors are found at different levels. On an individual level, there is forgetfulness, transportation costs, food costs etc. Structural level factors such as accessibility of ART sites, times that the services are available, availability of drugs as well as the ratio of HCWs to patients are also important. These have an impact on workload, waiting times and burnout. Factors that affect adherence to ART are interlinked and they interact with each other.

1.3 STATEMENT OF THE PROBLEM

The Lerato HIV clinic opened in 2006 and ART adherence rates have never been assessed. Nothing is really known about the patients' adherence behaviours and the factors that are having an impact on their adherence. Measuring adherence rates would enlighten managers about the performance of the program. To be able to improve adherence rates there is a need to know the factors that affect adherence so that the necessary interventions can be implemented.

In resource limited countries like South Africa it is important to look at the health system itself and how it affects adherence to treatment. Research has shown that health system failures were found to be at the root of the disappointing outcomes of tuberculosis control strategies (15). To reach the outcomes that we desire, there is a need for a robust health care system that is able to adapt to the changing environment. This study will focus on the health system factors affecting adherence to ARV treatment. The results of this study will inform the clinic so that it can achieve better health outcomes with the resources at its disposal.

1.4 AIM AND OBJECTIVES OF THE STUDY

The study aims to determine health system factors that have an impact on adherence to treatment at Lerato clinic in Germiston between July and September 2009.

The study has the following objectives:

1. To describe the demographic profile of patients attending the clinic,
2. To determine adherence rates to ART in the clinic using the pharmacy refill method,
3. To determine health system-related factors which affect adherence to ART,
4. To describe patient perceptions of their care and
5. To describe the HCWs' perception of challenges faced in the clinic which could impact on adherence.

2.0 CHAPTER TWO: METHODOLOGY

This chapter provides a description of the methodology including the design of the study, participant selection, data collection and ethical considerations. Finally a description of the development of the framework which informed the analysis process is provided.

2.1 STUDY DESIGN

This was a cross sectional study, that utilised both quantitative and qualitative approaches, of patients receiving antiretroviral treatment at Lerato clinic in Germiston Hospital and health care workers working there. While a case control study would have been considered to determine the factors which have an impact on ART adherence a cross-sectional study was more relevant to find out adherence in the clinic which was never done and also determine the factors that have an impact on adherence. Moreover patients move from being adherent to non-adherent at anytime during their treatment cycle and different factors can arise at anytime during the treatment cycle.

2.2 STUDY SITE

Lerato HIV/AIDS clinic was chosen by the researcher out of convenience. It was more accessible to the researcher than other CCMT clinics in the area.

2.3 STUDY POPULATION

- ✓ The study population was all patients (male and female) who were 18 years or older and had been on ART for six months or more at the Lerato clinic. All patients had records available for at least 6 months continuous treatment at this clinic.

A total of 2575 patients were on ART at the clinic. One thousand two hundred and twelve (1212) patients were excluded from the study leaving a study population of 1363 patients/patient records. These patients were either younger than 18 years of age, and or on ART for less than six months and those whose treatment had been stopped by the doctor and then reinitiated, but did not have six months continuous records on ART.

- ✓ All categories of health care workers working in Lerato clinic.

2.4 STUDY SAMPLE

Objective 2

From the study population of 1 363 patients, the appropriate sample size was calculated using Epi-Info 3.5.1. As adherence researchers in SA have found adherence rates ranging from 70% to 99 % (43, 48, 49, 50, 51, 52, 53), the adherence rate at Lerato clinic was

estimated to be 85% on average from the studies that were found. At $p = 0.85$, and the confidence level of 95% the required sample size was established to be 172. Although the sample size was calculated to be 172, data was collected data from 195 records to cover for any missing information.

A systematic sampling strategy was used to select patients for the study. From the population of 1363 patient records, every seventh record was selected to be part of the study. All the records that were not selected were then deleted from the excel spread sheet leaving a total of 195 records which is the study sample.

Objectives 3 and 4

A convenience sampling method was used to select the sixty seven patients who were interviewed. This number was limited by the researcher's resource constraints.

Starting at the beginning of the queue, patients who were waiting to collect medication at the pharmacy were asked to participate in the study. First the researcher established if they met the inclusion criteria, then the first patient who met the inclusion criteria was asked to participate in the study. After finishing the interview the next patient who was waiting to collect medication was asked to participate in the study. Where a patient did not want to take part in the study, the next patient was then asked to participate. This continued until sixty seven patients were selected over a period of seven weeks.

Objective 5

A stratified purposive sampling method was used to select HCWs to be interviewed. Fifteen health care providers were employed in the clinic at the time of the study. There were eight different categories of health care providers - project manager, the social worker, pharmacist, pharmacist assistant, medical officer, professional nurse, adherence counsellor as well as the dietician. Where there was more than one health care worker per category, one health care worker per category was selected to participate in the study. The researcher first approached the health care worker who had worked at the clinic for the longest time.

2.5 DATA COLLECTION

Data was collected from different sources, the pharmacy data base, the patient's files, their appointment cards, the patients themselves and from HCW interviews.

2.5.1 Calculation of adherence

From the pharmacy database, the following information was collected on 195 patients:

- Date of birth
- All the dates on which patients had collected their ARVs and
- Sex of the patient

2.5.2 Patient interviews

Patient interviews were done by the researcher from Monday to Thursday between 9h30 and 14h00.

Each patient who agreed to participate in the study was invited into a room allocated to the researcher to do interviews. This room was available as the social worker was on maternity leave and ensured privacy during the interviews. It encouraged patients to be open to disclose information without worrying about other people listening to them. Patients were requested to read and sign an information sheet and consent form (appendix 2). Where they did not understand, the researcher explained to them in the language they could understand.

The researcher then went through the questionnaire (appendix 3) with the patient. Where patients were not fully conversant in English, questions were explained in another language by the researcher to facilitate understanding. Information on selected demographic variables (age, gender, employment and educational status) was collected in Section A of the questionnaire.

Section B consisted of 11 closed and open-ended questions about their adherence to medication over the past month.

Studies highlighted that although ART is provided free of charge, there are other costs involved which can impact on adherence. Section C consisted of questions relating to the costs of care as well as the distances patients travel to the service point.

Literature suggests that patients who are satisfied with the service provided are easily retained by the system thus being adherent to treatment. Section D consisted of questions relating to the satisfaction with service. Section E consisted of questions about quality of care and service availability.

After the interview, as the patient had already given formal consent for their file to be reviewed, the following information was extracted from the patients file and appointment card and entered into the data collection tool, appendix 3.

- i. Two most recent viral loads.
- ii. The date that treatment was initiated.
- iii. The ARV regimen during the study period.
- iv. The dates of the six last consultations or treatment collections at the clinic.
- v. The six latest appointments

All this information was collected and inserted into the data collection sheet appendix 4.

2.5.3 Health care workers' interviews

HCWs were asked to read and sign the information sheet and consent form (appendix 5). An interview guide (appendix 6) adapted from WHO adherence studies (10) was used to collect information from health care workers in five main areas – their current tasks and training that they had received related to these tasks, availability of drugs and equipment in the clinics, their perceptions about patient adherence and challenges that they face in supporting patients. Interviews were all done in English as all the health care workers were fully conversant in English. As patients did not attend the clinic on Fridays, the researcher chose to do health care workers interviews on Fridays.

2.6 PILOT STUDY

The patient questionnaire was piloted on six patients from the Lerato clinic to check for understanding, feasibility and acceptability. Patients from the pilot study did not take part in the main study. The pilot identified, among others, terminologies in the questions that needed clarification shortfall in the responses on certain questions. For example in looking at the costs of attending the clinic, the number of responses had to be modified to accommodate those who walked to the clinic having no monetary costs to attend the clinic. These modifications were then incorporated in the questionnaire. The HCW instrument was however not tested as the researcher used a questionnaire used by the WHO (1).

2.7 ETHICAL CONSIDERATIONS

The first step in the research process after the proposal has been prepared is to obtain clearance from the Ethics Committee to ensure the ethical integrity of the research process. Ethical clearance was obtained accordingly from the University of the Witwatersrand Ethics Committee, Clearance certificate protocol number M090117 (See Appendix 1). The Chief Executive Officer of the hospital checked the certificate and gave approval to carry out research at the site and to further access the records of the patients.

Although the researcher was one of the HCW's in the facility in the past, she was not senior to any of the HCW's in the clinic. Although some participants may have recognised

her as having been one of the HCW's before she emphasized her new role as a researcher. Being responsible for collection of all the data the researcher went through an information sheet and formal consent form with the patients and the HCWs to introduce them to the study and obtained their formal consent before proceeding with data collection (appendix 2 and 5). Participants were informed about the aims and objectives of the study before being asked to give their informed written consent to be interviewed. Patients and HCWs were also informed of their right and choice to either participate or to opt out of the study at anytime even when the study had commenced and written consent was obtained. Contact details of the researcher as well as the secretary of the Human Research Ethics Committee were provided to the participants in case further clarification was required.

Particular attention was paid to anonymity and confidentiality. The researcher ensured that the interviews were anonymous with no names or other identifiers used on the data collection forms except for codes to help in analysis of results. Interviews took place in a closed room and there was no risk of auditory privacy being bridged. As there were only a few HCWs in the clinic there was a chance of some information being linked to a particular person. Even the category of the HCW was not given when the findings were presented and quotes used.

Two patients refused to be part of the research. They were not coerced or encouraged in any way to participate in the study. Their wishes were respected.

2.8 DATA ANALYSIS

Data was collected using the patient questionnaire, HCW questionnaire, data collection sheet and the pharmacy database. Before data analysis could commence data was checked for correctness and completion. Where data was missing an attempt was made to complete the data. With the pharmacy database, some entries did not have the sex of the patient and the patient number was used to draw the file and then find the sex of the patient and update the record accordingly. Some viral load results were missing for the data collection sheet and the researcher went back to the patient record to check if it was since updated. After ensuring that all the data was in order, even the forms had the correct identification, the data entry process began. Data was entered into an excel spreadsheet from the questionnaire by the researcher.

Patient interviews data as well as data from the information sheet was then exported to a software program Stata which was used to analyse data. A statistical analysis was carried out in STATA version 10 (STATA Corporation, Tx, USA).

No software was used to analyse qualitative data. Information from HCW interviews was triangulated with that from patient's interviews to see where there was consensus and where there was no convergence. Challenges that HCWs faced in the clinic, patient's satisfaction with services, costs of attending services, financial constraints for example, formed the basis of triangulation of information between HCWs and patients. Therefore triangulation was done to determine factors that have an impact on ART adherence.

2.8.1 Calculating adherence using the pharmacy refill method

From the information extracted from the pharmacy database, the researcher was interested to see the gaps if any in the collection of the ARV supplies. To give an example, if a patient collected ARVs on the 30th of June and then came for the next refill on the 3rd of August for instance they were classified as non-adherent on the basis of the three days when they, in theory, did not have a supply of their ARVs.

Adherence was calculated as follows:

$$\begin{aligned} & \frac{\text{Total number of days' treatment issued}}{\text{Actual number of days' treatment needed}} \\ &= 30/33 \\ &= 0.909 \end{aligned}$$

As shown in Appendix 7 an adherence value of 0.909 means this patient had enough medication to be 90.9% adherent. Patients were divided into two groups. Those who collected medication to be in a position to take 95% or more of their treatment were classified as adherent and those who collected medication to be in a position to take less than 95% of their treatment were classified as non-adherent.

2.8.2 Patient interviews and patient record reviews

Descriptive statistics (mean and simple frequencies using charts and tables, percentages etc) of the variables were presented. Proportions were compared using a chi-squared test

of association. The chi squared test was used to check the association between age, gender and length of time on ART and adherence to ART.

With open ended questions, words, quotes were used to communicate some findings. Responses were grouped together according to similarities and differences. In assessing whether patients were satisfied with the information about treatment, the time that they spend with health professionals as well as the clinic environment, patients who responded by either saying it's "ok", "right", "it's adequate" or "it's enough" referring to time spent with health professionals for example or those who used adjectives like "good", "right", "adequate", "ok", "enough", "excellent" or were classified as being satisfied with the either the treatment information, time spent with health care workers or the clinic environment.

2.8.3 Health care worker interviews

Information from health care workers was analysed taking into consideration that information should not be linked to a specific person. This was done in order to protect the health care workers so that they are not penalized in any way because of what they said.

Words, quotes, tables and summaries were used to illustrate the findings from HCW interviews. Descriptive statistics, in this case means, ranges and percentages, were also used to communicate the findings.

Besides just saying that training was inadequate, the following responses also showed that they were not satisfied with training;

- Indicating what an individual thinks is needed,
- Pointing out where the training is deficient.
- Indicating not attending training when they were supposed to get training that equips them to do their work well

2.8.4 Triangulation

The process of data analysis also involved bringing together various sources of data to develop a composite picture of adherence and health system factors that impact on adherence. This is called triangulation. In this study triangulation involved combining information provided by HCWs, patients and information obtained from records in the clinic. Also two methods, self-report and pharmacy refill were used to measure adherence to treatment.

3.0 CHAPTER THREE: RESULTS

This chapter will illustrate the study findings beginning with the pharmacy database record review results, followed by patient interviews and ending with health care worker interviews results.

A total of 165 patient records from the pharmacy database were reviewed, 67 patients and eight HCW were interviewed for the study. Information was further extracted from the records of the 67 patients who were interviewed. Eighty four percent of the interviewed patients came from the southern region of the Ekurhuleni district. These included patients from the Germiston town, the surrounding informal settlements and townships. The other 16% of the patients came from other regions in the district as well as outside the district (figure 3.1).

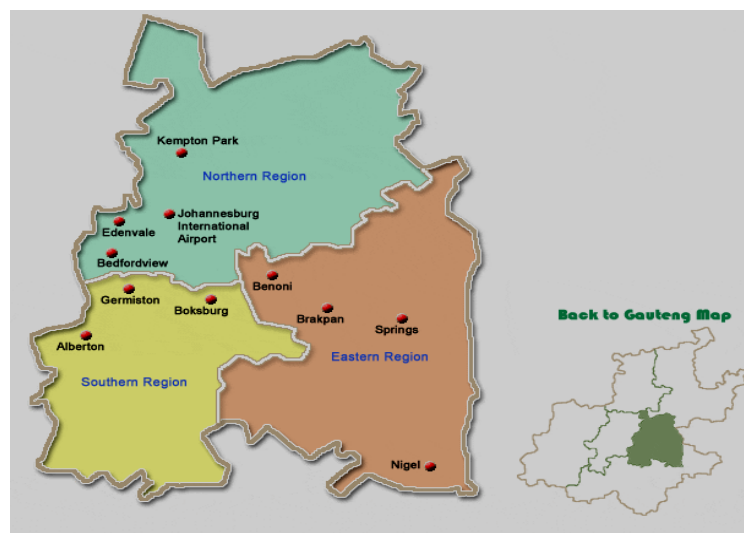


Figure 3.1 Map of Ekurhuleni district

3.1 RECORD REVIEW- PHARMACY REFILL ADHERENCE

A total of 195 patient records on the pharmacy database were identified and adherence results are shown in table 3.1 and 3.2. Eighty one percent (81%) of the patients were adherent to ART according to pharmacy refill method (range 71% - 141%, median 101% , mean 99% SD 8.7).

Table 3.1 Adherence to ART using pharmacy refill method			
Gender	Adherent	Non-adherent	Total
Male	50(68%)	12(32%)	62
Female	108(68%)	25((32%)	133
Total	158(81%)	37(19%)	195
Chi squared test= 0.85 p value =0.926			

A chi-squared test was used to check the association between gender and adherence. The probability value is more than five percent indicating that the test is statistically insignificant. There is no association between gender and adherence to treatment.

Table 3.2 Adherence and age using pharmacy refill method			
Age	Adherent	Non-adherent	Total
24- 35	64(82%)	14(18%)	78
36- 45	61(79%)	16(21%)	77
46-63	33(82.5%)	7(17.5%)	40
Total	158	37	195
Chi-squared test= 0.273 p value = 0.872			

In table 3.2, the p value is more than five percent indicating that the test is statistically insignificant meaning there is no association between adherence to ARV treatment and age.

3.2 PATIENT INTERVIEWS RESULTS

Table 3.3 and 3.4 shows the demographic and clinical characteristics of the patients who were interviewed for the study.

Table 3.3 Demographic characteristics of interviewed patients			
n=67			
Gender	Female	51	76%
	Male	16	24%
Employment status	Studying	1	2%
	Unemployed	33	49%
	Pensioner	2	3%
	Employed but not self-employed/ Casual / contract	29	43%
	Self- employed	2	3%
Educational status	No schooling	3	4%
	Any schooling up to grade 10	60	90%
	Grade 11- 12	0	0%
	Working towards/ having tertiary qualification	4	6%
Age in years		n	Mean
	24- 35	27	29.5
	36- 45	24	40
	46-65	16	53

Table 3.4 Clinical characteristics of interviewed patients			
			n=67
Period on ARV therapy in months		n	Median/Mean
	7 – 12 months	15	9
	13 - 24 months	38	18
	25- 36 months	7	27
	< 36 months	7	50
Latest Viral Loads	Detectable	12	26-3000 copies/ul
n= 60		n	%
	Lower than detectable limits	48	72%
Frequency of doses	Twice daily	65	97%
	Once a day	2	3%

3.2.1 Patient costs incurred by being on antiretroviral therapy

a. Patients spend money for transportation to attend the clinic as shown in figure 3.2.

The highest transportation cost was paid by those patients who did not come from the Ekurhuleni district.

b. Twenty three percent (7/31) of the employed (including self-employed) patients stated that they lost income as a result of coming to the clinic.

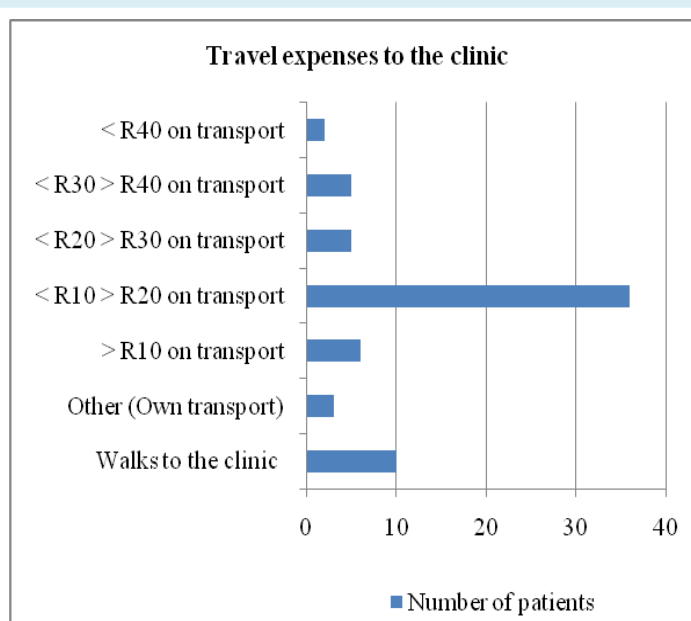


Figure 3.2 Travel expenses to the clinic

c. Forty two percent of the patients (28/67) felt that they gave up something as a result of being on ART. The majority of the things that they gave up were nutrition related, either focusing on eating habits or their choice of food. Some said they ate more as ART makes them hungry. They also had to buy extra fruit and vegetables that they were not buying before they were put on ART. Others felt that before ART they did not consider what they ate but now they have to choose food carefully. (Box 1 shows some of the responses given by patients.)

“I buy olive oil, vegetables and fish which are very expensive, as I am trying to live according to the advice that is given at the clinic.”

“When you are not on ARVs you can stay for a long time without food, but once you start taking ARVs you need to eat otherwise the tablets will cause harm to the body”.

Box 1

3.2.2 Missing ART and clinic appointments

Of the 67 patients 43(67%) never missed a dose of their ART since they started treatment. From the 24 patients who admitted to missing a dose of ART, 21% (5/24) had missed one dose or more of their ART in the last month as illustrated in figure 3.3.

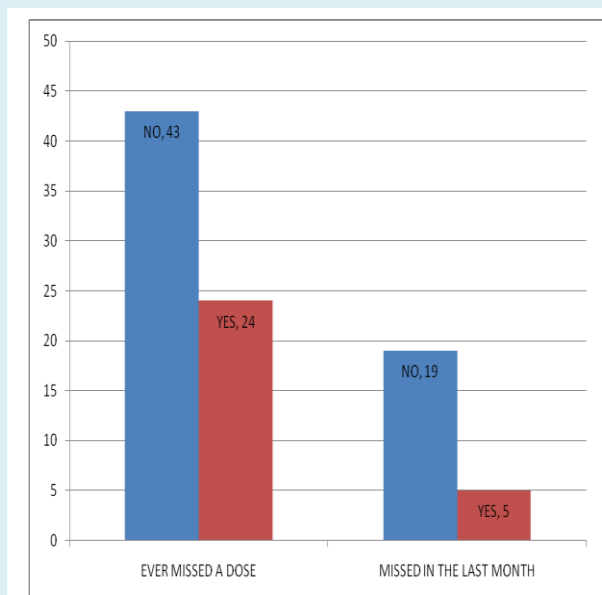


Figure 3.3 Missing antiretroviral treatments

As shown in the last section, 24 patients stated they had missed their ART. Figure 3.4 illustrates the reasons patients gave for missing ART. Forty eight percent of the responses for missing treatment were for the other category. This category included patients who said they no longer miss their treatment and do not recall reasons why they missed treatment before. Two patients said they missed their treatment when they were with

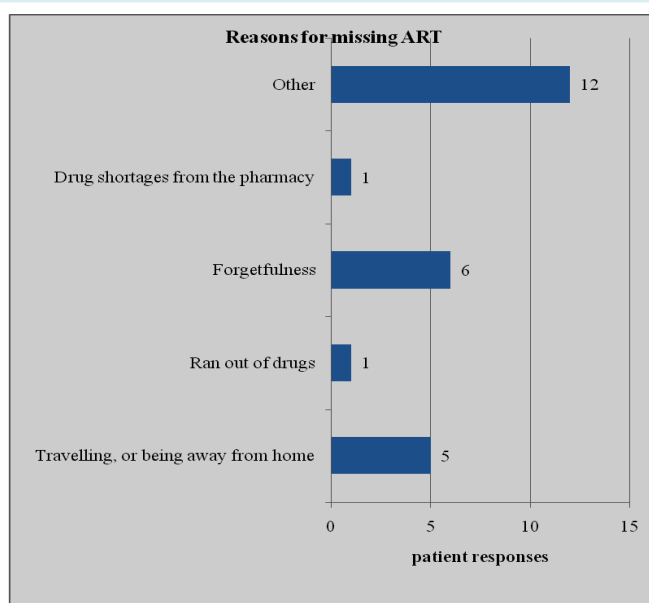


Figure 3.4 Reasons for missing ART

people they had not disclosed their HIV status to while the other two stated that they miss their treatment when they do not have food. The last patient mentioned that oversleeping was a reason for her missing ART.

Table 3.5 Association between demographic characteristics of patients and missing ART				
		Had never missed ART(43)	Missed ART(24)	Total (67)
Gender	Female	33(65%)	18(35%)	51
	Male	10(62%)	6(38%)	16
	Chi squared test= 0.258 p value= 0.872			
Employment status	Employed	21(68%)	10(32%)	31
	Unemployed/ Studying	22(61%)	14(39%)	36
	Chi squared test= 0.319 p value= 0.572			
Age in years	24- 35	17(63%)	10(37%)	27
	36- 45	17(71%)	7(29%)	24
	46-65	9(56%)	7(44%)	16
	Chi squared test= 2.54 p value 0.281			

Table 3.5 illustrates that there is no association between demographic characteristics and missing ART. The p value for gender and employment status and age was more than five percent showing that the test is statistically insignificant. There is no association between demographic characteristics and missing ART.

Table 3.6 explores the association between missing appointments, length of time on ART and missing ART.

Table 3.6 Association between missing appointments, length of time on ART and missing ART				
		Had never missed ART(43)	Missed ART (24)	Total (67)
Appointments Missed	Missed	8(36%)	14(64%)	22
	Never missed	35(78%)	10(22%)	45
Chi squared test= 11.1 df=1, p value = 0.001				
Period on treatment in months	7-12	10(67%)	5(33%)	15
	13-24	25(66%)	13(34%)	38
	25-53	8(57%)	6(43%)	14
Chi squared test= 0.385 df=2, p value = 0.825				

A chi-squared test showed a probability of 0.001 for missing appointments and missing ART. This result is statistically significant meaning missing ART is associated with missing appointments. Adherence decreases when patients miss their clinic appointments.

The period on ART however cannot be associated with missing ART as the probability value is higher than five percent. There is thus no relationship between the period on ART

treatment and missing ART. Adherence does not increase or decrease in relation to the period on treatment.

Missing clinic appointments

Thirty three percent (22/67) of the patients stated that they had missed an appointment to attend the clinic in the past two months whereas 45(67%) patients stated that they had not missed an appointment in the same time period. Patients missed clinic appointments for different reasons as shown in figure 3.5. Some patients gave more than one reason for missing appointments.

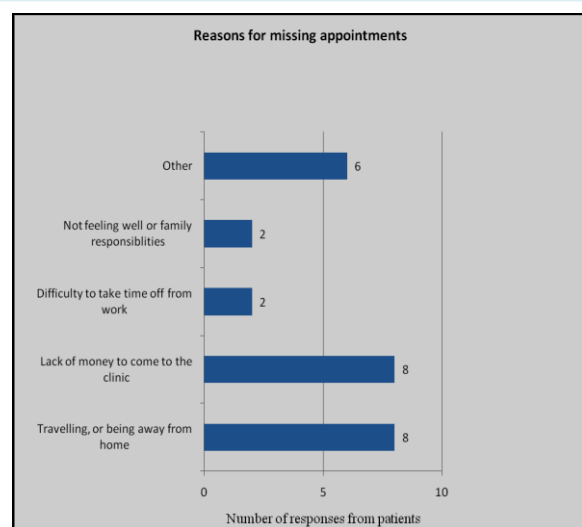


Figure 3.5 Reasons for missing clinic appointments.

Of the patients who indicated “other”, one patient out of the six missed the appointment to attend the clinic because she was writing exams, while the rest said they no longer remember the reasons they missed appointments. One explained that since she disclosed her HIV status to her boss she no longer had problems with attending the clinic. Another explained that since the clinic made provision for a treatment supporter to be able to come to the clinic to fetch treatment, she makes use of this opportunity and sends the treatment supporter when she is unable to come to the clinic to fetch the repeat prescriptions.

3.2.3 Service availability

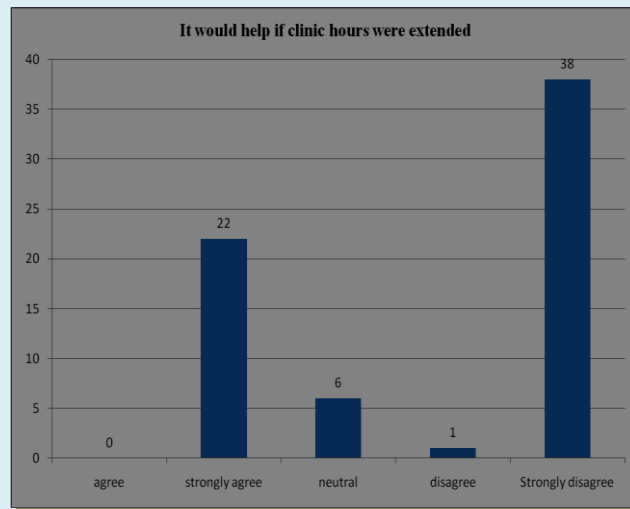


Figure 3.6 Extending clinic hours

Although ninety one percent (61/67) of the patients said that they did not have difficulty fetching medications during clinic hours, thirty two percent of the patients (22/67) felt it would be positive if clinic hours were extended (see figure 3.6).

One hundred percent of the patients said that the pharmacy never ran short of antiretroviral drugs such that they could not supply them with one month's medication.

3.2.4 Patient treatment information and understanding of HIV disease by HCWs

- Eighty four percent of the patients (56/67) were satisfied with the information that they received from the clinic. To highlight this, five patients pointed out the benefits that they

derive from the information that they obtain from the clinic. One patient stated that the information she acquired was encouraging and gave her hope. The other four patients stressed the helpfulness of the information. To elaborate on this further one patient mentioned that they do not only get information about treatment which helps them to understand their condition and treatment better, they get taught about other life issues as well.

- One patient said she did not receive any information from this clinic but only from the clinic where she initiated her ART.

- Fifteen percent of the patients (10/67) were however not satisfied with the information they received. One gets extra information on her own while others were

“They do it once off, but they must keep on repeating some of the information until it sinks in”.

“The initial information obtained cannot sustain us forever”

Box 2

concerned with the continuity of information sessions and or educational talks in the clinic (See box 2).

Patients believed that HCWs in their clinic understand HIV disease. Forty five percent (45%) of the patients said that their understanding of HIV disease by HCW was good while 52% said it was excellent. Only 1.5% said it was average and 0.5% percent felt they were not in a position to say anything about their HCWs knowledge.

3.2.5 Patient-provider relationship

Table 3.7 Patient- provider relationship/communication patterns in the clinic.									
	Treated with respect	Feel cared for in the clinic	Gets support from the clinic	Gets assistance to take medication	HCW's understand difficulties to adhere to ARV's	Difficulty communicating because of language	HCW are too busy to listen	Have privacy during consultation	I trust the HCW's here
Strongly agree	59	58	58	55	52	1	2	65	62
Agree	7	8	5	7	2	0	1	1	2
Neutral	0	1	3	5	11	2	2	1	1
Disagree	0	0	1	0	0	0	1	0	2
Strongly disagree	1	0	0	0	2	64	61	0	0

Table 3.7 illustrates overall patient-provider relationship and communication patterns in the clinic. Communication in the clinic was characterized by trust, respect and privacy. Language was not a barrier for communication between patients and HCWs. Patients generally felt cared for and supported in the clinic.

Figure 3.7 demonstrates that 37% of the patients said they would not tell anyone if they missed a dose of their medication. Only 63% of the patients would get help immediately if they start having problems adhering to treatment.

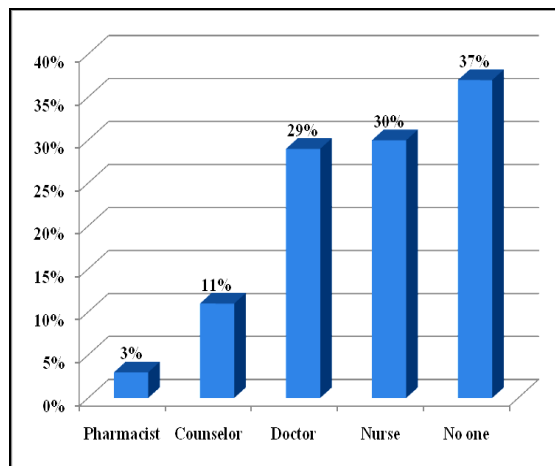


Figure 3.7 HCW to whom patients could communicate missed treatment.

Figure 3.8 indicates which relationship with people at the clinic is most helpful in enabling them to adhere to treatment. Nineteen percent (19%) of the patients acknowledged that they benefitted from their relationship with the whole team. Two patients however said they could not identify any relationships in the clinic as they were transferred from another clinic.

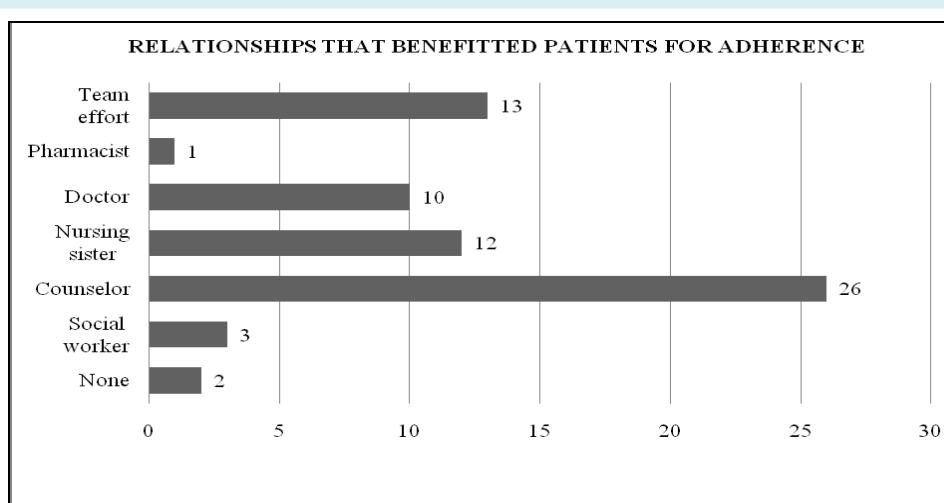


Figure 3.8 Supported patient adherence

When asked who they would approach for help in the ARV clinic if they encounter problems with adherence, patients said they would approach the nursing sister (37) followed by the doctor (18), then the counsellor (14).

3.2.6 Satisfaction with time spent with HCWs, waiting times and clinic environment

Ninety one percent of the patients (61/67) were satisfied with the time that they spend with health professionals. Most patients however spoke about the time that they spent with the doctor and not other HCWs. Box 3 highlights some of the responses patients gave indicating that they spend enough time with the doctor. Three percent of the patients were not satisfied with the time that they spend with HCWs saying that the HCWs are too busy. One patient stated that the doctors are hurried and they do not examine patients.

“You are not going in for two seconds and then you are out. The doctor listens and gives you advice.”

“You determine your time”.

Box 3

Satisfaction with waiting times and clinic environment

Sixty nine percent (46/67) of the patients said the waiting time was too long while thirty one percent believed that the waiting time was either “okay” or “not too bad”. Some added that they understand that there are too many patients for the number of HCWs that are working at the clinic. Nineteen percent (19%) of the patients had issues specifically about the pharmacy waiting time. Among these were patients who complained about the waiting

time at both the doctor rooms and by the admission clerks as well. Six percent complained about the waiting time at the doctors' rooms and four percent complained about waiting for files by the admission clerks. Some patients believed that the pharmacy opened late and it would help if they opened earlier like the rest of the clinic.

A high percentage of patients (60%) did not like the clinic environment. Thirty three percent of the patients believed that the clinic environment was okay while seven percent were indifferent about the clinic environment. Patients generally complained about space constraints, coldness during winter periods as well as waiting uncomfortably before being seen. They pointed out that they wait long for others to leave before they can get seats and which forces them to stand for long on their sore feet. Box 4 illustrates some of the responses given by patients.

"The atmosphere is not conducive to communicate with others; you are stressed when you come to the clinic because of long queues and no place to sit."

"I do not like it when I am waiting at the pharmacy and a corpse trolley passes by".

"I do not like the fact that very sick patients are mixed with healthy ones. You can end up catching TB at the clinic."

"We wait in a passage and people going to Out Patient Department (OPD) can see who is at the ARV clinic"

"It would be good to have some food while we wait." "Make the place look nice".

Box 4

3.2.7 Other issues important for adherence

Some issues raised by 52% of the patients about adherence are as follows:

- Adherence to ART could be boosted by issuing of food parcels and grants.

- Treatment supporters should attend the whole counselling session and not just the third counselling session before ART is initiated so as to be able to support them better.
- A peer support group should be organized in the clinic for patients to encourage each other to adhere to ART.
- Counselling after six months on ART.

Patients go for counselling before the initiation of ART and when and if required. However some patients propose that a second counselling session after six months on treatment should be compulsory.

- Pharmacies should issue adherent patients with two or three months' treatment to reduce costs and time to come and fetch treatment.

3.3 HEALTH CARE WORKERS' RESULTS

Eight HCWs from different categories as shown in table 3.7 were interviewed for this study. These HCWs were in the employment of the clinic for a period ranging between six to 39 months (26.4 months on average).

3.3.1 Tasks and training of HCWs

Different categories of HCWs were involved in different tasks according to the dictates of the service being provided in the clinic. See table 3.7 for tasks and training of HCWs.

- Five out of eight HCWs thought the training that they received was insufficient for the job they were doing. One had not received any HIV specific training. See box 5.

“HIV is dynamic and always changing”.

“Right to care” staff get training on a weekly basis while HCW’s employed by the Department of Health do not”.

“I did not receive training in tracing defaulters. I am just doing it my own way. “Right to care” has a program, but I have not been trained on it.”

Box 5

Table 3.8 Tasks and training of health care workers

Category	Tasks	Training undergone by HCWs
Adherence counsellor	Checks results of the HIV tests, CD4 counts, and viral loads. Does status awareness and acceptance counselling in 3 sessions before initiation of ARV treatment. From the second or the third session, counsels' treatment supporter if patient comes with them.	One day training focused on post exposure prophylaxis. Full adherence counselling not done.
Dietician	Give nutritional support and provides supplements to patients who meet the criteria.	University training only.
Medical officer	Medical service in the clinic	HIV, CCMT sexual assault, management of abused women and children.
Pharmacist	Pharmaceutical service in the clinic, including training of pharmacist assistants.	CCMT Training, Pharmacist training,
Pharmacist assistant	Previously adherence counsellor now supports pharmacist to offer pharmaceutical services.	Adherence counsellor training now busy with pharmacist assistant training.
Professional nurse	Supervises administrative staff and counsellors. Monitors' patients for adherence, tracing patients, preparing patients for ART. Verify monthly statistics.	CCMT, VCT, TB management, STI management, and HIV management course 2 from Right to care and nursing management.
Project Manager	Manages the project. Supervises nursing, administrative staff and counsellors.	Nursing CCMT and Project management.
Social worker	Social assessment of patients, tracing defaulters, transfer patients to hospice/ home based care and supervises counsellors. Ensures that before HIV inpatients are discharged they are connected to an HIV clinic. Refers patients for a disability grant. Distributes food parcels to patients who need poor relief.	HIV level 1 training (introductory cause), introduces all the parts like TB, PMTCT etc

Table 3.8 shows the tasks and training undergone by different categories of HCWs involved in antiretroviral therapy.

- One HCW could not comment on the adequacy of training as she was still waiting to be trained.
- One HCW stated that a post graduate diploma in HIV management, PHC nursing diploma as well as a project management course would enable him to be fully equipped for his job functions.
- Some HCWs focused on the benefits and gaps in the training they received. There were training gaps in handling patients who default on treatment, in both their counselling and their tracing. They were not equipped to deal with poverty issues which were raised as reasons for defaulting. The strategies that they used to facilitate ART initiation were not helpful for defaulters.
- Two HCWs however said that training was sufficient as it will never ever cover every problem faced by patients while the other believed in taking individual responsibility for updating herself.

3.3.2 Drug adequacy and procedures

In examining the availability of antiretroviral medication in the clinic, HCWs stated that the antiretrovirals prescribed are always available in the clinic. Pharmaceutical staff elaborated that they had periods in the past where they struggled to obtain their antiretroviral medications in time from their supplier such that they ended up borrowing antiretroviral medications from other pharmacies to meet their patient's needs.

Table 3.9 Reported procedures followed when initiating or changing the ARV regimen.

	Reported procedure followed when a patient is put on ART for the first time	Procedure followed when a patient changes ARV regimen
HCW 1	Finds out if a patient understands how to take treatment. Reinforces the directions given by pharmaceutical staff and counsels on treatment adherence	Explains to patient why their treatment was changed. Ensures patients understand how to take treatment. Reinforces directions and counsels on adherence.
HCW 2	Prescribes medication as per guidelines.	Changes medication as per guidelines and deviates only if a patient has specific problems. Reinforces adherence.
HCW 3	Relevant person involved follows guidelines	As per guidelines
HCW 4	Social assessment patients to see how the system can support them to adhere to treatment.	Assesses why patient needs to switch and reinforces adherence.
HCW 5	N/a	N/a
HCW 6	Group counselling of patients to check what they have learned about their condition, treatment and the general management of their disease.	Make patient aware of the change and explains to the patient how they are supposed to take the new medication. Finds out reason for switching and reinforce adherence.
HCW 7	Educates patients about their treatment, when to take their treatment, side effects & what to do if they encounter side effects and then reinforces adherence.	Depending on the reason for switching. If it is adherence, adherence counselling is done and if it is switching because of the side effects, this is explained to the patients as well.
HCW 8	Relevant person involved follows guidelines	Follow guidelines

On the reliability of laboratory and diagnostic support services HCWs responded that these services were reliable and they did not have any problems although they thought a computer-based electronic system instead of a paper-based system would enhance speed and accuracy as well as avoid misplacement of the results.

Table 3.9 shows the procedure followed when initiating or switching a patient on the ART regime. It is clear that the team reinforces adherence to treatment.

3.3.3 Adherence to ART and appointments

HCWs definition of “sufficiently adherent” was captured by the following two sentences. *“Daily, regular, the right dose at the time agreed upon”*. Secondly it was defined as *“fetching treatment every month, pill counts balancing, increasing CD4 count”*. No HCW at the clinic quoted an adherence rate of 95% or more as sufficiently adherent. Adherence rates ranging from 75% to 95% were estimated by HCWs. One HCW could not give a figure but estimated that it was low after seeing a patient who was consistently coming to the clinic but brought back eight months supply of antiretroviral medication untouched.

HCWs agreed that patients do not generally keep appointments. They explained that some come earlier others come later than the appointment dates written on their appointment cards. One HCWs explained that adherence to appointments is even worse during the winter period.

3.3.4 Challenges faced by HCW in the clinic

When asked about the standard practice in the clinic to support patients to adhere to ART, some HCWs could not describe what this was. Some did not even understand that whatever they were doing was to support patients to adhere to their ART. One HCW mentioned that the clinic had the services of adherence counsellors, social workers and previously had the support of an NGO which was doing home visits focused on ensuring that patients adhere to their antiretroviral medication. To elaborate further the HCW explained that they further ensure that needy patients get disability grants and food parcels when they are available.

Another HCW explained that they ask the patients to phone in when they cannot come for treatment on time. If the patient still has an active prescription, the HCWs prepare the medication and place it in casualty where the patient can either send someone to pick it up after hours or pick it up themselves.

One challenge that HCWs faced in supporting patients, was the lack of resources such that they cannot implement some other strategies. There is no dedicated transport or human resources for home visits to support patients to be adherent to their treatment. Added to this, the system does not alert staff about patients that have not visited the clinic for some time, such that steps can be taken to find these patients quickly. The social worker has to physically go through the pharmacy database to check which patients did not refill their medication before proceeding with telephonic defaulter tracing.

A lack of physical space results in activities taking place in areas that are not appropriate. In the counselling area the person who is waiting to be seen can hear what the other person in the counselling room is saying as the room is not closed on top. The pharmacy area is too small to accommodate the staff, work effectively and to store the drugs that are needed. The shortage of physical space is further seen in that there are no designated waiting rooms and patients wait in the passage.

Staff reported feeling stressed and burnt out. Box 7 illustrates the challenges that HCW

“We have a flood of patients that we cannot cope with at the moment.”

“There is no limit to the number of patients a health care worker is supposed to see. We end up seeing so many that we end up feeling stressed. To make matters worse debriefing is not consistent, some years like this one we did not go for debriefing”.

“I heard that there is debriefing but I have never been included. I have my own way of dealing with stress as a spiritual person, but if debriefing is a strategy that works, it must be applied to everybody.”

“Improve management of this clinic; the staff expects the manager to act.”

Box 7

face in the clinic that causes stress and burn out. Workload, poor personnel management and a lack of a consistent debriefing system were some of the issues mentioned. Another HCW believed that the problems with personnel management were emanating from poor management of the clinic.

There is not always agreement on how things should be done. There was no agreement on what criteria to use when deciding to give patients two months supply of medication. HCWs just do what seems right for them. Some of these disagreements are perceived to be due to poor staff management and conflict.

Patient related challenges are given below:

- a. Patients give wrong contact details such that it became impossible to trace them when they suddenly stopped coming for treatment.
- b. Patients bring a person from the street to be their treatment supporter when they are put on ART. This person will obviously not be available to support them to adhere to treatment.
- c. Patients are found to move around from place to place, some do not continue treatment when they are away.
- d. Financial circumstances of patients. HCWs found that most of the patients cited financial constraints as an issue impacting on adherence. Most of their patients were unemployed.

In conclusion, the study revealed that the clinic runs well, there is no shortage of staff but adherence is substandard. HCWs did not know the adherence in the clinic and they do not do defaulter tracing adequately.

3.4 STUDY LIMITATIONS

In considering the findings of this study it is important to bear in mind the following limitations. A non-representative group of patients was selected when doing patient interviews. In addition some patients excused themselves from participating in the study because they were in a hurry to go to work. Patients who defaulted on their treatment such that they no longer came to the clinic for their treatment were not represented in this

sample. As a result other factors that could have an effect on adherence could possibly be missed.

Although HCW participants were assured that their responses would not be linked to their names or even their category, there was a sense that some HCWs were afraid to disclose some information because it could easily be linked to them.

Initially the researcher wanted to use the appointment book to check adherence to appointment dates but because of workload, the clerks had stopped writing in the appointment book when they gave patients appointments. The researcher ended up making use of patients' appointment cards. Some patients did not bring their appointment cards to the clinic such that their appointment dates had to be extrapolated from the date of their last visit.

Some laboratory results were not in the patients files such that two patients' viral loads could not be obtained. As a result the researcher had to proceed without this information.

Despite the fact that the participants gave a wealth of information, there were not enough patients in the non-adherent group to be able to draw factors between adherent and non-adherent groups. This was however overcome by drawing information from both patients and health care workers. Information about health system factors impacting on adherence was therefore obtained from both patients and HCWs.

Taking into consideration that different methods have their advantages and disadvantages both the pharmacy refill and self- reporting methods were used. The self-reporting method of measuring adherence allows for a discussion on the reasons for non-adherence which cannot happen with the pharmacy refill method. A combination of both these method was chosen as the one method was good for determining factors that have an impact on adherence while the other was reliable for measuring adherence to treatments.

As stated above, the findings of this study although not generalizable can be useful for similar institutions and to check out factors that have an impact on adherence in developing countries.

4.0 CHAPTER FOUR: DISCUSSION

The aim of this project was to identify health system factors that have an impact on adherence to ART in the Lerato clinic. The previous chapter provided the findings, the adherence rate, reasons for non-adherence as well as the context in which adherence to ART takes place. This chapter will provide a discussion of the findings.

4.1 ADHERENCE TO ART IN THE CLINIC

A good proportion of the patients were adherent to ART in the clinic. Ninety seven percent (97%) of patients reported that they had never missed their treatment as measured by the self-reporting method while the pharmacy refill method revealed an adherence rate of 81%. A number of studies have used similar self-reporting methodology and found various adherence rates. In KZN (49) an adherence rate of 70.8% was observed, Chabikuli (8) found an adherence rate of 71% in the Northwest province while in the Limpopo Province (48), an adherence rate of 74.5% was recorded in one CCMT facility. Studies done in the Gauteng province however showed higher adherence rates (89.9% to 99%) than other provinces using the self-reporting method (50, 51). Different factors could account for the difference in adherence rates. Chabikuli showed a decline in staff-to-patient ratio as the reason for the low adherence rate in their facility (8).

An adherence rate of 97% which is higher than the pharmacy refill adherence rate of 81% obtained from the same population could be attributed to the disadvantages of the self reporting methodology (social desirability and recall bias) and the sampling method for patient interviews as previously mentioned. When asked which HCW they would tell if they missed their ARV medication, 37% of the patients said they would not tell the HCWs for fear of being mistreated.

Because of the sampling strategy followed, the pharmacy refill method adherence rate reflects adherence in this clinic better than the self-reporting method. Moreover research has shown that pharmacy refill irregularities are a powerful predictor of virological treatment failure when compared to the self-reporting method (54). In addition the pharmacy refill method has been proven to be as accurate as CD4 counts in measuring adherence (55) even if medication acquisition does not necessarily reflect adherence (9).

The results of the study showed that there was no association between period on ART and missing ART, but statistically this was insignificant. Missing appointments was however associated with non-adherence which is to be expected even though patients receive extra two days supplies of medication. This result suggests that improving the appointment system would improve adherence to treatments. The clinic did not have an appointment system at the time of the study. Clerical staff wrote the date when the patient is supposed to come back in the patient's appointment card and there was no record of how many patients were given any particular date to come to the clinic. A clinic appointment system would

not only improve waiting times in the clinic (21), but will also be the basis for the defaulter tracing system.

4.2 DEMOGRAPHIC PROFILE OF PATIENTS ATTENDING THE CLINIC

The researcher expected women accessing ART to outnumber men which was the case. Several studies are in corroboration (56, 57, 58). More patients were expected in the younger age group which was also the case. The HIV/AIDS statistics in SA shows that HIV/AIDS is more prevalent in the youth (59). Besides these two demographic characteristics the study looked at employment and educational qualifications of the patients.

At 49% the unemployment rate of the patients attending the clinic is high. In a district where the unemployment rate is approximately 40% (60) this is not surprising. Moreover HIV is more prevalent in the unemployed (61). Besides, two patients who were in a hurry to go to work declined to participate in the study. There is also a probability that more unemployed patients were included in the study because employed patients could also make use of private health care services. Moving to educational status, the study showed a high number of participants having schooling but very few attained or were in the process of attaining a tertiary qualification. This could be the reason why the unemployment rate is very high as these patients did not have the skills needed for employment.

“Education enhances the earnings potential of the poor, both in competing for jobs and earnings and as a source of growth and employment in itself”
(62).

Looking at the demographic profile of the patients attending the clinic, mainly female, unemployed, with educational status not supporting employment, one could conclude that the patients in this clinic are relatively poor. Studies also highlighted that HIV is more prevalent in the poor (63). One could conclude that the clinic caters mainly for poor patients and this should be taken into consideration in planning interventions to improve adherence to ART.

4.3 PATIENT-RELATED FACTORS WHICH AFFECT ADHERENCE TO ART

After looking at the demographic characteristics of patients attending the clinic the researcher checked if they feature in ART adherence. Table 3.5 illustrates this indicating that there is no association between missing ART and the demographic characteristics (age, gender and employment status). One age group or gender is not better off than the other as far as ART adherence is concerned.

Although this study indicates that there is no association between age/gender and adherence to ART as discussed above a study done in KZN indicated that female gender was associated with better adherence (49). However, in Nigeria a study demonstrated that being female, 35 and younger was associated with non-adherence (42). It is evident that findings from studies looking at contributors to antiretroviral adherence are not consistent.

Or there could be other factors that are showing themselves in demographic characteristics that are at play in different areas. Marmot argued that we need to look at the underlying factors, the “causes of the causes” (64). It is necessary to find the root of the problem and also remember that these things happen within a particular context. As Barnett and Casper pointed, there are social, economic, political resources and structures that influence health outcomes (65).

In considering employment status, although the results fully demonstrated that employment status is not a factor in ART adherence, the researcher was under the impression that those who are not employed were more likely to be non-adherent. Moreover some patients mentioned that they had difficulty attending clinic appointments because of work commitments. To complicate issues further other patients failed to honour their appointments because of financial constraints as they were unemployed. This was like a puzzle that could never be solved. An illumination to this predicament came as one patient stated that she no longer had difficulty attending her clinic appointments, since she disclosed her HIV status to her boss. Fear of disclosure and stigmatization was therefore the cause of missing clinic appointments.

Thirty one percent of the patients stated that the reason they were unable to consistently come for their appointments was lack of money to come to the clinic. If the nearest facility was within a walking distance, the issue of missing appointments because of money could be avoided. Only 25% of the patients could walk to the clinic.

Fear of disclosure and stigmatization also came up when patients stated reasons they miss their treatments. Although it was not a major reason why patients miss their treatment it came out that patients miss their treatment when they are in the company of those that do not know their HIV status. The main reasons patients gave for missing their treatment were forgetfulness followed by travelling or being away from home. Another reason mentioned was lack of food. These reasons are similar to those stated by other researchers in developing countries (33).

Studies done in Haiti and Zambia indicated that provision of food to food insecure patients improves adherence to ART (68, 69). South Africa supports collaboration of different sectors so that poor households can have their sustenance needs met. The “Operational Plan for Comprehensive HIV and AIDS care Management and Treatment for South Africa” recognised the importance of supporting social programmes of government and wider society that aim to reduce poverty through improving nutrition, job creation and social support. Disability grants are provided to meet the needs of HIV positive patients although these have been negatively associated with adherence where patients stop taking ART as disability grants are stopped when a patient’s condition improves as a result of ART. Some patients would rather suffer the consequences of non-adherence to treatment so that their disability grant can be maintained (25).

4.4 PATIENTS' PERCEPTION OF THEIR CARE

Although some patients understood that the long waiting time in the clinic was as a result of high patient volumes, 70% of the patients were unhappy that they had to put up with these long waiting times. There is a need to improve waiting times in this clinic. Moreover waiting times has a negative impact on ART adherence (27). However the quest to improve waiting times should not be at the expense of time spent consulting with the patients. Waiting time is associated with lower patient satisfaction and time spent with the physician is a stronger predictor of patient satisfaction (28). Waiting time was not a factor affecting adherence to treatment in this clinic as there was no evidence to support this.

Although thirty two percent of the patients felt that it would help if clinic hours were extended, current clinic opening times are not a factor in non-adherence to ART. Ninety one percent of the patients said that they did not have difficulty fetching medications during clinic hours. In addition extra options are provided for patients to have access to their treatment even if they did not attend the clinic during clinic hours. Patients have the option of phoning the clinic during working hours to request that their repeat medication be prepared and taken to casualty where they could be able to fetch it after hours. They are also allowed to send their treatment supporter to fetch their repeat medication if they are unable to come to the clinic themselves. In some cases two months medication is also supplied on request if the patient is unable to come to the clinic for the next appointment.

4.5 HCWS' PERCEPTION OF CHALLENGES IN THE CLINIC.

Although the study revealed that the clinic has the staff and the processes that are needed for quality CCMT services, a number of challenges were exposed. These included among others inadequate training, lack of a defaulter tracing system, irregular or a lack of debriefing and a lack of space.

HCW reported that they were inadequately trained for the duties that they were supposed to perform. Evidence of this was seen in dealing with defaulters in the clinic. Without training, the social worker traced defaulters who in addition to her other duties in the clinic. In addition adherence counsellors felt disempowered to counsel patients who were defaulting on treatment as they had no idea how to counsel patients who are defaulting on treatment. Adherence counsellors only had the skill to handle new cases. Letting workers undertake tasks that they may not be equipped to conduct, results in lack of confidence and feelings of powerlessness (70), this in turn increases concern about good adherence being maintained or improved in the clinic. What further compounds the problem is that lack of training also impacts on staff morale (71) which also have negative consequences for patients who are on ART.

Furthermore research reveals that lack of training leads to burnout and frustration which affects the quality of work. Some HCWs in this study were already experiencing burnout. Symptoms resulting from burnout are loss of a positive attitude towards clients (72). The consequences of lack of training are too devastating to be ignored as we already learned

that training highly affects the provider patient relationship which is essential for adherence to treatment (33, 34, 35, 36). Anything that affects the relationship directly or indirectly should be taken seriously.

Although accredited facilities are supposed to have the capacity to actively trace people on ART who are more than a month late for clinic or pharmacy appointments (4), there was no system in place for tracing defaulters in this clinic. A lack of defaulter tracing system continues to be a major issue in the CCMT program (51, 52, 73, 74). Defaulter tracing system is an integral part of the CCMT programme. Unless patients can be traced if they default on treatments adherence will continue to decrease.

The fact that some patients gave wrong contact details and their residential addresses such that they could never be traced when they default on their treatment is a concern. However, this is a health system problem as these patients would not be doing that if they understood the consequences of their actions. In addition researchers have documented the wrong contact details supplied by patients (17, 19, 23, 73, 74) and solutions to this problem should be coming from the health system. The issue of incorrect contact details has been around as long as TB treatment (75). Are patients making their a point about giving wrong addresses? Is this linked to fear of stigmatization? A study done in the same district of Ekurhuleni found that patients did not want Home Based Care organisations to visit them because of the fear of stigmatisation from the community (73). Will the sudden appearance of individuals doing defaulter tracing make neighbours indirectly aware of their HIV status? Ohkado suggests that consent for defaulter tracing be sought at initiation of ART or when patients get transferred to another HIV clinic (75) so that HIV patients are prepared for this if it eventually happens.

Tracing of patients would not be so difficult if the treatment supporter system was fully operational. This person could assist with the tracing of the patient, who missed appointments. However this system was frustrated by those patients who for fear of disclosure and stigmatization just picked a person from the street to fulfil the requests of the clinic for a treatment supporter and failed to find a person who will walk with them through their treatment journey (76). This shows that these patients were afraid to disclose their HIV status to family or friends who would be their treatment supporters.

Fear of disclosure and stigmatisation has a negative effect on adherence to treatments. This is also affecting the implementation of a functional defaulter tracing system which as indicated above could boost adherence to treatments.

The study showed that debriefing did not happen regularly, and when it happened, it did not include all members of staff. A lack of a counselling debriefing system in CCMT facilities was supported by other studies (51,52) which reported staff burnout and workoverload as well (51). Besides burnout was found in every profession concerned with AIDS care (77) which supports the need for debriefing of all professions concerned with AIDS care and not only nursing staff and adherence counsellors as found in this clinic.

Burnout has a negative impact on the health system. What is scary is that besides suffering from the consequences of burnout syndrome a HCW also affects others such that the whole team becomes disinterested in their work (72, 78). While the department of health recognised that burnout is common in HCWs working in HIV and AIDS (3) this has not transpired into a fully functional debriefing system.

The study indicated that staff was distressed about not meeting the needs of patients. They feel helpless when they see the suffering of patients but are not able to help substantially. One example was not being able to adequately deal with defaulters when they raise the problems that prevent them from accessing treatments regularly. Ross and Seeger pointed that in dealing with burnout, the starting point should be the emotional needs of patients and inability to deal with them. They stressed that providing information and support in these areas would reduce burnout in staff (79). Information that is picked up in debriefing should also be used to meet the training needs of HCWs. The study suggests that a functional debriefing system could have a positive impact on adherence to treatments.

4.6 AREAS OF AGREEMENT OR DISAGREEMENT BETWEEN HCW'S AND PATIENTS

Both HCW's and patients agreed that ARVs were always available in their pharmacy. Although studies indicate that access to medications is a concern in developing countries and it could influence adherence to treatment (33), this is not the case in this facility. Drug shortages did not feature in non-adherence to ART. The effort put in ensuring that non-adherence should not result because of ARV shortages from CCMT sites (3) is evident.

Another area where both patients and HCWs were in agreement was the clinic environment. Some patients were very unhappy with the clinic environment complaining terribly about waiting in a passage for their treatments where patients going through to

other areas could see them. This has implications for privacy and impacts on fear of stigmatization.

HCWs alluded to this in terms of compromised confidentiality and privacy during consultations. One HCW explained that during counselling patients who are outside waiting to be counselled are able to hear what the HCW and the patient in the consulting room are discussing. There is a chance of auditory privacy being bridged.

Although patients acknowledged these space constraints and the compromised confidentiality and privacy issues it presented, they indicated that they were not bothered about privacy during consultations. They were not bothered about their fellow patients overhearing what they were saying during consultations with adherence counsellors, but worried rather about others who they had not disclosed to passing through the clinic while they wait and recognizing them at the HIV clinic. Although Harris asserted that a lack of privacy affects patients' emotional responses and influences communication between the healthcare provider and the patient this does not feature highly in this clinic. Those that they already disclosed to or those that know their HIV status by default because they are working in the clinic as both the HCW and the patient already know what they are dealing with and have gained acceptance having significant implications for patient disclosure of information and health outcomes (80).

Therefore a clinic that is private and separate from the general outpatients' clinic reduces patients' fear of stigmatization (81). The clinic environment, the lack of space therefore has a negative impact on adherence to ART.

Although the importance of the training has been emphasized, and HCWs felt they needed training, patients were not yet feeling the effects of the deficiency in training. Most patients felt that HCWs in the clinic were highly knowledgeable with eighty four percent of the patients indicating that they were satisfied with the treatment information that they received from the clinic. Thiede (46) pointed out that if there is no trust between the provider and the patient, information is wasted. At this stage the trust that patients are still having in their HCWs might be covering for the deficiency in training as the study showed that a high percentage of patients trusted their HCWs. Alternatively HCWs could have had good initial training but lack continued training as they proceeded with the program as indicated by the defaulter tracing and defaulter counselling as discussed above.

5.0 CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

The study aimed to determine adherence to ART in the clinic. In addition, from patient's perceptions of their care, health care worker perception of challenges that they face in the clinic, the study aimed to determine the factors associated with non-adherence in the clinic.

According to the demographic profile examined the study showed that clinic caters for the disadvantaged members of the society. Although demographic characteristics were not associated with adherence to ART, interventions that are implemented should take this into consideration. The importance of knowing the adherence rate in HIV/AIDS programmes cannot be overemphasised. Interventions cannot be developed unless the adherence rate is known. Interventions have to be based on factors that are known to have an impact on adherence.

Due to the low number of patients who were found to be non-adherent to ART as compared to those who were adherent by the self-reporting method, the researcher could not fully achieve the aim of the study which was to determine health system factors that have an impact on adherence to ART. However, the study suggests that high levels of adherence can only be achieved and or maintained if structural barriers in ART facilities, community level factors like poverty, stigma and disclosure are attended to.

Lack of disclosure and fear of stigmatisation is at the root of problems that are encountered in adherence in this study. Lack of disclosure and fear of stigmatisation appears in households, at community level, at work as well as in health facilities themselves. In addition, it is connected to other reasons for non-adherence. For example when a patient mentions financial constraints as a reason for not adhering to appointments and or treatments it means that this patient is unable to use the resources that are available at a certain level for fear of disclosure and stigmatisation.

Lack of a functional systems had a negative impact on adherence. These are an appointment system, debriefing system and defaulter tracing systems. Apart from the need for good systems that would aid in management of patients attending HIV services, there is a need to take care of HCWs as an important resource. Particular attention should be paid to staff training.

Finally the health system must overcome the need to focus only on the disease and its treatment. Health needs to be looked at in a holistic way. Adherence or non-adherence is a symptom of this problem. Programme managers, policy makers, professional and other researchers should look much broader than the health sector itself to improve the health of the people. In addition an environment of caring in communities will go a long way to improve adherence to ART.

It would be interesting to look at what communities are doing to encourage adherence to ART.

5.2 RECOMMENDATIONS

Based on the findings of this study the researcher recommends, the following to managers, policy makers and service providers, professional, other researchers as well as patients and community:

- **Routine measurement** of ARV adherence
- **Staff debriefing** - Debriefing sessions should be planned and all HCWs should attend such sessions regularly.
- **Training** - HCWs need to be trained in the work that they perform in the clinic. Training needs to be assessed on a regular basis to ensure that HCWs are well equipped to do their work in the clinic.
- **Defaulter tracing system**

Implement an appointment system which will be the basis of defaulter tracing system.

- **Infrastructure** – The clinic needs to move to a private area to avoid confidentiality and privacy breaches. The clinic should be well equipped for patients to wait comfortably.
- **Food security/social exclusion**– Interventions to reduce poverty and social exclusion should be implemented. Collaboration with other sectors to meet patients needs in these areas.

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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Ms Mavis P Loate

CLEARANCE CERTIFICATE

Protocol M090117

PROJECT

School of Public Health
Health System Factors Affecting adherence to
antiretroviral Therapy in Germiston HIV/AIDS
Clinic

INVESTIGATORS

Ms Mavis P Loate.

DEPARTMENT

School of Public Health

DATE CONSIDERED

09.01.30

DECISION OF THE COMMITTEE*

Approved unconditionally

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

DATE 09.02.02

CHAIRPERSON
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr J Moorman

DECLARATION OF INVESTIGATOR(S)

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

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Approved.
[Signature]
Mrs. C.M. Mndaweni
Chief Executive Officer



INFORMATION SHEET AND CONSENT FORM FOR PATIENTS

Topic: Health system factors affecting adherence to antiretroviral therapy in Germiston HIV/AIDS clinic.

Dear participant

Hello, my name is Mavis Loate a student at the School of Public Health, University of Witwatersrand. I am undertaking a study to look at factors which determine why some people do and some people do not take their antiretroviral treatment.

This study will help us to understand better what problems patients are facing in trying to take their medication exactly as prescribed and explained to them. We will then know how to help patients to take their medication exactly as prescribed and or explained to them.

I would like to ask you some questions about the health system and how it affects adherence to treatment.

This interview will take about 20 minutes.

The information you provide will be treated with the strictest confidence. Please answer the questions freely. You cannot be identified from the information you provide. Neither your name nor your address will appear on the answer sheets. You are free to choose not to participate in the study and even if you decide to participate now you are free to withdraw if you decide not to continue. You will not be penalised in any way.

Do you wish to participate in the study?

A. If yes, continue with the next question. If no, thank the patient and let them go.

Y	N
---	---

B. Do you understand the purpose of the study and what will be required of you?

Y	N
---	---

If no, explain further what the study is about.

C. Do you understand that at any time you may withdraw from the study without giving any reason?

Y	N
---	---

If no, explain further.

D. Do you understand that the answers you give will not affect your receiving treatment in this facility?

Y	N
---	---

If no, explain further.

E. Do you give me permission to get some information from your file and your appointment card?

Y	N
---	---

If you wish to talk to anyone about the study on issues not clear to you, please contact the secretary, Human Research Ethics Committee, University of the Witwatersrand, Johannesburg at 011 717 1234 or fax to 011 339 5708 ; or call the principal investigator, Mrs. Mavis Loate at 072 1728144 or send email to loatem@webmail.co.za.

Name of respondent: _____

Signature: _____ Date: _____

Signature of interviewer: _____ Date: _____

QUESTIONNAIRE – PATIENT INTERVIEWS

SECTION A: PERSONAL INFORMATION OF PARTICIPANTS

1. SEX

M	F
1	2

2. AGE

18-24	25-31	32-39	40-46	47+
1	2	3	4	5

3. EMPLOYMENT STATUS

At school	Employed/but not self-employed	Self-employed	Unemployed	Pensioner
1	2	3	4	5

4. EDUCATIONAL STATUS

No schooling	Any schooling up to grade 10	Grade 11 -12	Working towards or having tertiary education	Other please specify
1	2	3	4	5

SECTION B: ADHERENCE TO APPOINTMENTS AND TREATMENT

5. How many times a day do you take your medication? _____

6. Have you ever missed your daily doses of ARV

Y	N
1	2

medication?

7. (Only answered by those who said yes to Question 6.) How many doses of your medicines would you say you missed in the last month?

None	1 dose	2 doses	3 doses	Other, please specify
1	2	3	4	5

- 8.** (Only answered by those who said yes to Question 6.) What is the most likely reason for you to miss a dose of your ARV medication?

Please tick all that is applicable.

Travelling, or being away from home	1
Ran out of drugs	2
Forgetfulness	3
Drug shortages from the pharmacy	4
Other, please specify	5

- 9.** In the last 2 months have you missed an appointment to see the doctor or to fetch medications?

Y	N
1	2

- 10.** (Only answered by those who said yes to Question 9). What is the most likely reason for you to miss appointments to attend the ARV clinic? Choose all applicable.

Travelling, or being away from home	1
Lack of money to come to the clinic	2
Difficulty to take time off from work	3
Not feeling well	4
Other, please specify	5

- 11.** Any comments concerning missing appointments?

- 12.** In the last two months, did your ARV pharmacy ever run short of drugs such that they did not give you a month supply of medication?

Y	N
1	2

13. Do you think you get enough information from the ARV clinic to enable you to adhere to ARV treatment?

Y	N
1	2

14. What do you think about the information that you get from the staff in the ARV clinic about your medication?

15. If you had problems with adherence, who would you approach for help in the ARV clinic?

16. What is the reason for you to approach this person?

SECTION C: COSTS AND DISTANCE FROM THE SERVICE POINT

17. How much money do you have to pay per day to cover for travel expenses when you visit the ARV clinic?

Walks to the clinic	Less than R10	R10 - R20	R21-R30	R31-R40	R41 +	Other, please specify.....
-1	0	1	2	3	4	5

18. Do you lose any income as a result of coming to the clinic? If yes please explain.

Y	N
1	2

19. Do you or your family have to give anything up for you to be on ARV medication?

Y	N
1	2

If yes Please explain.

20. How many kilometers do you stay away from this ARV clinic?

(Please ask for area if patient does not know the distance in kilo meters)

SECTION D: PATIENT-PROVIDER RELATIONSHIP

21. Please choose one.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
a. Staff here treats patients with respect.	1	2	3	4	5
b. I feel cared for in this ARV clinic.	1	2	3	4	5
c. I get the necessary support from this clinic.	1	2	3	4	5
d. My health providers assist me to take my ARV medication	1	2	3	4	5
e. Health care workers understand it is not easy to adhere to ARV medication.	1	2	3	4	5
f. I have difficulty communicating with my health providers because we do not speak the same language	1	2	3	4	5
g. I feel the health care providers are too busy to listen to me and my problems.	1	2	3	4	5
h. I have privacy during consultations	1	2	3	4	5
i. I trust the health care workers here	1	2	3	4	5

22. Which relationship do you think has mostly benefitted you concerning adherence to your ARV medication in the clinic? _____

23. Who would you tell if you missed your ARV medication for one reason or another?

Counselor	Doctor	Nurse	Pharmacist	Other, please specify.....
1	2	3	4	5

24. What do you think about the time that you spend with health professionals?

25. Do you think you spend enough time that you need with the doctor?

Sometimes	Always	Never
1	2	3

26. If you had to rate understanding of the HIV disease by health care workers, how would you rate it?

Good	Very good	Excellent	Bad	Neutral
1	2	3	4	5

SECTION E: QUALITY OF CARE AND SERVICE AVAILABILITY

27. What do you like or dislike about the clinic environment?

28. How do you feel about the waiting time at the clinic?

29. Do you ever have problems fetching your repeat medications during clinic working hours?

30. Please respond to the following statement. I think it would help if the clinic extended their working hours.

Neutral	Agree	Strongly agree	Disagree	Strongly disagree
1	2	3	4	5

31. Do you have any question that you would like to ask?

32. Are there any issues that you feel have been left out, but are important for adherence to ARV treatment.

Thank you for answering the questions, your answers will go a long way in helping us to improve adherence to medications.

DATA COLLECTION SHEET

Participant code _____

1. Date of start of HIV treatment

DD	MM	YY
----	----	----

2. Second latest Viral load

DD	MM	YY
----	----	----

3. Latest Viral load

DD	MM	YY
----	----	----

	REGIMEN	Date 1	Date 2	Date 3	Date 4	Date 5	Date 6
Quantity of ARV issued	ARV1						
	ARV2						
	ARV3						
	ARV4						
	ARV5						

4. Appointment dates

	Date 1	Date 2	Date 3	Date 4	Date 5	Date 6
Appointment date given						
Actual date of arrival						

INFORMATION SHEET AND CONSENT FORM FOR HEALTH CARE WORKERS

Topic: Health system factors affecting adherence to antiretroviral therapy in Germiston HIV/AIDS clinic.

Hello, my name is Mavis Loate a post-graduate student at the School of Public Health, University of Witwatersrand. I am undertaking a study to look at factors which determine adherence to antiretroviral treatment. I would like to ask you some questions about the health system and how it affects adherence to treatment. This interview will take approximately 30 minutes.

This study will help us to understand better the health system factors that have an impact on adherence. It will shed a light on problems patients are facing in trying to take their medication exactly as prescribed and explained to them. The findings will assist in the continual improvement of services in health facilities.

You have been chosen to participate in this study because of your position in the ARV clinic and your knowledge. Participating in the study is voluntary and if you choose not to participate in the study, there will not be any penalty. You have the right to withdraw from the study if you want to even after signing the forms consenting to participate.

I am going to request your formal consent to participate in this research. In the interest of confidentiality and anonymity, your name will not appear on the respondent's sheet. Information from health care workers will be analysed as a group and not according to staff category to prevent information being linked to a staff member.

If you wish to talk to anyone about the study on issues not clear to you, please contact the secretary, Human Research Ethics Committee, University of the Witwatersrand, Johannesburg at 011 717 1234 or fax to 011 339 5708 ; or call the principal investigator, Mrs. Mavis Loate at 072 1728144 or send email to loatem@webmail.co.za

Name of respondent: _____

Signature: _____ Date: _____

HEALTH CARE WORKERS INTERVIEWS

Topic: Health system factors affecting adherence to antiretroviral therapy in Germiston HIV/AIDS clinic.

A. TASKS AND TRAINING

1. What is your job in the clinic?
2. How long have you been doing this job?
3. What training have you received to be able to do this job in relation to ART? Tell me about the training. Details.
4. Do you think this training is sufficient? Details.

B. DRUGS, TREATMENTS AND PROCEDURES

5. Are the drugs prescribed always available?
(If not, give details- how often, reason and what you do about it).
6. How reliable are the laboratory and diagnostic support services? Details.
7. What is your procedure when patient is put on ART for the first time
8. What is your procedure when a patient switches regimens?

C. ADHERENCE ISSUES

9. How do you think your patients are doing in terms of adherence to ARV treatment?
10. Generally speaking, do your patients keep appointments?
11. Could you give an estimate of your patients who are sufficiently adherent to ART?
Respondent gives their definition of sufficiently adherent.
12. Do you have a standard practice at this facility to support your patients to adhere to ARV treatment? If yes, is it documented? Can we see it? In what way is it used?

13. What are the main challenges you face in supporting patients to adhere to ARV treatment?
14. Do you ever get patients who have financial constraints stated as a problem for coming for treatment?

D. CHALLENGES AND STAFF SUPPORT

15. What are the challenges you and your colleagues face more generally in your work?(if necessary, prompt re-workload, stress, burnout)
16. Have these challenges changed in any way since you started here?
17. Is any special support made available to staff engaged in ART in this facility?
18. Is there anything you would like to see done differently in this facility? If yes, what?

THANK YOU FOR YOUR TIME AND PARTICIPATION IN THIS STUDY.

ADHERENCE USING PHARMACY REFILL

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
1	680515	M	750	759	0.99	99.00%	03/05/2007	02/06/2009
2	760220	F	720	733	0.98	98.00%	11/05/2007	03/06/2009
3	710221	M	750	740	1.01	101.00%	18/05/2007	27/05/2009
4	590110	M	510	581	0.88	88.00%	02/10/2007	06/05/2009
5	720212	F	600	589	1.02	102.00%	08/10/2007	20/05/2009
6	590513	F	600	588	1.02	102.00%	08/10/2007	19/05/2009
7	730815	F	570	583	0.98	98.00%	04/10/2007	10/05/2009
8	700817	M	630	636	0.99	99.00%	03/09/2007	31/05/2009
9	750923	M	150	154	0.97	97.00%	14/01/2009	03/06/2009
10	790423	M	600	499	1.2	120.00%	02/10/2007	13/05/2009
11	681127	F	630	669	0.94	94.00%	29/06/2007	28/04/2009
12	700630	F	540	612	0.88	88.00%	09/10/2007	13/05/2009
13	650401	M	720	510	1.41	141.00%	13/06/2007	24/05/2009
14	761001	F	240	276	0.87	87.00%	17/09/2007	03/06/2009
15	770502	M	660	640	1.03	103.00%	28/08/2007	01/06/2009
16	660802	F	540	654	0.83	83.00%	16/08/2007	31/05/2009
17	640604	M	630	622	1.01	101.00%	31/08/2007	13/05/2009
18	680104	F	720	723	1	100.00%	29/05/2007	13/05/2009
19	660604	F	660	679	0.97	97.00%	17/07/2007	26/05/2009
20	761004	F	750	753	1	100.00%	10/05/2007	02/06/2009
21	850305	F	600	597	1.01	101.00%	26/09/2007	14/05/2009
22	660706	F	660	663	1	100.00%	19/07/2007	12/05/2009
23	530107	M	690	648	1.06	106.00%	07/08/2007	17/05/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
24	740707	F	690	685	1.01	101.00%	31/07/2007	14/06/2009
25	700508	M	570	621	0.92	92.00%	12/09/2007	25/05/2009
26	690309	F	450	581	0.77	77.00%	09/10/2007	13/05/2009
27	580210	F	570	653	0.87	87.00%	27/07/2007	10/05/2009
28	760810	M	660	700	0.94	94.00%	27/06/2007	27/05/2009
29	680411	M	660	650	1.02	102.00%	02/08/2007	19/05/2009
30	740911	M	480	591	0.81	81.00%	21/08/2007	04/05/2009
31	800512	F	630	646	0.98	98.00%	16/07/2007	22/04/2009
32	751212	M	600	625	0.96	96.00%	18/09/2007	03/06/2009
33	720214	F	690	685	1.01	101.00%	05/07/2007	20/05/2009
34	690315	F	570	712	0.8	80.00%	22/10/2007	12/05/2009
35	711215	M	720	687	1.05	105.00%	12/06/2007	17/05/2009
36	740816	F	630	629	1	100.00%	29/08/2007	19/05/2009
37	730117	F	690	691	1	100.00%	29/06/2007	20/05/2009
38	790917	F	690	701	0.98	98.00%	19/06/2007	20/05/2009
39	810218	F	540	609	0.89	89.00%	18/10/2007	19/05/2009
40	700619	F	690	697	0.99	99.00%	29/06/2007	26/05/2009
41	620720	F	660	651	1.01	101.00%	02/08/2007	20/05/2009
42	600221	F	720	720	1	100.00%	30/05/2007	19/05/2009
43	600721	F	690	733	0.94	94.00%	11/05/2007	13/05/2009
44	730822	M	570	565	1.01	101.00%	30/10/2007	17/05/2009
45	781123	F	750	684	1.1	110.00%	18/05/2007	02/06/2009
46	740824	F	630	642	0.98	98.00%	11/09/2007	03/06/2009
47	460125	M	630	629	1	100.00%	11/09/2007	02/06/2009
48	650725	F	600	595	1.01	101.00%	11/09/2007	28/04/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
49	560726	F	690	712	0.97	97.00%	21/06/2007	03/06/2009
50	740527	F	690	711	0.97	97.00%	30/05/2007	10/05/2009
51	700428	F	660	705	0.94	94.00%	14/06/2007	19/05/2009
52	690529	M	660	643	1.03	103.00%	29/08/2007	02/06/2009
53	791130	M	570	630	0.9	90.00%	04/09/2007	26/05/2009
54	610707	M	540	551	0.98	98.00%	07/11/2007	11/05/2009
55	640409	M	540	548	0.99	99.00%	09/11/2007	10/05/2009
56	571101	F	450	449	1	100.00%	13/11/2007	04/02/2009
57	660802	M	480	502	0.96	96.00%	14/11/2007	30/03/2009
58	750710	F	540	546	0.99	99.00%	19/11/2007	18/05/2009
59	571006	F	540	557	0.97	97.00%	21/11/2007	01/06/2009
60	600406	F	480	552	0.87	87.00%	22/11/2007	27/05/2009
61	730619	F	570	551	1.03	103.00%	26/11/2007	02/06/2009
62	560814	M	540	536	1.01	101.00%	28/11/2007	17/05/2009
63	510930	F	570	545	1.05	105.00%	29/11/2007	26/05/2009
64	730205	M	540	532	1.02	102.00%	03/12/2007	18/05/2009
65	750825	F	540	539	1	100.00%	04/12/2007	26/05/2009
66	730309	F	480	545	0.88	88.00%	06/12/2007	03/06/2009
67	740803	F	510	518	0.98	98.00%	10/12/2007	11/05/2009
68	730304	M	540	519	1.04	104.00%	11/12/2007	02/06/2009
69	770303	F	510	536	0.95	95.00%	12/12/2007	31/05/2009
70	660401	F	510	517	0.99	99.00%	27/12/2007	27/05/2009
71	660506	M	570	525	1.09	109.00%	18/12/2007	26/05/2009
72	640801	F	570	529	1.08	108.00%	19/12/2007	01/06/2009
73	720815	F	480	495	0.97	97.00%	09/01/2008	18/05/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
74	680319	M	540	529	1.02	102.00%	18/12/2007	31/05/2009
75	840404	F	450	481	0.94	94.00%	17/01/2008	12/05/2009
76	720413	M	510	487	1.05	105.00%	21/01/2008	22/05/2009
77	740525	M	450	448	1	100.00%	22/01/2008	14/04/2009
78	700505	F	210	211	1	100.00%	15/10/2008	12/05/2009
79	710310	F	210	198	1.06	106.00%	30/10/2008	17/05/2009
80	750403	F	450	461	0.98	98.00%	11/02/2008	18/05/2009
82	770606	F	480	450	1.07	107.00%	08/02/2008	13/05/2009
83	691225	F	420	456	0.92	92.00%	19/02/2008	20/05/2009
84	710404	F	480	468	1.03	103.00%	20/02/2008	02/06/2009
85	490730	M	480	461	1.04	104.00%	07/02/2008	13/05/2009
86	770303	F	450	460	0.98	98.00%	26/02/2008	31/05/2009
87	710319	M	420	459	0.92	92.00%	27/02/2008	31/05/2009
88	811127	F	390	453	0.86	86.00%	28/02/2008	26/05/2009
89	611012	F	450	434	1.04	104.00%	04/03/2008	12/05/2009
90	581015	M	450	466	0.97	97.00%	06/02/2008	17/05/2009
91	720315	M	450	462	0.97	97.00%	06/02/2008	13/05/2009
92	600307	M	450	448	1	100.00%	12/03/2008	01/06/2009
93	680510	F	450	454	0.99	99.00%	13/02/2008	12/05/2009
94	740408	F	420	412	1.02	102.00%	17/03/2008	03/05/2009
95	840522	F	450	439	1.03	103.00%	18/03/2008	31/05/2009
96	731017	F	420	407	1.03	103.00%	31/03/2008	12/05/2009
97	801127	F	360	425	0.85	85.00%	03/04/2008	01/06/2009
98	691225	F	420	415	1.01	101.00%	09/04/2008	26/05/2009
99	771227	F	450	419	1.07	107.00%	10/04/2008	03/06/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
100	701020	F	420	401	1.05	105.00%	14/04/2008	20/05/2009
101	780602	M	420	411	1.02	102.00%	16/04/2008	01/06/2009
102	680711	F	390	388	1.01	101.00%	17/04/2008	10/05/2009
103	660730	M	390	385	1.01	101.00%	21/04/2008	11/05/2009
104	740624	F	420	399	1.05	105.00%	22/04/2008	26/05/2009
105	600519	F	420	401	1.05	105.00%	31/03/2008	06/05/2009
106	691125	F	300	343	0.87	87.00%	06/05/2008	14/04/2009
107	630627	F	270	382	0.71	71.00%	07/05/2008	24/05/2009
108	750320	M	390	383	1.02	102.00%	08/05/2008	26/05/2009
109	700105	F	390	379	1.03	103.00%	12/05/2008	26/05/2009
110	501129	M	360	264	1.36	136.00%	14/08/2008	05/05/2009
111	821128	F	270	354	0.76	76.00%	15/05/2008	04/05/2009
112	640912	F	360	365	0.99	99.00%	27/05/2008	24/05/2009
113	541013	F	360	349	1.03	103.00%	29/05/2008	13/05/2009
114	610424	M	330	342	0.96	96.00%	03/06/2008	11/05/2009
115	590805	M	300	345	0.87	87.00%	04/06/2008	17/05/2009
116	790722	F	360	351	1.03	103.00%	09/06/2008	26/05/2009
117	591024	F	360	348	1.03	103.00%	10/06/2008	24/05/2009
118	760518	M	330	350	0.94	94.00%	11/06/2008	27/05/2009
119	751021	F	360	351	1.03	103.00%	17/06/2008	03/06/2009
120	780528	F	360	342	1.05	105.00%	18/06/2008	26/05/2009
121	540101	M	330	342	0.96	96.00%	23/06/2008	31/05/2009
122	680107	F	330	322	1.02	102.00%	24/06/2008	12/05/2009
123	790917	F	330	334	0.99	99.00%	26/06/2008	24/05/2009
124	760207	F	360	328	1.1	110.00%	02/07/2008	25/05/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
125	610712	F	300	295	1.02	102.00%	07/07/2008	28/04/2009
126	620606	M	330	322	1.02	102.00%	09/07/2008	27/05/2009
127	600103	F	330	322	1.02	102.00%	10/07/2008	28/05/2009
128	790818	F	330	321	1.03	103.00%	14/07/2008	31/05/2009
129	770521	M	300	293	1.02	102.00%	22/07/2008	11/05/2009
130	761210	F	300	301	1	100.00%	22/07/2008	19/05/2009
131	600323	M	330	313	1.05	105.00%	23/07/2008	01/06/2009
132	700202	F	300	288	1.04	104.00%	28/07/2008	12/05/2009
133	741015	F	300	299	1	100.00%	31/07/2008	26/05/2009
134	730615	F	300	388	0.77	77.00%	05/08/2008	28/05/2009
135	760419	F	300	256	1.17	117.00%	07/08/2008	20/05/2009
136	670216	F	300	265	1.13	113.00%	12/08/2008	03/06/2009
137	600702	M	270	290	0.93	93.00%	14/08/2008	02/06/2009
138	710922	M	270	277	0.97	97.00%	19/08/2008	25/05/2009
139	680828	F	300	256	1.17	117.00%	21/08/2008	03/06/2009
140	650904	F	270	257	1.05	105.00%	26/08/2008	12/05/2009
141	651012	M	270	263	1.03	103.00%	28/08/2008	20/05/2009
142	761212	F	270	263	1.03	103.00%	02/09/2008	25/05/2009
143	830730	F	270	261	1.03	103.00%	03/09/2008	24/05/2009
144	550912	M	270	250	1.08	108.00%	08/09/2008	18/05/2009
145	621206	F	270	264	1.02	102.00%	10/09/2008	03/06/2009
146	810303	F	240	209	1.15	115.00%	15/09/2008	13/05/2009
147	701107	F	270	255	1.06	106.00%	16/09/2008	31/05/2009
148	730522	F	210	236	0.89	89.00%	17/09/2008	11/05/2009
149	760930	F	240	255	0.94	94.00%	18/09/2008	31/05/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
150	760216	M	240	233	1.03	103.00%	23/09/2008	14/05/2009
151	741224	F	240	226	1.06	106.00%	29/09/2008	13/05/2009
152	630310	F	150	140	1.07	107.00%	30/09/2008	17/02/2009
153	780611	F	240	267	0.9	90.00%	01/09/2008	26/05/2009
154	520116	M	240	238	1.01	101.00%	06/10/2008	31/05/2009
155	640831	F	240	233	1.03	103.00%	07/10/2008	27/05/2009
156	790629	M	240	232	1.03	103.00%	08/10/2008	27/05/2009
157	720925	M	240	238	1.01	101.00%	08/10/2008	02/06/2009
158	680103	F	210	210	1	100.00%	13/10/2008	12/05/2009
159	731225	F	180	231	0.78	78.00%	14/10/2008	03/06/2009
160	660607	F	240	231	1.04	104.00%	15/10/2008	03/06/2009
161	610202	M	180	208	0.87	87.00%	29/10/2008	26/05/2009
162	760228	F	210	211	1	100.00%	20/10/2008	20/05/2009
163	800605	M	210	200	1.05	105.00%	29/10/2008	18/05/2009
164	690116	M	180	174	1.03	103.00%	21/10/2008	14/04/2009
165	550614	F	210	207	1.01	101.00%	30/10/2008	26/05/2009
166	740625	F	210	209	1	100.00%	03/11/2008	31/05/2009
167	750301	F	210	188	1.12	112.00%	18/11/2008	25/05/2009
168	780212	M	210	201	1.04	104.00%	06/11/2008	26/05/2009
169	640911	M	180	216	0.83	83.00%	21/10/2008	26/05/2009
170	651024	F	210	203	1.03	103.00%	10/11/2008	01/06/2009
171	770906	F	150	159	0.94	94.00%	11/11/2008	19/04/2009
172	721225	F	210	201	1.04	104.00%	22/10/2008	12/05/2009
173	500729	F	180	175	1.03	103.00%	17/11/2008	11/05/2009
174	841201	F	210	197	1.07	107.00%	18/11/2008	03/06/2009

RESP NO.	DATE OF BIRTH	SEX	TOT TX FETCHED	NO OF DAYS	ADHERENCE		INITIAL DATE	END DATE
175	701029	F	210	197	1.07	107.00%	27/10/2008	13/05/2009
176	770814	F	180	181	0.99	99.00%	20/11/2008	20/05/2009
177	650765	F	180	186	0.97	97.00%	27/11/2008	01/06/2009
178	750714	F	150	153	0.98	98.00%	08/12/2008	10/05/2009
179	830428	F	180	170	1.06	106.00%	08/12/2008	27/05/2009
180	820517	F	180	167	1.08	108.00%	10/12/2008	26/05/2009
181	781126	F	180	174	1.03	103.00%	11/12/2008	03/06/2009
182	730201	M	150	149	1.01	101.00%	22/12/2008	20/05/2009
183	731221	F	180	151	1.19	119.00%	06/01/2009	31/05/2009
184	830626	F	150	154	0.97	97.00%	12/01/2009	03/06/2009
185	870228	F	150	154	0.97	97.00%	15/01/2009	03/06/2009
186	551201	M	690	712	0.97	97.00%	30/05/2007	11/05/2009
187	820803	F	690	683	1.01	101.00%	17/05/2007	13/04/2009
188	771010	F	750	737	1.02	102.00%	21/05/2007	27/05/2009
189	591211	F	570	547	1.04	104.00%	04/10/2007	22/05/2009
190	760130	M	540	588	0.92	92.00%	02/10/2007	13/05/2009
191	840715	F	600	498	1.2	120.00%	08/10/2007	12/05/2009
192	820518	F	360	359	1	100.00%	08/04/2008	01/04/2009
193	741120	F	570	588	0.97	97.00%	09/10/2007	20/05/2009
194	561224	F	600	596	1.01	101.00%	09/10/2007	27/05/2009
195	741228	F	720	749	0.96	96.00%	09/05/2007	27/05/2009

TABLE 8.1 Advantages, Disadvantages, and Key Challenges of Commonly Used Adherence Measures

MEASURE	ADVANTAGES	DISADVANTAGES	KEY CHALLENGES
SELF-REPORT	No cost Easily implemented in clinical settings Moderate correlation with virologic outcomes Allows discussion of reasons for non-adherence Low participant burden	No standardized questions Overestimates adherence Relies on recall of forgotten events Vulnerable to social desirability, bias, Poor sensitivity	Mitigate ceiling effect Include measurement of all aspects of adherence (e.g., dose interval) Continue to rigorously develop and test adherence new measures (e.g., cognitive interviewing or item response theory)
EDM (MEMS)	Best correlation with virologic outcomes Allows analysis of dose-interval adherence and patterns of adherence over time	Expensive Not feasible for most clinical settings May underestimate adherence Vulnerable to technologic malfunction. Potential for selection bias High participant burden (e.g., multiple visits to down data, bulky caps, pillbox use load problematic)	Understand intervention (“Hawthorne”) effect Accurately censor of data (e.g., standard questions about periods of non-use, “pocket doses,” or “curiosity openings”) Develop evidence-based guidelines for use, quality control, and data management

TABLE 8.1 Continued. Advantages, Disadvantages, and Key Challenges of Commonly Used Adherence Measures

MEASURE	ADVANTAGES	DISADVANTAGES	KEY CHALLENGES
PILL COUNTS	Inexpensive Moderate correlation with virologic outcomes	Time-consuming Inappropriate for most clinical settings May overestimate adherence Vulnerable to “pill dumping” Difficult to determine refill start date Assumes no medication stockpile or alternative supply	Manage logistic challenges of unannounced pill counts
EDM (MEMS)	Best correlation with virologic outcomes Allows analysis of dose-interval adherence and patterns of adherence over time	Expensive , Not feasible for most clinical settings May underestimate adherence Vulnerable to technologic malfunction Potential for selection bias High participant burden (e.g., multiple visits to down data, bulky caps, pillbox use load problematic)	Understand intervention (“Hawthorne”) effect Accurately censor of data (e.g., standard questions about periods of non-use, “pocket doses,” or “curiosity openings”) Develop evidence-based guidelines for use, quality control, and data management

MEASURE	ADVANTAGES	DISADVANTAGES	KEY CHALLENGES
PHARMACY REFILL	Data are easily obtained in “closed pharmacy systems” (e.g., Veterans Administration, health maintenance Medicaid) organizations, Moderate correlation with virologic outcomes Allows for population-level analyses Immune to social desirability, recall bias, and tampering	Feasible only in “closed pharmacy systems” May demonstrate poor adherence Cannot measure dose-interval adherence Cannot differentiate non-adherence from other forms of treatment interruptions (e.g., discontinuation by provider) Assumes that patients have a single source of medication Assumes that medication acquisition reflects adherence No standard method for operationalising adherence (e.g., days covered vs. medication gaps) Not useful if refills are mailed automatically or if several months’ supply is dispensed at one time	Evaluate use in “open systems” (e.g., populations using numerous pharmacies with multiple payers) Determine optimal method for operationalising adherence

MEASURE	ADVANTAGES	DISADVANTAGES	KEY CHALLENGES
THERAPEUTIC DRUG MONITORING	Only direct adherence measure Plasma concentration directly determines virologic response May allow for detection or prevention of drug toxicity, which can lead to non-adherence May be advantageous for populations at risk for altered pharmacokinetics(e.g., pregnant women, those with hepatic dysfunction, children, those taking drugs that interact with antiretrovirals)	Invasive, Expensive. Nonstandard procedures for collection, testing, and interpretation Cannot routinely measure nucleoside reverse transcriptase inhibitor levels because active moieties are intracellular Levels may be low for other reasons than non-adherence (e.g., diet, drug interactions) Assumes no individual pharmacokinetic variation Vulnerable to “white coat adherence” Only provides a snapshot of recent adherence Higher plasma levels may be necessary to suppress replication of resistant virus	Standardize procedures for collection, testing, and interpretation Develop protocols for quality assurance Determine optimal monitoring frequency Determine optimal parameters (e.g., minimum concentration, ratio of an individual’s level to a population or expected level, or area under the concentration-time curve)