Determinants of Adherence in Patients on ART on the Copper belt Province in Zambia

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DECLARATION

By submitting this assignment electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety, or in part, submitted it for obtaining any qualification.

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ABSTRACT

Chronic drug therapy has been fraught with many issues such as adherence, drug intolerance, long-term toxicity and resistance. In HIV/AIDS care, adherence is a major problem due to the fact that for success of the therapy, adherence must be in the region of ninety five percent. If this is not maintained the virus begins to mutate and resistant moieties appear, and this in turn leads to failure of the therapy. This high level of adherence is very difficult to maintain especially in patients who begin antiretroviral therapy (ART) for various reasons such as persuasion by health workers and family, and not due to their own conviction. They usually tend not to adhere to the therapy when symptoms resolve and they start feeling better. There are a number of factors that promote adherence and these are incorporated into HIV care for the programme to succeed.

The research was intended to explore and describe factors causing patients to default ART on the Copper belt in Ndola at Ndola Central Hospital and to ultimately propose appropriate interventions to ensure improved return rates of patients on ART.

Qualitative tools i.e. interviews and focus group discussions respectively were used, taking into account ethical considerations and data collected was then analyzed.

Factors causing patients to default on ART were found to be poor social economic background, inadequate finance, unavailability of food, poor or little understanding of instructions, poor quality of counseling or low literacy levels, high pill burden, unpalatability of drugs and patient readiness to life time commitment to taking ARVS.

OPSOMMING

Chroniese medisyneterapie is gepaard gaande met vele kwessies soos trou bly, weerstandsgebrek aan medisyne, langtermyn toksisiteit en weerstand. In MIV/Vigs sorg, is trou bly 'n groot probleem weens die feit dat vir sukses in terapie moet dit oor vyf-en-negentig persent wees. As dit nie gehandhaaf word nie sal die virus begin verander en weerstand weestandbiedende gedeeltes sal verskyn, en dit op sy beurt lei tot die mislukking van die terapie. Hierdie hoë vlak van trou bly is baie moeilik om te handhaaf veral in pasiente wie antiretrovirale terapie (ART) vir verskeie redes begin het soos oorreeding deur gesondheids werkers en familie, en nie deur hul eie oortuiging nie. Hulle neig gewoonlik om die terapie te laat vaar wanneer simptome verminder en hulle begin beter voel. Daar is verskeie faktore wat trou bly bevorder en wat ingelyf word in MIV sorg om die program te laat slaag.

Die doel van hierdie navorsing was om die faktore te beskryf wat veroorsaak dat pasiente op die Copperbelt in Ndola by Ndola Sentrale Hospitaal hul ART verpligtinge nie nakom nie en om uiteindelik geskikte intervensies voor te stel om verbeterde terugkeer koerse van pasiente op ART te verseker.

Kwalitatiewe insrumente, dit is, onderhoude en fokusgroupe is gebruik, met in agneming etiese kwessies, en data is daarna geanaliseer.

Dit is gevind dat faktore wat veroorsaak dat pasiente versuim het om aan te hou met ART was 'n swak sosio-ekonomiese agtergrond, onvoldoende finansies, kosskaarste, swak of geen begrip van instruksies, swak kwalitiet van raadgewing of lae lees-en-skryf-kennis vlakke, hoë pil las, onsmaaklikheid van medisyne en die gereedheid van pasiente tot lewenslange toevertrouing tot die neem van ARVs.

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1. Introduction

According to UNAIDS (2006), the Sub-Saharan region of Africa is the worst hit by the Human Immunodeficiency Virus (HIV) pandemic with the current number of infected people standing at 24.7 million of the 40 million infected worldwide. As of 2007, the current average Zambian national HIV prevalence rate stands at fourteen point three percent (14.3 %) (Adonis, 2008) and the Copper belt Province's prevalence rate stands at twenty percent (20 %).

Zambia's total population as of the 2006 census survey was estimated to be 11, 6 million (Bureau of African Affairs, 2009). Copperbelt Province has a total population of 1,200,000 and currently has a total 30,712 patients on ART in the 35 antiretroviral therapy (ART) sites whose service provision started in 2005.

The Copperbelt Province is one of the nine provinces of Zambia and for three years Zambia Prevention Care and Treatment partnership (ZPCT) has been supporting ART services on the Copperbelt.

The management of HIV has progressed from simple palliation in hospices and hospitals to chronic care as out-patients. Cornerstones in its management include the early diagnosis of HIV infection, the diagnosis and treatment of opportunistic infections; the provision of necessary prophylaxis; the monitoring of immunological and virological markers, one of the cornerstones of managing HIV is the provision of antiretroviral therapy. Drugs have been developed since the mechanism of viral replication became known.

The HIV virus is unique as it uses the host cell's own machinery for its own replication. There are a number of important steps, each with its own important enzymes and or receptors necessary for viral replication. The first step is binding and fusion followed by reverse transcription, integration, viral transcription, translation and budding.

The first antiretrovirals were developed in the late 1980's and ever since then, more drugs have been fast tracked through drug and clinical trials in order to alleviate the mortality and morbidity associated with the HIV/AIDS pandemic.

These drugs target various enzymes which are important in the formation of new viral particles. The first groups of drugs developed are known as the nucleoside reverse transcriptase inhibitors, these were followed by the non nucleoside reverse transcriptase inhibitors and the protease inhibitors. Newer classes of drugs include fusion inhibitors. Up to date, these drugs are still the mainstay of antiretroviral therapy. In addition there are other drugs which have been developed with novel approaches to retarding the progression of HIV. Initially, in the years preceding their introduction, these drugs were expensive and inaccessible to the general population; with political will, and an ever changing political climate the prices of these drugs has gone down. Unfortunately cost is still important because the newer drugs are still out of the reach of the majority of patients living in resource constrained countries.

The first drug put into use in clinical services is Zidovudine (Conrad, 2005) which is still in use today. This was followed by didanosine, zalcitabine and stavudine. The first protease inhibitor was licensed in the United States of America in 1995, together with another nucleoside reverse transcriptase inhibitor called lamivudine. In 1996 nevirapine the first non nucleoside reverse transcriptase inhibitor was licensed for use and in that same year indinavir, another protease inhibitor and ritonavir a very important protease inhibitor was added to the repertoire of antiretroviral drugs (Conrad, 2005).

In the initial stages of the HIV pandemic, single drugs where used to treat HIV infection but this practice was abandoned due to the results of trials and evidence showing that monotherapy had no effect. This particular mode of therapy was then abandoned in favour of dual and then triple therapy. The mainstay of therapy is currently therapy making use of a minimum of three agents from at least two different drug classes. This type of therapy has been termed highly active antiretroviral therapy (HAART). It is very efficacious and has been shown to suppress the viral load for long periods of time.

Adherence to ART plays a pivotal role in the suppressing of viral suppression and drug resistance avoidance. Good adherence to ART is believed to be a critical determinant of long term survival among HIV infected individuals. In the Zambia, a nation of limited resources, the availability of second line and salvage regimen is limited. This places the nation at a point where emphasis is on leveraging maximum durability for the first line regimen.

1.1 Research problem

Since the introduction of antiretroviral therapy, research has been conducted to determine at what stage of HIV infection the therapy will have the greatest effect. In resource-limited countries the eligibility criteria for ARVs is such that people who receive ARVs are the ones who would die if they were withheld. All the patients in Zambia eligible for ART and willing to commence ARVs are initiated on the standard first line regimen. This first line is composed of a fixed dose combination drug – truvada – composed of emtricitabine and tenofovir and a non nucleoside reverse transcriptase inhibitor – either nevirapine or efavirenz. This regimen is unique because it has a low pill burden with higher rates of tolerance and lower rates of resistance than when other drugs are used. Those who fail on the first line are initiated on the standard second line regimen an evaluation. Treatment failure can be immunological, virological or clinical and must be diagnosed by a clinician conversant with the management of HIV/AIDS. The majority of patients adhere to treatment, as the benefits of taking the drugs outweigh the risks of not taking them. For patients enrolled in the ART care and treatment programme, it has been observed that some have been defaulting treatment. In some cases it is incidental on routine questioning and in other instances it is as a result of compiling reports from various clinic sources such as registers, pharmacy registers and patient files. This has led to some patients being initiated on second line antiretroviral therapy (ARVs) as a result of defaulting by non compliance or non adherence to the ARVs which has resulted in first line ARVs being resistant to HIV. Furthermore our national guidelines on the management of HIV/AIDS are not elaborate and specific as to the identification, tracing and monitoring of defaulters and non adhering patients despite stating clearly the importance of 100% adherence to ART (Ministry of Health, Zambia, 2007).

Most researchers focus more attention on adherence assessment of regular follow-up patients and overlook or give minimal attention to defaulters (Ministry of Health, Zambia, 2007). I, however, will focus on the '**Determinants of adherence in patients on ART on the Copper belt province in Zambia'.** By definition and in the context of the above topic, adherence is defined as taking the right drug, the right amount and the right dose (formulation) for the total duration, the correct intervals and under the right circumstances e.g., with or without food, not

with certain other drugs (Zimicki, 2004). In view of the above I have chosen this research topic especially that my organization deals primarily with provision of ART to HIV infected patients.

2. Literature review

Highly Active Antiretroviral Treatment (HAART) interruption entails important potential risks, including viral rebound, the decrease in number of CD4+ T-lymphocytes, and increased resistance to drugs (Gregory, 2005). Disease progression is currently monitored through virological, immunological and clinical means. If the immunity of an infected person drops and the viral load increases there is disease progression. 'Development of resistance is based on the high rate of errors with reverse transcription resulting in an average of one mutation for each HIV genome transcribed, coupled with a high replication rate that results in infection of $10^6 – 10^8$ lymphoid cells per day,' (Clavel & Hance, 2004). These mutations confer specific resistance to different ART drugs, reducing their sensitivity and ultimately rendering them ineffective. For both the individual and community this is a serious situation, as the emergence of these mutated viruses could lead to their transmission and subsequent failure of the ART programme. Limitations to alternative antiretroviral regimens with documented efficacy might also make it difficult to make changes in therapy should the need arise. Therefore careful monitoring of patients is essential to avoid the emergence of such problems.

Despite time spent on counseling new patients, on physical examinations and on stressing the importance of adherence, a significant number of patients still do not keep their follow-up appointments at various stages of their treatment (Bartholomew, 2004). Barriers to adherence to ART vary from setting to setting. Some researchers consider non-adherence to be a biosocial and dynamic phenomenon (Castro, 2005). This is a major concern throughout the world as it seriously affects the treatment of HIV/AIDS and the success of intervention programmes in containing the spread of the disease. Interruption of HAART entails significant risks such as viral rebound and decrease in number of CD4+ T-lymphocytes (Gregory, 2005).

There is growing evidence that defaulting on HAART is associated with virological failure, as most patients who default on HAART do not introduce any drugs into their bodies for viruses to mutate. However, good adherence in the absence of complete viral suppression is associated with increased rates of drug resistance (Bangsberg, et al., 2003). HIV has a very high replication and mutation rate. If drug doses are intermittently missed, the virus quickly

begins to replicate. This supports the evidence that with defaulters, the major challenge is virological failure and disease progression. When there are low drug concentrations (in non adherent patients), viral mutations that confer drug resistance thrive (Anderson, 2000). According to Clavel et al. (2004), this is based on the high rate of errors with reverse transcription resulting in an average of one mutation for each HIV genome transcribed. Nevertheless, non-adherent patients are likely defaulters of most treatment protocols and the threat of a plethora of consequences such as virological failure and resistance retard achievement of goals for HIV/AIDS treatment worldwide.

Disease progression spread of resistant viral strains, and the introduction of salvage treatment regimens are consequences likely to result when patients default HAART programmes. Many second line ART drugs remain too costly for use in many countries and this might prove an ongoing obstacle to expanding treatment access to vulnerable populations (UNAIDS, 2006). Expanding momentum in treatment scale-up demands the monitoring of key barriers to HIV management, which include adherence and defaulter measurement. Furthermore, it is necessary to understand the reasons for default after initiation of treatment for planning strategies to reduce default and increase successful treatment outcome.

A study done by Pienaar (2008) found that the major determinants of adherence are:

- Clinic placement relative to the patients' home. Patients living at a distance of 20 minutes walking had a higher chance of defaulting;

- Health service design. Co-infected patients with TB had a higher chance of defaulting if they were attending two separate clinics as compared to those that were attending clinics housed under one roof;

- Patients with a treatment supporter had a higher chance of adhering to treatment;

- Time for treatment. The longer on treatment the more likely a patient is to default.

Furthermore, according to an article by Lucille (2008) the determinants of adherence are as follows:

- Individual factors: socio-demographics; basic needs (food, shelter, heating, cooling, refrigeration), economic factors (health insurance, prescription coverage, employment status, disability insurance, income), education (language, literacy, health literacy), cultural beliefs, values, practices, cognitive factors (cognitive impairment,

forgetfulness, confusion), psychological Factors (depression, anxiety) and substance Abuse (drug and alcohol use).

- ART regimen and treatment experience: side effects, early toxicity and complexity of regimen, food restrictions, history of reasons for non-adherence and history of missed medical appointments.

- Disease characteristics: symptoms, immune status and illness severity.

- Social support: disclosure status with friends & family, support from friends, family support and partner support.

- Patient-provider relationship: provider competence, trust, communication, adequacy of referrals and inclusion of patient in decision-making.

- Informational resources: education and information about ARVs, side effects.

- Health care environment: access, insurance, transportation, convenience, confidentiality and adherence services at site of medical care.

- Health beliefs: purpose of treatment, effectiveness of treatment, treatment experiences and self-efficacy.

Strategies to ensure that patients on chronic treatment religiously take their medicines have evolved and improved significantly from other similar programmes that have been implemented before. Examples that come to mind include the TB, diabetes, cancer and hypertension programmes. Lessons learned from these programmes can be applied to HIV/AIDS programmes to reduce the default rate of patients.

In Kenya, a directly observed treatment (DOT) plan called directly administered anti-retroviral therapy (DAART) was implemented to promote adherence. Furthermore, the plan ensured that patients are consistent with their follow up schedules. In the DAART strategy a patient takes one dose of medication in the presence of a health worker during the visit to the facility (Sarna, 2005). This strategy can be employed in Zambia during the monthly medicine collection visits by patients.

'Health education provides knowledge and information, and helps people to develop the necessary skills so that they can make informed choices,' (Naidoo & Wills, 2004). It is the cornerstone of imparting knowledge and skill. However under coverage of counseling services

serves as a drawback to anti-retroviral therapy programs (Lucille, 2008). The counseling offered to patients tested for CD4 count is mainly limited to patients diagnosed with CD4 count less than 200copies/ml of blood and eligible for HAART. Extending this education to the community and HIV positive patients waiting to be eligible for HAART may be of necessity if people are to know more about the goals for anti-retroviral therapy. This will serve as a gentle reminder to the patients as well as the community of the essence of treatment and compliance with the prescribed regimen and follow up.

3. Research objectives and hypothesis

3.1 Objectives

The Principle Research Objective is:

- To explore and describe factors causing patients to default ART on the Copperbelt Province of Zambia and to propose appropriate interventions.

And Specific objectives are:

- To identify and trace defaulters on ART on the Copperbelt province in Zambia;
- To describe the profile of defaulters to highly active anti-retroviral therapy;
- To determine what factors cause patients on highly active anti-retroviral therapy to default;
- To propose interventions to ensure improved return rates of anti-retroviral therapy patients.

3.2 Hypothesis

The research hypothesis is that, patients on ART with good socio-economic backgrounds, adequate finance, adequate food, proper understanding of instructions, intensive counseling or high literacy levels, low pill burden, palatable drugs, patient readiness to lifetime commitment to taking ARVS will contribute **to better adherence of ART**.

Contrary to the above statement, those with poor social economic background, lack of finance, inadequate food, lack of understanding of instructions which could be due to poor/inadequate counseling or illiteracy levels, pill burden, unpalatability of drugs, and lack of patient readiness to life time commitment to taking ARVS will contribute to defaulting on **ART and a poorer treatment outcome.**

4. Research design.

The research design was non experimental and qualitative. By definition, Christensen (2007) describes qualitative research as an interpretative, multi-method approach that investigates people in their natural environment. Interpretative in the sense that meaning has to be extracted from qualitative data which consists of words, pictures or other non numerical information. Diverse data collecting methods are used hence the word multi-method. Lastly, qualitative research is conducted in a person's natural surroundings and in our case at the ART clinic when patients are coming for their routing follow up. The design involved the following tools: interviews with one doctor, one nurse and a lay counselor working at the ART clinic, and two focus group discussions (FGDs) with patients who had defaulted on ART. By utilizing this approach I developed an in-depth understanding of the determinants of adherence of patients on ART.

4.1 Sampling criteria

The population was that of defaulters on ART. A day before a clinic day a defaulter list was generated for the past one year from the ART dispensing tool which is electronic software used for dispensing ARVs but is able to generate reports. Patients who came on that particular day were checked against the list until a total of 25 were arrived at. The same was done the second group for focus discussions. As for interviews they were done on participants who happen to be running the clinic that particular week.

4.2 Sample size

The research was guided by the objectives and the sample being looked at is that of defaulter on ART. Approximately the clinic sees 125 patients per day, 4 days in a week and the defaulter rate is approximately 10%. Therefore it was possible that from this method at least 50 clients were selected. Two focus groups were held for a group of 25 patients each on a clinic day and three interviews for health staff (doctor, nurse and counselor). These interviews were conducted individually on a one-on-one basis with the respective health care workers.

4.3 Pilot study

A pilot study is a run-through of the experiment with a small number of participants. It is a pretest of the experiment or research and should be done as conscientiously as if data were actually being collected (Christensen, 2007). In view of the above a pilot study was conducted at Ndola Central Hospital on the 25th August 2009, three days before the actual study was carried out. Three interviews were conducted in the morning and one focus group with ten participants in the afternoon. This gave the researcher an experience with the procedure of using an interview schedule and focus groups as well as the recording of both. The tools were tested leading to refinement in clarity of questions and statements, setting of time required to conduct focus groups and interviews all in line according to Christensen (2007) that the pilot allows for proper changes to be made to the data collection tools until intended state is achieved.

4.4 Data Collection

The sampling framework was the pharmacy ART dispensing tool which was used to generate data on patient's pharmacy follow-ups for the past one year and a list of defaulters later generated. The study used data collecting instruments namely interviews and focus group discussion.

4.4.1 Focus groups

Focus group discussion is a method used for data collection in qualitative research where a researcher leads a discussion with a small group of participants. The purpose is to allow participants bring out their views about a topic of discussion.

Two focus group discussions involving patients on ART were tape recorded and transcribed on two respective days, namely Thursday the 28th October, 2009 and Monday the 31st October, 2009. The group discussions were each for two hours. The focus of discussion was to find out the 'determinants of adherence on patients on ART on the Copperbelt, Zambia' bearing in mind the objectives of the study. This method of collecting data proved useful as

the participants brought out their views on the topic for discussion. This proved to be cost effective as it was done over a short period of two days within the patients' schedule of visiting the clinic.

The proceedings of the focus discussions only started after a total of twenty five participants were identified against a generated list and referred by the counselor. The venue was the ART clinic conference room. All the participants were made to introduce themselves, and the aim of the discussion was clarified. Consent forms were handed out and participants were given a choice to leave if they did not consent. Ground rules were laid down for the group so that participants do not get distracted or get off the topic. Participants were taken through the discussion guided by the researcher using the guide (See appendix 9.2). Participants were encouraged to share their views and experiences. This encouraged participants to open up not only to the researcher, but to the other participants. Participants were comfortable with each other as they had a common background (defaulters) and the conference room provided an ideal environment for this kind of discussion; refreshments were a bare cold drink with a scone and participants were given a pen and paper to write down important points during the discussion and questions to ask.

Shortcomings of the focus group discussion included the tendency of having less control of the group which may have led to loss of time and inability to resolve relevant issues. This was controlled by actively facilitating and leading the discussions.

The proceedings above took the same format for the focus discussions conducted on the two respective days.

4.4.2 Interviews

By definition interviews are a form of verbal communication between two people with information being provided. Participants were contacted a day before and the venue was the ART conference room. All the three structured interviews with the medical officer, nurse and counselor were held on the same day in the morning, each lasting for about 45 minutes.

Questions on the interview schedule were designed to focus on the research objectives and these were used during interviews.

Proceedings of the interviews involved welcoming each participant and giving a brief background of the research as well as the consent. Consent forms were handed out and participants were given a choice to withdraw. Later participants were given the interview question guide and given time think through and familiarize themselves with the questions and answers that they were going to give. Interviews were done individually and face to face and after going through the questions, participants were given time to ask questions on issues that they did not understand, and clarifications were made. The interviews were tape-recorded and transcribed and taking of notes was done. All discussions were carried out in an environment that respected participants' confidentiality and ethical considerations.

One shortcoming with this method of collecting data as compared to other qualitative methods is that the respondent is more removed from his or her context and may feel threatened, resulting in data collected being biased. (Katzenellenbogen et al, 1997). In this study the health care workers were responding on experience and knowledge they had gathered from interacting and talking to patients who have defaulted on ART, from the counseling sessions they have had with these patients. They were not talking about themselves and this removed the aspect of bias.

4.5 Data analysis

Analysis in qualitative research begins with data collection. Therefore a thick description of data was collated from focus group discussions and the interviews. The content was analyzed eliciting recurring themes related the research topic. A process of coding and categorization of the content of the data assisted in bringing meaning to the responses. Data was transformed into various variables and analyzed accordingly.

Results from the tools used were then triangulated to see whether they supported findings in the literature review.

From the research topic 'Determinants of adherence in patients on ART on the Copperbelt province in Zambia', determinant was the independent variable and adherence was the dependent variable.

4.6 Ethical considerations

Ethical clearance was sought from the National Ethics Committee based at the University of Zambia. Before data was collected from participants, verbal and written consent were sought from each of them after clearly explaining the purpose of the study to them. Participants not willing to take part in the focus group and interviews were not penalized for doing so. To ensure confidentiality all the responses were anonymous and information collected was only used by the researcher.

4.7 Expected results

Patients will default as a result of the lapse in the health care system and/or heath care providers (i.e. inadequate counseling, erratic ARVs, etc), factors affecting patients (readiness to start ART, decision to stop after improving, inadequate food, funds, illiteracy levels) and drugs (such as pill burden, palatable drugs).

4.8 Contribution to my organisation

As an organization that seeks to put and retain as many HIV/AIDS patients on treatment and care, the findings of this study will be communicated to the Ministry of Health, the provincial health office, district health boards, hospital boards and my co-workers so that we ultimately help improve adherence to treatment that will ensure success of our programme.

5. Findings and Discussion

The research was conducted at Ndola Central Hospital over one week period. Three interviews were conducted on an individual basis with health care workers, working in the ART clinic using interview schedules and two focus groups. The first group had composition nineteen (19) females and six (6) males where as the second group had fourteen (14) females and eleven (11) males i.e. twenty five (25) patients for each group respectively.

The medical officer had one and a half years experience managing patients with HIV/AIDS, the nurse had 2 years experience with HIV/AIDS care, and the adherence support worker had 3 years experience dealing with patients on ART.

5.1 Findings from interviews

5.1.1 Health care provider

Interviews revealed that the medical officer, nurse and counselor see patients four days a week from Monday to Thursday. Patients being seen include those that are about to be initiated on ART (Pre-ART), those currently stable on ART, those initiated on the current first line, defaulters and those who are being placed on second line therapy.

Currently as per approved national guidelines by the Ministry of Health, Zambia (2007) the most preferred regimen to patients is Tenofovir (TDF)/ Emtricitabine (FTC) /Nevirapine (NVP) or Efavirenz (EFV); other regimens include Zidovudine (AZT)/ Lamivudine (3TC)/ Nevirapine (NVP) or Efavirenz (EFV), Stavudine (D4T)/ Lamivudine (3TC)/ Nevirapine (NVP) or Efavirenz (EFV) which are equally popular among prescribers.

5.1.2 Counseling

Adherence is monitored by asking patients to recite how they have been taking their medicines. This happens at the first contact with the heath care workers. Pill counts and pill balancing are then done by the doctor and the pharmacist.

Measures put in place to reinforce adherence include counseling at every visit by all health care workers the patient comes into contact with.

Patients who default tend to have pre-existing disease conditions most commonly tuberculosis, pneumocystis pneumonia, anaemia and gastroenteritis, and in these instances the patient generally and erroneously assumes – without any consultation – that they should only take one type of medication at a time. Those with preexisting medical conditions account for the majority of patients who default on therapy during the first month of treatment. In this group patients who were receiving treatment for tuberculosis were sent to outlying clinics for their TB drugs – as per national guidelines for TB treatment to be provided at clinics – thus leading to a higher defaulter rate. This is consistent with literature stating that if a patient on ART and another drug for either chronic ill health or co-infection; and they are being treated at two clinics at a distance from each other, they are most likely to default on their therapy (Pienaar, 2008). Some defaulters are those who develop immune reconstitution syndrome whilst on therapy, for these they feel that they have to stop ART in order to take the other drugs supplied. In general the patients prefer not to ask the clinician or health care workers about stopping their therapy.

Prior to being initiated on ART, patients are counseled on their drugs by the counselor and pharmacist. Counseling sessions are standardized for all patients with the same message being given to all the patients. The patients are given an opportunity to divulge problems peculiar to their situation in a private counseling session, at which the counseling is then tailored towards that problem.

Counseling is conducted routinely on patients on each and every visit. The responsible person is the adherence support worker who is supervised by the nursing staff member on duty for that day. Unfortunately due to ongoing staff shortages and an increasing number of patients accessing the service, it is a rare occurrence – one session per month - for the counseling session to be monitored.

5.1.3 Patients

It is a requirement that any patient who tests HIV positive and decides to access care at the hospital has to have a treatment supporter to whom they have disclosed their status. This is not strictly enforced and not all patients are able to do this. It is found that patients who commence ART with an active treatment supporter are less likely to default than those who did not have one (Pienaar, 2008).

The most common reason is that they do not have money to pay for transport to the ART site, which is too far from their homes. On inquiring why the do not simply move to sites closer to their homes they state that stigma is rife around ART sites where their homes are located. Sixty percent of patients i.e. thirty (30) out of fifty (50) participants for the two focus groups claim to be legally married, the rest are divorced, widowed or never married. The majority of these people are in the informal employment sector and those in formal employment are the low paid workers.

5.1.4 ART Regimen

Ndola Central hospital is a referral hospital and ART services were decentralized and rolled out to nearby clinics three years ago. The majority of patients at the ART clinic have been on ART for between two and five years. There are some patients who have been on therapy for up to 8 years and these started ART at other sites in the country. Patients who have been on therapy for longer than three years, and who have seen remarkable improvement in their clinical condition are more prone to default on their therapy, (Pienaar, 2008).

Antiretroviral drugs and regimens have been changed for most patients who started therapy more than three years ago and the most common reason is due to associated side effects, commonly that of a Nevirapine associated rash. The second reason is immunologically and clinically observed treatment failure. Whether virological failure was present or not was not determined due to the absence of viral load facilities locally.

Side effects were experienced by most patients ranging from mild and insignificant, minor itching after taking the drugs, and some mild gastrointestinal upset to severe and life threatening complications including Steven Johnson's syndrome, suspected lactic acidosis and fulminant hepatitis.

Patients have stopped taking ARV's on their own volition, with the major reason being that they had no money to purchase food and finance their transportation to attend to hospital follow-ups. Some complained of intolerable side effects and others felt that the drugs had produced an adequate result and could thus be stopped.

5.1.5 Patient provider relationship

Whenever a decision has to be made, patients are involved in the decision-making process to come up with a plan that suits their life style. Unfortunately health care providers are unable to discuss all aspects of care with the client as they are constrained by a lack of time to spend enough with each patient. For those patients who fall ill whilst on therapy, they are referred to the appropriate clinical department; the challenge faced is one of documentation between the unit receiving the patient and the unit to which the patient returns.

5.1.6 Social Support

It is a necessary requirement for all persons registering at the clinic to have a treatment partner to whom they have disclosed their sero-status. These treatment supporters are not required to attend clinical sessions with the patient. Married patients tended to disclose to their spouses, and those in relationships to their partners. Most of the spouses and partners tend to be supportive although a few – mostly men – tended not to offer support. Either these partners would divorce their wives, or separate from their girlfriends. Some would also verbally and physically abuse their infected spouse.

In relationships, most of the support received was emotional, though some support was financial. In some instances the spouse would escort the patient to the hospital if the patient

were bedridden, and collect medications if they were out of town. Support of this nature was commonly afforded to male patients by their female partners.

5.1.7 Substance abuse

Most of the patients seen in the clinic denied taking alcoholic beverages on straightforward questioning. With further questioning most state that their alcohol intake is infrequent and irregular. A few confessed to drinking alcohol and of these, over 50% had treatment interruptions as a result of forgetting to take doses after a bout of heavy drinking. There were no added incentives to cease taking alcohol, so they felt that it was acceptable to continue taking their alcohol.

Those patients still smoking, conceded that their substance abuse did not lead to any discontinuation of therapy. In general ART clinicians did not stop therapy in patients who take alcohol on a regular basis, unless the patient has defaulted for more than six months of therapy.

5.1.8 Other factors causing patients to default ART.

Some patients reported that they were intimidated by their spouse and family to stop therapy, or not to seek therapy at all. On some occasions parents would stop taking ART in order to concentrate on their children's therapy if newly initiated. Movement away from the ART without proper counseling by health care workers also led some people to default on their therapy. The fact that antiretroviral therapy is still seen as a therapy which is in potency and side effects similar to chemotherapy makes it difficult for people to consider initiation of ART on their own initiative and would prefer to discuss initiation with family members.

5.1.9 How the Hospital/Clinic/Health staff should have assisted these patients after defaulting.

All three HCWs' stated that they were aware of smart care programme used for data management and it is used from time to time to generate reports on patients follow-up. They all further stated that there is a pharmacy dispensing tool that can generate reports on patients' collection of drugs and able to generate a list of defaulters. These tools should have picked up the defaulters at an earliest time and even after identifying them should have been used as a tracking tool. Furthermore, hospitals or health institutions should be more proactive in finding out the reasons patients are defaulting and go a step further referring them or connecting to support groups and follow up these patients actively. Counseling should be given to these patients at each and every visit once a patient is identified to be at risk or has defaulted.

5.2 Findings from focus group discussions

Two focus groups were conducted. Most of the patients stay a distance that is five to ten kilometers away from the hospital and most of them are in informal employment. They all have to use public transport to get to the hospital.

In general each patient spends approximately 1 (one) US dollar for the shortest distance between two points. In a country where the GDP is USD 1386 per capita (Zambia economy profile, 2008) this becomes an intolerable expense resulting in a number of missed follow up visits, where money is spent on more urgent needs, like food or home rentals. Some of the people involved in the discussions expressed their observation that people who lived very far away from the clinic tended to attend the majority of their clinic visits, whilst those who lived within walking distance, (Pienaar, 2008), were prone to default and these people would give reasons ranging from stigma, to a belief that using herbal immune modulators would heal them.

Most of the patients are unemployed. Of those in attendance of the two focus groups only ten (10%) i.e. five (5) out of the fifty (50) present were in formal employment. The type of

employment included cleaning staff of government institutions, cooks and teaching assistants. Most of the patients who are in formal employment and have better paying jobs have medical schemes or insurance and consequently seek medical services from private surgeries.

Approximately ninety percent of the female patients for both groups i.e. thirty (30) out of thirty three (33) females have disclosed their status to their spouses or partners while ten percent (10%) have not. Just over fifty-two percent (52.9%) of the male patients i.e. nine (9) out of seventeen (17) for both groups have disclosed their status while forty (47%) have not i.e. eight (8) out of seventeen (17). In general the male patients assume that they will be deserted if they divulge their status. In order to encourage this, clients are encouraged to attend couple counseling with their partners and their disclosure happens. Patients who are on the ART programme tend to enter (over eighty percent) through other clinical departments. As such they have intercurrent infections prior to or during initiation of ART and are thus on other therapy. These patients consist of those brought by relatives and those coming in to the programme on their own volition. Most of the patients are adherent to their scheduled visits but some miss their appointments.

The married ones had children prior to knowing their status. None confessed to having children after they knew their status, even though many said their fellow patients are conceiving and delivering HIV negative babies.

Most of those patients have been on ART for between two and five years, with outliers of three months and 8 years. A few who had been on ART for a long time started off ART with private clinics or private doctors in the private sector.

Pre-ART counseling is routinely performed, with one session of pharmacy or ART counseling. A minimum of two counseling sessions were conducted. Patients with special needs, for example those requiring referral to other health services beyond this point or those unable to disclose to their partners had extra counseling sessions. Twenty percent (20%) of patients i.e. ten (10) out of fifty (50) for both focus groups did not receive any counseling at all.

Counseling sessions were conducted for the most part by counselors. Medical officers and nurses were too busy to participate in the routine counseling of patients. Patients stated that they would have liked to have the participation of a health care worker in order to ensure that any questions that they had would have been answered by a professional.

Counseling was conducted in groups rather than on an individual one to one basis and patients who had unique problems had individual counseling sessions performed with an adherence support worker.

Topics discussed in the counseling sessions are standardized and these are tabulated by the counselors and included the importance of correct dosing and timing of dosages, of not missing doses or stopping medication without the doctors' supervision, the importance of not abusing alcohol, the importance of using condoms and disclosure of one's status to partners. It was felt by the majority of both groups, 94% (47 out of 50 patients), that the number of counseling sessions was few, and this has made some of the patients default.

Patients were generally not involved in the decision-making and this has contributed to them not adhering to treatment since taking the drugs does not blend in with their lifestyle. The timing of the doses is not arrived at with the patients' participation and this effectively imposes something on the patient that they are either unwilling or unable to concur with.

Side effects were experienced and these varied from a nevirapine associated rash to nucleoside reverse transcriptase inhibitor associated peripheral neuropathy. Patients who experienced more severe side-effects would stop therapy temporarily before being seen by a health care provider and those with milder side-effects would be more inclined to continue their therapy in consultation with a health care provider.

Five (5) out of fifty (50) patients i.e. ten percent (10%) of patients said they stopped taking ARV's before consulting the clinician and twenty (20) out of fifty (50) i.e. forty percent

(40%) said they only came back to seek consultation after being off treatment for more than three months.

Patients confirmed that they missed medical appointments with reasons ranging from forgetting their dates, being committed to work, and working out of town (drivers). The frequency of missed visits ranged from once to as many as five times.

Many participants reportedly stopped taking ARV's, and all of these stated that they had stopped taking ARV's during the occurrence of side effects. These patients were very difficult to capture by normal tracing procedures and pill counts by health care workers.

Many patients reported to have received additional counseling. On average, two to three additional counseling sessions were conducted, the number of sessions directed by the specific problems that the patient had declared.

Forty (40) out of fifty (50) i.e. eighty percent of the patients reported that they felt that they would have appreciated more counseling sessions with more qualified personnel rather than with just the volunteer counseling staff. Another concern which they raised was a lack of home follow-ups and a relaxed support system. The small numbers of staff accounted for a distinct lack of extra counseling services, and a relaxed atmosphere.

6. Limitations of the study

Being aware of the strengths and limitations, the following would have affected the study;

- Only one site was used for the study and this was an urban site;
- Time for conducting data collection was short;
- No funds/transport to do home visits to check on patients in outlying areas.

7. Conclusion

Management of ART with antiretroviral drugs has turned a fatal condition into a chronic and somewhat manageable condition. In the absence of a known cure, this treatment is lifelong and requires unwavering commitment on the part of all stakeholders. Unlike diabetes and hypertension, where drug therapy has been available for over thirty years and multiple modalities for their management exist, antiretroviral therapy in resource constrained areas has been present for merely eight years. The drugs available for its management are expensive, prone to resistance, and there are very few combinations available. Coupled with a lack of time for counseling this will lead to an eventual increase in cost to the patient and the suppliers of drugs.

A lot has been done on rolling out ART services and this is evidenced by the increasing numbers of patients on ART, as well as on the many ART facilities scattered all over the province and the country at large. This progress has come with a lot of challenges especially in terms of ensuring that quality is maintained and that the large numbers of people who are put on medication continue to benefit from these services. Despite the rapid enrollment of patients on HAART, there is little attempt to increase the numbers of health care workers who service them. This leads to limited contact between patients and health care providers, with serious implications on the content and quality of the counseling given to the patients.

At some sites, patients are seen and assessed by medical assistants who are torn between clinical duties and the antiretroviral clinic.

In identifying and defaulter tracing of patients on ART on the Copperbelt province there is a system of tracking which makes use of the smart care system. Patients who have missed their appointment dates can be traced. However, there are limitations to this system. Smart care is available at an ART site as a data management tool used to keep track of patients. Pharmacy has a dispensing tool to keep track of patients' collection of antiretroviral therapy. These two systems are not linked and as such some patients who collect drugs but miss their appointments or vice versa are not singled out or tagged and no action is taken. In order to

trace defaulters a list from the pharmacy and one from the registry (smart care) has to be made and compared with each other. Perhaps a far better system would be to tag patients who have been screened and are considered a high risk for defaulting including those who have not disclosed their status to family or friends, clients who were convinced to start ART by family and friends, those who had a pre-existing medical condition prior to initiation of antiretrovirals and including those who have a history of alcohol abuse.

In general patients most prone to default are those who have no support system – either they are widowed, migrant workers (people living outside their own province) or they have not disclosed their status to close family or to friend. Patients coming from a poor financial background were also more prone to default because of the unavailability of food, transport and in some instances a stable address. Patients on a regimen with fewer pills to take and where a conscious decision on when to take the medication by the patient was made tended not to default their therapy.

The findings reveal that patients on ART with a good socio-economic background, adequate finance, adequate food, proper understanding of instructions, intensive counseling or high literacy levels, low pill burden, palatable drugs, patient readiness to lifetime commitment to taking ARVS do contribute to adhere to ART. There appears to be a strong component of subjectivity in antiretroviral therapy with patients associating improvement of clinical condition and immunological status with partial cure of their disease and thus accepting that stopping the therapy is acceptable.

Stigma is still very evident. Self stigma appears to be a stronger deciding factor than external stigma, with patients less likely to seek therapy if they reside close to the health facility. This is paradoxical in that most patients do not have finances to support both their therapy and family needs, and thus resulting in increased risk of defaulting from their therapy.

Studies such as these will help bring out results that could help not only the people of the Copper belt Province of Zambia, but also other areas equally hit by the pandemic.

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9. Appendices

Appendix 1; Interviewer schedule for HCW

A. Epidemiological data.

Serial number……………………………………………………………………………..

Facility…………………………………………………………………………………….

Date……………………………………………………………………...........

Demographic.

Sex…………………………………………………………………………………

Profession……………………………………………………………………………………

How long have you worked with HIV positive patients?…………………………………..

B. Reason for defaulting

1. Health care provider

1.1 How often do you see patients?

1.2 Do you see pre or post ART patients?

1.3. What is the most common regimen prescribed to patients?

2. Counseling

2.1 How do you monitor adherence?

2.2 What measures are in place to monitor adherence?

2.3 How are they enforced?

2.4 Are measures consistent for all patients who are non adherent?

2.5 Do patients that default have pre existing infections/conditions?

2.6 Is counseling given by the HCW to patients before the commence treatment?

2.7 Is the counseling similar in all cases?

2.8 Who is responsible for giving the patients counseling?

2.9 Who counterchecks to see if counseling has been conducted effectively?

3. Patient

3.1Do they have or come with treatment supporters?

3.2 Do patients disclose their status to their partners?

3.3 Do patient have any history of intercurrent co infection e.g. TB?

3.4 Are patients on medication for the above infection?

3.5 Do patients ever miss hospital appointments for ART?

   If yes (tick appropriate reasons)

   i) Too far ii). No transport money for taxi/bus iii). Forgot

3.6 Are these patients married?

3.7. Are these patients employed……………………………………………………….

.

4. ART Regimen

4.1 How long have these patients been on ART?

4.2 Have the ARVs been changed?

4.3 Reason for change of ARV regimen…………………………………………………

4.4 Do they experience side effects when they take the ARVs?

4.5 Have they reported any food restriction?

4.6 Have they missed any medical appointments?

4.7 Have the patients ever stopped taking ARVs? YES

   If yes, why? Tick appropriate answers

   i. Too many pills/tablets

   ii. Intolerable side effects e.g. vomiting, diarrhea, abdomen pains, headache, dizziness, abnormal fat accumulation

   iii. Unpalatable drugs e.g. bitter to swallow, unpleasant smell

   iv. Food interactions

   v. Other…………………………….

5. Patient provider relationship

5.1 Does the HCW in ART management include patients in the decision making?

5.2 When Patients fall sick or need assistance where are they referred for assistance?

6 Social Support

6.1 Have these patients disclosed their HIV status?

6.2 If YES to who have they disclosed a. Spouse b. Friends c. Family. other

6.3 Are they supportive?

6.4 If yes what kind of assistance. A) Financially B) Socially C) Emotionally D) Physically

7. Substance abuse

7.1 Do patients drink alcohol?

7.2 Do patients smoke?

7.3 Does taking alcohol and smoking cause patients to stop taking ART

8. What other factors cause patients to default ART?

9. How would you have wanted the Hospital/clinic/Health staff to have assisted these patients after defaulting……………...…………………………………………………

Appendix 2; Focus Group Discussion (FGD) question guide.

Date …………………………………………………………………………………

Time Start:………………………………..**Stop**………………………………………..

Clinic………………………………………………………………………………….

Conducted by………………………………………………………………………….

Number of participants………………………………………………………………..

1. How long does it take the patient to get to the hospital?

2. Does the patient need public transport to travel to the hospital?

3. How much does the patient spend on a trip to the hospital?

4. Is the patient employed?

5. Does the patient have any other sources of income?

6. Has the patient disclosed your HIV status and if yes to whom?

7. Does the patient have any children or keep dependants?

8. How long has the patient been on ART?

9. Did the patient receive counseling before starting ART?

10. How may sessions?

11. Who conducted the counseling session?

12. When the counseling was done was the patient in a group or alone?

12. What topics were discussed?

14. Is the patient involved in the decision making?

15. Did the patient experience side effects after starting ART?

16. How did the patient manage them?

17. Did the patient miss any medical appointments and if yes how many?

18. Did the patient stop taking ARVs and if yes what were the reasons?

19. Did the patient receive any additional counseling?

20. Are there any things that could have been done to make you adhere to treatment?

Thank you!!

Appendix 3; Participants/patients' consent to participate in research.

Researcher: Chisha Sume Percival

Contact: +260977749556

Email:sumechisha@yahoo.com

<u>**Introduction.**</u>

The purpose of the study is to look at determinants of adherence in patients on ART on the Copper belt Province in Zambia.

Patients on ART are requested to participate in a focus group to assist in determining factors that affect adherence in patients on ART.

Confidentiality will be observed and information collected will be used for this research in coming up with recommendations. The participation of patients is voluntary.

<u>**Consent:**</u>

I ………………………………………. have read through the information on the consent and understand all the contents and the implication of signing it. I therefore agree voluntarily to participate in the group discussion.

Participants signature…………………………….Date…………………………………….

Researchers signature………………………………Date…………………………………….

Appendix 4; Health cares workers' consent to participate in research

Researcher: Chisha Sume Percival

Contact: +260977749556

Email:sumechisha@yahoo.com

Introduction.

The purpose of the study is to look at determinants of adherence in patients on ART on the Copper belt province in Zambia.

Patients on ART are requested to participate in an interview to assist in determining factors that affect adherence in patients on ART.

Confidentiality will be observed and information collected will be used for this research in coming up with recommendations. The participation of patients is voluntary.

Consent:

I ………………………………………. have read through the information on the consent and understand all the contents and the implication of signing it. I therefore agree voluntarily to participate in the group discussion.

Participants signature…………………………….Date…………………………………….

Researchers signature………………………………Date…………………………………….

Appendix 5; Letter to the Permanent Secretary Ministry of Health, Lusaka.

Box 72728

Ndola

Zambia.

3rd August, 2009.

The Permanent Secretary,

Ministry of Health,

Ndeke House,

Lusaka.

Dear Sir,

RE: REQUEST TO CONDUCT A RESEARCH AT NDOLA CENTRAL HOSPITAL ART CLINIC

Reference is made to the above subject matter.

I am kindly requesting that you allow me to conduct a research at the above mentioned hospital. I am currently studying for a master of philosophy (MPHIL) in HIV medicine at University of Stellenbosch and doing a thesis entitled '**determinants of adherence in patients on ART on the Copper belt province in Zambia'**.

The research is qualitative in nature and the methodology involves conducting three interviews with a medical officer, a nurse and a counselor scheduled for Friday, the 28th August, 2009.The two focus groups of patients, each group with twenty five participants are scheduled for 27th August, 2009 and 31st August, 2009 respectively.

All the discussions and information given by the participants will be confidential.

Find attached here with my research proposal.

Waiting for your prompt response

Yours faithfully,

Dr Chisha Sume Percival

Cell;+260977749556

Email address;sumechisha@yahoo.com

Appendix 6; Letter to the Executive Director for Ndola Central Hospital

Box 72728

Ndola

Zambia

19th August, 2009.

The Executive Director,

Ndola Central Hospital,

PBX,

Ndola.

Dear Sir /Madam

RE: REQUEST TO CONDUCT A STUDY AT THE ART CLINIC AND FOR HCW AND PATIENTS AT THE ART CLINIC TO IDENTIFY THE DETERMINANTS OF ADHERENCE IN PATIENTS ON ART

Reference is made to the above subject matter.

I am kindly requesting to conduct a research at the above mentioned clinic. I am currently studying for a master of philosophy (MPHIL) in HIV medicine at University of Stellenbosch and doing a thesis entitled '**determinants of adherence in patients on ART on the Copper belt province in Zambia'**.

The research is qualitative in nature and the methodology involves conducting three interviews with a medical officer, a nurse and a counselor scheduled for Friday, the 28th August, 2009.The two focus groups of patients, each group with twenty five participants are scheduled for 27th August, 2009 and 31st August, 2009 respectively.

All the discussions and information given by the participants will be confidential.

Waiting for your prompt response

Yours faithfully,

Dr Chisha Sume Percival.Cell :0977749556 .