CHAPTER 1

1.1: INTRODUCTION

Diabetes mellitus is a silent, but serious disease. This disease is not only the most common cause of non traumatic amputations and a leading cause of blindness but also accounts for a significant proportion of end stage renal disease requiring dialysis and transplantation. It is estimated to be the 5th leading cause of death in the year 2000, accounting for 5.2% of all deaths globally {Wild et al, 2004}. Patient adherence to oral hypoglycaemic agents is integral to reducing the health care costs and chronic complications of diabetics {Lee and Taira, 2005}. Identifying which patients are at the greatest risk for non adherence to oral hypoglycaemic agents is an important first step toward developing interventions that improve adherence {Lee and Taira, 2005}.

Matlala district hospital is a 288 bed hospital with outreach to seven primary health clinics, located in the heart of Tsimanyane in Sekhukhune district, Limpopo. This hospital serves a population of 74,867 people from various surrounding rural settlements. An average of 120 patients attends the outpatient department daily. More than 34% of these patients are on chronic medication {excluding patients on antipsychotics} of which hypertension is top on the list, followed by diabetic mellitus {7.6%}. An average of 139 patients with diabetes mellitus is seen monthly in the hospital. This average was calculated from statistics gathered from April 2008 to March 2009. Of this number, an average of eight newly diagnosed diabetes patients is seen monthly. Many of the admissions into the medical wards are due to complications of the diabetes, a likely consequence of poor or non adherence to treatment.

Socio-demographic variables have been found to be predictive of entry into the healthcare system, but have not been predictive of adherence level once treatment commenced {Chatterjee, 2006}. The low incidence of patients with diabetes in the hospital could be explained by patients' behaviour. Many people choose to employ the services of traditional healers rather than visiting the hospital for help. The impact of this health seeking behaviour on adherence should not be underestimated.

The burden of the disease on the limited resources of the hospital prompted the researcher to investigate the level of adherence to treatment among type2 diabetic patients in Matlala district hospital. This investigation aims to identify the reasons for poor or non adherence to treatment.

1.2: PURPOSE OF THE STUDY

The aim is to assess adherence to treatment among type2 diabetic patients.

1.3: OBJECTIVES

To assess the demographic profile of patients with poor adherence to medication in type2 diabetes.

To assess the level of adherence to treatment among type2 diabetic patients.

To determine the possible reasons for poor adherence to diabetic medication.

To determine the possible reasons for poor adherence to lifestyle changes in type2 diabetes.

CHAPTER 2

LITERATURE REVIEW

2.1: SOURCES OF REFERENCES

Literature was obtained by searching Pubmed, using the keywords: diabetes mellitus AND adherence. A total of 2,045 articles were obtained. The search was then limited by requesting articles;

- published in the last 10years,
- only in English,
- limited to human studies,
- involved individuals 19 years and older and
- available as full text.

This narrowed the search articles to 266. Of these articles, 37 were found relevant to the planned investigation and after critical appraisal, 18 articles met the required standard. A further search was done on the British Medical Journal, using the same search words.

Additional articles from the South African Journal of Family Physicians and the South African Medical Journal were added. The aim of the literature search was to obtain the best available literature, which described previous studies done, to determine the assessment of adherence to treatment among type2 diabetic patients.

2.2: REVIEW

The review centred on the general knowledge of diabetes mellitus and adherence. Particular effort was focused on the following sub headings, as gathered from the literature search;

- Overview
- Local background
- Trend of diabetes mellitus in South Africa
- Burden of diabetes on available structures
- Management of diabetes mellitus
- Blood glucose target in diabetes mellitus
- Rates of adherence to treatment
- Effects of Polypharmacy on adherence
- Definition of adherence
- Classification of adherence
- Measure of adherence
- Subjective strategy of measurement
- Objective strategy of measurement
- Biochemical strategy of measurement
- Demerits of non adherence
- Determinants of adherence
- Improving adherence to treatment
- Conclusion.

2.2.1: OVERVIEW

Non communicable diseases and mental disorder, human immunodeficiency virus/acquired immunodeficiency syndrome and tuberculosis together, represented 54% of the burden of all diseases worldwide in 2001 and will exceed 65% worldwide in 2020 {Sabate, 2003}. The prevalence of diabetes for all age groups worldwide was estimated to be 2.8% in 2000 and could reach 4.4% in 2030 {Wild et al, 2004}.

The world health organization estimated that, in 1998 there were 135 million people with diabetes, the estimate rose to 171 million people in 2000 and has been projected to increase to 366 million in 2030 (Wild et al, 2004). Much of the increase will occur in

developing countries, arising from growth and the ageing of the population, as well as urbanization associated with increasing trends towards unhealthy diets and obesity and sedentary lifestyles, resulting in late onset diabetes {Bradshaw et al,2007}.

2.2.2: LOCAL BACKGROUND

Based on available epidemiology data, approximately 1-1.5 million South Africans are considered to have diabetes {Bradshaw et al, 2007}. The international diabetes federation {IDF} diabetes atlas reported a prevalence figure of 3.4% for the 24 million South Africans between the ages of 20 and 79 in 2003, with an expected increase to 3.9% by 2025 {Rheeder, 2003}. The increase in diabetes is linked to the worldwide increase in obesity. Figures from the South African demographics and health survey published in 2002, show that 29.2% of men were overweight or obese {kg/m²} compared to 56.6% of South African women {Rheeder, 2003}. SEMDSA put the prevalence of type2 diabetes between 3% and 28.7%.

Studies carried out in South Africa, that compared prevalence of type2 diabetes, reported the highest prevalence in the Indian population, followed by the coloured and lest in the black population {Bradshaw et al, 2007}. This is slightly different from the findings of SEMDSA, which found the highest prevalence in the coloured community of Cape Town {28.7%}, followed by the Indian population of Durban {13%}, then the blacks, with values ranging between 4.8 % in the rural community of QwaQwa, 8% in an urban settlement of Cape Town and the Caucasians in Durban with a prevalence of 3%. Recent studies indicated that the prevalence of type2 diabetes is an increasing health concern in black South Africans {Nthangeni, Steyn and Albert, 2001}.

2.2.3: TREND OF DIABETES IN SOUTH AFRICA

A number of epidemiological studies were conducted in selected communities in South Africa in the 1980s and 1990s {Bradshaw et al, 2007}. These studies revealed a clear rural-urban gradient, with higher prevalence in urban settings, in addition to a gradient

across different population groups. This gap is believed to be closing because of the urbanization of our rural areas with its associated consequences.

2.2.4: BURDEN OF DIABETES ON THE AVAILABLE STRUCTURE

The South African national burden of disease study examined the provincial estimates of age-standardized deaths due to various diseases, including cardiovascular and metabolic disorders. These estimates vary little between provinces. The age-standardized death rate for diabetes was found to be from 40 to 80/100,000 {Rheeder, 2006}. The South African national burden of disease study reported that diabetes was the 10th leading cause of death among persons of all ages in 2000, accounting for an estimated 13,500 deaths {2.6% of total deaths} {Bradshaw et al, 2007}.

It is clear that the number of diabetic patients will continue to rise, even in rural settings and the number of diabetic patients will continue to impact on the resources of the communities. The effect of such a burden will be even more significant if the various complications that come with substandard management of diabetes mellitus are added to the impact.

The first step in assessing the level of care health care workers give to this category of patients is to measure the patients' level of adherence, in an effort to expose the pitfalls, both on the side of the patients and of the health care providers. Identifying which patients are at greatest risk for non adherence to oral hypoglycemic agents is an important first step towards developing interventions that improve adherence {Lee and Taira, 2005}.

2.2.5: MANAGEMENT OF DIABETES MELLITUS

Diabetes is considered to be one of the most psychologically and behaviourally demanding of the chronic diseases {Kalyango, Owino and Nambuya, 2008}. Managing diabetes requires frequent self monitoring of blood glucose, dietary modifications,

exercise and administration of medication on schedule {Kalyango, Owino and Nambuya, 2008}.

Many of the complications associated with diabetes can be delayed or prevented through improved disease management and self care, including aggressive management of cardiovascular risk factors; early identification and treatment of hypertension, kidney disease, retinopathy, peripheral neuropathy and vascular disease; and increased glycemic control through diet, exercise, and/or taking insulin or oral diabetes medications {Hepke, Marthus and Share, 2004}.

Studies emphasized the importance of achieving optimal glucose control through strict adherence to medications, diet, and exercise in order to minimize serious long term complications {Kalyango, Owino and Nambuya, 2008}. The main goal of therapy for chronic diabetic patients is to optimize quality of life and to prevent acute metabolic and long term complications with reduction of premature morbidity and mortality {Nthangeni, Steyn and Albert, 2001}.

In managing the disease, dietary therapy should form an essential component of treatment. One study suggested that nutrition therapy for black patients is unsuccessful when the diet prescription does not relate to the patient's cultural environment and economic situation and is presented in ways that are difficult for low literacy patients to understand and implement {Nthangeni, Steyn and Albert, 2001}.

2.2.6: BLOOD GLUCOSE TARGET IN DIABETES MELLITUS

The South African national guidelines set optimal glycemic control targets at 4-6 mmol/l fasting and 5-8 mmol/l 2 hours post prandial. This guideline conforms to control targets set by the society for endocrinology metabolism and diabetes of South Africa {Van Zyl, 2006}.

2.2.7: RATE OF ADHERENCE TO TREATMENT

Patient adherence to oral hypoglycaemic agents is integral to reducing the health care costs and chronic complications of diabetes {Lee and Taira, 2005}. Adherence to long term therapy for chronic illness averages 50% in developed countries. In developing countries the rates of adherence are even lower, given the paucity of health resources and the inequities in access to health care {Sabate, 2003}. A systematic review to determine the extent to which patients omit doses of medication prescribed for diabetes, put the range between 36% and 93%, depending on the method of assessment used {Cramer, 2004}. This result is buttressed by another study, which estimates poor compliance/adherence to be between 30% and 50%, irrespective of disease, prognosis or setting {Morris and Schutz, 1992}.

Patient adherence to a prescribed regime of oral hypoglycaemic agents to prevent diabetes is generally low and difficult to maintain, even in a population with adequate access to health care and drug coverage {Lee and Taira, 2005}.

2.2.8: EFFECTS OF POLYPHARMARCY ON ADHERENCE

Polypharmacy is the natural consequence of providing evidence based medical care to patients with type2 diabetes {Grant, Devita and Meigs, 2003}. Studies have demonstrated that, for an individual, medicine adherence declines when comparing once- daily to a multiple dosing regimen {Grant, Devita and Meigs, 2003}.

2.2.9: DEFINITION OF ADHERENCE

Adherence can be defined as the extent to which a person's behaviour regarding taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider {Sabate, 2003}. Non adherence may consist of not initiating therapy, finishing therapy and not beginning it again if necessary, or following indications incorrectly {Ronquillo et al, 2003}.

CLASSIFICATION OF ADHERENCE

Non adherence can be divided into categories; Primary non adherence, when the patient fails to have the medication dispensed} and Secondary non adherence, when medication is not taken as instructed {Chatterjee, 2006}.

Further categories relate to intentionality i.e. Intentional non adherence may occur when the doctor's diagnosis or treatment is rejected by the patient and Unintentional non adherence which can be related to social, demographic, psychological and clinical variables {Chatterjee, 2006}.

2.2.10: MEASURE OF ADHERENCE

Adherence is a dynamic process that needs to be followed up and there is no gold standard for adherence measurement, although the use of variety of strategies has been reported in the literature {Sabate, 2003}. Approaches to the measurement of adherence include: subjective strategies, objective strategies and biochemical measurement {Sabate, 2003}.

Because of the difficulties in measuring, no estimate of compliance/adherence or non compliance/ non adherence can be generalized {Wens et al, 2005}.

2.2.10: SUBECTIVE STRATEGY OF MEASUREMENT

A subjective strategy of measuring adherence involves; asking provider and patients for their subjective rating of adherence behaviour and the use of standardized, patient administered questionnaires.

2.2.11: OBJECTIVE STRATEGY OF MEASUREMENT

Objective strategies include; counting the remaining dosage units {e.g. tablets} at clinic visits {therapeutic adherence can be measured by calculating the percentage of missing tablets. The required amount of medication taken, for a patient to be considered adherent, is 80% (Ronquillo et al, 2003)},

Use of an electronic monitoring device {medication event monitoring system (MEMS)}, which record the time and date when a medication container was opened, thus better describing the way patients take their medications and

Use of a pharmacy database, to check when prescriptions are initially filled, refilled over time and prematurely discontinued.

Patients who consumed less than 80% or more than the advised quantity of drugs were considered as non adherent {Jose et al, 2007}.

Although objective strategies may initially appear to be an improvement over subjective approaches, each approach has drawbacks in the assessment of adherence behaviour.

2.2.12: BIOCHEMICAL STRATEGY OF MEASUREMENT

Biochemical measurement employs the addition of non-toxic biological markers to medications. These markers and their presence in blood or urine can provide evidence that a patient recently received a dose of the medication being examined {Sabate 2003}.

2.2.13: DEMERITS OF NON ADHERENCE

Adherence has long been recognized to be a major barrier to the optimum care of chronic diseases, including diabetes {Littenberg, Maclean and Hurowitz, 2006}. Successful control of diabetes mellitus requires lifelong adherence to multiple self management activities in close collaboration with health professionals. Lack of adherence to such activities have been demonstrated to be associated with unfavourable diabetes outcomes {Schectman, Schorling and Voss, 2008}. The

consequences of poor adherence to long term therapy are poor health outcomes and increased health care costs {Sabate, 2003}.

2.2.14: DETERMINANTS OF ADHERENCE

Research on compliance/adherence has shown that that neither the features of a disease, nor the referral process, nor the clinical setting, nor the therapeutic regime seem to influence compliance/adherence {Anion, 1997}.

2.2.15: IMPROVING ADHERENCE TO TREATMENT

Therapeutic interactions with patients should no longer be viewed simply as opportunities to reinforce instructions around treatment: therapeutic interactions should rather be seen as a space where the expertise of patients and health professionals can be pooled, to arrive at mutually agreed goals {Bissell, May and Noyce, 2004}. In primary care, patients strongly want a patient centred approach, with communication, partnership and health promotion {Wens et al, 2005}. Evidence, that involving patients more in consultations can increase compliance/adherence to treatment, is increasing {Wens et al, 2005}.

2.2.16: CONCLUSION

The consequences of poor adherence to long term therapy are poor health outcomes and increased health care costs {Sabate, 2003}. Therefore, the researcher finds it important to assess the level of adherence to treatment in his own, hospital, setting and use the information gathered to make recommendations to improve the management of patients with type2 diabetes mellitus in the Matlala district hospital.

CHAPTER 3

METHOD

3.1: PURPOSE OF THE STUDY

The aim of the study is to assess adherence to treatment among type2 diabetic patients.

3.2: OBJECTIVES

To assess the demographic profile of patients with poor adherence.

To assess the level of adherence to treatment among type2 diabetic patients.

To determine the possible reasons for poor adherence to diabetic medication.

To determine the possible reasons for poor adherence to lifestyle changes.

3.3: RESEARCH QUESTIONS

What is the state of adherence to treatment among type2 diabetic patients in Matlala district hospital?

What is the demographic profile of the patients with poor adherence to treatment in Matlala district hospital?

What is the level of adherence to treatment among type2 diabetic patients in Matlala district hospital?

What are the possible reasons for poor adherence to medication among diabetic patients in Matlala district hospital?

What are the possible reasons for poor adherence to lifestyle changes among diabetic patients in Matlala district hospital?

3.4: STUDY DESIGN

A cross-sectional study was designed to assess the level of adherence to diabetes treatment among type2 diabetic patients, in Matlala district hospital. Participants included male and female diabetic patients who had been on diabetes treatment for more than one month. Participation was voluntary and consent was obtained from each respondent.

3.5: SAMPLE/STUDY POPULATION

The sample population was type2 diabetic patients attending the outpatient department of Matlala district hospital. The patients receive free medical care including medication, from the hospital. Based on the statistics available, the sample population was estimated to be 500.

Inclusion criteria: Type2 diabetic patients attending the outpatient department of Matlala district hospital and who gave written informed consent were included in the study.

Exclusion criteria: All type 1 diabetic, all type2 diabetics who refused to be part of the study and newly diagnosed diabetics, less than 1 month, were excluded.

3.6: SAMPLE SIZE

Literature reviewed estimated an adherence rate in developed countries at 50% and lower in developing countries. The total number of diabetic patients attending the out patients' department of Matlala district hospital was estimated to be 500.

The required sample size was then calculated using the formula: $n = Nz^2pq/e^2 \{N-1\} + z^2pq$.

Where n = sample size

```
N = population size \{500\}

Z = critical value \{1.96\}

p = estimated proportion \{30\% = 0.3\}

q = 1 - p

e = level of precision \{\pm 5\% = 0.05\}
```

The rate of adherence was set at 30% with a confidence interval of 95% and the required sample size was calculated to be 196.

3.7: DATA COLLECTION

Data was collected from December 2009 till March 2010, a period of 4 months. Sampling was done using a convenience method. A trained interviewer administered a tested structured questionnaire to each respondent. The interviewer was one of the outpatient department nurses; she spoke both English and Sotho, the local language, fluently. The sister was selected because of her genuine interest in patients' care. The researcher and the sister discussed the questionnaire; the sister had time to ask questions, to clarify the purpose of each question and to determine what response could be expected. A pilot study was conducted to test the reliability and validity of the questionnaire, the understanding of the interviewer and to correct mistakes. Respondents were counselled about the need to give correct information about their treatment. The questionnaire was limited to 22 questions and took an average of 10 minutes to complete. The questionnaire was adapted from studies on bio-psychosocial determinants of self management in culturally diverse South African patients with essential hypertension, by Professor KFH Botha (Botha et al, 2002) and on Tuberculosis patients' reasons for defaulting on tuberculosis treatment: a need for a practical patient-centred approach to tuberculosis management in primary health care by IS Ukpe {Ukpe 2007}. With the help of Dr Marincowitz, the researcher's supervisor, the necessary adjustment was made to the questionnaire, to suit the purpose of the

study. The final draft of the questionnaire was given to Sister Maila, a professional nurse, for translation into Sotho. The Sotho version of the questionnaire was then given to Matron Makola for translation back to English. The initial final draft and the final English translation were compared to make sure that the questionnaire had not lost any meaning in translation. The help of local translators was employed because of the need to translate this questionnaire into the local dialect convincingly. The questionnaire assesses the demographic details of the respondents, the type of medication, adherence to medications and lifestyle changes, and the reasons for non adherence to treatment. A small pilot study was done: The questionnaire was tested on five participant patients, to check for ease of use and whether the answers would lead to achieving the set aim. The result was successful. Results from the pilot study were not included in the main study.

3.8: DATA ANALYSIS

An Excel spreadsheet was used for data capturing. Percentage and numbers were used to interpret data and cross tabulation was used to determine association.

Adherence to medication and lifestyle changes were assessed by asking the respondents to recall how they had been taking their medications and observing the lifestyle changes on a day by day basis, during the week preceding their visit to the hospital. The responses were categorized as; always, frequently, only when I experienced diabetic symptoms and never. Respondents were marked always if they did not miss treatment or miss a day of treatment only and frequently if they miss more than a day. Respondents that took their medication always were classified as adherent and those that took theirs frequently, only when they experience diabetic symptoms and never, were classified as non adherent.

Assessment of lifestyle changes were evaluated by asking the patients whether they performed the prescribed 30minutes brisk walking 5 days in a week as recommended. Respondents who kept to recommended lifestyle behaviour, or missed only a day out of

the 5 days were marked always and adherent to lifestyle changes while all others were classified as non adherent.

When analysing the result treatment was used synonymously as diabetic medication and was interpreted as such. The family size in the questionnaire was defined as the number of people leaving in the same house.

3.9: RELIABILITY, VALIDITY AND OBJECTIVITY

3.9.1: Reliability

Reliability refers to the reproducibility and consistency of the instrument. Reliability is assured by using a tested and standardized questionnaire and the help of a professional statistician.

A pilot study was done to test the questionnaire, before the research was conducted.

3.9.2: Validity

Validity is an assessment of whether an instrument measures what it aims to measure. The instrument used was a tested and standardized questionnaire. The questionnaire was given to Sister Maila, a professional nurse, for translation into the local language, Sotho, and this was then given to Matron Makola for translation back into English. The translated questionnaires were compared, to make sure that the questionnaire had not lost meaning. The help of local translators was employed because of the need to translate this questionnaire into the local dialect convincingly.

3.9.3: Objectivity

All sources of potential bias were identified and an effort was made to reduce these sources. The questionnaire was a prototype of a tested and standardized questionnaire and it was translated into the local language and back to English and then compared to the original, to make sure no meaning had been lost.

A trained nurse collected the data. The nurse did not wear a uniform when she administered the questionnaire.

Hospital based patients were selected for the study because they represent various groups of people from the community.

All type2 diabetes mellitus patients attending the hospital were included in the study, to eliminate selection bias.

3.10: LIMITATIONS

The researcher found it very difficult to assess the level of adherence to treatment among these respondents, objectively. He researcher needed to rely on the memory, power of recall and on the truthfulness of the information given by the respondents. Considering the sample size and the setting, a convenience method of sampling was used in order to meet the sample size and to be able to generalize the results, as representative of the study population. This sampling could represent a likely source of selection bias.

3.11: ETHICAL CONSIDERATIONS

The study was approved by the MEDUNSA Research and Ethics Committee, University of Limpopo, South Africa and the Department of Health and Social Development, Limpopo, South Africa.

- 3.11.1: Confidentiality; respondents were assured that the information given will not be divulged to any third party except for the purpose of the study. No form of identification linked a questionnaire to a respondent.
- 3.11.2: Consent; written consent was obtained from the respondents before proceeding with information collection.

CHAPTER 4

RESULTS

In this chapter the results will be explained and presented in tables, figures and charts. Results describe;

Level of adherence,

The demographic information of the study participants,

The association between adherence and selected demographics,

The association of adherence and anti diabetic drug types prescribed,

The association of adherence and distance travelled to facility

The association of adherence and the keeping of appointments

Strategies patients use, to take medication,

Reasons for poor adherence to diabetes treatment and

Reasons for poor adherence to lifestyle changes.

4.1 LEVEL OF ADHERENCE TO TREATMENT

A total of one hundred and ninety six respondents took part in the study. The study was conducted over a period of four months. The convenience method of sampling was used, considering the sample population and the targeted sample size.

Table 4.1: Level of adherence to treatment

Adherence	Number	Percentage
Yes	137	70
No	59	30
Total	196	100

The table reveals that of the 196 respondents that participated in the study, 137{70%} adhere to diabetes treatment and only 59{30%} did not adhere to the treatment.

4.2: DEMOGRAPHIC FEATURES OF THE RESEARCH PARTICIPANTS.

A hundred and ninety six diabetic patients participated in the study. Of these, 143 were female, 130 were married and 163 were 50 years or older. Ninety of the patients had no formal education, 61 had primary education and 45 had secondary and tertiary education. There were 170 of the respondents who were unemployed, including pensioners. Of the participants unemployed, the majority, 140, indicate a grant as a source of income; 17 said that they get support from their respective families and only 13 mentioned other sources of income.

Table 4.2.1: Age.

		Number of	Percentages of
		respondents	respondents
Age	<30	1	1
	30-39	5	3
	40-49	27	13
	50-59	63	32
	60+	100	51
Total		196	100

Slightly more than half of the respondents were older than 60years. About one third of the respondents were between 50 and 59 years old, 13% and 3% were aged between 40 to 49 and 30 to 39 years old respectively. One respondent was younger than 30.

Table 4.2.2: Gender.

		Number of	Percentages of
		respondents	respondents
Gender			
	Male	53	27
	Female	143	73
Total		196	100

Of the 196 respondents, 143 which made up 73% of the sample size were females and 27% were males.

Table 4.2.3: Marital status.

		Number of	Percentages of the
		respondents	respondents
Marital status			
	Single	14	7
	Married	130	66
	Divorced	3	2

	Separated	10	5
	Widowed	39	20
Total		196	100

Two thirds of the respondents, 130, were married, one fifth, 39, were widowed, 14 were single, 10 were separated and only 3 of the respondents were divorced.

Table 4.2.4: Family size.

		Number of	Percentages of
		respondents	respondents
Family			
size			
	1-3	40	20
	4-6	94	48
	7-9	35	23
	10+	17	9
Total		196	100

Family size in the range of 4-6 had the highest number of respondents, 94, followed by a family size of 7-9 with 35 respondents, then a family size in the range 1-3, with 40 respondents and 10 and more in a family with 17 respondents.

Table 4.2.5: Level of education.

		Number of	Percentages of the
		respondents	respondents
Level of			
education			
	None	90	46
	Primary	61	31
	Secondary	34	17
	Tertiary	11	6
Total		196	100

90 of the respondents had no formal education, 61 of the respondents had primary education as the highest level of education and 34 and 11 of the respondents had secondary and tertiary education as the highest level of education respectively.

Table 4.2.6: Employment status.

		Number of respondents	Percentages of respondents
Employment status			
	Unemployed	170	87
	Employed in formal sector	12	6

	Employed in informal	2	1
	sector		
	Self employed	12	6
Total		196	100

A vast majority of the respondents, 170, were unemployed while 12 each were employed in the formal sector or self employed and only 2 of the respondents were employed in the informal sector.

4.3: DEMONSTRATION OF ASSOCIATIONS AND ADHERENCE TO TREATMENT.

Table 4.3.1: Association between adherence and age

	Adhere	Adherence	
	Yes	No	
Age <50	28 {20%}	28 {20%} 5 {8%}	
≥5	109 {80%} 54 {92%}		

Of the selected demographics, age was found to be significantly associated with non adherence {0.028}. 92% of respondents non adherent to treatment were age above 50years. Also the majority of the respondents, 109, who were adherent to treatment, were 50 years old, or older.

Table 4.3.2: Association between adherence and gender

		Adherence	Adherence	
		Yes	No	
Gender	Male	38 {28%}	15 {26%}	0.441
	Female	99 {72%}	44 {74%}	

Table 4.3.2 shows that gender was not significantly associated with adherence {0.441}. The majority of the respondents, 99, were female and 38 were male. Of those respondents not adherent to treatment, 44 were female and 15 were male.

Table 4.3.3: Association between adherence and marital status

		Adherence		p-value
		Yes	No	
Marital status	Married	93 {68%}	37 (63%)	0.294
	Not married	44 {32%}	22 {37%}	

Table 4.3.3 shows that marital status was not significantly associated with adherence {0.294}. The majority of the respondents, 93, who were adherent to treatment, was married and the rest of the respondents, 44, were not married. Of the respondents who were non adherent, 37 were married and 22 were not married.

Table 4.3.4: Associated between adherence and level of education

		Adherence		p-value
		Yes	No	
Level of education	None/primary	104 {76%}	47 {79%}	0.567
	Secondary/tertiary	33 {24%}	12 {21%}	

Table 4.3.4 reveals that level of education was not significantly associated with adherence {0.567}, 104 of the respondents who were adherent to treatment had, at most, primary education as their highest qualification and 33 respondents had secondary or tertiary education as their highest qualification.

Table 4.3.5: Association between adherence and employment status

		Adherence		p-value
		Yes	No	
Employment status	Employed	23 {17%}	3 {5%}	0.018
	Unemployed	114 {83%}	56 {95%}	

Table 4.3.5 reveals that employment status was significantly associated with non adherence {0.018}, 114 of those respondents that adhere to treatment were unemployed and 23 were employed while 56 of the non adherent respondents were unemployed and only 3 were employed. This shows the strong association between unemployment and non adherence.

Table 4.3.6: Association of adherence and anti diabetic drug types prescribed.

	Adherence		p-value
	Yes	No	
Anti diabetic drug type			
Metformin	23 {16%}	11 {19%}	0.928
Glibenclimide/Gliclize	2 {2%}	1 {2%}	
Both	112 {82%}	47 {79%}	

Table 4.3.6 shows that there was no statistical significance between non adherence and anti diabetic drug types {0.928}. Of the respondents that were adherent to treatment, 112 take both metformin and glibenclimide/gliclize, 23 take metformin only and 2 take glibenclimide/gliclize only.

Table 4.3.7: Association between adherence and distance travelled to facility

	Adherend	ce	p-value
	Yes	No	
Distance travel to facility			
≤10k	m 90 {66%}	42 {71%}	0.452
≥10k	m 47 {34%}	17 {29%}	

Table 4.3.7 shows the association between non adherence and distance travelled to the health care facility. The distance travelled to the facility had no statistical significance to adherence {0.452}. Of those respondents adherent to treatment, 90 travelled a distance of less than 10km to the health facility and 47 travelled a distance greater than 10km, 42

respondents who were non adherent, travelled a distance of less than 10km to the nearest health facility and 17 respondents travelled more than 10km to the health care facility.

Table 4.3.8: Association between adherence and keeping of appointments

	Adherence		p-value
Keeping of appointments	Yes	No	
Yes	135 {98%}	52 {88%}	0.001
No	2 {2%}	7 {12%}	

Table 4.3.8 reveals a strong association between the keeping of appointments and adherence {0.001}. Of those respondents that kept their appointments, 135 were adherent to treatment and 2 were not, 52 of those who were not adherent kept their appointment and 7 did not.

Table 4.4: Reasons for poor adherence to diabetic treatment

Table 4.4 reports on the various reasons for poor adherence to diabetic medication. Of the 58 respondents that were poorly adherent to medication use, 17{29%} stated that the clinic did not have their pills, 9{16%} stated that they forgot to take the medication, 8{14%} stated that they travelled to visit and did not have enough pills.

	Number of	% of
	respondents	respondents
I forgot	9	16
Long wat was a special after taking way was alignting	1	0
I am not responsible for taking my medication	1	2

I am too old to go to the clinic by myself	1	2
I do not have transport money to go to clinic	2	3
I am taking care of a sick family member	4	7
I do not have food to eat before I take my pills	5	9
I do not have to drink my pill if I feel better	3	5
The clinic did not have my pills	17	29
The medicine makes me feel worse	1	2
I travelled to visit and did not have enough pills	8	14
I don't have to take my medication if am going to	1	2
the hospital		
My medication was finished	6	10
Total	58	100

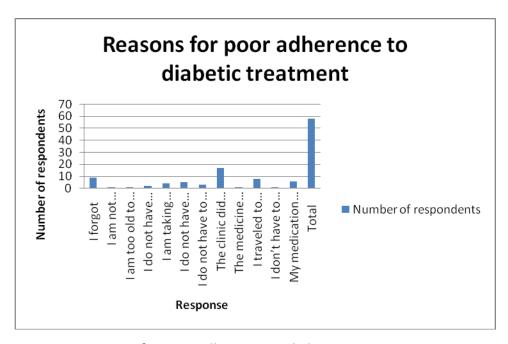


Figure 4.1: reasons for poor adherence to diabetic treatment.

Table 4.5: Reasons for poor adherence to lifestyle changes

Table 4.5 shows the reasons for poor adherence to lifestyle. Most of the respondents 20 {29%} stated that the main reason for not adhering is that they were too old, 15 {22%} of the respondents stated no specific reason, 9 {13%} struggled to motivate themselves and 7 {10%} simply said that they forgot.

	Number of	% of
	respondents	respondents
I forgot	7	10
I am not responsible for carrying out the changes	2	3
I do not believe that it will help me	1	1
I struggle to motivate myself	9	13
I do not have enough time for that	4	6
I am too old	20	29
I do not have to adhere to lifestyle changes if I feel better	2	3
There is no specific reason for me not to	15	22
The lifestyle changes makes me feel worse	5	7
Work did not allow me to carry out the changes	3	4
Has an amputated foot	1	1
Total	69	100

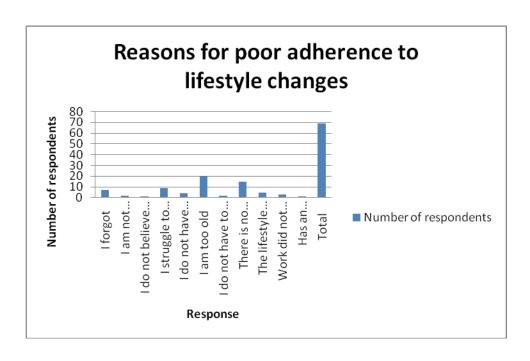


Figure 4.2: Reasons for poor adherence to lifestyle changes.

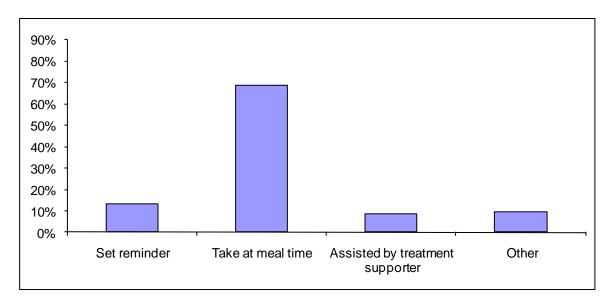
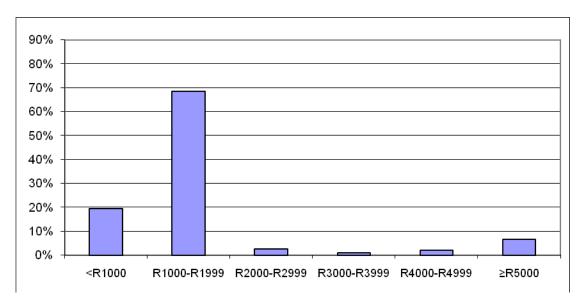


Figure 4.3: Strategies used by patient to take medication.

Figure 4.3 reveals the strategies used by patients, to remind them to take medication; 68% of the respondents that adhere to the recommended use of medication agreed that

they take it at meal times, 14% set a reminder, 8% employed the assistance of a treatment supporter and the rest of the respondents use other means.



Figure

4.4: Respondents income per month

About 134(68%) of the respondents have an income of R1000-R1999 per month, followed by 38(19%) respondents who survive on an income of less than R1000 per month.

SUMMARY

The results show that the overall level of adherence to diabetic treatment among diabetic patients at Matlala district hospital is 70% and that age and unemployment status is significantly associated with adherence. The majority of respondents who were adherent to treatment kept their appointment {98%}. Of those respondents that were non adherent to treatment, 29%, blamed the clinic that did not have their medication, 16% forgot to take medication and 14% travelled and forgot to take their medication with them. Regarding life style, 29% of the respondents who were non adherent to lifestyle changes stated old age as the main reason, 22% said that they did not have a specific reason for not adhering, 13% said that they struggled to motivate themselves and 10% agreed that they simply forgot to take the medication. Taking medication with diet remains the most important strategy for adhering to treatment.

CHAPTER 5

DISCUSSION

5.1: DEMOGRAPHICS OF THE RESPONDENTS

Successful control of diabetes mellitus requires lifelong adherence to multiple self management activities, in close collaboration with health professionals. Lack of adherence to such activities has been demonstrated to be associated with unfavourable diabetes outcomes {Schectman, Schorling and Voss, 2008}. About three quarters of the respondents of this research study were female and 83% were 50 years and older, confirming what was previously found about the demographics of people with type2 diabetes mellitus. The majority of the articles reviewed e.g. the study on the global prevalence of diabetes {Wild et al, 2004}, found that diabetes is more prevalent among men but there are more women with diabetes, than men. The greater number of women with diabetes can be explained by understanding that prevalence of diabetes increases with age and more women live into old age than men.

5.2: LEVEL OF ADHERENCE OF THE RESPONDENTS

Table 4.1 shows the level of adherence, placed 70%, this is within the range found in most studies. A systematic review, to determine the extent to which patients omit doses of medication prescribed for diabetes, found the range to be between 36% and 93% depending on the method of assessment used {Cramer, 2004}. This result was buttressed by another study which estimates poor compliance/adherence to be between 30% and 50%, irrespective of disease, prognosis or setting {Morris and Schutz, 1992}. Similar studies done in Uganda, using a self report questionnaire {Kalyango, Owino and Nambuya, 2008}, in Hawaii, using prescription refill claim for oral hypoglycaemia {Bradshaw et al, 2007} and a retrospective study that followed diabetic patients for 12

months from date of the first oral hypoglycaemic fill, {Rozenfeld et al, 2008} put adherence at 71.1%, 61.4% and 81% respectively.

A cohort study, to assess the relationship between patients' initial medication adherence and subsequent regime intensification put adherence at between 79.8% and ±19.3% {Grant R. et al 2007}. The difference found might be due to the different methods used in assessing/calculating adherence, different study duration and the demographic profile of each study.

It is important to note that in one of the studies listed mentioned, the level of adherence is actually close 71.1% vs. 70%, this is probably due to the fact that the demographics are similar because the settings are close and the method used is similar.

Patient adherence to a prescribed regimen of oral hypoglycaemic agents is generally low and difficult to maintain, even in populations with adequate access to health care and drug coverage {Lee and Taira, 2005}. Therefore it is possible that the method used overestimated the true value of adherence in our setting. The subjective nature of the method of assessment, which solely places the response on the power of recall, attitude and trustworthiness of the patient, might have contributed to this high value. This is further buttressed by a study which stated that patient self report tend to overestimate adherence, unlike electronic monitoring {Prado-Aguilar et al, 2009}.

Considering the level of adherence, it is logical to assume that good adherence corresponds to good metabolic control and this correspondence would be a very important area to explore. Research assessing concurrent adherence to multiple medicines in HIV therapy found that, although self report likely over estimates adherence, less than perfect self reported adherence correlates well with suboptimal adherence as measured by electronic medication cap monitors {Grant, Devita and Meigs, 2003}, self report also correlates well with pill count {Dunbar-Jacob and Mortimer-Stephens, 2001}.

5.3: ASSOCIATION BETWEEN ADHERENCE AND AGE AND EMPLOYMENT STATUS

There are two demographic characteristics that are significantly associated with non adherence: age and employment status. This research found that the majority of patients who were not adherent to treatment were older than 50 and were unemployed. When the reasons why patients do not take the medications as prescribed, were compared, the majority, 29%, said that the clinic did not have their pills, 16% said they forgot to take the medication, 14% said they travelled to visit and did not take enough pills with. A possible interpretation of the data indicates that a typical patient could be an elderly woman, unemployed, who did not get her medication in the clinic and could not go to the hospital because she could not afford to, or she is just too old to move around. Gender, marital status and level of education were not significantly associated with non adherence, contrary to a similar study which found gender and educational level associated with non adherence and age, marital status and occupation not significantly associated with non adherence {Kalyango, Owino and Nambuya, 2008}. Other studies found no association between gender and non adherence {Kalyango, Owino and Nambuya, 2008}.

5.4: ASSOCIATION BETWEEN ADHERENCE AND KEEPING OF APPOINTMENT

Adherence to appointments, independent of visit frequency, was a strong predictor of diabetes metabolic control {Schectman, Schorling and Voss, 2008}. Of those respondents who kept their appointments, 98% were adherent to treatment. The high level of adherence is a positive sign and could indicate the possible advantage of emphasizing the benefit of adherence to treatment, at each visit. It could also be valuable to investigate whether adherence to appointments correlates well with metabolic control, as described in the reference.

5.5: STRATEGIES USED BY RESPONDENTS TO ADHERE TO MEDICATION

Figure 4.9 reveals the strategies patients use to take medication; 68% of the respondents who adhere to the recommended use of medication indicated that they take it at meal time, 14% set a reminder, 8% employed the assistance of a treatment supporter and the rest of the respondents use other means. This is contrary to the findings of {Littenburg, Maclean and Hurowitz, 2006} which showed that the most popular aid to treatment adherence was the day of the week pill box {50% of all respondents}, keeping medicines in a special place {41%} and associating medicine with a daily event such as a TV show or a meal {17%}. The main difference between the two studies is the contrast between the levels of education of the respondents. In the latter mentioned study the majority of the respondents were educated, with at least 4 years of tertiary study, compared to our setting where the majority of the patients, 77% reported primary school as their highest level of education. Adherence aids are in common use among adults with diabetes; there is little evidence that they are efficacious, but this same study found few associations with better control {Littenburg, Maclean and Hurowitz, 2006). This researcher assumes that it will be reasonable to advise our diabetic patients to take their medication with food, given the number of respondents who use this method successfully.

5.6: REASONS FOR POOR ADHERENCE TO DIABETIC TREATMENT

Of the total number of respondents who were poorly adherent to medication use, 17 {29%} stated that the clinic did not have their pills, 9 {16%} stated that they forgot to take their medication, and 8 {14%} stated that they travelled to visit and did not take enough pills with them. A study done by Grant, Devita and Meigs, {2003}, found that the single most common reason why patients do not take a particular medicine was side effect {58%}, followed by difficulty remembering to take all doses {23%} and cost {4%}. The disparity between these results and results obtained in this study might lie in the number of medications to be taken and co morbidity; these factors were not explored in

this study. Cost was not considered in this study because medications were given free in our setting.

5.7: REASONS FOR POOR ADHERENCE TO LIFESTYLE CHANGES

Table 4.5 shows the reasons for poor adherence to lifestyle changes. Most of the respondents 20 {29%} stated that the main reason for not adhering was that they were too old, 15 {22%} of the respondents stated no specific reason, 9 {13%} struggled to motivate themselves and 7{10%} simply said they forgot to take their medication. In a study to measure adherence and barriers of complying with lifestyle recommendations among patients with high cardiovascular risk factors in Kuwaiti, 64.4% of participants were not participating in regular exercise and the main barriers to adherence to exercise were lack of time 39%, co existing diseases 35.6%, and adverse weather conditions 27.8% {Serour et al, 2007}. The main difference in findings is mainly in the demographic and the setting. Most of the respondents were not counselled about lifestyle changes; especially recommended exercise and the majority of the few that were counselled were not adhering to recommendations. Old age top the list of reasons for not adhering to recommended lifestyle changes and most of our diabetics are old, therefore it is recommended that designing a form of lifestyle changes that will suite their age should be considered.

CHAPTER 6

RECOMMENDATIONS

Early educational interventions for patients with diabetes resulted in better outcomes. Diabetes educational centres are valuable resources and patients should be referred soon after diagnosis {Brown et al, 2002}.

At the hospital and the clinic level, ongoing education in the form of health talks to the patients and the distribution of information, education and communication {IEC} materials, made available in all languages in the outpatient department and clinics, should be considered especially in the aged and unemployed.

Management of diabetes mellitus must be seen as multidisciplinary. Other healthcare providers should be involved in the treatment, especially the pharmacists. An uninterrupted supply of medications should also be made a priority at provincial level.

Studies have shown that physicians can significantly influence adherence by the level of trust they engender {Armstrong et al, 2006} and by their skills in communicating and motivating patients to engage in health improving behaviours {Grant et al, 2007}. Each medical practitioner involved in the management of diabetes needs to update himself and put the information acquired into use so as to adequately treat these categories of patients. Effort should be made to design a form of exercise that suits most of our patients and continuous motivation of these patients is important in order to ensure that they adhere. To this end, the principle of family medicine should be incorporated into the training of doctors as this will help to manage our patients holistically.

Electronic monitoring systems were useful in improving adherence for individual patients {Cramer, 2004}. These systems may be difficult to put into use in our setting, considering the cost implication and the demographics of our patients. It will be more appropriate if health care workers continue to encourage patients to take their medication with food because this practice has been shown to help with adherence.

This study revealed an above average level of adherence to treatment, compared to previous studies. It would be valuable to do more research, to assess whether the high level of adherence reported corresponds to the metabolic control expected of good adherence.

CONCLUSION

The study revealed an above average level of adherence to treatment, 70%, in my setting. Results indicated that age and employment status are significantly associated with non adherence and of those respondents that are adherent to treatment 98% kept their appointment regularly. Therefore, more needs to be done on the reasons why our patients do not adhere to both medication and lifestyle changes and each stakeholder need to address their short comings.

REFERENCES

ANION: Working party from compliance to concordance. Achieving goals in medicine taking. London, Royal Pharmaceutical society of Great Britain 1997.

ARMSTRONG K, ROSE A, PETERS N, LONG J.A, MURPHY S, SHEA J.A. Distrust of the health care system and self reported health care system and self reported health in the United State. J Gen Intern Med 21:292-297, 2006.

BISSELL P, MAY C.R, NOYCE P.R. From compliance to concordance: barriers to accomplishing a re-framed model of health care interactions. Social science and medicine 2004; 58{4}:851-62.

BOTHA K.F.H, DU PLESSIS W.F, VAN ROOYEN J.M, et al. Biopschycosocial determinants of self-management in culturally diverse South African patients with essential hypertension. J Health Psycho, 2002; 7: 519.

BRADSHAW D, NORMAN R, PIETERSE D. et al. South Africa comparative risk assessment collaboration group. Estimating the burden of disease attributed to diabetes in South Africa in 2000, South Africa Medical Journal, August, 2007; 97:700-706.

BROWN J.B, HARRIS S.B, WEBSTER-BOGAERT S, WETMORE S, FAULDS C, STEWART M. The role of patient, physician and systematic factors in the management of type2 diabetes mellitus. Family practice 2002; 19{4}:344-349.

CHATTERJEE J.S. From compliance to concordance in diabetes. Journal of medical ethics. 2006; 32: 507-510.

CRAMER J.A. A systematic review of adherence with medications for diabetes. Diabetes care. 2004; 27: 1218-1224.

DUNBAR-JACOB J, MORTIMER-STEPHENS M.K. Treatment adherence in chronic disease. J Clin Epidemiology. 2001; 54:S57-S60.

GRANT R, ADAMS A.S, TRINACTY C.M, ZHANG F, KLEINMAN K, SOUMERAI S.B, MEIGS J.B, ROSS-DEGNAN D. Relationship between patient medication adherence

and subsequent clinical inertia in type2 diabetes glycaemia management. Diabetes care. 2007; 30: 807-812.

GRANT R.W, DEVITA N.G, MEIGS J.B. Polypharmacy and Medication adherence in patients with type2 diabetes. Diabetic care 2003; 26: 1408-1412. Pubmed.

Hepke K.L, Marthus M.T, Share D.A. Costs and utilization associated with pharmaceutical adherence in a Diabetic population. AmJ Manag Care. 2004; 10{part2}:144-151.

http://www.semdsa.org.za/prevalencedatahtm {accessed 18/05/2010}.

JOSE V.M, BHALLA A, SHARMA N, et al. study of association between use of complementary and alternative medicine and non compliance with modern medicine in patients presenting to the emergency department. Journal of postgraduate medicine. 2007; 53: 96-101.

KALYANGO J.N, OWINO E, NAMBUYA A.P: Non adherence to diabetes treatment at Mulago hospital in Uganda: prevalence and associated factors. African health science 2008; 8{2}:67-73.

LEE R, TAIRA D.A. Adherence to Oral Hypoglycemic Agents in Hawaii. Prev Chronic Dis {serial online} 2005 Apr. available from:

URL: http://www.cdc.gov/pcd/issues/2005/apr04_0049.htm. {Accessed 08/01/2010}.

LITTENBERG B, MACLEAN C.D, HUROWITZ L. The use of adherence aids by adults with diabetes: A cross sectional survey. BMC Family Practice. 2006; 7:1. http://www.biomedcentral.com/1471-2296/7/1. {Accessed 08/01/2010}.

MORRIS L.S, SCHUTZ R.M. Patient compliance: an overview. J clin pham ther. 1992; 17:283-295.

NTHANGENI G, STEYN P.N, ALBERT M. Dietary intake and barriers to dietary compliance in black type2 diabetic patients attending primary health care services. Public health nutrition {accepted on 15 August 2001}; 5{2}:329-338. Pubmed.

PRADO-AGUILAR C.A, MARTINEZ Y.V, SEGOVIA-BERNAL Y, et al. Performance of two questionnaires to measure treatment adherence in patients with type2 diabetes. BMC Public Health 2009, 9-38. http://www.biomedcentral.com/1471-2458/9/38. {Accessed 26/12/2009}.

Rheeder P. Type2 Diabetes: The Emerging epidemic. SA Fam Pract. 2006; 48(10):20.

RONQUILLO L.H, ZENTENO J.F.T, ESPINOSA J.G, et al. factors associated with therapy non compliance in type2 diabetes patients. Salud publica Mex 2003; 45:3.

ROZENFELD Y, HUNT J.S, PLAUSCHINAT C et al. Oral antidiabetic medication adherence and glycaemic control in managed care. Am J Manag C. 2008; 14:71-75.

SABATE E. Adherence to long term therapies {evidence for action}. Switzerland: World health organization; 2003.

SCHECTMAN J.M, SCHORLING J.B, VOSS J.D. Appointment adherence and disparities in outcomes among patients with diabetes. J Gen Intern Med. 2008; 23{10}:1685-7.

SEROUR M, ALQHENAEI H, AL-SAQABI S, et al. Cultural factors and patients' adherence to lifestyle measures. British journal of general practice. 2007; 57: 291-295.

Ukpe I.S. Tuberculosis patients' reasons for defaulting on tuberculosis treatment: a need for a practical patient-centered approach to tuberculosis management in primary health care. SA Fam Pract. 2007; 49[6]: 17.

VAN ZYL D.G. Optimal glucose control in type2 diabetes mellitus-a guide for the family practitioner. SA Fam Pract. 2006; 48{10}:22-29.

WENS J, VERMEIRE E, VAN ROOYEN P, et al. GPs' perspectives of type2 diabetes patients' adherence to treatment: A qualitative analysis of barriers and solutions. BMC family practice. 2005; 6-20. http://www.biomedcentral.com/1471-2296/6/20. { Accessed 08/01/2010}.

WILD S, ROGLIC G, GREEN A, et al. Global prevalence of diabetes, estimate for the year 2000 and projections for 2030. Diabetes care. 2004; 27; 5.

APPENDICES

RESEARCH PROTOCOL

TITLE: ASSESSMENT OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL, LIMPOPO PROVINCE.

NAME OF STUDENT: DR ADEGBOLA SAHEED ADEKUNLE.

STUDENT NUMBER: 200729240

SUPERVISOR: GJO MARINCOWITZ

CONTENTS

TITLE	46
INTRODUCTION	46
STUDY PROBLEM	47
LITERATURE REVIEW	47-50
RESEARCH QUESTION	50-51
PURPOSE OF THE STUDY	51
OBJECTIVES	51
STUDY DESIGN	51
SAMPLE/STUDY POPULATION	51-52
DATA COLLECTION	53
DATA ANALYSIS	53
RELIABILITY, VALIDITY AND OBJECTIVITY	53-54
ETHICAL CONSIDERATIONS	54
REFERENCES	55-56
QUESTIONNAIRES	57-66
CONSENT FORMS	67-70
REQUEST LETTER	71-72
APPENDIX	57-73

TITLE

ASSESSMENT OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL, LIMPOPO PROVINCE.

INTRODUCTION

Diabetes is a silent, but serious disease. This disease is not only the most common cause of non traumatic amputations and a leading cause of blindness, it also accounts for a significant proportion of end-stage renal disease requiring dialysis and transplantation. It is estimated to be the 5th leading cause of death in the year 2000 accounting for 5.2% of all deaths globally {1}.

Matlala district hospital is a 288 bedded hospital with outreach to 7 primary health clinics, located in the heart of Tsimanyane in Sekhukhune district. The hospital serves a population of 74867 people from various villages surrounding it, with an average of about 120 patients attending the outpatient department daily. More than 34% of these patients are on chronic medication {excluding patients on psychotic medication} of which hypertension is top of the list and followed by diabetes mellitus {7.6%}. The majority of the admissions into the medical wards are due to complications of these diseases, a consequence of poor or non adherence to treatment. More than half of the hospital beds are occupied by these categories of patients.

Despite adequate counselling at each contact, many of the diabetes patients still return with uncontrolled blood glucose, which is cause for concern and prompted this researcher to look into the issue of adherence in diabetics.

THE STUDY PROBLEM

The researcher has worked in Matlala district hospital for more than 23 months and found that, for the majority of patients on diabetic treatment, reviews came with uncontrolled blood glucose or complications resulting from this, despite adequate counselling with the health care provider at each contact.

LITERATURE REVIEW

Non communicable diseases and mental disorders, human immunodeficiency virus/acquired immunodeficiency syndrome and tuberculosis together, represented 54% of the burden of all disease worldwide in 2001 and will exceed 65% worldwide in 2003 {13}. The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030 {12}. The world health organization estimated that, in 1998 there were 135 million people with diabetes, the estimated rose to 171 million people in 2000 and has been projected to increase to 366 million in 2030 {1}. Much of the increase will occur in developing countries, arising from growth and ageing of the population, as well as urbanization associated with increasing trends towards unhealthy diets, obesity and sedentary lifestyle, resulting in late onset diabetes type2 {1}.

Based on the available epidemiology data, approximately 1-1.5 million South Africans are considered to have diabetes {1}. The South African National Burden of disease study reported that diabetes was the 10th leading cause of death among persons of all ages in 2000, accounting for an estimated 13,500 deaths (2.6% of the total) {1}. This figure rose to 18,524 in 2003 and 18,654 in 2004 and accounted for 6th leading cause of death {5}.

Studies carried out in South Africa reported the highest prevalence in the Indian population, followed by the coloured, then whites and lastly the black population {1}. Recent studies indicated that the prevalence of type2 diabetes is an increasing health concern in black South Africans {2}.

A number of epidemiological studies have been conducted in selected communities in South Africa in the 1980s and 1990s {1}. These studies revealed a clear rural-urban

gradient, with higher prevalence in urban settings, in addition to a gradient across different population groups.

An average of 139 patients with diabetes mellitus are seen monthly in the hospital, this average was calculated from statistics gathered from April 2008 to March 2009. Of this number, an average of 8 newly diagnosed diabetic patients is seen monthly.

Socio-demographic variables have been found to be predictive of entry into the healthcare system, but have not been predictive of adherence level once treatment has been commenced {6}. The low incidence of diabetes in our setting may be due to patients who chose to employ the services of a traditional healer rather than to visit the hospital for help.

The main goal of therapy for chronic diabetic patients is to optimize quality of life and to prevent acute metabolic and long term complications, with reduction of premature morbidity and mortality {2}.

The South Africa national guidelines set optimal glycemic control targets at 4 to 6mmol/l fasting and 5 to 8mmol/l 2 hours post prandial and this guideline is in conformity with the society for Endocrinology Metabolism and Diabetes of South Africa {10}.

In managing the disease, dietary therapy should form an essential component of treatment. One study suggested that nutrition therapy for black patients is unsuccessful when the diet prescription does not relate to the patient's cultural environment and economic situation and is presented in ways that are difficult for low literacy patients to understand and implement {2}.

Adherence to long-term therapy for chronic illness in developed countries averages 50%, in developing countries, the rates are even lower, given the paucity of health resources and the inequities in access to health care {13}. Patient adherence to a prescribed regime of oral hypoglycaemic agents, to prevent diabetes, is generally low and difficult to maintain, even in a population with adequate access to health care and drug coverage {4}.

Polypharmacy is the natural consequence of providing evidence based medical care to patients with type2 diabetes {3}. Studies have demonstrated that, for an individual medicine, adherence declines when comparing once-daily to multiple dosing regimens {3}.

Adherence can be defined as the extent to which a person's behaviour-taking medication, following a diet and/or executing lifestyle changes corresponds with agreed recommendations from a health care provider {13}. Non adherence may consist of not initiating therapy, finishing therapy and not beginning it again if necessary, or following indications incorrectly {7}.

Non adherence can be divided into categories; primary non adherence (when the patient fails to have the medication dispensed) and secondary non adherence (when medication is not taken as instructed) {6}.

Further categories relate to intentionality i.e. intentional non adherence may occur when the doctor's diagnosis or treatment is rejected by the patient and unintentional non adherence can be related to social, demographic, psychological and clinical variables {6}.

Adherence is a dynamic process that needs to be followed up and there is no gold standard for its measurement, although the use of a variety of strategies has been reported in the literature {13}.

Approaches to measurement of adherence include: subjective strategies, objective strategies and biochemical measurement {13}. The subjective strategies involve; asking provider and patients for their subjective rating of adherence behaviour and the use of a standardized, patient administered questionnaire. Objective strategies include; counting the remaining dosage units (e.g. tablets) at clinic visits (therapeutic adherence can be measured by calculating the percentage of missing tablets. The required amount for a patient to be considered adherent, is 80% {7}. Patients who consumed fewer than 80% or more of the advised quantity of drugs, were considered non adherent), use of electronic monitoring device (medication event monitoring system {MEMS}), which record the time and date when a medication container was opened, thus better

describing the way patients take their medications and the use of a pharmacy database to check when prescriptions are initially filled, refilled over time and prematurely discontinued. Although objective strategies may initially appear to be an improvement over subjective approaches, each approach has drawbacks in the assessment of adherence behaviour. Biochemical measurement employs the addition of non toxic biological markers to medications. The presence of these markers in blood or urine can provide evidence that a patient recently received a dose of the medication under examination.

The consequences of poor adherence to long term therapy are poor health outcomes and increased health care costs {13}. Non adherence is one of the most important risk factors implicated in precipitating diabetic ketoacidosis {9}. Results from these studies differ from previous studies, involving mostly white populations, where infection represented the most common precipitating event {9}.

The research on adherence and diabetes in South Africa is not sufficient and the author had access to a limited number of relevant studies.

METHOD

RESEARCH QUESTIONS

- ♣ WHAT IS THE STATE OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL?
- ♣ WHAT IS THE DEMOGRAPHIC PROFILE OF THE PATIENTS WITH POOR ADHERENCE TO TREATMENT IN MATLALA DISTRICT HOSPITAL?
- ♣ WHAT IS THE LEVEL OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL?
- ♣ WHAT ARE THE POSSIBLE REASONS FOR POOR ADHERENCE TO DIABETIC MEDICATION IN MATLALA DISTRICT HOSPITAL?

♣ WHAT ARE THE POSSIBLE REASONS FOR ADHERENCE TO LIFESTYLE CHANGES?

PURPOSE OF THE STUDY

The aim of this research is to assess adherence to treatment among type2 diabetic patients in Matlala district hospital.

OBJECTIVES

- ♣ To assess the demographic profile of patients with poor adherence
- ♣ To assess level of adherence to treatment among type2 diabetic patients
- To determine the possible reasons for poor adherence to diabetic medication
- To determine the possible reasons for adherence to lifestyle changes

THE STUDY DESIGN

A cross-sectional design will be used to assess the level of adherence to treatment among type 2 diabetic patients who attend Matlala district hospital. Male and female patients will be included in the study. Consent will be obtained from all participants and participation will be voluntary.

SAMPLE/STUDY POPULATION

The sample population will be all type2 diabetic patients attending the outpatient department of Matlala district hospital. Using the statistics gathered from April 2008 to March 2009 an average of 139 diabetic patients is seen on a monthly basis. All volunteer type2 diabetic patients attending the outpatient department will be selected, until the recommended number of patients has been included.

Inclusion criteria; all type 2 diabetic patients attending the outpatient department who give written informed consent to participate in the study.

Exclusion criteria; all type 1 diabetic and newly diagnosed diabetics [less than 1 month].

Literature reviewed estimated adherence rate in developed countries at 50% and lower in the developing countries. The total number of diabetic patients, who attend Matlala district hospital out patients department, is estimated to be about 500. Sample size [n] can be calculated using the formula below;

$$n = Nz^2pq/e^2[N-1] + z^2pq$$

Where n; sample size

N; population size [500]

z; critical value [1.96]

p; estimated proportion [30% = 0.3]

q; 1-p

e; level of precision [\pm /-5% = 0.05]

The rate of adherence is set at 30% with a confidence interval of 95% and the sample size calculated to be 196.

It is estimated that a total of 500 diabetic patients attend Matlala district hospital. It is also important to note that an average of 139 diabetic patients attend the outpatient department on a monthly basis, the majority of whom were the same patients who chose to be attended to in the hospital monthly. Therefore a health care worker may see the same population of patients twice in two months.

DATA COLLECTION

Data will be collected using interviewer administered structured questionnaire. The questionnaire will be designed to probe the subject's demographic information, assess the level of adherence and the reasons for medication and lifestyle non adherence. The questionnaire will be made available in the local languages, Sotho and English and the same format will be used for all respondents. All diabetic patients attending the outpatient department and who are willing to participate are targeted. Considering the population size and sample size together with the limited time, the convenience method of sampling will be utilized. Data will be collected until the calculated sample size is reached.

The questionnaire will be limited to 22 questions. The selected questionnaire was adapted from studies on Bio-psychosocial determinants of self management in culturally diverse South Africa patients with essential hypertension {11} and Tuberculosis patients' reasons for defaulting on tuberculosis treatment: a need for a practical patient-centred approach to tuberculosis management in primary health care {14}. Necessary adjustment was made to suite the purpose of the study. A small pilot study was done: the questionnaire was tested on 5 patients to check for ease of use and whether it will achieve the set aim. The result was successful. Results from the pilot study will not be included in the main study.

DATA ANALYSIS

Data will be analyzed using the statistical package of social sciences (SPSS) version 14.0 software. Description statistics will be used. The data will be presented using graphs and tables. The T-test will also be used with a P-value of less than 0.05 to indicate significance.

RELIABILITY, VALIDITY AND OBJECTIVITY

Reliability refers to the reproducibility and consistency of the instrument and will be ensured by using a standardized questionnaire. A professional statistician will be employed to further ensure reliability.

Validity is an assessment of whether an instrument measures what it aims to measure. The questionnaire will be translated into the local language [Sotho] and back into English. This will be compared with the original questionnaire to be sure it has not lost any meaning.

Objectivity; all sources of potential bias will be identified and an effort will be made to reduce bias. The questionnaire is a prototype of a standardized questionnaire and will be translated into the local language and then translated back into English, and the translation will be compared to the original, to ensure it has not lost meaning.

A trained nurse will collect the data. The nurse will not be in uniform, to reduce bias. The choice of patients attending the hospital can also introduce a selection bias but it is important to use the hospital setting because majority of the people in the community prefer the hospital to the clinics and they also attend the hospital to renew their chronic medication form.

Considering the estimated sample size and the research objectives, it will be most appropriate to administer the questionnaire to all the patients with diabetes in the outpatient department, till the required number of questionnaires had been completed. Voluntary participation will be stressed.

ETHICAL CONSIDERATIONS

Confidentiality is very important, patients will be assured that whatever information they give, will be treated in confidence and will not be divulged to any third party except for the purpose of research. No form of identification will link any questionnaire to a particular patient. The researcher will obtain permission from the REPC of the University of Limpopo before the start of the research.

Written consent will be obtained both from the patients and from the hospital management, before the research is embarked on.

REFERENCES

- Bradshaw D, Norman R, Pieterse D, Levitt SN. and the South African Comparative Risk Assessment Collaboration Group. Estimating the burden of disease attributed to diabetes in South Africa in 2000, South Africa Medical Journal August 2007; 97: 700-706.
- Nthangeni G, Steyn PN, Alberts M. Dietary intake and barriers to dietary compliance in black type2 diabetic patients attending primary health-care services. *Public Health Nutrition* [accepted on 15 august 2001]; 5[2]: 329-338. PUBMED.
- 3. Grant RW, Devita NG, Meigs JB. Polypharmacy and Medication Adherence in Patients with Type2 Diabetes. *Diabetic care* 2003; 26: 1408-1412. PUBMED.
- 4. Lee R, Taira DA. Adherence to Oral Hypoglycemic Agent in Hawaii. Preventing chronic disease, Public Health Research, Practice and Policy 2005; 2[2]: A09. PUBMED. statistic South Africa.
- 5. Chatterjee JS. From compliance to concordance in diabetes. *Journal of Medical Ethics* 2006; 32:507-510. comp7
- 6. Ronquillo LH, Zenteno JFT, Espinosa JG, et al. Factors association with therapy noncompliance in type2 diabetes patients. *Salud publica Mex* 2003; 45:3.comp3
- 7. Jose VM, Bhalla A, Sharma N. et al. Study of association between use of complementary and alternative medicine and non compliance with modern medicine in patients presenting to the emergency department. *Journal of postgraduate medicine* 2007; 53: 96-101. comp6
- Mudly S, Rambiritch V, Mayet L. An identification of the risk factors implicated in diabetic ketoacidosis [DKA] in type1 and type2 diabetes mellitus. SA Fam Pract 2007; 49[10]: 15. comp1
- 9. Van Zyl DG. Optimal glucose control in type2 diabetes mellitus- a guide for the family practitioner. *SA Fam Pract* 2006;48[10]: 22-29.comp1.1
- 10. Botha KFH, du Plessis WF, Van Rooyen JM, et al. Bio-pschosocial determinants of self-management in culturally diverse South African patients with essential hypertension. *J Health Psychol* 2002; 7; 519.

- 11. Wild S, Gojka R, Green A, et al. Global prevalence of diabetes, estimate for the year 2000 and projections for 2030. *Diabetes care* 2004; 27; 5.
- 12. Sabate E. Adherence to long-term therapies [evidence for action]. Switzerland: World Health Organization; 2003
- 13. Ukpe I.S. Tuberculosis patients' reasons for defaulting on tuberculosis treatment: a need for a practical patient-centered approach to tuberculosis management in primary health care. *SA Fam Pract* 2007; 49[6]: 17.

APPENDIX A

ENGLISH VERSION

BIOGRAPHIC QUESTIONNAIRE

PERSONAL DATA

- 1. SEX
- a. Male b. Female
- 2. AGE
- a. 20 29 years b. 30 39 years c. 40 49 years d. 50 59 years. 60 and above.
- 3. MARITAL STATUS
- a. Single b. Married c. Divorced d. Separated e. Widowed
- 4. FAMILY SIZE
- a. 1-3 b. 4-6 c. 7-9 d. 10 and more.
- 5. LEVEL OF EDUCATION
- a. None b. Primary c. Secondary d. Post secondary
- 6. SOURCE OF INCOME
- a. Unemployed b. Employed in formal sector c. Employed in informal sector d. Self employed
- 7. IF UNEMPLOYED WHAT IS THE SOURCE OF INCOME
- a. Family support b. Grant c. Others
- 8. INCOME PER MONTH
- a. R0 999 b. R1000 1999 c. R2000 2999 d. R3000 3999 e. R4000 4999
- f. R5000 and more

- 9. HOW LONG HAS THE PATIENT BEEN DIABETIC
- a. Less than a month b. More than a month
- 10. DOES PATIENT KEEP ALL APPOINTMENT
- a. Always b. Most of the time c. sometimes d. Seldom
- 11. HOW FAR DO YOU LIVE FROM HEALTH FACILITY WHERE YOU TAKE TREATMENT
- a. 0 5KM b. 6 10KM c. 11 15KM d. 16 20KM e. 20KM and more
- 12. WHAT MEDICATION(S) DO YOU TAKE
- a. Metformin alone b. Glibenclimide/Gliclize alone c. Both
- 13. HAVE YOU BEEN COUNSELED ABOUT RECOMMENDED LIFESTYLE CHANGES
- a. Yes b. No
- 14. INFORMATION ABOUT ADHERENCE ON PATIENT FILE
- a. How many times has the patient been admitted since diagnosis b. Others
- 15. DO YOU TAKE YOUR MEDICATION AS PRESCRIBED REGULARLY?
- a. Always b. Frequently c. Only when I experience symptoms of diabetes d. Never
- 16. WHAT STRATEGIES DO YOU USE TO HELP YOU TO TAKE YOUR MEDICATION REGULARLY?
- a. Set reminder b. Take at meal time c. Assisted by treatment supporter d. Others

17. IF YOU DO NOT TAKE YOUR MEDICATION REGULARLY AS PRESCRIBED, WHY?

- a. I forgot
- b. I am not responsible for taking my medication
- c. I do not believe that it will help me
- d. I miss my clinic appointment because I must go to work
- e. I also use traditional medicine
- f. I need only spiritual or Godly power to get better
- g. when I drink alcohol, I forget to use my medication
- h. Treatment supporter was not available to give medications
- i. I am too old to go to the clinic by myself
- j. My diabetic pills got lost
- k. Do not have transport money to go to clinic
- I. I am taking care of a sick family member
- m. I do not have food to eat before I take my pills
- n. I do not have to drink my pills if I feel better
- o. There is no specific reason for me to stop drinking my pills
- p. The clinic did not have my pills
- q. The health worker at the clinic said I could stop my pills
- r. The medicine makes me feel worse
- s. I travelled to visit family/friends/job and did not have enough pills for my stay

- t. Did not take medication because I was not informed about how to take it
- u. Work did not allow time to go the clinic
- 18. DOES THE PATIENT BECOME ADHERENT TO MEDICATION AFTER A PERIOD OF ILLNESS DUE TO TEMPORARY PROBLEM WHICH CAUSE POOR ADHERENCE TO MEDICATION
- a. Yes b. No
- 19. DO YOU ADHERE TO THE RECOMMENDED LIFESTYLE CHANGES
- a. Always b. Frequently c. Only when I experience symptoms of diabetes d. Never
- 20. WHAT STRATEGIES DO YOU USE TO HELP YOU TO ADHERE TO THE LIFESTYLE CHANGES THAT ARE RECOMMENDED?
- a. Set a reminder b. Assisted by a family member c. Others
- 21. IF THE LIFESTYLE CHANGES WAS RECOMMENDED TO YOU BUT YOU DO NOT MANAGE TO KEEP TO IT, WHY?
- a. I forget
- b. I am not responsible for carrying out the changes
- c. I do not believe that it will help me
- d. I struggle to motivate myself
- e. I do not have enough time for that
- f. I need only spiritual or Godly power to get better
- g. when I drink alcohol, I forget
- h. I am too old
- i. I am taking care of a sick family member

- j. I do not have to adhere to lifestyle changes if I feel better
- k. there is no specific reason for me not to
- I. the health worker at the clinic ask me to stop
- m. the lifestyle changes makes me feel worse
- n. work did not allow me to carry out the changes
- 22. DOES THE PATIENT BECOME ADHERENT TO LIFESTYLE
 RECOMMENDATIONS AFTER A PERIOD OF ILLNESS DUE TO TEMPORARY
 PROBLEM WHICH CAUSES POOR ADHERENCE TO LIFESTYLE MODIFICATION?
- a. Yes b. No

APPENDIX B

SOTHO VERSION

BIOGRAPHIC QUESTIONNAIRE

DITABA TSA GAGO

- 1. BONG
- a. monna b. Mosadi
- 2. MENGWAGA
- a. 20 29 mengwaga b. 30 39 mengwaga c. 40 49 mengwaga d. 50 59 mengwaga e. 60 and above
- 3. LENYALO
- a. O nnosi b. O nnyetswe c. O hladile d. ahlologane e. O mohwana
- 4. BA LAPA
- a. 1-3 b. 4-6 c. 7-9 d. 10 and more
- 5. MAEMO A THUTO
- a. Aowa b. primary c. secondary d. post secondary
- 6. LETSENO LA CHELETE
- a. Ga o bereke b. O dipolaseng c. Dipolaseng d. O wa ibereka
- 7. GEOSA BEREKE O THUSWA KE
- a. Ba lapa b. Thuso ya mmuso c. Tse dingwe
- 8. LETSENO LA KGWEDI
- a. R0 999 b. R1000 1999 c. R2000 2999 d. R3000 3999 e. R4000 4999
- f. R5000 and more

- 9. ONA LE NAKO YE KAE O PHELA LE BOLWETSI BO
- a. ka fase ga kgwedi b. kgwedi lego feto
- 10. A MOLWETSI O LATELA MABAKA KAMOKA AO A FIWAGO
- a. ka mehla b. nako efe le efe c. na kong engwe d. gatee ka na ko
- 11. O DULA BOKGOLE BO BO KAE LE MOO O TSEAGO DIPIISI
- a. 0 5KM b. 6 10KM c. 11 15KM d. 16 20KM e. 20KM and more
- 12. O TSEA DIPILISI TSE DIFENG
- a. metformin alone b. glibenclimide/gliclizide c. ka moka
- 13. O BONWE KE MOLEKWA KA BOPHELO BJO BO KAONE
- a. eng b. aowa
- 14. TSEBO MABAPI LE FILE
- a. O robetse sepedlele ga kae b. Tse dingwe
- 15. O TSEA DIHLARE KA MOO O LAETSWEGO
- a. ka mehla b. gantshl c. feela ge ke bona dika tsa diabetesi d. aowa le ga tee
- 16. KE MOKGWA OFENG WO O SUMISAGO WA GO GO GOPOTSA GO TSEA DIHLARE
- a. sa go nkgopotja b. ka na ko ya dija c. mothusi waka d. tse dingwe
- 17. REBOTSE GORE KE KA BAKA LA ENG O SANWE DITLHARE?
- a. kea lebala
- b. ga se mohola wa ka go tsea dihlare

- c. ga ke kgolwe gore ditla mpholida
- d. gake bone carata-clinic kea mmerekong
- e. ke somisa hlare tsa Sesotho
- f. ke nyaka pnodiso ya bona pedi
- g. ge nwele jwala ke lebala dipilisi
- h. mothusi ga ago yo mpha dipilisi
- i. ke godile go ya cliniking ka bonna
- j. ke timeditse dipilisi
- k. ga ke nale chelete ya transport go ya cliniking
- I. go motho wa go iwala ka gae
- m. ga go dijo ka lapong gore ke new dipilisi
- n. ga kenwe dipilisi ge ke le kaone-ga go bohlokwa
- o. ga go lebaka la gore ke togele dipilisi go dinwa
- p. dipilisi ga di go cliniking
- q. nurse orile nka tlogela dipilisi
- r. dihlare di godisa bolwetsi
- s. ge ke etile/ kea merekong dipilisi ga di lekane leeto
- t. ga se ka botswa ka go tsea dihlare
- u. mmusomong ga badumele ge kea clinicking

- 18. A OILE WA THOMA GONWA DIHLARE KA TSHWANELO KA MORAGO GA BOLWETSI BJO BO KOPANA BJO BO THOMILENG KE GO SENWE DIHLARE KA TSHWANELO.
- a. eng b. aowa
- 19. O KGONTHISISA MEKGWA YA BOPHELO JO KAONE
- a. ka mehla b. kgafi tsa kgatisa c. feela ge ke ekwa dihlati tsa diabetes d. aowa le ga tse
- 20. O SHOMISHA MEKGWA EFE GO KGONTHISHISHA GORE O LATELA MEKGWA E MESWA YA BOPHELO YEO O E FILWEGO.
- a. seo se gopotsang-nakong b. ka thuso ya balapa c. tse dingwe
- 21. O BODITSWE KA GO FETOLA BOPHELO, FEELA GONO PALA, LEBAKA?
- a. kea lebala
- b. ga se mai karabelo aka
- c. ga ke kgolwe gore ditla mpholida
- d. I struggle to motivate myself
- e. I do not have enough time for that
- f. ke nyaka pnodiso ya bona pedi
- g. ge nwele jwala ke lebala
- h. ke godile go
- i. go motho wa go iwala ka gae
- j. ge bona gore ke kaone
- k. ga go lebaka bjale kea lesa

- I. mooki ore ke lese
- m. ke kwa bohloko kudu ge ketlogela
- n. mosomo o ampaledisa
- 22. NGWALA DITSHUPETSO GE EBA MOLWETSI O LATELA LE DIPHETOGO TSA BOPHELO TSEO DI NYAKEGAGO MORAGO GA LEBAKA LA BOLWETSI KA BOTHATA BJA LEBAKANYANA BJOO BOMO PALEDISAGO GO LATELA LEDIHLARE TSA GAGWE
- a. eng b. aowa

APPENDIX C

UNIVERSITY OF LIMPOPO (Medunsa Campus) CONSENT FORM

Statement concerning participation in a Research Project.

Name of Study

ASSESSMENT OF THE ADHERENCE TO TREATMENT AMONG TYPE 2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL, LIMPOPO PROVINCE.

I have heard the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Study has been approved by the Research, Ethics and Publications Committee of Faculty of Medicine, University of Limpopo (Medunsa Campus). I am fully aware that the results of this Study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent	to participate in this Stud	ly.
Name of patient		Signature of patient or guardian.
Place.	Date.	Witness

Statement by the Researcher

I provided verbal and/or w	ritten information rega	rding this Study		
I agree to answer any future questions concerning Study as best as I am able.				
I will adhere to the approv	ed protocol.			
Name of Researcher	Signature	Date	Place	

APPENDIX D

CONSENT FORM

Setatamente sa go tseya karolo tekong porojeke ya dinyakisiso

Leina la thuto;

ASSESSMENT OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL, LIMPOPO PROVINCE.

Ke nepo le morero wa thuto kakanyo ke filwe sebaka sa go botsisa dipotsiso le nako ya maleba ya go naganisisa ka se morero le nepo ya thuto ye di kwesisagala ga botse go nna. Ga se ka gapeletswa go tsea karolo.

Ke kwesisa gore go tsea karolo mo go thuto ke go ithaopa le gore nka tlogela nako ye nngwe le ye nngwe ntle le go fa mabaka. Seo se ka se be le amane le meriana ya tlwaelo go bolwetsi bjaka le go se amane le hlokomelo yeo ke e hwetsago go ngaka ya ka ya tlwaelo.

Ke tseba gore thuto e dumeletswe ke komiti ya di nyakisiso, Botho le phanlalatso lefapeng la Dihlare, Yunibesithing ya Limpopo [kampaseng Medunsa]. Ke kwesisa ka botlalo gore dipoelo tsa thuto ye di tla somiswa morerongwa tsa mahlale tsa phahlalatswa. Ke dumela go se ge fela tshireletso ya ka e kgonthisisitswe.

Ke fa tumelelo ya go ts	ea karolo mogo thuto		
Name of patient		Signature of patient	
Place	Date	Witness	

Setatamente ka monyakisisi
Ke file molaetsa wa polelo le/ goba wo o ngwetsego mabapile thuto.
Ke dumela go araba potsiso ye nngwe le ye nngwe ya lebaka le le tlago mabapi le thuto ka bo kgoni bjaka.
Ke tla ikgolaganya le porotokolo veo e dumeletswego.

Name of researcher Signature Date Place

APPENDIX E

REFERENCE: 001

ENQUIRIES: DR ADEGBOLA S.A.

MATLALA DISTRICT HOSPITAL, TSIMANYANE.

PRIVATE BAG X9624, MARBLE HALL, LIMPOPO. 0450.

TELEPHONE NO. 013 264 9602, FAX NO. 013 264 9616.

THE CHIEF EXECUTIVE OFFICER,

MATLALA DISTRICT HOSPITAL, TSIMANYANE. LIMPOPO.

THROUGH THE OFFICE OF THE

CLINICAL MANAGER,

MATLALA DISTRICT HOSPITAL, TSIMANYANE. LIMPOPO.

Dear Sir/Ma,

RE: REQUEST FOR AUTHORITY TO CONDUCT A STUDY ON ASSESSMENT OF ADHERENCE TO TREATMENT AMONG TYPE2 DIABETIC PATIENTS IN MATLALA DISTRICT HOSPITAL, LIMPOPO PROVINCE.

I am Dr ADEGBOLA S.A. I am one of the medical doctors presently working in Matlala district hospital. I enrolled for a Masters Degree program in the department of Family Medicine, University of Limpopo and as part of the institution's requirement towards the award of the degree; I am expected to carry out a research.

I am using this medium to request the permission of hospital to carry out the research. The study will not interfere with the hospital budget.

I hope my request will be favorably considered. Thank you for the anticipated cooperation.

Yours faithfully,

Dr ADEGBOLA S.A.

UNIVERSITY OF LIMPOPO

Medunsa Campus



MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

P O Medunsa Medunsa 0204 SOUTH AFRICA

MEETING:

06/2009

PROJECT NUMBER:

MREC/M/99/2009: PG

Tel: 012 - 521 4000

Fax: 012 - 560 0086

PROJECT:

Title:

Assessment of adherence to treatment among type 2 diabetic

patients in Matlala District Hospital, Limpopo Province

Researcher:

Supervisor:

Dr S Adegbola Dr GJO Marincowitz

Hospital Superintendent:

Dr RL Phasha (Matlala Hospital)

Department:

Family Medicine & PHC

School:

Medicine

Degree

MMED

DECISION OF THE COMMITTEE:

MREC approved the project.

DATE:

05 August 2009

PROF GA OGUNBANJO CHAIRPERSON MREC

Note: i)

Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.

The budget for the research will be considered separately from the protocol. ii)

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.