FACTORS ASSOCIATED WITH DRUG ADHERENCE AMONG SELF REPORTED DIABETIC PATIENTS IN RURAL THIRUVANANTHAPURAM

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH

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GLOSSARY OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CGHS</td>
<td>Central government health scheme</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>ESI</td>
<td>Employees state insurance</td>
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<tr>
<td>INR</td>
<td>Indian rupees</td>
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<tr>
<td>MPCE</td>
<td>Monthly Per Capita Expenditure</td>
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<tr>
<td>NCD</td>
<td>Non Communicable Disease</td>
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<td>OR</td>
<td>Odds Ratio</td>
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<tr>
<td>PCE</td>
<td>Per Capita Expenditure</td>
</tr>
<tr>
<td>SES</td>
<td>Socio Economic Status</td>
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<td>USD</td>
<td>United State Dollars</td>
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ABSTRACT

Background: In India 35 million people are suffering from diabetes. Poor adherence to treatment of diabetes is a worldwide problem of striking magnitude and leads to poor health outcomes and increased health care costs. Data on adherence to diabetic medication in India are extremely limited particularly in rural area. Therefore this study was conducted with an objective to find the extent of drug adherence and factors associated with drug adherence among the rural diabetics in Trivandrum.

Methods: A cross sectional survey was carried out among 348 self reported diabetic patients (mean age 54 years, 52% women) selected using multistage cluster sampling. Information on socio-demographic variables, treatment related factors and medication use related factors were collected using a pre-tested structured interview schedule. Morisky eight item adherence scale was used to collect information on drug adherence. Adherence was classified into good adherence and poor adherence using the score of six as the cut off value in the above scale. Stepwise multiple logistic regression analysis was done to find the predictors of poor adherence.

Results: Prevalence of poor adherence was 74 percent. Patients without family support were four times [Odds ratio (OR) 4.32;95% CI 2.20-8.43], those who did not monitor blood sugar regularly were four times (OR 4.10;CI 2.01-8.38), patients preferring symptomatic management for diabetes were three times (OR 3.01;CI 1.51-6.04), patients whose per capita expenditure was ≤ 1250 rupees were three times (OR 2.79;CI 1.40-5.57) and patients who received short/no instructions from their physicians were two times (OR 2.29;CI 1.16-4.50) more likely to have poor adherence compared to their counterparts.

Conclusion: Nearly three fourth of the diabetic patients were poorly adherent to drugs in this study. Efforts should be made to enhance drug adherence among the diabetic patients focusing on family support, regular monitoring of blood sugar, those who prefer symptomatic management of diabetes and the poor. Physicians should be encouraged to provide detailed instructions to their diabetic patients to enhance drug adherence.
1. INTRODUCTION

Diabetes is recognized as a group of heterogeneous disorders with the common elements of hyperglycemia and glucose intolerance, due to insulin deficiency, impaired effectiveness of insulin action or both. Diabetes is the leading cause of blindness, renal failure, stroke, diabetic neuropathy, lower limb amputation and cardiovascular diseases. The main impact of diabetic complication is the huge socio economic cost through morbidity and mortality. Occurrence of the diabetic complications is very high (11 percent) in the developing countries. Most of the complications can be avoided by glycaemic control achieved through good adherence to medication. The magnitude of adherence to diabetic medications in developing countries is not studied well.

Background

Prevalence of Diabetes and diabetic complications

Global scenario

The number of people with diabetes in the world is increasing due to population growth, ageing, urbanization and increasing prevalence of obesity and physical inactivity. World health organization in 2010 reported that global prevalence of diabetes was 6.6 percent (285 million), most of the patients are in the age group of 29 to 79 years and the numbers of people with diabetes will more than double over the next 25 years, to reach a total of 366 million by 2030. Almost 80 percent of diabetes deaths occur in low and middle income countries. Poor drug adherence to recognized standards of care is the principal cause of development of complications of diabetes and their associated individual, societal and economic costs and it results in avoidable
suffering for the patients, excess cost to health system and questioning the treatment effectiveness.\textsuperscript{2,3,5}

**Indian scenario**

In India, NCDs were responsible for 53 percent of deaths and 44 percent of disability adjusted life years lost.\textsuperscript{6} India had an estimated 35 million people with diabetes, amounting to eight percent of the adult population which is projected to reach 50 million in 2025. The anticipated increase in diabetic prevalence is 8.4 percent in 2030 which is very much a consequence of the increasing life expectancy and the increasing urbanization of the population in India.\textsuperscript{6,7} The proportion of the population over 50 years is expected to increase from 16 percent to 23 percent between 2010 and 2030 in India.\textsuperscript{9} So the diabetic population is also likely to be doubled. Almost 1.1 million adults are expected to die from diabetes related causes, accounting for 14.3 percent of all deaths in the 20-79 age group. India, with the second largest number of diabetic patients is expected to spend 2.8 billion USD, less than one percent of the global total and about 236.6 billion USD will be lost from the national income of India in the years between 2005 and 2015 for diabetes and related complications.\textsuperscript{4} Onset of diabetes occurs at a younger age in Indians, giving ample time for development of the chronic vascular complications. The prevalence of micro vascular complications of diabetes such as retinopathy, nephropathy and neuropathy are 16.3 percent, 20.5 percent and 8.4 percent respectively due to poor diabetic control.\textsuperscript{8,9} The prevalence of CAD was 21.4 percent among the diabetic patients in India. Prevalence of the complications is higher in low socio-economic groups due to lack of good control of glycemia followed by poor drug adherence. The highest rate of diabetes and diabetic complications are in India’s southern states.\textsuperscript{9,10}
Kerala scenario:-

In India, Kerala is the most advanced state in health transition, and a harbinger of what will happen to the rest of India in future. The prevalence of diabetes in Kerala was 16.2 percent. Higher prevalence of diabetes could be expected in Kerala since Kerala has the highest proportion of elderly and due to the drastic change in the living standards and lifestyle in the age group of 20-25 years. The prevalence was higher in rural area (20.6 percent) compared to the urban area (14.8 percent). There are very few studies on the prevalence of complications in Kerala. In Kerala, limited studies have focused on diabetes care. Most of the time patients are not aware of the treatment adherence and they do not know about the importance of adherence to prevent complications of diabetes.
2. LITERATURE REVIEW

This chapter describes the available published literature on diabetic drug adherence and factors associated with drug adherence. It lists the known factors of diabetic treatment adherence and identified barriers to undergo drug adherence, globally particularly in developing countries.

Diabetes is a major threat to global public health and that is rapidly getting worse, and the biggest impact is on adults of working age in developing countries. In developed countries, adherence among the patients suffering from chronic diseases averages only fifty percent. There are many terms used to describe medication-taking behavior including compliance, adherence, intelligent compliance, and drug forgiveness. The term compliance and adherence are often applied to long-term treatment of chronic disease. The difference between compliance and adherence is that compliance implies physician driven treatment while adherence implies more of a collaborative partnership between patient and doctors. More recently, clinicians have focused on the need for a collaborative partnership with patients to attain medication adherence. Problems identified include patient’s failing to initiate therapy, under using or overusing a drug, stopping a drug too soon and mistiming or skipping doses.

2.1 Impact of poor drug adherence:-

Medication non-adherence is a pervasive problem resulting in significant morbidity and mortality. The magnitude and impact of poor adherence in country like India developing is even higher because of the scarcity of health resources and inequities in health care access. Poor adherence makes the challenges of improving health in poor countries, resulting in
underutilization and wasting of limited resources and is the primary reason for suboptimal clinical benefit. These impair the ability of health care system around the world to achieve population health goals.\textsuperscript{14-16}

As per the CODE -2 (Cost of diabetes in European countries-type II diabetes) studies, poor adherence results in excess cost to the health system. Those patients who had a good adherence achieved good glycaemic control. The CODE 2 study was done in developed countries with full access to medicine, where the adherence among diabetic patients was only 50percent.\textsuperscript{16}

Patients with diabetes have co-morbidities like hypertension, obesity and depression that make their treatment regimen even more complex.\textsuperscript{16} Poor adherence resulting in micro and macro vascular complications of diabetes causes two to three fold increase in the total cost of diabetes.\textsuperscript{17} The indirect cost like premature death and poor quality of life make the condition more complex.\textsuperscript{18} Economic consequences of adherence were a decrease in health care costs, ranging from nine percent to 29percent, with an approximate 10percent increase in MPR (medication possession ratio), mostly in the form of a four percent to 31percent decrease in hospitalization.\textsuperscript{19}

\textbf{2.2 Prevalence of diabetic drug adherence:-}

Poor adherence to medications is a dangerous and costly outcome of diabetic treatment. In a recent study, medication adherence was associated with increased all-cause hospitalization by 58 percent and all-cause mortality increase by 81 percent in patients with diabetes.\textsuperscript{20}

Reviews of studies found that lack of adequate treatment adherence (36percent-87percent) among patients with diabetes were confirmed, primarily measured by medication possession ratio (MPR) and self report measures. Adherence varied among oral agent-only (36percent-
87 percent) versus concomitant or insulin-only (54 percent-81 percent) regimens.\textsuperscript{21,22} The prevalence of adherence to insulin administration varies widely. In a study conducted in Finland, 84 percent of respondents reported insulin administration adherence daily and 15 percent of them adhered ‘almost’ daily.\textsuperscript{23} Other studies have framed the question related to insulin adherence differently. In that rates for “never missing a shot” varied from 92 percent in a sample of young adults to 53 percent in a sample of children and in younger adolescents mismanagement if insulin injection doses were very common.\textsuperscript{24,25} Among the patients receiving their medication from the community pharmacies, adherence to oral hypoglycemic agents was 75 percent.\textsuperscript{26} Similar adherence rates of between 70 percent and 80 percent were reported from United states in a study of oral hypoglycemic agents in a sample patients whose health insurance paid for prescribed drugs.\textsuperscript{27} Pharmacological therapy for DM can facilitate excellent control, with the potential for normalization of hemoglobin A1-C by insulin and a reduction in hemoglobin A1-C of 0.5 percent to two percent for oral anti hypoglycemic agents therapy depending on the agent or agents used.\textsuperscript{28}

2.3 Different forms of non-adherence:

Dose omission represented the most prevalent form of non-adherence in OHA administration and insulin administration. More than one third of the patients in one study took more doses of OHA tablets than prescribed. This overmedication was observed more frequently in those patients prescribed once daily dose.\textsuperscript{26} A study conducted by Wing et al in United states assessed the quality of performance of insulin administration. In that 58 percent of the diabetic patients were administered incorrect dose of insulin.\textsuperscript{29} In studies assessing the intentional omission of insulin to control the weight, 31 percent of the study participants admitted to
intentional omission of insulin, but only nine percent reported frequent omission to control weight.\textsuperscript{30}

**Importance of self care management in drug adherence**

Self care implies patient actively monitors and responds to the changing biological conditions. Self care behaviors include the glucose monitoring, adjustment in food intake, administration of medication, regular physical activity, foot care and regular medical visit monitoring.\textsuperscript{25} In a study conducted in India, dietary prescriptions were followed regularly by only 37 percent of patients,\textsuperscript{31} while in a study in the United States about half of the patients (52 percent) followed a suggested meal plan.\textsuperscript{32} A study conducted in Cuba among Type 1 diabetes mellitus patients, 75 percent of the participants were not adhering to the dietary recommendations. Those who were following good dietary adherence had good adherence to medication also in type 2 diabetic patients.\textsuperscript{33} Literature about extent of adherence to prescribed physical activity in type 1 diabetes is very scarce. A study conducted in Finland indicated that 30 percent of the participants did regular exercise, while ten percent did not do the exercise at all. In the same study 20 percent of the study participants reported taking care of their feet daily.\textsuperscript{34} In a study conducted in Canada among the sample of patients with type 2 diabetes, 37 percent of the respondents participated in the informal physical activity programs, seven and a half percent of the respondents were attending the organized physical activity programs.\textsuperscript{35}

**2.4 Factors associated with drug adherence in diabetic patients:**

Adherence is a complex behavior. Number of variables that have been considered to influence adherence behaviors in diabetes can be grouped into four clusters.
2.4.1 Treatment & disease characteristics:

Complexity of the medication regimens and concern about the side effects of medication are the barriers to maintain good adherence. The use of multiple medications is often required and beneficial in helping patients with diabetes achieve optimal blood glucose, blood pressure, and lipid control and manage other diabetes related complications and co-morbidities. But this poly pharmacy makes complexity of regimen. A survey in the US of 2307 adults found that 45 percent of the respondents did not take medication because of concerns about side effect. However, the aggressive use of OHA combinations, particularly those containing long acting sulphonylureas, was fraught with increased risk of severe hypoglycemic side effects. Indicators of treatment complexity include frequency of self-care behavior such as medicine taking behavior performed by the patient. Higher adherence level is associated with less frequent doses compared to those prescribed more frequent doses.

Duration of diabetes appears to have a negative relationship with adherence: the longer a patient has diabetes, he/she is less likely to be adherent to the medication. In a study by Glasgow et al Type 1 diabetes patients, who had longer history of diabetes reported eating more inappropriate foods, greater proportion of saturated fats and subsequently had low medication adherence.
Out-of-pocket payment mandatory for the purchase of all medications may be compounding the financial difficulty being experienced by patients in purchasing their medicines. The average monthly cost of anti-diabetic medications to the patient in Nigeria was 30 dollars. One of the studies conducted in the United States, the most common medication adherence challenge was paying for medication.

2.4.2 Intrapersonal factors:

Age has been associated with adherence to insulin administration in a study of adolescents with type I diabetes. Older adolescents were more likely to mismanage insulin (missing injections) than their younger counterparts. But in self monitoring of blood glucose, younger adolescents reported more frequent monitoring of blood glucose than older adolescents. In case of oral hypoglycemic agents, older patients reported good adherence than younger ones because they were serious about the disease.

Many patients do not take their medications as directed simply because they forget or they do not understand the directions on the prescription labels. It is dependent on the health literacy level. ‘Health literacy’ is the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. It can be attained through diabetes patient education and can influence the medication adherence. In regard to schooling; more educated patients were more adherent to therapy. Patients are required to have more complex cognitive skills to be able to understand the prescribed drug therapy. Self esteem has been associated with adherence to medication in type 1 diabetes patients. High levels of self esteem were related to high levels of adherence to adjustment of insulin doses. Aljasem et al showed that self efficacy beliefs predicted adherence to prescribed regimen in 309 adults with
type2diabetes after controlling for health beliefs and perception barriers.\textsuperscript{44} Peyrot et al reported that psychosocial stress was associated with poor adherence to medication and poor metabolic control in a mixed group of patients with type 1 and 2 patients.\textsuperscript{45}

Johnson et al studied 392 type 2 diabetic patients from ethnic minority groups in Los Angeles and found that alcohol consumption within the last month was associated with poor adherence to oral medications and self monitoring of blood glucose.\textsuperscript{46} Cox et al examined alcohol use in 154 older men with diabetes and found that greater alcohol use was associated with poor adherence to insulin injections.\textsuperscript{47}

Drug adherence behavior of patients depends on experiences, perceptions about the nature and severity of the illness and understanding about the disease. Assumptions like diabetes needs symptomatic management make the patient discontinue the treatment when patient feels better or when symptoms improve. Beliefs about the effectiveness of treatment also help the patient to stick on the medications. Patient’s knowledge about the disease and disease management makes the patient take medications for preventive purpose and for symptomless conditions. Individual patient attitudes toward their disease play an important role in treatment adherence.\textsuperscript{48} Some patients may not adhere with their prescribed treatment regimen because of indifference. Although this attitude can result from a lack of awareness of the need to adhere to treatment to control the disease, even patients who are aware of the importance of treatment adherence may still remain indifferent. Perceptions of the clinician as well as personal and social circumstances within which the patient lives are also important. What might seem to be an irrational act of non-adherence from the physician’s point of view may be a very rational action when seen from the patient’s perspective.\textsuperscript{49} One study found that children with diabetes who made internal attributions for negative events—holding themselves responsible—had better glycaemic control,
even though this attributional style is typically associated with depression. Thus, it appears that a clearer understanding of both the long-term consequences and the cognitions related to “internalizing behavior problems” is necessary to achieve good adherence. Lifelong treatment makes depression in diabetic patients. Those depressed patients had more chance for showing poor drug adherence.

2.4.3 Interpersonal factors:

Quality of the relationship between patients and providers of care, and social support has been found to correlate with medication adherence. Good communication between patient and provider has been related to medication adherence. Among patients with type 2 diabetes, adherence to administration of oral hypoglycemic agents was significantly worse in patients who rated their communication with their care provider as poor. The dismissing/poor provider communication group had significantly worse adherence to glucose monitoring and had a significantly greater number of interruptions in treatment with oral hypoglycemic drugs. Kazeeb M et al identified factors for poor communication between the patient and provider such as lack of privacy due to patient overcrowding/sharing of the consulting rooms by physicians and short consultation time leading to short physician-patient contact in 200 type 2 diabetic patients in Nigeria. Limited time to provide information at physician visit, failure to provide the information in the way the patient can understand and authoritarian approach instead of patient empowerment approach are the prescriber related issues making poor medication adherence. Yawn et al observed interactions between patients and providers in a family practice setting and they received counseling for diabetes showing good adherence to medication because they seen diabetes as chronic disease. Kern & Mainous found that although physicians preferred to follow planned, systematic strategy for treating diabetes, acute illness and failure of patients to
adhere forced them to spend less time on diabetes care. Yusuf et al also found that awareness and practice of diabetes self management may be critical to improving adherence to drug therapy, ensuring achievement of adequate glycaemic control and minimizing likelihood of diabetic complications.

Social support has been associated with adherence. Greater social support was found to be associated with better level of adherence to insulin administration in women with gestational diabetes. Family support was associated with insulin administration and glucose testing in one of the studies conducted in Type 1 diabetic adolescents. The presence of a chronic disease is a source of stress for the family, especially if the stress requires changes that interfere with the family’s roles and tasks. When the family is dealing with an acute disease, the changes are usually brief and transitory. In the case of diabetes, a chronic disease, changes are long term and may create tension and conflicts in the family. Family support increases the self efficacy level and decreases the depressive symptoms and increases the medication adherence. Parents become the most important social support providers for adolescents, directly monitoring meal planning, insulin administration, and glucose monitoring, and indirectly, through modeling and encouraging a healthy lifestyle.

2.4.4 Environmental factors:

High risk situations and environmental systems have been linked to poor adherence in patients with diabetes. Self care behaviors occur in the context of a continually changing series of environmental situations at home, at work, in public etc which are associated with different demands and priorities. Patients are frequently called upon to choose between giving attention to diabetes self management or to some other life priority. Situations associated with poor
adherence have been called ‘high risk’ situations. Schlundt et al observed taxonomy of high risk situations that posed difficulties for patients to follow medications. The changes in the food pattern, easy availability of inexpensive food, rich with fat, salt and calories make them difficult to maintain the glycaemic control. It is evident that dosage of medications influences the glycaemic level in the blood and subsequently patient follows overmedication to maintain the normal level.

2.5 Measures of adherence:-

Two basic methods have been employed to assess adherence: Direct method and indirect method. Direct method of measuring adherence involves clinical observations, including serum or urine drug level assays. Drug levels in the blood are good measures of adherence to medication. However diet and physical activity alter this drug levels. It depends on patient’s specific kinetic variations in the body. Finally, clinical measures such as blood pressure or glucose levels, may reflect adherence but may also be influenced by other factors, such as intrinsic severity of disease, efficacy of treatment, and quality of care. Electronic monitoring is the modifiable form of pill count method.

Indirect method includes prescription refill, pill counts, patient self reports, “Collateral" reports by family members, friends, or health care providers. Pill count provides no data on regimen adherence; patient can forget or alter unused portions. Patient self-reports may be prone to error, but they are simple and convenient. It is easy to administer and validate and may provide insight for patient’s behavior. Collateral reports are limited by the extent to which the family member, friend, or health care provider knows the patients. Adherence is a complex behavior, can only be assessed by asking the patients in their natural setting. The Morisky adherence scale is a reliable tool with good predictive and concurrent validity in low income
hypertension patients and might function as a screening tool for other chronic disease patients. It measures the specific medication behavior in chronic disease.58

2.6 Consequences of Non-adherence:-

Non-adherence also incurred more costs for outpatient services and physician office visits. In multivariate analysis, patients who were persistent with their medications incurred 12.5 percent lower medical costs. On average, non-adherence was associated with higher costs across all types of health care services.17 Adherence was associated with 62 percent lower costs for hospital admissions, 13 percent lower for outpatient visits, 45 percent lower for visits to the Emergency Department, and 49.8 percent lower overall total health care cost.59 Low medication possession ratios (MPRs) were generally associated with higher costs. Bal Krishnan et al. found that a 10 percent increase in MPR for an anti-diabetic medication was associated with an 8.6 percent reduction in total annual health care costs.19

2.7 Theoretical models explain medication adherence:-

Several theoretical models have shown some usefulness as a basis for developing adherence-promotion interventions. The health belief model (HBM) has four core beliefs: perceived susceptibility to illness, perceived potential severity of illness, perceived benefits of treatment, and perceived barriers to treatment. The specific components of the HBM have been analyzed in several studies to predict medication adherence.60 The factors that positively or negatively affect adherence include costs, risks, benefits, barriers, and cues to act. The locus of control model demonstrates that people differ in how much perceived control they have over actions in their lives. Those with an internal locus of control are more likely to take steps to stay well or to conquer health problems when they develop, compared to patients with an external locus of control who believes that what happens to them is independent of what actions they
take. The stages of change model in adherence include the following five phases of change: (1) pre contemplation, (2) contemplation, (3) preparation, (4) action, and (5) maintenance. This model suggests that there are different approaches to improve adherence based on the particular stages the patient is in.61

2.8 Rationale for the study

Although several studies on prevalence of diabetes and diabetic complications are available in various parts of India, studies on prevalence of drug adherence and factors associated with the drug adherence are limited. Diabetes is a chronic condition requiring a lifelong process of adherence to health regimens. Co-morbidity, multiplicity, complexity and long-term therapy of treatment make the treatment a hard task for the patient. Early age onset of disease and late diagnosis make diabetes treatment in Kerala complex. Many villages in Kerala have undergone a drastic change in living standards and lifestyles in the age group of 20-25 years, on account of the influx of money in recent years from people working abroad in the Gulf States and other affluent countries. The change in disease profiles to lifelong disease brought about by this sudden affluence, and its differential impact on different social classes, largely remain unstudied. This was one of the reasons for undertaking this study.62-64

Most of the studies in diabetic patients have reported that good adherence to the treatment results in reducing vascular complications of diabetes. Prevalence of co-morbid conditions like hypertension and obesity are also high in Kerala.11 Most of the time, they are not aware of the importance to stick to the treatment plan and glycaemic control. Unexplained treatment failure and increased use of the expensive, specialized medical resources are the major impacts of non adherence in diabetic patients. Costs of diabetes are manifested in both direct and indirect costs that put pressure on individuals, families, societies and governments. Direct costs include
medical costs for long-term care and cost of treatment. The health seeking behavior and direct expenditure to chronic disease are very high in Kerala.

It is evident that even today drugs are the main stay of treatment and control of high blood sugar while low adherence to pharmacotherapy is the most important cause of treatment failure. Poor drug adherence in diabetes severely compromises the effectiveness of the treatment and it is a critical issue in population health both from the perspective of the quality of life and of health economics. It can be assumed that like other countries in the world with low Human Development Index and cost of drugs could be the most important determinant of non-adherence to anti-diabetic medication in India. Still there is a need to explore and analyze quantitatively the pattern as well as the factors associating adherence to anti-diabetic medication in India. It is also evident that the prevalence of diabetes in rural Kerala is high. More over the rural poor, due to economic constraints, generally have lower access to all the health facilities and the drugs compared to the urban patients. So they are the vulnerable group in the total population. Non-adherence to anti-diabetic medication leads to increased risk of complications leading to increased costs of care in future which these rural people might not be able to bear and thus enter into the vicious cycle of poverty. Identifying the factors associated with that behavior is very important for planning the interventions for improving the adherence behavior. Thus, their adherence to anti-diabetic treatment is of paramount importance and need to be explored in order to address their public health needs. This is why I have taken up this topic to study the extent of adherence to anti-diabetic medications and the factors associated with drug adherence among rural diabetics. The following questions were addressed in this study

1. What is the prevalence of drug adherence among the diabetic patients?

2. What are the factors associated with drug adherence?
3. What is the average drug expenditure of a diabetic patient per month?

4. What are the various options by the individual patients to meet the drug expenditure?

2.9 Study Objectives

1. To find the extent of drug adherence among self reported rural adult diabetic population

2. To find the factors associated with the drug adherence among them.

3. To estimate the expenditure for diabetic medication among them

4. To study the various options exercised by the diabetic patients to meet the expenditure of medication
Fig 2.1 Conceptual Framework

Self readiness
To undertake health behavior

Value of illness
(awareness about the complication)
- Awareness about the disease management
- Subjective estimate of susceptibility

Environment

- Health care system
- Income status of the patient
- Per capita income
- Accessibility of healthcare services

Modifying and enabling Factors

Demographic
Age, sex, occupation, education

Co-morbidity

Clinical variables
Diagnosis of disease

Structural
Form and expenditure of drug, duration of illness, frequency, side effects

Supportive measures
Family support and social support

Cues to action
Instructions from the provider (physician)

Attitudes
Satisfaction with the regimen, benefits from the regimen

Previous experience
Previous h/o hospitalization

Adherence behavior

Likelihood of adherence with health recommendations and prescribed behavior
3. METHODOLOGY

This chapter details the methodology used to undertake the survey and the analysis.

3.1 Study design:

This was a cross sectional survey.

3.2 Study setting:

This survey was conducted in eight randomly selected Panchayaths of the Thiruvananthapuram district of Kerala. Two Panchayaths were randomly selected from each of the four taluks. From these four selected Panchayaths three wards were selected from each of the eight Panchayaths making a total of 24 wards. From each of these 24 wards a cluster of 15 diabetic patients was selected.

3.3 Study population: -

The study population consisted of self-reported diabetic patients of 18 years and older. Effort was made to identify equal number of male and female patients in each cluster.

3.4 Inclusion criteria:

Self reported diabetic patients aged 18 years and above, who were permanent residents in the Panchayaths, those who had a written prescription of diabetic medication and those who were willing to give consent for the study were included in the study.
3.5 Exclusion criteria:

Those who were unable to respond to the interview for various reasons including debilitating illness that made it difficult for them to respond, those were below the age of 18 years and those who were not willing to give a consent for the study were excluded.

3.6 Sample size:

Sample size was estimated by Epi info version 3.3.2. According to the study done in Tamilnadu, 30 percent of the interviewed diabetic patients were adhering to the diabetic medications. Taking 30 percent as the anticipated prevalence of adherence to medication among the diabetic patients with a 95 percent confidence interval between 24 percent and 36 percent the sample size was estimated to be 233. Since the sample selection procedure was cluster sampling a design effect of 1.5 was used to estimate the final sample size using the following formula.

\[ N = \frac{(1.96)^2 \times P \times Q}{D^2} \]

\[ P = .30, \; Q = .70 \]

Anticipated proportion of adherence was assumed to be between 24 percent and 36 percent.

I took \( D = 6\% \)

\[ = .06 \]

\[ N \text{ (adults)} = 1.96^2 \times .30 \times .70 / .06^2 \]
233.33 rounded to 233

As it was cluster-sampling ‘design effect’ of 1.5 was used to calculate the final sample size

\[ 233 \times 1.5 = 349.49 \text{ rounded off to 360.} \]

Estimated sample size was 360 diabetic patients in 24 selected clusters across Thiruvananthapuram rural area. In each cluster 15 adult diabetic patients were interviewed. \( 360/24 = 15 \). Thus, fifteen diabetic patients in one ward of a panchayath formed a cluster.

### 3.7 Sample selection procedure:

The first stage of sampling was selection of two Panchayaths from each of the four Taluks of Thiruvananthapuram district. This was done by lottery method. The second stage of sampling was the selection of three wards each from the eight selected Panchayaths. This was also done by lottery method. From each of the selected 24 wards, 15 self reported diabetic patients were identified using cluster sampling technique as suggested by the WHO. A central location of the selected ward was identified with the help of a local person and then the first house was identified as suggested from earlier studies. Starting from the first house all houses were visited till 15 self reported diabetic patients were identified.
Fig 3.1 Sample selection procedure:

District: Thiruvananthapuram

4 Taluks
- Chirayinkeezhu
- Thiruvananthapuram
- Nedumangad
- Neyyatinkara

8 Panchayaths
- sreekaryam
- Kudappankunnu
- Balaramapuram
- Vizinjam

24 Clusters
- Kadakkavor
- Chirayinkeezhu
- Ward 1
- Ward 3
- Ward 4
- Ward 6
- Ward 7
- Ward 10
- Ward 7
- Ward 3
- Ward 9
- Ward 14
- Ward 13
- Ward 1
- Ward 2
- Ward 5
- Ward 6
- Ward 14
- Ward 15
- Ward 17
- Ward 15
- Ward 14
3.8 Data collection procedure:

The tools used for data collection was a structured interview schedule for identifying the factors associated with drug adherence and Morisky adherence scale to know the extent of adherence among the diabetic patients. Four experts in diabetic management and a psychologist validated translated Morisky adherence scale. Copyright permission was obtained from Donald E. Morisky prior to the study. Morisky adherence scale was translated into the local language (Malayalam) and back translated into English. The back translation process was continued till the back translated version matched with the original English version of the scale. A final correction to the scale was made after pilot testing.

The pretesting of the interview schedule was done from 14th May 2010 till 18th may 2010. The data were collected from 25th June 2010 till 7th August 2010 without interruption. Informed consent from each participant was obtained before collecting the data; all interviews were conducted by the principal investigator.

3.9 Data collection process:

Table 3.1. Summary of sample recruitment process

<table>
<thead>
<tr>
<th>Number of taluks</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of panchayths</td>
<td>8</td>
</tr>
<tr>
<td>Number of clusters/wards</td>
<td>24</td>
</tr>
<tr>
<td>Number of houses visited</td>
<td>638</td>
</tr>
<tr>
<td>Patients eligible to participate</td>
<td>362</td>
</tr>
<tr>
<td>Patients willing to participate</td>
<td>346</td>
</tr>
<tr>
<td>Patients interviewed</td>
<td>346</td>
</tr>
</tbody>
</table>
Accredited Social Health Activists (ASHA) workers in that particular ward provided help to identify the location of the ward.

Using the center of the ward as a starting point; a spin bottle method was used to identify the direction of proceeding for the survey. All consecutive houses on the right side of the road were visited until the required number of 15 diabetic patients was reached.

On reaching the house, the nature and purpose of the study were explained to the head or senior member of the household and the consent (annexure 4) was obtained. Information on the demographic profile and socioeconomic status was also assessed. The drug price was cross checked with available drugs prices list published by government of Kerala.

3.10 Variables under the study: -

3.10.1 Definition of variable: -

Diabetes: was defined as self reported with a prescription for diabetes treatment from a modern medical practitioner.

A Household was defined as those were sharing the same kitchen

3.10.2 Operational definitions: -

Good Adherence to the medications: Patients who had a score more than six in Morisky adherence scale were classified as having good adherence.

Poor Adherence to medications: Patients who had a score of 6 or below in the Morisky adherence scale.
3.10.3 Outcome variable definitions: -

*Poor adherence was defined as an outcome variable.* A diabetic patient who had poor adherence to medications means he/she had score of 6 or below 6 in Morisky adherence scale.

### 3.11 Measurement of adherence:

For measuring the drug adherence among the diabetic patients, we used the Morisky adherence scale. It consisted of seven binary version questions and one likert type question (response question). Morisky adherence Scale has an alpha reliability of .83 for hypertensive patients. Seventy five percent completions in the response to the scale are required for eligibility to be included in the sample. This scale can be applied for all type of chronic diseases. It measures the persistence and compliance of medication. As adherence is a behavior, knowledge and motivation are the main components. Questions in this scale are divided into assessing the knowledge and motivation of the patient. Through this way, it measures both intentional and unintentional adherence behavior. Lack of motivation is the measure of unintentional and lack of knowledge comprises the intentional adherence. Total score of the scale is 8. Value ranges from 0 to 8. Scoring below 6, 6.25 to less than 8 and equal to 8 are categorized as low adherence, average adherence and good adherence respectively.

### 3.12 Predictor variable definitions: -

#### 1. Individual characteristics: -

Age, sex, marital status, education, occupation and personal habits were the six variables under the individual characteristics.

**Age:** Age was recorded as reported by the patient.
**Sex:** Females are more neglected in families with low socio economic status in rural areas, which could affect their adherence depending upon the power relationships.

**Marital status:** Presence of spouse can affect adherence as the help and support obtained from spouse could increase the adherence compared to a single person.

**Education:** Poor educational status would lead to a poor understanding of the disease status and leading to lower adherence in diabetic patients.

**Occupation:** Unemployed individuals and homemakers may show lower adherence to their prescribed drugs unless financially supported by the family. Professionals and skilled workers have occupational health centers and health insurance for giving support for their diabetic treatment. Manual laborers and self-employed workers need to support their family with their low income and they may not be able to focus on their health care.

**Personal habits:** Personal habits like using tobacco and alcohol consumption increase the incidence of complication in diabetes.

2. **Socio economic Characteristics:-**

Total household expenditure in the last month and per capita health expenditure were the two variables under the socio economic characteristics.

**Total Household expenditure in last month**-It was one of the proxy indicators of the total monthly income.

\[
\text{Per capita expenditure in last month} : \quad \frac{\text{Total household expenditure in last month}}{\text{Total number of family members}}
\]
3. **Diabetes related factors:** - Initial detection of diabetes, duration of diabetes, knowledge about the complications and disease management were the variables considered under this category

**Initial detection of diabetes:** Those who were diagnosed during check up for conditions like heart disease or stroke or other diseases related to diabetes were generally found to be serious and concerned about their glycaemic level that increase their adherence to medications. On the other hand those who are detected of having high glycaemic level during regular checkups or screening do not perceive the seriousness of disease condition and are less likely to adhere to their prescribed regimen.

**Knowledge about the complication and disease management:** Those who are aware about the complication of diabetes are likely to be more adherent compare to their counterparts.

4. **Treatment related characteristics:** Type of health facility used for treatment, regular treatment follow up, self-perception about current treatment regimen, patient provider relation were included under these characteristics.

**Type of health facility:** Public sector in Kerala suppose to provide drugs free of cost and patients accessing public sector are likely to more adherent compared to those accessing private sector.

**Regular treatment follow up:** Follow up visit to physician and blood glucose monitoring are the components of the variables.

**Self-perception about the treatment:** It includes the perception related to the satisfaction and benefit from the treatment.
**Patient provider relationship**: - It includes the relationship between the patient and physician. Those who have good relationship with the physician are likely to get instructions about lifestyle modifications and importance of the drug adherence.

**5. Co morbidity**: - Presence of chronic illness like hypertension, heart disease and kidney disease can affect the adherence. Severity of these associated illnesses can either increase their adherence behavior or decrease it when the cost of treatment becomes high for the rural patients.

**6. Medication use related characteristics**: - It includes the form of medicine used for the treatment of diabetes, dose and frequency of medicine, direct expenditure for buying medication, family support for remembering the medication management, insurance and other health allowances.

**Form of medicine**: - Those who are receiving insulin (injection) are more likely to adhere compared to the oral hypoglycemic agents. Drugs are divided into generic drugs and combination drugs.

**Direct expenditure of medications**: - Those who needs more traveling and spend more money for buying medicines for diabetes will have low adherence to the medications.

**Family support for medication management**: - Those who have at least one family member to remember the dosages of medicines or taking insulin injections are likely to be more adhering to medication.

**Insurance and other health allowances**: - Those who have health insurance like ESI, CGHS are likely to be more adhere to medication.
3.13 Data storage and data cleaning

Along with data collection the data were entered in Epidata version 3.1 and then imported to SPSS for windows version 17.0 for analysis purpose. The hard copies of interview schedule are stored in a locked chamber under my vigilance. The privacy and confidentiality of the participants is being strictly maintained.

Manually all the data sheets were checked before data entry. If there was any mistake it was corrected, for example Sex was coded as, “male=1 and female =2” but in some survey forms it was coded as 3 which was a wrong entry, so it was checked thoroughly and corrected before proceeding further. Computerized data cleaning was again done after data entry and before proceeding to data analysis.

3.14 Data analysis and statistical methods: -

The data analysis for the quantitative process included sample characteristics, bivariate and multivariate analysis. Mean were computed for all continuous data. Frequencies (with percentages) were calculated for categorical and binary variables. Morisky score was classified into two groups. Good adherence and poor adherence. Chi square test was used to find out statistically significant associations. Odds ratios with 95percnt confidence intervals were calculated. Bivariate and binary logistic regressions were done using poor adherence status as the outcome variable; while various study variables were used as independent variables. A p-value of less than .05 was considered to be statistically significant for all analysis. Variables that were significantly associated with the outcome variables in the bivariate analysis were used for regression analysis.
Fig 3.2 Framework for analysis

<table>
<thead>
<tr>
<th>Univariate analysis</th>
<th>Multivariate analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>. To identify the prevalence of drug adherence</td>
<td>Step wise logistic regression: To identify the factors significantly associated with poor drug adherence adjusted to other factors</td>
</tr>
<tr>
<td>. Estimate the drug expenditure among the diabetic patients</td>
<td></td>
</tr>
<tr>
<td>. Identify the various options by the individual to meet the expenditure of medication</td>
<td></td>
</tr>
</tbody>
</table>

3.15 Expected outcomes: -

Extent of adherence among the self reported diabetic patients and factors associated with poor adherence can identified at the end of study.

3.16 Ethical considerations: -

Ethical clearance was obtained from the Technical Advisory committee (TAC) and Institutional Ethics committee (IEC) of Sree Chitra Tirunal Institute for Medical sciences and Technology. Written informed consent was obtained from all the participants in the study. The information about the patient’s identity was not included with the main data. All materials, which identify the respondent, were kept strictly confidential and will never be made public or will be brought to the public domain. The database being used for analysis do not contain any identifiers but only codes and will be destroyed after the completion of the thesis so that there is no possibility of these documents ever to be used as any legal evidence.
4. RESULTS

The survey was completed for 346 respondents (response rate: 96.4 percent). The mean age of the study population was 54.26±11.54 years (range: 30-80 years). The median reported total expenditure for last month was INR 6000 (range: 1000-25000) and the median per capita monthly expenditure was INR 1250 (range: 222-8333). All expenditure values described in the study are in Indian Rupees (INR) and relate to 2009-10.

4.1 Socio demographic and co-morbidity profile

Table 4.1 gives sociodemographic and co morbidity profile of the study participants and total respondents which was categorized based on sex. Fifty eight percent of the study participants were women. The proportion of men and women were high in the age group between 50-60 years. Twenty one percent of women were widowed as compared to 14 percent of men. Secondary education was the median category of education and based on that, education was grouped into two categories for analysis purpose. Seventy percent of the males were above secondary education compared to women. Clerical, professional, and self employed population were kept under the employed group and manual laborers, homemakers, unemployed, and retired population were under the heading of unemployed group. Seventy eight percent of the women were unemployed compared to 68 percent men. Four percent of the females were using alcohol compared to 63 percent of men. The prevalence of alcohol use was high in males. Seventy eight percent of the total respondents were having hypertension and 65 percent were having cholesterol disorders. Twenty eight percent had heart problems. The co morbidity profile was almost similar in both men and women. All co morbidities of the respondents were self reported.
Table: 4.1 characteristics of the study sample

<table>
<thead>
<tr>
<th>Variable</th>
<th>Female N (%)</th>
<th>Male N (%)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-40</td>
<td>28(14)</td>
<td>15(10.3)</td>
<td>43(12.4)</td>
</tr>
<tr>
<td>40-50</td>
<td>51(25.5)</td>
<td>31(21.2)</td>
<td>82(23.7)</td>
</tr>
<tr>
<td>50-60</td>
<td>54(27)</td>
<td>50(34.2)</td>
<td>104(30.1)</td>
</tr>
<tr>
<td>60-70</td>
<td>37(18.5)</td>
<td>35(24.0)</td>
<td>72(20.8)</td>
</tr>
<tr>
<td>70-80</td>
<td>30(15)</td>
<td>15(10.3)</td>
<td>45(13.0)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>146(73)</td>
<td>116(79.5)</td>
<td>262(75.7)</td>
</tr>
<tr>
<td>Single</td>
<td>13(6.5)</td>
<td>10(6.8)</td>
<td>23(6.6)</td>
</tr>
<tr>
<td>Widow</td>
<td>41(20.5)</td>
<td>20(13.7)</td>
<td>61(17.6)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2° education</td>
<td>136(68)</td>
<td>76(52.1)</td>
<td>212(61.3)</td>
</tr>
<tr>
<td>&gt;2° education</td>
<td>64(32)</td>
<td>70(47.9)</td>
<td>134(38.7)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>44(22)</td>
<td>57(39)</td>
<td>101(29.2)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>156(78)</td>
<td>89(61)</td>
<td>245(70.8)</td>
</tr>
<tr>
<td><strong>Tobacco consumption</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17(8.5)</td>
<td>91(62.3)</td>
<td>103(29.8)</td>
</tr>
<tr>
<td>No</td>
<td>183(91.5)</td>
<td>55(37.7)</td>
<td>243(70.2)</td>
</tr>
<tr>
<td><strong>Alcohol consumption</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8(4)</td>
<td>92(63)</td>
<td>94(27.2)</td>
</tr>
<tr>
<td>No</td>
<td>192(96)</td>
<td>54(37)</td>
<td>252(72.8)</td>
</tr>
<tr>
<td><strong>Co morbidity</strong>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>157(78.5)</td>
<td>111(76)</td>
<td>268(77.5)</td>
</tr>
<tr>
<td>Heart disease</td>
<td>59(29.5)</td>
<td>39(26.7)</td>
<td>98(28.3)</td>
</tr>
<tr>
<td>Cholesterol disorders</td>
<td>131(65.5)</td>
<td>92(63)</td>
<td>223(64.5)</td>
</tr>
<tr>
<td><strong>Per capita expenditure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 1000</td>
<td>52(26)</td>
<td>35(24)</td>
<td>87(25.1)</td>
</tr>
<tr>
<td>1000-2000</td>
<td>86(43)</td>
<td>56(38.4)</td>
<td>142(41)</td>
</tr>
<tr>
<td>Above 2000</td>
<td>62(31)</td>
<td>55(37.7)</td>
<td>117(33.8)</td>
</tr>
<tr>
<td><strong>Insurance &amp; other health</strong> allowances</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>46(23)</td>
<td>54(37)</td>
<td>100(43.4)</td>
</tr>
<tr>
<td>No</td>
<td>154(77)</td>
<td>92(63)</td>
<td>246(36.6)</td>
</tr>
</tbody>
</table>

Source: primary survey 2010 Thiruvananthapuram. * percentage does not add to 100 because of multiple responses.

The socio economic status was categorized into low, middle and upper socio economic strata based on tertiles of monthly expenditure. The distribution of men and women respondents
belonging to three groups was almost equal. In men, the proportion of high socio economic status was 40 percent. In the women population, the proportion of low and middle were same. The per capita expenditure was calculated by dividing total monthly expenditure and total family members. The middle SES strata of the women population were comparatively higher than men. Mean per capita expenditure was INR1730.14

4.2 Pattern of drug expenditure among the diabetic population:-

One of the objectives of this study was to estimate the expenditure for the medication and various options by the individual to meet the expenditure for the medication. Even though health seeking behavior and prescription pattern was not an objective, this section had some important findings which cannot be overlooked and hence has been considered separately.

4.2.1 Health seeking behavior:-

The poor people were approaching the public health sector more often compared to the high SES group.

Table 4.2. Health seeking behavior across the socio economic status

<table>
<thead>
<tr>
<th>Socio economic status</th>
<th>Public sector</th>
<th>Private sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (n=110)</td>
<td>85(77.3)</td>
<td>25(22.7)</td>
</tr>
<tr>
<td>Middle(n=117)</td>
<td>60(51.3)</td>
<td>57(48.7)</td>
</tr>
<tr>
<td>High (n=119)</td>
<td>21(17.6)</td>
<td><strong>98(82.4)</strong></td>
</tr>
</tbody>
</table>


4.2.2 Prescription pattern across the type of providers:-

The mean value of drug expenditure for those who went to the private sector (239.22) was comparatively higher than public sector (185.03). Most of the public sector practitioners were prescribing the generic drugs than the combination drugs. The Generic drugs were less
costly and available in the public health centre itself. If generic drugs were not available in the public sector, physicians were forced to prescribe the combination drugs.

Table 4.3 Prescription pattern across type of providers:

<table>
<thead>
<tr>
<th>Types of drugs</th>
<th>Public sector</th>
<th>Private sector</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Generic drugs</td>
<td>86(52%)</td>
<td>46(25%)</td>
</tr>
<tr>
<td>Combination drugs</td>
<td>80(48%)</td>
<td>134(75%)</td>
</tr>
</tbody>
</table>

Source: primary survey 2010.

4.2.3 Drug expenditure pattern by the type of provider:

The mean additional expenditure (Travelling expenditure) was not much different for patients who went to public sector (mean expenditure: INR89) in comparison with private sector (mean expenditure: INR98). Only nineteen percent of the diabetic patients were getting the medicines free of cost from the government sector.

Table 4.4 Drug expenditure pattern by the type of providers:

<table>
<thead>
<tr>
<th>Drug expenditure(monthly)</th>
<th>Public N (%)</th>
<th>Private N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication expenditure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 120</td>
<td>67(40.4)</td>
<td>46(25.6)</td>
</tr>
<tr>
<td>120-250</td>
<td>53(31.9)</td>
<td>61(33.9)</td>
</tr>
<tr>
<td>Above 250</td>
<td>46(27.7)</td>
<td>73(40.6)</td>
</tr>
</tbody>
</table>

Additional expenditure(travelling expenditure)

<table>
<thead>
<tr>
<th></th>
<th>Public N (%)</th>
<th>Private N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 60</td>
<td>63(38)</td>
<td>52(28.9)</td>
</tr>
<tr>
<td>60-100</td>
<td>12(7.2)</td>
<td>8(4.4)</td>
</tr>
<tr>
<td>Above 100</td>
<td>91(54.8)</td>
<td>120(66.7)</td>
</tr>
</tbody>
</table>

Source: primary survey 2010 Thiruvananthapuram.
4.2.4 Supportive measures for the individual medication management:

Majority of the women were dependent on their family members for meeting the expenditure for the medication than men. Seventy seven percent of the women did not have insurance coverage compared to men. Family support for remembering the dose was higher in men than women. Women was privileged by family support shows good adherence to medication than those who don’t.

Table 4.5 .supportive measures for the individual medication management (N=346)

<table>
<thead>
<tr>
<th>variables</th>
<th>Female N (%)</th>
<th>Male N (%)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paying options</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self</td>
<td>49(24.5)</td>
<td>77(52.7)</td>
<td>126(36.4)</td>
</tr>
<tr>
<td>Family member</td>
<td>121(60.5)</td>
<td>48(32.9)</td>
<td>171(49.4)</td>
</tr>
<tr>
<td>Free of cost</td>
<td>30(15)</td>
<td>21(14.4)</td>
<td>49(14.2)</td>
</tr>
<tr>
<td><strong>Insurance &amp;Health allowance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>46(23)</td>
<td>54(37)</td>
<td>100(28.9)</td>
</tr>
<tr>
<td>No</td>
<td>156(77)</td>
<td>92(63)</td>
<td>246(71.1)</td>
</tr>
<tr>
<td><strong>Family support(remembering the dose)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>77(38.5)</td>
<td>73(50)</td>
<td>150(43.4)</td>
</tr>
<tr>
<td>No</td>
<td>123(61.5)</td>
<td>73(50)</td>
<td>196(56.6)</td>
</tr>
<tr>
<td><strong>Any help for taking injections(N=29)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12(80)</td>
<td>7(50)</td>
<td>19(65.5)</td>
</tr>
<tr>
<td>No</td>
<td>3(20)</td>
<td>7(50)</td>
<td>10(34.5)</td>
</tr>
</tbody>
</table>

Source primary survey 2010. Thiruvananthapuram.

4.3 Prevalence of drug adherence among the diabetics:-

Prevalence of drug adherence in male and females was given in the following figure.
Fig 4.3 Prevalence of drug adherence among the males and females:

4.4 Gender difference in the pattern of good adherence and family support:

Gender difference in the pattern of good adherence and family support was given in the table 4.6. and which cannot be overlooked and hence has been considered separately.

Table 4.6 Gender difference pattern among the good adherence and family support

<table>
<thead>
<tr>
<th>Age group</th>
<th>Good adherence Among the men (n=46)</th>
<th>Good adherence Among the women(n=44)</th>
<th>Men who have Family support n=73(%)</th>
<th>Women who have Family support (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-40</td>
<td>14 (30.4%)</td>
<td>11(19.0%)</td>
<td>28(38.4%)</td>
<td>13(24.9%)</td>
</tr>
<tr>
<td>40-50</td>
<td>10 (21.7%)</td>
<td>12(23.6%)</td>
<td>16(21.9%)</td>
<td>25(26.1%)</td>
</tr>
<tr>
<td>50-60</td>
<td>10(21.7%)</td>
<td>8(24.2%)</td>
<td>13(17.8%)</td>
<td>24(31.4%)</td>
</tr>
<tr>
<td>60-70</td>
<td>7(15.2%)</td>
<td>8(21.2%)</td>
<td>9(12.3%)</td>
<td>8(10.4%)</td>
</tr>
<tr>
<td>70-80</td>
<td>5(10.9%)</td>
<td>5 (11.4%)</td>
<td>7(9.6%)</td>
<td>7(9.1%)</td>
</tr>
</tbody>
</table>

As they grow older and more dependent on their family members, the drug adherence levels are low and similar across gender, whereas the working age group (30-40 years) men are far more adhere than women. The same pattern also observed in family support. After the age of 70 years, family support and good adherence decreases for both genders.

4.4 Bivariate analysis: Poor adherence associated with specific characteristics:-

Poor adherence subjects have high risk for developing diabetic complication. The association was considered significant if ‘P’ value was less than 0.05. Unadjusted for other variables, it was found that fourteen independent variables were significantly associated with poor adherence.

4.4.1 Individual characteristics associated with poor adherence:-

Factors associated with poor adherence based on bivariate analysis are given in table 4.7. Poor adherence was significantly more among women compared to men. Compared to patients who had more than secondary education, those who had less than secondary education were three times more likely to have poor adherence. Diabetic patients with per capita expenditure of less than or equal to rupees 1250 per month were five times more likely to have poor adherence compared to their counter parts. Patients without insurance and other health allowances were five times more likely to have poor adherence compared to their counter parts.
Table 4.7 Factors associated with poor adherence: Results of bivariate analysis

<table>
<thead>
<tr>
<th>Variables</th>
<th>Poor adherence</th>
<th>Odds ratio(95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N  %</td>
<td></td>
</tr>
<tr>
<td>Sex *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>women(n=200)</td>
<td>100(68.5%)</td>
<td>2.31 (1.08- 4.59)</td>
</tr>
<tr>
<td>men(n=146) *</td>
<td>156(78%)</td>
<td></td>
</tr>
<tr>
<td>Education **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2ºeducation(n=212)</td>
<td>174(82%)</td>
<td>2.90 (1.77-4.76)</td>
</tr>
<tr>
<td>&gt;2ºeducation *(n=134)</td>
<td>82(61%)</td>
<td></td>
</tr>
<tr>
<td>Per capita expenditure **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1250rupees (n=174)</td>
<td>154(89%)</td>
<td>5.28 (3.03-9.22)</td>
</tr>
<tr>
<td>&gt;1250rupees *(n=172)</td>
<td>102(59%)</td>
<td></td>
</tr>
<tr>
<td>Insurance and other health allowances **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes *(n=100)</td>
<td>51(51%)</td>
<td>4.80 (2.87-8.05)</td>
</tr>
<tr>
<td>No (n=246)</td>
<td>205(83%)</td>
<td></td>
</tr>
</tbody>
</table>

Source: Primary survey, 2010 Thiruvananthapuram . * Chi-square P value < .05 levels, ** Chi-square P value< .001  *X* is the reference category.

4.4.2. Disease and treatment related characteristics associated with poor adherence: results of bivariate analysis.

Disease and treatment related factors associated with poor drug adherence is given in the table 4.8. Those who are diagnosed as diabetic during the treatment of other disease were showing approximately two times poor adherence compared to those who were detected when they had symptoms of diabetes. Patients who approached public facility were four times poorly adherent as compared with patients consulting private practitioners. Those who were not aware of the complications were three times more likely to have poor adherence to medication than who were aware of the diabetic complication. Respondents who were monitoring blood sugar level less frequently were five times poorly adherent to medications compared to those who frequently
checked blood sugar. Patients who got two or more instructions were considered as detailed instructions and less than two or no instructions were considered as short/no instructions about disease management.

Table 4.8 Disease and treatment related characteristics associated with poor drug adherence: Results of bivariate analysis:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Poor adherence n (%)</th>
<th>Odds ratio (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease related characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial detection of diabetes **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) medical consultation for other disease (n=181)</td>
<td>144 (80%)</td>
<td>1.84 (1.13-2.99)</td>
</tr>
<tr>
<td>b) symptomatic r (n=165)</td>
<td>112 (68%)</td>
<td>(1.13-2.99)</td>
</tr>
<tr>
<td><strong>Type of health facility utilized</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Government (n=166)</td>
<td>144 (86.7%)</td>
<td>3.97 (2.30-6.98)</td>
</tr>
<tr>
<td>b) Private r (n=180)</td>
<td>112 (62.2%)</td>
<td>(2.30-6.98)</td>
</tr>
<tr>
<td><strong>Knowledge about the complication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes r (n=254)</td>
<td>176 (69%)</td>
<td>2.99 (1.52-5.73)</td>
</tr>
<tr>
<td>No (n=92)</td>
<td>80 (87%)</td>
<td>(1.52-5.73)</td>
</tr>
<tr>
<td>**blood sugar monitoring **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1 month (less frequently) (n=155)</td>
<td>139 (90%)</td>
<td>5.40 (3.04-9.93)</td>
</tr>
<tr>
<td>≤1 month r (frequently) (n=191)</td>
<td>117 (61%)</td>
<td>(3.04-9.93)</td>
</tr>
<tr>
<td><strong>Treatment related characteristics:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician’s instructions about the disease management **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detailed instructions about disease management r (n=149)</td>
<td>124 (83%)</td>
<td>2.971</td>
</tr>
<tr>
<td>Short/no instructions about disease management (n=197)</td>
<td>132 (67%)</td>
<td>(1.794-4.920)</td>
</tr>
<tr>
<td><strong>Patient’s knowledge about the treatment strategy of diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Lifestyle modifications &amp; drugs r (n=196)</td>
<td>121 (62%)</td>
<td>5.57</td>
</tr>
<tr>
<td>b) Symptomatic management only (n=150)</td>
<td>135 (90%)</td>
<td>(3.04-10.23)</td>
</tr>
</tbody>
</table>

Source: Primary survey, 2010 Thiruvanathapuram. **Chi-square P value<.001.Xr is the reference category. Other disease means “fever epidemics” and screening for surgery”. Private clinic of government physician were considered as private clinic consulting patients.
Patients who got short instructions were showing six times poor adherence as compared to those received detailed instructions. Patients who preferred symptomatic management for diabetes was six times poorly adherent to medication than who preferred lifestyle management for diabetes.

4.4.3 Medication use related characteristics and associated with poor drug adherence: Results of bivariate analysis:-

Medication use related factors associated with poor drug adherence are given in the table 4.9

Oral hypoglycemic agent users were three times poorly adherent to medication than insulin users. Those who spent less than or equal to 180 rupees for drugs were two times poorly adherent to medication as compared with their counterparts.

Table 4.9 Medication use related characteristics associated with poor drug adherence:

Results of bivariate analysis:-

<table>
<thead>
<tr>
<th>Variables</th>
<th>Poor adherence N (%)</th>
<th>Odds ratio(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form of medicine *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Oral hypoglycemic agents (n=317)</td>
<td>242(76.3%)</td>
<td>3.46(1.59-7.49)</td>
</tr>
<tr>
<td>b) Insulin r (n=29)</td>
<td>14(48.3%)</td>
<td></td>
</tr>
<tr>
<td>Drug expenditure for last month *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤180rupees(r=192)</td>
<td>156(81%)</td>
<td>2.34(1.43-3.82)</td>
</tr>
<tr>
<td>&gt;180rupees r (n=154)</td>
<td>100(65%)</td>
<td></td>
</tr>
<tr>
<td>Family member help to remember the medicine *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes r (n=150)</td>
<td>85(55.3%)</td>
<td>6.07(3.53-10.43)</td>
</tr>
<tr>
<td>No (n=196)</td>
<td>173(88.3%)</td>
<td></td>
</tr>
<tr>
<td>Getting any help for taking the injections*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes r (n=19)</td>
<td>10(52.6)</td>
<td>2.01(1.22-3.64)</td>
</tr>
<tr>
<td>No (n=10)</td>
<td>4(40)</td>
<td></td>
</tr>
</tbody>
</table>

Source: Primary survey, 2010 Thiruvananthapuram . * Chi-square P value< .001  Xr is the reference category.
Those who did not get support from family members in taking injections were two times poorly adherent to medication compared to those who did. Those who did not receive help from family member for remembering the dose and frequency of medication were six times more likely to have poor adherence to medications than those who did not have.

4.5 **Predictors of poor adherence: Results of Multivariate Analysis**

Multivariate logistic regression model was built in a stepwise manner.

**Step 1**

In the first step the socio demographic and socio economic variables such as sex, education per capita expenditure for last month and insurance & HA were included in the model. Among these covariates per capita expenditure for last month and insurance was found to be significant.

**Step 2**

Keeping only the significant variable(s) from the previous step the diabetes related factors were added to the model. This included initial detection of diabetes, type of health facility utilized for diabetes treatment, Regular blood sugar monitoring and Knowledge about the diabetic complications. In this model per capita expenditure for last month, insurance and other health allowances for the patient, regular blood monitoring and Knowledge about the diabetic complications were found to be significant.

**Step 3**

Per capita expenditure for last month, blood sugar monitoring and knowledge about complications were found significant in the previous step. The significant variables from the previous step, diabetes treatment related factors like detailed diabetes management instructions from the physician, knowledge about the treatment strategy were included in this step.
Step 4

Per capita expenditure for last month, blood sugar monitoring, physician’s instructions about disease management and patient’s knowledge about the disease management were found significant in the previous step. In this step, medication use related factors such as form of medicine, direct expenditure for last month and family support for medication management and significant variables of the previous steps were added.

Step 5

The covariates that were found to be significant in the step wise approach were entered into the final model. Per capita expenditure for last month, blood sugar monitoring, physician’s instructions about disease management and family member help to remember the medication management were found to be significant in the previous step.

Final model

Age, sex, education, direct expenditure for the medication, per capita expenditure, blood sugar monitoring, physicians instructions about the disease management, patients’ knowledge about the treatment strategy of diabetes and help from the family member to remember to take the medications were the variable that were included in the final model.

Variables that were significant in the final model were the following. If there was member in the family to help the patient remember taking medication those patients had better adherence compared to their counterparts who were four times more likely to have poor adherence.

Frequent blood sugar monitoring was another variable that came significant in the final model. Those who had less frequent blood sugar monitoring were four times more likely to have poor adherence compared to their counterparts. Patients who believed in symptomatic management of
diabetes were three times more likely to have poor adherence. Patients who spent less than or equal to 1250 rupees per month were three times more likely to have poor adherence compared to those who spent more than the above amount. Those who received short or no instructions from their physicians were two times more likely to have poor adherence compared to those who received detailed instructions from their physicians.

### 4.10. Factors associated with poor adherence: Results of multiple logistic regression analysis.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Per capita expenditure for last month</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1250 rupees only</td>
<td>2.79</td>
<td>1.40 – 5.57</td>
<td>0.001</td>
</tr>
<tr>
<td>&gt;1250 rupees only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood sugar monitoring</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1 month (frequently)</td>
<td>4.10</td>
<td>2.01 – 8.38</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>&gt;1 month (less frequently)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Physician’s instructions about diabetes management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short or no instructions from the provider</td>
<td>2.29</td>
<td>1.16 – 4.50</td>
<td>0.001</td>
</tr>
<tr>
<td>Detailed instructions from the provider</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient’s knowledge about the treatment strategy of diabetes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle modifications and drugs</td>
<td>3.01</td>
<td>1.50 – 6.04</td>
<td>0.012</td>
</tr>
<tr>
<td>Symptomatic management only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Family member help to remember the medication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4.32</td>
<td>2.20 – 8.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Primary survey, 2010 Thiruvananthapuram. Dependent variable: poor adherence. Other variables included in the final model but not significant were age, sex and direct expenditure for the drug for last month.
Fig 4.4  Model predicting the adherence:

- Motivation
- Family support
- Behavioral
- Regular blood sugar monitoring
- Resource based (PCE)

Cognitive-Provider instructions improves

Drug adherence behavior
5. Discussion

India has the second largest population with diabetes mellitus in the world. Studies on prevalence of diabetes are abundant in India. Ethnically, Asian population is more prone to diabetes.\textsuperscript{10} Hence, thinking about the outcome of disease, treatment and adherence, is far more important than prevalence. Identification of an individual as diabetic and treating him in the right way is equally important.

In this study, the medication adherence among the study population was 22 percent. A hospital based study in Chennai found that 30 percent of the study populations were adhering to the medication which is slightly more than that we found in this study.\textsuperscript{31} Another study in Hawaii Island reported that 61.4 percent of the study population was adhering to the medication measured by medication possession ratio (MPR).\textsuperscript{40} The variation in medication adherence in these studies may be due to the different methods for measuring adherence. They were trying to view the adherence as a medical outcome. Seeing it as behavior rather than outcome is good for identifying the multiple players for medication adherence behavior.\textsuperscript{56} Another study conducted in urban population of the United States using four item Morisky adherence scale found that 28 percent were poorly adherent to the medication.\textsuperscript{22} Another possible explanation for poor adherence in my study is the rural setting which poses barriers to health care access for diabetic patients. Poor adherence is likely to lead to increased complications of diabetes. These complications may increase the costs of health care because of increased morbidity and may also decrease productivity of the affected persons.
5.1 Family Support for adherence

The most important variable in this study that predicted adherence was family support. Since diabetes is a chronic disease family support is crucial for drug adherence. Someone to remember medication adherence in diabetes and other chronic diseases will be a strong support to the patients. Delmeter et al. showed that diabetes management resides primarily within the family.48

5.2 Importance of blood sugar monitoring

The patients were doing their blood sugar monitoring less frequently (more than one month) was more likely to showing poor drug adherence in this study. Bjork et al reported that patients were unaware of the potential seriousness of their condition, if they were monitoring their blood sugar less frequently.10 Compounding this problem is the belief by many patients that their disease is under control because they are ‘feeling well’. The absence of comprehension that patients exhibit with regard to the risks they are facing is a serious concern.10,38 The interrupted frequency of blood sugar monitoring may also be due to the costs involved.

Those patients whose diabetes was detected during checkups for conditions related to diabetes (symptomatic) were more likely to have poor adherence compared to those detected during the time of treatment of other diseases like fever or screening for the surgery. Those who were diagnosed as diabetic during check up for conditions like heart disease or stroke or other diseases related to diabetes were generally found to be serious and concerned about their glycaemic level that increases their adherence to medications.51 Possible reason for this finding was perceived seriousness about the disease.

5.3 Importance of patient-provider communication

Diabetes management instructions from the healthcare provider are an important modifiable factor for adherence. Shobhana et al identified that diabetic patients require constant
motivation and intensive patient education for improving the treatment adherence. Reviews of studies are suggesting that physician is the primary point of contact for diagnosis and treatment of the diabetic patient. A study from Nigeria reported that length and depth of interaction between the patients and physicians during consultation as a factor for adherence. Short consultation time in the public sector due to high patient load and staff shortage results in inadequate physician patient interaction in the rural public health care settings. When there are shorter instructions or no instructions from the physicians patients had a feeling of neglect from the provider and they were suspicious of the benefit of treatment. If they get instructions without reasons then also the patients are suspicious. Shobhana et al found that lack of external and internal motivation and negative social environment from the health care setting were the important predictors of poor adherence. Shobhana et al demonstrated a 59 percent reduction in foot lesions when patients get education about the diabetes management. So the patient education combined with appropriate reinforcement of health care behavior advised by health care team enforce the individual to rationalize the adherence behavior. It helps the individual to identify taking medication as a basic and strong need for glycaemic control. Education programs for practitioners and patients will be clearly a priority.

5.4 Knowledge of treatment strategy of Diabetes

Those who were believed in symptomatic management as a strategy for treating diabetes were showing poor adherence compared to those who had known about lifestyle management of diabetes. Murray et al suggested that lack of understanding exists in the treatment requirements for diabetic patients. These findings indeed state the critical role played by the patient’s awareness and practice of diabetes self management behaviors in improving the drug adherence, ensuring achievement of adequate glycaemic control and minimizing likelihood of
diabetic complications. The importance of patient centered education and empowering the patient for their own health matters are considered as an important component in a treatment strategy of diabetes.

5.5 Per capita expenditure and adherence

Those with high per capita expenditure were reported to be more likely to be adherent to the medications as compared to those with lower per capita expenditure. It is one of the proxy indicators of income status of the individual. Thus a higher family income increases the probability of meeting the expenses of the long term treatment of diabetes. Thus, inability to meet the expenses incurred during buying of medicines was probably the most important cause of non adherence in the rural area which is consistent with the results of a study conducted in Nigeria.38

5.6 Limitations

The study was a cross sectional survey and associations in found in this study should be viewed with caution. Additional expenditure included in the study was not verified by any means.

5.7 Strengths of the study

The data collection was carried out by a single investigator thus eliminating the chances of inter–observer bias. The agreement between the reported drug expenditure was verified by the drug price rate register of the drug council of India. To the best of my knowledge, this is the first epidemiological study using a qualitative tool (8 item morisky adherence scale) for measuring the drug adherence in India.
5.8 Conclusions

A very high proportion (74 percent) of the diabetic patients was poorly adherent to the medications. If there was a member in the family to help the patient remember taking medication, those patients had better adherence compared to their counterparts who were four times more likely to have poor adherence. Frequent blood sugar monitoring was another variable that came significant in the final model. Those who had less frequent blood sugar monitoring were four times more likely to have poor adherence compared to their counterparts. Patients who believed in symptomatic management of diabetes were three times more likely to have poor adherence. Patients who spent less than or equal to 1250 rupees per month were three times more likely to have poor adherence compared to those who spent more than the above amount. Those who received short or no instructions from their physicians were two times more likely to have poor adherence compared to those who received detailed instructions from their physicians.

5.9 Policy recommendations:

Diabetes treatment should be considered as a family issue and efforts should be made to convince the family members that their support is crucial in drug adherence which in turn will result in avoiding diabetic complications.

Patients and their relatives should be encouraged to regular blood sugar monitoring. Facilities for regular blood sugar monitoring should be made available in rural hospitals and primary health centres

Specific education programs should target diabetes patients on the importance of lifestyle management for diabetes
Poor diabetes patients should be provided free treatment and blood sugar monitoring facilities in the rural areas

Physicians should be encouraged to provide detailed instructions to diabetes patients to enhance drug adherence
REFERENCES


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34. Tolijamo M, Hentinen M, Adherence to self care and glycemic control among people with insulin dependent diabetes mellitus. Journal of advanced nursing 2001;34:780-786


42. Gimenes et al. Factors related to patient adherence to antidiabetic therapy. Rev Latino-am Enfermagem 2009;17:46-51


Appendix 1

Multivariate logistic regression model-adjusting for the known risk factors

Step 1.

<table>
<thead>
<tr>
<th>Socio demographic risk factors for adherence</th>
<th>Adjusted odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 20 education</td>
<td>1.08</td>
<td>.58 – 2.00</td>
<td>.818</td>
</tr>
<tr>
<td>&gt; 20 education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per capita expenditure for last month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1250 rupees only</td>
<td>3.83</td>
<td>2.04 – 7.18</td>
<td>.001</td>
</tr>
<tr>
<td>&gt; 1250 rupees only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insurance &amp; other health allowances</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>2.63</td>
<td>1.45 - 4.77</td>
<td>.001</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Step 2

<table>
<thead>
<tr>
<th>Disease related factors for adherence &amp; socio economic variables for adherence</th>
<th>Adjusted odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance and other health allowances</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2.027</td>
<td>1.08 - 3.82</td>
<td>.059</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per capita expenditure for last month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1250 rupees only</td>
<td>3.017</td>
<td>1.57 – 5.79</td>
<td>.001</td>
</tr>
<tr>
<td>&gt; 1250 rupees only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood sugar monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;= 1 month</td>
<td>4.521</td>
<td>2.39-8.56</td>
<td>.001</td>
</tr>
<tr>
<td>&gt; 1 month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge about the complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2.443</td>
<td>1.17-5.09</td>
<td>.017</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Step 3

<table>
<thead>
<tr>
<th>Diabetes treatment related factors and diabetes factors for adherence</th>
<th>Adjusted Odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per capita expenditure for last month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 1250 rupees only</td>
<td>2.29</td>
<td>1.14 - 4.58</td>
<td>.019</td>
</tr>
<tr>
<td>&gt;1250 rupees only</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Blood sugar monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1 month</td>
<td>4.77</td>
<td>2.45 – 9.31</td>
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<tr>
<td>&gt;1 month</td>
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<tr>
<td>Knowledge about the complications</td>
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</tr>
<tr>
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<td>2.16</td>
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<td>.046</td>
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<tr>
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<tr>
<td>Diabetes management instructions from the provider</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Short instructions from the provider</td>
<td>2.29</td>
<td>1.16 – 4.50</td>
<td>.017</td>
</tr>
<tr>
<td>Detailed instructions from the provider</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Patient’s knowledge about the treatment strategy of diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle modifications and drugs</td>
<td>3.01</td>
<td>1.50 – 6.04</td>
<td>.002</td>
</tr>
<tr>
<td>Symptomatic management only</td>
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</table>
### Step 4

<table>
<thead>
<tr>
<th>Diabetes, treatment and Medication use related factors for adherence</th>
<th>Adjusted Odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
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<td></td>
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<tr>
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<td>2.79</td>
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<tr>
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<tr>
<td>Blood sugar monitoring</td>
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<td></td>
<td></td>
</tr>
<tr>
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<td>4.10</td>
<td>2.01 – 8.38</td>
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<tr>
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<tr>
<td>Short instructions from the provider</td>
<td>2.29</td>
<td>1.16 – 4.50</td>
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<tr>
<td>Detailed instructions from the provider</td>
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<td>Patient’s knowledge about the treatment strategy of diabetes</td>
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<td>Lifestyle modifications and drugs</td>
<td>3.01</td>
<td>1.50 – 6.04</td>
<td>.002</td>
</tr>
<tr>
<td>Symptomatic management only</td>
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</tr>
<tr>
<td>Form of medicine</td>
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</tr>
<tr>
<td>Insulin</td>
<td></td>
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<tr>
<td>Oral hypoglycemic agent</td>
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<td>&lt;=180 rupees</td>
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<tr>
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<td>Sex</td>
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<td></td>
</tr>
<tr>
<td>Female</td>
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<tr>
<td>≤ 1 month</td>
<td>4.10</td>
<td>2.01 – 8.38</td>
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<tr>
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</tr>
<tr>
<td>----------------------------------------------------------</td>
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<td>------</td>
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<tr>
<td>Lifestyle modifications and drugs ( r )</td>
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<tr>
<td>Symptomatic management only</td>
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<td></td>
<td></td>
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<tr>
<td>Family member help to remember the medication ( r )</td>
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<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4.32</td>
<td>2.20 – 8.43</td>
<td>&lt;0.001</td>
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</table>
Appendix 2

Participant information sheet

You are invited to take part in the research study: Factors associated with drug adherence among the self reported diabetic patients in rural Thiruvananthapuram. Before you decide it is important for you to understand why the research is being done and what it will involve.

1. What is the purpose of the study?
I am a public health student at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. The main aims of the research are:

- To find the extent of drug adherence among the self reported rural adult diabetic population.
- To find the factors associated with the drug adherence among them.
- To estimate the expenditure for diabetic medication among the self reported diabetics.
- To study the various options exercised by the diabetic patients to meet the expenditure of medication

2. How your village was chosen?

The study will be conducted in rural Thiruvananthapuram. This district is selected because of my convenience and it is the capital of Kerala. Out of 79 Panchayaths 8 are selected randomly. Out of these eight Panchayaths, twenty four wards are selected by lottery method. Lottery method ensured that your village had an equal opportunity to be selected in either of these groups.

3. Why have you been chosen?

The study includes diabetic patients, living in this Panchayaths and their age more than 18 years of age. Men who are suffering from severe debilitating illness.

4. What will happen to me if I take part in the study?

Your involvement in the study is in interview session.

- Information regarding socio-demographic profile, socio economic profile, other factors and morisky adherence scale measurement will be collected. This can take 20-25 minutes. You may even refuse to answer any question if you are uncomfortable.

   It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time and without any reason.
5. Will your participation in the study be kept confidential?
All information collected during the course of this research will be kept strictly confidential. All personal information collected will be destroyed at the end of the research. Your personal information will not be included while writing the report.

6. What will be the benefit if you participate in the study?
If you participate in this study you have no direct benefits, but you will indirectly involving in the policy formulations for diabetic patients.

7. Who is funding the research?
I am doing this research from my own expenses.

8. What will happen to the results of the study?
The results of the study will be used in my MPH thesis. The findings will be presented at academic and professional conferences and in academic journals. Findings from the study will help in designing better health policy for diabetic patients in rural areas of Thiruvananthapuram.
Appendix 3

INFORMED CONSENT

Achutha Menon Centre for Health Science Studies
Sree Chitra Tirunal Institute for Medical Sciences & Technology,
Thiruvananthapuram, Kerala-695011

Factors associated with drug adherence among the self reported diabetic medications in rural Thiruvananthapuram

MPH dissertation
June – September ‘2010

“Namaskaram” - my name is xxx and presently I am studying the course-Master of Public Health (MPH) at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram. As part of my dissertation, I am conducting this survey and interviewing the people suffering from diabetic mellitus, living in the rural area of Thiruvananthapuram, to assess their adherence to diabetic medications, and its factors associated with them. The purpose of the study is to gather information that is going to help to make policies to improve adherence to diabetic management among the rural Thiruvananthapuram populations.

There will be no direct benefits to you for participating in this interview. You may chose to answer all or some of the questions that I put to you. Everything you will say will remain private and confidential. If you have any further queries, you are free to contact me at my mobile number given below and I will answer all your queries and if you still have any further queries you can address them to the Member secretary of the Institute Ethics Committee at Sree Chitra Tirunal Institute for any further clarification that you need.

The approximate time I will take is about 20-30 minutes. If you agree to participate in the interview please indicate your agreement. Your name will not be used in any report but your ideas and experiences will be of great help to make better strategies in order to improve adherence to therapy in the management of Hypertension, which will be good for the people in future. However you are free to quit the interview at any point of time if you feel so.

☒ Yes, the respondent has agreed to the interview
☒ No, the respondent did not agree to the interview

Signature/Left thumb impression

..........................

Or

☒ The respondent is not willing to sign or give thumb impression (verbal consent)
Signature of the witness…………………………………….. 
Name and address of the witness:
……………………………………………………………………... 

If you are not willing to participate, then thank you for your time.
Name of the respondent:………………………………………..
Address:………………………………………………………….. 

Identification code:__________ Date: /0 /2009
Appendix 4

Interview Schedule

Factors associated with drug adherence among the self reported adult diabetic patients in Rural Thiruvananthapuram

<table>
<thead>
<tr>
<th>Identification code:-</th>
<th>serial number :-</th>
<th>date:- ---/----/2010</th>
</tr>
</thead>
</table>

1. Age(in completed years)
2. Sex: 1[ ]male. 2[ ]female
3. Marital status : 1[ ]married. 2[ ]single . 3[ ]widow/widower. 4[ ]divorced
5. Others (specify---)

4. Total number of house hold members --------------------------
5. Education:- 1[ ]Illiterate. 2[ ]Primary (up to class 4). 3[ ]Secondary (up to class 10). 4[ ]Higher Secondary (up to class 12) . 5[ ]Graduate 6[ ]Postgraduate

6. Occupation:- 1[ ]clerical. 2[ ]manual laborers/unskilled workers. 3[ ]Professionals 4[ ]Home maker 5[ ]unemployed . 6[ ]self employed 7[ ]retired /pensioned
7. Did you consume any tobacco products in last one month? Yes/no
8. Did you consume any alcoholic products in the last one month? yes/no
9. What was your total household expenditure last month?------
10. When were you diagnosed to have diabetic for the first time?
   1. during regular checkup
   2. during medical consultation for other diseases
   3. screening camps
   4. during the screening for any surgery
   5. others (specify)

11. Duration of diabetic treatment?  1. > 6 months  2. 6 months-1 year  3. > 1 year

12. Where did you seek treatment for diabetes?
   1. government  2. private  3. ESI  4. others (specify)

13. Which system of medicine do you use for treatment of diabetes?
   1. allopathy
   2. ayurveda
   3. both ayurveda and allopathy
   4. homeopathy
   5. unani
   6. others (specify)

14. How much is the distance to your nearest healthcare facility from your home?
   1. < 1 km  2. > 1 km

16. When did you last visit your physician/clinic?
   1. within last two weeks
   2. within 2 weeks to 1 month
   3. within 1-6 months
   4. within 6 months to 1 year
   5. more than one year
   6. cannot say

17. How often have you got your blood sugar checked in the last one year?  
   1. in less than two weeks
   2. in 2-4 weeks
   3. one month to six months
   4. more than six months

18. How do you follow your medication?
   1. taking medicine as per doctor’s advice.
   2. take more when I feel necessary.
   3. take less tablets when asymptomatic.
   4. taking medicine as per convenience

19. Do you modify your medicine dose when you are attending any festivals/functions?
   Yes/no
20. If yes, how do you modify the dosage of medicine?
   1. increasing the number of tablets at a time.
   2. decreasing the number of tablets at a time.
   3. stop taking the tablets

21. What kind of medicines are you taking for diabetes?
   1. oral hypoglycemic tablets
   2. insulin
   3. others. (specify)

22. If you are taking insulin, are you getting any help from someone else for taking injections?
   1. yes 2. no 3. self

23. If yes, from whom you are getting the help?
   1. family member 2. friends 3. relatives 4. home nurse 5. health clinic 6. health professionals

22. Expenditure for anti-diabetic medicines last month? (direct expenditure)

<table>
<thead>
<tr>
<th>Si no</th>
<th>Name of the medicine</th>
<th>dose</th>
<th>frequency</th>
<th>Rate/tab</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional expenditure (transportation):----------

23. Who pays for your medication?
   1. self
   2. family member
   3. free of cost
   4. others

24. Have you ever cutback/stopped taking the medicine because you could not afford the expenditure of medication? Yes/no

25. Do you find any difficulty to get the medication? Yes/no

26. If yes, what are they?-------------------
   1. needed long distance travelling to purchase
27. In your family, does any one help you to remember to take the medicine?  Yes/no

28. If yes, who helps you?--------

29. Do you have any health insurance /medical reimbursement coverage?  Yes /no

30. In your opinion, what kind of treatment strategy is suitable for diabetes?
   1  lifelong treatment .
   2  short term treatment .
   3  lifestyle modification only.
   4  symptomatic treatment.
   5  no medicine.
   6  Life style modification and drugs
   7  don’t know

31. Do you think untreated diabetes can cause any problem?
   Yes/no

32. If yes, what are the problems?------------------

33. What do you think about the benefits of your current medication?
   1  beneficial
   2  not beneficial
   3  cannot say

34. Are you satisfied with current treatment regimen? Yes/no

35. Do you think that your blood sugar is under control? Yes /no

36. Do you have any of the following condition now?
   1. Hypertension  yes/no
   2. Heart disease  yes/no
   3. Kidney disease  yes/no
   4. Disorders of blood cholesterol  yes/no
   5. Disease of brain/nervous system  yes/no
   6. Psychiatric illness  yes/no
   7. Others  (specify----------)

37. How is your relationship with your healthcare provider?
1. ☐ good
2. ☐ average
3. ☐ poor

38. Do you get any instructions about your disease management from the doctor?  Yes/No
39. If yes, what are they?
   1. Taking medicine regularly  yes/no
   2. Diet modification  yes/no
   3. Physical activity  yes/no
   4. Follow up visit  yes/no
   5. Checking blood sugar periodically  yes/no

40. Were you hospitalized in the last year?  Yes/no
41. If yes, how many times?  -----------
©Morisky Medication Adherence Scale (MMAS-8-Item).

You indicated that you are taking medication for your (identify health concern, such as “high blood pressure”). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.

(Please circle the correct number)

<table>
<thead>
<tr>
<th>Question</th>
<th>No=1</th>
<th>Yes =0</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you sometimes forget to take your [health concern] pills?……...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medicine?……...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?.........</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication?..............................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Did you take your [health concern] medicine yesterday?...........</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. When you feel like your [health concern] is under control, do you sometimes stop taking your medicine?............................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?........................................</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. How often do you have difficulty remembering to take all your medications? 
   (Please circle the correct number)
Never/Rarely.................................................4
Once in a while.............................................3
Sometimes....................................................2
Usually........................................................1
All the time...................................................0

Coding Instructions for the ©Morisky Medication Adherence Scale

(8-Item)
Re-codes:
If Item5 = 0 Item5r = 1 (high adherence)
If Item8=4 Item8r = 1 (highest adherence)
If Item8=3 Item8r = .75 (high adherence)
If Item8=2 Item8r = .50 (moderate adherence)
If Item8=1 Item8r = .25 (low adherence)
If Item8=0 Item8r = 0 (lowest adherence)

Adherence score:
Low Adherence (≤6)
Medium Adherence (6.25 to <8)
High Adherence (= 8)