

# **Factors Associated with Medication Adherence among Dyslipidemic Patients in Kottayam District, Kerala, India**

**Merryson Roy Mathew**

Dissertation submitted in partial fulfilment of the requirement for  
the award of the degree of  
**Master of Public Health**



Achutha Menon Centre for Health Science Studies,  
Sree Chitra Tirunal Institute for Medical Sciences and Technology  
Trivandrum, Kerala

October 2013

## **CERTIFICATE**

I hereby certify that the work embodied in this dissertation entitled “**Factors associated with medication adherence among dyslipidemic patients in Kottayam district, Kerala, India**” is a bonafide record of original research undertaken by Mr. Merryson Roy Mathew, in partial fulfillment of the requirement for the award of the “Master of Public Health” degree from Sree Chitra Tirunal Institute of Medical Science and Technology Thiruvananthapuram under my guidance and supervision

**Dr. V. Raman Kutty**

Professor

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram, Kerala

October 2013

## **DECLARATION**

I Merryson Roy Mathew hereby declare that the work embodied in this dissertation entitled **“Factors associated with medication adherence among dyslipidemic patients in Kottayam district, Kerala, India”** has been carried out by me under the guidance of Dr. V Raman Kutty, Sree Chitra Tirunal Institute of Medical Science and Technology Thiruvananthapuram, Kerala. This is the result of original research. This has not been submitted for any degree in any other University or Institution.

**Merryson Roy Mathew**

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram, Kerala

October 2013

# ACKNOWLEDGEMENT

“I can do all things through him who strengthens me”: Philippians 4:13

I would never have been able to finish my dissertation without the guidance of my guide **Dr. V. Raman Kutty**, my teachers, and my family. I take immense pleasure to express my sincere gratitude to my guide **Dr. V. Raman Kutty** for his excellent guidance, caring, support and patience throughout my research. His extensive discussion and personal guidance have been very helpful in carrying out this work. I would like to thank the faculty members **Dr. K.R. Thankappan, Dr.P. Sankara Sarma, Dr.T.K.Sundari Ravindran, Dr.Mala Ramanathan, Dr.Manju.R.Nair, Dr.Kannan Srinivasan, Dr.Biju Soman, Dr.Ravi Prasad Varma and Ms.Jissa.V.T** who stood along with me during these two years and giving their inputs.

I would also like to thank **Rev Father Thomas Mattam** who gave me all support during my whole life. I extend my thanks to my friends **Dr. Sathish, Jasmine and Kamarudheen** who supported, cheered me during tough times. I place on record, my sincere gratitude to **Dr.T.K Sundari Ravindran** who guided me morally. I also would like to thank my all ancestors and relatives who prayed for me from heaven. I would also like to thank my mother for her unceasing support, encouragement, prayers and sufferings.

Merryson Roy Mathew

October 2013

# Table of content

<b>Content</b>	<b>Page no</b>
<b>Acknowledgement</b>	<b>iv</b>
<b>Glossary of abbreviation</b>	<b>viii</b>
<b>Abstract</b>	<b>ix</b>
<b>1. Introduction and background</b>	<b>1</b>
<b>2. Literature review</b>	<b>4</b>
2.1 Adherence among dyslipidemic patients	6
2.2 Impact of Non adherence and economic burden	6
2.3 Measure of adherence	6
2.4 Factors associated with medication adherence	7
2.4.1 Treatment and disease related factors	7
2.4.2 Co morbidity related factors.	8
2.4.3 Patient and demographic related factors	9
2.4.4 System related factors	9
2.4.5 Patient decisions attitude and belief	10
2.5 Rationale of the study	11
2.6 Objective of the study	12
<b>3. Methodology</b>	<b>14</b>
3.1 Study design	14
3.2 Study setting	14
3.3 Study population	14
3.4 Inclusion criteria	14
3.5 Exclusion criteria	15
3.6 Sample size	15
3.7 Sample selection procedure	15
3.8 Data collection procedure	17

3.9 Data collection process	18
3.10 Variable under the study	18
3.10.1 Definition of the variable	18
3.10.2 Operational definition	18
3.10.3 Outcome variable	19
3.10.4 Measurement of medication adherence	19
3.11 Predictor variable	19
3.11.1 Socio demographic factors	19
3.11.2 Dyslipidemia factors	20
3.11.3 Life style risk factors of NCDs	21
3.11.4 System related factors	21
3.11.5 Family related factors	22
3.11.6 Subject related factors	22
3.12 Data entry and plan of analysis	22
3.13 Ethical clearance	23
3.13.1 Confidentiality	23
3.13.2 Privacy	23
3.13.3 Consent	23
3.13.4 Referral	
<b>4. Results</b>	<b>24</b>
4.1 Socio demographic characteristics	24
4.2 Treatment related factors	25
4.3 Co morbidity related factors	26
4.4 Behavior related factors	27
4.5 Knowledge related factors	28
4.6 Family support	28
4.7 Health system factors	29
4.8 Prevalence of drug adherence	30
4.9 Prevalence of drug adherence across age group	31
4.10 Bivariate analysis	32
4.10.1 Socio demographic characteristics	32
4.10.2 Treatment and co morbidities related factors	33

4.10.3 Co morbidities	33
4.10.4 Behavioral /perceptonal factors	35
4.10.5 Knowledge related factors.	35
4.11 Multivariate analysis predictors of high adherence	35
4.11.1 Results of multivariate analysis with high adherence.	37
4.11.2 Model predicting adherence	38
<b>5. Discussion</b>	<b>39</b>
<b>6. Conclusion</b>	<b>43</b>
<b>7. References</b>	<b>44</b>
Annexure 1	53
Annexure 2	56

## List of tables

<b>Table no</b>	<b>Table</b>	<b>Page no.</b>
4.1	Distribution of Socio –demographic variable by sex	25
4.2	Distribution of Treatment related variable by sex	26
4.3	Distribution of co morbidities related factors by sex	27
4.4	Distribution of behavior related factors by sex	27
4.5	Distribution of knowledge and perception related factors	28
4.6	Distribution of family related factors	29
4.7	Distribution of health system related factors	30
4.8	Prevalence of dyslipidemia drug adherence across age group	32
4.10.1	Bivariate analysis- Socio demographic status to outcome variable	33
4.10.2	Bivariate analysis- treatment related factors to outcome variable	34
4.10.3	Bivariate analysis -Co morbidities to outcome variable	34
4.10.4	Bivariate analysis-Behavioral/perceptual related factors to outcome variable	35
4.10.5	Bivariate analysis-knowledge related factors to outcome variable	35
4.11.1	Multiple logistic regression results with outcome variable	37

## **List of abbreviations**

CVD	Cardio vascular disease
W.H.O	World Health Organization
C.A.D	Coronary artery diseases
NCEP	National cholesterol education program
ATP	Adult treatment plan
CHD	Coronary artery diseases
MMAS	Morisky medication adherence scale
FDC	Fixed dose combination

## Abstract

**Introduction:** Dyslipidemia is one of the major risk factors of cardiovascular diseases. Worldwide, dyslipidemia is estimated to cause about 2.6 million deaths annually. Low drug adherence has been found to be a significant problem leading to poor health outcome. Only a few studies have been conducted on drug adherence in dyslipidemia till now. Hence, this study was undertaken to find out the prevalence of drug adherence among dyslipidemic patients and factors associated with it.

**Methods:** A cross sectional survey was done among dyslipidemic patients of Madappally block Panchayat of Kottayam District to find out the medication adherence, with multistage clustering sampling method. Morisky medication adherence scale was used to assess the level of adherence among subjects. A structured interview schedule was used to collect information regarding socioeconomic status, treatment factors, co-morbidities related factors, behavioral, perceptual, knowledge factors and health system factors. Adherence level was grouped into low and high adherence with score 8 as the cut off value. Chi square and Multivariate logistic regression were the methods of analysis.

**Results:** Prevalence of high adherence was 30.4 %. Patients with co morbidities such as cardiac, brain and nervous system disorders are five times [odds ratio (OR)5.09,95% C.I 1.76-14.7],subjects with adequate knowledge about long term complication of dyslipidemia are three times [odds ratio(OR) 3.45,95% C.I 1.85 -6.407], subjects who perceive that prescribed medications are not costly are two times [odds ratio(OR) 2.8,95 % C.I 1.36 - 5.77], and people without memory deficit have also chance to become highly adherent [odds ratio(OR) 1.91, 95 % C.I (1.07 - 3.43)] more likely to have adherence compared to their counterparts.

**Conclusion:** Only a very low proportion of the patients were found to be high adherent. Essential steps should be taken to enhance the medication adherence among dyslipidemic patients. Appropriate health education about long term complication of dyslipidemia, risk factors of cardiac disease, essentiality, adequate financial support, reminder system to sticking on to long term therapy has to be made as a matter of concern.

# 1. INTRODUCTION

Cardiovascular disease (CVD) is one of the leading causes of death worldwide.<sup>1</sup> There are several major risk factors for CVD including dyslipidemia, hypertension, smoking, age, sex, type 2 diabetes, obesity and family history of CVD.<sup>2</sup> Dyslipidemia refers to an abnormal level of serum lipid (including LDL, HDL, total cholesterol and triglyceride).<sup>2</sup> It has been closely linked to the pathophysiology of CVD and is a crucial modifiable risk factor.<sup>4</sup> By itself, the condition has no unusual signs or symptoms. Thus, many people fail to know that their cholesterol levels are high.<sup>2</sup> High cholesterol is a leading cause of many complications such as cardiovascular diseases and stroke.<sup>3</sup> Many of such complications can be avoided by maintaining strict adherence to medication.

## Background

### Prevalence of dyslipidemia and its complications

#### a. Burden of dyslipidemia globally

Raised cholesterol is estimated to cause 2.6 million deaths annually. WHO global status report of 2010 elucidates that the global prevalence of raised total cholesterol among adults in 2008 to be 39% (37% for males and 40% for females).<sup>3</sup> The prevalence of raised cholesterol level shows an increasing trend according to the income level of the country. More than 50% of adults in high-income countries had raised cholesterol which is twice over that in low-income countries.<sup>3</sup> Prevalence of dyslipidemia is high and is on increasing level in developed as well as in developing countries, mainly due to westernization of diet and other lifestyle changes.<sup>4</sup> The prevalence of elevated total cholesterol was highest in the WHO European Region with 54% for both sexes, followed by the WHO Region of the Americas with 48% for

both sexes. The WHO African Region and the WHO South-East Asia Region showed the lowest percentages with 23% and 30% respectively.<sup>3</sup> Farzafdar et al in a study on 199 countries and territories in 2008 found out that the age standardized mean total cholesterol was 4.64 mmol/l for men and 4.76 for women. There was only a slight change in the mean total cholesterol level between 1980 and 2008, declining by less than 0.1 mmol/L in both men and women<sup>5</sup>. According to WHO estimates, dyslipidemia is associated with more than half of the global cause of ischemic heart diseases.<sup>4</sup>

## **b. Burden of dyslipidemia in India**

Increase in burden of CVD is becoming a major concern in developing countries like India.<sup>6</sup> The global burden of diseases study reported the estimated mortality from coronary heart disease in India to be 1.6 million in the year 2000.<sup>7</sup> Estimates reveal that 13% of all deaths in India could be due to CVD.<sup>9</sup> Overall, the prevalence of dyslipidemia in India ranges from 10-73%.<sup>12</sup> Though the burden of diabetes and dyslipidemia in India is mainly contributed by urban population, an increasing trend of dyslipidemia is observed in rural population too. Specifically, it is higher in urban areas (20%) than rural areas (10%) with a clear declining gradient in its prevalence from semi-urban to rural populations.<sup>7,9</sup> Significant difference has been observed in the prevalence of dyslipidemia between the two sexes. A study conducted on urban adult population in Andhra Pradesh concluded that it is higher among males (52.9%) than females (42.9%).<sup>10</sup> Sawant A M et al conducted a study on 1805 urban dwellers and concluded the prevalence of dyslipidemia to be higher in males (38.7%) than females (23.3%). It also found a high prevalence of dyslipidemia among the age group 31 to 40 years among men in Mumbai which suggests that younger people are more prone to develop coronary artery disease (CAD).<sup>11</sup> Another study conducted to find the prevalence of cardiac

risk factors among the age group of 15 to 39 showed an increasing trend of prevalence of risk factors with age.<sup>12</sup> The Indian Council of Medical Research (ICMR) surveillance project reported a prevalence of dyslipidemia of 37.5% among adults aged 15-64 years, with an even higher prevalence of dyslipidemia (62%) among young male industrial workers.

### **c. Burden of dyslipidemia in Kerala**

Kerala is well known for its better health at low cost and as the most advanced state in India in this transition. But, it has a leading trend of non-communicable diseases and its associated risk factors.<sup>8</sup> Mean total cholesterol level in Kerala is paradoxically higher than most of the developed countries of the world.<sup>48</sup> James in his study states that Keralites have dyslipidemia (71%) as the major risk factor for CAD.<sup>47</sup> Mean cholesterol level is around  $203.9 \pm 40.2$ . Sex difference is indicated by a prevalence of total cholesterol >200 mg/dl which is 52.1% in males and 61.4% in females.<sup>49</sup> In an another community based survey to estimate the risk factor profile of chronic non communicable diseases, the estimated Hypercholesterolaemia was 54.1%. The cholesterol level was significantly high in females.<sup>8</sup>

## 2. LITERATURE REVIEW

This chapter includes published literature on dyslipidemia drug adherence and the factors associated with drug adherence. It lists the known factors of dyslipidemia treatment adherence and identified barriers to undergo drug adherence globally, particularly in developing countries. Participants at the WHO Adherence meeting in June 2001 defined adherence to a medication regimen as the extent to which patients take medications as prescribed by their health care providers. The term compliance is often confused with adherence. Compliance refers to the practice of patients passively following the doctor's orders and their treatment plan is not based on any contract between physician and patient.<sup>50</sup>

<sup>51</sup> In developed countries, adherence among the patients suffering from chronic diseases averages only 50%. The impact and magnitude of poor adherence in developing countries is assumed to be even higher, given the paucity of health resources and inequalities in access to health care.<sup>12</sup> Ways by which non-adherence is practiced includes patients failing to initiate the therapy, under using or overusing a drug, stopping a drug too soon and mistiming or skipping doses. By understanding the severity and prevalence of non-adherence, WHO has published an evidence-based guide for clinicians, health care managers and policy makers to improve strategies of medication adherence.<sup>50</sup>

### **Dyslipidemia**

According to NCEP (National Cholesterol Education Program) - ATP III (Adult Treatment Panel) Guidelines, hypercholesterolemia is defined as TC (total cholesterol)  $\geq 200$ mg/dl, LDL-C (low density lipoprotein) as  $> 100$ mg/dl, hypertriglyceridemia as TG (triglyceride)  $> 150$ mg/dl and HDL (high density lipoprotein)-C  $< 40$ mg/dl. Dyslipidemia is defined by presence of one or more than one abnormal serum lipid concentration.<sup>2, 11</sup>

## Management of dyslipidemia

Management of dyslipidemia includes both non-pharmacological and pharmacological measures. Non pharmacological management consists of lifestyle modifications with diet control, weight management and increased physical activity. Pharmacological treatment for dyslipidemia includes statins, bile acid sequestrates, nicotinic acid, and fibric acid.<sup>2</sup> Initiating a pharmacological therapy is mainly based on the risk categories which are listed as follows:

Risk category	LDL to start drug therapy
CHD	$\geq 130$ mg/dl
2 <sup>+</sup> risk factors*	$\geq 130$ mg/dl
0-1 risk factor*	$\geq 190$ mg/dl

### \*Risk factors:

- Cigarette smoking
- Hypertension (BP  $\geq 140/90$  mmHg or on antihypertensive medication)
- Low HDL cholesterol ( $<40$  mg/dl)
- Family history of premature CHD
- Age (men  $>45$  years; women  $>55$  years)

Statins (otherwise known as HMG CoA reductase inhibitors) are one of the most widely used antidyslipidemic drugs. In high versus low statin therapy clinical trial, it was noted that there was an overall 15% reduction in major vascular diseases and procedures, including reduction of 19% coronary revascularization, 16% stroke and 13% nonfatal myocardial infarction events.<sup>13</sup> However, benefits of lipid-lowering drugs are compromised by poor adherence to medication.

## **2.1 Adherence among dyslipidemic patients**

Globally, statin discontinuation rate ranges from 15 to 60 % with greatest variation in low income countries<sup>14,15</sup>. In South India, the statin use among the patients with stroke and coronary heart diseases is very low (3 to 7%) compared to 15% in other countries.<sup>15,16</sup>

## **2.2 Impact of Non Adherence and Economic Burden**

Non adherence is a pervasive health problem. It accounts for substantial worsening of disease, death and increased health care costs. The cost of non adherence in USA is calculated to be around 100 billion annually.<sup>18</sup> The impact of non adherence would be severe in a country like India where the resources are scarce in amount. 100% compliance with treatment will help in reduction of the risk, case, and cost reduction to 13.6%, 0.9 million and 9.3 billion U.S dollar respectively<sup>17</sup>.

## **2.3 Measure of adherence**

The methods employed to assess adherence are of two kinds - direct method and indirect method<sup>19</sup>. Direct method of measuring adherence is based on physiological measures such as serum or urine drug level assays to detect trace levels of medication. In addition to this, total cholesterol, blood pressure, blood glucose level and changes in body weight are also monitored for checking the adherence. However, physical activity, other drugs and several other factors may alter these measures and health outcomes.<sup>20</sup> Indirect methods include prescription refill, pill counts, health professional ratings and patient self reports.

Self reported medication adherence is simple and easy to administer and may provide insight for patient's behaviour. Morisky Medication Adherence Scale (MMAS-8) has a good

predictive and concurrent validity. It might function as a screening tool among chronic disease patients by measuring their specific medication behaviour.<sup>20, 21</sup>

## **2.4 Factors associated with medication adherence**

### **2.4.1 Treatment and Disease Related Factors**

The biggest stumbling block is the complexity of the regimen. One study revealed that patient on once daily scheduled medication regimen are more likely to adhere than patients who are on more frequently scheduled medication regimens.<sup>22, 23</sup> Duration of the disease is another factor associated with adherence. Adherence rates are typically higher in patients with acute conditions; as compared with those in chronic conditions.<sup>24</sup> The number of medications a person takes has a negative impact on adherence. A study shows that the number of tablets / medications taken is inversely associated with adherence rates. In a study to compare adherence rates between patients who have been prescribed a single-pill FDC (fixed dose combination) and those on two-pill regimen. Results demonstrate that after adjusting observed confounders using propensity score method, patients on FDC showed an increase in adherence rates by 12.8% when compared to patients prescribed a 2-pill regimen.<sup>25</sup> Adults aged 65 years and older are taking more number of medications. According to a survey conducted among older age group above 65 years by the American Society of Health-System Pharmacists in 2001, 82% of patients were found to be using at least one prescription medicine while more than 44% take three or four prescription medicine and around 33% take eight or more prescription medicines to treat their health conditions.<sup>26</sup> Adherence also decreases when patient is instructed to follow a special technique in order to take the medications such as using devices to test blood levels as a part of treatment protocol, using inhalers or self-administering injections.<sup>27</sup> Concern about the medication side effects are also

a major cause for not adhering to the medication. Some studies show that high doses of statin intake can cause mild to moderate muscular problems.<sup>29</sup> In a survey of 2507 adults conducted by Harris Interactive in 2005, nearly half of the respondents (45 percent) reported not taking their medicines due to concern about side effects.<sup>28</sup> Patients are less likely to adhere if they have less severe symptoms for the condition for which they are treated.<sup>14</sup> Duration of the treatment also played a major role in adherence. A retrospective cohort study in 2002 conducted among older patients in US showed that persistence with statin therapy declines significantly over time, with maximum drop happening in the first 6 months of treatment.<sup>30</sup>

#### **2.4.2 Co morbidity related factors**

Patients who have other coexisting illnesses in addition to dyslipidemia are less likely to adhere. Evidence from studies show that patients' who had suffered a stroke, demonstrated a gradual increase in statin discontinuation rates up to 39% after 1 year of treatment initiation. Also, patients who were non adherent to statins had a significantly increased mortality during the first year following stroke.<sup>31</sup> Diabetic and other chronic CHD patients have been associated with lower statin discontinuation rates. Another study investigated the effect of adherence to statins following acute myocardial infarction on the recurrence of myocardial infarction and all-cause mortality after a mean follow-up period of 2.4 years. Of 5590 patients who experienced myocardial infarction, 717 (12.8%) experienced at least one further myocardial infarction during the study period. Only 7.7% of patients used the prescribed statin after the first acute myocardial infarction during the study period.<sup>63</sup> Another study done among diabetic patients who were under treatment for cholesterol showed a poor adherence in long term treatment.<sup>32</sup>

### **2.4.3 Patient and demographic related factors**

Adherence is also influenced by age and sex. As age increases, patients tend to forget the dose. In a study conducted among stroke patients, the individual profile of non adherence showed that females and older patients were found to be discontinuing more than other group<sup>21</sup>. The common reason for patient not taking medication is forgetfulness.<sup>31, 33</sup> Literacy, limited English proficiency, ability of patients to read and understand and ability to act on instructions about the medication use can also act as a major factor in patient's adherence. According to one study involving patients who were treated in two public hospitals in the age group above 60 years, 81% were not able to read or understand the basic materials including prescription or labels.<sup>34,35</sup> 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 diabetes<sup>36</sup>. Alcoholism was a major factor that Cox et al examined in 154 older men with diabetes and found that greater alcohol use was associated with poor adherence to insulin injections.<sup>37</sup>

### **2.4.4 System related factors**

People from low socio economic background are less likely to adhere due to the cost of medication. Ellis et al highlighted that the level of patient copayment was an independent factor for statin discontinuation<sup>38</sup>. Since health system is not funding or subsidizing the medication, it can lead to poor adherence. Good relation with and encouragement from clinician was also a major factor that affected the adherence level. Complexity of regimen has affected patient's adherence. Help from system and clinician is very necessary for proper adherence.<sup>39,40</sup> Physicians contribute to patient's poor adherence by prescribing complex regimen, failing to sufficiently clarify the benefits and side effects of a medication, not giving

concern to the patient's lifestyle or the cost of the medications and having reduced therapeutic relationships with their patients.<sup>38</sup> Two major problems in the doctor-patient relationship are the patient's dissatisfaction with the communication aspect of the consultation and the patients not following advice given to them.<sup>41</sup> Stressing the benefits of statin therapy at the time of prescribing as well as discussing potential adverse side effects and their incidence and seriousness, may improve patient's adherence. The patient's perception of the time that his physician spends to explain and to discuss the different aspects of cholesterol and the CVD problem has been directly correlated with a higher compliance.<sup>42</sup>

#### **2.4.5 Patient decisions, attitude and belief**

Certain patients, especially those with chronic conditions requiring long-term therapy may consciously choose not to fill the prescription or not to take their medications as prescribed or may discontinue their therapy. These mainly depend on perceptions about the nature and severity of their illness<sup>40</sup>. Some patients will deny the presence of illness thereby refusing to take medicine. Some of the patients have an assumption that once the symptoms improve, discontinuation of therapy can be done. Media influence regarding safety or risk issues associated with particular medicines can affect the patient's attitude about medication. Worries about the social stigma associated with taking medicines are another main factor.

Patient's belief about the effectiveness of the treatment also plays a major role. Some patients would be reluctant to accept the benefits of taking medications for preventive purposes and for symptomless conditions. Lack of positive motivations and incentives to make necessary changes in behaviour are all contributing factors for non adherence. Perceptions of personal need for medication are influenced by symptoms, outlook and experiences, and by disease cognition. According to the Health Belief Model, 33 patients who had a perceived need to treat their conditions were more likely to take the recommended

medications than those who had no such perception. Awareness about the severity of disease and the treatment has a positive effect on medication adherence as well as on the control of cholesterol level. A study among Americans showed a significant increase in the level of control of cholesterol with increase in level of awareness among the patient over decades.<sup>43</sup>

Locus of control also plays major role in the adherence. Locus of control refers to the belief individuals have in the amount of control they have over their lives. A recent study done in a sample of Iranians concluded that there is a positive association between internal locus of control and adherence to diabetes regimen.<sup>44</sup> Burkhart et al in his study among children with asthma concluded that children who have a positive self-concept are more adherent to their recommended asthma regimen.<sup>45</sup> Studies also demonstrate that patients are more likely to be adherent with therapy after experiencing serious complications due to CVD, potentially due to an increased appreciation of the importance of managing their risk factors.<sup>30,46</sup>

## **2.5 Rationale/justification of the study**

Although there are several studies available on the prevalence of dyslipidemia and its complications, studies showing the adherence pattern to cholesterol lowering medication are comparatively less. Poor adherence to drug for dyslipidemia has been associated with increased economic burden, cardiovascular morbidity and mortality. Only a few such studies have been conducted in India. Co-morbidity, multiplicity, complexity and long-term therapy of medications make the treatment a hard task for the patient. Statin use is substantially low in South Asian countries in comparison with other parts of the world<sup>15</sup>. It can be assumed that cost of drugs could be the most important determinant of non- adherence to cholesterol lowering medication in countries with low Human Development Index including India. In this country, we have a different belief system, alternative medications, cost and support system. Considering all these, the factors associated with medication adherence may not be

the same as that of other countries. Studies show that majority of patients find it difficult to follow the medications prescribed by the physician. So, it is very essential to find the barriers behind the medication non adherence. Non adherence can lead to financial burden to the individual as well as to the health care system of the state. The impact of non adherence in a country like India where the resources are scarce would be overwhelming. There is only a little data available about the treatment adherence of patients with dyslipidemia in Kerala. So there is a need to explore and analyze quantitatively the pattern as well as the factors associating with adherence to cholesterol lowering medication in India.

## **2.6 Objective of the study**

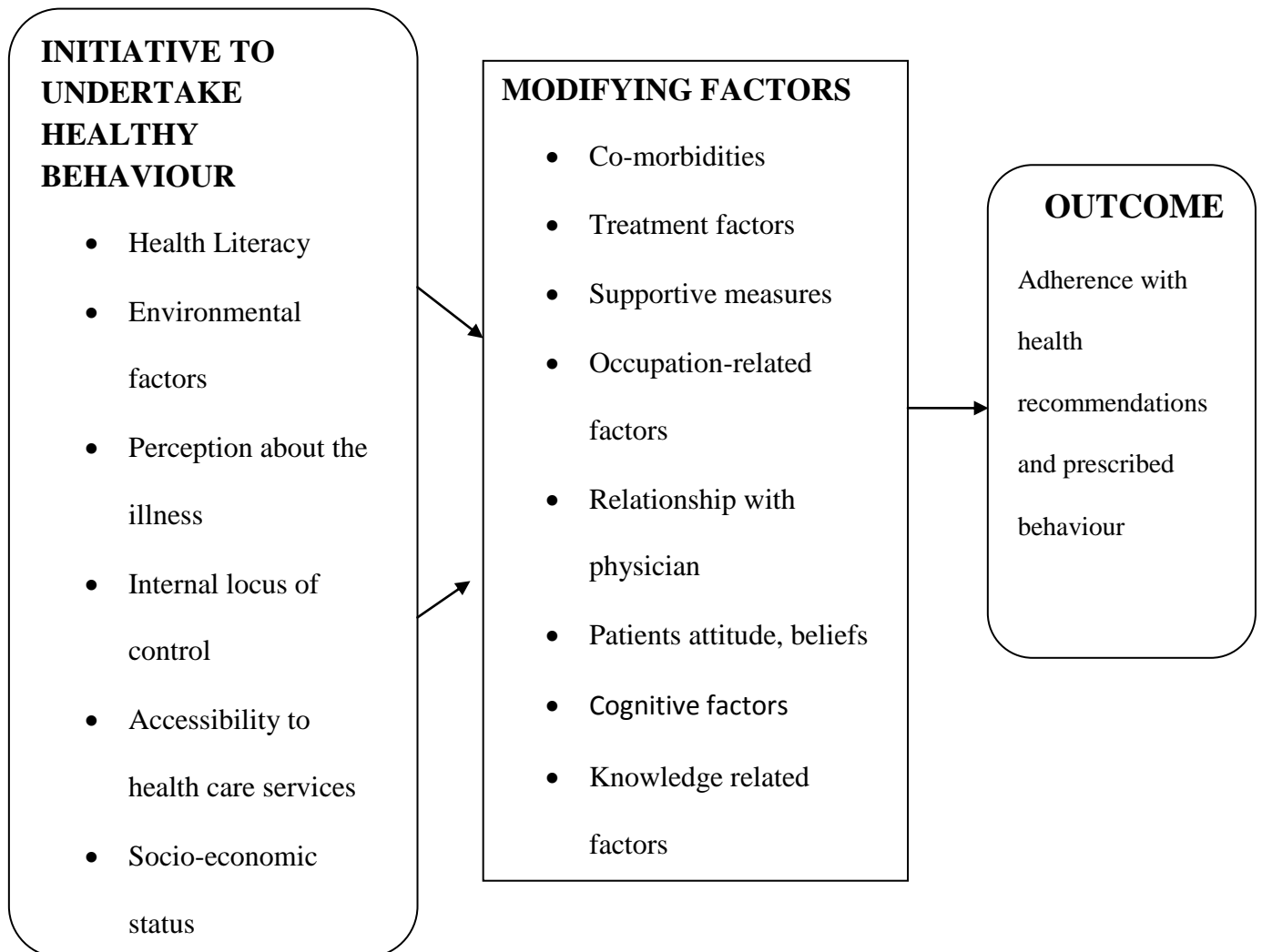
### **Major objective**

1. To estimate the prevalence of medication adherence among dyslipidemia patients in Kottayam district, Kerala

### **Minor objectives**

1. To find the factors associated with medication adherence among dyslipidemic patients.
2. To find the impact of co-morbidities on adherence to medication

**Figure 2.1 - Conceptual frame work**



### **3. METHODOLOGY**

This chapter describes the various methodologies undertaken to do survey and analysis.

#### **3.1 Study design**

Study was a cross sectional survey with multistage cluster sampling technique.

#### **3.2 Study setting**

This survey was conducted in 3 randomly selected Gram Panchayats of Madappally Block, Kottayam district Panchayat, Kerala state. Madappally block Panchayat was selected for the study out of 11 block Panchayats of Kottayam district. From Madappally block Panchayat, 3 Grama Panchayats were randomly selected using lottery method. From each Panchayat, seven wards were randomly chosen, forming a total of 21 wards. From ward, a cluster of 13 subjects was selected.

#### **3.3 Study population**

Self reported dyslipidemic subjects who were between the age group of 35 to 75 were included.

#### **3.4 Inclusion criteria**

Self reported dyslipidemic subjects who had been diagnosed and prescribed medications for at least one year. The subjects had to be willing to participate in the study and a permanent resident of the concerned area.

### **3.5 Exclusion criteria**

Subjects who were debilitating ill that made them difficult to respond. Those who had any kind difficulty to respond to the questions raised were excluded.

### **3.6 Sample size**

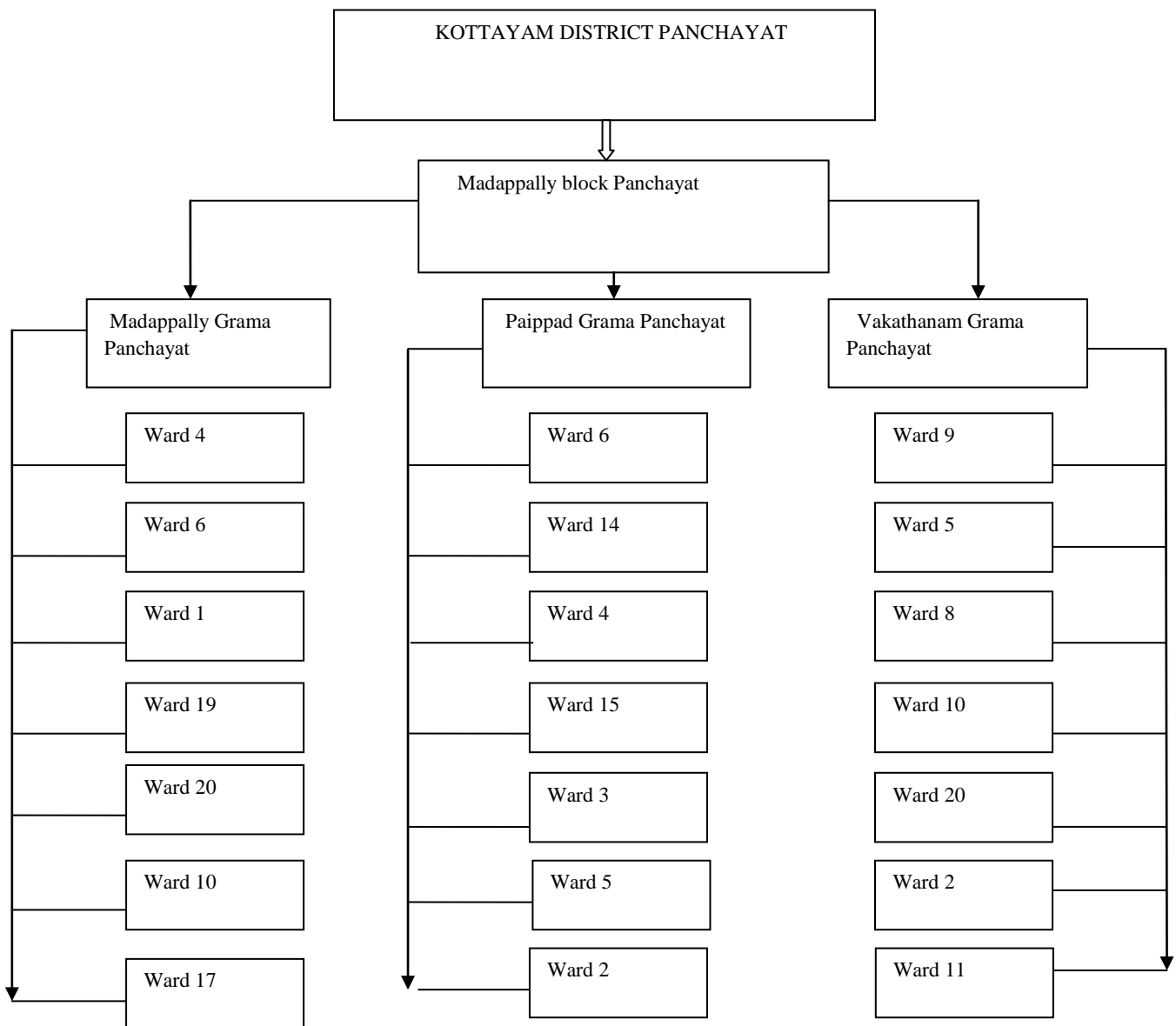
Sample unit: Every subject in each ward

Final sample size: From various world studies, the anticipated proportion of highly adherent patients varies from 4 to 15 %. Sample size was calculated using Open Epi version 3. With an anticipated prevalence of adherence 5%, 4% precision, 80% power and design effect of 2.0, the sample size was calculated to be 229. Considering a non response rate of 19%, the final sample size came out to be 273. Estimated sample size was 273 across 21 clusters, with 15 subjects in each cluster.

### **3.7 Sample selection procedure**

In first stage of procedure, Madappally block Panchayat from Kottayam district Panchayat was selected out of convenience. During the second stage of sample selection, 3 Grama Panchayats from Madappally Block Panchayat were selected using lottery method. Seven wards from each Grama Panchayat were selected through lottery method in third stage. The identified Panchayats were Madappally, Paippad, and Vakathanam. Each ward was taken as a cluster. From each selected cluster, 13 self reported dyslipidemic patients were identified using W.H.O cluster sampling technique. The centre portion of the ward was identified with the help of local person; lottery method was used to select the street of survey. Once after identifying the street, continuous house hold visit was done till the required sample was achieved.

**Figure 3.1 Sample selection procedures**



### 3.8 Data collection procedure

Data collection tools:

1. Structured interview schedule
2. Morisky Medication Adherence Scale (MMAS-8-Item)

Data collection was done using structured questionnaire for identifying the factors associated with medication adherence and Morisky Medication Adherence Scale (MMAS-8-Item) was used to measure the medication adherence among the subjects. The scale had a reliability of  $\alpha=0.83$  and was importantly used in blood pressure control.<sup>62</sup> Morisky Medication adherence scale (MMAS-8-Item) is a validated scale in India and have already been used for assessing the adherence among several other chronic non communicable diseases conditions. It consisted of seven binary version questions and one likert type question (response question). The questionnaire and Morisky medication adherence scale was translated into local language (Malayalam) and back translated till the back translated version matched the original version. Data collection period extended from June 28 to September 28. The whole data was collected by the principle investigator himself.

The interview schedule has seven sections.

1. Section 1: Socio and demographic factors:
2. Section 2: Morisky Medication adherence scale (MMAS-8-Item)
3. Section 3: Behavioural factors
4. Section4 : Co morbidity related factors
5. Section 5: Cost related factors

6. Section 6: Therapy and system related factors
7. Section 7: Support related factors
8. Section 8: Patient related factors

### **3.9 Data collection process**

**Table 3.1 Summary of sample recruitment process**

Number of Panchayats	3
Number of wards	21
Number of houses visited	712
Number of eligible	273
Number willing to participate	270
Number of subject interviewed	270

### **3.10 Variable under the study**

#### **3.10.1 Definition of the variables**

*Subject:* A self reported dyslipidemic patient who had been under treatment for more than one or more than one year.

*Household* was defined as those who shared the same kitchen

#### **3.10.2 Operational definition**

*High adherence:* high medication adherence among dyslipidemic patients, that is with a score equal to 8 on Morisky Medication Adherence Scale.

*Poor adherence:* medication adherence among dyslipidemic patients who had a score of less than 8 on Morisky Medication Adherence Scale was considered poorly adherent.

### **3.10.3 Outcome variable**

A dyslipidemic patient who is highly adherent to medications with a score of 8 in Morisky Medication Adherence Scale

### **3.10.4 Measurement of medication adherence**

Measurement of drug adherence among dyslipidemic patients was done using Morisky medication adherence scale. In the scale, about three fourth of the responses had to be completed for the eligibility of participation. This scale is used among many of the chronic diseases. Persistence and compliance to medication was measured using this scale. Questions in the scale are divided to assess the knowledge and motivation. Total score of the scale is 8. The score less than 8 were categorized as poor adherence and equal to 8 as high adherence.

## **3.11 Predictor variable**

### **3.11.1 Socio and demographic factors**

Age, sex, marital status, household members, education status, occupation and type of floor in the house as proxy for the socio economic status of the house

**Age:** There are chances that adherence level changes according to the age and can affect health behavior.

**Sex:** Sex is one of the most important determining factor. Females are one of the most neglected group and this could be a determining factor.

**Marital status:** Sticking to the treatment plan might be affected by the presence of spouse, as the help and support obtained from spouse could increase the adherence.

**Type of family:** Comparatively, less support was seen for taking care of the health among nuclear families.

**Educational status:** High education might lead to good adherence as people would have more awareness and knowledge about the disease condition

**Occupation:** Depending on the occupation status and earnings, medication adherence varies across people. Unemployed had a less chance of being adherent unless they had any other external support. Informal employees work for their daily living and may not have any social security that also can affect compliance. In case of formally employed, they might have some kind of health insurance or system which increases the chance of them being more adherent.

**Socio economic status:** This can be major factor in adherence, Economic status may affect pattern of being adherent. In this study, type of flooring used in the house was used as a proxy to find out the socio economic status of the family. Since, there are chances that people may not reveal the exact status out of fear. People from low socio economic status have more chances of being poor adherent due to non affordability.

### **3.11.2 Dyslipidemia factors**

**Initial detection of dyslipidemia:** Subjects who were diagnosed during serious health conditions such as Heart diseases or stroke might be more concerned about their lipid level. So, they have more likelihood to be adherent. On the other hand, subjects diagnosed to have dyslipidemia during regular checkups or during any less severe conditions might be lead to low adherence.

**Duration of the treatment:** People who are in acute stage are more likely to be adherent during the initial days. But as time goes on, their level of adherence might come down. In case of chronic patients they might be high adherent as medicines have been added in their daily routine.

**Number of medications:** In most of the studies, it was shown that the number of medications is inversely proportional to the level of adherence.

**Individual perception and characteristics:**

Concepts about the medication such as medicine is not effective and diseases could be cured using folk remedies can shift people from being adherent. Skipping / reducing the dosage of medicine at the time of their intake is a common trend found among many people. Some patients feel that the timing of medicine is not much important.

**3.11.3 Life style risk factors of NCDS:**

Habits such as alcoholism and tobacco use can adversely affect the use of medicine. Exercise and dietary control can also affect the medication adherence in some way. Some may purposefully avoid medication perceiving that, with the control over diet or with proper exercise, one could actually manage dyslipidemia.

**3.11.4 System related factors**

Relationship with the health care providers, distance to health care facility and types of health systems used can also affect the medication adherence. Sometimes people might find it difficult to acquire medication.

### 3.11.5 Family related factors

Subjects who have someone to remind or care them have a more chance to show high adherence. In order to assess this, questions about reminding to take medicine and someone to accompany to health care facility was asked.

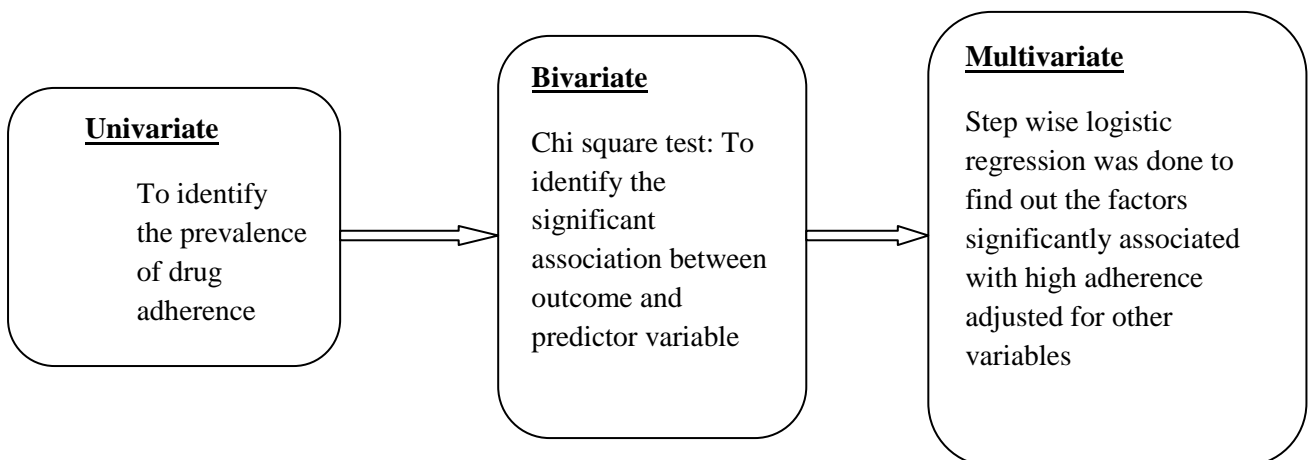
### 3.11.6 Subject related factors

Some subject related factors such as physical difficulties and cognitive factors like sensory loss, memory deficit and mood swings can affect the adherence of the subject.

## 3.12 Data entry and plan analysis

Data entry was done in Epidata software. Further, the entered data was exported to MS Excel for data cleaning purposes. After cleaning the data, it was imported into IBM SPSS Version 17 software for further analysis. The data was analyzed for prevalence of drug adherence and univariate descriptive study of all variables was also done. Then, bivariate and multivariate analyses were done to determine the significance and the strength of association between several factors and high adherence.

**Figure 3.2 Plan of analysis**



### **3.13 Ethical clearance**

#### **3.13.1 Confidentiality**

The identities of subjects were kept anonymous from the initial stage of data collection. In the entry form, only the dummy ID number was kept.

#### **3.13.2 Privacy**

The interview was conducted in subjects' home. Visual and auditory privacy was kept to the maximum extent possible.

#### **3.13.3 Consent**

Informed written consent was obtained from every subject prior to the start of interview [in local dialect – Malayalam] after being read, understood and all doubts were clarified to the subject. The subjects had the freedom to refuse at the outset or even withdraw from the study at any stage. No requests for monetary benefits or favors in any form was given, only the referral and health and safety related counseling services was entertained if demanded by subject or others related.

#### **3.13.4 Referral**

The subject, who was poor adherent were advised or made aware about essentiality of the medication adherence. The patients who needed further reference were directed to the local government hospital.

With all the above considerations, approval for the study was obtained from Institutional Ethics Committee or Review Board [IRB] of the Sree Chitra Tirunal Institute for Science and Technology.

## 4. RESULTS

This chapter briefly describes the outcome of data analysis in concordance with the objective. The survey started on June 28 and was completed by September 28 .The total samples collected were 270. The mean age of population was  $57.53 \pm 9.65$ . Out of 272 subjects approached about 270 were ready to participate in the study thus achieving a response rate of 98.2%.

### 4.1 Socio- demographic characteristics

Table 4.1 describes the socio demographic characteristics of the population. The characteristics of sample were categorized according to sex. Out of total respondents, 58% were females. Majority of the subjects belonged to 55-64 age group. Eighty eight percent of subjects were married while only a few were single/ widowed which were mostly females. Subjects belonged either to nuclear or joint family in equal proportion, with more of males in nuclear family. Educational status was grouped into two categories based on secondary education. More than three-quarters of subjects had education status belonging to below secondary status with majority of females. Manual laborers, formal employment, professional, any kind of small business, owning a farm or any other working class were categorized under Employed. A greater part of females were unemployed while the employed section was contributed by a negligible number of 5%. Fifty five percent of the subjects were from middle income family while only 11 % belonged to high income and 32 % to low income families.

**Table 4.1 Socio demographic variables**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Age group</b>			
35-44	10(6.4)	15(13.2)	25(9.3)
45-54	43(27.6)	36(31.6)	79(29.3)
55-64	60(38.5)	28(24.6)	88(32.6)
65-74	43(27.6)	35(30.7)	78(28.9)
<b>Marital status</b>			
Married	131(84.0)	109(95.6)	240(88.9)
Single /widowed	25(16.0)	5(4.4)	30(11.1)
<b>Type of family</b>			
Nuclear	76(53.9)	65(46.1)	141(52.2)
Joint	80(51.3)	49(38.0)	129(47.8)
<b>Education</b>			
Below secondary	124(79.5)	71(62.3)	195(72.2)
Above secondary	32(20.5)	43(37.7)	75(27.8)
<b>Occupation</b>			
Unemployed	147(94.2)	71(62.3)	218(80.7)
Employed	9(5.8)	43(37.7)	52(19.3)
<b>Socio-economic status</b>			
High income	20(12.8)	12(10.5)	32(11.9)
Middle income	81(51.9)	70(61.4)	151(55.9)
Low income	55(35.3)	32(28.1)	87(32.2)

## 4.2 Treatment related factors

In Table number 4.2 treatment related factors are given. Nearly three fourth of patients detected themselves to have dyslipidemia initially when screening was done for other diseases or for surgery. Mostly females were diagnosed during their routine checkup. Sixty four percent of the subjects were on dyslipidemic drug since three or more years. Fifty six percent of people consumed tablets which had a cost of Rs.5 or more. Costly drugs were comparatively taken more by males. Most of the subjects monitored their blood irregularly with males more than females.

**Table 4.2 Treatment related factors**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Initial detection of dyslipidemia</b>			
During regular check up/signs and symptoms	60(38.5)	34(29.8)	94(34.8)
During screening for other diseases/surgery	96(61.5)	80(70.2)	176(65.2)
<b>Duration of treatment</b>			
Less 3 years	60(38.5)	36(31.6)	96(35.6)
3 or more years	96(61.5)	78(68.4)	174(64.4)
<b>Rate of per tablet</b>			
More than 5 Rs	84(53.3)	68(59.6)	152(56.3)
Less than or equal to 5 Rs	72(46.2)	46(40.4)	118(43.7)
<b>Lipid monitoring</b>			
Irregular	98(62.8)	78(68.4)	176(65.2)
Regular	58(37.2)	36(31.6)	94(34.8)

### 4.3 Co-morbidities related factors

Details of co morbidities are given on table no 4.3. One of the secondary objectives was to find out the impact of co-morbidities on drug adherence in dyslipidemia. Almost 87 percent reported having other co-morbidities. Co-morbidity profile of males had a greater percentage than females. Sixty three percent of dyslipidemic patients had hypertension and forty three percent had diabetes. Thirteen percent were suffering from some other diseases like rheumatic fever, osteoporosis and breast cancer.

**Table 4.3 Co morbidities**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Co morbidities</b>	136(87.2)	99(86.8)	235(87.0)
<b>Heart diseases</b>	28(17.9)	37(32.5)	65(24.1)
<b>Diabetes</b>	60(38.5)	58(50.9)	118(43.7)
<b>Hypertension</b>	97(62.2)	73(64.0)	170(63.0)
<b>Brain and nervous system</b>	6(3.8)	13(11.4)	19(7.0)
<b>Thyroid disease</b>	29(18.8)	3(2.6)	32(11.5)
<b>Others disease</b>	26(16.7)	10(8.8)	36(13.3)

**4.4 Behavior related factors**

This table describes the substance use among the subjects. Seventeen percent were current users of tobacco. Half of the male subjects were using alcohol. More than three-fourth of the subjects were not physically active. Seventy percent of the subjects were not following any kind of control in their diet.

**Table 4.4 Behavior related factors**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Tobacco use</b>			
Current user	10(6.4)	38(33.3)	48(17.8)
<b>Alcohol use</b>			
Current user	3(1.9)	57(50.0)	60(22.2)
<b>Physical activity</b>			
Not active	136(87.2)	78(68.4)	214(79.3)
Active	20(12.8)	36(31.6)	56(20.7)
<b>Diet control</b>			
Not following	116(74.4)	75(65.8)	191(70.7)
Following	40(25.6)	39(34.2)	79(29.3)

## 4.5 Knowledge and perception related factors

About twenty eight percent of the sample subjects perceived that medication prescribed to them were costly. This proportion was higher among females. Half of the samples were not aware of the future complications of dyslipidemia with major share from females. Nearly, three fourth of the subjects were worried about the side effects that medicines might cause if they took it for a longer duration. Females had more concern about the side effects that drug can cause.

**Table 4.5 Knowledge and perception related factors**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Perception about cost</b>			
Costly	54(34.6)	24(21.1)	78(28.9)
Not costly	102(65.4)	90(78.9)	192(71.1)
<b>Knowledge about future complication of dyslipidemia</b>			
Don't know	84(53.8)	35(30.7)	119(44.1)
Adequate knowledge	72(46.2)	79(69.3)	151(55.9)
<b>Awareness about side effects of drug</b>			
Aware	125(80.1)	79(69.3)	204(75.6)
Not aware	31(19.9)	35(30.7)	66(24.4)

## 4.6 Family support

Table 4.6 shows the family support that subjects received by reminded to take medicine or accompanying to health care facility. About thirty percent had someone to remind them for the intake of medicine, that too mostly males. About sixty percent of females had someone to accompany them to health care facility.

**Table 4.6 Family support**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Remind to take medicine</b>			
No	103(66.0)	60(36.8)	163(60.4)
Yes	53(34.0)	54(47.4)	107(39.6)
<b>Accompany for going to health care centre</b>			
No	64(41.0)	56(49.1)	120(44.4)
Yes	92(59.0)	58(50.9)	150(55.6)

#### **4.7 Health system factors**

Table number 4.7 details about the various health system factors explained across both the sexes. Nearly three fourth of the subjects were utilizing private treatment facilities for their health needs, almost similar between both the sexes. Seventy one percent of the sample had to travel more than 1 km to reach their nearest health care facility. Regarding the explanation of the prescribed medicines to subjects, about ninety three percent of the sample received explanation from physicians on how to take medicine. Ten percent of the subjects were using alternate health care systems such as Homeopathy and Ayurvedha for their treatment. Insurance and other support was present only for nine percent; rest of the others depended on other family members or took it out of their own pocket.

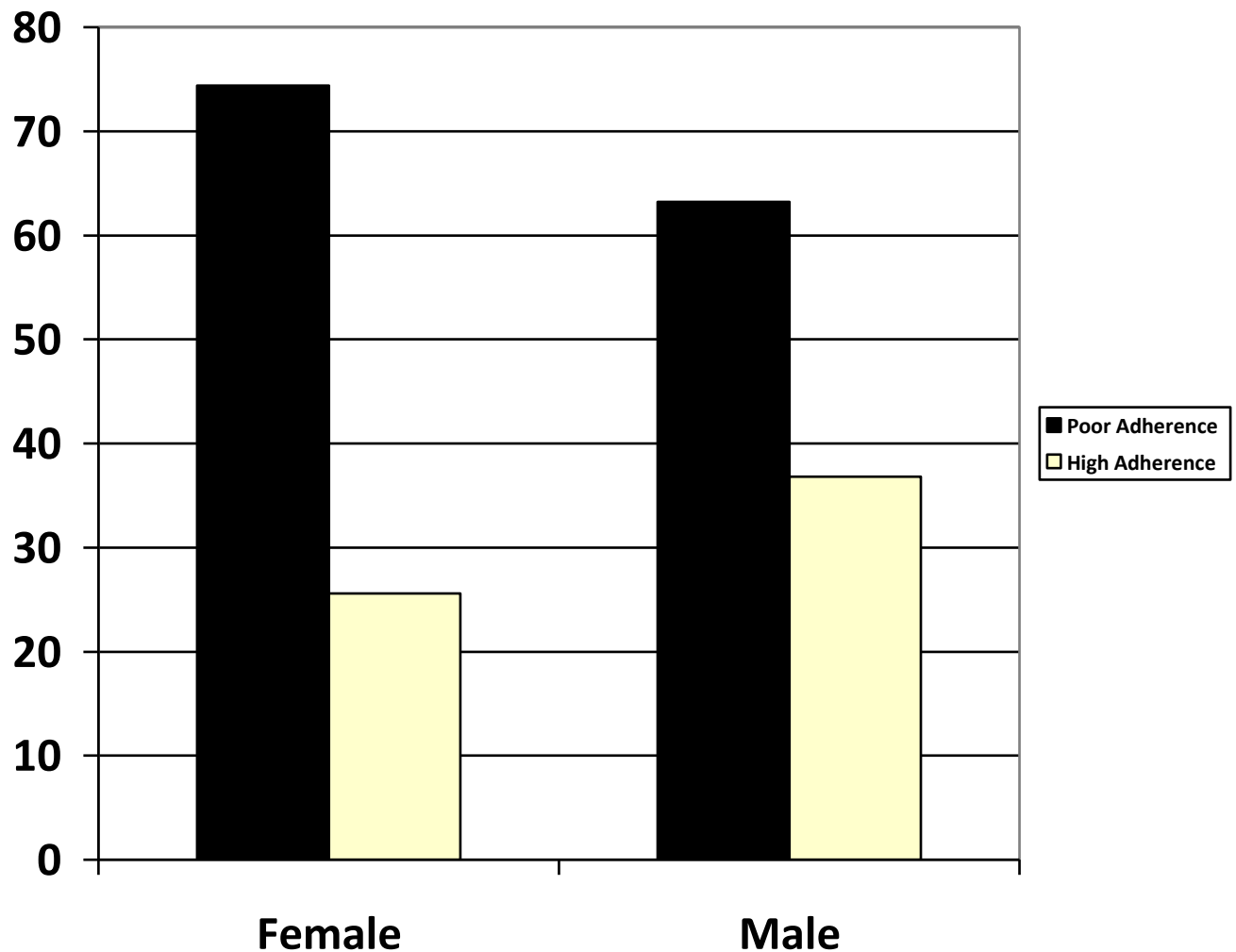
**Table 4.7 Health system factors**

<b>Variable</b>	<b>Female N (%)</b>	<b>Male N (%)</b>	<b>N=270(%)</b>
<b>Health facilities utilized</b>			
Government facilities	42(26.9)	30(26.3)	72(26.7)
Private facilities	114(73.1)	84(73.7)	198(73.3)
<b>Distance to nearest health facilities</b>			
≤1 km	47(30.1)	31(27.7)	78(28.9)
>1 km	109(69.9)	83(72.8)	192(71.1)
<b>Explanation about prescription</b>			
No	11(7.1)	6(5.3)	17(6.3)
Yes	145(92.9)	108(94.7)	253(93.7)
<b>Utilization of other health system</b>			
Other system	22(12.8)	7(6.1)	29(10.7)
Allopathy only	134(85.9)	107(93.9)	241(89.3)
<b>Mode of payment for medicine</b>			
No insurance /assistance	147(94.2)	99(86.8)	246(91.1)
Insurance /other support mechanism	9(5.8)	15(13.2)	24(8.9)

#### **4.8 Prevalence of drug adherence among dyslipidemic patients**

Out of 270 subjects identified only a minor proportion were found to be drug adherent. The prevalence of drug adherence was high among males. Seventy four percent of the females were poor adherent to their dyslipidemia medication.

**Figure 4.1 Prevalence of drug adherence among dyslipidemic patients**



#### **4.9 Prevalence of dyslipidemia drug adherence across age group**

Prevalence of drug adherence was found to be high among the age group between sixty five and seventy four for both the sexes. As age increases, adherence also increases, it shows a correlation between age and adherence.

**Table 4.8 Prevalence of dyslipidemia drug adherence across age group**

Age categories	Females		Males	
	Poor adherent N (%)	High adherent N (%)	Poor adherent N (%)	High adherent N (%)
35 to 44	8 (6.9)	2(5.0)	14(19.4)	1(2.4)
45 to 54	33(28.4)	10(25.0)	24(33.3)	12(28.6)
55 to 64	46(39.7)	14(35.0)	18(25.0)	10(23.8)
65 to 74	29(25.0)	14(35.0)	16(22.2)	19(45.2)

#### **4.10 Bivariate analysis: High adherence with specific factors**

High adherence was considered to be the outcome variable. Proper adherence would prevent the complication of dyslipidemia. Bivariate analysis was done to find out the factors associated with high adherence. P value less than 0.05 was considered significant. There were five significant predictor variables that became significant, when they were unadjusted with other predictor variables.

##### **4.10.1 Sex and adherence**

In bivariate analysis of socio demographic factors against high adherence, sex came out to be a significant factor. High adherence was significantly more in males compared to females. Males had 1.69 times more chance to be high adherent.

**Table 4.10.1 Sex and adherence**

<b>Variables (N=270)</b>	<b>High adherence N(%)</b>	<b>Crude Odds ratio (95% CI)</b>
<b>Sex</b>		
Females (n=156) <sup>Ref</sup>	40(25.6)	1.69(1.00 to 2.85)
Males (n=114)	42(36.8)	

#### **4.10.2 Treatment and co morbidities related factor**

In treatment related factors, people who regularly monitored their blood lipid levels had 2 times more chance to become a higher follower of medication compared to subjects who did not monitor regularly. In case of subjects with one or the other co morbidities, they had two times more chance to be adherent than others who did not have. Cardiac patients and patients suffering from brain and nervous system related diseases showed three and two times respectively more chance to become high adherent.

**Table 4.10.2 Regular lipid monitoring and adherence**

<b>Variables (N=270)</b>	<b>High adherence N (%)</b>	<b>Odds ratio (95% CI)</b>
<b>Regular lipid monitoring</b>		
Irregular (n=176) <sup>Ref</sup>	42(51.2)	
Regular month(n= 94)	40(48.8)	2.36(1.38 to 4.03)

**Table 4.10.3 Co morbidities and adherence**

<b>Variables (N=270)</b>	<b>High adherence N(%)</b>	<b>Odds ratio(95% CI)</b>
<b>Any other Co morbidities</b>		
No (n=35) <sup>Ref</sup>	5(14.3)	
Yes (n=235)	77(32.8)	2.92(1.09 to 7.83)
<b>Diabetes</b>		
No (n=152) <sup>Ref</sup>	38(25.0)	
Yes (n=118)	44(37.3)	1.78(1.05 to 3.01)
<b>Cardiac diseases</b>		
No (n=205) <sup>Ref</sup>	49(23.9)	
Yes (n=65)	33(50.8)	3.28(1.83 to 5.88)

### 4.10.3 Behavioral/ perceptual factors

In behavioral and perceptual related factors, people who have the perception that medication are costly have three times more chance to be highly adherent than others who perceive them to be less costly.

**Table 4.10.4 Perception about cost and adherence**

Variables (N=270)	High adherence N (%)	Odds ratio (95% CI)
<b>Perception about cost</b>		
Costly (n=78) <sup>Ref</sup>	12(14.6)	3.156 (1.60 to 6.24)
Not costly(n=192)	70(36.5)	

### 4.10.4 Knowledge related factors

In the assessment of subjects' knowledge about complications of dyslipidemia, those who had adequate knowledge were found three times more likely to adhere.

**Table 4.10.5 Knowledge about complication and adherence**

Variables (N=270)	High adherence N (%)	Odds ratio (95% CI)	P value
<b>Knowledge about complication</b>			
Don't know(n=119) <sup>Ref</sup>	19(16.0)	3.76(2.09 to 6.78)	<0.001
Adequate knowledge(n=151)	63(41.7)		

### 4.11 Predictors of high adherence: results of multivariate analysis

Multivariate logistic regression was done in step wise manner with predictor factors. Step one to step four enter method was used with alpha value less than 0.5. In the final model Backward LR method was used with alpha less than 0.05.

### **Steps 1 Enter method**

In the first step, socio demographic variables such as sex, age, marital status of subjects, educational status, socio economic level and employment were taken into the model and enter method was used. Covariates with P value less than 0.1 were taken to the next step of analysis. Among those co- variables, sex, age, and education status were found to have P value less than 0.1.

### **Step 2 Enter method**

During the second step, covariates such as treatment related factors and co morbidities were included along with the significant factors from the step one. Sex, Education, Age and any other co morbidities were found to be significant.

### **Step 3 Enter method**

Along with the significant factors from step two, all behavioral, knowledge, perception, and family support factors were added. This included tobacco use, alcohol use, physical activity, dietary habits, family support, knowledge about complications and drug adverse effects. Out of this, age, co morbidities, knowledge about future complication of dyslipidemia came out to be significant.

### **Step 4 Enter method**

In this step, health system factors were added to the significant factors from the previous step. Types of health facility, distance from the nearest health facilities, explanation about treatment and related factors, types of other health system and payment mechanisms were added. Many co variants including co morbidities, knowledge about future complication of dyslipidemia, memory loss and types of medical system came out to be significant.

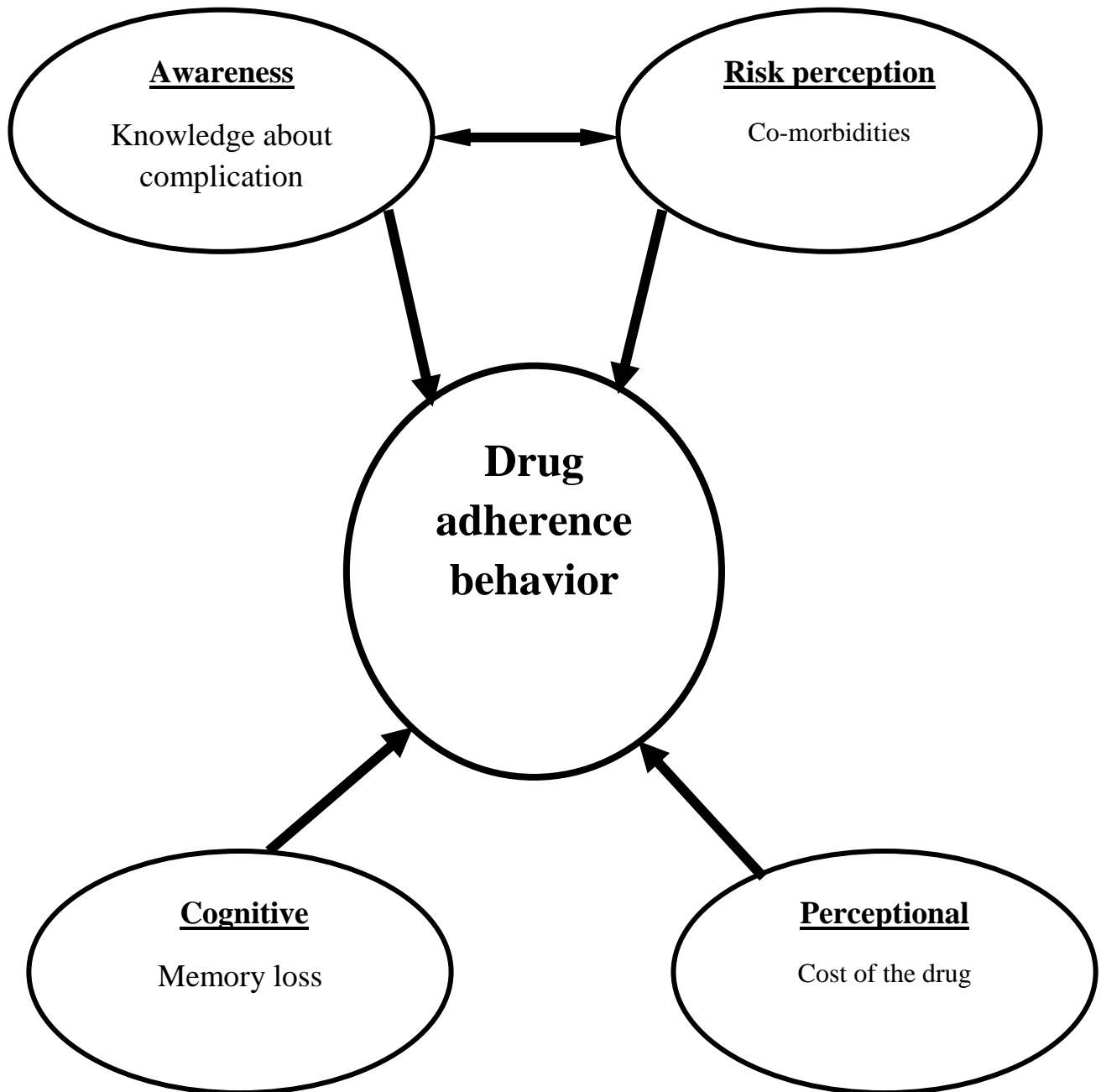
### Final model Backward L.R

All the significant factors from step 4 were included to the final model. Backward L.R method was used to analyze this step. Predictors which had a P value less than 0.05 was considered to be significant at this level. Presence of some or the other co morbidities was found to be significantly associated with high adherence. People with any other co morbidities were found to be 5 time more likely to be adherent. Subjects with adequate knowledge about future complications of dyslipidemia were three times more likely to adhere to medication. Memory loss also found to be significant with an odds ratio of 1.9. Another factor was the perception about cost. The subjects who perceived that medicines are cheaper were two times more

**Table 4.11.1 Factors associated with High adherence: Results of multiple logistic regression analysis.**

Variables	Adjusted odds ratio	95% CI
<b>Co morbidities</b>		
No <sup>Ref</sup>		
Yes	5.09	1.76 to 14.7
<b>Knowledge about future complication of dyslipidemia</b>		
Less knowledge <sup>Ref</sup>		
Adequate knowledge	3.45	1.85 to 6.407
<b>Perception about cost</b>		
Not costly		1.36 to 5.77
Costly <sup>Ref</sup>	2.8	
<b>Memory deficit</b>		
No	1.91	1.07 to 3.43
Yes <sup>Ref</sup>		

**Figure 4.2 Factors associated with High adherence: Results of multiple logistic regression analysis.**



## 5. DISCUSSION AND CONCLUSION

Lipid abnormalities have become one of the known major risk factors of premature coronary artery disease since a few decades.<sup>10</sup> In India, coronary heart disease and stroke are higher in Southern and Eastern India respectively. There are several risk factors for CVDs, majority of which are completely amenable. CVDs can be totally prevented using proper medication.<sup>7</sup> The increase in aged population and predominant western culture, combined together forms high level of dyslipidemia in population leading to increased incidences of cardio vascular diseases.<sup>53</sup> Statins are highly recommended for both primary as well as secondary prevention of cardio vascular diseases.

In the present study, major objective was to estimate the prevalence of drug adherence among dyslipidemic patients. Thirty percent of the study population was found to be taking their drugs properly, mostly males. In a prospective epidemiological study to assess the use of secondary preventive drugs for CVDs in Karnataka in India, it was found that only 3.5% of people were taking medicine properly. This was not in congruent with the present study, which could be attributed to the different methods used to assess the adherence level or due to geographical variation. A systematic study on statin discontinuation across different countries showed that the discontinuation rate varied from 15 to 60 %.<sup>14</sup> Several other studies conducted in Kerala on chronic diseases such as diabetes had an almost similar prevalence of drug adherence of twenty six percent.<sup>52</sup> Another drug adherence study conducted in United States using the same tools for evaluating adherence was estimated to have an almost same prevalence of 51.7% drug adherence among hypertension patients.<sup>53</sup> Demographic characters were not found to be significantly affecting the adherence even though there was a slight variation in the adherence pattern with different education status, employment and marital status. Similar kind of finding was stated in the field of epilepsy drug adherence research.

Many of the investigators in epilepsy field could not find much co relation between the demographic characteristics and different measures of compliance.<sup>54</sup>

### **5.1 Co morbidities**

In the present study, one of the most important factors that influenced adherence was the presence of co-illness. Subjects with any existing co-morbidities were found to be significantly adherent. Diabetic, cardiac, brain and nervous system patients were some among them. In a study conducted on coronary prevention in West Scotland, it was found that people who had a history of regular medication for other diseases were more compliant to their treatment regime than others.<sup>55</sup> This could be due to the fact that such chronic disease patients have already been acquainted with their long course of treatment.<sup>55</sup> Subjects having prior experience to serious complications such as cardiac disease, brain and nervous system disorders had more adherence. Researchers found that, subjects who knew that they were prone to develop serious complications need not necessarily be compliant to medication. In a study among glaucoma patients, only 42 percent of patients were proper adherent to medication despite after the clear instructions were given on complication of glaucoma which could arise due to non-adherence. But in the same study, patients who had gone blind in one eye showed a 52 percent increase in compliance. These are all based on the concept of perceived risk.<sup>56</sup> Models of health behavior proclaims that the health protective behavior occurs due to the anticipation of negative outcome along with the hope of avoiding such an outcome. The anticipation of negative health outcome includes the feeling that one is personally susceptible to some disease which when coupled with the anticipation of severity of disease becomes a very strong motivator.<sup>57</sup>

## 5.2 Knowledge related factors

Knowledge about the future complication of dyslipidemia was another main factor that determined the level of adherence among the subjects. Forty four of the patients did not have adequate knowledge about the future complications of dyslipidemia. Subjects who had adequate knowledge about the future complication of dyslipidemia showed higher adherence than others. Knowledge deficit was found to be higher in females. Such kind of a finding was surprising in a state with almost percent literacy. It clearly indicates that the successful management of dyslipidemia depends on adequate awareness of the condition by the patients themselves. Gulabani's study among diabetes patients in a tertiary hospital of South India found that, patients' knowledge regarding the treatment and complication of diabetes were threateningly low, with comparatively less knowledge among female patients.<sup>58</sup> A randomized controlled trial was done in Canada to find out the effectiveness of calculating informed coronary risk profile on dyslipidemia therapy. It was shown that, patients who were informed about their coronary risk profile calculation showed an achievement in their lipid target compared with those who received the usual care. It was also concluded that discussing the coronary risk profile with patients can enhance their adherence towards statin therapy.<sup>59</sup> The office of U.S Surgeon General estimates that more than ninety million Americans cannot understand even the basic health information which leads to loss of billions of dollars for health system due to the building up of further complications.<sup>56</sup> Educational status had a significant relation with knowledge about complication of dyslipidemia in the current study. Low health literacy and lack of English literacy were one of the major barriers in accessing health information. Hence, teaching aids and patient education programs must be incorporated to enhance effective oral communication between health care providers and patients.

### **5.3 Perceptual factors**

Another important factor that determined high adherence was ones' own feeling / perception about the cost of medication that they are taking. Subjects who felt that medication which was given to them are costly were found to be less adherent compared to the others. Medical models on health behavior explains cognitive and perceptual factor as one of the major factors affecting the level of adherence. Financial distress was a major component of cognitive and perceptual factor. In Dodrill's study among adult epilepsy patients, compliance was not related to actual cost of medication. Instead, adherence was related to the perception of financial distress .Those who had less distress were found to more adherent.<sup>54</sup> In a study conducted among the Americans to find the influence of different types of health insurance and its status on self reported medication use, it was found that the patients who had some kind of insurance had a good adherence compared to non insured patients. Many of the subjects reported that medication underuse was due to cost related difficulties.

### **5.4 Cognitive factors**

Cognitive factors like memory deficit among subjects were another factor which was significantly associated with high medication adherence. Patients who reported memory deficit were found to be poor adherent compared to others. Memory loss and several kind of other complex cognitive disorders are often found among older patients. In a cross sectional study among independently living elders to find out their ability in being adherent, it was found that subjects even very mild or moderate cognitive impairment showed low medication adherence. The complex process of medication intake is severely influenced by the impairment in multiple cognitive functions. Seven days reminder box or instrumented pills are some of the strategies to tackle such issues. Hence, making them understand the early

signs of degeneration and taking adequate measures to make the elderly cope with their disabilities are very crucial in maintaining their compliance.

### **Strengths of the study**

- Medication adherence was assessed using MMAS which is a standard scale
- This was a community based study, thus increasing its validity .
- Chances of inter observer bias is minimized as data collection was done by a single investigator.

### **Limitations of the study**

- Since survey was done during working days, possibility of selection bias.
- Many of the variables were self reported which could lead to over reporting or under reporting

### **Conclusion**

The present study looks at the prevalence and factors associated with the drug adherence among dyslipidemia patients. In a state where more than half of the population is affected with lipid abnormalities, medication adherence was drastically low. There were several factors associated with the medication adherence such as the presence of co illness, Knowledge, perceptual and cognitive related factors. These factors showed a serious failure in the dimension towards prevention of cardio vascular diseases in a state with the high ranking of health index and accessibility. Immediate efforts are required to tackle this situation. Multiple kinds of processes are required to improve the drug adherence such as to provide proper health education focusing on preventive aspect as well as financial support for the care. Such acts might prevent future complication thereby reducing costs of health care and eventually turns out to be reducing morbidity and mortality in the long run.

## REFERENCES

1. World Health Organisation. World Health Statistics report 2012. Available from: [http://www.who.int/gho/publications/world\\_health\\_statistics/2012/en/](http://www.who.int/gho/publications/world_health_statistics/2012/en/). Accessed on April 17, 2013.
2. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). JAMA 2001; 285: 2486–97.
3. World Health Organization. Global status report on non communicable diseases. 2010. Available from: [http://www.who.int/nmh/publications/ncd\\_report\\_full\\_en.pdf](http://www.who.int/nmh/publications/ncd_report_full_en.pdf). Accessed on April 20, 2013.
4. Yousef S Khader, Anwar Batieha, Mohammed El-Khateeb, Mousa Al Omari, Kamel Ajlouni. Prevalence of dyslipidemia and its associated factors among Jordanian adults. J Clin Lipidology 2010;4:53-58.
5. Farzadfar F, Finucane MM, Danaei G, Pelizzari PM, Cowan MJ, Paciorek CJ, et al. National, regional and global trends in serum total cholesterol since 1980: systematic analysis of health examination surveys and epidemiological studies with 321 country-years and 3·0 million participants. Lancet 2011;377:578–86.
6. Jamshed J Dalal, T N C Padmanabhan, Piyush Jain, Shiva Patil, Hardik Vasnawala, Ashish Gulati. Lipitension: Interplay between dyslipidemia and hypertension. Indian J Endocrinol Metab 2012; 16: 240-245.

7. Bela Shah and Prashant Mathur. Surveillance of cardiovascular disease risk factors in India: The need and scope. *Indian J Med Res* 2010; 132: 634-642.
8. Thankappan KR, Shah B, Mathur P, Sarma PS, Srinivas G, Mini GK, et al. Risk factor profile for chronic non-communicable diseases: results of a community-based study in Kerala, India. *Indian J Med Res* 2010;131:53–63.
9. World Health Organization. Non communicable diseases in South- East Asia region. A profile. New Delhi : profile 2002. Available from:  
[http://209.61.208.233/LinkFiles/NCD\\_InforBase\\_ncd-profile.pdf](http://209.61.208.233/LinkFiles/NCD_InforBase_ncd-profile.pdf). Accessed on: September 20,2013.
10. M Estari, A S Reddy, T Bikshapathi, J Satyanarayana, L Venkanna, M K Reddy. The investigation of serum lipids and prevalence of dyslipidemia in urban adult population of Warangal district, Andhra Pradesh, India. *Biology and Medicine* 2009;1:61-65.
11. Sawant AM, Shetty D, Mankeshwar R, Ashavaid TF. Prevalence of dyslipidemia in young adult Indian population. *J Assoc Physicians India* 2008;56:99–102.
12. Baigent C, Blackwell L, Emberson J, Holland LE, Reith C, Bhala N, et al. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet* 2010; 376: 1670–81.
13. Jotideb Mukhopadhyay, Saubhik Kanjilal, Monodeep Biswas. Diabetic Dyslipidemia: Priorities and Targets in India. *Lipids Health Dis* 2010;9:144
14. Liberopoulos EN, Florentin M, Mikhailidis DP, Elisaf MS. Compliance with lipid-lowering therapy and its impact on cardiovascular morbidity and mortality. *Expert Opin Drug Saf* 2008; 7: 717–25.

15. Yusuf S, Islam S, Chow CK, Rangarajan S, Dagenais G, Diaz R, et al. Use of secondary prevention drugs for cardiovascular disease in the community in high-income, middle-income, and low-income countries (the PURE Study): a prospective epidemiological survey. *The Lancet* 2011; 378: 1231–43.
16. American Heart Association. Fatal and Nonfatal Cardiovascular Disease and the Use of Therapies for Secondary Prevention in a Rural Region of India. *Circulation* 2009; 119:1950 - 1955
17. Koçkaya G, Wertheimer A. Can We Reduce the Cost of Illness With More Compliant Patients? An Estimation of the Effect of 100% Compliance With Hypertension Treatment. *Journal of Pharmacy Practice* 2011; 24: 345–50.
18. Noncompliance with Medications: An economic tragedy with important implication for health care reform. A report by The Task Force For Compliance 1993; Available from: <http://www.npcnow.org/system/files/research/download/Noncompliance-with-Medications-An-Economic-Tragedy-with-Important-Implications-for-Health-Care-Reform-1994.pdf> . Accessed on April 21,2013.
19. Krousel-Wood M, Islam T, Webber LS, Re RN, Morisky DE, Muntner P. New medication adherence scale versus pharmacy fill rates in seniors with hypertension. *Am J Manag Care* 2009; 15: 59–66.
20. Cummings KM, Kirscht JP, Becker MH, Levin NW. Construct validity comparisons of three methods for measuring patient compliance. *Health Serv Res.* 1984; 19: 103–16.

21. Korb-Savoldelli V, Gillaizeau F, Pouchot J, Lenain E, Postel-Vinay N, Plouin P-F, et al. Validation of a French version of the 8-item Morisky medication adherence scale in hypertensive adults. *J Clin Hypertens (Greenwich)* 2012; 14: 429–34.
22. Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clin Ther* 2001; 23: 1296–310.
23. Libby AM, Fish DN, Hosokawa PW, Linnebur SA, Metz KR, Nair KV, et al. Patient-level medication regimen complexity across populations with chronic disease. *Clin Ther* 2013; 35: 385–398.
24. Coleman CI, Limone B, Sobieraj DM, Lee S, Roberts MS, Kaur R, et al. Dosing frequency and medication adherence in chronic disease. *J Manag Care Pharm* 2012; 18: 527–39.
25. Pan F, Chernew ME, Fendrick AM. Impact of Fixed-Dose Combination Drugs on Adherence to Prescription Medications. *J Gen Intern Med* 2008; 23: 611–4.
26. International Communications Research for the American Society of Health-System Pharmacists. Medication use among older Americans. *Am J Health Syst Pharm* 2001; Available from: [http://www.ashp.org/s\\_ashp/docs/files/PR\\_Over65.pdf](http://www.ashp.org/s_ashp/docs/files/PR_Over65.pdf). Accessed on April 22,2013.
27. Krueger KP, Felkey BG, Berger BA. Improving adherence and persistence: a review and assessment of interventions and description of steps toward a national adherence initiative. *J Am Pharm Assoc* 2003; 43: 668–678.

28. Harris Interactive. Prescription Drug Compliance a Significant Challenge for Many Patients. Available from: <http://www.marketresearchworld.net/content/view/289/>. Accessed on April 22,2013.
29. Bruckert E, Hayem G, Dejager S, Yau C, Bégaud B. Mild to moderate muscular symptoms with high-dosage statin therapy in hyperlipidemic patients--the PRIMO study. *Cardiovasc Drugs Ther* 2005; 19: 403–14.
30. Benner JS, Glynn RJ, Mogun H, Neumann PJ, Weinstein MC, Avorn J. Long-term persistence in use of statin therapy in elderly patients. *JAMA* 2002; 288: 455–61.
31. Colivicchi F, Bassi A, Santini M, Caltagirone C. Discontinuation of statin therapy and clinical outcome after ischemic stroke. *Stroke* 2007; 38: 2652–7.
32. Donnelly LA, Doney ASF, Morris AD, Palmer CNA, Donnan PT. Long-term adherence to statin treatment in diabetes. *Diabet Med* 2008; 25: 850–5.
33. Casula M, Tragni E, Catapano AL. Adherence to lipid-lowering treatment: the patient perspective. *Patient Prefer Adherence* 2012; 6: 805–14.
34. Institute Of Medicine Of The National Academies. Health Literacy: A Prescription ToEnd Confusion 2004. Available from: [http://hospitals.unm.edu/health\\_literacy/pdfs/HealthLiteracyExecutiveSummary.pdf](http://hospitals.unm.edu/health_literacy/pdfs/HealthLiteracyExecutiveSummary.pdf). Accessed on: March 2,2013.
35. Gottlieb H. Medication Nonadherence: Finding Solutions to a Costly Medical Problem CME. *Drug Benefit Trends* 2000; 12: 57–62.

36. Peyrot M, McMurry JF Jr, Kruger DF. A biopsychosocial model of glycemic control in diabetes: stress, coping and regimen adherence. *J Health Soc Behav* 1999; 40: 141–58.
37. Cox WM, Blount JP, Crowe PA, Singh SP. Diabetic patients' alcohol use and quality of life: relationships with prescribed treatment compliance among older males. *Alcohol. Clin. Exp. Res* 1996; 20: 327–31.
38. Ellis JJ, Erickson SR, Stevenson JG, Bemstein SJ, Stiles RA, Fendrick MA. Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations. *J Gen Intern Med* 2004; 19: 638–45.
39. Sankar UV, Lipska K, Mini GK, Sarma PS, Thankappan KR. The Adherence to Medications in Diabetic Patients in Rural Kerala, India. *Asia Pac J Public Health* 2013. Available from : <http://www.ncbi.nlm.nih.gov/pubmed/23417905>. Accessed on: March 2,2013.
40. National Council on Patient Information And Education. Enhancing Prescription Medicine Adherence: A National Action Plan.report 2007. Available from : [http://www.talkaboutrx.org/documents/enhancing\\_prescription\\_medicine\\_adherence.pdf](http://www.talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf) . Accessed on April 25,2013.
41. Dulmen S van, Sluijs E, Dijk L van, Ridder D de, Heerdink R, Bensing J. Patient adherence to medical treatment: a review of reviews. *BMC Health Services Research* 2007; 7: 55.
42. Kiortsis DN, Giral P, Bruckert E, Turpin G. Factors associated with low compliance with lipid-lowering drugs in hyperlipidemic patients. *J Clin Pharm Ther* 2000; 25: 445–51.

43. Hyre AD, Muntner P, Menke A, Raggi P, He J. Trends in ATP-III-Defined High Blood Cholesterol Prevalence, Awareness, Treatment and Control Among U.S. Adults. *Ann Epidemiol* 2007; 17: 548–55.
44. Morowatisharifabad MA, Mahmoodabad SSM, Baghianimoghadam MH, Tonekaboni NR. Relationships between locus of control and adherence to diabetes regimen in a sample of Iranians. *Int J Diabetes Dev Ctries* 2010; 30: 27–32.
45. Burkhart PV, Rayens MK. Self-concept and health locus of control: factors related to children's adherence to recommended asthma regimen. *Pediatr Nurs* 2005; 31: 404–9.
46. Avorn J, Monette J, Lacour A, Bohn RL, Monane M, Mogun H, et al. Persistence of use of lipid-lowering medications: a cross-national study. *JAMA* 1998; 279: 1458–62.
47. Cyril James. Risk Factors for Coronary Artery Diseases: A Study Among Patients With Ischemic Heart Disease in Kerala. *Heart India* 2013; 1 : 7-11.
48. Geevar Zachariah. Prevalence of risk factors of CAD- Is it different in Kerala?. *Health Sciences* 2013; 2. Available from: <http://healthsciences.ac.in/apr-jun-13/3.DSpecialSection-2.html>. Accessed on: September 20,2013.
- 49 Kerala Chapter. Cardiological Society of India. Available from: <http://www.csikerala.org/acsregistry.php>. Accessed on Sep 20,2013.
50. Lars Osterberg, Blaschke T. Adherence to medication. *N Engl J Med* 2005; 353: 487-497.
51. Sabate E. Adherence to long-term therapies: Evidence for Action. Geneva; WHO report 2003. Available on: <http://whqlibdoc.who.int/publications/2003/9241545992.pdf>. Accessed on: Sept 21,2013.

52. Uma V S, Kasia Lipska, G. K Mini, P S Sarma, PhD and K R Thankappan. The Adherence to Medications in Diabetic Patients in Rural Kerala, India. *Asia Pac J Public Health* 2013; 20: 1-11.
53. M Krousel-Wood, P Muntner, Tareq Islam, D E Morisky, Larry S. Webber. Barriers to and Determinants of Medication Adherence in Hypertension Management: Perspective of the Cohort Study of Medication Adherence Among Older Adults. *Med Clin North Am* 2009; 93: 753-69.
54. David S Gochman. Health Belief Model. *Handbook of health behavior and Research-2 Provider Determinants* 1997: 221-25.
55. The West of Scotland Coronary Prevention Study Group. Compliance and adverse event withdrawal: their impact on the West of Scotland Coronary Prevention Study. *Eur Heart J* 1997; 18: 1718-1724.
56. Enhancing Prescription Medicine Adherence: A National Action Plan. National Council on Patient Information and Education 2007. Available from:  
[http://www.talkaboutrx.org/documents/enhancing\\_prescription\\_medicine\\_adherence.pdf](http://www.talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf)
57. A Baum, T A Revenson and J Singer. *Handbook of health psychology- 2<sup>nd</sup> edition*. 2012.
58. M Gulabani, M John, and R Isaac. Knowledge of Diabetes, its Treatment and Complications Amongst Diabetic Patients in a Tertiary Care Hospital. *Indian J Community Med* 2008; 33: 204-206.
59. S A Grover, I Lowensteyn, L Joseph, M Kaouache, S Marchand, L Coupal et al. Patient Knowledge of Coronary Risk Profile Improves the Effectiveness of Dyslipidemia Therapy. *Arch Intern Med* 2007; 167: 2296-303.

60. T L Hayes, N Larimer, A Adami and J A Kaye. Medication adherence in healthy elders: small cognitive changes make a big difference. *J Aging Health* 2009 ; 21: 567–580.
61. Piette JD, Wagner TH, Potter MB, Schillinger D. Health insurance status, cost-related medication underuse, and outcomes among diabetes patients in three systems of care. *Med Care* 2004; 42: 102-9.
62. Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. *J Clin Hypertens* 2008; 10(5):348-354
63. Wei L, Wang J, Thompson P, Wong S, Struthers AD, MacDonald TM. Adherence to statin treatment and readmission of patients after myocardial infarction: a six year follows up study. *Heart* 2002; 88:229-33.

## **Factors associated with medication adherence among self reported dyslipidemic patients**

### **Research Subject Information Sheet**

“Namaskaram”- my name is Merryson Roy Mathew and presently I am studying the course- Master of Public Health (MPH) at AMCHSS (Achutha Menon Centre For Health Sciences) Sree Chitra Tirunal Institute for Medical Sciences & Technology,(SCTIMST) Thiruvananthapuram. I am doing a community based study among the patients suffering from high cholesterol. This study is being carried out as part of the course requirement for the MPH . This study is under the supervision of the Dr. Ramankutty.V, professor of the AMCHSS.

#### **Purpose of the study:**

The main purpose of the research is to assess the adherence of patient’s to cholesterol lowering 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 cholesterol lowering medication. There will be no direct benefits to you for participating in this interview.

#### **Objective of the study**

Major objective

- 1.To find the prevalence of medication adherence among dyslipidemia patients in Kottayam district, Kerala

Minor objectives

1. To find the factors associated with medication adherence among dyslipidemic patients.
2. To find the impact of co-morbidities on adherence to medication

**Procedure:**

The survey would take approximately 30- 45 minutes of your valuable time. You would be asked a few questions related to high cholesterol and its treatment. The collected data will be used for research purpose only.

**Risk and discomfort:**

Participating in this study imposes no risk to your health. However, you would be asked some questions which could be personal in nature. You may choose to answer all or some of the questions that I have put to you.

**Confidentiality:**

Everything you say will remain private and confidential .Priority will be given to protect the privacy and confidentiality of your personal information. The collected information will not be shared with anyone not involved in the study and reporting will be done in aggregate form only.

**Voluntary participation:**

Your participation in this study is voluntary and you have the right to withdraw your participation at any time during the interview without any explanation. Refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled.

If you have additional questions about this research you may contact me or the IEC member secretary.

Dr Anoop Kumar Thekkuveetil,

0471-2520256/7

[anoop@sctimst.ac.in](mailto:anoop@sctimst.ac.in)

Merryson Roy Mathew

09539212825

[merryson143@gmail.com](mailto:merryson143@gmail.com)

Dr. Raman Kutty.V

09847060199

[kuttyr@gmail.com](mailto:kuttyr@gmail.com)

## **Factors associated with medication adherence among self reported dyslipidemic patients**

I have read/been read the details of the information sheet. The nature of the study and my involvement has been explained and all my questions regarding the study have been answered satisfactory. By signing / providing thumb impression on this consent form, I indicate that I understand what will be expected from me and that I am willing to participate in this study. I have also been informed who should be contacted for further clarifications. I know that I can withdraw my participation at any time during the interview without any explanation.

Identification code: \_\_\_\_\_

Name of the participant: \_\_\_\_\_

Signature / left thumb print:

Date of consent:

D	D	M	M	Y	Y
---	---	---	---	---	---

***If the participant is illiterate:***

Name of witness: \_\_\_\_\_

Signature of the witness:

Signature of the investigator:

Date:

Annexure -2

D	D	M	M	Y	Y
---	---	---	---	---	---

# INTERVIEW SCHEDULE

## Factors associated with medication adherence among self reported dyslipidemic patients in Kottayam district.

Identification code:	Serial No.:	Date: __/0_/2013
----------------------	-------------	------------------

### Patient and demographic related factors

01. Name of the subject	
02. Age (in completed years):	
03. Sex:	0 <input type="checkbox"/> F 1 <input type="checkbox"/> M
04. Marital status	1 <input type="checkbox"/> Single 2 <input type="checkbox"/> Married 3 <input type="checkbox"/> Divorced / <input type="checkbox"/> Separated 4. <input type="checkbox"/> Widowed 5. <input type="checkbox"/> Other(specify)_____
05. Type of family	0 <input type="checkbox"/> Nuclear 1 <input type="checkbox"/> Joint
06. No. of household members: (specify)	
07. Education status	1 <input type="checkbox"/> Illiterate 2 <input type="checkbox"/> Primary(up to class 4) 3 <input type="checkbox"/> Secondary (up to class 10) 4 <input type="checkbox"/> Higher Secondary (up to class 12) 5 <input type="checkbox"/> Graduate 6 <input type="checkbox"/> Postgraduate 7 <input type="checkbox"/> others(specify)_____

08. Occupation	1 <input type="checkbox"/> Manual laborer/Unskilled worker 2 <input type="checkbox"/> Formal employment 3 <input type="checkbox"/> Home maker 4 <input type="checkbox"/> Professional 5 <input type="checkbox"/> small business 6 <input type="checkbox"/> Unemployed 7 <input type="checkbox"/> Own farm 8 <input type="checkbox"/> Retired/Pensioner 9 <input type="checkbox"/> Others (specify)_____
09. Type of floor in home (please tick)	1 <input type="checkbox"/> Marble/Granite 2 <input type="checkbox"/> Tiles 3 <input type="checkbox"/> Cement 4 <input type="checkbox"/> Red Oxide 5 <input type="checkbox"/> Other
10. How were you diagnosed to have high cholesterol?	1 <input type="checkbox"/> During regular checkup 2 <input type="checkbox"/> During medical checkup for other disease conditions 3 <input type="checkbox"/> During screening for surgery 4 <input type="checkbox"/> Others (specify)_____
11. Once after diagnosis when was treatment started?	1 <input type="checkbox"/> less than 6 months 2 <input type="checkbox"/> 6 months to one year 3 <input type="checkbox"/> > 1year to <3 years 4 <input type="checkbox"/> >=3 years
12. How long have you been on treatment?	
13. Total number of medications taken daily for this condition	

©Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.

You indicated that you are taking medication for your (identify health concern, such as “high cholesterol”). 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 check your response below)

	No=1	Yes=0
1. Do you sometimes forget to take your cholesterol lowering pills?		
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 cholesterol lowering medicine		
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your cholesterol lowering medication?		
5. Did you take your cholesterol lowering medicine yesterday?		
6. When you feel like your cholesterol is under control, do you sometimes stop taking your medicine?		
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your cholesterol treatment plan?		

8. How often do you have difficulty remembering to take all your medications?  
(Please circle your response below)

- Never/Rarely.....4  
 Once in a while.....3  
 Sometimes.....2  
 Usually.....1  
 All the time.....0

**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 Level**

Low Adherence (< 6)

Medium Adherence (6 to <8)

High Adherence (= 8)

**Only for those subject who are poorly or medium adherent**

14. An increased number of medicines is hindering your medication adherence?	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes
15. Have you ever felt that medication is not effective	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes
16. Cholesterol level can be controlled using home remedies?	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes
17. During festivals have you cut back/stopped taking medications?	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes
18. Once after the medicine finishes, have you ever felt difficulty in re buying your medicines?	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes(if no skip to 18)
19.If yes ,specify		
20. Medication is necessary only when you eat high fatty food?	0 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes

21. When you miss the timing of medicine what would you do?	1. <input type="checkbox"/> Takes extra medicine in the next dose 2. <input type="checkbox"/> Continue with the normal schedule 3. <input type="checkbox"/> others (specify) _____
---	--

**Other risk factors for NCDS**

22.	Have you ever used any tobacco product?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
23.	If yes, did you use any tobacco product in the last 30 days?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
24.	Have you ever used any alcoholic product?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
25.	Did you use any alcoholic product within the past 30 days? :	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
26.	Did your doctor advise any physical activity?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
27.	If yes, are you currently following this advice?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
28.	Did your doctor advise you to restrict the consumption of fatty diet?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
29.	If yes, do you follow fat restricted diet now?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes

**Co morbidity related factors**

30. Do you have any others illness: 0  No 1  Yes [If yes, answer the following:]

Sl. No.	Disease	Duration (months)	Continuing Treatment	Number of medication
1.	Diabetes Mellitus		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
2.	High blood pressure		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
3.	Heart diseases		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
4.	Kidney disease		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
5.	Disease of brain and nervous system		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	

6.	Thyroid disorders		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
7	Respiratory diseases		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	
8.	Others (specify):		0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	

31. Since you are taking medicines for other diseases have you felt difficulty in taking cholesterol lowering drugs?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
--	--

### Cost related factors

32. Expenditure for cholesterol medicines in the last month

Sl no	Name of medication	Frequency	Dose	Rate/tablet	Any Side Effect
					0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes

### Therapy related and Health System related factors

33. Where do you seek treatment for high cholesterol?	1 <input type="checkbox"/> Government hospital 2 <input type="checkbox"/> ESI hospital 3 <input type="checkbox"/> Private hospital 4 <input type="checkbox"/> Other specify
34. How much is the distance to your nearest healthcare facility from your home?	1 <input type="checkbox"/> ≤1km 2 <input type="checkbox"/> >1km

35. Did anyone explain to you how to follow medication?	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes
36. If yes, who	
37. (only for those who received advice) Were you able to follow the advice given?	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes
38. If no, specify	
39. Did you feel any difficulty in following medication regimen?	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes
40. If no, specify	
41. Have you ever stopped taking medication thinking it is costly?	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes
42. Which all other medical systems do you avail for treatment?	Ayurvedha    0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes Homeopathy 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes Unani        0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes Others specify _____
43. If yes in any, why do you avail these non-allopathic systems?	1 <input type="checkbox"/> lower cost 2 <input type="checkbox"/> light with fewer side-effects 3 <input type="checkbox"/> easily available 4 <input type="checkbox"/> good for chronic diseases 5 <input type="checkbox"/> others: (specify) _____
44. Have you ever felt difficulty in acquiring medicine	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes

45. If yes, specify	
46. When did you last visit your Physician/clinic?	1 <input type="checkbox"/> ≤ 1 month 2 <input type="checkbox"/> >1to ≤3 months 3 <input type="checkbox"/> >3 to ≤6 months 4 <input type="checkbox"/> >6 to ≤1 year 5 <input type="checkbox"/> >1 year
47. How often do you get your cholesterol level checked?	1 <input type="checkbox"/> ≤ 1 month 2 <input type="checkbox"/> >1to ≤3 months 3 <input type="checkbox"/> >3 to ≤6 months 4 <input type="checkbox"/> >6 to ≤1 year 5 <input type="checkbox"/> >1 year

**Support related factor**

48. Does anybody accompany you during your visit to clinic or doctor visits in most of the time?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
If yes, who	
50. Who pays for your Medication?	1 <input type="checkbox"/> Self 2 <input type="checkbox"/> Other Family member 3 <input type="checkbox"/> Employer 4 <input type="checkbox"/> others (specify) _____
51. In your family, does anyone help you to remember to take the medicine?	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes (if no skip 38)
52.If yes, specify who	

**Patient related factors: Physical difficulties /cognitive**

53. Do you have any difficulties such as	<input type="checkbox"/> Memory loss <input type="checkbox"/> Difficulties in paying attention <input type="checkbox"/> Difficulties in judgment (confusion) <input type="checkbox"/> Mood swings <input type="checkbox"/> Any other specify _____
54. Did you ever felt any difficulty in taking medicine due to your job?	

**Patient's attitudes and beliefs and knowledge**

55. In your opinion what all complication can be caused by high cholesterol?	
56. In your opinion what adverse effect can be caused by long term cholesterol lowering drugs therapy?	
57. Did someone other than doctor ask you to stop medicine?	0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes
58. If yes, who?	

59. Before concluding what is your opinion regarding the medication taking?

---

That's all. Thank you for your cooperation