Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka

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DECLARATION

Candidate

"I declare that the work presented here is my original work, and generated from the research conducted by me to fulfill the part requirement of the degree of MSc Community Medicine"

Signature of Candidate:

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Date: 19.06.2018

Supervisor

"I confirm that I supervised the above indicated work of the candidate".

Signature of Supervisor:

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ABSTRACT

Introduction: Coronary heart diseases are responsible for a major proportion of morbidity, mortality and high economic cost in Sri Lanka. Among treatment options, drug treatment is the commonest method to preserve optimal heart function and to prevent mortality. Hence, compliance to cardiovascular drugs is imminently important for heart disease patients.

Objectives: To describe factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka.

Methods: A descriptive cross sectional study was conducted among coronary heart disease patients attending outpatient cardiology clinic of National Hospital of Sri Lanka during August / September 2017. Calculated sample size was 403. Study participants were selected by systematic random sampling technique. 393 (97.5%) responded to interviewer administered questionnaire. Drug compliance was measured by adapting MMAS-8 questionnaire. Association between drug compliance with patient related, disease and treatment related and healthcare system related factors were identified by applying chi square test. 0.05 was considered as significance level.

Results: Only 43.0% (n=168) of the participants had good compliance to their drug treatment. Patient related factors were not significantly associated with drug compliance ($p>.05$). Disease related factors significantly associated with drug compliance were, duration of the disease ($p<.001$) and symptom severity of the patients ($p=.013$). Of the treatment related factors, drug compliance was significantly associated with, number of drug types prescribed per day ($p=.026$), daily drug dosing frequency ($p=.030$), frequent change of drugs ($p=.035$) and presence of side effects ($p=.006$). Healthcare system related factors significantly associated with drug compliance were, time spent by doctor ($p=.033$), providing explanations about the treatment ($p=.022$), the time taken to complete the clinic visit ($p=.041$) and cost per clinic visit ($p=.005$).

Conclusions and Recommendations: The drug compliance was found to be low among coronary heart disease patients. Poor compliance was associated with several disease, treatment and healthcare system related factors. Developing multidisciplinary intervention programs to address the factors identified is necessary to improve compliance.

Key words: coronary heart disease, drug compliance, factors associated, MMAS-8

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LIST OF ABBREVIATIONS AND SYMBOLS

NCD	- Non Communicable disease
CVD	- Cardiovascular disease
CHD	- Coronary heart disease
ACEi	- Angiotensin-converting enzyme inhibitors
ARB	- Angiotensin receptor blockers
PCI	- Percutaneous Coronary Intervention
CABG	- Coronary Artery Bypass Grafting
MMAS-8	- Eight-item Morisky Medication Adherence Scale
WHO	- World Health Organization
HF	- Heart failure
UK	- United Kingdom
US	- Unites States
MI	- Myocardial infarction
MMAS-4	- Four-item Morisky Medication Adherence Scale
MEMS	- Mediation Event Monitoring System
ACS	- Acute coronary syndrome
NYHA	- New York Heart Association
NHSL	- National Hospital of Sri Lanka
PI	- Principal investigator
CSTH	- Colombo South Teaching Hospital

CHAPTER 1 – INTRODUCTION

Chronic non-communicable diseases (NCDs) are the leading cause of mortality in the world. Of 56.4 million global deaths in 2015, around 70% (39.5 million) were due to chronic NCDs (WHO, 2017). The main types of chronic NCDs include; cardiovascular diseases (CVDs), cancers, chronic respiratory diseases and diabetes. According to World Health Organization (WHO) data, CVDs are the leading cause of NCD deaths (17.7 million people annually or 45% of chronic NCD deaths), followed by cancers (8.8 million or 22% of chronic NCD deaths), respiratory diseases (3.9 million or 10% of chronic NCD deaths), and diabetes (1.6 million or 4% of chronic NCD deaths) (WHO, 2017). In Sri Lanka also CVDs has been ranked as the leading cause of death (Medical Statistics Unit, 2015) and about 4.8% (around 12360 million rupees) of health expenditure is spent for the management of CVD patients (Ministry of Health, 2016).

1.1 Coronary heart disease

CVDs include all the diseases of the heart and circulation including coronary heart disease (CHD), stroke and peripheral vascular disease. Out of total deaths due to CVDs, the majority (41.8%, 7.4 million) were due to coronary heart disease (WHO, 2017). In Sri Lanka from 2008 to 2015 trend of hospitalization due to CHD has increased from 423 to 523 per 100,000 population respectively (Medical Statistics Unit, 2015). Also the number of hospital deaths due to CHD has gradually increased from 22.1 to 29.7 per 100,000 population from 2008 to 2015 (Medical Statistics Unit, 2015).

Risk factors for the development of CHD are multifactoral. These factors are categorized as modifiable and non-modifiable risk factors (O'Donnell & Elosua, 2008; Wood D., 2001). Modifiable risk factors include unhealthy lifestyles, certain biochemical and physiological characteristics. Unhealthy diet, tobacco smoking, alcohol consumption and physical inactivity are considered as unhealthy lifestyles. Biochemical characteristics include hyperglycaemia and high cholesterol level, while physiological characteristics include high blood pressure and obesity. Non-modifiable risk factors are age, sex, family history of CVD at early age and personal history of CVD.

Above mentioned risk factors results in development of atherosclerotic plaques inside the coronary arteries. Over time these plaques get harden or ruptured. Ruptured plaques

form blood clots inside the coronary artery. Both hardened and ruptured plaques narrow the coronary arteries and lead to acute or chronic limitation of blood supply to heart. This limitation of blood supply to the heart leads to CHD (National Institute of Health, 2016).

Coronary heart disease patients need life-long treatment and the treatment is important to achieve following objectives.

- To lower the risk of blood clot formation since blood clots can cause further heart attacks
- To control risk factors which will ultimately slow, stop or reverse the build-up of plaques
- To relieve symptoms
- To prevent complications of CHD

The ultimate goals of achieving above mentioned treatment objectives are to reduce mortality, morbidity, prevention of further worsening of the condition and to reduce financial burden to the society.

Treatment for CHD include heart-healthy lifestyle changes, medicines, medical or surgical procedures, and cardiac rehabilitation (National Institute of Health, 2016). Heart healthy life style changes include dietary modifications, engage in regular physical activities, quitting tobacco smoking, cessation of alcohol consumption and managing stress. These life style changes lower the risk of development of biochemical and physiological risk factors of CHD. But, lifestyle changes alone are not enough to control CHD. So use of cardiovascular medicines, in particular anti-platelet drugs, lipid-lowering drugs such as statins and blood pressure-lowering drugs such as beta-blockers, angiotensin-converting enzyme inhibitors (ACEi), angiotensin receptor blockers (ARB), calcium channel blockers and diuretics is also crucial (Kolh et al., 2014). These drugs are essential to decrease the chance of developing another heart attack and dying suddenly. Apart from that, these drugs are required to control blood pressure and cholesterol levels, to prevent further blood clot formation, to reduce workload of the heart thus relieve symptoms and to prevent or delay the need of a medical procedure or a surgery (National Institute of Health, 2016). Sometimes CHD patients might need to undergo a medical procedure such as Percutaneous Coronary Intervention (PCI) or a surgery such as Coronary Artery Bypass Grafting (CABG) to treat blocked arteries. Nearly every patient might be prescribed cardiac rehabilitation to teach them how to cope up with the stress of adjusting to new lifestyle. So that

compliance to each treatment method is important to achieve ultimate goals of CHD patient management. But among all the treatment strategies, use of cardiovascular medicines is the commonest approach to preserve optimal heart function and to prevent mortality of CHD patients' (Yusuf et al., 2000).

1.2 Drug compliance

Compliance has been defined by different authors and different organizations in different ways. In late 1970's compliance was defined as "patient's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincide with healthcare providers' recommendations for health and medical advice"(Sackett & Haynes, 1976). It included initiation, implementation and discontinuation of prescribed treatment method (Vrijens et al., 2012). Often, the term "adherence" has been used instead of "compliance" (Lam & Fresco, 2015). WHO has defined adherence as "the extent to which the person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider" (WHO, 2003). Recently the term "concordance" has also been used instead of "compliance" where it makes the patient the decision maker in the process and denotes patient-prescriber agreement and harmony (Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). Though there are subtle differences between the terms, they are used interchangeably in clinical practice and research.

Patients' compliance with treatment regimes may be one of the most studied and least understood behavioural issue in medicine. Hippocrates (400 BC) first noted that some patients do not take their mediations as prescribed. He stated that "the physician should keep aware that patients often lie when they state that they have taken certain medicines" (Reddy, 2012). In 1882, for the first time in modern medicine, Robert Koch stipulated that "noncompliant patients with tuberculosis were vicious consumptives, careless and/or irresponsible" (Lerner, 1997). Since 1970s, compliance to treatment has been a topic of clinical concern.

According to healthcare providers' viewpoint, drug compliance is a major clinical issue for several reasons. Maintaining good compliance is important to control and prevent treatment failures which result in increased morbidity and mortality. Regardless of prescribing drugs, treatment goals might not be able to achieve if the patients are not compliant to the treatment (Jin, Sklar, Min Sen Oh, & Chuen Li, 2008). Hence it

directly associates with treatment failures which lead to increased morbidity and mortality. Besides the above mentioned direct impact, good compliance reduces excess emergency care visits and hospitalizations which indirectly reduce the cost of care of the patient. (Bonnie L. Svarstad, Theresa I. Shireman, & J. K. Sweeney, 2001). Apart from that, good drug compliance minimizes the loss of productivity which indirectly controls the financial burden and improves the quality of life of patients as well as their families. Moreover, good drug compliance avoids physicians to change the drug regime or increase the drug dose unnecessarily which also increases the complexity and costs of treatment.

In general, patients who need long term treatment are non compliant to the treatment than who need short term therapy (DiMatteo, 1995) and different types of non-compliances has been found in clinical practice. Some of which include; receiving a prescription but not taking drugs from the pharmacy, taking incorrect doses, taking drugs at wrong times, increasing or decreasing the frequency of doses, stopping treatment too early, stopping treatment for a while and restart the treatment (drug holidays) and compliant to the treatment around the time of clinic appointment (white-coat compliance).

1.3 Measurement of drug compliance

Accurate measurement of drug compliance may provide valid evidence on clinical consequences, factors affecting compliance and clues to formulate different strategies to improve the drug compliance. Inaccurate measurement of drug compliance causes potentially costly and dangerous outcomes. Sometimes effective treatment may be judged as ineffective and expensive investigations may be ordered and treatment may be changed or intensified unnecessarily. Since compliance varies from patient to patient it is important to both clinicians and researches to measure it accurately.

Selection of an appropriate method should be based on individual attributes, goals of the study and availability of resources or the clinical setting. There are numerous methods available to measure drug compliance. Generally, these measurements are categorized as subjective and objective measurements (De Geest & Sabate, 2003). Subjective measurements are based on healthcare provider's or patient's evaluation of their medication taking behaviour. Patient-kept diaries, patient interviews and questionnaires are few examples of subjective methods. Objective measurements of

drug compliance include pill counts, electronic monitoring and biochemical measures. Both subjective and objective methods have their own advantages and disadvantages.

Subjective measurements can be used to identify those who are compliant and non-compliant. And also it is used to gather information on social, situational and behavioural factors leads to non-compliance (Hawkshead & Krousel-Wood, 2007). Yet, subjective method has the problem of over-estimating compliance (George, Kong, & Stewart, 2007). Most commonly used subjective method of measuring drug compliance in clinical practice is questionnaires (Dawn I. Velligan et al., 2007). It is the most simple, inexpensive method of measuring compliance and feasible to be used in clinic settings. Several validated questionnaires have been developed to assess drug compliance among patients with chronic diseases including coronary heart disease patients. Some of these questionnaires include Eight-item Morisky Medication Adherence Scale (MMAS-8) (D. E. Morisky, A. Ang, M. Krousel-Wood, & H. J. Ward, 2008), Brief Medication Questionnaire (Svarstad, Chewning, Sleath, & Claesson, 1999), Hill-Bone Compliance Scale (Kim, Hill, Bone, & Levine, 2000) and Adherence scale (Culig, Leppee, Boskovic, & Eric, 2011).

From above mentioned questionnaires, MMAS-8 is the most widely used scale in measuring drug compliance (Al-Qazaz et al., 2010). It focuses on medication taking behaviours and has several advantages: it is the shortest and easiest tool to score which is adaptable for various groups of drugs. Also it identifies barriers to drug compliance and permits healthcare provider to reinforce positive behaviours. It has been shown to be predictive to assess the compliance to long-term medication including cardiovascular drugs (Wong et al., 2014).

1.4 Factors affecting drug compliance

Compliance is a complex human behavioural process. The environments in which patients live, healthcare providers practice and healthcare systems deliver care strongly influence the compliance (Miller, Hill, Kottke, & Ockene, 1997).

Drug compliance is a multidimensional phenomenon, which is determined by the interplay of five main factors. WHO has classified these factors as: patient related factors, socioeconomic factors, treatment related factors, disease related factors and health system / healthcare team related factors (WHO, 2003). Patient related factors represent demographic characteristics as well as knowledge, attitudes, beliefs,

perceptions and expectations of the patients. Among socioeconomic factors although socioeconomic status has not constantly been found to be an independent predictor of drug compliance, some factors such as poor socioeconomic status, low level of education, unemployment and high cost of transport and medications have been reported to have an effect on drug compliance. There are many treatment related factors that affect the drug compliance. Most notable factors are complexity of drug regime such as number of daily doses and number of drugs, duration of treatment, frequent changes in treatment and side effects. Some disease related factors that affect the drug compliance includes severity of the symptoms, severity of the disease, level of disability and the availability of effective treatment. Relatively little research has been conducted to assess the relationship between health system or healthcare team related factors that affect the drug compliance such as short consultations, weak capacity of the system to educate patients and provide follow up, poor mediation distribution systems and lack of knowledge of healthcare providers in managing chronic diseases (WHO, 2003).

Justification

WHO states that "in developed countries, compliance to long term therapies in general population is around 50% and it is estimated to be much lower in developing countries" (WHO, 2003). There are many studies conducted in relation to the drug compliance in different disease entities such as diabetes (Donnan, MacDonald, & Morris, 2002), hypertension (Jankowska-Polańska, Uchmanowicz, Dudek, & Mazur, 2016), chronic obstructive pulmonary disease (Sanduzzi et al., 2014), tuberculosis (Castelnuovo, 2010), HIV/AIDA (Chesney et al., 2000) etc. and most of which have been done in developed world. Similarly much of the studies on CHD patients' drug compliance have been conducted in developed world (Atkins et al., 2017; Awad, Osman, & Altayib, 2017) and only a limited number of studies have been done in developing world; very little is known in relation to drug compliance there. Also, majority of the studies that have been conducted so far had mainly focused on the patient related factors of drug compliance where other equally important factors such as socioeconomic, disease, treatment and healthcare system/healthcare team related factors has not been focused well.

As mentioned in the introduction, CHD remains a major threat to global and local health whether measured by mortality or morbidity. And in Sri Lanka CHD has been ranked as the leading cause of death (Medical Statistics Unit, 2015) and a considerable proportion of Sri Lankan health expenditure is been spent for the patients with cardiovascular diseases (Ministry of Health, 2016). So that, knowing the status of drug compliance among CHD patients in Sri Lanka is important. But no published literature is found in relation to the drug compliance of Sri Lankan CHD patients. Hence there is a real need and paramount importance to conduct a tailor-made research which suits Sri Lankan setting to assess drug compliance and factors associated with it.

This study will attempt to identify and provide basic information on the status of drug compliance among CHD patients and different factors that affect it in a context where no published data are available. Results obtained from this study will provide a basement to design further researches in future on CHD patients' drug compliance and compliance to non-pharmacological treatment as well. Further it will allow policy makers, program planners and clinicians to understand the magnitude of the problem and to develop strategies to facilitate drug compliance which will finally help to minimize negative clinical and economic outcomes and to improve the utmost healthcare status of CHD patients.

Objectives

General objective

To describe factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka

Specific objectives

1. To assess drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka
2. To describe patient related factors (demographic and socioeconomic characteristics, status of smoking and alcohol consumption, disease related knowledge) associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka
3. To describe disease and treatment related factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka
4. To describe healthcare system related factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka

CHAPTER 2 – LITERATURE REVIEW

Coronary heart disease accounts for higher rates of morbidity, mortality and financial burden in Sri Lanka (Medical Statistics Unit, 2015). The global situation was also reported to be the same (WHO, 2017). Among several treatment options, drug treatment is the commonest method used to treat CHD patients to preserve optimal heart functions. Hence, it was strikingly important to search literature related to drug compliance of the patients.

Patients' compliance with treatment regimes may be one of the most studied and least understood behavioural issues in medicine (Reddy, 2012). Comprehensive web and paper based literature search was undertaken. Local and international literature was searched using following key words: patient compliance, adherence, coronary heart disease and disease related knowledge. The topics of interest in the field of drug compliance were: the extent of compliance or non-compliance, factors associated with drug compliance, factors that affect drug compliance and compliance measurement methods. Articles were reviewed when the compliance was the main research topic of the study and when they gave an answer to at least one topic of interest.

Availability of literature exactly related to the drug compliance among patients with CHD was rare. So that literature available on drug compliance among patients with CHD related complications such as heart failure (HF) and drug compliance among patients with diabetes, hypertension were also considered in literature review where necessary.

2.1 Prevalence of drug compliance

Drug compliance had been studied extensively not only for CHD but for other diseases also.

A cross sectional study was conducted in one of the out-patient clinics in the New Territories Region during 2012. Aim of the study was to assess the drug compliance profiles and the factors associated with antihypertensive drug compliance among Chinese patients. 18 years or older patients; who were taking at least one long-term antihypertensive drug; and are able to communicate and understand Cantonese were invited to participate in the study. Data were collected by self-administered questionnaire. Drug compliance was measured by the Chinese version of MMAS-8

which has been demonstrated to have good concurrent and predictive validity. 1154 consecutive patients completed and returned the questionnaires. Chi-square test and Student's t-test were used for statistical analysis where p value ≤ 0.05 was regarded as statistically significant. 65.1% of patients demonstrated good drug compliance according to the MMAS-8 scale. Author concluded that, "since studies on drug compliance to antihypertensive agents among Chinese population are scarce, further investigation is required to evaluate the applicability of MMAS as a tool of drug adherence measurement among Chinese patients" (Lee et al., 2013).

All hypertensive patients aged 40 or over, registered from January to June 2004, who had been on treatment for at least 3 months, were screened At the Family Medicine Clinic, Hospital Universiti Sains Malaysia, Kelantan, Malaysia. 246 patients were selected to participate in a cross sectional study aimed to identify the predictors of medication noncompliance in hypertensive patients. Previously validated self-administered MMAS-8 questionnaire was used to assess the compliance. According to the results, more than half (55.8%) of the study participants were non-compliant to the treatment (Hassan et al., 2005).

With the Objective of assessing stroke risk factors and anti-hypertensive drug compliance among hypertensive patients a cross-sectional study was conducted among hypertensive subjects with stroke from two Kampala city hospitals in Kampala, Uganda. Study period ranged from 2013 to 2014. 112 hypertensive adults consecutively admitted with a diagnosis of an acute stroke were selected to the study. A standardized pre-tested questionnaire was used to collect data. The MMAS-8 was used to assess the compliance to anti hypertensive medication of the participants. 77 % of the study participants were poorly compliant according to the MMAS-8 scores (Mugwano et al., 2016).

A cross-sectional study conducted in Aga Khan University Hospital and National Institute of Cardiovascular Diseases, Karachi, Pakistan (Hashmi et al., 2007), to measure the compliance among Pakistani population. The inclusion criteria were patients of age 18 years and above, diagnosed with 'essential' hypertension on prescribed antihypertensive medications for at least previous one month, irrespective of having other co-morbidities. Study included a sample of 460 patients selected by simple random sampling. Data was collected via a pre-tested interviewer administered questionnaire. Patients' self-reports were used to measure compliance. To obtain more accurate results by minimizing recall bias patients were asked about the number of

tablets they have been prescribed per week and how many pills they took and missed during last 3, 5 and 7 days rather than assessing compliance for a long period of time. To further increase the strength and consistency of results compliance has been assessed by four-item Morisky Mediation Adherence scale (MMAS-4) with high validity and reliability. Compliance was represented in percentage. Study revealed that 77% were compliant with the treatment and only 23% were non-compliant.

A study conducted in Pittsburgh and Memphis in US to examine the prevalence and correlates of self-reported drug compliance among community-dwelling elders with chronic cardiovascular conditions such as diabetes mellitus, CHD, and/or hypertension. Data were used from a population-based, prospective, observational study named "Health, Aging and Body Composition (Health ABC) study" (Peterson et al., 2009). Study population included 3075 individuals. But, data from a subset of 897 participants participated in Year 10 (2006-07) and Year 11 (2007-08) interviews were included in analysis. Self-reported drug compliance was assessed using MMAS-4 questionnaire. At year 11, 40.7% reported non compliance to the medication based on MMAS-4 (Marcum et al., 2013).

To evaluate the compliance to cardiovascular medicines in patients of rural India, a study was carried out over one year period in the Department of Medicine of a tertiary care teaching hospital. Patients with essential hypertension, congestive cardiac failure and ischemic heart disease attending the outpatient clinic or admitted in indoor were selected for the study. MMAS-4 was used to assess drug compliance. Majority of patients showed poor compliance to their drug therapy. Only 20.83% of the hypertensive patients were compliant to the treatment. Among patients with congestive cardiac failure, 28.37%, individuals and 32% of ischemic heart disease patients were compliant to their treatment.. Author concluded that patients in rural India had poor compliance to cardiovascular medicines. Non-compliance should be attended to with due concern that it deserves (Gouranga Santra, 2015).

Between 2003 and 2004, a multicenter prospective cohort study was conducted in United States (US) to identify patient and myocardial infarction (MI) treatment factors associated with medication therapy discontinuation. It also assessed the impact of medication discontinuation one month after MI, on 12-month mortality of patients with MI. Study was termed as the Prospective Registry Evaluating Myocardial Infarction: Event and Recovery (PREMIER) study. A total of 2498 patients above 18 years of age with acute MI were recruited from 19 US hospitals. Data was collected through patient

interview and medical record abstraction. Medication use was abstracted from hospital admission and discharge records as well as from telephone interviews at 1, 6, and 12 months after discharge. Chi square test was used to compare rates of medication use for aspirin, β-blockers, statins, and the combination of all 3 medications at hospital discharge and 1, 6, and 12 months after MI for the overall cohort. Of the patients who completed the 1-month interview (n=1521), majority (n=1009, 66.3%) had taken all 3 medications. But, 184 (12.1%) patients had discontinued use of all medications, 56 (3.7%) discontinued use of 2 medications, and 272 (17.9%) discontinued use of 1 medication. Study concluded that medication therapy discontinuation after MI is common (Ho, Spertus, Masoudi, & et al., 2006).

In Brazil, a cross sectional study was conducted to evaluate the degree of compliance with pharmacological therapy and to identify the predictors of non compliance. It included 485 outpatients from a tertiary cardiology referral centre in Sao Paulo, Brazil. Patient interview was used to decide the compliance status. Compliance was recorded if the patient said he took the prescription correctly, without interruption in medicine use. Noncompliance was recorded if the patient said he took the prescription incorrectly, or with interruption in medicine use. Results revealed that majority (n=286, 59%) were non compliant to their treatment (Chizzola, Mansur, Luz, & Bellotti, 1996).

Heart and Soul study evaluated the risk of cardiovascular events associated with self reported drug compliance using 1024 outpatients with established CHD recruited from 3 medical centres and 9 community health clinics in California, US. Overall drug compliance was assessed using a single question "In the past month, how often did you take your medications as the doctor prescribed?" Possible responses were: "All of the time" (100%), "Nearly all of the time" (90%), "Most of the time" (75%), "About half the time" (50%), or "Less than half the time" (<50%). 75% or less was defined as non-compliant. 1015 individuals were included in the final analysis. Of the 1015 individuals 83 (8.2%) were non-compliant to their treatment (Gehi, Ali, Na, & Whooley, 2007).

A follow up study (L. Kristin Newby et al., 2006) was conducted in North Carolina and southern Virginia of United States to examine changes in the prevalence of compliance of evidence-based therapies over time. Study period was from 1995 to 2002. Study population was all patients who have undergone a cardiac procedure at Duke University Medical Centre since 1969, those patients still living with documented CHD who had at least 1 follow-up survey completed during the period 1995 to 2002. Data on self-reported medication use was gathered annually through email or telephone contact from

31750 CHD patient. Prevalence of compliance of the specified drugs or combinations of drugs was summarized by percentages for each year under study. Yearly prevalence of compliance to aspirin, β-blockers, lipid-lowering agents, and the combination of aspirin and β-blockers; aspirin and β-blockers and lipid-lowering agents among all patients with CHD has gradually increased over the period of 1995 to 2002. But in general, compliance of all medications and their combinations was low; only aspirin showed compliance in more than half of patients (71%). Compliance of β-blockers was 46% and for lipid-lowering agents was 43%. Use of the combination aspirin, β-blockers, and lipid-lowering therapy was consistently reported by only 21% of patients and of aspirin plus β-blocker, 36%. Compliance to evidence-based therapies for CHD has improved but remains suboptimal (L. Kristin Newby et al., 2006).

A retrospective cohort study was conducted using a population based acute MI registry in Ontario, Canada during 1999 to 2001. Objectives of the study were to determine factors of, and to measure outcomes associated with non-compliance after acute MI. The primary data source for patient identification was the Enhanced Feedback for Effective Cardiac Treatment (EFFECT) study registry. Eligible subjects were those enrolled in EFFECT who were ≥66 years at the time of hospital discharge after acute MI. 4591 patients were included in the study and found that after acute myocardial infarction almost one fourth of the patients (around 24%) did not even fill their cardiac medications by day seven of discharge (Cynthia A. Jackevicius, Li, & Tu, 2008).

A sub sample of patients participated in Coordinating study evaluating Outcomes of Advising and Counselling in Heart Failure (COACH) study were recruited into a separate cross sectional study, to describe differences in subjectively and objectively measured medication compliance. It included 37 HF patients. Revised Heart Failure Compliance Questionnaire was used as the subjective method of measuring drug compliance. Medication Event Monitoring System (MEMS) - an electronic monitoring system was used as the objective method. All the patients (100%) were compliant to ACEi/ARB when compliance was measured by subjective method. But when it was measured by MEMS, only 76% of the patients were compliant to their treatment. Study concluded that subjectively measured compliance was remarkably higher than objectively measured compliance (Nieuwenhuis, Jaarsma, van Veldhuisen, & van der Wal, 2012).

2.2 Factors associated with drug compliance

The drug compliance of a patient is determined by many factors. These factors are inter-connected. WHO has described them under five main dimensions and demonstrated using the multi-dimensional modal: patient related factors, socio-economic factors, disease related factors, treatment related factors and healthcare team/system related factors (WHO, 2003). In broader terms these factors fall into categories of patient related factors, disease and treatment related factors and healthcare system related factors.

2.2.1 Patient related factors

Age, sex, ethnicity, educational level, marital status, income, living situation, smoking status, alcohol use, medical history, and depressive symptoms were also determined by questionnaire during Heart and Soul study (Gehi et al., 2007) mentioned above, while assessing the drug compliance. Differences in characteristics between compliant and non-compliant participants were compared using the standard 2-tailed *t* tests for continuous variables and chi square tests for dichotomous variables. Compared to compliant participants, non-compliant participants were younger (p=.006), more likely to be female (p=.005), and less likely to be high school educated (p=.002). No significant association was found between marital status (p=.20), income (p=.44) and living alone (p=.47) with compliance. Although current smoking was significantly (p=.03) associated with non-compliance, regular alcohol use showed no significant association (p=.71).

PREMIER study conducted in US concluded that acute myocardial infarction patients who were non-compliant to drugs were more likely to be older (p<.001), less likely to be married (p<.001) and less likely to be completed high schools (p<.001). But non-compliance was not significantly associated with current smoking status (p=.18) (Ho et al., 2006).

The study conducted among hypertensive Pakistani study sample (Hashmi et al., 2007) also investigated the factors affecting compliance to antihypertensive drugs among Pakistani population. Categorical variables were compared using Chi-square and Fisher's exact tests. Odds ratios (with 95% confidence intervals) were also calculated. Associations of study variables with the MMAS-4 score were checked with linear regression using MMAS score as the dependant variable. A p-value of less than 0.05

was considered to be statistically significant. Factors significantly associated with poor compliance were younger age (p=.02), lower education status (p=.03), lower monthly income (p=.001) and lack of support (p<.001).

The study mentioned in section 2.1 (Marcum et al., 2013) also conducted bivariate logistic regression to identify each of the individual correlates (i.e., demographic, health status, and access to care factors) of non-compliance. Results showed no significant difference between age, sex, education level, marital status, income, current smoking and drug compliance.

During 2002, a study conducted in USA to examine the factors associated with non-compliance to warfarin treatment among chronic heart failure patients. Patients treated by Rush Heart Failure Programme who were on warfarin were eligible and 80 patients with four or more INR measurements were included in the study. Data were collected on number of INR measurements scheduled, the number of INR measurements actually obtained and INR readings itself. Apart from that socio-demographic data, New York Heart Association (NYHA) class was obtained. Non-compliance was defined as 25% or more of the number of out of range (INR 2 – 3.5) INR measurements. Statistical comparison of categorical data was performed using chi-square test. It found no significant association between gender and compliance. State of non smoking was significantly associated with good compliance (p=0.006). But, There was no significant association between compliance and current smoking (p=0.23) (Pamboukian et al., 2008).

Study mentioned in section 2.1 (Lee et al., 2013) showed that good compliance to antihypertensive drugs was more common among those with advanced age and unemployed. Those factors were significantly (p=.037 and p=.041 respectively) associated with good drug compliance. Sex, marital and monthly income status showed no significant association.

The association between age, sex, employment status also examined in the study (Chizzola et al., 1996) mentioned in section 2.1. Chi-square test used for statistical analysis with significance level of 0.05. But there were no significant association found between above mentioned variables and drug compliance (p>.05).

Study mentioned in section 2.1 (Hassan et al., 2005) examined associations between noncompliance and other factors using univariate logistic regression method. Age was significantly associated (p=.012) with non-compliance. Sex, ethnicity,

educational level and monthly income had no association with non-compliance (p>.05).

A descriptive cross-sectional study was conducted to examine the relationship between awareness of the disease and compliance to treatment among cardiac patients admitted to hospitals affiliated to Mashhad University of Medical Sciences in Mashhad, Iran (Heydari, Ziaee, & Gazrani, 2015). The study population consisted of all patients with cardiac disease referred to the selected hospitals from 2009 to 2010 and met the inclusion criteria of the study. 340 patients were selected using the convenience sampling with a variety of cardiac problems including heart failure, ischemic heart disease, valvular problems and cardiac arrhythmias. Demographic data, patients' awareness of the disease and the state of compliance was assessed using an interviewer administered questionnaire. Kruskal-Wallis and Spearman's tests were used to examine the relationship between the study variables. Majority (79%) of patients had good drug compliance. Only 14% of the population had satisfactory awareness about the disease. Study showed a positive correlation between the awareness of disease and treatment compliance (P=.001). But no significant relationship was found between awareness on the disease and compliance to drugs (p=.069) during sub categorical analysis.

In Netherlands, a descriptive cross-sectional study was conducted to examine all dimensions of compliance and its related factors among heart failure patients. The sample consisted of 501 consecutive patients hospitalized for HF and participating in the COACH study; a multicentre study in the Netherlands. Data was gathered via patient interview and medical records. The Revised Heart Failure Compliance Scale was used to assess drug compliance and the Dutch Heart Failure Knowledge Scale was used to assess knowledge on disease. Study found that compliance was positively related with knowledge on the disease (OR=5.67; CI 2.87-11.19) (van der Wal et al., 2006).

A study was performed in Kosmonautów health centre in Wroclaw, Poland (Jankowska-Polańska et al., 2016), to investigate the relationship between knowledge on hypertension and on its management, and drug compliance in hypertensive patients. Study included 233 patients, who were >18 years and above diagnosed with hypertension at least one year before the commencement of the study. Two validated instruments were used in the study. Polish version of Hypertension Knowledge-Level Scale was used to assess hypertension related knowledge. MMAS – 8 was used to assess self-reported drug compliance. Pearson's chi-squared test and was used for

statistical analysis. Results revealed group with low knowledge level had lower drug compliance compared to group with high knowledge level. It was statistically significant (p=.023). Study concluded that knowledge on hypertension is a significant independent determinant of drug compliance.

The cross-sectional study conducted among a sub sample of patients participated in COACH study as mentioned in section 2.1 (Nieuwenhuis et al., 2012) also examined factors associated with drug compliance. Demographic data and other clinical variables were gathered by patient interview and medical records. Knowledge on HF and the regimen was measured with the Dutch Heart Failure Knowledge Scale. Differences between compliant and non-compliant patients were tested using Chi-square tests or Fisher's exact tests and Mann–Whitney tests were used for statistical analysis at 0.05 significance level. There was no statistically significant difference (p>.05) in knowledge was found in compliant and non-compliant patients.

2.2.2 Disease and treatment related factors

According to the study results of Ho et al., (Ho et al., 2006) which was described in section 2.1, the largest decline in rates of medication use occurred between hospital discharge and 1 month (p<.001) during follow-up,. Study concluded that non compliance to drug treatment after MI is common and occurs early after discharge.

According to Hashmi et al (Hashmi et al., 2007), a factor significantly associated with poor drug compliance was presence of drug side effects (p=.006). An inverse relationship was observed between compliance and the number of drugs prescribed. Patients who were on 3 drugs or more had a good compliance compared to those who were on monotherapy (OR=0.3, 95% CI=0.1-0.6).

Study mentioned in section 2.2.1 (Nieuwenhuis et al., 2012) found that non-compliant patients had a short duration of disease (p=.04) and were prescribed drugs 2 – 3 times a day rather than once a day (p<0.01).

A cohort study conducted in Ontario (C. A. Jackevicius, Mamdani, & Tu, 2002) to compare two year compliance following statin initiation in three cohorts of patients: 22379 with recent acute coronary syndrome (ACS), 36106 with chronic CHD and 85020 without CHD. It found that relative to the ACS cohort, non compliance was more likely among patients receiving statins for chronic CHD (RR=1.14, 95% CI=1.11-1.16).

There is a progressive decline in compliance to prescribed cardio-protective drugs such as statins and beta-blockers over time. A study found that consistent use of cardiac drugs after six to twelve months of diagnosis of coronary heart disease was low, with approximately three fourths (71%) of patients report persistent use of aspirin, whereas less than half reported persistent use of β-blockers (46%), lipid lowering agents (44%) and all three drugs (21%) (L. K. Newby et al., 2006).

Study mentioned in section 2.1 (Marcum et al., 2013) showed no significant association between number of prescribed drugs, presence of co-morbidities and drug compliance.

The study mentioned in section 2.2.1 (Pamboukian et al., 2008), revealed that non-compliant individuals were more often from New York Heart Association (NYHA) class I or II when compared to compliant individuals, who were in NYHA class III or IV (p=0.04). There was no significant association between compliance and number of co-morbidities present (p=0.48).

The association between duration of disease, functional class, number of drugs and drug compliance also examined in the study (Chizzola et al., 1996) mentioned in section 2.1. Chi-square test used for statistical analysis with significance level of 0.05. But no significant association found between the duration of disease (p=.596), functional class (p=.053), number of drugs (p=.115) and drug compliance.

A prospective study conducted to assess the role of mediation adherence and to determine the outcomes in 134 heart failure patients attending outpatient cardiology clinics in Central Kentucky demonstrated that severe the symptoms as reflected by worse NYHA functional class was related to poor drug compliance.(Wu, Moser, Chung, & Lennie, 2008).

A randomized, controlled trial was conducted in an outpatient setting to examine the effect of beta-blocker dosing frequency on patient compliance, clinical outcome, and health-related quality of life in patients with stable angina pectoris (Kardas, 2007). 112 beta-blockers-naive outpatients with stable angina pectoris aged 40 – 75 years were randomized into two groups. One group was prescribed betaxolol 20 mg once daily while the other group was prescribed metoprolol tartrate 50 mg twice daily for 8 weeks. Drug compliance was measured by MEMS. The overall compliance was 86.5% in the betaxolol group and 76.1% in the metoprolol group. According to the results, patient compliance with once-daily betaxolol is significantly better (p=0.002) than with twice

daily metoprolol. Results demonstrated the advantage of once daily over twice daily treatment of stable angina pectoris.

A study conducted in United Kingdom (UK) among 367 patients who have taken ACEi or lipid lowering agent for at least three consecutive months to assess the effect of number of drugs on cardiovascular treatment compliance. Univariate and multivariate analyses has been used to identify the significance. There, the non compliant individuals have taken fewer number of drugs per day (5.3 ± 3.6 vs. 9.2 ± 7.1; $p<.001$), fewer number of scheduled drugs per day (4.1 ± 2.7 vs. 5.9 ± 3.4; $p=.001$) and had fewer administration frequency per day (1.8 ± 0.7 vs. 2.4 ± 0.9; $p=.001$). (Shalansky & Levy, 2002).

Study mentioned in section 2.1 (Lee et al., 2013) showed significant association between duration of disease ($p=.006$) with compliance. Lesser the duration of disease, individuals had good compliance. But number of antihypertensive drugs was not associated with compliance ($p=.813$). Author stated that, "some factors associated with antihypertensive drug compliance among Chinese patients using the MMAS-8 were novel findings and future research studies are needed identify the reasons for their non-adherence".

But above mentioned study (Hassan et al., 2005) found that drug side effects were significantly associated with non-compliance (adjusted OR=0.95; 95% CI=0.91–0.987; $p=.009$) although duration of disease found no significant association ($p>.05$) (Hassan et al., 2005).

Number of cardiovascular medication found to be significantly associated with drug compliance ($p<.001$) in the study mentioned in section 2.2.1 (Gehi et al., 2007). But presence of co-morbidities showed no significant association ($p>.05$).

A study conducted to determine the relationship between prescribed daily dose frequency and drug compliance found an improvement in the drug compliance from 59.0% on three times daily regime to 83.6% on once daily regime.(Eisen, Miller, Woodward, Spitznagel, & Przybeck, 1990).

Previous studies have demonstrated heterogeneous association between drug compliance and disease and treatment related factors.

2.2.3 Healthcare system related data

The study mentioned in section 2.2.1 (Hashmi et al., 2007) also concluded that poor compliance was significantly associated with cost of medication (p=.02). There was no significant association between good relationship with the doctor and drug compliance.

Communication is an essential component of healthcare process. Through the relationship between physician and patient, patients are informed about their drug regimes, encouraged and supported by providing assistance in adhering to treatment. Of total 127 studies, a meta-analysis has summarized that there is a significant association between patient's compliance and physician's communication (OR=2.16, CI=1.91-2.35, p<.001) (Haskard Zolnierek & DiMatteo, 2009). Also that has stated that patients of physicians who communicate well had 19% higher compliance and training communication skills among physicians improves patient compliance by 12%.

A study conducted with 128 hypertensive patients at hypertension clinic in Komfo Anokye Teaching Hospital, Ghana in 2001/2002 (Ohene Buabeng, Matowe, & Plange-Rhule, 2004), 96% of the non compliant patients cited unaffordable drug price as the reason for non compliance.

A cross-sectional study conducted in a sample of 460 patients from Aga Khan University Hospital and National Institute of Cardiovascular Diseases, Karachi, Pakistan (Hashmi et al., 2007) to measure the compliance to anti-hypertensive therapy and to investigate the factors associated with compliance found significant association between cost of medication (p=.02) and lack of access to medication (p=.01) with drug compliance

Study mentioned in section 2.1 showed no significant association between provision of health education to patients and their drug compliance (p=.80) (Tadesse, Demissie, Berhane, Kebede, & Abebe, 2013).

CHAPTER 3 – METHODS

3.1 Study design - Descriptive cross-sectional study.

3.2 Study setting - Study was conducted at Outpatient Cardiology clinic of National Hospital of Sri Lanka.

Cardiology unit of National Hospital of Sri Lanka (NHSL) is the final referral centre of the country and provides both inward care and clinic care to the patients. Outpatient Cardiology clinics provide services for the patients requiring long term regular follow-up. Patients who received initial inward care at Cardiology unit as well as some patients who received care at medical wards of NHSL and other hospitals in the country are then referred to outpatient clinic for long-term follow up. Clinics are held in weekdays from 8.00 am to 12 noon. Around 8000 patients attend outpatient clinics in a given month.

3.3 Study period – Total duration of the study was from April 2017 to December 2017. Data collection was done during August/September 2017

3.4 Study population – Coronary heart disease patients attending Outpatient Cardiology clinic of NHSL formed the study population. Final study sample included patients who fulfilled following eligibility criteria.

Inclusion criteria – CHD patients over 19 years of age, who has been diagnosed by a Consultant Cardiologist or a Consultant Physician, with ongoing treatment for more than 6 months from the diagnosis of CHD.

Exclusion criteria – Mentally unsound patients.

3.5 Sample size calculation – Sample size was calculated using the following formula;

$n = Z^2p(1-p)/d^2$ (Lwanga & Lemeshow, 1991)

Where;

n = sample size

Z = critical value for 95% confidence level was taken as 1.96

p = expected proportion of population drug compliance

Since no literature was available with regards to drug compliance among Sri Lankan CHD patients; it was taken as 50% (Lwanga & Lemeshow, 1991)

d = precision was taken as 5%

Substituting these values, the minimum required sample size n = $[1.96^2 \times 0.5 \times (1- 0.5)] \div 0.05^2 = 384$

Considering the 5% non-response rate, the final required sample size N = 403

3.6 Sampling technique – There are five outpatient clinic sessions for a week from Monday to Friday for CHD patients. An average of 400 patients attends each clinic session. Each day sampling frame was prepared based on the order in which patients were registered in the clinic register. Systematic random sampling technique was applied to get the sample. Sampling interval was calculated as follows.

The average number of patients attending outpatient clinics in two weeks is 4000.

Sample size is 403

Sampling interval is: (400×15)/403 = 14.9

So that sampling interval was considered as 15.

A random number was selected between number one and fifteen of the patients registered in the clinic register using lottery method. That was considered as the first individual to be recruited into the study. Thereafter every fifteenth patient registered in the clinic register was selected to be recruited. If these individuals fulfilled eligibility criteria they were invited to participate in the study. In instances where the selected patient does not fit into eligibility criteria the next immediate patient registered in the clinic register was invited to participate in. In instances where the eligible patient does not give consent the next patient in the systematic order was invited to participate in without replacing with the next immediate patient in the clinic register. This procedure was repeated till the total sample size was achieved

3.7 Study instruments – Pretested interviewer administered questionnaire was used (Annex VII). Both close and open ended questions were included in the questionnaire.

3.7.1 Main components of the questionnaire.

The questionnaire consisted of two parts namely Part A and Part B to achieve specific objectives of this study.

Part A was prepared to achieve specific objectives 2, 3, and 4, considering the methodical sequence of gathering information from the participant. It was used to gather data on factors related to drug compliance under the subheadings of patient

related factors, disease and treatment related factors and healthcare system related factors. Data gathered under those subheadings is summarized below.

1. Patient related factors –

a. Demographic and socioeconomic data – It included patient information such as age, sex, educational status, marital status, average monthly income of the patient's or his/her family and the status of their smoking and alcohol consumption.

b. Disease related knowledge – To assess patient's knowledge on causes, risk factors, symptoms, diagnosis and treatment related to heart disease fifteen statements were inoluded with 'yes', 'no' and 'don't know' responses.

2. Disease and treatment related factors – It included several questions pertaining to disease related factors such as duration of the disease since first diagnosed, symptom severity and presence of co-morbidities. Symptom severity was operationalized as Canadian Cardiovascular Society functional class classification (Kaul et al., 2009). Functional class was determined by careful patient interview. Questions pertaining to treatment related factors included questions related to complexity of treatment regime, frequent change in treatment, presence of drug side effects and taking other treatment methods for heart disease. Complexity of the treatment was operationalized as the number of different types of drugs taken per day and the maximum medication frequency per day.

3 Healthcare system related factors – It contained questions on distance to the clinic, average time spend at clinic, average time spend by the doctor, whether healthcare person has explained about the importance of drug compliance, the setting from where drugs are taken and the average cost per clinic visit.

Part B was prepared to achieve specific objective 1 of this study which was to assess the drug compliance.

It was used to assess drug compliance by evaluating the behaviour of patients on taking their medications. Questions were adapted from MMAS-8 questionnaire (D. E. Morisky et al., 2008). It consisted of 8 questions in relation to their worry in sticking to treatment plan; stopping drugs when the symptoms are under control; stopping drugs when the side effects are there; not taking drugs when they leave home; whether they

forget to take drugs and if so how frequently; whether they forget to take drugs during last two weeks and yesterday to evaluate the behaviour of taking drugs.

3.7.2 Construction of the questionnaire

The questions to be included and the order of the questionnaire were prepared by the principal investigator (PI) after going through the available literature under the supervision of the supervisor.

Part A

1. Patient related factors –

a. Demographic and socioeconomic data – Questions to gather patients' demographic and socioeconomic details were prepared after going through available literature.

b. Disease related knowledge – Questions used to assess disease related knowledge were originally adapted from Heart Disease Knowledge Questionnaire (Bergman, Reeve, Moser, Scholl, & Klein, 2011) which contained 25 questions with 'true" or 'false' type answers. Considering socio-cultural aspects and patients' general awareness of medial jargons it was modified with the assistance of the supervisor. So that the final questionnaire consisted of 15 questions to assess disease related knowledge which covered causes, risk factors, symptoms, diagnosis and treatment related to heart disease. Each question was offered with 'yes', 'no' or 'don't know' answers. Each correct answer was given one mark and incorrect or 'don't know' answers were given zero marks. Minimum and maximum possible scores ranged from 0 – 15.

2. Disease and treatment related factors – Questions to gather disease and treatment related details were prepared after going through available literature.

3. Healthcare system related factors - Questions to gather health system related details were prepared after going through available literature and discussion with the supervisor.

Part B

Questions used to measure drug compliance were adapted from MMAS-8 (D. E. Morisky et al., 2008). MMAS-8 consists of eight questions to identify barriers and behaviours associated with drug compliance such as forgetfulness, leaving home, stopping mediations due to side effects, stopping medications when the symptoms are under control and the inconvenience related to sticking to long term treatment plan.

Considering socio-cultural aspects of the patients attending the clinic several modifications were made accordingly with the advice of the supervisor to improve the face and content validity of the scale.

Among the eight questions, question 1 – 5, 7 and 8 had "yes/ no" type answers while question 6 had a 5 point likert scale type of answers. Responses were assessed using a scoring system.

Scoring system used to assess responses for the eight questions was as follows.

Question 1 -5 and question 7: "yes" answer was given 1 mark and "no" answer was marked as 0

Question 8: "yes" answer was given as 0 and "no" answer was given 1 mark.

Question 6: marks were given as a scale where responses 1 – 5 were given 0, 0.25, 0.5, 0.75 and 1 mark respectively.

Minimum possible score and maximum possible score ranged from 0 – 8.

Questionnaire was originally developed in English by the PI and then was reviewed by the supervisor, after which necessary corrections were made. The corrected questionnaire was translated to Sinhala and Tamil versions and then they were back translated to English by independent translators. Accuracy and meaning of both forward and backward translations were checked and amendments were made where necessary before being finalized.

3.8 Pre testing of the study instrument – Pre testing of the study instrument was carried out among twenty CHD patients attending Outpatient Cardiology clinic at Colombo South Teaching Hospital (CSTH). NHSL and CSTH are situated in less than 10km apart. Population attending clinics in both these hospitals were more or less similar.

The proper understanding of the questions by patients, any ambiguity of language, cultural acceptability of the wording, deficiencies in the structure of the questionnaire and the time taken for completion was assessed. Once the pre testing was done modifications were made as necessary so that the questionnaire was simple to understand and answer yet giving accurate data.

3.9 Study implementation – Collaborations were made with Cardiology team from the beginning. Once ethical approval and permission to conduct the study were obtained,

relevant clinic staff was informed about the study and the date of commencing data collection. Data collection was done by PI and two trained data collectors.

3.9.1 Training data collectors

The data collectors were two 4th year medical students from the Faculty of Medicine, University of Colombo who were on vacation during the period of data collection. Both of them were fluent in both English and Sinhala languages and one was fluent in Tamil language too. Both had previous experience in conducting research. They were trained as follows.

Step 1 – Purpose of the study was explained according to the general and specific objectives. A detailed description on the study implementation plan was given to them. Importance of building a good rapport with patients and the way of obtaining informed consent was explained. Ethical issues relevant to the study were explained with special reference to maintaining privacy and confidentiality of information given by participants.

A brief introduction was given about the Part A and Part B of study instrument. Then, a detailed description on the content of the study instrument was given. The flow of collecting data was explained by taking each question in the study instrument into consideration. The way of scrutinizing certain information given by patients such as duration of the disease, number of varieties of drugs taken per day and the maximum drug frequency per day, with their clinic records were explained. The importance of completeness and accuracy of data was emphasized.

Step 2 – A practical exposure was given on study implementation and data collection using the study instrument at CSTH clinic setting during pre-testing under the supervision of PI. Issues aroused were discussed with data collectors following pre-testing.

3.9.2 Data collection – Each patient who attended Outpatient Cardiology clinic was given a clinic registration number from the front reception desk according to the time order they reach the clinic. Then patients handed-over that number to a separate registration counter in the outpatient clinic. Registration of clinic patients started around 7a.m. A Nursing officer and a health assistant at the registration counter registered patients in the registration book according to the ascending order of the clinic registration numbers. This registration list was taken as the sampling frame.

Study participants were selected at the registration counter with the help of the nursing officer and the health assistant when patients arrive there to get registered. Principal investigator selected patients to be included in the study according to the systematic sampling technique and the fulfilment of eligibility criteria by the patients. Eligibility criteria were checked by going through medical records and patient interview.

Information sheet and the consent form were given to the selected patients at the registration counter itself and then directed them to the seating area. Adequate time was given them to go through the information sheet. People who had difficulties in reading, writing and understanding the content of the information sheet and consent form were given adequate support of the data collectors. Informed written consent was obtained by patients willing to participate in the study.

Then Principal investigator and data collectors carried out the interview with the participants in a pre arranged space in the consultation area which maintained privacy of the information given by them. After each interview, completeness of the questionnaires was checked. Individuals who were eligible but did not wish to participate in the study were marked as non respondents. They were allowed to withdraw from the study after informing the interviewers.

To avoid interviewer exhaustion, the maximum number of interviews to be done for a day by each interviewer was set to ten. This whole procedure was repeated for three weeks until the total sample was achieved.

3.9.3 Measures taken to improve the quality of data

Every possible effort was taken during the design, implementation and analysis phases to minimize errors, biases and to maximize the validity by improving the quality of data.

- Minimizing sampling error –
  - During the design stage the sample size was calculated ensuring to get an adequate sample size. 5% was added as non response rate to get the final sample size. Eligibility criteria were set up and systematic random sampling technique was applied ensuring the validity of study design and minimizing the selection bias.
- Minimizing measurement errors –
  - Minimum possible number of individuals was occupied as data collectors.
  - Steps were taken to improve the precision, accuracy and to minimize the interviewer bias by training the data collectors at the beginning of the implementation stage. Data

collection was done by both Principal investigator and data collectors. Principal investigator was available in the field throughout the implementation stage to provide clarifications to the data collectors where necessary.

- Measures were taken to minimize the information bias. Patients were selected strictly adhering to the eligibility criteria. Information on certain disease and treatment related factors such as duration of the disease, presence of co-morbidities, number of drug types and maximum drug frequency were gathered from written clinic documents.
- Face validity of the questionnaire was ensured. To make sure that face validity was maintained the study instrument was prepared under the supervision, guidance and advises from the supervisor. Consultant Cardiologists' opinions were taken where necessary. Non experts, patients, nursing officers' opinions were also considered.
- Content validity was ensured through literature review and advises taken from the supervisor.

- To minimize non-response rate, all necessary information and instructions were given to the patients and their privacy was maintained.

3.10 Data analysis - Collected data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) software – version 21. Descriptive statistics of certain numerical variables were expressed as mean and standard deviation. Certain numerical variables were re-arranged into categorical variables accordingly. Categorical variables were presented as frequencies and percentages.

Disease related knowledge was assessed using a scoring system (refer section 3.7.2). It consisted of 15 questions with 'yes', 'no' and 'don't know' answers. Each correct response were given '1' mark and incorrect or 'don't know' responses were given '0' marks. Total score ranged from 0 to 15. Mean score of the study sample was calculated and, individuals obtained a mark above the mean score were categorized as having 'good knowledge' and individuals obtained less than the mean score were categorized as having 'poor knowledge'.

Level of drug compliance also measured using a scoring system (refer section 3.7.2). It consisted of 8 questions and the scoring system was adapted from original scale (D. E. Morisky et al., 2008). Question 1 – 5, 7 and 8 had ''yes'' or ''no'' type answers while question 6 had a 5 point likert scale type of answers. Scoring system used to assess responses for the 8 questions was as follows.

Question 1 -5 and question 7: "yes" answer was given 1 mark and "no" answer was marked as 0

Question 8: "yes" answer was given as 0 and "no" answer was given 1 mark.

Question 6: marks were given as a scale where responses 1 – 5 were given 0, 0.25, 0.5, 0.75 and 1 mark respectively.

Total score allocated for the questionnaire was 8. Individuals who scored 8 marks were categorized as "good compliance", scores between 6 to less than 8 marks were categorized as "moderate compliance" and who scored below 6 was categorized as "poor compliance". For the purpose of statistical analysis, both "good" and "moderate compliance groups were re-categorized as "good compliance". "Poor compliance" group remained same.

Drug compliance as well as patient, disease, treatment and healthcare system related factors were arranged into categorical variables. Chi square test was applied to find the association between factors related to drug compliance as the independent variable and drug compliance as the dependent variable. Results were expressed as Probability value (p value). Probability value less than 0.05 was considered as statistically significant.

3.11 Administrative requirements – Approval of the study proposal was obtained from Board of study in Community Medicine, Postgraduate Institute of Medicine. Permission to conduct the study was obtained from the Director, National Hospital of Sri Lanka and the Consultant Cardiologists in Charge of the respective Cardiology clinics, National Hospital of Sri Lanka.

3.12 Ethical issues and clearance - The purpose of the study, voluntary participation, participant's responsibilities, risks, benefits and issues regards to confidentiality and termination of participation was explained and an information sheet also was given to participants. Participants were convinced that they may withdraw from participation at any time after notifying the PI with no penalty or effect on medical care; and non participation in the study wouldn't carry any disadvantage when seeking future healthcare. If participants had any question with regards to the information provided; they were given the opportunity to ask for clarifications from the principal investigator and the contact numbers was provided. Participants were informed that, the same contact number can be used to inquire about the study results once the study is over.

Participants were provided the information sheet and consent form. They were asked to fill it with relevance to whether they had opportunity to discuss / ask questions, whether

they got satisfactory answers and whether they received enough information about the study. If they decided to participate, informed written consent was taken for participation.

Participants' name and address were not collected and interviewing was done while maintaining their privacy. Information provided by them was not used in such a way that they can be identified personally at any stage. Only the PI and data collectors had the access to the medical records with the sole purpose of confirming the accuracy of medical information provided by participants. All the information gathered were kept secured and confidentiality was maintained strictly throughout the study.

Hard copies of questionnaires will be kept locked for seven years and then only will be destroyed by burning. Soft copies of data files were saved as a locked document in a hard drive and two other pen drives which belong to the principal investigator.

Ethical clearance to conduct the study was obtained from Ethical Review Committee – Faculty of Medicine, University of Colombo and Ethical Review Committee – National Hospital of Sri Lanka.

3.12 Definition of variables

Age – age in completed years

Ethnicity – distinguished as Sinhalese, Tamil, Moor, Burger, Malay and Other

Level of education – the highest level of education obtained by the patient – no formal education, pre-school, Grade 1 - 5, Grade 6 - 11, passed GCE O/L, passed GCE A/L, university degree/diploma

Marital status – current marital status was distinguished as unmarried, married, widowed and divorced

Current employment status – distinguished as employed, unemployed or retired

Duration of the disease – number of years/months since the heart disease was diagnosed for the first time by a Consultant Physician or Cardiologist

Functional capacity – severity of angina symptoms were operationalized according to the Canadian Cardiovascular Society Functional Classification of Angina.

- No symptoms - No symptoms with strenuous or rapid or prolonged exertion at work or recreation

- Grade I - Chest pain occurs with strenuous or rapid or prolonged exertion at work or recreation. Walking or climbing stairs does not cause chest pain
- Grade II - Chest pain occurs on walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals or under emotional stress, or only during few hours after awakening. When walking more than 200 meters on level ground, or when climbing more than one flight of stairs at a normal pace and in normal conditions
- Grade III - Chest pain occurs on walking around 100 to 200 meters on level ground or climbing one flight of stairs at a normal pace in normal conditions
- Grade IV - Inability to perform any physical activity without discomfort. Chest pain may be present at rest.

Number of drugs – number of drugs prescribed per day by the doctor for current use of the patient with heart disease

Side effects – any unwanted reaction experienced by a patient attributed to be caused by the drug

Time spend in the clinic – the average number of hours the patient has to spend in the clinic from the given time to get the complete service including taking drugs from the hospital pharmacy

Time spend by the doctor – average time the doctor spend for the consultation

Cost per clinic visit – the average amount of money that participant has to pay or spend during a clinic visit (for transport, food, accompanying person etc.)

Compliance – *"patient's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincide with healthcare providers' recommendations for health and medical advice"*

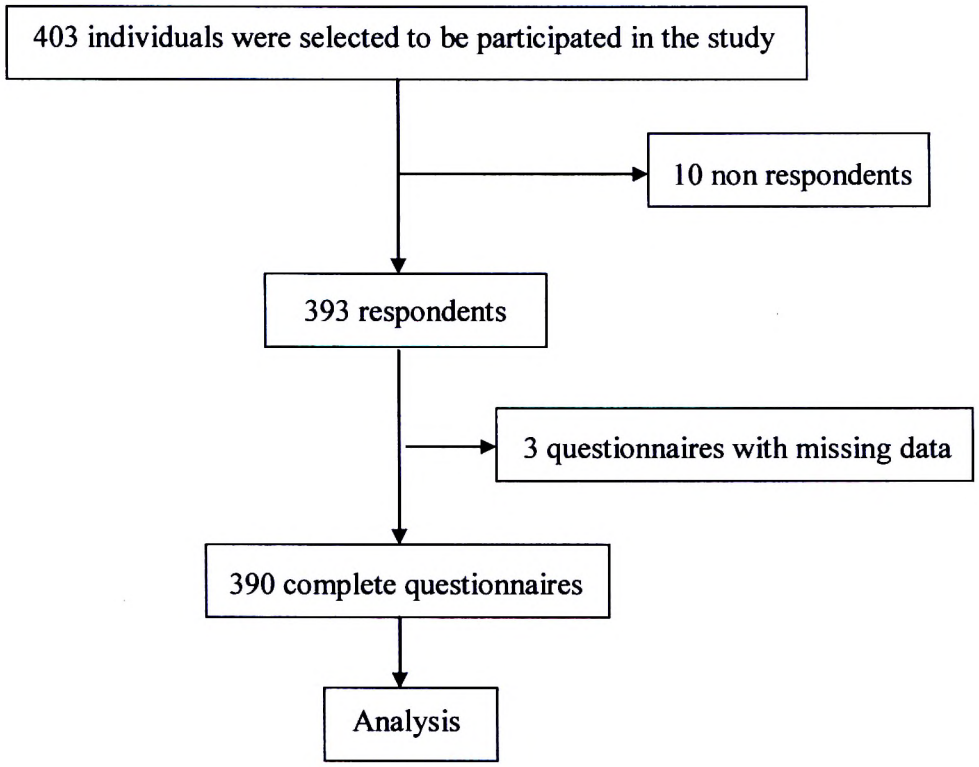
CHAPTER 4 - RESULTS

A descriptive cross sectional study was carried out to assess the extent of drug compliance among CHD patients attending outpatient cardiology clinic – NHSL and to find the factors associated with drug compliance. A sample of 403 patients was selected using systematic random sampling technique. 10 individuals did not respond due to lack of interest in participating in this study. So the response rate was 97.5%. Three questionnaires with missing data were excluded from the analysis. Therefore, only 390 complete questionnaires were included in the analysis.

Chi square test was used to determine association between drug compliance and selected factors arranged as categorical variables and the significant level of the statistical test was considered as 0.05.

Figure 1 summarises the methodology of the study.

Figure 1: Summary of the methodology



The results of the study will be presented under following headings.

4.1 Demographic and socio-economic characteristics of study participants

4.2 Disease related knowledge of study participants

4.3 Disease and treatment characteristics of study participants

4.4 Healthcare system related characteristics of study participants

4.5 Drug compliance of study participants

4.6 Association of drug compliance with selected factors

4.6.1 Association of drug compliance with patient related factors

4.6.2 Association of drug compliance with disease and treatment related factors

4.6.3 Association of drug compliance with healthcare system related factors

4.1 Demographic and socio-economic characteristics of study participants

Table 1 illustrates the demographic and socio-economic characteristics of study participants. About 3/5th (58.7%, n=229) of the sample were males. Mean age of study sample was 61.4 (SD=9.5) years with a range of 28 to 81 years. The majority (55.9%) were above 61 years age group. 334 (85.6%) participants were currently married. Most (85.6%) were Sinhalese. The majority (55.8%) had education above GCE O/L. Only 136 (34.9%) participants were currently employed. 58.4% (n=228) had monthly income <Rs20000.00.

Table 1: Distribution of demographic and socio-economic characteristics of participants

Socio-demographic characteristic	**Number (%) (N = 390)**
Socio-demographic characteristic	
Male	229 (58.7%)
Female	161 (41.3%)

Table 1 Contd'

Socio-demographic characteristic	Number (%) (N = 390)
Age (years)	
<50	51 (13.1%)
51 – 60	121 (31.0%)
61 – 70	157 (40.3%)
>71	61 (15.6%)
Marital status	
Currently unmarried	10 (2.5%)
Currently married	334 (85.6%)
Divorced	7 (1.8%)
Widowed	39 (10.0%)
Ethnicity	
Sinhalese	334 (85.7%)
Tamil	28 (7.2%)
Moor	24 (6.2%)
Burger	4 (1.0%)
Educational level	
< Grade 5	56 (14.4%)
Grade 6 – 11	116 (29.7%)
Passed GCE O/L	153 (39.2%)
Passed GCE A/L	54 (13.8%)
University degree / diploma	11 (2.8%)
Current employment status	
Employed	136 (34.9%)
Unemployed	176 (45.1%)
Retired	78 (20.0%)
Average monthly income of the patient / family (Rs)	
Less than 10000	136 (34.8%)
10001 – 20000	92 (23.6%)
20001 – 30000	82 (21.0%)
30001 – 50000	58 (14.9%)
More than 50001	22 (5.6%)

Table 2 illustrates the status of smoking and alcohol consumption among participants. Of the participants, about 60% (n=232) have never smoked. All the female (n=161) have never smoked. All the ever smoked and current smokers were males. There were around 55% (n=215) participants who have never consumed alcohol. Among them all were females (n=161). All the participants who have ever consumed alcohol and current consumers were males.

Table 2: Status of tobacco smoking and alcohol consumption among participants

Characteristic	Number (%)		Total
	Male (n=229)	Female (n=161)	(n=390)
Tobacco smoking			
Never smoked	71 (18.2)	161 (41.3%)	232 (59.5%)
Ever smoked	150 (38.5%)	0 (0%)	150 (38.5%)
Current smokers	8 (2.0%)	0 (0%)	8 (2.0%)
Total	**229 (58.7%)**	**161 (41.3%)**	**390 (100.0%)**
Alcohol consumption			
Never consumed	54 (13.8%)	161 (41.3%)	215 (55.1%)
Ever consumed	133 (34.1%)	0 (0%)	133 (34.1%)
Current consumers	42 (10.8%)	0 (0%)	42 (10.8%)
Total	**229 (58.7%)**	**161 (41.3%)**	**390 (100.0%)**

4.2 Disease related knowledge of study participants

A 15 itemed questionnaire was used to assess the disease related knowledge of study participants. It consisted of knowledge related to aetiology, risk factors, symptoms, diagnosis and treatment related to CHD.

Table 3 shows the responses given by participants to each item in the questionnaire.

Table 3: Participants' responses to 15 items in the questionnaire to assess disease related knowledge

Item	Number (%)		
	Correct response	Incorrect response	Total
Aetiology			
The most common cause of heart attack is a blood clot that forms inside the coronary artery	359 (92.1%)	31 (7.9%)	390 (100.0%)
Formation of fatty plaques inside the coronary arteries occur not only during adulthood	175 (44.9%)	215 (55.1%)	390 (100.0%)
Risk factors			
High cholesterol is a risk factor for CHD	368 (94.4%)	22 (5.6%)	390 (100.0%)
Smoking is a risk factor for CHD	348 (89.2%)	42 (10.8%)	390 (100.0%)
Control of hypertension reduces the risk of heart attack	327 (83.8%)	63 (16.2%)	390 (100.0%)
Control of overweight/obesity has an effect on developing CHD	307 (78.7%)	83 (21.3%)	390 (100.0%)
Symptoms			
Chest pain is a common symptom of heart disease	368 (94.4%)	22 (5.6%)	390 (100.0%)
Not every person who has heart disease has symptoms	212 (54.4%)	178 (45.6%)	390 (100.0%)
Diagnosis			
Coronary angiography is done to see the inside of coronary arteries	294 (75.4%)	96 (24.6%)	390 (100.0%)
An ECG does not always detect the presence of heart disease	138 (35.4%)	252 (64.6%)	390 (100.0%)
Treatment			
Routine physical activities (like walking, running, gardening) are recommended for heart disease patients	317 (81.3%)	73 (18.7%)	390 (100.0%)
It is recommended to reduce the salt consumption for heart disease patients	310 (79.5%)	80 (20.5%)	390 (100.0%)
Aspirin is prescribed to reduce the risk of blood clot formation inside the vessels	308 (79.0%)	82 (21.0%)	390 (100.0%)
Relieving symptoms is not the only goal of treating heart disease	118 (30.3%)	272 (69.7%)	390 (100.0%)

Though 92.1% (n=359) knew that most common cause for heart attack is a blood clot that forms inside the coronary arteries, only 44.9% (n=175) knew that atherosclerotic plaque formation occur from early ages of life

More than 75% of the participants had knowledge on risk factors of coronary heart disease.

Except a few, majority (94.4%) knew that chest pain is a common symptom of heart disease. But, only about half (54.4%) of the sample knew that heart disease can occur even without symptoms.

Majority (69.7%, n=272) had no knowledge on overall goals of the treatment of heart disease. But more than 75% had knowledge on selected recommended lifestyle modifications like routine physical activities and reduction of salt consumption.

A scoring system was used to allocate marks when assessing the disease related knowledge. Minimum and maximum marks obtained by the study participants ranged from 0 to 15 with a mean value of 11 (SD=2.79). As mentioned in methods (refer section 3.10); mean value was taken as the cut-off value to categorize participants' disease related knowledge as 'good' or 'poor'. So that participants who have obtained >=12 marks were categorized as having 'good' knowledge while participants who have obtained <=11 marks were categorized as having 'poor' knowledge.

Table 4 presents the level of disease related knowledge among participants.

Around half (49.7%) of the study participants had good disease related knowledge according to the scoring system.

Table 4: Level of disease related knowledge among participants

Level of knowledge	**Number (%) (N = 390)**
Good	194 (49.7%)
Poor	196 (50.3%)
Total	**390 (100.0%)**

4.3 Disease and treatment characteristics of study participants

Disease characteristics considered in this study were duration of the disease since first diagnosed, severity of symptoms and presence of co-morbidities. Symptom severity was categorized according to Canadian Cardiovascular Society Functional Classification of Angina.

Table 5 shows the distribution of disease characteristics among participants.

Table 5: Distribution of disease related characteristics among study participants

Characteristic	Number (%) (N = 390)
Duration of the disease (years)	
<1	34 (8.7%)
1 – 5	186 (47.7%)
>=6	170 (43.6%)
Functional capacity	
No symptoms	117 (30.0%)
Grade 1	86 (22.1%)
Grade 2	91 (23.3%)
Grade 3	60 (15.4%)
Grade 4	36 (9.2%)
Chronic illnesses other than CHD	
Present	332 (85.1%)
Absent	58 (14.9%)

The duration of disease among participants ranged from 7 months to 25 years. Only 8.7% (n=34) were there with duration of disease less than one year. 30.0% (n=117) had no symptoms even with strenuous, rapid or prolonged exertion. But, 9.2% were in the Grade 4 category. Around 85.0% participants had chronic illnesses apart from CHD.

Table 6 shows the chronic illnesses that were present among participants.

Of the participants who had chronic illnesses (n=332) apart from CHD, more than 60% had hypertension, hypercholesterolemia and diabetes mellitus. The most prevalent chronic illness was hypertension (64.2%, n=213). Less than 1% of participants had hypothyroidism, psychiatric illnesses and cancers.

Table 6: Distribution of chronic illnesses among participants

Chronic illness	Number (%)
Hypertension	213 (64.2%)
Hypercholesterolemia	210 (63.3%)
Diabetes mellitus	203 (61.1%)
Osteoarthritis	14 (4.2%)
Bronchial asthma	7 (2.1%)
Chronic kidney disease	4 (1.2%)
Hypothyroidism	3 (0.9%)
Psychiatric illness	3 (0.9%)
Cancer	2 (0.6%)

Table 7 shows the treatment characteristics of participants

The number of drugs prescribed for a day ranged from two to twelve. Mean number of drugs prescribed was 6.7 (*SD*=2.0). Just above 50% of the sample (52.3%, n=204), were on seven or more drug types per day. Majority (77.2%, n=301) were on twice daily drug doses. About 1/3rd (30.0%, n=117) of the sample have ever experienced drug side effects. But more than half (56.6%, n=221) of the participants' drug regimes had been changed frequently. 41 (10.5%) participants have taken alternative medicines other than treatment prescribed from the cardiology clinic.

Table 7: Treatment characteristics of participants

Characteristic	Number (%) (N = 390)
Number of drug types per day	
<=3	18 (4.6%)
4 – 6	168 (43.1%)
7 – 9	168 (43.1%)
>=10	36 (9.2%)
Drug frequency per day	
Once	28 (7.2%)
Twice	301 (77.2%)
Thrice	61 (15.6%)
Drug side effects	
Present	117 (30.0%)
Absent	273 (70.0%)
Drugs were changed frequently	
Yes	221 (56.7%)
No	169 (43.3%)
Alternative medicine taken	
Yes	41 (10.5%)
No	349 (89.5%)

4.4 Healthcare system related characteristics of study participants

Healthcare system related characteristic considered in the study were; distance to the clinic from residence, time spent by the doctor during the visit, whether participants were explained about the drug compliance, place of taking prescribed drugs, the average amount of money participants were spending during a clinic day and the average time taken to complete the clinic visit from the given time.

Table 8 presents the distribution of average distance from the participants' residents to the cardiology clinic.

Table 8: Distribution of distance to the cardiology clinic from the participants' residence

Distance to the clinic from residence (km)	Number (%) (N = 390)
<10	100 (25.6%)
11 – 20	124 (31.8%)
21 – 30	79 (20.3%)
>31	87 (22.3%)

About 1/4th (25.6%, n=100) of the sample were travelling less than 10km from their residence to cardiology clinic. 31.8% (n=124) of participants were travelling for 11 – 20 km distance.

Table 9 shows the distribution of healthcare service related characteristics.

The average time spent by the doctor for each patient during a clinic visit ranged from one minute to twenty minutes. The mean time spent was five minutes (SD=3.5). For most (76.7%, n=299) of the patients, the time spent by the doctor was less than five minutes. Majority (66.9%, n=261) patients were provided clear explanations about the drug regimes, objectives of drug treatment and expected treatment outcomes.

Table 9: Distribution of healthcare service related characteristics.

Characteristic		Number (%) (N = 390)
Time spent by the doctor (min)		
<=5		299 (76.7%)
6 – 10		71 (18.2%)
>=11		20 (5.1%)
Healthcare person explained about the drug compliance		
Yes	Doctor	193 (49.5%)
	Nursing officer	41 (10.5%)
	Both doctor and nursing officer	2 (0.5%)
	Pharmacist	25 (6.4%)
No		129 (33.1%)

Table 10 presents the place of taking prescribed drugs and the cost per clinic visit.

Table 10: Place of taking prescribed drugs and the average cost per clinic visit

Characteristic	Number (%) (N = 390)
Place of taking prescribed drugs	
Pharmacy within the hospital	323 (82.8%)
Pharmacy outside the hospital	9 (2.3%)
Both with the hospital and outside the hospital pharmacies	58 (14.9%)
Cost per clinic visit (Rs)	
<=250	197 (50.5%)
>=251	193 (49.5%)

Around 4/5th (82.8%, n=323) of the participants took their prescribed drugs from the pharmacy within the hospital. But, nearly 15% took from both within the hospital and outside the hospital pharmacies.

Average cost per clinic visit included all the money participants had to pay or spent to visit the clinic. Around 50% (n=197) spent less than Rs. 250.00 during a day they visit the clinic

Table 11 shows the average time taken to complete the clinic visit for participants who have taken their drugs only from the clinic pharmacy or from both clinic and outside pharmacies. Participants who take their drugs from outside pharmacies were excluded in analysis. Of 381, more than three hours was taken to complete the clinic visit only for 122 (32%) participants

Table 11: The average time taken to complete the clinic visit.

Characteristic	**Number (%)** **(N = 381)**
Time taken to complete the clinic visit (hr)	
<3 hrs	259 (67.9%)
>3hrs	122 (32.0%)
Total	**390 (100.0%)**

4.5 Drug compliance of study participants

Drug compliance of the participants was measured using eight itemed MMAS-8. Reasons that affected the drug compliance of patients as identified by MMAS-8 are shown in table 12.

Table 12: Reasons that affected the drug compliance of participants

Behaviour		Number (%)
Worried about sticking to CHD treatment plan		209 (53.6%)
Could not bring along drugs when travel or leave home		118 (30.3%)
Stopped taking drugs when feel like disease is under control		51 (13.1%)
Stopped taking drugs without telling doctor because of side effects		25 (6.4%)
Ever forgotten to take drugs		273 (70.0%)
Frequency of forgetting to take drugs		
	All the time	5 (1.3%)
	Usually	48 (12.3%)
	Sometimes	157 (40.3%)
	Once in a while	63(16.2%)
	Never / Rarely	117 (30.0%)
During two weeks before the clinic visit, there were days that participant did not take drugs		63 (16.2%)
During the day before clinic visit, participant did not take drugs		18 (4.6%)

Of all the participants, 209 (53.6%) were worried about sticking to their drug treatment. 118 (30.3%) participants had instances where they were unable to take drugs as they could not bring along their drugs when travel or leave home. Only 51 (13.1%) participants stopped taking drugs at some point when they feel like the disease is under

control and around 6% (n=25) have stopped taking drugs due to side effects. Majority (70.0%; n=273) of the participants have ever forgotten to take their CHD drugs (Table 12). According to Table 12, the commonest behaviour that affected the drug compliance was forgetting to take drugs.

Responses for the eight items in the MMAS-8 were assigned scores to measure drug compliance of the participants. For question 1 -5 and question 7: "yes" answer was given 1 mark and "no" answer was given 0 marks. For question 8: "yes" answer was given as 0 and "no" answer was given 1 mark.

Question 6: marks were given as a scale where responses 1 – 5 were given 0, 0.25, 0.5, 0.75 and 1 mark respectively. Maximum score assigned was 8. Participants were categorized into three levels of compliance depending on the scores they have obtained (D. E. Morisky et al., 2008).

- 8 marks – Good compliance
- 6 – <8 marks – Moderate compliance
- <6 marks – Poor compliance

Table 13 presents the drug compliance of study participants.

Table 13: Drug compliance of participants

Category	**Number (%)** **(N = 390)**
Good compliance(8 marks)	45 (11.5%)
Moderate compliance (6 – <8 marks)	123 (31.5%)
Poor compliance (<6 marks)	222 (57.0%)
Total	**390 (100.0%)**

Minimum and maximum scores obtained by participants ranged from 1.50 to 8.00 with a mean of 5.71 (SD=1.48). Only 11.5% (n=45) of the study sample had good compliance and majority (57.0%; n=222) of the participants' compliance was poor.

But for the purpose of statistical analysis, both "good" and "moderate" compliance groups were re-categorized as "good compliance". "Poor compliance" group remained

same. Table 14 shows the amalgamated categories. Then 43.0% (n=168) participants demonstrated good compliance.

Table 14: Distribution of participants in two categories of drug compliance

Category	Number (%) (N = 390)
Good compliance(6 - 8 marks)	168 (43.0%)
Poor compliance (<6 marks)	222 (57.0%)
Total	**390 (100.0%)**

4.6 Association of drug compliance with selected factors

Factors considered in this study included patient related factors, disease and treatment related factors and healthcare system related factors.

4.6.1 Association of patient related factors with drug compliance

Selected patient related factors included demographic and socio-economic characteristics, status of tobacco smoking and alcohol consumption and disease related knowledge of the participants.

Table 15 and Table 16 show the association between patients' demographic and socio-economic characteristics and drug compliance.

Table 15: Association between socio-demographic characteristics of study participants' and drug compliance

Characteristic	Number (%)			Chi square
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (n=390)	Degrees of freedom *P* value
Age (years)				$\chi^2 = 0.359$
<60[a]	77 (44.8%)	95 (55.2%)	172 (100.0%)	df=1
>61[b]	91 (41.7%)	127 (58.3%)	218 (100.0%)	$p = .549$
Sex				$\chi^2 = 0.485$
Male	102 (44.5%)	127 (55.5%)	229 (100.0%)	df=1
Female	66 (41.0%)	95 (59.0%)	161 (100.0%)	$p = .486$
Marital status				$\chi^2 = 1.278$
Currently married	140 (41.9%)	194 (58.1%)	334 (100.0%)	df=1
Other [c]	28 (50.0%)	28 (50.0%)	56 (100.0%)	$p = .258$
Ethnicity				$\chi^2 = 0.383$
Sinhalese	146 (43.7%)	188 (56.3%)	334 (100.0%)	df=1
Other [d]	22 (39.3%)	34 (60.7%)	56 (100.0%)	$p = .536$
Educational level				$\chi^2 = 2.134$
<Grade 11 [e]	67 (39.0%)	105 (61.0%)	172 (100.0%)	df=1
>Passed GCE O/L[f]	101 (46.3%)	117 (53.7%)	218 (100.0%)	$p = .144$

Table 16: Association between socio-economic characteristics of study participants' and drug compliance

Characteristic	Number (%)			Chi square
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (n=390)	Degrees of freedom *P* value
Current employment status				$\chi^2 = 0.008$
Employed	59 (43.4%)	77 (56.6%)	136 (100.0%)	df=1
Unemployed [g]	109 (42.9%)	145 (57.1%)	254 (100.0%)	$p = .929$
Monthly income (Rs)				$\chi^2 = 0.211$
<20000 [h]	96 (42.1%)	132 (57.9%)	228 (100.0%)	df=1
>20001 [i]	72 (44.4%)	90 (55.6%)	162 (100.0%)	$p = .646$

Following groups were amalgamated to calculate χ^2.

[a] <60 = <50 + (51 – 60), [b]>61 = (61- 70) +>71, [c] Other = Unmarried + Divorced + Widowed, [d] Other = Tamil + Moor + Burger, [e] <Grade 11 = No formal education + Grade 1 – 5 + Grade 6 – 11, [f]>Passed GCE O/L = Passed GCE O/L + Passed GCE A/L + University degree/diploma, [g] Unemployed = Currently Unemployed + Retired, [h] <20000 = less than 10000 + 10001-20000, [i]>20001= 20001-30000 + 30001-50000 + more than 50001

There was no significant association found between demographic and socio-economic characteristics of the patients and their drug compliance.

Since none of the females were smokers or alcohol consumers; analysis of association between smoking and alcohol consumption status was limited only for males.

Table 17 illustrates the association between status of smoking and alcohol consumption with drug compliance among males.

Table 17: Association between smoking and alcohol consumption with drug compliance

Characteristic	Number (%)			Chi square
	Good compliance	Poor compliance	Total (n=229)	Degrees of freedom *P* value
Tobacco smoking				$\chi^2 = 0.012$
Never smoked	32 (45.1%)	39 (54.9%)	71 (100.0%)	df=1
Smoked [a]	70 (44.3%)	88 (55.7%)	158 (100.0%)	$p = .914$
Alcohol consumption				$\chi^2 = 1.529$
Never consumed	28 (51.9%)	26 (48.1%)	54 (100.0%)	df=1
Consumed [b]	74 (42.3%)	101 (57.7%)	175 (100.0%)	$p = .216$

Following groups were amalgamated to calculate χ^2.

[a] Smoked = Ever smoked participants + Currently smoking participants

[b] Consumed = Ever alcohol consumed participants + Current alcohol consumers

The proportion (55.7%) of smoked individuals with poor compliance was higher than never smoked individuals with poor compliance. Higher proportion (57.7%) of alcohol consumed individuals had poor drug compliance compared to never alcohol consumed (48.1%) participants with poor compliance. But the difference was not statistically significant at 0.05 significance level.

Table 18 illustrates the association between disease related knowledge and drug compliance.

There was no significant association found between disease related knowledge and drug compliance at 5% significance level.

Table 18: Association between disease related knowledge and drug compliance

Level of disease related knowledge	Number (%)			Chi square Degrees of freedom *P* value
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (n=390)	
Good	82 (42.3%)	112 (57.7%)	194 (100.0%)	$\chi^2 = 0.103$ df=1
Poor	86 (43.9%)	110 (56.1%)	196 (100.0%)	$p = .748$

4.6.2 Association of drug compliance with disease and treatment factors

Table 19 presents the association between disease characteristics of patients and drug compliance.

The proportion (73.5%) of participants with duration of disease less than one year with good compliance was higher than other two categories. The association between duration of disease and drug compliance was statistically significant ($p<.001$). Functional capacity of the participants showed significant association with drug compliance ($p<.05$). Although the proportion (58.4%) participants with other chronic illnesses whose compliance was poor was higher than the participants without chronic illnesses the difference was not statistically significant ($p>.05$).

Table19: Association between disease related factors and drug compliance

Characteristic	Number (%)			Chi square
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (n=390)	Degrees of freedom *P* value
Duration of the disease (years)				
<1	25 (73.5%)	9 (26.5%)	34 (100.0%)	χ^2=16.818
1 - 5	67 (36.0%)	119 (64.0%)	186 (100.0%)	df=2
>=6	76 (44.7%)	94 (55.3%)	170 (100.0%)	*p* <0.001
Functional capacity				
No symptoms	62 (53.0%)	55 (47.0%)	117 (100.0%)	χ^2=12.728
Grade 1	33 (38.4%)	53 (61.6%)	86 (100.0%)	df=4
Grade 2	35 (38.5%)	56 (61.5%)	91 (100.0%)	*p* = .013
Grade 3	18 (30.0%)	42 (70.0%)	60 (100.0%)	
Grade 4	20 (55.6%)	16 (44.4%)	36 (100.0%)	
Other chronic illnesses				
				χ^2 = 2.078
Present	138 (41.6%)	194 (58.4%)	332 (100.0%)	df=1
Absent	30 (51.7%)	28 (48.3%)	58 (100.0%)	*p* = .149

Table 20 presents the association between treatment characteristics and drug compliance

A statistically significant ($p<.05$) difference was observed between the number of drug types per day and drug compliance. The proportion (62.3%) of participants who were taking seven or more drug types per day with poor compliance was higher than those who were taking six or less drug types. The association between frequency of drug doses and compliance was statistically significant ($p<.05$). Higher proportion (65.6%) of participants taking drugs thrice a day had poor compliance compared to those who took once a day and twice a day doses. A higher proportion (61.5%) of participants

whose drugs were frequently changed showed poor compliance compared to whose drugs were not changed. That showed a significant (p<.05) association between frequent change of drugs and compliance. Experience of drug side effects showed a statistically significant (p<.05) association with drug compliance. A higher proportion (67.5%) of individuals experienced drug side effects showed poor compliance compared to those who have not experienced side effects. There was no statistically significant difference (p>.05) observed between taking alternative drugs for heart disease and drug compliance.

Table 20: Association between treatment related factors and drug compliance

Characteristic	**Number (%)**			**Chi square**
	Good compliance (n = 168)	**Poor compliance (n = 222)**	**Total (n=390)**	**Degrees of freedom** *P* **value**
Number of drug types per day				$\chi^2 = 4.959$
<=6 [a]	91 (48.9%)	95 (51.1%)	186 (100.0%)	**df=1**
>=7 [b]	77 (37.7%)	127 (62.3%)	204 (100.0%)	$p = .026$
Drug frequency per day				
Once	18 (64.3%)	10 (35.7%)	28 (100.0%)	$\chi^2 = 7.004$
Twice	129 (42.9%)	172 (57.1%)	301 (100.0%)	**df=2**
Thrice	21 (34.4%)	40 (65.6%)	61 (100.0%)	$p = .030$
Drugs were frequently changed				$\chi^2 = 4.431$
Yes	85 (38.5%)	136 (61.5%)	221 (100.0%)	**df=1**
No	83 (49.1%)	86 (50.9%)	169 (100.0%)	$p = .035$

Table 20 Contd'

Characteristic	Number (%)			Chi square
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (n=390)	Degrees of freedom *P* value
Drug side effects				**$\chi^2 = 7.656$**
Present	38 (32.5%)	79 (67.5%)	117 (100.0%)	**df=1**
Absent	130 (47.6%)	143 (52.4%)	173 (100.0%)	***p* = .006**
Alternative medicine				$\chi^2 = 0.013$
Taken	18 (43.9%)	23 (56.1%)	41 (100.0%)	df=1
Not taken	150 (43.0%)	199 (57.0%)	349 (100.0%)	*p* = .910

Following groups were amalgamated to calculate χ^2.

[a] <=6 = <=3 + 4-6, [b] >=7 = 7-9 + >=10

4.6.3 Association of drug compliance with healthcare system related factors

Table 21 presents the association between healthcare system related factors and drug compliance.

Although a higher proportion (59.4%) of participants residing <20 km distance from the clinic had poor drug compliance compared to participants residing >21 km distance; this association was not statistically significant ($p>.05$).

The association between time spent by the doctor during the clinic for each patient was significantly ($p<.05$) associated with drug compliance. Participants were less likely to be compliant to the drug treatment when the time spent by the doctor was less than five minutes compared to time spent was more than five minutes.

A higher proportion (65.1%) of participants who were not explained about the drug compliance by a healthcare person had poor drug compliance compared to those who were explained yet having poor compliance. There was a statistically significant ($p>.05$) difference in the relationship between providing explanations by a healthcare person and drug compliance.

Although a higher proportion of participants took drugs from the clinic pharmacy showed poor drug compliance compared to other group, the relationship was not statistically significant (p>.05).

There was a statistically significant (p<.05) difference between the average time taken to complete the clinic visit and the drug compliance. Participants were less likely to comply with the treatment when more than three hours were taken to complete the clinic visit compared to less than three hours were taken.

The proportion of participants who spent >Rs.250 with poor compliance was higher than those who spent <Rs. 250. This was statistically significant (p<.05).

Table 21: Association between healthcare system related factors and drug compliance

Characteristic	**Number (%)**			**Chi square**
	Good compliance (n = 168)	**Poor compliance (n = 222)**	**Total (n=390)**	**Degrees of freedom** *P* **value**
Distance to the clinic from participant's residence (km)				$\chi^2 = 1.290$
<20 [a]	91 (40.6%)	133 (59.4%)	224 (100.0%)	df=1
>21 [b]	77 (46.6%)	89 (53.6%)	166 (100.0%)	$p = .256$
Time spent by the doctor (min)				**$\chi^2 = 4.527$**
<5	120 (40.1%)	179 (59.9%)	299 (100.0%)	**df=1**
>5	48 (52.7%)	43 (47.3%)	91 (100.0%)	**$p = .033$**
Healthcare person explained about the drug compliance				**$\chi^2 = 5.277$**
Yes	123 (47.1%)	138 (52.9%)	261 (100.0%)	**df=1**
No	45 (34.9%)	84 (65.1%)	129 (100.0%)	**$p = .022$**
Place of taking prescribed drugs				$\chi^2 = 1.259$
Pharmacy within the hospital	135 (41.8%)	188 (58.2%)	323 (100.0%)	df=1
Other [c]	33 (49.3%)	34 (50.7%)	67 (100.0%)	$p = .262$

Table 21 Contd'

Characteristic	Frequency (%)			Chi square
	Good compliance (n = 168)	Poor compliance (n = 222)	Total (390)	Degrees of freedom *P* value
Time taken to complete the clinic visit (hr)				**$\chi^2 = 4.164$**
<3 hrs	125 (46.6%)	143 (53.4%)	268 (100.0%)	**df=1**
>3hrs	43 (35.2%)	79 (64.8%)	122 (100.0%)	***p* = .041**
Cost per clinic visit (Rs)				**$\chi^2 = 8.038$**
<=250	97 (50.3%)	96 (49.7%)	193 (100.0%)	**df=1**
>=251	71 (36.0%)	126 (64.0%)	197 (100.0%)	***p* = .005**

Following groups were amalgamated to calculate χ^2

[a] <20 = <10 + 11-20, [b] >21 = 21-30 + >31, [c]: Other = Pharmacy outside the hospital + Both hospital and outside pharmacies

CHAPTER 5 – DISCUSSION

Number one cause of mortality in Sri Lanka is CHD over last two decades (Medical Statistics Unit, 2015). CHD patients warrant lifelong treatment to achieve objectives of the patient management, hence to achieve ultimate goals of the treatment. Among all treatment strategies, use of cardiovascular drugs is the commonest approach to preserve optimal heart functions (Yusuf, Reddy, & Ounpuu, 2001). So that compliance to drugs is immensely important for CHD patients.

Research conducted on drug compliance in Sri Lanka is very limited. Hence, present study was carried out among coronary heart disease patients attending outpatient cardiology clinic of NHSL to identify their drug compliance and associated factors as an attempt to bridge the gap.

5.1 Summary of results

According to the present research, more than half (57%) of the CHD patients attended outpatient cardiology clinic of NHSL had poor compliance to their drug treatment. Patient related factors such as demographic and socio economic factors, status of tobacco smoking, status of alcohol consumption and disease related knowledge showed no significant association ($p>.05$) with drug compliance. However, among disease related factors, duration of the disease ($p<.001$) and symptom severity of the patients ($p=.01$) showed significant association with drug compliance. Apart from that, few treatment related factors such as number of drugs prescribed per day ($p=.026$), drug frequency per day ($p=.030$), frequent change of drug treatment ($p=.035$) and presence of drug side effects ($p=.006$) were significantly associated with drug compliance. Healthcare system related factors that showed significant association with drug compliance were, time spent by the doctor during the clinic ($p=.033$), provision of clear explanations about the treatment ($p=.022$), time taken to complete the clinic visit ($p=.041$) and cost per clinic visit ($p=.005$).

5.2 Methodological aspects

5.2.1 Study design

Objective of the study was to describe drug compliance and to find the association of drug compliance with selected factors. Cross sectional study design allows the investigator to measure both exposure and outcome of the study participants at a single point of time. It also provides opportunity to estimate the prevalence and find the association between these variables in clinic based studies (Setia, 2016). Usually, cross-sectional studies can be conducted relatively faster and are inexpensive too. So that, a clinic based cross sectional study was conducted to assess the drug compliance and to identify factors associated with drug compliance among CHD patients within the limited time period available without compromising the quality of the study.

Though most of the researchers (Hassan et al., 2005; Mugwano et al., 2016; G. Santra, 2015) have conducted cross sectional studies to assess drug compliance, there were instances where cohort studies have been done (Cynthia A. Jackevicius et al., 2008; L. Kristin Newby et al., 2006) to assess drug compliance. Since CHD is chronic illness which renders long term drug treatment, cohort studies would allow the investigator to follow up the participants regularly and assess the compliance at different points in time rather than assessing compliance in a single point in time.

5.2.2 Study setting

For the current study, outpatient cardiology clinic of NHSL was selected as the preferred study setting since it is the final referral center of the country. A large number of patients from all over the country receive follow up care from outpatient cardiology clinic. Hence it allowed selecting a reasonably representative sample for the current study.

Similarly, most of the time clinic based studies had been conducted elsewhere in the world to assess drug compliance (Hassan et al., 2005; Lee et al., 2013). Selecting a clinic based study setting would result in biased measurement in compliance since it recruits participants with satisfactory health seeking behaviours. But conducting a community based study (Marcum et al., 2013) would yield more valid results. Although the present study was conducted in a single study setting, multi centered studies (Ho et al., 2006) would give more valid results.

5.2.3 Study population

Coronary heart disease patients attending outpatient cardiology clinic of NHSL was considered as the study population irrespective of their socio demographic, disease or treatment characteristics. So that, results obtained were applicable to all coronary heart disease patients. Hence external validity was maintained.

Similar study populations had been considered in several other studies too (Chizzola et al., 1996; L. Kristin Newby et al., 2006)

5.2.4 Sample size

An adequate sample size is necessary to obtain a valid statistical significance when significance and to generalize the study results to the target population. When calculating the sample size, estimated prevalence was taken as 50%s as similar studies conducted in local context was not available (Lwanga & Lemeshow, 1991). It enabled to get the maximum sample size (n=403) for the present study. Having a sufficiently large sample size would have enabled to draw meaningful conclusions from the study.

Much larger samples were recruited for multicentered or community based prospective cohort studies conducted in developed world (Ho et al., 2006; Marcum et al., 2013; L. Kristin Newby et al., 2006). Larger sample sizes give more reliable results with greater precision and power, but they also cost more time and money.

But a sample of 37 patients were included in a study conducted to assess differences between compliant and non-compliant patients (Nieuwenhuis et al., 2012) which would have affected the generalizability of study results.

5.2.5 Sampling

Systematic sampling method is considered as the most suitable sampling method for the clinic setting as the simple random sampling was not feasible to be carried out. For the current study systematic sampling technique was applied to recruit the study sample. This ensured representativeness of the study sample to the study population. It improved internal validity of the study and minimized selection bias. A study

conducted in CSTH among hypertensive patients also has applied systematic sampling technique (Jayawerdane, 2016).

But most of the studies (Lee et al., 2013; Mugwano et al., 2016) used convenience sampling technique, while a single study (Hashmi et al., 2007) had applied simple random sampling to recruit a sample from a clinic setting though it was cumbersome to apply.

5.2.6 Study instrument

For the current study, Part A of the questionnaire which is on factors associated with drug compliance was developed by PI together with supervisor after extensive literature search. Part B of the questionnaire was designed to measure drug compliance. Drug compliance was measured by eight itemed Morisky Mediation Adherence Scale (MMAS-8) which is a widely used tool to measure drug compliance. it has several advantages; identifies barriers to non compliance, it is the shortest, easiest to score and very adaptable for various groups of medication (Culig & Leppee, 2014) . 93%sensitivity and 53% specificity were reported while validating MMAS-8 for a study in patients treated for hypertension seeking routine care in a outpatient clinic setting (D. E. Morisky et al., 2008). MMAS-8 was also validated with outstanding validity and reliability in patients with other chronic diseases apart from hypertension (Chang, 2016). For the present study, the content and face validity of the MMAS-8 was ensured following assessment by experts. This minimized occurrence of measurement bias. A pre-test was conducted among a similar group of patients at CSTH, which further ensured the clarity of the questionnaire quality of data.

MMAS-8 has been used in many studies (Hassan et al., 2005; Lee et al., 2013; Mugwano et al., 2016) to measure drug compliance among patients while only few have used MMAS-4 (Marcum et al., 2013). More valid objective measurements such as Medication Event Monitoring System (MEMS) – an electronic monitoring system also has been used in developed countries (Nieuwenhuis et al., 2012).

5.2.7 Data collection

An interviewer administered questionnaire was used for data collection in the current study. So that respondents' literacy was not a factor to exclude illiterate individuals from the study. Hence it minimized the opportunity for selection bias and missing data. Total sample size was 403. Participation was potentially increased by personal contact

and 393 individuals participated in the study. So that a satisfactory response rate (97.5%) was obtained. Only three questionnaires were there with missing data. Non response rate and the presence of missing data were minimized by using an interviewer administered questionnaire.

Minimum number of data collectors was employed to minimize inter-observer bias. A vigorous training on data collection procedure was given to them to minimize interviewer bias.

But compliance has been assessed through an email or a telephone conversation in certain studies (L. K. Newby et al., 2006).

5.2.8 Statistical analysis

During data analysis, score for MMAS – 8 was calculated and compliance was categorized as specified by authors (Donald E. Morisky, Alfonso Ang, Marie Krousel-Wood, & Harry J. Ward, 2008). Chi square test was applied to determine statistical significance of associations with the significance level of 0.05. Most of the studies (Gehi et al., 2007; Ho et al., 2006; Jankowska-Polańska et al., 2016; Lee et al., 2013) have used chi square test for statistical analysis but use of multivariate analysis would give more valid results after controlling the effect of confounding factors.

5.3 Drug compliance of study participants

Though there are several methods available to measure drug compliance of the patients, more commonly used subjective method was used to in the current study. From the subjective methods available, MMAS-8 was applied to measure patients', drug compliance. it categorize compliance into three categories named, 'good', 'moderate' and 'poor'. But in the current study 'good' and 'moderate' compliance groups were amalgamated for the purpose of analysis.

According to the current study, prevalence of good drug compliance among coronary heart disease patients attending outpatient cardiology clinic of NHSL was 43.0% (95% CI: 0.38-0.48) (Table 14) when measured using MMAS-8. Using questionnaires to measure compliance is simple and cost effective but known to overestimate compliance, because patients tend to give socially acceptable responses (George et al.,

2007). Yet, in the current study majority demonstrated poor level of compliance and it highlights the lack of attention CHD patients are giving toward their health.

However, studies used MMAS-8 to in different settings have shown different results. Good compliance was reported as 44.2% in a study conducted among Malaysian hypertensive patients attending a Family Medicine Clinic (Lee et al., 2013). Among 1154 Chinese hypertensive patients attending an outpatient clinic, prevalence of good compliance was much higher than above values (65.1%) (Hassan et al., 2005). But, significantly lower proportion (23%) of participants showed good drug compliance in a study conducted in Uganda (Mugwano et al., 2016). In local context, good compliance was reported as 53.3% among 400 hypertensive patients attended outpatient medical clinic of CSTH (Jayawerdane, 2016).

The differences in results obtained from studies may be due to socio-demographic variations inherent to different populations, their health seeking behaviours, availability of healthcare facilities and development status of the countries.

Apart from MMAS-8, researches have used MMAS-4 questionnaire also to measure compliance. It also uses a scoring system to categorize participants to 'good' and 'poor' compliance categories. When drug compliance was measured by MMAS-4 scale, good compliance was reported as 20.83%, 28.37%, and 32% in HTN, CCF, and IHD patients, respectively in India (G. Santra, 2015). But in US, it was 59.3% among patients with chronic cardiovascular conditions (Marcum et al., 2013).

However, when drug compliance is measured by a subjective method such as questionnaire, the compliance tend to be much higher than when measured by an objective method such as MEMS (Lam & Fresco, 2015). It was observed even in the same study sample (Nieuwenhuis et al., 2012) which may be due to an over-estimation occurs when using subjective methods.

5.4 Association of drug compliance with selected factors

The associations between drug compliance with patient related, disease and treatment related and healthcare system related factors were analyzed in the current study using chi square test at 0.05 significance level.

5.4.1 Association of drug compliance with patient related factors

patient related factors that were selected to find association with drug compliance included demographic, socio economic, status of smoking, status of alcohol consumption and participants' disease related knowledge.

5.4.1.1 Demographic and socio economic characteristics

Selected demographic characteristic in the current study were age, sex, ethnicity, marital status and level of education of the participants. Current employment status and average monthly income of the patients or their families were selected socio economic characteristics. However, current study revealed that none of the demographic and socio economic factors were significantly associated with drug compliance (Table 15 and Table 16). But according studies conducted in various study settings, patient characteristics related to drug compliance tend to vary.

Results obtained from the study conducted in Pittsburgh and Memphis in US (Marcum et al., 2013), also revealed no significant association (p>.05) between demographic and socio economic factors such as age, sex, marital status, educational level and income with drug compliance. Age, sex and employment status showed no significant association (p>.05) with drug compliance in the study conducted at cardiology referral center in Sao Paulo, Brazil (Chizzola et al., 1996). Similarly, in study conducted at Family Medicine clinic, Malaysia (Hassan et al., 2005), also revealed no significant association (p>.05) between socio demographic factors such as sex, ethnicity, educational level and monthly income with drug compliance. But Heart and Soul study conducted in US reported several socio- demographic factors were significantly associated with compliance where non-compliant participants were more likely to be younger (p=.006), females (p=0.005) and less likely to be educated (p=0.002). But marital status (p=.20) and income (p=.44) revealed no significance (Gehi et al., 2007). PREMIER study exhibited patients who were non-compliant to drugs were more likely to be older, less likely to be married and less likely to be educated (p<0.001) (Ho et al., 2006). According to the study done in Aga Khan University Hospital and National Institute of Cardiovascular Diseases, Karachi, Pakistan, several socio demographic and economic factors that demonstrated significant association with poor drug compliance included younger age (p=0.02), lower education status (p=0.03) and lower monthly income (p=0.001) (Hashmi et al., 2007).

5.4.1.2 Status of smoking and alcohol consumption

In the current study although the proportion of smokers with poor compliance (55.7%) was higher than never smoked individuals with poor compliance (54.9%), and a higher proportion of alcohol consumed individuals had poor drug compliance (57.7%) compared to never alcohol consumed (48.1%) participants with poor compliance, the difference was not significant (Table 17). The observed result may be due to the fact that participants believes in revealing true status of smoking and alcohol consumption to a healthcare personal.

Several other studies (Ho et al., 2006; Marcum et al., 2013; Pamboukian et al., 2008) also have exhibited similar results where there was no association between current smoking status and drug compliance ($p>.05$). But in Heart and Soul study, though current smoking was significantly associated with poor compliance ($p=.03$), regular alcohol use showed no significant relationship (Gehi et al., 2007).

5.4.1.3 Disease related knowledge

Good knowledge and health awareness on the disease, as well as of the drugs being taken, have shown to be associated with good compliance to drug regimes in several studies. (Jankowska-Polańska et al., 2016; van der Wal et al., 2006).

But in the present study, only 49.7% of the participants had good disease related knowledge (Table 4), and no significance was there between disease related knowledge and drug compliance ($p=.748$) (Table 18). Patient's knowledge about the disease is not the only fact that determines the drug compliance. Their knowledge about the value of good compliance and the consequences of poor compliance also matters. Assessment of such facts might also be important to identify the elements of knowledge that affect the drug compliance.

Study conducted among 340 cardiac patients admitted to hospitals affiliated to Mashhad University of Medical Sciences in Mashhad, Iran (Heydari et al., 2015) also revealed similar results. Getting patients involved in their treatments by providing relevant knowledge often empowers patients to be more concerned about their health. This can be achieved through more patient counselling, health education and health promotion sessions and satisfactory health care professional–patient interactions.

5.4.2 Association of drug compliance with disease and treatment related factors

Disease related factors considered in the current study were, duration of the disease, symptoms severity as operationalized according to Canadian Cardiology Society Functional Classification and the presence of co-morbidities. Number of drugs prescribed per day, drug frequency per day, frequent change of drugs, presence of side effects and have had alternative treatment were selected treatment related factors.

5.4.2.1 Duration of disease

In the present study, only 8.7% were there with the duration of disease for less than one year but, majority (47.7%) had disease for one to five years duration (Table 5). However, duration of disease was significantly associated with drug compliance ($p<.001$) where higher proportion of participants with duration of disease less than one year had good compliance (73.5%) compared to participants with longer duration of disease (36.0%) (Table 19). Similar results have been observed in a cohort study conducted in Ontario, where poor compliance was relatively more likely among patients with recent ACS compared to patients with chronic CHD (C. A. Jackevicius et al., 2002). Newly diagnosed patients are frequently stressed on the importance of good compliance when they are discharged from the hospital and during initial clinic visits compared to patients on treatment for years. This might be the reason that participants with shorter duration of disease showed good compliance.

However, some studies found that longer duration of disease resulted in good compliance and newly diagnosed patients had poor compliance ($p=0.04$) (Ho et al., 2006; Nieuwenhuis et al., 2012). Longer the duration of disease hence treatment period, patients might change their attitude of denying the disease and well accept their treatment.

5.4.2.2 Symptom severity

In the current study, a greater proportion (30.0%) had no symptoms with strenuous, rapid or prolonged exertion and only 9.2% had more severe symptoms according to Canadian Cardiology Society functional classification (Table 5). There was a significant association between symptom severity and drug compliance in the current study ($p=.013$) (Table 19). Patients tend to have good compliance when they have a marked improvement in symptoms with drug treatment. However instead of actual

severity of the symptoms, patient's perceived health status may also have more significant influence on compliance.

Study conducted among 134 heart failure patients attending outpatient cardiology clinics in Central Kentucky, US demonstrated similar results where severe the symptoms was related to poor drug compliance (J. R. Wu et al., 2008). According to certain studies non-compliant individuals were having less severe symptoms compared to compliant individuals with more severe symptoms (Pamboukian et al., 2008). However, there are studies which revealed no association between drug compliance and symptom severity (Chizzola et al., 1996).

5.4.2.3 Co-morbidities

Presence of co-morbidities demonstrated no significant association with drug compliance in the current study (p=.149) though a higher proportion of participants who had co-morbidities showed poor compliance (58.4%), compared to participants without co-morbidities (48.3%) (Table 19). Similar results were found in the studies conducted by Marcum et al., Pamboukian et al., and Gehi et al.,. Patients with co-morbidities generally have more drugs from different pharmacological classes. This complex treatment regimen might be a factor that contributes toward poor compliance. But that was not evident may be because of the fact that majority of them were already on complex treatment for CHD.

5.4.2.4 Number of drugs and frequency of drugs per day

Complex treatment is believed to threaten the patient's compliance and the rate of compliance decrease as the number of daily doses increase (Jin et al., 2008). This was demonstrated in the current study. More than half (53.2%) of the sample were on seven or more drugs per day (Table 7) and the number of drugs prescribed per day showed a significant association with drug compliance(p=.026) (Table 20). Participants were more likely to show poor compliance when higher the number of drugs prescribed per day. This emphasizes the importance of keeping the number of drugs prescribed for patients to a minimum. But an inverse relationship was observed between compliance and the number of drugs prescribed in the studies done at Aga Khan University Hospital (AKUH) and National Institute of Cardiovascular Diseases, Karachi (Hashmi et al., 2007) and in UK (Shalansky & Levy, 2002) where patients who were on fewer

drugs demonstrated poor compliance. There were studies which did not exhibit any association between compliance and number of prescribed drugs (Chizzola et al., 1996; Marcum et al., 2013).

Frequency of taking drugs showed a significant association with drug compliance in the present study (p=.03) (Table 20). Participants showed poor compliance when taking drugs thrice a day when compared to twice a day or once a day regime. Similar results were found other studies too (Kardas, 2007; Nieuwenhuis et al., 2012). This demonstrated the importance of keeping the daily dose frequencies to a minimum. But quite opposite results were found from the study conducted in UK among 367 patients. It revealed that poor compliant individuals had taken fewer administration frequency per day (Shalansky & Levy, 2002). In the current study, since 50% of patients received more than seven medications in their prescription, and more than 90% of patients were on twice a day or thrice a day treatment, the drug regimen for CHD patients have become complex, and compliance may definitely be a challenge for these patients.

5.4.2.5 Drug side effects

Presence of drug side effects was associated with poor compliance in the current study (p=.006) (Table 20). Side effects might have compromised patient's beliefs about medication effectiveness. Therefore, healthcare providers should pay more attention on therapy related problems when designing the treatment plan.

5.4.3 Association of drug compliance with healthcare system related factors

Studies conducted to find the association between drug compliance and healthcare system related factors are scarce.

Participants who were provided clear explanations about the treatment plan and the importance of drug compliance demonstrated good compliance compared to who were not given proper instructions (p=.22) (Table 21). Also, the time spent by the doctor for patients during the clinic visit showed a significant association with compliance (p=.033) (Table 21). Lesser the time taken by the doctor the patients demonstrated poor compliance towards treatment. These direct associations suggest that health care professionals are not in the best position to disseminate appropriate information for

better treatment outcome. It might be a result of the large number of patients they get to provide care within the very limited time period and facilities available.

Waiting time for the clinic visit showed a significant association with drug compliance (p=.041) (Table 21). Participants with poor compliance had long waiting time for the clinic visit in the present study.

Cost is a crucial issue in patient's compliance especially for patients with chronic disease as the treatment period could be life-long. In the current study, cost per clinic visit was significantly associated with compliance (p=.005) (Table 21).

5.5 Limitations of the study

- Subjective method was used as the only method of measuring drug compliance. Assessment of behaviours related to drug compliance was not limited to a specified time period. This might have lead to recall bias. These factors might have caused overestimation of drug compliance. A combination of subjective and objective measures may yield a higher accuracy concerning compliance behaviours.
- MMAS-8 questionnaire was not validated to be used in Sri Lanka. A validated tool with satisfactory psychometric properties needs to be used in local context to obtain more valid results. Only face validity and content validity was considered during this study. It might have affected the final results of the study.
- During analysis, only chi square test was used to find the association between drug compliance and selected factors. There might have an effect of confounding factors which need to be controlled by carrying out multivariate analysis. However multivariate analysis was not performed since it is beyond the level of a MSc study.

CHAPTER 6 – CONLUSIONS AND REOMMENDATIONS

6.1 Conclusions

- The sample consisted of 390 patients. Around 60% of them were males. Mean age of the sample was 61.4 (SD=9.5). Majority (55.9%) were above 61 years age group. 85.6% of the participants were currently married. Most (85.7%) were Sinhalese.
- According to MMAS-8 questionnaire, only 43.0% (n=168) of the participants had good compliance to their drug treatment.
- Of the patient related factors, all demographic and socio economic characteristics of the participants such as age, sex, marital status, ethnicity, educational level, employment status and monthly income were not significantly associated with drug compliance (p>.05). Apart from that, status of smoking and alcohol consumption were also not significantly associated with drug compliance (p>.05). Although around 50% of the participants had good disease related knowledge, it did not show any significant association with drug compliance (p>.05)
- Disease related factors significantly associated with drug compliance were, duration of the disease (p<.001) and symptom severity of the patients (p=.013).
- Of the treatment related factors, drug compliance was significantly associated with, number of drug types prescribed per day (p = .026), daily drug dosing frequency (p = .030), frequent change of drugs (p = .035) and presence of side effects (p = .006).
- Healthcare system related factors significantly associated with drug compliance were, time spent by doctor (p =.033), providing explanations about the treatment (p = .022), the time taken to complete the clinic visit (p = .041) and cost per clinic visit (p = .005).

6.2 Recommendations

- At the adherence rate of 43% found in the current study, it is clear that there is plenty of room for improvement in patients' compliance to their prescribed medications. Patients, health care providers, and health care systems, all have a role in improving patients' compliance. A single method cannot improve drug

compliance; instead a combination of various techniques should be implemented.

- On most occasions, missing drug doses was mainly due to patients' forgetfulness. Use medication adherence improving aids. Provide medication calendars or schedules that specify the time to take medications, drug cards, medication charts or medicine related information sheets or specific packaging's indicating the time of dose.
- Regular health education sessions on disease related knowledge, treatment plan and the importance of drug compliance and health promotion sessions might also help patients to organize their medication taking behaviour.
- One of the most important strategies for improving compliance is to first make sure patients are receiving the most appropriate drugs. Evaluate the drug regimen frequently to ensure that it is appropriate. Promote rational, conservative drug prescribing. Use the most possible simplified regimen based on patient characteristics at the first level of drug use.
- The availability of long acting formulations and fixed drug combinations at an affordable cost is expected to improve drug taking behaviour. Availability of such formulations of CHD medications would help to improve compliance.
- The duration of time spent by the treating physician is viewed as unsatisfactory. It limits both patients' opportunity of clarifying doubts and physician providing sufficient explanations to the patient. Time spends for the patient need to be adjusted and consultation skills training for the physicians may have to be strengthened to overcome these challenges.

- More research is required to identify the major local factors that influence the drug compliance. Future research need to be carried out in community setting which represents the full spectrum of people with CHD. Cohort studies with more frequent follow-ups and larger sample size would be recommended.
- Furthermore, an in-depth qualitative study exploring the factors associated with drug compliance needs focus.
- In addition, a more standard, objective method needs to be used to assess compliance rather than using a subjective method.

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Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka

INFORMATION SHEET

I, Dr. G.W.K.C. de Silva, postgraduate trainee in MSc Community Medicine attached to the Postgraduate Institute of Medicine, University of Colombo would like to invite you to take part in the research study on factors associated with the extent to which heart disease patients' medication taking behaviour corresponds with recommendations given by doctors, conducted by myself among patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka.

1. **Purpose of the study**

   This research is carried out by me to fulfil one of the requirements of the MSc Community Medicine programme conducted by the Postgraduate Institute of Medicine, University of Colombo. Information provided by you will be useful in assessing the current prevalence of drug compliance and associated factors among Coronary heart disease patients.

2. **Voluntary participation**

   Your participation in this study is voluntary. You are free not to participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. **Duration, procedures of the study and participant's responsibilities**

   This study will be carried out during day time. If you volunteer to participate in this study, we will ask you to answer a questionnaire administered by an interviewer, which would take around 20 minutes.

4. **Potential benefits**

   Although there is no direct benefit for you, information obtained by you in this study will be beneficial to develop strategies in improving the healthcare status of coronary heart disease patients in Sri Lanka.

5. **Risks, hazards and discomforts**

   We ensure that you will not be exposed to any potential or actual risk by participating in this study. The only inconvenience is that you have to spend around 20 minutes of your valuable time. You will not be paid any allowance for participating in this study.

6. **Confidentiality**

   Your name or address will not be collected and all other information provided by you will be used in such a way that you could not be identified. Confidentiality of all data provided will be maintained strictly.

7. **Termination of study participation**

   You may withdraw from this study at any time with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

8. Clarifications

If you have questions about any of the information please feel free to ask from the principal investigator.

Dr. G.W.K.C. de Silva

Postgraduate Institute of Medicine

Colombo

Mobile: 0712440739

This project has been approved by the Ethics Review Committee, Faculty of Medicine, University of Colombo. You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112695300 extension 240 (between 9am and 4pm) or by sending an email to info.ethics@med.cmb.ac.lk

ශ්‍රී ලංකා ජාතික රෝහලේ හෘද රෝග බාහිර රෝගී සායනයට සහභාගී වන හෘද රෝගීන්ගේ ඖෂධ ගැනීමේ අනුකූලතාවය සම්බන්ධ සාධක

තොරතුරු පත්‍රිකාව

කොළඹ විශ්ව විද්‍යාලයේ පශ්චාත් උපාධි වෛද්‍ය ආයතනයේ ප්‍රජා වෛද්‍ය විද්‍යාව පිළිබඳ විද්‍යාපති උපාධි අපේක්ෂකයෙකු වන වෛද්‍ය ජී. ඩබ්. කේ. සී. ද සිල්වා වන මම, මා විසින් ශ්‍රී ලංකා ජාතික රෝහලේ හෘද රෝග බාහිර රෝගී සායනයට සහභාගි වන හෘද රෝගීන්ගේ ඖෂධ ගැනීමේ හැසිරීම වෛද්‍යවරයෙකු විසින් ලබාදුන් නිර්දේශ සමඟ අනුරූප වන ප්‍රමාණය සම්බන්ධ සාධක පිළිබඳ පවත්වනු ලබන සමීක්ෂණයට සහභාගි වන ලෙස ඔබට ආරාධනා කිරීමට කැමැත්තෙමි.

1. සමීක්ෂණයේ අරමුණ

මෙම සමීක්ෂණය පවත්වනු ලබන්නේ පශ්චාත් උපාධි වෛද්‍ය ආයතනය මගින් පවත්වන ප්‍රජා වෛද්‍ය විද්‍යාව පිළිබඳ විද්‍යාපති උපාධියේ එක් කොටසක් සම්පූර්ණ කිරීම සඳහා වේ. හෘද රෝගීන්ගේ වර්තමාන ඖෂධ ගැනීමේ අනුකූලතාවයේ ව්‍යාප්තිය සහ ඒ සමබන්ධ සාධක නිර්ණය කිරීම සඳහා ඔබ විසින් සපයනු ලබන තොරතුරු වැදගත් වේ.

2. ස්වේච්ඡා සහභාගීත්වය

මෙම සමීක්ෂණය සඳහා සහභාගි වීම ඔබගේ අභිමතය මත පමණක් සිදු වේ. කිසිසේත් සහභාගි නොවීමට හෝ පළමුව කැමැත්ත පළකර ඇතත් ඉන් අනතුරුව අතරමඟ ඕනෑම අවස්ථාවක සමීක්ෂණයෙන් ඉවත්වීමේ නිදහස ඔබට ඇත. මෙයට සහභාගී නොවීමෙන් ඔබට දැනට හිමිවිය යුතු වෛද්‍ය ප්‍රතිකාරවල හෝ ඔබේ රෝගයට අදාල වෙනත් ප්‍රතිකාරවල කිසිදු අහිමිවීමක් සිදු නොවනු ඇත. සමීක්ෂණයට සහභාගී නොවීමට හෝ ඉවත්වීමට තීරණය කලහොත් එය ඔබට ඕනෑම අවස්ථාවක සිදු කල හැක.

3. කාල පරාසය, සමීක්ෂණය සිදු කරන ආකාරය සහ සහභාගීවන්නන්ගේ වගකීම

සමීක්ෂණය දිවා කාලයේදී පවත්වනු ලැබේ. මෙම සමීක්ෂණය සඳහා ඔබ ස්වේච්ඡාවෙන් සහභාගී වුවහොත්, විනාඩි 20ක් පමණ වැයකර අප විසින් සම්මුඛ සාකච්ඡාවක් මඟින් ඉදිරිපත් කරනු ලබන ප්‍රශ්නාවලියක් සඳහා පිළිතුරු සැපයීමට සිදුවේ.

4. ලැබිය හැකි ප්‍රතිලාභ

මෙම සමීක්ෂණයෙන් ඔබට සෘජු ප්‍රතිලාභයක් නොලැබෙන අතර, මෙහිදි ඔබගෙන් ලබාගන්නා තොරතුරු හෘද රෝගීන්ගේ සෞඛ්‍ය තත්වය වැඩි දියුණු කිරීම සඳහා වන ප්‍රතිපත්ති සකස් කිරීමට මහත් පිටුවහලක් වනු ඇත.

5. හානි, උවදුරු සහ අපහසුතා

මෙම සමීක්ෂණයට සහභාගීවීමෙන් ඔබ කිසිඳු හානියකට නිරාවරණය නොවන බවට අපි වගබලා ගන්නෙමු. ඔබ පත්වන එකම අපහසුතාවය නම් ඔබේ කාලයෙන් විනාඩි 20 ක පමණ කාලයක් මේ සඳහා වැය කිරීමට සිදු වීමයි. මෙම සමීක්ෂණයට සහභාගීවීම සඳහා ඔබට කිසිඳු ගෙවීමක් හෝ දීමනාවක් ගෙවනු නොලැබේ.

6. රහස්‍යභාවය

මෙම සමීක්ෂණයට ඔබේ නම හෝ ලිපිනය සඳහන් කිරීම අනවශ්‍ය වන අතර ඔබ හඳුනා ගත හැකි අකාරයට දත්ත කිසිඳු ලෙසකින් භාවිතා නොකෙරනු ඇත. සපයනු ලබන සියලු දත්ත වල රහස්‍යභාවය තරයේ ආරක්ෂා කරනු ලැබේ.

7. සමීක්ෂණයට සහභාගීවීමෙන් ඉවත් වීම

ඕනෑම අවස්ථාවකදී ඔබට මෙම සමීක්ෂනයට සහභාගීවීමෙන් ඉවත් විය හැක. එමඟින් ඔබේ වෛද්‍ය ප්‍රතිකාර හෝ වෙනත් පහසුකම් අහිමි වීමක් සිදු නොවේ. ඔබ සමීක්ෂණයෙන් ඉවත්වීමට තිරණය කළ වහාම සමීක්ෂණ නිලධාරියාට ඒ බව දැනුම් දෙන්න.

8. පැහැදිලි කිරීම්

තොරතුරු පිළිබඳ ඔබට කිසිඳු ගැටළුවක් තිබේ නම් කරුණාකර ප්‍රධාන සමීක්ෂණ නිලධාරියාගෙන් ඒ පිළිබඳ විමසන්න.

වෛද්‍ය ජී. ඩබ්. කේ. සී. ද සිල්වා
පශ්චාත් උපාධි වෛද්‍ය ආයතනය
කොළඹ
දුරකථන 0712440739

வெளி நோயளர் இதய சம்பந்தமான சிகி;ச்சை நிலயத்திற்கு சமுகம் தரும் இதய நோயாளிகளுக்கிடையிலேயே காணப்படும் போதைப் பொருள் இணக்கம் தொடர்புடைய காரணிகள்- தேசிய வைத்தியசாலை - ஸ்ரீ லங்கா.

தகவல் தாள்

நான், டாக்டர் G.W.K.C. டி சில்வா சமுதாயத்தின் முதுகலைப் பட்டப்படிப்பு மருத்துவத்துடன் இணைக்கப்பட்டுள்ள MSc சமுதாய மருத்துவத்தில் முதுகலை பட்டப்படிப்பு, கொOk;G பல்கலைக்கழகம், இதய நோய் நோயாளிகளுக்கான நடத்தை எடுக்கும் எந்தவொரு காரணிகளின் மீதான ஆய்வு ஆய்வுகளில் கலந்து கொள்ள உங்களை அழைக்க விரும்புகிறேன். வெளிநோயாளிகளுக்கான கார்டியலஜி கிளினிக்கில் கலந்துகொண்டுள்ள நோயாளிகளிடையே நானே நடத்திய டாக்டர்கள் - ஸ்ரீ லங்கா தேசிய வைத்தியசாலை

1. ஆய்வு நோக்கம்

இந்த ஆராய்ச்சிக் கழகம், எம்.எஸ்.சி. சமுதாய மருத்துவ திட்டத்தின் தேவைகளை நிறைவேற்றுவதற்காக என்னை நடத்தியது. இதனுடன் வழங்கப்பட்ட தகவல், மருந்து இணக்கம் மற்றும் இதய நோய்க்குரிய நோயாளிகளிடையே தொடர்புடைய காரணிகளின் தற்போதைய தாக்கத்தை மதிப்பிடுவதில் பயனுள்ளதாக இருக்கும்

2. தன்னார்வ பங்களிப்பு

இந்த ஆய்வில் உங்கள் பங்களிப்பு தானாகவே உள்ளது. நீங்கள் பங்கேற்க விரும்புவதில்லை அல்லது எந்த நேரத்திலும் ஆய்வு செய்யாமல் விடுவதற்கு அனுமதிக்காதீர்கள். உங்கள் வியாதியோ அல்லது உங்களுக்கு வேறு எந்த உரிமையோ கிடையாது என்ற மருத்துவத்திற்கோ அல்லது வேறு எந்த சிகிச்சையோ இழப்பு ஏற்படாது. ஆய்வில் இருந்து பகுப்பாய்வு அல்லது பின்வாங்க வேண்டாம் என நீங்கள் முடிவு செய்தால், எந்த நேரத்திலும் நீங்கள் அவ்வாறு செய்யலாம்.

3. கால, செயல்முறை மற்றும் பங்கேற்பாளரின் பொறுப்புகள்

இந்த ஆய்வானது நாள்தோறும் மேற்கொள்ளப்படும். இந்த ஆய்வில் கலந்து கொள்ள நீங்கள் தன்னார்வத் தொண்டு செய்தால், ஒரு பேட்டியாளரால் நிர்வகிக்கப்படும் ஒரு கேள்வித்தாளைப் பதிலளிப்போம், இது சுமார் 20 நிமிடங்கள் எடுக்கும்

4. சாத்தியமான நன்மைகள்

உங்களுக்காக நேரடியான பயன் இல்லை என்றாலும், இந்த ஆய்வில் நீங்கள் பெறும் தகவல்கள் ஸ்ரீ லங்காவில் உள்ள கரோனரி இதய நோயாளிகளுக்கான சுகாதார நிலையை மேம்படுத்துவதில் உத்திகள் உருவாக்க பயன்மிக்கதாக இருக்கும்.

5. அபாயங்கள், அபாயங்கள் மற்றும் சிக்கல்கள்

இந்த ஆய்வில் கலந்துகொள்வதன் மூலம் எந்த சாத்தியமான அல்லது உண்மையான ஆபத்துக்கும் நீங்கள் வெளிப்பட மாட்டீர்கள் என்று உறுதிபடுத்துகிறோம். இந்த சிக்கலில் நீங்கள் 20 நிமிடங்களை செலவழிக்க வேண்டும் என்பதே ஒரே சிரமத்திற்கு காரணம்.

6. இரகசியத்தன்மை

உங்கள் பெயர் அல்லது tpyhrk; சேகரிக்கப்படாது மற்றும் நீங்கள் வழங்கியிருக்கும் அனைத்து வழிகளிலும் உங்களுக்கு வழங்கப்படும் பிற தகவல்கள் உங்களுடையதாக இருக்காது. வழங்கப்பட்ட அனைத்து தரவு இரகசியத்தன்மை கடுமையாக பராமரிக்கப்படும்

7. ஆய்வு பங்கேற்பு நிறுத்தல்

மருத்துவ பராமரிப்பு அல்லது நன்மைகள் இழப்பு எந்தவொரு தண்டனையோ அல்லது விளைவுகளோ எந்த நேரத்திலும் இந்த படிப்பில் இருந்து நீங்கள் பெறலாம். உங்கள் கருத்தைத் தீர்த்து வைப்பதை முடிவுசெய்துவிட்டால் உடனடியாக புலனாய்வாளரை கவனியுங்கள்

8. தெளிவுரைகள்

நீங்கள் எந்த தகவலையும் பற்றி கேள்விப்பட்டிருந்தால், பிரதான ஊனமுற்றவரிடம் இருந்து விலகி விடுமாறு கேட்டுக் கொள்ளுங்கள்

DR, G.W.K.C.DE.SILVA
மருத்துவப் படிப்பு நிறுவனம்
கொழும்பு
மொபைல்: 0712440739

இந்த திட்டம் நெறிமுறை மறுஆய்வு குழு, மருந்தியல், கொழும்பு பல்கலைக்கழகம் ஆகியவற்றால் அங்கீகரிக்கப்பட்டுள்ளது. 204 (காலை 9 மணி முதல் மாலை 4 மணி வரை) அழைப்பு அல்லது ஒரு மின்னஞ்சலை அனுப்புவதன் மூலம் நீங்கள் விளக்கங்களைத் தேட விரும்பினால், எந்தவொரு கருத்தையும் பதிவு செய்யலாம் அல்லது படிப்பு பற்றி புகார் செய்ய விரும்பினால் தொடர்பு கொள்ளவேண்டிய தொலைபேசி, இல 0112695300 / **மின்னஞ்சல்** info.ethics@med.cmb.ac.lk

Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka.

CONSENT FORM

Part A - To be filled by the participant

The participant should complete the whole of this sheet herself or with the assistance of investigator.

1. Have you read the information sheet or investigator read it for you? YES/NO
2. Have you had an opportunity to discuss this study and ask any questions? YES/NO
3. Have you had satisfactory answers to all your questions? YES/NO
4. Have you received enough information about the study? YES/NO
5. Who explained the study to you? .....
6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO
7. Information held by the investigators relating to your participation in this study may be examined by other data collectors. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records? YES/NO
8. Have you had sufficient time to come to your decision? YES/NO
9. Do you agree to take part in this study? YES/NO

Participant's signature: ..... Date: .....

Name (BLOCK CAPITALS): .....

Part B - To be filled by the investigator

I have explained the study to the above volunteer and she has indicated her willingness to take part.

Signature of investigator: ... . Date: .....

Name (BLOCK CAPITALS): .....

ශ්‍රී ලංකා ජාතික රෝහල් හෘද රෝග බාහිර රෝගී අංශයට සහභාගී වන හෘද රෝගීන්ගේ ඖෂධ ගැනීමේ අනුකූලතාවය සම්බන්ධ අධ්‍යන

කැමැත්ත ගැනීමේ ප්‍රකාශය

කොටස - සහභාගී වන අය විසින් පිරවිය යුතුයි.

මෙම පිටුවෙහි සියළු තොරතුරු සහභාගිවන පුද්ගලයා ඔහු/ඇය විසින්ම හෝ සමීක්ෂණ නිලධාරියාගේ මඟ පෙන්වීම මත සම්පූර්ණ කළ යුතුයි.

1. ඔබ තොරතුරු පත්‍රිකාව කියවුවේද? හෝ සමීක්ෂණ නිලධාරියා එහි අඩංගු දෑ ඔබට විස්තර කලේද? ඔව්/නැත
2. මෙම සමීක්ෂණය පිළිබඳ තොරතුරු සාකච්ඡා කිරීමට හා ඒ සම්බන්ධ ප්‍රශ්න ඇසීමට ඔබට අවස්ථාව ලැබුනිද? ඔව්/නැත
3. ඔබේ සියළු ප්‍රශ්නවලට සෑහීමකට පත්විය හැකි පිළිතුරු ලැබුනාද? ඔව්/නැත
4. සමීක්ෂණය පිළිබඳ ප්‍රමාණවත් තොරතුරු ඔබට ලැබුනාද? ඔව්/නැත
5. අධ්‍යයනය පිළිබඳ ඔබට පැහැදිලි කලේ කවුද?.....
6. හේතු පැහැදිලි කිරීමකින් තොරව හා ඉදිරි වෛද්‍ය ප්‍රතිකාරවලට බලපෑමකින් තොරව ඕනෑම අවස්ථාවකදී සමීක්ෂණයෙන් ඉවත්වීමට නිදහස ඇති බව ඔබ අවබෝධ කරගත්තාද? ඔව්/නැත
7. සමීක්ෂණ නිලධාරියා සතු අධ්‍යනයට සහභාගීවීමට අදාල ඔබේ තොරතුරු සමීක්ෂණ සහකරුවන් විසින් පරීක්ෂා කරනු ඇත. සියළු තොරතුරු අතිශය රහසිගත ලෙස සලකනු ඇත. පරීක්ෂණ සහකරුවන්ට ඔබේ වාර්තා පරීක්ෂා කිරීමට ඔබ අවසර දෙන්නේද? ඔව්/නැත
8. ඔබේ තීරණයට එළඹීමට ප්‍රමාණවත් කාලයක් ඔබට ලැබුනාද? ඔව්/නැත
9. මෙම සමීක්ෂණයට සහභාගීවීමට ඔබ එකඟ වන්නේද? ඔව්/නැත

සහභාගීවන්නාගේ අත්සන ..... දිනය.....

ඊ කොටස - සමීක්ෂණ නිලධාරියා විසින් පිරවිය යුතුයි.

මම, ඉහත සඳහන් පුද්ගලයාට අධ්‍යනය පිළිබඳව පැහැදිලි කළෙමි. ඔහු/ඇය සහභාගීවීමට කැමැත්ත ප්‍රකාශ කරන ලදී.

සමීක්ෂණ නිලධාරියාගේ අත්සන .....

නම .....

வெளிநோயாளிகளுக்கான கார்டியலஜி கிளினிக்கில் கலந்துகொள்கின்ற கரோனரி இதய நோயாளிகளிடையே மருந்து இணக்கத்துடன் தொடர்புடைய காரணிகள் - இலங்கையின் தேசிய வைத்தியசாலை

ஒப்புதல் படிவம்

பாகம் A- பங்கேற்பாளரால் நிரப்பப்பட வேண்டும்

பங்குதாரர் இந்த தாள் முழுவதையும் முடிக்க வேண்டும் அல்லது புலன்விசாரணை உதவியுடன்

1. நீங்கள் தகவல் தாள் அல்லது முதலீட்டாளர் அதை படித்துள்ளீர்களா? ஆம்இ / ல்லை

2. இந்த ஆய்வில் கலந்துரையாட மற்றும் ஏதேனும் கேள்விகள் கேட்க உங்களுக்கு வாய்ப்பு கிடைத்ததா? ஆம்இ / ல்லை

3. உங்களுடைய எல்லா கேள்விகளுக்கும் நீங்கள் திருப்திகரமான பதில்களைக் கொண்டிருந்திருக்கிறீர்களா? ஆம்இ / ல்லை

4. ஆய்வு குறித்த போதுமான தகவலை நீங்கள் பெற்றுள்ளீர்களா? ஆம்இ / ல்லை

5. நீங்கள் படிப்பை விளக்கியவர் யார்?.....

6. எந்தவொரு முறையிலும் படிப்பைத் திரும்பப் பெற உங்களுக்கு விருப்பம் இருக்கிறதா, உங்கள் எதிர்காலத்தை வழங்காமலும் உங்கள் எதிர்கால மருத்துவ பராமரிப்பு பாதிக்கப்படாமலும் இருக்கிறீர்களா? ஆம்இ / ல்லை

7. இந்த ஆய்வில் உங்கள் பங்கேற்பு தொடர்பான புலனாய்வாளர்கள் வைத்திருக்கும் தகவல்கள் பிற ஆராய்ச்சி உதவியாளர்களால் ஆராயப்படலாம். இந்த நபர்களுக்கான எல்லா நபர்களும் உங்களிடம் பதிவுகள் வைத்திருக்க வேண்டும்? ஆம்இ / ல்லை

8. உங்கள் முடிவை நீங்கள் பெற போதுமான நேரம் இருந்தது? ஆம்இ / ல்லை

9. இந்த ஆய்வில் பங்கேற்க நீங்கள் ஒப்புக்கொள்கிறீர்களா? ஆம்இ / ல்லை

பங்கேற்பாளரின் கையொப்பம்..... தேதி.....
பெயர் (பெரிய எழுத்தில்) .....

பாகம் - B விசாரணைக்கு உட்படுத்த வேண்டும்

நான் மேலே உள்ள தன்னார்வத் தொண்டுக்கு விளக்கத்தை விளக்கினேன், அவள் பங்கேற்க விருப்பம் தெரிவிக்கிறார்

புலன்விசாரணை கையொப்பம் ..... தேதி .....
பெயர் (பெரிய எழுத்தில்) .....

Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka

Serial No.	

Part A – Factors related to drug compliance

A. Patient related data

I. Demographic and socioeconomic data

1. How old are you at your last birthday? .....

2. What is your sex?

A	Male	
B	female	

3. Which ethnic group you belong to?

A	Sinhalese	
B	Tamil	
C	Moor	
D	Burger	
E	Malay	
F	Other	

4. What is the highest educational qualification you have obtained?

A	No formal education	
B	Pre-school	
C	Less than Grade 5	
D	Passed Grade 5	
E	Passed GCE O/L	
F	Passed GCE A/L	
G	University degree / diploma	

5. What is your current marital status?

A	Unmarried	
B	Married	
C	Divorced	
D	Widowed	

6. What is your current employment status?

A	Unemployed	
B	Employed	
C	Retired	
D	Other (Specify)	

7. What is the average monthly income of you / your family?

A	No income/ looked after by children or relatives	
B	Less than Rs. 10000	
C	Rs. 10001 – 20000	
D	Rs. 20001 – 30000	
E	Rs. 30001 – 50000	
F	More than Rs. 50001	

8. Have you ever smoked?

1	Yes	
B	No	

9. If yes to question 8; do you still smoke?

A	Yes	
B	No	

10. Have you ever consumed alcohol?

A	Yes	
B	No	

11. If yes to question 10; do you still consume alcohol?

A	Yes	
B	No	

II. Coronary heart disease related knowledge assessment

Following questions are asked to assess patient's knowledge on causes, risk factors, symptoms and treatment related to coronary heart disease

Item	Content	Yes	No	Don't know
1	Formation of fatty plaques inside the coronary arteries occurs only in adulthood.		X	
2	The most common cause of heart attack is a blood clot that forms inside a coronary artery.	X		
3	People who have diabetes are at risk of getting heart attack.	X		
4	Smoking is not a risk factor for heart disease		X	
5	Control of hypertension reduces the risk of developing heart attacks.	X		
6	Control of overweight/obesity has no effect on development of heart attack		X	
7	High level of cholesterol in blood is a risk factor for developing heart disease.	X		

8	Chest pain is a common symptom of heart disease	X		
9	Every person who has heart disease has symptoms		X	
10	An ECG always detects the presence of heart disease		X	
11	Coronary angiography is done to see the inside of coronary arteries.	X		
12	The only goal of treating coronary heart disease is relieving symptoms		X	
13	Aspirin is prescribed to reduce the risk of blood clot formation inside the blood vessels.	X		
14	Routine physical activities (like walking, running, yoga, gardening, etc,) are not recommended for patients with heart disease.		X	
15	It is recommended to reduce salt consumption for heart disease patients.	X		

B. <u>Disease and treatment related data</u>

12. How long you have been diagnosed to have heart disease? .....

13. What is the current level of your functional capacity?

	Patient symptom	
A	No symptoms with strenuous or rapid or prolonged exertion at work or recreation	
B	Chest pain occurs with strenuous or rapid or prolonged exertion at work or recreation. Walking or climbing stairs does not cause chest pain	
C	Chest pain occurs on walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals or under emotional stress, or only during few hours after awakening. When walking more than 200 meters on level ground, or when climbing more than one flight of stairs at a normal pace and in normal conditions	
D	Chest pain occurs on walking around 100 to 200 meters on level ground or climbing one flight of stairs at a normal pace in normal conditions	
E	Inability to perform any physical activity without discomfort. Chest pain may be present at rest	

14. Do you have any other chronic illnesses which needs long term treatment apart from heart disease?

A	Yes	
B	No	

If 'yes', please specify .....

15. Currently how many types of drugs you have been prescribed by the doctor for heart disease? .....

16. What is the maximum prescribed drug frequency per day?

A	Once a day	
B	Twice a day	
C	Thrice a day	
D	Four times a day	
E	Other (Specify)	

17. Have your heart disease drugs been frequently changed by the doctor?

A	Yes	
B	No	

18. Have you ever experienced drug side effects?

A	Yes	
B	No	

19. Other than treatment given by the cardiology clinic, have you ever used any other treatment method (such as Ayurvedic medications, Homeopathy, Acupuncture, etc.) for your heart disease?

A	Yes	
B	No	

C. Healthcare system related data

20. What is the average distance to the clinic from your home in kilo meters? .....

21. What is the average time the doctor spends for you in a clinic visit? .....

22. Has a healthcare person provided clear explanations to you about how to take drugs, why drugs are necessary and what to expect from treatment?

A	Yes	
B	No	

23. Who provided explanations to you?

A	Doctor	
B	Nursing officer	
C	Pharmacist	
D	Other (specify)	

24. Usually from where do you get heart disease drugs?

A	Pharmacy within the hospital	
B	Pharmacy outside the hospital	
C	Both within the hospital and outside pharmacies	

25. How much it costs you per clinic visit (for transport, food, etc.)? Rs.....

Part B – Questionnaire to assess the drug compliance

Patients take drugs for their heart disease. Individuals have identified several issues regarding their drugs taking behaviour and the investigator is interested in their experience. There is no right or wrong answer. Please try to get the answer for each question based on their personal experience with heart disease drugs.

		Yes	No
1	Have you ever feel worried about sticking to your heart disease treatment plan?		
2	When you travel or leave home, have you ever forgotten to bring along your heart disease drugs?		
3	When you feel like your heart disease is under control, have you ever stopped taking your drugs?		
4	Have you ever cut back or stopped taking your drugs without telling your doctor, because you felt worse when you took it?		
5	Have you ever forgotten to take your heart disease drugs?		
6	How often do you forget to take all your drugs? (Please circle the relevant number.) Never / Rarely.....5 Once in a while.....4 Sometimes .....3 Usually .....2 All the time 1		
7	Thinking over the past two weeks, were there any days when you did not take your heart disease drugs?		
8	Did you take your heart disease drugs yesterday?		

ශ්‍රී ලංකා ජාතික රෝහලේ හෘද රෝග බාහිර රෝගී සායනයට සහභාගී වන හෘද රෝගීන්ගේ ඖෂධ ගැනීමේ අනුකූලතාවය සම්බන්ධ සාධක

අනු අංකය	

A කොටස - ඖෂධ ගැනීමේ අනුකූලතාවය සම්බන්ධ සාධක

A. රෝගයා සම්බන්ධ සාධක

I. සාමාජීය දත්ත පිළිබඳ ප්‍රශ්නාවලිය

1. ඔබේ අවසාන උපන්දිනයට වයස කීයද? .....

2. ඔබේ ස්ත්‍රී/පුරුෂ භාවය කුමක්ද?

A	පුරුෂ	
B	ස්ත්‍රී	

3. ඔබ අයත්වන ජන වර්ගය කුමක්ද?

A	සිංහල	
B	දෙමළ	
C	මුස්ලිම්	
D	බර්ගර්	
E	මැලේ	
F	වෙනත්	

4. ඔබ ලබාගෙන ඇති ඉහළම අධ්‍යාපන සුදුසුකම කුමක්ද?

A	විධිමත් අධ්‍යාපනයක් ලබා නොමැත	
B	පෙර පාසල	
C	5 ශ්‍රේණියට අඩු	
D	5 ශ්‍රේණිය සමත්	
E	සාමාන්‍ය පෙළ සමත්	
F	උසස් පෙළ සමත්	
G	විශ්ව විද්‍යාල උපාධි/ඩිප්ලෝමා	

5. ඔබේ වර්තමාන විවාහක තත්වය කුමක්ද?

A	අවිවාහක	
B	විවාහක	
C	දික්කසාද	
D	වැන්දඹු	

6. ඔබේ වර්තමාන රැකියා තත්වය කුමක්ද?

A	රැකියා විරහිත	
B	රැකියාවක නියුතු	
C	විශ්‍රාමික	
D	වෙනත්	

7. ඔබගේ/ඔබ පවුලේ දළ මාසික ආදායම කුමක්ද?

A	ආදායමක් නැත	
B	රු 10000 ට අඩු	
C	රු 10001-රු 20000	
D	රු 20001- රු 30000	

E	රු 30001- රු 50000	
F	රු 50000 ට වැඩි	

8. ඔබ කවදා හෝ දුම් පානය කර තිබේද?

A	ඔව්	
B	නැත	

9. ඉහත ප්‍රශ්නයට පිළිතුරු ඔව් නම්, ඔබ තවමත් දුම් පානය කරනවාද?

A	ඔව්	
B	නැත	

10. ඔබ කවදා හෝ මත්පැන් පානය කර තිබේද?

A	ඔව්	
B	නැත	

11. ඉහත ප්‍රශ්නයට පිළිතුරු ඔව් නම්, ඔබ තවමත් මත්පැන් පානය කරනවාද?

A	ඔව්	
B	නැත	

II. <u>රෝගය ආශ්‍රිත දැනුම පක්සේරු කිරීම සඳහා වන ප්‍රශ්නාවලිය</u>

මෙම පිටුවෙහි, හෘද රෝගයෙහි විවිධ පැතිකඩ පිළිබඳ ඔබේ දැනුම සම්බන්ධයෙන් ප්‍රශ්න කිහපි යකට පිළිතුරු සැපයීමට ඔබගෙන් අසනු ලැබේ.

අයිතමය	අන්තර්ගතය	ඔව්	නැත	නොදනී
1.	කිරීටක ධමනි තුල මේද තැන්පතු සෑදීම රුධිර කැටි ඇති වීමට හේතුවන මූලික සාධකයකි.			
2.	කිරීටක ධමනි තුල ඇතිවන රුධිර කැටිය, හෘද රෝග සඳහා බලපාන වඩාත් පොදු හේතුවකි.			
3.	දියවැඩියාව ඇති පුද්ගලයින් හෘදයාබාධ ඇතිවීමේ අවදානමක් ඇත.			
4.	දුම්පානය හෘද රෝග සඳහා අවදානම් සාධකයක් නොවේ.			
5.	අධි රුධිර පීඩනය පාලනය හෘදයාබාධ වර්ධනය වීමේ අවදානම අඩු කරයි.			
6.	අධි බර / තරබාරුකම පාලනය හෘදයාබාධ වර්ධනය කිරීම කෙරෙහි කිසිදු බලපෑමක් නැත			
7.	රුධිරයේ ඇති ඉහළ කොලෙස්ටරෝල් මට්ටම හෘද රෝග ඇති කිරීම සඳහා අවදානම් සාධකයකි			
8.	පපුවෙහි වේදනාව හදවත් රෝගයේ පොදු රෝග ලක්ෂණයකි			
9.	හෘද රෝග ඇති සෑම කෙනෙකුටම රෝග ලක්ෂණ ඇත			
10.	ECG නිරන්තරයෙන් හෘදයාබාධ ඇති බව හඳුනා ගනී			
11.	ඇන්ජියෝග්‍රම් පරීක්ෂණය කිරීමෙන් කිරීටක ධමනි තුළ දැකිය හැකියග			
12.	කිරීටක හෘද රෝග ප්‍රතිකාර කිරීමේ එකම ඉලක්කය රෝග ලක්ෂණ අඩු කරවයි			
13.	රුධිර වාහිනී තුළ රුධිර කැටි වෙන්වී යාමේ අවදානම අඩු කිරීමට ඇස්ප්‍රයින නිර්දේශ කරනු ලැබේග			
14.	හෘද රෝගවලින් පෙළෙන රෝගීන් සඳහා භෞතික ක්‍රියාකාරකම් (ඇවිදීමල ධාවනයල යෝග ගෙවතු වගාවල ආදිය) නිර්දේශ නොකරයිග			
15.	හදවත් රෝගීන් සඳහා ලුණු පරිභෝජනය අඩු කිරීම නිර්දේශ කෙරේග			

B. රෝග හා ප්‍රතිකාර ආශ්‍රිත දත්ත

12. ඔබට හෘද රෝගයක් ඇති බවට රෝග විනිශ්චය කර කොපමණ කල්ද? .....

13. ඔබේ ක්‍රියාකාරකම් ධාරිතාවේ මට්ටම කුමක්ද?

A	**රෝග ලක්ෂණ** නොමැත	
B	ඇවිදීම, ගෙවතු වගාව වැනි සාමාන්‍ය ශාරීරික ක්‍රියාකාරකම් අනවශ්‍ය තෙහෙට්ටුව,පපුවේ ගැස්ම, හුස්ම ගැනීමේ අපහසුතා හෝ පපුවේ කැක්කුම ඇති නොකරයි.	
C	විවේකයෙන් සිටින විට අපහසුතාවක් නැති නමුත් ඇවිදීම, ගෙවතු වගාව වැනි සාමාන්‍ය ශාරීරික ක්‍රියාකාරකම් අනවශ්‍ය තෙහෙට්ටුව,පපුවේ ගැස්ම, හුස්ම ගැනීමේ අපහසුතා හෝ පපුවේ කැක්කුම ඇති කරයි.	
D	විවේකයෙන් සිටින විට අපහසුතාවක් නැති නමුත් ඇවිදීම, ගෙවතු වගාව වැනි සාමාන්‍ය ශාරීරික ක්‍රියාකාරකම් වලටත් අඩු ක්‍රියාකාරකම් අනවශ්‍ය තෙහෙට්ටුව,පපුවේ ගැස්ම, හුස්ම ගැනීමේ අපහසුතා හෝ පපුවේ කැක්කුම ඇති කරයි.	
E	අනවශ්‍ය තෙහෙට්ටුව, පපුවේ ගැස්ම, හුස්ම ගැනීමේ අපහසුතා හෝ පපුවේ කැක්කුම වැනි රෝග ලක්ෂණ විවේකයෙන් සිටින විට වුවද පවතී. කිසියම් ශාරීරික ක්‍රියාකාරකමක් සිදුකලහොත් අපහසුතා වැඩිවේ.	

14. **හෘද රෝගවලින් කොරව, දිගුකාලීන ප්‍රතිකාර අවශ්‍ය වෙනත් ශාරීරික රෝගයක් ඔබට තිබේද?**

A	ඔව්	
B	නැත	

ඔව් නම්, සඳහන් කරන්න

15. හෘද රෝගය සඳහා වෛද්‍යවරයා විසින් ඔබට නියම කර ඇති ඖෂධ වර්ග ගණන කීයද? .....

16. දවසකට නියම කර ඇති උපරිම ඖෂධ වාර ගණන කීයද?

A	දවසකට වරක්	
B	දවසකට දෙවරක්	
C	දවසකට තුන් වරක්	
D	දවසකට හතර වරක්	
E	දවසකට හතර වරකට වඩා	

17. **ඔබේ ඖෂධ වෛද්‍යවරයා නිතර නිතර වෙනස් කර තිබේද?**

A	ඔව්	
B	නැත	

18. ඔබට කවදා හෝ ඖෂධ නිසා වන අතුරු ආබාධ අත්විඳ තිබේද?

A	ඔව්	
B	නැත	

19. **හෘද රෝග සායනය මගින් ලබා දුන් ප්‍රතිකාර හැරුණු විටල ඔබ වෙනත් කිසිදු ප්‍රතිකාර ක්‍රමයක් භාවිතා කර තිබේද ?**

A	ඔව්	
B	නැත	

C. සෞඛ්‍යය පද්ධතිය ආශ්‍රිත දත්ත

20. ඔබේ නිවසේ සිට මෙම සායනයට ඇති දුර දළ වශයෙන් කිලෝ මීටර් කොපමණද? .....

21. සායන වාරයකදී වෛද්‍යවරයා ඔබ වෙනුවෙන් ගත කරන වේලාව දළ වශයෙන් කොපමණද?.....

22. ඖෂධ ලබා ගත යුතු ආකාරය පිළිබඳව ඖෂධ අවශ්‍ය වන්නේ ඇයි සහ ප්‍රතිකාරවලින් අපේක්ෂා කළ යුත්තේ කුමක් ද යන්න ගැන සෞඛ්‍යාරක්ෂක පුද්ගලයෙකු ඔබට පැහැදිලි පැහැදිලි කිරීම් ලබා දී තිබේද ?

A	ඔව්	
B	නැත	

23. ඔබට පැහැදිලි කිරීම් ලබා දුන්නේ කවුද?

A	වෛද්‍යවරයෙක්	
B	හෙදියක්	
C	ඖෂධවේදියෙක්	
D	වෙනස්	

24. ඖෂධ ගන්නෙ කොහෙන්ද?

A	රෝහලේ ඖෂධාගාරය	
B	රෝහලේ පිටත ඖෂධය	
C	දෙකම	

25. එක් සායන වාරයක් සඳහා ඔබට කොපමණ මුදලක් වැය වෙනවාද? .....

B කොටස - ඖෂධ ගැනීමේ අනුකූලතාවය නිර්ණය කිරීම සඳහා වන ප්‍රශ්නාවලිය

රෝගීන් ඔවුන්ගේ හෘද රෝග සඳහා ඖෂධ ලබා ගනී. ඔවුන්ගේ ඖෂධ ගැන සැලකිලිමත් විය යුතු ගැටළු ගණනාවක් හඳුනාගෙන ඇති අතර පුද්ගලයින්ට ඔවුන්ගේ අත්දැකීම් පිළිබඳව උනන්දුවක් දක්වන්නන් විසින් හඳුනාගෙන ඇත. නිවැරදි හෝ වැරදි පිළිතුරක් නැත. හෘදයාබාධ ඖෂධ සමඟ ඔවුන්ගේ පෞද්ගලික අත්දැකීම් මත පදනම්ව සෑම ප්‍රශ්නයක් සඳහාම පිළිතුරු ලබා ගැනීමට උත්සාහ කරන්න.

	ඔව්	නැත
1. දිනපතා ඖෂධ ගැනීම ඇතැම් පුද්ගලයන්ට සැබෑ අපහසුතාවයකි. හෘද රෝග ප්‍රතිකර සැලැස්මට අනුව කටයුතු කිරීමට සිදුවීම පිළිබඳ ඔබ කවදා හෝ කනස්සල්ලට පත්වී තිබේද?		
2. ඔබ ගමන් කරන විට හෝ නිවසින් පිටව යන විට, හෘද රෝගයට භාවිතා කරන ඖෂධ රැගෙන යාමට ඔබට කවදා හෝ අමතක වී තිබේද?		
3. ඔබේ හෘද රෝගය පාලනය වී ඇතැයි සිතෙන විට, ඔබ කවදා ඖෂධ ගැනීම නතර කලේද?		
4. ඖෂධ ගැනීමෙන් පසු දැනෙන අපහසුතා නිසා, කවදා හෝ වෛද්‍යවරයාට නොදන්වා ඔබ ඖෂධ ගැනීම නතර කළාද?		
5. ඔබට කවදාක හෝ හෘද රෝගයට ගනු ලබන ඖෂධ ගැනීමට අමතක වී තිබේද?		
6. කොපමණ වාරයක් ඔබට සියඳු බෙහෙත් වර්ග ගැනීම අමතක වෙනවාද? (කරුණාකර අදාල අංකය රවුම් කරන්න) කවදාකවත් නැත/ ඉතා කලාතුරකින් .....5 ඉඳ හිට .....4 සමහර විට .....3 නිතර .....2 සැමවිටම 1		
7. පසුගිය සති දෙක පිළිබඳ සිතන කල, ඔබ ඖෂධ භාවිතා නොකළ දින තිබේද?		
8. ඊයේ ඔබ හෘද රෝග ඖෂධ ගත්තාද?		

வெளிநோயாளிகளுக்கான கார்டியலஜி கிளினிக்கில் கலந்துகொள்கின்ற கரோனரி இதய நோயாளிகளிடையே மருந்து இணக்கத்துடன் தொடர்புடைய காரணிகள் - இலங்கையின் தேசிய வைத்தியசாலை

தொடர் இல	

பாகம் A - மருந்து இணக்கம் தொடர்பான காரணிகள்

A. நோயாளி தொடர்பான தரவு

I. மக்கள் தொகை மற்றும் சமூக பொருளாதார தரவு

1.உங்கள் கடந்த பிறப்பு எவ்வளவு பழையது? .....

2.உங்கள் செக்ஸ் என்ன?

A	ஆண்	
B	பெண்	

3.நீங்கள் எந்த இனத்தைச் சேர்ந்தவர்கள்?

A	சிங்களம்	
B	தமிழ்	
C	முஸ்லிம்	
D	புறங்கியர்	
E	முலையாளி	
F	மற்ற	

4.நீங்கள் பெற்ற மிக உயர்ந்த கல்வித் தகுதி என்ன?

A	சாதாரண கல்வி இல்லை	
B	பாலர்	
C	தரம் 5 ஐ விட குறைந்தது	
D	தரம் 5 ஐ கடந்துவிட்டது	
E	GCE O / L ஐ நிறைவேற்றியது	
F	GCE A / L ஐ நிறைவேற்றியது	
G	பல்கலைக்கழக பட்டம் / டிப்ளமோ	

5. உங்கள் தற்போதைய திருமண நிலை என்ன?

A	திருமணமாகாத	
B	திருமணம்	
C	விவாகரத்து	
D	விதவை	

6.உங்கள் தற்போதைய வேலைவாய்ப்பு நிலை என்ன?

A	வேலையற்ற	
B	வேலைவாய்ப்பு உடைய	
C	ஓய்வுபெற்ற	
D	மற்ற	

7. நீங்கள் / உங்கள் குடும்பத்தின் சராசரி மாத வருமானம் என்ன?

A	வருமானம் இல்லை/ குழந்தைகள் பார்த்துக்கொண்டிருக்கிறார்கள்	
B	ரூgh.10000/- விட குறைந்த	
C	ரூgh.10001-20000	
D	ரூgh.20001-30000	
E	ரூgh.30001-50000	
F	ரூgh.50001 விட கூடியது	

8. நீ எப்போதும் புகைபிடித்திருக்கிறாயா?

A	ஆம்	
B	இல்லை	

9. ஆம் என்றால், மேலே கேள்விக்கு நீங்கள் இன்னும் புகைக்கிறீர்களா?

A	ஆம்	
B	இல்லை	

10 நீங்கள் எப்போதாவது மதுவை உட்கொண்டிருக்கிறீர்களா?

A	ஆம்	
B	இல்லை	

11 ஆம் என்றால், கேள்விக்கு மேலே, நீங்கள் இன்னும் மதுவை உட்கொள்கிறீர்களா?

A	ஆம்	
B	இல்லை	

II. கரோனரி இதய நோய் தொடர்பான அறிவு

காரணங்கள், ஆபத்து காரணிகள், அறிகுறிகள் மற்றும் கரோனரி இதய நோய் தொடர்பான சிகிச்சையில் நோயாளியின் அறிவுரைகளை மதிப்பிடுவதற்கு பின்வரும் கேள்விகளுக்கு கேட்கப்படுகிறது

	உள்ளடக்கம்	ஆம்	இல்லை	தெரியாது
1	இதயத் தமனியில் உள்ள கொழுப்புப் பிளேக்குகளை உருவாக்குவதே இரத்த உறைவு உருவாவதற்கு மூல காரணியாகும்.			
2	மாரடைப்பு மிகவும் பொதுவான காரணம் ஒரு இதய தமனியில் உள்ள ஒரு இரத்த உறை			
3.	உயர் இரத்த அழுத்தம் இதய நோய் ஒரு ஆபத்து காரணி.			
4	நீரிழிவு இதய நோய் ஒரு ஆபத்து காரணி			
5	மார்பு வலி தாடை அல்லது இடது / இரு கை / கள் இரண்டிற்கு ஒரு அறிகுறியாகும்			
6	மார்பின் வலியை தாடை அல்லது இடது / இரு கை / இரண்டும் சேர்த்து இதய நோய் அறிகுறியாகும்			
7	எப்போதாவது இதய நோய் எந்த வலி இல்லாமல் ஏற்படுகிறது			
8	பொதுவாக, ஒரு ஈசிஜி மற்றும் இரத்த பரிசோதனைகள் (எ.கா: டிராபோனின்) இதய நோய் உறுதிப்படுத்த செய்யப்படுகின்றன.			

9	இதய நோய் வந்தவுடன், உங்கள் வாழ்நாள் முழுவதும் வழக்கமான மருந்துகளை எடுத்துக் கொள்ளுமாறு அறிவுரை வழங்கப்படுகிறது.			
10	இதய நோய்க்கு நோயாளிகளுக்கு அதிக எபிசோட்களின் வாய்ப்பு குறைக்கப்படுவதோடு, இதய நோயை மோசமாக்குவதை தடுக்கவும் மருந்துகள் பரிந்துரைக்கப்படுகின்றன.			
11	75mg ஆஸ்பிரின் இரத்தக் குழாய்களின் உள்ளே இரத்த உறைவு ஏற்படுவதற்கான அபாயத்தை குறைக்கிறது.			
12	Statins (Atovasatatin, Simvastain, Rosuvastatin) கொழுப்பு அளவு குறைக்கிறது.			
13	உயர் இரத்த அழுத்தம் கட்டுப்பாட்டை மேலும் இதய தாக்குதல்கள் வளரும் ஆபத்தை குறைக்கிறது			
14	நீரிழிவு கட்டுப்பாட்டை மேலும் இதய தாக்குதல்கள் வளரும் ஆபத்தை குறைக்கிறது			
15	இதய நோய்க்குரிய சில சிக்கல் சிக்கல்கள் இதயத்தின் திறனை குறைப்பது, அசாதாரண இதய தாளங்கள் மற்றும் இதயத் தாக்குதல்களை அதிகரிப்பது ஆகியவை அடங்கும்.			

B. நோய் மற்றும் சிகிச்சை தொடர்பான தரவு

12. இதய நோய் எப்படி நீண்டகாலமாக கண்டறியப்பட்டிருக்கின்றன?
. . . . . .

13. உங்கள் ∴பெடரல் திறனின் நிலை என்ன?

	நோயாளி அறிகுறி	
A	அறிகுறிகள் இல்லை	
B	நடைபயிற்சி, தோட்டக்கலை போன்ற சாதாரண உடல் நடவடிக்கைகள், தேவையற்ற சோர்வு, களைப்பு, படபடப்பு, சுவாசிக்முடியாத தன்மை தசைநார் அல்லது மார்பு வலியை ஏற்படுத்தாது	
C	நடைபயிற்சி வசதியாக ஆனால் நடைபயிற்சி போன்ற சாதாரண உடல் செயல்பாடுகளை, சோர்வு உள்ள தோட்டம் முடிவு, படபடப்பு, சுவாசிக்முடியாத தன்மை அல்லது மார்பு வலி	
D	வசதியாக வசிக்கும் ஆனால் நடைபயிற்சி தோட்டம் போன்ற சாதாரண நடவடிக்கைகள் குறைவாக சோர்வு ஏற்படுகிறது, தசைப்பிடிப்பு, படபடப்பு, சுவாசிக்முடியாத தன்மை அல்லது மார்பு வலி	
E	அறிகுறிகள் அநாவசிய சோர்வு, களைப்பு, படபடப்பு, சுவாசிக்முடியாத தன்மை மற்றும் மார்பு வலி ஆகியவை கூட ஓய்வெடுக்கலாம். உடல் ரீதியான நடவடிக்கை, அசௌகரியம் அதிகரிக்கும் மேற்கொள்ளப்பட்டால்.	

14. இதய நோய் தவிர வேறு ஏதேனும் நீண்ட கால நோய்கள் உங்களுக்கு இருக்கிறதா?

A	ஆம்	
B	இல்லை	

ஆம் என்றால், தயவுசெய்து குறிப்பிடவும்.....

15. எத்தனை வகையான மருந்துகள் தற்போது இதய நோய்க்கான மருத்துவரால் பரிந்துரைக்கப்படுகின்றன? .....

16. நாள் ஒன்றுக்கு அதிகபட்ச பரிந்துரைக்கப்பட்ட மருந்து அதிர்வெண் என்ன?

A	ஒரு நாளுக்கு ஒரு முறை	
B	ஒரு நாளுக்கு இரு தடவைகள்	
C	ஒரு நாளுக்கு மூன்று முறை	
D	ஒரு நாளுக்கு நான்கு முறை	
E	பிற	

17. உங்கள் இதய மருத்துவ மருந்து பெரும்பாலும் ஒரு டாக்டரால் மாறியிருக்கிறதா?

A	ஆம்	
B	இல்லை	

18. நீங்கள் எப்போதாவது மருந்து பக்க விளைவுகளை அனுபவித்திருக்கிறீர்களா? ஏதாவது ஆதரவு கிடைக்குமா?

A	ஆம்	
B	இல்லை	

19. கார்டியாலஜி கிளினிக்கால் கொடுக்கப்பட்ட சிகிச்சை தவிர வேறு எந்த சிகிச்சையையும் நீங்கள் எப்போதாவது பயன்படுத்தியிருக்கிறீர்களா?

A	ஆம்	
B	இல்லை	

c. சுகாதார அமைப்பு தொடர்பான தரவு

20. கிலோ மீட்டர் உங்கள் வீட்டில் இருந்து மருத்துவமனைக்கு சராசரியாக என்ன ஆகும்? .....

21. டாக்டர் ஒரு மருத்துவ விடுதியில் நீங்கள் செலவிடுகிற சராசரி நேரம் என்ன? .....

22. ஒரு மருத்துவரால் பரிந்துரைக்கப்பட்டுள்ள போதைப்பொருட்களை எடுத்துக்கொள்வதன் முக்கியத்துவத்தை நீங்கள் ஒரு மருத்துவர் / செவிலியர் மூலம் எப்போதாவது படித்திருக்கிறீர்களா? ஏதாவது ஆதரவு கிடைக்குமா?

A	ஆம்	
B	இல்லை	

23. உங்களிடம் விளக்கம் அளித்தவர் யார்?

A	மருத்துவர்	
B	செவிலியர்	
C	மருந்து	
D	மற்ற	

24. பொதுவாக எங்கிருந்து இதய நோய் மருந்துகள் கிடைக்கும்?

A	மருத்துவமனை மருந்து	
B	மருத்துவமனைக்கு வெளியே பார்மசி	
C	இருவரும்	

25. மருத்துவமனையின் வருகையை நீங்கள் எவ்வளவு செலவிடுகிறீர்கள்? ரூபாய்.....

பாகம் B - <u>மருந்து இணக்கத்தை அணுகுவதற்கான கேள்வி</u>

நோயாளிகள் தங்கள் இதய நோய்க்காக மருந்துகளை எடுத்துக்கொள்கிறார்கள். இதய நோய் மருந்துகளுடன் தனிப்பட்ட அனுபவத்தை அடிப்படையாகக் கொண்ட ஒவ்வொரு கேள்விகளுக்கும் பதில் பெற முயற்சி செய்யுங்கள்

		ஆம்	இல்லை
1	தினமும் மருந்துகளை எடுத்துக் கொள்வது சிலருக்கு ஒரு அசாதாரண சிரமமாகும். உங்கள் இதய நோய் சிகிச்சை திட்டத்தில் ஒட்டிக்கொள்வதைப் பற்றி எப்போது கவலைப்படுகிறீர்கள்?		
2	நீங்கள் வீட்டிலிருந்து வெளியேறும்போது அல்லது வெளியேறும்போது, உங்கள் இதய நோய் மருந்துகள் கொண்டு வர மறந்துவிட்டீர்களா?		
3	உங்கள் இதய நோய் கட்டுப்பாட்டின் கீழ் இருப்பதாக உணரும்போது, உங்கள் மருந்துகளை நீங்கள் எப்போதாவது நிறுத்திவிட்டீர்களா?		
4	நீங்கள் எப்போதாவது வெட்டிக்கொண்டிருக்கிறீர்களா அல்லது உங்கள் மருந்துகளை எடுத்துக்கொள்வதை நிறுத்திவிட்டீர்களா? ஏனெனில் நீங்கள் எடுத்துக் கொண்டபோது மோசமாக உணர்ந்தீர்கள்?		
5	உங்கள் இதய நோய் மருந்துகளுக்கு நீங்கள் எப்போதும் மறந்துவிட்டீர்களா?		
6	உங்கள் மருந்துகள் எல்லாவற்றையும் எப்படி அடிக்கடி மறக்கிறீர்கள்? (தயவுசெய்து சம்பந்தப்பட்ட எண்ணை வட்டம் செய்யவும்) அரிதாகத்தான் .....5 எப்பொழுதாவது ஒருமுறை..... 4 சில நேரங்களில்.....3 வழக்கமாக..... 2 எல்லா நேரமும்..... 1		
7	கடந்த இரண்டு வாரங்களாக யோசித்துப் பார்த்தால், உங்கள் இதய நோய் மருந்துகளை எடுத்துக் கொள்ளாத நாட்களில் அங்கே இருந்தீர்களா?		
8	நேற்று உங்கள் இதய நோய் மருந்துகளை எடுத்தீர்களா?		

Postgraduate Institute of Medicine

University of Colombo, Sri Lanka

PGIM/AC/16

12th June 2017

Dr. G.W.K.C. De. Silva
23/C,
Kularathna Road
Ambalangoda

Dear Dr. Silva,

RESEARCH PROPOSAL OF MSc. TRAINEES – 2017 (COMMUNITY MEDICINE/ COMMUNITY DENTISTRY).

The Board of Study in Community Medicine at its meeting held on 05.06.2017, has approved your proposal with suggested modifications.

Title: "Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka."

Yours sincerely,

Dr. Achala Jayatilleke
Senior Lecturer
For Director/PGIM

Cc: PF

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Postgraduate Institute of Medicine
University of Colombo, Sri Lanka

Professor H. Janaka de Silva
MD, DPhil (Oxon.), FRCP, Hon. FRACP, FNASSL
Director

PGIM/AC/16

23rd June 2017

Director
National Hospital of Sri Lanka
Colombo

Dear Sir/Madam,

PERMISSION TO COLLECT DATA FOR RESEARCH
MSC COMMUNITY MEDICINE TRAINING PROGRAMME -2017
DR G.W.K.C.DE SILVA

Dr G.W.K.C.de Silva is a postgraduate trainee in the MSc. (Community Medicine) training programme of the Postgraduate Institute of Medicine, University of Colombo. She has selected a research project titled **"Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka."**

I would be very much thankful to you if you could grant permission to collect data enabling her to carry out the study in the areas identified by her.

Appreciated very much your kind co-operation in this regard.

Yours sincerely,

H-J Cecile

Professor. H. Janaka De Silva
Director/PGIM.

Permission granted
provided ethical
approval given

DEPUTY DIRECTOR
(OPD & CARDIOLOGY)
The National Hospital of Sri Lanka
Colombo-10

Cc: Deputy Director, National Hospital of Sri Lanka, Colombo

ral Office: 160, Prof. Nandadasa Kodagoda Mawatha, Colombo 07, Sri Lanka. Tel: +94 11 2696758/2696261 Web: www.pgim.cmb.ac.lk

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Postgraduate Institute of Medicine
University of Colombo, Sri Lanka

Professor H. Janaka de Silva
MD, DPhil (Oxon.), FRCP, Hon. FRACP, FNASSL
Director

PGIM/AC/16

23rd June 2017

Dr W.S. Santharaj, Consultant Cardiologist, NHSL, Colombo
Dr Sepalika Mendis, Consultant Cardiologist, NHSL, Colombo
Dr Nimali Fernando, Consultant Cardiologist, NHSL, Colombo
Dr Stanley Amarasekara, Consultant Cardiologist, NHSL, Colombo
Dr. Sampath Withanawasam, Consultant Cardiologist, NHSL, Colombo

Dear Sir/Madam,

PERMISSION TO COLLECT DATA FOR RESEARCH
MSC COMMUNITY MEDICINE TRAINING PROGRAMME -2017
DR G.W.K.C.DE SILVA

Dr G.W.K.C.de Silva is a postgraduate trainee in the MSc. (Community Medicine) training programme of the Postgraduate Institute of Medicine, University of Colombo. She has selected a research project titled **"Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka."**

I would be very much thankful to you if you could grant permission to collect data enabling her to carry out the study in the areas identified by her.

Appreciated very much your kind co-operation in this regard.

Yours sincerely,

Professor. H. Janaka De Silva
Director/PGIM.

Dr. Sampath Withanawasam
MBBS, MD, MRCP (UK) MRCP (Lond)
Resident Cardiologist
Institute of Cardiology
National Hospital - Sri Lanka.

DR. STANLEY AMARASEKERA MD FCCP
Consultant Cardiologist &
Cardiac Interventionalist
National Hospital of Sri Lanka
Colombo

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Ethics Review Committee

Faculty of Medicine
University of Colombo
P O Box 271, Kynsey Road, Colombo 8, Sri Lanka
Telephone: +94-11-2695300 ext 240 Fax: +94-11-2691581
Email: ethicscommitteemfc@gmail.com

REFERENCE: EC-17-085

20th July 2017

Dr. G.W.K.C. de Silva
No. 23c
Kularathna Road
Ambalangoda

Dear Dr. de Silva,

Re : Protocol No EC-17-085

Title : Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic- National Hospital of Sri Lanka

Thank you for submitting the above research proposal, which received expedited ethics approval from the Executive Committee on 11.07.2017.

The proposal was considered by the Ethics Review Committee at its meeting on 20.07.2017, and approval is granted to proceed.

This approval relates to the following:

- Research Proposal (Version 1.0)
- Information sheets (Version 1.1)
- Consent forms (Version 1.0)
- Data collection forms (Version 1.0)

Ethics Review Committee

Faculty of Medicine
University of Colombo
P O Box 271, Kynsey Road, Colombo 8, Sri Lanka
Telephone: +94-11-2695300 ext 240 Fax: +94-11-2691581
Email: ethicscommitteemfc@gmail.com

You are asked to note the following:

- This approval is valid for one year from the date of issue of this letter, and the commitee requires that you furnish a final report once the study is concluded.
- If the study is continued for a period beyond one year, you are required to furnish an annual progress report for the year and an application for the extension of approval by a further year. The ERC will issue such extension after consideration of the progress report and any other information it may require from you for this purpose.
- Progress reports and final reports should be submitted in the recommended template, which can be downloaded from the ERC web page of the Faculty of Medicine, University of Colombo website.
- In similar manner, you are required to furnish a progress report and an application for the extension of approval for each subsequent year as long as the study is continued. If no such application is made or extension of approval given, the ethics clearance lapses automatically once the current year of approval is finished.
- If the progress report and/or the final report is/are delayed more than one month beyond the due date (which is the final date of ethics approval in force), approval for the study will lapse and you will be required to furnish a new application should you wish to resume or continue the study.
- If a PI has three or more research proposals in which the progress reports and/or final reports have lapsed in this manner, no further applications for ethics review shall be entertained from such PI.

This approval relates to the ethical content of the study only, and you are responsible for the following:

- negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved,
- If appropriate, informing the study sponsor that the membership and procedures of the Faculty of Medicine ,University of Colombo Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL).

Yours sincerely,

Dr. Enoka Corea
Chairperson
Ethics Review Committee
Faculty of Medicine
University of Colombo

Ethics Review Committee
Faculty of Medicine
University of Colombo
Kynsey Road
Colombo 8

දුරකථනය
தொலைபேசி
Telephone
94-11-2691111

අධ්‍යක්ෂ
பணிப்பாளர்
Director
94-11-2698443
94-11-2685933

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தொலைநகல்
Fax No.
94-11-2698443

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விசாரணை
E-mail
drphsl@sltnet.lk

මගේ අංකය
எனது இல.
My Ref.
AAJ/ETH/COM/2017

ඔබේ අංකය
உமது இல.
Your Ref.

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இலங்கை தேசிய வைத்தியசாலை கொழும்பு 10.
THE NATIONAL HOSPITAL OF SRI LANKA COLOMBO 10.

30 .08.2017

Dear Dr. G.W.K.C. de Silva ,

e : **ETH/COM/2017/07**

Title : "Factors associated with drug compliance among Coronary heart disease patients attending Outpatient Cardiology clinic – National Hospital of Sri Lanka."

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee for full board review, at its meeting on 29.08.2017.

Hereby approval is granted to proceed.

- This approval is valid for one year, and the Committee requires that you furnish it with an annual report on the study's progress beginning on 29.08.2017.

- This approval relates to the ethical content of the study only, and you are responsible for the following:

- Negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved.

Yours sincerely,

Dr. Cyril de Silva
Chairman
Ethical Review Committee