# PATIENT SATISFACTION & CARDIOVASCULAR RISKS AMONG PATIENTS ATTENDING KLINK RAWATAN KELUARGA, HOSPITAL USM

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**BY**

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Masseni Binti Abd. Aziz

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## ABBREVIATIONS

| | |
|---|---|
| **ATP III** | **Adult treatment panel III** |
| **BMI** | **Body Mass Index** |
| **CHD** | **Coronary heart disease** |
| **CVD** | **Cardiovascular disease** |
| **DBP** | **Diastolic Blood pressure** |
| **FRS** | **Framingham coronary risk prediction tools** |
| **HDL** | **High density lipoprotein** |
| **KRK** | **Klinik Rawatan Keluarga** |
| **LDL** | **Low Density Lipoprotein** |
| **NHMS** | **National Health Morbidity Survey** |
| **SBP** | **Systolic Blood Pressure** |
| **SKIP** | **Skala Kepuasan Interaksi Perubatan** |
| **TC** | **Total Cholesterol** |
| **WC** | **Waist Circumference** |
| **WHO** | **World Health Organization** |

## ABSTRACT

**English**

**Introduction: Cardiovascular disease (**CVD) accounted for 30% of an estimated 58 million death globally from all causes in 2005 and death due to non-communicable disease (half from CVD) is expected to increase by 17% from 2006 to 2015 (1).

**Objective:** To evaluate patient satisfaction, modifiable cardiovascular risk factors and their relationship after 6 months follow up among moderately-high cardiovascular risk patient attending Klinik Rawatan Keluarga (KRK), Hospital Universiti Sains Malaysia (USM) .

**Material and method:** A cross sectional study and prospective study was conducted among patient with moderately-high cardiovascular (CV) risk patient attending KRK, USM hospital, Kelantan. Patient with moderately-high CV risk underwent structured counseling on CV risk prevention and their satisfaction to the doctor-patient interaction was assessed using SKIP 11, patient was also assessed on their modifiable CV risk (SBP, TC & HDL) at baseline and at 6 months post counseling to see the changes in the outcome. The association between satisfaction and outcome were evaluated. Descriptive analysis, paired t test and general linear regression were used using PASW version 19.

**Result:** A total of 104 patients responded giving a response rate of 98.1%. 76.5% of the patient was satisfied with doctor-patient interaction with the favorable domain of distress relief (85.3%) and rapport (91.2%). The unfavorable domain was interaction outcome with only 67.6% patient satisfied in this domain. There were also significant changes in the modifiable CV risk namely

total cholesterol (TC) $p<0.022$ and systolic blood pressure (SBP) $p<0.001$ after 6 months post intervention counselling. However, there was no relationship between patient satisfaction and changes in modifiable cardiovascular risk.

**Conclusion:** With the use of structured cardiovascular risk prevention counseling based on WHO (2007) guideline, majority (three quarter) of moderately-high risk CV patients showed satisfaction in doctor-patient interaction, specifically in terms of distress relief and rapport. Even though there is improvement in the modifiable risk factors namely SBP and TC at 6 months follow-up, however this changes were not related with the patients' satisfaction. It can be concluded that the improvement of modifiable CV risk factors studied do not solely result from single intervention counselling but can be contributed by many factors such as content of intervention counselling, drug dosage adjustment, frequent medical visit and compliance intent.

## ABSTRAK

**Bahasa Melayu**

**Pengenalan:** Penyakit Kardiovaskular adalah penyebab kepada 30% kematian yang dianggarkan di dalam 58 juta kematian dunia daripada semua penyebab pada tahun 2005. Kematian kerana penyakit tidak berjangkit ini (separuh daripadanya adalah kardiovaskular) di jangka akan meningkat dari 17% dari tahun 2006 hingga 2015 (1)

**Objektif:** Untuk menilai kepuasan pesakit , risiko kardiovaskular yang boleh diubah dan hubung kait diantaranya selepas 6 bulan rawatan susulan dalam kalangan pesakit yang mempunyai faktor risiko sederhana-tinggi di Klinik Kesihatan Keluarga, Hospital Universiti Sains Malaysia (USM).

**Bahan dan Kaedah:** Satu kajian hirisan lintang dan kajian prospektif (kehadapan) telah dilakukan di kalangan pesakit-pesakit yang mempunyai risiko kardiovaskular sederhana-tinggi yang menghadiri Klinik Rawatan Keluarga, Hospital USM, Kelantan. Pesakit–pesakit ini akan di beri kaunseling mengenai cara-cara mencegah penyakit kardiovaskular. Kemudian tahap kepuasan pesakit terhadap interaksi antara doktor dan pesakit di nilai melalui soalan daripada SKIP 11.Pesakit juga akan dinilai kadar perubahan faktor risiko (TC, HDL dan SBP) selepas enam bulan kaunseling. Hubungkait diantara nilai-nilai ini akan diukur melalui analisa deskriptif, t-berkembar dan regresi linear umum mengunakan PASW 19.

**Keputusan:** Seramai 104 orang pesakit bertindak memberi kadar respon 98.1%. 76.5% pesakit berpuas hati dengan interaksi di antara doktor dan pesakit, dengan domain yang disukai lega

tekanan (85.3%) dan domain hubung baik (91.2%).Domain yang kurang diminati ialah domain hasil interaksi (67.6%). Terdapat juga perubahan yang positif selepas 6 bulan di dalam faktor risiko boleh ubah seperti perubahan dalam tahap kolesterol dan tekanan darah sistolik. Tetapi tiada perkaitan di antara kepuasan pesakit dan perubahan nilai faktor risiko.

**Kesimpulan:** ¾ daripada pesakit kategori sederhana-tinggi risiko CV, berpuashati dengan interaksi diantara doktor dan pesakit terutama di dalam domain hubung baik dan lega tekanan selepas sesi kaunseling intervensi. Walaupun terdapat perubahan yang baik dalam faktor risiko boleh ubah seperti SBP dan TC selepas enam bulan, tetapi perubahan ini tidak berkait dengan kepuasan pesakit. Dapat disimpulkan bahawa perubahan baik dalam faktor risiko CV tidak hanya bergantung kepada satu kaunseling ini sahaja tetapi ia juga boleh disebabkan oleh perubahan dalam dos ubat, kekerapan rawatan susulan dan kesanggupan pesakit untuk patuh kepada arahan.

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Dr Azlina Ishak (Supervisor)

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# CHAPTER 1

# INTRODUCTION

Cardiovascular disease (CVD) accounted for 30% of an estimated 58 million deaths globally from all causes in 2005 (1) and between 2006 and 2015, deaths due to non-communicable diseases (half of which will be due to CVD) are expected to increase by 17% (1).

According to data from the Information and Documentation System Unit of the Ministry of Health of Malaysia showed that CVD had been the main cause of death in government hospitals over the years which accounted for 23% to 26% of deaths from 1994 to 2001. Out of this figure, heart disease accounted for 14% to 16.6%. (2)

Cardiovascular risk is defined as probability of an individual experiencing a cardiovascular event over a 10-year period(3). It is important for attending physician or other health care personnel to identify patient with 10-year risk of coronary heart disease event in order to address the problems earlier and more aggressive intervention could be instituted. The used of scoring system to categorize patient into low, moderate, moderately-high and high risk is important for disease management(4).

Many risk score have been implemented and used worldwide such as Framingham Coronary Risk Prediction Tool (FRS), Adult Treatment Panel (ATP) III, Framingham Risk Equations (FRS) 2008 risk score, the Systematic Coronary Risk Evaluations(SCORE) project, the

Assessing Cardiovascular Risk to Scottish Intercollegiate Guidelines Network (ASSIGN) risk score, the QRESEARCH cardiovascular risk algorithm (QRISK) CVD risk score, Reynolds risk score for woman, Reynolds risk score for men and World Health Organization/ International Hypertension Society (WHO/ISH) risk score(5, 6). Among those risk scores listed above, the original Framingham Risk Score and the ATP III are more or least similar. The other risk scores had been modified to involve other variables and outcomes according to their research characteristic, interest and population studies.

This study choose the traditional Framingham risk score because this score is being used worldwide since 1998 and being validated across population (men, women, blacks, Europe, Mediterranean and Asian)(5, 6). Recently, this score (using low information equations) was used to compare data from Framingham study with Asian cohort study on the accuracy of cardiovascular risk prediction resulted in similar accuracy in Asian population after recalibrated (7).

Framingham equation in Asian study used low information equation (7), thus in this current study, we used the traditional Framingham equations that derived from Framingham cohort, even though there are existing new equations such as FRS 2008 and other equations available(5, 6) as listed above. To our knowledge, only the traditional FRS equation being validated across population(5, 6).

In addition to that, the outcome of traditional FRS equations is fatal and nonfatal Myocardial Infarction (CHD) but not the global cardiovascular disease as a whole including stroke,

peripheral arterial disease or heart failure(5, 8). Thus, this study used asymptomatic patient with no history of coronary heart disease or cardiac event as a participant because the predicted risk only applies to individual without diagnosed heart disease(8) to predict the hard end point of fatal and nonfatal CHD.

Even though the traditional FRS had some limitations (8) as compared to other new model of equations(5, 6) in term of the variables and outcome measure, but the low information equations is suitable to be used in the outpatient clinic with limited resources and it is user friendly whereby the equations does not need high information such as C-peptide or C reactive protein and it is easy to calculate and efficient because it only has 5 risks in the equations. The used of equations that need the measurement of C reactive protein example Reynolds CAD risk is not suitable to be used in center with limited resources(6). Besides that, the FRS equations also had a wide range of age, from 20 years old to 79 years old both in men and women as compared to FRS (2008). The FRS (2008) starting age is 30 years old up to 75 years old in both men and women(9).

The variable in the traditional FRS are sex, age, systolic blood pressure treated or untreated, total cholesterol, high density lipoprotein and smoking status(8). This FRS is not originally designed for use in diabetic populations. The cohort that was originally used to derive this equation included relatively few diabetic patients, specifically 4% of 5573 participants from a restricted age range(8). Thus, the prediction with the original FRS equations is less precise in this population.

Up to year 2010, there is no consensus as to which is the best risk assessment tools to follow and to use for risk stratification in Asian population as there were many calculator or risk chart being produced worldwide(5, 6, 10) Ideally, each country should have its own risk score that takes into account other factors as well(5).

The role of diabetes as a prediction of cardiovascular disease also became a major interest in many physicians and researchers(4). The labeling of 'diabetes' as a CHD risk equivalent also become a popular hypothesis(4). However, a meta-analysis done in year 2009 did not support the hypothesis that diabetes is a 'coronary heart disease equivalent'. Patients with diabetes without prior myocardial infarction have a 43% lower risk of developing total CHD events compared with patients without diabetes with previous myocardial infarction(11).

It doesn't matter which calculation being used to predict cardiovascular risk. However, it is worthwhile to be familiar with one of these scores, select one that is most appropriate for the patient and discuss treatment options based on the estimated risk(5). The risk score is only an assessment tool to help us as a physician to start treatment and to counsel patient. The most important is the assessment of the patient as a whole including history, physical examination and if available biochemical test. We must not depend totally on this calculator or risk prediction chart alone to decide our management and need to weigh between risk and benefit of medication stated for primary prevention (4, 5, 8, 11).

In addition to that, since diabetes is not a coronary heart disease risk equivalent(11), we should not treat diabetes patient as  a primary prevention(11), for example starting all diabetes patients

with aspirin without their estimated global CHD risk. Public health decisions to initiate cardio-protective drugs in patients with diabetes for primary CHD prevention should therefore be based on appropriate patients' CHD risk estimates rather than a 'blanket' approach of treatment(11).

The other study also showed that expensive testing of biomarkers such as coronary calcium score and C-reactive protein can improve risk estimation, but the evidence on outcome improvement are lacking. Another example is the use of sophisticated risk identification by using nuclear stress imaging to screen patient for coronary heart disease. Patients who were screened did not have significantly fewer cardiac events compared with those who were not screened(12). Thus, the prediction tools only help us to guide our management. There is no guarantee that the expensive tools will result in good outcome. The most important is how clinicians make use of it in daily clinic visit and at the same time helping patient to reduce their cardiovascular risk.

Nowadays, patient preferences for disease management are increasingly important and there should be shared decision making in which both patient and physician are equally and actively involved and share information in order to reach an agreement(13). Patient satisfaction with doctor-patient interaction also influences the outcomes of the physician-patient discussion(14). Hence, it is important to measure patient satisfaction. A high satisfaction with physician-patient interaction is associated with increased adherence, better continuity of care, treatment decisions and even positive adjustment (15).

To measure satisfaction, there are two validated questionnaire being used that are the Medical Interview Satisfaction Scale (MISS) and the Consultation Satisfaction Questionnaire (CSQ).

However, MISS measure humanness more consistent than CSQ(16). In addition to that, MISS had been translated to Malay version and being validated to be used in Malaysia and known as Skala Kepuasan Interaksi Perubatan (SKIP)(17).

According to Peter Ham , there is no studies showing that coronary heart disease risk calculation alone changes outcome and this suggests that the physician-patient interaction is more important. The systematic review of coronary heart disease showed that the quality of educational interventions can result in improvement in risk and compliance(12). However, there is no specific module or decision aids had been used to guide the counseling on cardiovascular risk in Klinik Rawatan Keluarga (KRK) in the current practice. The counseling depends on physicians' style and knowledge to counsel patient.

**1.1 Justification of the study**

In Malaysia, cardiovascular disease has become a burden and the leading cause of death both in men and women. There is also very few studies in Malaysia that described our population 10-year CHD risk and address the necessary intervention (18-20).

There is strong evidence from clinical tools that reducing the levels of risk factors has beneficial effect on CHD and CVD. Thus, risk factor screening and management have now been widely used in cardiovascular prevention guideline in most high income countries(3, 21).

The 10-year risk using Framingham risk score has divided the person into mild, moderate, moderately-high and high risk group(4). The high risk group may have already experienced a coronary heart disease event and risk stratification is not necessary for making treatment decisions for these individuals because all of them need intensive lifestyle interventions and appropriate drug therapy(3). In addition to this, almost all asymptomatic individual with 0-1 risk factor have a 10-year risk < 10%, thus 10-year risk assessment is not necessary(4).

Thus, risk stratification is important for asymptomatic patient with two or more risk factors to enable the intensity of intervention to be matched with the degree of total risk(3, 5). 10-year risk stratification using traditional Framingham risk score can give prediction to the probability of this patient developed fatal and nonfatal CHD event in next 10 years(8). Patient with 2 or more risk factor can fall into moderate CHD risk (<10%) and also moderately-high CHD risk (10-20%)(4). Hence, this study will focus on patients with 10-year CHD risk of 10-20% (moderately-high) in view of the probability for fatal or non-fatal events and higher probability of getting changes in the outcome parameters of interest within the specific period of time.

In this study, we are focusing on a counselling related to risk stratification approach to guide us in prevention of cardiovascular event. This is a preliminary study of patient satisfaction on doctor-patient interaction on cardiovascular disease risk prevention in ordinary setting. It helps to assess whether the risk stratification approaches(3) will be able to motivate patients, particularly to change behavior and when appropriate, to take antihypertensive and lipid-lowering drugs.

Patient satisfaction influences the outcomes of the doctor-patient encounter(14) and a high satisfaction will lead to increase adherence and even positive adjustment of the patients(15). Hence, studying the local setting is important for identifying rooms of improvement and the possibility of intervention in the future. This is because there is no standard module or decision aids had been used for counseling on cardiovascular risk in KRK, Hospital USM.

# CHAPTER 2

# LITERATURE REVIEWS

## 2.1 Cardiovascular disease

Population wide public health approaches alone will not have an immediate tangible impact on cardiovascular morbidity and mortality (22). A combination of population-wide strategies and strategies targeted at high risk individuals is needed to reduce the cardiovascular disease burden. The extent to which one strategy should be emphasized depends on achievable effectiveness, cost-effectiveness and availability of resources (1, 22-24).

Determining a patient's global coronary heart disease (CHD) risk may improve appropriate prescribing (12). A 2003 study of six subspecialists in diabetes and 323 patients found a non-significant trend toward increased overall prescribing of cardiovascular drugs (25). In a high-risk subset of these patients, physicians prescribed significantly more blood pressure and lipid lowering medications when the global CHD risk score was known (25). This is a promising example of behavior change among physicians. However, changing physicians' intent to prescribe does not guarantee improved outcomes. For example, a study of patients with hypertension found that physicians who were given charts to calculate CHD risk prescribed more antihypertensive drugs (resulting in a reduction of 4.6 mm Hg in systolic blood pressure) but the overall risk of cardiac events did not change (26). Identifying risk and doing something about it are two distinct entities(12).

## 2.2 Patient Satisfaction

Patient satisfaction influences the outcomes of the physician-patient encounter(14). For every patient, a medical consultation forms part of a continuing process of coping with illness. Patients have expectations when they visit their doctors and the degree to which these expectations are met influences satisfaction (14). A high satisfaction with physician-patient interaction is associated with increased adherence, better continuity of care, client participation in important treatment decisions and even beneficial/positive adjustment (15).

The role of the patient in healthcare decision making has changed. There is a trend towards greater involvement by patients in their personal healthcare management. Patient preferences for disease management are considered increasingly important and some feel they should influence individual decision-making (13). Shared decision making is particularly important with regard to CVD prevention. Physicians are not only expected to inform and involve their patients in CVD prevention but the focus is also shifting from individual risk factors, such as hypertension or hyperlipidemia alone to global risk (multiple risk factor) as a guide for preventive action (27).

## 2.3 Patient Satisfaction Questionnaire

The consultation is the central act of medicine. There are different tools of questionnaire to measure consultation outcome. The consultation outcomes can be divided into symptoms relief, diseases control, enablement, general health, compliance or adherence, efficiency, satisfaction and also quality of consultation(28).

As an example, Patient Enablement Instrument is used to assess patient ability to understand the illness and coping with symptoms. This is usually used in patient centered assessment because it measures immediate effect to the current enablement(28). Patient Enablement Questionnaire had been compared with MISS and CSQ to see their correlation and the result showed that although enablement is an outcome of the consultation but it was different from MISS and CSQ and cannot be used to measure satisfaction (29).

For the general health, an example of the questionnaires is the Medical Outcome Study 11 and "Eurocol 5 dimension". These questionnaires are used to grade the patient's general health. The three quality instruments are Europep, Improving Practice Questionnaire (IPQ) and General Practice Assessment Questionnaire (GPAQ)(28, 30). The Europep instrument has been used for evaluation of care and for evaluation of the General Practitioners, for comparison between health care in different countries and for comparison between health care systems in different countries and other studies(28). IPQ and GPAQ Questionnaire measures opinion of the patient towards GP service as used in UK (28, 31). Shared Decision Making Questionnaire (SDM-Q) is used in studies investigating the effectiveness of SDM and as a quality indication in health. It aims in assessing the decision process (32).

To measure satisfaction there are two tools that are validated and reliable, The Consultation Satisfaction Questionnaire (CSQ) and Medical Interview Satisfaction Scale (MISS)(16, 28). These two questionnaires measure satisfaction with different aspect of doctor performance. CSQ was developed by Baker (33) and used in British General Practice whereas MISS was originally

elaborated in USA as MISS 29 but it was adapted to English Standard version which known as MISS-21. Both of these questionnaires are validated and reliable (16)

The 29-item Medical Interview Satisfaction Scale (MISS-29) was developed to assess patient satisfaction with individual doctor-patient satisfaction with four subscales and patients were asked to indicate their level of agreement on a seven-point Likert scale(34)

A modified MISS-21 with the same four original subscales was produced and tested in a wider UK general practice population. Correlation between subscales ranged from 0.46 to 0.65. Values of Cronbach's alpha ranged between 0.67 and 0.92 (35).

Most of the surveys had focused on general evaluations of doctor and/or health care service. Only a few have shown evidence of careful methodology. Methods of item generation and pretesting in the MISS-26 are detailed. The overall reliability of the scale (Cronbach's coefficient alpha) is 0.93. The distribution of satisfaction scores is broader than that reported for other scales and approaches the normal in shape. It is internally consistent, easily administered measure of three aspects of patient satisfaction; cognitive, affective and behavioral. Correlations of the scale with socio demographic variables are low or no significant, which suggests that these factors do not seriously contaminate responses(34).

The second study comparing MISS 29 and CSQ was done by Kinnersley.P, Nigel (16) showed that both questionnaires were not superior than another in psychometric term. Both have high level of internal consistency. However MISS measure humanness more consistent than CSQ. A

third study done by Meakin and Weinman (35) in British General Practice using MISS-29 to measure validity, reliability and applicability of MISS-29 in British General Practice population resulted in the development of a new 21-item version with the same four subscales as the 29-item MISS which has satisfactory internal reliability. The correlations between subscales suggest that they represent fairly discrete but overlapping aspect of satisfaction. Evidence produced suggesting that patients have less difficulty completing the MISS-21. It is a valid and reliable instrument for the assessment of patient satisfaction with individual consultation.

The MISS-21 questionnaire also being used in cross sectional study in Nigeria (14) to measure patient satisfaction. Other studies that assessed patient satisfaction in out-patient clinic were a study in Trinidad and Tobago(36) and in Netherland(37). A modified version of MISS-21 adapted to Nigerian population consists of statements to which patients indicate their level of agreement on a five-point Likert scale of responses. The original MISS-21 was pretested and the items were reduced from seven to a five-point scale (14)

SKIP-11 is the validated Malay version questionnaire originated from Medical Interview Satisfaction Scale (MISS). It can be used to assess patient satisfaction on patient-physician interaction in primary health care setting because it is acceptably valid, reliable and simple(17)

## 2.4 Framingham Coronary Heart Disease Risk Prediction Score (FRS)

The Framingham Risk Assessment tools have been used extensively with men and women and with a number of ethnic groups. They are considered the "gold standard" for risk assessment (38). Risk factors used in Framingham scoring include age, total cholesterol, high density lipoprotein cholesterol, blood pressure and cigarette smoking and divides persons with multiple risk factors into those with 10-year risk for CHD of >20%, 10-20%, and <10% (39). Cardiovascular risk equations are traditionally derived from the Framingham Study (1948). Risk scores have different accuracy in different populations, tending to over predict in low-risk populations and under predict in high-risk populations. Risk scores using the Framingham equations have been widely tested in North American and European populations of European origin (40-43) and validated in a Chinese population (44) but not in other populations.

Framingham risk equation systematically overestimated risk in the Chinese cohorts by an average of 276% among men and 102% among women. The corresponding average overestimation using the Asian cohort equation was 11% and 10%, respectively. Recalibrating the Framingham risk equation using cardiovascular disease incidence from the non-Chinese Asian cohorts led to an overestimation of risk by an average of 4% in women and underestimation of risk by an average of 2% in men (7). Despite these quantitative differences in the HRs for the associations between certain risk factors (total cholesterol and SBP) the risk equations from the Framingham and the Asian cohorts ranked individual risk similarly, resulting in comparable, good cardiovascular risk discrimination. This indicates that, qualitatively, the major determinants of cardiovascular risk are broadly similar, and act similarly, across populations that such differences may not be of major practical importance in risk prediction (7).

One study to find the accuracy and utility of the FRS was done in University of Malaya (18) using retrospective cohort of 600 patients attending the Family Clinic from year of 1997 and the event of CHD were captured up to 10 years from the baseline year. The FRS was calculated and they were divided into 3 CHD risk groups ie low (<10%) medium (10-20%) and high (>20%). The number of observed CHD events over a 10-year period was 7%, 15% and 19% for the low, medium and high risk group respectively. This showed that FRS accurately estimate 10-year risk of CHD in low and moderately high risk patient and marginally lower for the high risk group. The study in Kuala Langat(20) also used this FRS as their tool.

In year 2010, the data from semirural area in Kuala Langat was used to see the accuracy of FRS and new FRS (2008)(9) and the comparison was made. The FRS (2008) was found to overestimate patient in this community. The distribution of the different risk categories changed from 14.9% to 11.8% for low, 48.5% to 24.5% for medium and 36.6% to 63.7% for high risk based on the CHD and CVD scores respectively (19).

| Risk Category | LDL-C Goal | Initiate TLC | Consider Drug Therapy** |
|---|---|---|---|
| *High risk:* CHD* or CHD risk equivalents† (10-year risk >20%) | <100 mg/dL (optional goal: <70 mg/dL)‖ | ≥100 mg/dL# | ≥100 mg/dL†† (<100 mg/dL: consider drug options)** |
| *Moderately high risk:* 2+ risk factors‡ (10-year risk 10% to 20%)§§ | <130 mg/dL¶ | ≥130 mg/dL# | ≥130 mg/dL (100–129 mg/dL; consider drug options)‡‡ |
| *Moderate risk:* 2+ risk factors‡ (10-year risk <10%)§§ | <130 mg/dL | ≥130 mg/dL | ≥160 mg/dL |
| *Lower risk:* 0–1 risk factor§ | <160 mg/dL | ≥160 mg/dL | ≥190 mg/dL (160–189 mg/dL: LDL-lowering drug optional) |

*CHD includes history of myocardial infarction, unstable angina, stable angina, coronary artery procedures (angioplasty or bypass surgery), or evidence of clinically significant myocardial ischemia.

†CHD risk equivalents include clinical manifestations of noncoronary forms of atherosclerotic disease (peripheral arterial disease, abdominal aortic aneurysm, and carotid artery disease [transient ischemic attacks or stroke of carotid origin or >50% obstruction of a carotid artery]), diabetes, and 2+ risk factors with 10-year risk for hard CHD >20%.

‡Risk factors include cigarette smoking, hypertension (BP ≥140/90 mm Hg or on antihypertensive medication), low HDL cholesterol (<40 mg/dL), family history of premature CHD (CHD in male first-degree relative <55 years of age; CHD in female first-degree relative <65 years of age), and age (men ≥45 years; women ≥55 years).

§§Electronic 10-year risk calculators are available at www.nhlbi.nih.gov/guidelines/cholesterol.

§Almost all people with zero or 1 risk factor have a 10-year risk <10%, and 10-year risk assessment in people with zero or 1 risk factor is thus not necessary.

‖Very high risk favors the optional LDL-C goal of <70 mg/dL, and in patients with high triglycerides, non-HDL-C <100 mg/dL.

¶Optional LDL-C goal <100 mg/dL.

#Any person at high risk or moderately high risk who has lifestyle-related risk factors (eg, obesity, physical inactivity, elevated triglyceride, low HDL-C, or metabolic syndrome) is a candidate for therapeutic lifestyle changes to modify these risk factors regardless of LDL-C level.

**When LDL-lowering drug therapy is employed, it is advised that intensity of therapy be sufficient to achieve at least a 30% to 40% reduction in LDL-C levels.

††If baseline LDL-C is <100 mg/dL, institution of an LDL-lowering drug is a therapeutic option on the basis of available clinical trial results. If a high-risk person has high triglycerides or low HDL-C, combining a fibrate or nicotinic acid with an LDL-lowering drug can be considered.

‡‡For moderately high-risk persons, when LDL-C level is 100 to 129 mg/dL, at baseline or on lifestyle therapy, initiation of an LDL-lowering drug to achieve an LDL-C level <100 mg/dL is a therapeutic option on the basis of available clinical trial results.

Table 1.0 ATP III LDL-C Goals and Cut points for TLC and Drug Therapy in Different Risk Categories and Proposed Modifications Based on Recent Clinical Trial Evidence(4)

ATP III guideline identified diabetes as a high-risk condition. This designation was based on evidence that the majority of patients with 'diabetes' in 'higher-risk populations' have a relatively high 10-year risk for developing CVD. In addition to that, the onset of CVD in patients with diabetes carries a poor prognosis, both at the time of an acute CVD event and in the post-event period(4).

The conclusion made by ATP III committee to label 'diabetes' as a high risk because most patients with type 2 diabetes, are older and have multiple risk factors. Epidemiological studies and clinical trials demonstrate that in 'higher-risk populations' these patients have a risk for

CVD events approximately equal to that of non-diabetic patients with established CVD. Heart Protection Study data found both a high risk in this group and benefit from LDL-lowering therapy, supporting the LDL-C goal of <100mg/dl(4).

On the other hand, in those diabetic patients without CVD who had an LDL-C at baseline of <116 mg/dl, risk reduction accompanying statin therapy was only marginally significant for first coronary event. Thus, whether to start an LDL-lowering drug when LDL-C is <100 mg/dL in this category of patient must be left to clinical judgment(4).

Besides that, a portion of patients with diabetes can be considered to be at only moderately high risk because of young age or lack of other risk factors. Such patients were not studied in Heart Protection Study. For the category of moderately high risk (10-year risks 10% to 20%), ATP III guidelines favored institution of LDL-lowering drugs along with dietary therapy when LDL-C levels are >130 mg/dl. Thus, if a patient with diabetes is considered to be at lower risk, an LDL-lowering drug might not be started if the LDL-C level is < 130 mg/dl. Maximal TLC clearly is indicated but clinical judgment must be exercised with regard to when to initiate an LDL-lowering drug(4).

Although, 'ATP III' had suggested 'diabetic' as a 'high risk 'patient or 'CVD equivalent', but we must correlate it with our clinical judgment. Hence, not all patients with diabetic may need to be started on aspirin or high intensity statin. According to Diabetes Malaysian guideline, newly diagnosed patient needs to be screened with FRS or SCORE to estimate the risk for CHD because diabetes increased risk 2-3 fold from normal population to developed CVD. Treatment

with statin should be started in diabetic patient more than 40 years old regardless of their baseline lipid and aspirin is not recommended as a primary prevention in all diabetic patients without CVD unless low dose aspirin for patient above 65 years old(45).

A few studies had being conduct following the labeling of diabetes as CHD risk equivalent to see the accuracy of the hypothesis in their population. As an example, a study regarding the influence of single and multiple risk factors on the 10-year cumulative incidence of fatal and nonfatal CHD and cardiovascular disease (CVD) in diabetic and non-diabetic men and women, with and without baseline CHD or CVD, in a population (n= 4,549) with a high prevalence of diabetes was done. The conclusion in this study after comparable was made from previous study showed that wide variation in the rate of CHD in diabetes, depending on the population and existing risk factors. The cumulative incidence in individuals had been variable and some of them had risk >20%, but only those with multiple risk factors had a 10-year cumulative incidence that was equivalent to that of patients with CHD. The author in this study suggested that until more data are available, it may be prudent to consider targets based on the entire risk factor profile rather than just the presence of diabetes alone(46).

This study was further supported by a meta-analysis done in year 2009. This meta-analysis did not support the hypothesis that diabetes is a ‘coronary heart disease equivalent’. Patients with diabetes without prior myocardial infarction have a 43% lower risk of developing total CHD events compared with patients without diabetes with previous myocardial infarction (11)

In Malaysia, a study on CVD risk of a semirural community over the age of 55 years old (mean age of 65) in Kuala Langat using FRS score found a total of 40.5% of men had 10-20% risk of having a CHD event in the next 10 years whereas women with 10-20% risk is 51.4%. The percentage of moderately-high CHD risk in both sexes is almost equally distributed. However, 55.8% of the men had >20% risk of having a CHD event in the next 10 years compared to women's with only 15.1% having a risk of ≥20%. Demographics data of both women and men in this study were almost similar except for the men who smoke is 54.2% whereas women who smoke are only 11%. Smoking may contribute to the discrepancy between men and women in the high risk categorized(20). This study showed that the distribution of moderately-high risk CHD patient in our country is equally important with the high risk CHD patient for probability of developing CHD in next 10 year. An attempt to address the important of this group in CVD prevention is needed.

This also supported by study done among low-income urban dwellers of metropolitan in Malaysia where the prevalence of moderately-high (7-20%) risk patients were almost equal both in men (43%) and women (34%) with the mean age of 44 years old. However, in the high risk group, the prevalence was more in men (35%) as compared to women (11.6%) (47). Although, they took diabetes, hypertension and smoking as one of the demographic data in their method, but they did not presented it in their result. In addition to this, they also compared FRS score with FRS (2008) modified version using BMI as replacement for TC/HDL model. Both score did not have significant different. However, need to take note that their cutoff score between low and moderate is 7% and not 10%.

The low income community in metropolitan (Kuala Lumpur)(47) also similar with community in semirural area in Kuala Langat(20) whereby men and women in the moderately-high CHD had similar demographic profile to develop CHD in next ten years. Thus, this supported our justification to do prevention of cardiovascular disease counseling in moderately-high CHD risk patient in our clinic.

Recent study (48) regarding cardiovascular risk in KRK also supported the finding of above study whereby the prevalence of patient attending KRK was 32.7% belonged to moderately high risk, another 36.2% belonged to high risk patient and 31.1% belonged to low risk according to FRS and their mean age was 55 years old, the percentage of patients with diabetes were 31.6% and smoker 7.7%(48). This showed that there was equal distribution between high risk, moderately-high and low risk in KRK, Kelantan(48) where majority of the patient were non-smokers. This was also similar with population in Kuala Langat where the total risk score (men and women) was low risk 18.6%, moderately-high risk 46% and high risk 35.4%(20). The total risk score for (men and women) in low income metropolitan of Kuala Lumpur were 38.8% of low risk, moderately-high risk was 38.5% and high risk was 23.3%(47).

According to the Third National Health and Morbidity Survey in 2006, only 19.7% were aware of their hypercholesterolemia state and from these, only 44.1% were on treatment. However, only 69% were controlled. Awareness among the hypertensive patients have changed very little over the years i.e. 33%, 35.8% in 1996, 2006 respectively. However, only 23% of those who were aware received treatment in 1996 but it has increased to 87.7% in 2006 (49, 50).

The NHMS III survey had almost similar with population study in Kuala Langat. The mean systolic BP is in the stage I hypertensive range. More than half of the participants were hypertensive, of whom only 18.8% were reported and the remaining 33.5% were undiagnosed. This was again similar with hypercholesterolemia, where more than half have total serum cholesterol of greater than the desired upper limit of 5.2mmol/l. Nearly two thirds of the subjects have LDL-cholesterol levels ≥3.4mmol/l and about a third have low HDL-cholesterol. They remain unaware of their status(20).

In patients with a systolic blood pressure above 150 mmHg, or a diastolic pressure above 90 mmHg, or a blood cholesterol level over 5.0mmol/l, drug treatment reduces the relative risk of cardiovascular events by between one-quarter and one-third. If blood pressure was reduced by 10–15 mmHg (systolic) and 5–8 mmHg (diastolic) and blood cholesterol by about 20% through combined treatment with antihypertensive and statins, then cardiovascular disease morbidity and mortality would be reduced by up to 50% (3). Even modest reductions, such as few mmHg that might be expected from reducing salt intake, if applied across the population could result in reductions of at least a tenth in cardiovascular disease (51). People at higher CVD risk would benefit more, in terms of number of events avoided, because the relative risk reduction would be applied to a higher baseline risk (51).

Therefore, targeting patients with a high risk is the first priority in a risk stratification approach. However, risk stratification charts are unnecessary to arrive at treatment decisions for these

categories of patients because they require both lifestyle and pharmacological interventions to help them reduce their risk and number of cardiac event(3)

Thus, risk stratification is important for asymptomatic patient with moderate and moderately-high risk CHD patient to enable the intensity of interventions to be matched to the degree of total risk(3). For the individual with 0 to 1 risk factor, assessment of 10-year risk using FRS is unnecessary since this individual usually fall into < 10 % CHD risk score(4). Although, cardiovascular events are less likely to occur in people with low levels of risk(3) but CHD events still can occur in asymptomatic people with moderate and moderately-high CHD risk group. It is relatively easy to identify those who are obviously at high risk and those at the lowest risk for CVD, it is often the large group of individuals with what appears to be modestly abnormal risk factors who contributes most to the burden of CVD.(5). Thus 10-year risk stratification using traditional Framingham risk score can give prediction to the probability of this patient developed fatal and nonfatal coronary heart disease event in next 10 years(8). In other words, the great strength of the risk scoring approach is that it provides a rational means of making decisions about intervening in a targeted way, thereby making best use of resources available to reduce cardiovascular risk (3).

In the past, an approach focused on single risk factors, or concepts such as pre hypertension or pre diabetes have been popular. Such an approach, however, leads to a very large segment of the population being labeled as high risk, most of them incorrectly. If health care resources were allocated to such false-positive individuals, a large number of individuals with other multiple risk factor would remain without medical attention(3) example a man, age 45 who smoke, had low

HDL cholesterol of <1.1 mmol/l and TC of 5mmol/l with no hypertension (SBP of 122 mmHg) will be missed because this individual did not have hypertension. This patient had multiple risk factors (2 or more) and when calculated using FRS, his 10-year CHD risk are 12%. So it is important to use risk stratification to initiate treatment or guide the counselling in cardiovascular risk prevention.

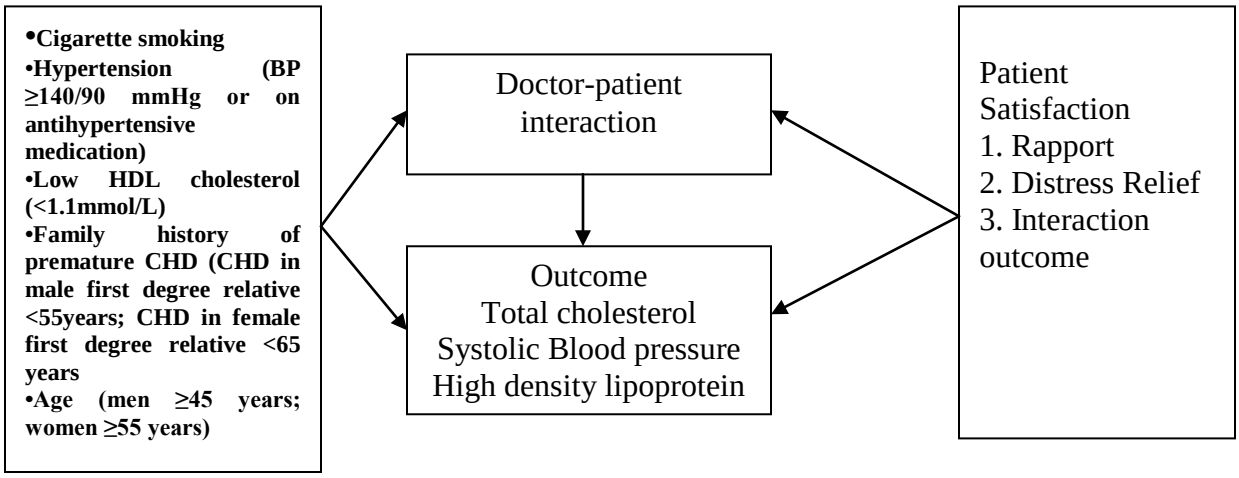


Figure1. Conceptual framework

# CHAPTER 3

# OBJECTIVES AND RESEARCH HYPOTHESES

## 3.1 General objective

To evaluate patient satisfaction, modifiable cardiovascular risk factors and their relationship after six months follow-up among moderately-high risk patients attending Klinik Rawatan Keluarga, USM Hospital.

## 3.2 Specific objectives

1. To determine patient satisfaction score on doctor-patient interaction after cardiovascular disease risk prevention counseling.
2. To determine changes in modifiable cardiovascular risk factors (TC, HDL, SBP) between baseline and 6 month follow up.
3. To determine the association between patient satisfaction score and changes in modifiable cardiovascular risk factors (TC,HDL, SBP) among moderately-high risk patients attending Klinik Rawatan Keluarga, HUSM.

## 3.3 Research hypotheses

1. There are significant changes in modifiable cardiovascular risk factors (TC, HDL, SBP) after six months follow-up.
2. There are significant association between patient satisfaction score and changes in modifiable cardiovascular risk factors (TC, HDL, SBP) after adjusting for socio-