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# Perceived versus Actual Risk of Coronary Heart Disease in Women

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Patience R. McCoy

#### DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Nursing

in die

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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Ву

Patience R. McCoy

To my husband Matt, for all your support, encouragement and endurance.

To my two beautiful daughters, Callie Ann and Sara Renee, for always brightening my day with your smiles.

I can do all things through Christ which strengthens me Philippians 4:13

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#### **Abstract**

Coronary Heart disease (CHD) is the leading cause of death in women. CHD claims more lives than the next six causes of death combined with more than one-half million women dying of CHD each year (AHA, 2006). The gap between women's perceived knowledge of CHD risk and their actual risk may contribute to these alarming statistics. The aims of this descriptive, cross-sectional study is to explore the perceived versus actual risk of CHD in women and to assess the relationship between knowledge of CHD in women and understanding of perceived risk. A sample of 106 subjects was evaluated with a self report questionnaire to determine knowledge and perception of CHD in women and their personal risk. All subjects underwent a lipid profile and blood pressure check to calculate their actual CHD 10 year risk using the Framingham Risk Score (FRS). The sample of women was on average 53 years old; 68% were Caucasian; were well educated (69% being college educated or more) and report an annual household income of \$75,000 to \$100,000. Important new findings of this study are the comparison between the women's perception of their CHD risk versus estimated 10 year risk of CHD. More than half of the women (55%) accurately perceived their risk; 7 % underestimated and 38% overestimated their risk. In addition, greater knowledge was significantly correlated with a more accurate perceived risk score (r=0.23; p $\leq$  0.05). This study is unique in that it describes women's perceived versus actual risk of CHD, after the national study by Mosca (2006 & 2004) identified the inadequate knowledge and awareness of women regarding heart disease risk. This study shows that knowledge, awareness and perception of CHD in women continue to progressively improve. This study also shows that opportunities for patient-health care provider discussions could be

increased. Continued education and awareness for women about heart disease being the leading cause of death, risk factors for CHD and atypical heart attack symptoms is essential at the national level as well as in the clinical setting.

Approved by Dissertation Chair:

Erika S. Proelicher, RN, MA, MPH, PhD

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Chapter 1

Introduction

## Significance of the problem

Coronary Heart disease (CHD) is the leading cause of death in women. According to the American Heart Association (AHA) (2006), CHD claims more lives than the next six causes of death combined with more than one-half million women dying of CHD each year. The gap between women's perceived knowledge of CHD risk and their actual risk may contribute to the following alarming statistics. Reseach findings suggest that even though 34% of women identified CHD as a leading cause of death, only 8% perceived CHD as their greatest health risk (Mosca, 2004). Also, women indicate that they are not well informed about heart disease and can not identify risk factors associated with CHD. Although 90% of women report that they would like to discuss heart disease or risk reduction with their physician, more than 70% report that they had not (Mosca, 2006). Improving knowledge and changing perception of heart disease risk in women is the first step to prevention. Primary prevention efforts are paramount in women who are at risk for an acute myocardial infarction to decrease the devastating

#### Purpose and aims of the study

effects an AMI has on a women's life.

The purpose of this study is to compare women's perceived and actual risk of CHD as well as report women's knowledge of CHD risk factors. Research questions of this study are to: (1) describe the knowledge of women about CHD risk factors and heart attack symptoms; (2) describe the self- reported presence of CHD risk factors in women; (3) describe the proportion of women who received counsel about CHD by their Health Care Providers (HCP); (4) describe the women's perception of CHD prevention strategies; and (5) compare perceived versus actual coronary heart disease risk of women.

## Chapter Review

Chapter 2 describes the literature regarding CHD risk in women and discusses two tools that can easily be used in the practice setting to identify those women that are at risk for CHD. Chapter 3 describes two theories relevant to women and heart disease: the Health Belief Model and the Physiological Theory. Chapter 4 reviews testing strategies for the early identification of women in need of primary prevention of CHD. Chapter 5 describes the methods used in this cross sectional study. Chapter 6 presents the results of this study. Chapter 7 presents a discussion and implications for practice and further research.

Chapter 2 "Coronary Heart Disease Risk in Women" is under review in the Journal of Cardiovascular Nursing and Chapter 4 "Testing Strategies for Women for Primary Prevention of Coronary Heart Disease" has been accepted by the American Journal of Nurse Practitioners.

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- Mosca, L., Mochari, H., Christian, A., Berra, K., Taubert, K., Mills, T., Burdick, K.A., Simpson, S.L. (2006). National Study of Women's Awareness, Preventive Action, and Barriers to Cardiovascular Health. *Circulation*, 113, 525-534.

# Chapter 2

Coronary Heart Disease Risk in Women: An Underappreciated Threat Coronary heart disease (CHD) is the leading cause of death in women and claims more lives than the next six causes of death combined (American Heart Association, 2007). More than one-half million women die of CHD each year and most (325,000) CHD deaths occur out of the hospital or in the emergency department (National Center for Health Statistics, 2003). About two thirds of unexpected cardiac deaths occur without prior diagnosis of CHD, a number that has not changed over the past decade (Fox, 2005; Theisen, 1995). In addition, women have a three-fold greater chance of developing a CHD event (24-32%) than breast cancer (7-12.5%) during their lifetime (Kannel, 2002).

Women are at risk for CHD and their risk is underappreciated (ref). Nurses and other health care providers (HCP) need to understand that prevention for women is as critical as it is for men, even though women tend to develop CHD on average ten years later than men. The publication of AHA (2007) evidence-based guidelines for CHD prevention for women establishes, for the first time, the importance of gender specific guidelines for screening, prevention, and treatment. The development and dissemination of these recommendations further emphasizes the need for nurses to be able to accurately understand the significance of the problem of CHD in women as well as be able to use screening tools to identify risk. It is also crucial to identify where a woman's risk falls in the categories of low, medium or high risk (Table 1). This gives nurses and HCP direction for aggressive preventation or treatment action.

The purpose of this paper is to present evidence about the barriers and benefits of risk assessment for CHD in women; describe risk factors of CHD in women and risk

factor stratification using the Framingham Risk Score (FRS) and the Reynold's Risk score; and provide nurses and other health care professionals (HCP) with information and examples of how to use these tools to assess risk in women to identify those who would benefit from risk reduction.

Table 1: Reductions in the Risk of Coronary Heart Disease in Women

INTERVENTION	ESTIMATED MEAN REDUCTION IN
	RISK OF CHD
Smoking cessation	50 to 80% within 3 to 5 years
Reduction in serum cholesterol level	Women 2 to 3% for every 1% reduction serum cholesterol
Treatment of hypertension	16% after 3 to 6 years of treatment
Treatment of isolated systolic hypertension	25%
Maintenance of normoglycemia in diabetic patients	Insufficient data to provide estimates for women or men
Avoidance of obesity	35 to 60% for women at ideal weight, as compared with obese women
Small-to-moderate daily alcohol intake	Approximately 50% for women and men, as compared with nondrinkers
Antioxidant-vitamin supplementation	Insufficient data
Postmenopausal hormone-replacement	44% with estrogen alone
Physical activity	50 to 60% for physically active women, as compared with sedentary women
Prophylactic low-dose aspirin	Inconsistent data on women

Rich-Edwards, J. W., Manson, J.E., Hennekens, C.H., Buring, J.E. (1995). The Primary Prevention of Coronary Heart Disease in Women. The New England Journal of Medicine, 332, 1760-1766. (permission received)

#### Barriers to Prevention of CHD in Women

Given the scientific evidence, one might ask why CHD in women is not identified and treated more rigorously. The disparity in morbidity and mortality in women, in part, may be secondary to a lack of awareness among women and their health care providers regarding a woman's risk for CHD. A woman's risk for CHD should be assessed as part of their routine evaluations, yet most women receive their health care primarily from an obstetrician/gynecologist (OB/GYN) and traditional medical training focuses on body systems. In the National Ambulatory Medical Care Survey (2002), there was an increase of 20,000 women during an eight year period that were mainly seeing an OB/GYN instead of a primary care physician (CDC, 2006).

Barnhart (2007) surveyed internists and OB/GYNs to determine whether physicians' knowledge, attitudes, or practice patterns contribute to gender disparities in the primary prevention of CHD and to identify barriers to the assessment, identification, and treatment of coronary risk factors in women. Lack of time was the most frequently cited barrier to implementing CHD risk factor prevention. Other barriers include lack of understanding of the benefits of prevention, deficiency in behavioral intervention skills to assist in lifestyle modification counselling, lack of knowledge about existing guidelines for intervention, inadequate financial returns for the time spent, the perception that the patient does not need or want the intervention, the sense that the intervention will not substantially affect risk, and discomfort with primary prevention as a part of their role (Liebson, 1999).

There are major gaps in physicians' knowledge and the American Heart

Association CHD prevention guideline implementation, as well as differences in the

perception of CHD risk between women and men. In one study, 500 physicians (300 primary-care physicians, 100 cardiologists and 100 OB/GYNs) were presented with a questionnaire relating to a set of case studies that described CHD risk in women and men. Findings showed physicians were significantly more likely to assign a lower CHD status to women than men and less likely to suggest preventive measures for women. Lack of knowledge of women's CHD risk was cited as the main finding. In fact, 92% of primary-care physicians, 87% of OB/GYNs and 83% of cardiologists were not aware that more women than men died annually of CHD (Mosca, 2005). Thus, major opportunities for improvement exist.

Wenger (2006), in a review of CHD prevention studies from 2003-2005, concluded that overall, under use of guideline-based preventive and therapeutic strategies for women probably contributed to their less favorable CHD outcomes. Under use of available preventative services was also seen in the Women's Initiative for Nonsmoking study which found that more than half of the women had one or more risk factors for CHD; however these women were not referred for further evaluation and only a small minority of women took part in available preventative services (Froelicher, 2004). Execution of recommendations by HCP is needed to reduce CHD risk in women.

#### Benefits of Prevention of CHD in Women

Primary prevention is warranted in all patients that are at risk for CHD. The level of primary prevention, including lifestyle and medical interventions, needs to be initiated based on risk assessment. Early screening and primary prevention of women who have risk factors is imperative as women are at higher risk than is appreciated. Greenland (1995), in a national survey, found that 64.3% of women surveyed had at least one CHD risk factor. A multifactorial approach to primary prevention and risk factor reduction

needs to become the national standard to reduce the prevalence of CHD in women (AHA/ACC). Basic screening tests for CHD are also recommended by the U.S. Preventive Services Task Force (USPSTF) as follows: Blood pressure screening in adults aged ≥18 years and routine screening of women aged ≥45 years for lipid disorders. The American Diabetes Association (2008) also recommends screening high-risk people for Type II diabetes every three years after the age of 45.

Primary prevention has been shown to reduce costs and improve quality of life. Lightwood and Glantz (1997) estimated that over 98,000 hospitalizations could be prevented, and \$3 billion dollars could be saved in the U.S. over seven years with a 1% reduction in smoking. Krumholz et al. (2002) found that the cost per year of life saved with a nurse-based education program for smoking cessation was \$300. They also found a 20% reduction in mortality in a high-risk population when looking at lipid lowering therapy. Because diabetic patients are at a high risk for CHD, diagnosis and treatment of hypertension and elevated lipids in these patients is especially economically efficacious (Grover, 2000; Clark, 2001). The Diabetes Control and Complications Trial Research Group (DCCT) (1996) found that intensive therapy resulted in a cost-effectiveness ratio of \$34,000 per year of life gained. Also, because sedentary lifestyle further increases the risk of CHD by 1.9-fold in the U.S., \$6.4 billion would be saved if the sedentary population initiated and maintained a regular walking program (Krumholtz, 2002).

Risk factor reduction has many benefits in women (Table 2). Clearly, when women quit smoking, maintain ideal body weight though dietary changes, and increased physical activity, as well as the control hypertension and hyperlipidemia, a substantial reduction can be realized in the risk of CHD. Small daily amounts of alcohol and

postmenopausal hormone-replacement therapy provide benefit as well. Evidence of the benefits of antioxidant vitamins and aspirin in this study remain inconclusive and require further study (Rich-Edwards, 1995).

Table 2. Coronary Heart Disease Risk in Women

Risk Group	Framingham Global Risk (10-y Absolute CHD Risk)	Clinical Examples
High risk	>20%	• Established CHD • Cerebrovascular disease* • Diabetes mellitus
Intermediate risk	10% to 20%	• Subclinical CHD <sup>‡</sup> (eg, coronary calcification) • Multiple risk factors • Markedly elevated levels of a single risk factor • First-degree relative(s) with early-onset (age: <55 y in men and <65 y in women) CHD
Lower risk Optimal risk	<10% <10%	<ul> <li>May include women with 1 or no risk factors</li> <li>Optimal levels of risk factors and heart-healthy lifestyle</li> </ul>

CHD indicates coronary heart disease

‡Some patients with subclinical CHD will have >20% 10-year CHD risk and should be elevated to the high-risk category.

Mosca, L., Appel, L. J., Benjamin, E. J., Berra, K., Chandra-Strobos, N., Fabunmi, R. P., et al. (2004). Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women. *Circulation*, 109, 672-693. (permission received)

#### Cardiovascular Risk Factors in Women

Coronary Heart Disease is a multifactorial disease that involves several risk factors that predispose and contribute to the development of CHD. Two thirds of women in the United States have at least one risk factor for CHD (National Center for Health

<sup>\*</sup> Carotid artery disease (symptomatic or asymptomatic with >50% stenosis) confers high risk.

Statistics, 2006). There is a four-fold increased risk of CHD mortality rates with at least one major risk factor in women age 40-59 (Stamler, 1999); this statistic is substantial justification that there exists an urgent need that justifies basic risk factor screening, especially in women. Each of the risk factors that have been identified and incorporated in the Framingham Risk Score (FRS) and the Reynold's Risk Assessment as elevating risk will be presented next, placing special emphasis on magnitude of risk for women. *Hypertension* 

CHD risk doubles starting at a blood pressure (BP) of 115/75 mm Hg for each increment of 20/10 mm Hg (Chobanian, 2003) making it imperative to monitor the BP at each office visit in patients with elevations in BP. In those older than age 50, systolic blood pressure (BP) > 140 mm Hg is a more important CHD risk factor than diastolic BP (JNC 7, 2004). Thus 30 years of research findings have documented considerable efficacy and benefit in terms of outcomes for adequately controlled blood pressure. *Hyperlipidemia* 

A very strong association exists between low density lipoprotein cholesterol (LDL-c) level and CHD. For moderately high-risk persons (2 or more risk factors or a 10-year risk 10% to 20%), the recommended LDL-C goal is <130 mg/dL, but an LDL-C goal <100 mg/dL is a therapeutic goal (ATP III, 2002). The association between LDL-C levels and CHD risk is curvilinear, thus risk rises more steeply with increasing LDL-C concentrations (Grundy, 2004). Studies show that for every 1% reduction in LDL-C levels, relative risk for major CHD events is reduced by approximately 1% (Shepherd, 2002; Sever, 2002; Ballantyne, 2003). In addition, an HDL-c of at least 50mg/dl is recommended for women (ATP III, 2002). An HDL-c of 50 mg/dL and above is

considered protective against CHD (AHA, 2008). There is an inverse relationship between CHD risk and HDL-c, meaning if the HDL-c level is low, the risk for CHD is higher and vice versa (Miller, 2003). Studies have also shown that a 22 to 24% CHD event reduction can be achieved by raising the HDL-c by an average of 5% to 10% (Alsheikh-Ali, 2007; Miller, 2003).

#### **Smoking**

Women who smoke double their risk for developing CHD and 21.5 million women smoke in the United States (American Lung Association, 2004). Although the proportion of women who smoke is lower than that for men, smoking in younger women is on the increase, thus the difference between men and women has continued to narrow. Smoking acts synergistically with other risk factors that substantially increase the risk of CHD. Cigarette smoking is the single most modifiable risk factor contributing to premature morbidity and mortality in the U.S. (American Lung Association, 2004). However, smoking cessation yields immediate and long term health benefits. The risk for CHD among women is substantially reduced within 1 or 2 years of smoking cessation with continued benefit thereafter (Fiori, 2008; Surgeon General's Executive Summary, 2001).

#### Diabetes Mellitus

More than 65% of men and women with diabetes mellitus die from CHD and its complications and approximately 8.9% of all women in the U.S. have diabetes mellitus (DM), however, about a third of them are unaware and undiagnosed for may years until DM becomes fully manifest and diagnosed (American Diabetes Association, 2002). Diabetes increases the CHD risk 3 to 7-fold in women versus 2 to 3-fold in men, putting

women at a much higher risk of developing CHD, even if diabetes is their only risk factor (American Heart Association, 2003). Interventions that include intensive lifestyle modification and/or medication therapy have been shown to produce a 58% reduction in risk after 3 years (American Diabetes Association, 2008).

High Sensitivity C-Reactive Protein (hsCRP)

High sensitivity CRP is a more recently identified biomarker found to be an independent predictor of cardiovascular risk (Cook, 2006). It measures acute inflammation more specific to coronary arterial walls, which differs from the basic CRP that measures inflammation anywhere in the body (AHA, 2008). Ranges for hsCRP are low risk: less than 1.0 mg/L; moderate risk: 1.0 to 3.0 mg/L; and high risk: above 3.0 mg/L (AHA, 2004). Most of the work has been done by Ridker and colleagues (2005, 2002, 2001). In their studies they have found that the hsCRP level is consistently associated with CHD risk. This is relevant because inflammation plays an important role in CHD events and the reduction of inflammation may reduce risk of plaque rupture (Ridker, 2005; Nissen, 2005; Ridker, 2002, Ridker, 2001). Cook (2006) found that in non-diabetic women age 45 or greater, among those with a 10-year risk of 5% to 20%, hsCRP improved prediction at least as much as lipid measures when used with a prediction model that included age, blood pressure and smoking status. This marker is part of the new Reynold's Risk prediction model.

#### Family history of CHD

Family history of premature CHD is a well established independent risk factor for CHD in asymptomatic adults (Nasir, 2004; Sesso, 2001; Myers, 1990; Colditz, 1986).

Michos (2005) studied 102 asymptomatic women who had a sibling with documented

CHD and found that among these women who were classified as low risk by FRS, a third had significant subclinical atherosclerosis based on a coronary calcium scan. Lloyd-Jones (2005) found that parental cardiovascular disease independently predicted future events in middle-aged offspring (n=2302). Mindfulness of the addition of family history may be useful for nurses and HCP to be aware of when counseling women in primary prevention of cardiovascular disease, especially when patients are at intermediate risk based on levels of single or multiple risk factors. However, the FRS in its current form does not include family history. Risk assessment based on the FRS may underestimate the true burden of atherosclerotic vascular disease in women with a family history of premature CHD. This may result in missed opportunities to use preventive therapies. Family history was added to the Reynold's Risk Assessment to address this issue (Ridker, 2005).

## Approaches to Risk Factor Screening and Stratification

The concept of risk factors constitutes a major advance for the prevention of CHD and the above mentioned risk factors can be assessed in a population using a number of tools. When a screening method is advocated, it should meet the following general criteria: (1) identify a treatable problem; (2) employ a well-studied and validated instrument; (3) identify substantially more cases then would otherwise have been diagnosed; and (4) result in better outcomes in the screened cohort compared to a cohort that was not screened. CHD screening meets all of these criteria at a very high level. Two risk assessment tools will be discussed: the well known Framingham Risk Score (FRS) and the more recent Reynold's Risk Assessment that was specifically developed to enhance risk assessment in women.

#### Framingham Risk Score

The FRS has been used for primary screening to predict the 10-year risk for CHD from a set of standard risk factors (D'Agostino, 2001; Dawber, 1966; Kannel, 1966). The major risk factors that have been studied extensively at Framingham are cigarette smoking, hypertension, high cholesterol and various cholesterol fractions (HDL, LDL, triglycerides), and diabetes mellitus. Age is also included as a risk factor in the Framingham charts because absolute CHD risk increases with age (Kannel, 1966). Approximately 85% of CHD risk for the entire U.S. population is explained by the sum of major risk factors (Grundy, 1998).

Investigators of the Framingham Heart Study developed CHD risk equations for use by HCP to predict the development of CHD (Kannel, 1987; Grundy, 1998). The FRS was developed to help nurses and HCP estimate actual risk of an individual patient developing clinically manifest CHD within 10 years and has been used as a screening tool to determine those that have multiple risk factors and need aggressive risk factor reduction as primary care prevention. It can also be used to motivate patients to modify their risk factors and initiate risk reduction behaviors to decrease their CHD risk (Murabito, 1995).

#### Framingham Risk and Women

The onset of CHD in women lags behind men by 10 years, often secondary to the onset of menopause. Even so, the data from the Framingham Heart Study has clearly documented that the major risk factors have a substantial impact on actual CHD risk in women. Encouragingly, the Framingham study is one of the few research studies that included a substantial number of women since its beginning in 1948. The study has

estimated gender specific CHD incidence for multiple risk factors. It also developed gender specific risk factor prediction charts that can determine a woman's probability of CHD year 10-risk (Murabito, 1995).

Traditional risk factors (cholesterol, diabetes, hypertension and smoking) were predictive in both men and women. The relationship between multiple risk factors in women was stronger than in men, meaning that a combination of risk factors had greater deleterious synergistic effect in women than men with respect to CHD events (Murabito, 1995). Furthermore, the rate of CHD increases three-fold in women from age 35-65 and only two fold in men in the same age range. When the risk factors are compared individually in men and women, there are some significant differences:

- Women who have diabetes have a four-fold increase of CHD events over men
- A low HDL cholesterol level is more predictive for CHD events in women than men
- A higher systolic blood pressure (SBP) in women over 55 correlates with CHD incidents rising with any subsequent rise in SBP in women
- For women with documented left ventricular hypertrophy (LVH) on ECG, their risk of having a CHD event is substantially higher than in men. Furthermore, when there are three or more risk factors present in women, there was a 56% occurrence of a CHD event in women compared to 30% in men (Kannel, 2002; Murabito, 1995).

How to Use the Framingham Risk Score (Example- Figure 1)

There are eight variables needed to calculate a FRS: age, gender, total cholesterol, HDL cholesterol, smoking status, systolic blood pressure, diabetes and if the

patient is on medication for high blood pressure. These data are easily entered into a free FRS calculator found at <a href="http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof">http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof</a> and can be downloaded into the nurses or HCP's palm pilot or computer software. It calculates the individual's 10 year risk of a myocardial infarction or CHD death. For example, in Figure 1, this woman would have a 5% greater chance of having a coronary event than a woman of her same age with no risk factors.

# Reynold's Risk Assessment

Health care professionals know what to recommend for people whose FRS indicates high or low risk. But it's less clear how to manage patients with intermediate risk, yet for women, up to 20 percent of all coronary events occur in the absence of the major risk factors in the FRS. Although the understanding of CHD has changed dramatically in the past half-century, the predictive models for women are largely unchanged from those recommended 40 years ago.

An advancement in this realm has been made with a new commercially avaliable tool called the Reynolds risk score (Ridker, 2007). Reynold's et al. (2007) conducted a study to assessed 35 risk factors in 24,558 healthy women who were free of CHD and cancer. This study followed women 45 years or older from the Women's Health Study for 10.2 years (median) for the identification of new incidents of CHD, such as MI, ischemic stroke, coronary revascularization, and CHD deaths. The researchers used data from a randomly selected two-thirds of the sample of women (n = 16,400) to develop new algorithms to test the observed verses predicted outcomes in the remaining one-third of women (n = 8,158).

The Reynolds Risk Score includes age, total cholesterol, HDL cholesterol, smoking status, systolic blood pressure, with the addition of hsCRP and family history of MI before age 60. It is of note that a relationship among these chosen risk factors in women was stronger than in men, meaning that they have a greater synergistic effect in women for a CHD event (Murabito, 1995). The RRS was developed from the FRS for women who do not have diabetes. The RRS predictes for women at high and low risk as well as the Framingham risk score. For those in the intermediate risks range, the Reynolds risk prediction equation performs better than the FRS. The importance of this advancement is that the RRS reclassifies almost half of these women in the intermediate risk category into high-risk and low-risk groups. The new assignment to predicted level of risk corresponded almost perfectly to their actual subsequent 10-years (Ridker, 2007).

## How to Use the Reynold's Risk Score (Example- Figure 2)

Seven pieces of data are needed to calculate a Reynolds Risk score: age, total cholesterol, HDL cholesterol, smoking status, systolic blood pressure, with the addition of hsCRP and family history. These data are easily entered into the free Reynolds Risk calculator found at <a href="http://www.reynoldsriskscore.org/">http://www.reynoldsriskscore.org/</a>. It will calculate the patient's 10 year CHD risk. The Reynolds Risk Score is not suitable for women with diabetes, as they are already considered at high-risk group for CHD. For example, in Figure 2, this woman would have an 8% greater chance of having an event than a woman of her same age with no risk factors. The Reynold's final risk score analysis provides the user data on how risk would change if the risk factors were optimal.

## Gaps in Screening Tools for Risk Assessment

While the FRS and the RRS score have been tested in large samples of women, there are still other important risk factors that contribute to CHD risk that are not included in either of these tools and need to be considered as part of a thorough risk assessment. These factors are post-menopausal status, physical inactivity, and obesity. *Post-menopausal status* 

Women have the same risk factors as men until menopause and then their risk of a CHD event more than doubles and it has been demonstrated that post menopausal status is an independent risk factor for CHD (Lokkegaard, 2006; Kannel, 1966). This becomes a concern because menopause is a natural developmental stage in a women's life and is not a modifiable risk factor. Several studies have evaluated using post-menopausal hormone therapy to decrease CHD risk which include the Women's Health Inititive (WHI, 1991 start date), Heart and Progesterone Replacement Study (HERS I, 1998 start date & HERS II, 2002), Women's Ischemia Study Evaluation (WISE, 2001 start date). The most recognized studies in this area are the HERS I and II (n = 2763) and the WHI (n = 16608). Neither study showed an overall significant reduction in CHD risk by using hormone replacement therapy (Grady, 1998; Rossouw, 2002). Even though there was a reduction seen between 3 and 5 years, hormone replacement therapy was not shown to have beneficial long- term benefits; and was even shown to be harmful within the first 3 years of use (Grady, 2002).

#### Physical inactivity

Physical inactivity has multiple adverse effects on health in general. Conversely, regular physical activity has many benefits that extend to CHD prevention. It is an

important risk factor to evaluate because it is modifiable and has become a central aspect of risk reduction interventions. At least 75% of Americans have less than the recommended level of activity (30 minutes of moderate physical activity, equivalent to a brisk walk) on most or all days of the week (Department of Health and Human Services, 1996). There was a strong inverse association between physical activity and the risk of coronary events (Li, 2006; Manson, 2002; Manson, 1999). A moderate walking program is associated with a 30% reduction in CHD risk in women (Myers, 2005; Manson, 1999). Conversely, prolonged inactivity predicts increased cardiovascular risk (Manson, 2002; Manson, 1999).

Obesity

Being overweight or obese affects heart structure and function, and it is recognized as an independent risk factor for CHD that requires treatment (Poirier, 1997; Dagenais, 2004). Obesity is also associated with an increased risk of morbidity and mortality because of its synergistic effects with other risk factors (hyperlipidemia, hypertension, diabetes, and a prothrombotic state) (Poirier, 2006). Even a modest weight gain (4 to 10 kg) during adulthood in women is associated with 27% increased risk of CHD compared with women with a stable weight (Li, 2006). It can, however, be addressed by dietary modification, exercise and using behavioral interventions.

#### Summary

Women are at risk for CHD and their risk is underappreciated, so primary prevention is often delayed or inadequate. Health care providers need to understand that prevention in women is just as critical as it is for men. Early screening and primary

prevention in women at risk is imperative. Nurses and other HCP need to be more active in and aggressive toward identifying women who are at risk for CHD. The FRS and RRS are useful tools that are recommended, simple and can be completed by using free online software in a practice setting. By using the Framingham risk score or the Reynold's risk score, more women could be accurately risk stratified. Women who are identified as being at risk for CHD need to be offered counseling and begin aggressive risk factor modification for the primary prevention of CHD before they experience the devastating effects a CHD event can have on their life.

Figure 1. Framingham Risk Score Example

Risk Assessment Tool for Estimating 10-year Risk of Developing Hard CHD (Myocardial Infarction and Coronary Death)

50 year old female with a total cholesterol of 210 mg/dL, HDL cholesterol of 40 mg/dL, blood pressure of 140/82, and a smoker.

Age:	years years
Gender:	Female Male
Total Cholesterol:	mg/dL
HDL Cholesterol:	mg/dL
Smoker:	C No E Yes
Systolic Blood Pressure:	140 mm/Hg
Currently on any medication to treat high blood pressure.	<b>c</b> No <b>c</b> Yes
Calculate 10-Year Risk	
Risk score results:	
Risk score results: Age:	50
	50 female
Age:	
Age: Gender:	female
Age: Gender: Total Cholesterol:	female 210 mg/dL
Age: Gender: Total Cholesterol: HDL Cholesterol:	female 210 mg/dL 40 mg/dL

This means that the coronary risk for this woman is approximately 5 times that of a woman the same age with a low risk profile (defined as: same age, optimal blood pressure, total cholesterol 160-199 mg/dL, HDL cholesterol 55 mg/dL for women, non-smoker and no diabetes.

5%

.

Risk Score\*

<sup>\*\*</sup>Available online at <a href="http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof">http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof</a>

Figure 2. Reynold's Risk Score Example

Same 50 year old female with a total cholesterol of 210 mg/dL, HDL cholesterol of 40 mg/dL, blood pressure of 140/82, and a smoker.

Age	50	Years
Do you currently smoke?	E Yes	C No
Systolic Blood Pressure (SBP)	140	mm/Hg
<b>Total Cholesterol</b>	210	mg/DL
HDL or "Good" Cholesterol	40	mg/DL
High Sensitivity C-Reactive Protein (hsCRP)	5	mg/L
Did your Mother or Father have a heart attack before age 60 ?	E Yes	C No
	Calculate 10 y	ear ri <u>s</u> k

As shown in the graph below, at Age 50, your chance of having a heart attack, stroke, or other heart disease event at some point in the next 10-years is **8 percent.** This risk is approximately **8 times higher** than that of a woman the same age who has optimal levels of all modifiable risk factors.

Age	50
-----	----

Your 10-year risk (age 50)	8%
Your 10-year risk (age 50) if,	
□ you didn't smoke	4%
☐ your blood pressure were optimal	5%
☐ your cholesterol were optimal	3%
□ your hsCRP were optimal	5%
☐ all the above were optimal	1%

<sup>\*\*</sup> Avaliable online at <a href="http://www.reynoldsriskscore.org/">http://www.reynoldsriskscore.org/</a>

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# Chapter 3

Theoretical Framework for Women and Heart Disease: Physiological Theories and the Health Belief Model

# Theoretical Framework for Women and Heart Disease: Physiological Theories and the Health Belief Model

Coronary heart disease (CHD) is the leading cause of death in women (AHA, 2006). In approximately 60% of cases, the initial presentation of heart disease in women is AMI or sudden cardiac death (Bairey, 2006). Unfortunately, primary prevention for women is underutilized and could potentially decrease these devastating statistics. In addition to a lack of preventative screening, the gap between women's perceived knowledge of CHD risk and their actual risk may contribute to the alarming statistics. Even though 34% of women identify CHD as a leading cause of death, only 8% perceive CHD as their greatest health risk. This discrepancy is even more dramatic in younger women, age 25-34, where only 4% of women perceive CHD as their own greatest health risk. Most women (60-70%) perceived cancer as their greatest health risk (Mosca, 2004). Regardless of the fact that women tend to have manifestations of CHD later in life than cancer, the process of the disease has already started by the second decade of life (American Academy of Pediatrics, 1998). Women lack knowledge and educating them about CHD risk factors could result in substantial reduction in the risk of CHD (Rich-Edwards, 1995). Improving awareness and changing the perception of CHD symptoms and its risk in women is the first step to prevention.

In this paper, a two-fold theoretical basis for CHD prevention in women will be discussed. First, the physiological theory of atherosclerosis will be presented. Second, the Health Belief Model will be described. It was selected as the framework that can help explain why women do not perceive or personalize their CHD risk.

## Physiological Theory of Atherosclerosis

Atherosclerosis is a pathological process that evolves over many years and often its first manifestation is heart failure, sudden death, angina or acute myocardial infarction (AMI). In women specifically, the first clinical manifestation is usually AMI or sudden death (Merz, 2006). Also, CHD does not manifest itself clinically until 70% or more of one of the coronary arteries is occluded. It is for these reasons that primary prevention of CHD for women is necessary and crucial. Early identification of risk factors and preventative strategies must be initiated to avoid/minimize the development of CHD in women.

# Basic pathophysiology

Three main coronary arteries lie on the surface of the heart and supply the muscle of the heart with its entire blood supply. The left side of the heart is fed by the left anterior descending artery (LAD) which supplies mainly the anterior and lateral portions of the heart muscle along with the left circumflex artery (LCX) which supplies the lateral and posterior part of the left ventricle and the left atrium. The right side of the heart is fed by the right coronary artery (RCA), which supplies the right atrium, right ventricle and posterior part of the left ventricle by a branch called the posterior descending artery (PDA).

Coronary vessels have three layers, the intima, media and adventitia. Normal coronary blood flow in humans averages about 225 ml/min, or 4-5% of total cardiac output. During strenuous exercise or extremely stressful situations, cardiac output increases 4 to 7 times the normal and the coronaries attempt to increase the blood flow 6 to 9 times the normal. Thus, this increases the stress and workload on the heart. In normal

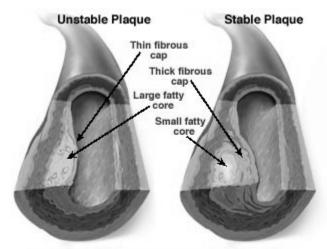
coronary arteries this increase is not significant because the heart compensates for the extra need, but in a diseased heart or in the presence of occluded coronaries, these excess demands can represent a problem. This leads to a supply/demand imbalance, which results ultimately to ischemia (Guyton & Hall, 2000).

Theories on atherosclerosis development

Lipid theory: This is the oldest and most well known theory of the development of atherosclerosis. Developed as a result of autopsy reports of persons dying of CHD, this theory postulated that through a complex process, lipoproteins are insinuated into the coronary arteries causing plaques, or blockages, of the arteries. Lipoproteins consist of triglycerides, very low density lipoproteins (VLDL), low density lipoproteins (LDL), high density lipoproteins (HDL) and intermediate density lipoproteins (IDL). The LDL and the HDL are primary lipids that are considered when evaluating for risk factors of CHD and play a role in plaque development (LDL) or protection (HDL) (Gotto, 2004).

The lipid theory proposes that higher levels of LDL (and possibly triglycerides) in the body results in accumulation of plaque in the arterial wall. LDL particles break down in the presence of endothelial cells, become more atherogenic and bind to the inner wall of the artery (Gotto, 2004). As the plaque forms and becomes larger, the endothelium becomes exposed to more blood, platelets aggregate and clots begins to form (Braunwald, 2001). The most vulnerable plaques are those that cause only a mild to moderate blockage, have a lipid-rich core and a thin cap (Gustein, 1999; Doering, 1999). Also, unstable plaques tend to have high lipid and macrophage content and contain less collagen, smooth muscle cells, and calcium than stable plaques (Braunwald, 2001; Davies, 1991; Kragel, 1989). (Figure 1) It is the rupture of these plaques that cause AMI.

Figure 1- Plaque



As plaque builds up, it can become either stable or unstable. Unstable plaque is more prone to sudden rupture, a potentially life-threatening event.

*Inflammatory response and endothelial dysfunction* 

The endothelium, an ultra-smooth lining of all blood vessels, provides a protective barrier for the artery from the blood being carried within it (Eagle, 2003). Its functions are to help maintain normal vasomotion, inhibit platelet aggregation and maintain the impermeability of the artery (Quyyami, 2006). Risk factors for CHD, including sedentary lifestyle, obesity, high cholesterol, high blood pressure, diabetes, smoking and aging are all associated with endothelial dysfunction (Quyyami, 2006; Bonetti, 2003; Widlansky, 2003). These risk factors have been shown to initiate a chronic inflammatory process that leads to the loss of vasodilator and anti-thrombotic factors and an increase in vasoconstriction and platelet aggregation (Widlansky, 2003, Libby, 2002).

Elevated circulating levels of inflammatory markers (CRP) have been linked to atherosclerosis (Johnson, 2004; Haverkate, 1997; Ridker, 1997), particularly in women. Endothelial injury produces loss of endothelium integrity and causes platelet aggregation, the release of platelet derived growth factors (PDGF) that cause migration of monocytes,

T-lymphocytes and smooth muscle cells from the media (middle layer of the artery) into the intima (inner layer of the artery) where they multiply to form a fibrous plaque (Braunwald, 2001). Endothelial dysfunction also leads to abnormal vasomotor tone, causing the arteries to lose the ability to vasodilate when appropriate (Braunwald, 2001; Gustein, 1999). Intravascular ultrasound and coronary angiography have proven that endothelial vasomotor dysfunction is an independent predictor of long-term CHD events in women (vonMering, 2004).

#### Microvascular disease

This theory is relatively new and seems to have special relevance for women. It has been developed over the past 12 years and hypothesizes that the smaller coronary arteries are affected by plaque buildup and the plaque may be more diffuse, not concentrated in one area in a large artery. This is why it is often called non-obstructive CHD (NHLBI, 2007). It is known that women have smaller coronary arteries than men (Sheifer, 2000) and tend to have more diffuse atherosclerotic disease than men (Tremmel, 2007; Khuddas, 2006). Recent data from Wessel, (2007), Quyyami (2006) and Reis (2001) suggests that women have CHD events as a result of microvascular disease. It is thought to affect up to 3 million women with heart disease in the United States (NHLBI, 2007). It has been shown that half of women who have an angiogram will not demonstrate flow limiting atherosclerosis. Despite this, these women will still have an adverse CHD event over the following 5 years (Pepine, 2004).

The Women's Ischemia Syndrome Evaluation (WISE study) was conducted over a four year period in three phases to 1) optimize symptom evaluation and diagnostic testing for ischemic heart disease in women; 2) explore mechanisms for symptoms and

myocardial ischemia in the absence of significant coronary artery blockage, and 3) evaluate the influence\_of reproductive hormones on symptoms and diagnostic test response (Merz, 1999). This study showed that the CHD event rates (for 936 women followed for four years) were seven fold higher in those women whose arterial mediated flow did not improve on angiography when compared to those whose did improve, using intracoronary acetylcholine and nitroglycerin for vasodilitation (Quyyami, 2006). This has been termed microvascular flow dysfunction. In the WISE study, it was reported that 60% of women had microvascular flow dysfunction (Reis, 2001). This evidence suggests that while there is no flow limiting plaques on angiography for many women, there are still other malignant processes that are taking place within the coronary arteries of women at risk that could lead to a CHD event (AMI, heart failure or sudden death). *Summary* 

The physiological theories just described emphasize beginning knowledge of how heart disease development is different in women than in men. In the next section, the Health Belief Model (HBM) will be used to theorize how women respond to CHD risk factor knowledge and why they are reluctant to participate in preventative CHD care. By understanding both the physiological process together with the psychological influences put forth by the HBM, the health care providers can offer guidance, understanding and can proceed with appropriate and individualized preventative measures.

#### Health Belief Model

The Health Belief Model was originally developed in the 1950s by a group of social psychologists in response to the public not taking advantage of tuberculosis

screening x-rays or polio vaccinations (Hochbaum, 1956; Rosenstock, 1959). They developed the theory to explain peoples' behaviors and beliefs with regard to preventative care. The theorists proposed that individuals will take action to prevent a disease or condition if they perceive themselves to be (1) susceptible to that condition, (2) perceive the consequences of the condition as serious and (3) if they believe that the benefits to taking preventative action will outweigh the barriers to taking that action (Rosenstock, 1974). Six main concepts of belief or behavior were incorporated into the model: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy (Table 1).

Table 1: Concept Definitions in Health Belief Model

Concept	Definition	Application
Perceived Susceptibility	One's opinion of chances of getting a condition	Define population(s) at risk, risk levels; personalize risk based on a person's features or behavior; heighten perceived susceptibility if too low.
Perceived Severity	One's opinion of how serious a condition and its consequences are	Specify consequences of the risk and the condition
Perceived Benefits	One's belief in the efficacy of the advised action to reduce risk or seriousness of impact	Define action to take; how, where, when; clarify the positive effects to be expected.
Perceived Barriers	One's opinion of the tangible and psychological costs of the advised action	Identify and reduce barriers through reassurance, incentives, assistance.
Cues to Action	Strategies to activate "readiness"	Provide how-to information, promote awareness, reminders.
Self-Efficacy	Confidence in one's ability to take action	Provide training, guidance in performing action.

Glanz, K., Lewis, F. & Rimer, B.K. (1990) definitions taken from book

Over the years, the HBM has been modified to include Bandura's (1977) concepts of self-efficacy to explain health promotion and prevention behavior. The concept of self-efficacy and defined it as the confidence that an individual can successfully accomplish the behavior necessary to produce the desired outcome. This concept of self-efficacy was added to the Health Belief Model in 1988 to increase the explanatory power of the model. Later, Rosenstock (1988) added that there are other factors (such as race, educational level and sex) that influence an individual's perception regarding whether they will act or not.

## Research using the Health Belief Model

In the 1980's, the Health Belief Model began to be used to predict health promotion behavior and adherence to treatment for a variety of diseases. Most of the research has been conducted in the areas of breast cancer (Lostao, 2001; Aiken, 1994; Fulon, 1991; Rutledge, 1988; Champion, 1985; Calnan, 1984), and HIV/AIDS (Lollis, 1997; Falck, 1995; Gielen, 1994; Carmel, 1990; Mongomery, 1989). Research related to CHD validating the HBM has included diet modification, exercise programs, cardiac rehabilitation, smoking cessation interventions, and adherence to hypertension medication. However, these have mainly focused on secondary prevention, after a CHD event has already occurred. (Cerkoney, 1980; Becker, 1985; Harrison, 1992; Robertson, 1992; Lutfey, 1999, Stutts, 2002).

The HBM shifted focus in the mid- eighties to prevent or delay of the onset of CHD, stroke, cancer or diabetes (Glanz, 1990). In CHD, the perception of barriers has been most consistently correlated with prevention behaviors in smoking cessation and health behavior changes in the context of cardiac rehabilitation programs (Tirrell, 1990;

Slenker, 1984; Hiatt, 1990; Kirscht, 1989). Perception of benefits have most consistently been correlated with adherence to antihypertensive medication regimes and participation in exercise or diet programs (Hiatt, 1990; King, 1983; Mirotznik, 1985).

Research related to CHD in both genders using the HBM includes Sapp & Jansen (1998) evaluating its ability to predict perceived versus actual dietary quality of what people eat daily (men =302, women= 1200). They hypothesized that by understanding people's perception of their food, this would influence their food choices to improve their health. They found that the HBM was a good model to predict people's perception of their dietary intake. Mirotznik et.al. (1995) used the HBM to explain attendance at a supervised community based exercise program for CHD prevention (men=72, women=28). They found that two dimensions of the model were associated with attending the program: perceived benefit and perceived severity of CHD. They concluded that health beliefs are associated with CHD exercise adherence by using the HBM and surmised that by predicting these two aspects of the HBM, improved clinical adherence with exercise would result.

The literature is limited with respect to testing the HBM in the realm of CHD prediction in women. Most relevant to this paper, Ali (2002) adapted the HBM's major concepts to explain women's participation of CHD preventative behaviors (See Figure 2 on the next page). This study included 178 women from 3 mid-western churches who were 50 years old or greater and did not have a history of heart disease. In her model, a woman's perception consists of 1) how susceptible she perceives herself to be to CHD and 2) how serious she perceives CHD to be. These two perceptions are, in turn, influenced by internal modifying factors that include age, sex, ethnicity, personality,

education, socioeconomic status, as well as knowledge of CHD risk, risk factors and symptoms and overall perceived threat of CHD. Cues to action are external modifying factors that also influence perception e.g. family history of CHD, personal symptom experience and media information. Ali hypothesized that a woman's likelihood of action balances between what her perceived benefit would be if she were to take preventative action versus the perceived barriers that she foresees (e.g. cost, time away from family or job) in undertaking preventative behaviors. Whether the benefits or the barriers take precedence in a women's decision making process will result in her action of participating in preventative behaviors or not. Self-efficacy is the overall guiding force; the woman has to have the confidence that she can take part in and achieve her goals in preventing CHD.

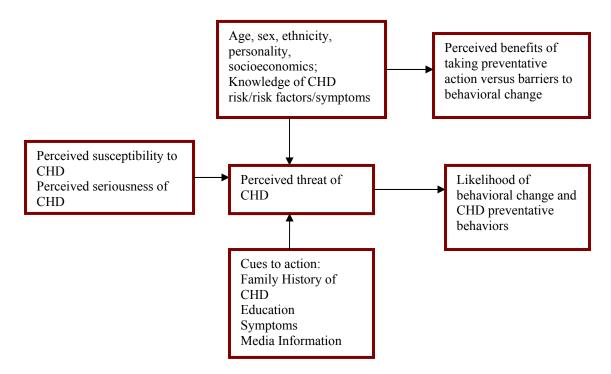
Using this model, Ali found that perceived susceptibility to CHD explained the majority of the variance (50.7%) followed by knowledge of risk factors explaining 19.5%. Both were statistically significant predictors of preventative CHD behaviors in women. Interestingly, she also found that perceived seriousness of CHD did not predict preventative behaviors for these women (and a majority of these women had at least one significant risk factor: diabetes, hypertension, hyperlipidemia or family history). This implies that women do not personalize their risk of developing CHD despite their awareness of their risk factors. It also appears women subscribe to the old adage: "It won't happen to me."

In the past decade, the HBM has been used more as a theoretical basis for explaining prevention health behaviors and has been able to yield valid conclusions to improve practice. Even though the HBM has been studied specifically in the realm of

CHD prevention and women only once, it appears to have a valid theoretical basis for understanding preventative behavior in cardiac patients.

Figure 2. Conceptual Model- Modified for CHD Preventative Behaviors in Women

INDIVIDUAL PERCEPTION MODIFYING FACTORS LIKELIHOOD OF ACTION



Source: adapted from Ali, 2002 (permission obtained)

#### Discussion

The theoretical basis for CHD prevention in women using the Health Belief

Model was the main focus of this paper. The physiological theory was also discussed for
the benefit of understanding the physiology of CHD between the genders. Atherosclerosis
is a complicated, active process that leads to coronary events or even death if left
untreated. Often, this is a silent process in women, making risk factor modification and
prevention more crucial for them. Many women still believe that CHD is a "man's

disease" and doesn't have any relevance for them. The HBM hypothesizes why women do not perceive or personalize their CHD risk and therefore take part in recommended screening behaviors or preventative care. This is a key element. By determining what concept(s) (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy) explain most of the variance for women, it will hopefully provide information so health care providers can tailor their educational and/or interventions to improve primary prevention for women. Ultimately, it is hoped CHD outcomes in women who develop CHD will also improve. By understanding women's perceptions and reasoning regarding CHD prevention actions, it can lead to improved screening and preventative care measures to decrease the devastating effects of CHD in women.

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# Chapter 4

Testing Strategies for Women for Primary Prevention of Coronary Heart Disease

Accurate and safe screening for CHD in women provides a crucial link to optimal prevention and management of the disease. Once the underlying disease is identified, measures can be taken to reduce the risks of acute myocardial infarction (MI) and CHDrelated death. Unfortunately, noninvasive screening for CHD is less accurate in women than in men, and may lead to false-positive results, prompting invasive and possibly dangerous tests that will prove to have been unnecessary (Shaw, 2000). At the same time, false-negative results of noninvasive testing may lead to under-diagnosis and undertreatment of potentially lethal disease. Table 1 defines false-positive, false-negative, and other terms used for validity and reliability in physiologic measures (Munro, 2005). A consensus statement issued jointly by the Cardiac Imaging Committee, the Council on Clinical Cardiology, the Cardiovascular Imaging and Intervention Committee, the Council on Cardiovascular Cardiology and Intervention, and the American Heart Association (AHA) in 2005 recommends screening for CHD in both asymptomatic and symptomatic women (Gibbons, 2002). The aim of the initial test is to classify women into a low-, an intermediate-, or a high-risk category. However, much of the evidence supporting the use of traditional noninvasive screening methods (primarily stress testing) is based on research performed on middle-aged men, raising questions about the validity of these noninvasive tests in women.

Table 1. Definition of Terms Used for Validity and Reliability in Physiologic Measures

True-negative: Both diagnosis and testing are negative for the disease

False-positive: Diagnosis is positive and test is negative for disease

False-negative: Diagnosis is negative and test is negative for disease

True-positive: Both diagnosis and testing are positive for the disease

Specificity (TN/(TN + FP): % of patients without disease who have a normal test result

Sensitivity (TP/TP + FN): % of patients with disease who have an abnormal test result

TN = true-negative; FP = false-positive; TP = true-positive; FN = false-negative.

Munro, B. H. (2005). *Statistical Methods for Health Care Research* (Fifth ed.). Philadelphia: Lippincott Williams & Wilkins. (Content taken from book)

Nurse practitioners (NPs) screening women for CHD, especially those with risk factors, need to choose an appropriate test for each woman. The most common noninvasive stress test techniques used for CHD risk stratification in women are exercise stress treadmill tests using electrocardiography (ECG), nuclear stress testing, and exercise stress echocardiography. Coronary angiography, an invasive test used for high-risk situations and in patients with positive noninvasive test results, is beyond the scope of the article. However, NPs should become familiar with a new noninvasive test—electronic beam computed tomography (EBCT)—a technique that may be more accurate in ascertaining risk in women at intermediate to high risk for CHD (Greenland, 2000).

## **Exercise Stress Testing**

In 1963, the U.S. cardiologist Robert A. Bruce developed an exercise stress test that is usually administered in a maximum of seven stages—the Bruce protocol (Bruce, 1971).

In this protocol, the elevation and speed of the treadmill increase every 3 minutes, as tolerated, or until maximum exercise capacity is reached (maximum duration, 21 minutes) (Bruce, 1971). Important findings include ECG abnormalities (eg, arrhythmia, ST-segment changes), exercise duration, and onset of signs and symptoms, especially a drop in systolic blood pressure (SBP) or chest pain. ST-segment changes provide information on myocardial response to stress and decreased coronary blood flow (Bruce, 1971). A positive ECG response is defined as ST-segment depression ≥1 mm versus the baseline tracing. A rapid increase in heart rate that does not recover quickly after the test is stopped is also a predictor of CHD (Falcone, 2005; Leeper, 2007. The exercise stress test is terminated if angina, dyspnea, muscle fatigue, ST-segment depression >2 mm, or major arrhythmias occur (Falcone, 2005). Other absolute reasons for stopping the test include ST-segment elevation > 1 mm, a drop in SBP of 10 mm Hg below baseline despite an increase in workload, central nervous system symptoms (eg, ataxia, dizziness, near-syncope) or signs of poor perfusion (eg, cyanosis, pallor) (Fletcher, 2001). The most serious indication of ischemia is an inadequate SBP or an initial rise and then a drop in SBP in the setting of an increased workload (Bruce, 1971).

A modified Bruce protocol is available for patients who cannot tolerate the more intense protocol. The modified version increases the treadmill slope, but not the speed, in the first few intervals (Sivarajan, 1977). This protocol is often used for patients who are elderly and/or sedentary and/or who have arthritis (Sivarajan, 1977).

#### Predictive Value in Women

Exercise stress testing in women has questionable usefulness within both cardiology and primary care. The predictive value of this test in women is insufficient.

On average, 30% of positive exercise ECG findings in women are false positives (Morise, 2002). ECG changes during exercise have been reported to be of diminished accuracy in women because of more frequent resting ST-T-wave changes, lower ECG voltage, and hormone therapy use in postmenopausal women (Waters, 2004). Presence of ST-segment depression >1 mm during or immediately following exercise in women, relative to that in men, has much lower predictive accuracy (Shaw, 1999). ST-segment changes and symptoms with stress testing in asymptomatic women do not provide additional prognostic information (Gulati, 2005). Conditions such as mitral valve prolapse (MVP), left bundle branch block (LBBB), left ventricular (LV) hypertrophy (LVH), and digitalis use may cause an abnormal baseline ECG or cause false stress testinduced ECG changes (Redberg, 1998).

# Sensitivity and Specificity

A meta-analysis of 19 exercise ECG studies in 3721 women showed that mean sensitivity and specificity were 61% and 70%, respectively, as compared with 72% and 77%, respectively, in 1977 A study performed in conjunction with the Women's Ischemia Syndrome Evaluation (WISE) found that the exercise treadmill test was of limited diagnostic value in women with suspected myocardial ischemia referred for coronary angiography (Lewis, 2005). Sensitivity and specificity were poor. Of 29 women with stenosis of ≥50% in one coronary artery by angiography, only 9 had abnormal treadmill stress test findings, yielding an overall sensitivity of 31%. Among 67 women with minimal or no coronary stenosis, 35 had no ischemic ST-segment changes during stress testing, yielding an overall specificity of 52%. After analysis with the exclusion of women with non-diagnostic study findings, a sensitivity of 43% and a specificity 66%

were identified (Lewis, 2005). The Coronary Artery Surgery Study (CASS), which evaluated patients post-coronary artery bypass graft surgery who had previously undergone exercise ECG stress tests and angiography, showed that sensitivity and specificity for women (n = 580) were 76% and 64%, respectively, compared with 80% and 74%, respectively, in men. In addition, a true-positive exercise stress test result occurred in only 33% of women, compared with 89% of men (Goodman, 2001).

## **Nuclear Stress Testing**

Nuclear stress testing uses radioisotopes to evaluate structures, contractility, and myocardial perfusion. This two-stage test consists of a baseline resting evaluation scan and a post-exercise challenge scan. Isotopes are injected 1 minute before the end of exercise. Images are then obtained 15-60 minutes after exercise (Henzlova, 2006).

Results of both scans are compared to identify any changes in perfusion of the coronary arteries or a decrease in the Left Ventricular ejection fraction (LVEF) that would indicate the presence of CHD. Left ventricular function data adds important prognostic value to data obtained from perfusion imaging alone in predicting adverse cardiac events. A low LVEF increases the CHD event rate from 6% to 7.5% in both men and women (Travin, 2004). In women specifically, the combination of severe ischemia and abnormal LVEF identifies women at very high risk better than in men (Sharir, 2006). Perfusion defects that are present during exercise but not at rest indicate myocardial ischemia. Perfusion defects that are present during exercise and that persist at rest suggest previous MI (Fletcher, 2001). The exercise portion of the test provides information about cardiac

function and the ECG is interpreted for any ST-segment depression, indicating ischemia, or ST-segment elevation, indicating injury or infarction.

Individuals who cannot exercise at all (eg, those with amputations) or who cannot reach maximum exercise capacity on a treadmill (eg, the elderly, persons with severe osteoarthritis) can undergo nuclear stress testing wherein the stimulus is a pharmacologic agent. Two adrenergic agents, adenosine and dobutamine, are used to increase blood flow 3-5 times the normal amount, causing vasodilatation (Henzlova, 2006; Travin, 2004). Adenosine is infused intravenously (IV) at a dosage of 140 mcg/kg/minute over 6 minutes. The time to maximal vasodilation with adenosine is approximately 84 seconds (Bokhari, 2007). Dobutamine, which is used more often than adenosine because it has fewer side effects, is infused IV starting at 5 mg/kg/minute, with the dosage increased to 10 mg/kg/minute and then, if tolerated, increased every 3 minutes thereafter by 10 mg/kg/minute until a maximal dosage of 40-50 mg/kg/minute is reached. With these agents, the goal is to reach a heart rate that is 85% of the age-predicted maximal value. For myocardial perfusion imaging, the radioisotope is injected at the peak dobutamine dose. Dobutamine infusion is then continued for 1 minute after injection of the radioisotope. The dobutamine/adenosine stress test aims to elicit the same outcomes as the exercise nuclear stress test in terms of assessing for CHD (Fletcher, 2001; Henzlova, 2006).

Sensitivity and Specificity

With the addition of the nuclear component to the exercise treadmill test, specificity is still only 70% in women. However, the use of gated single-photon emission computed tomography (SPECT) combined with thallium as the radioisotope has

improved specificity substantially to 80% (Elhendy, 2006). Nevertheless, myocardial perfusion imaging, or nuclear stress testing, may also have technical limitations in women, including false-positive results related to breast-tissue attenuation and small LV chamber size (Mieres, 2003).

Sharir (2006) evaluated 6713 patients (2735 women and 3978 men). They underwent rest thallium-201/stress technetium-99m sestamibi gated myocardial perfusion SPECT and were followed up for 35 months. The combination of severe ischemia and abnormal left ventricular function identified women at very high risk of cardiac events (Sharir, 2006). In addition, Elhendy (2006) studied 88 women who underwent exercise or dobutamine nuclear stress testing and coronary angiography within 3 months. Myocardial perfusion abnormalities were detected in 44 of 53 patients with significant CAD and in 7 of 35 patients without significant CAD (overall sensitivity of 83% and specificity of 80%). The sensitivity was 72% in patients with single-vessel CAD and 93% in patients with multivessel CAD (Elhendy, 2006).

### Exercise Stress Echocardiography

Exercise stress echocardiography (stress echo) can provide information about the presence of LV systolic/diastolic dysfunction or valvular heart disease and the extent of infarction or exercise stress-induced ischemia. Stress echo may be performed on a treadmill or a supine or upright bicycle (Cacciabaudo, 1998). The exercise portion of the test gives functional data and the ECG is interpreted for any ST-segment depression, indicating ischemia, or ST- segment elevation, indicating injury or infarction. The echo portion of the test reveals any EF changes under stress that, if the value is low, may

indicate CHD. Images of the heart must be obtained within 1-2 minutes after exercise because abnormal wall motion begins to normalize after this point. Rest and stress images are then compared for changes, especially hypokinesis (slow movement) or akinesis (no movement) of an area (Fletcher, 2001). The stress echo also provides information about valvular function. A change in valvular status does not necessarily represent CHD, but it will cause symptoms that the patient may be having (eg, shortness of breath, palpitations). However, stress echo results can be affected by pulmonary disease or obesity, compromising the accuracy of the test in some cases (Redberg, 1998). *Sensitivity and Specificity* 

Compared with exercise stress ECG, exercise stress echo offers improved sensitivity of 88% and specificity of 84% in women. Stress echo has shown diagnostic accuracy for detecting or excluding significant CHD, with a mean sensitivity of 81% (89% in women with multi-vessel disease) and a specificity of 86% (Cheitlin, 2003; Grundy, 1999; Ho, 1998; Hunink, 1999; Kim, 2001; Kwok, 1999; Lewis, 1999). In patients who cannot exercise or may not achieve target heart rate, dobutamine is the most commonly used pharmacologic stress agent. The same test is administered, but dobutamine is used instead of the exercise stimulus. A meta-analysis of dobutamine stress echo found an overall sensitivity of 80% and a specificity of 84% in patients with multi-vessel disease; once again, this test had a lower diagnostic sensitivity for single-vessel disease (Kim, 2001).

# Electronic Beam Computed Tomography

EBCT uses an electron sweep of stationary target rings that generate very rapid radiographic images. This test can eliminate blurring of the image due to cardiac motion through the use of ECG triggering using approximately 30-40 axial scans that are completed during one or two breath-holding sessions. The test takes only about 10 minutes and overcomes some of the limitations that cause abnormal or inaccurate results in exercise stress testing. The software then quantifies the area and density of calcium in the coronary arteries and calculates a coronary artery calcium (CAC) score. Because CAC occurs exclusively as a result of atherosclerosis, a score of 0 is normal and scores of 1->400 are abnormal (O'Rourke, 2000). Three standard categories of CAC scores are used for risk stratification: 1-100 (mild disease), 101-400 (moderate disease), and >400 (severe disease) (Pletcher, 2004). Because the presence of CAC has a high specificity for atherosclerosis, any detectable calcium is regarded as evidence of CHD. Higher calcium scores correlate with older age, higher levels of coronary risk factors, and a greater extent of coronary atherosclerosis (Greenland, 2003).

#### Predictive Value in Women

EBCT, the most recent test developed to stratify women for CHD risk, is used as an additional method or as an alternative method for risk stratification in persons with suspected CHD. The American College of Cardiology and the AHA Executive Summary on EBCT endorse this method as a highly sensitive technique for detecting CAC, and these agencies have recommended EBCT for screening of asymptomatic persons to identify those who are at high risk for developing CHD and cardiac events (O'Rourke, 2000).

EBCT is beneficial for risk stratification of asymptomatic women who are at moderate or high risk of having a coronary event because it provides information to initiate preventive measures to reduce the risk of CHD events (Raggi, 2000). Findings from several studies are illustrative:

- More than 3000 asymptomatic, healthy individuals were screened via EBCT for CAC and their risk-factor profiles were collected (Hoff et al., 2003). CAC scores rose incrementally as the number of coronary risk factors increased. In women, increased CAC scores correlated with high cholesterol, hypertension, or diabetes.
- A study of 425 asymptomatic persons (229 men and 196 women) with 0 or 1
   CHD risk factor in most cases who underwent EBCT and follow-up evaluation of cardiac outcomes (cardiac death, acute MI, revascularization, stable angina) showed that CAC scores were independent predictors of CHD (Alexopoulos, 2003).
- Results of a study of 1173 asymptomatic individuals followed for a mean of 19
  months after screening with EBCT confirmed that the risk of cardiovascular
  events correlated with the extent of CAC (Arad, 2000). Risk of stroke, MI, death,
  or revascularization was twice as high in persons with a CAC score >160 than in
  those with no visible calcium.
- A study of 1312 persons >45 years who were followed for a median of 8.5 years
   after a baseline EBCT scan showed that cardiac events for those with CAC scores
   >300 were nearly 4 times more common than in those with a CAC score of 0
   (Greenland, 2004).

Survival has been found to decline in women with increasingly higher CAC scores, a finding that is more than likely due to their relatively smaller artery size—making *any* amount of calcium a higher risk for CHD in women than in men (Shaw, 2000).

Women who are asymptomatic and have a calcium score of >400 have an annual risk of CHD death or MI of 2% and should be considered at high risk. Guidelines on CHD prevention in women note that a 2% risk of major adverse cardiac events places a person at high risk (Mosca, 2007). Data also support the use of EBCT for verification of the Framingham Risk Score because a high CAC score can modify predicted risk obtained from Framingham Risk Assessment alone, especially in women in the intermediate risk category in whom clinical decision making is more difficult (Greenland, 2004). Use of EBCT has great potential in determining CHD risk, particularly in elderly, asymptomatic patients, women, and others at intermediate risk.

Sensitivity and Specificity

Presence of coronary calcium on EBCT is highly sensitive in identifying obstructive CHD (95%-99%), but the specificity for obstructive CHD varies, depending on the persons age and the amount of coronary arteriosclerosis present (Nasir, 2004). CAC for decades has been shown to be highly correlated with atherosclerotic coronary disease using autopsy verification (Rumberger, 1999) and angiographic comparisons (Deetjen, 2007; Schmermund, 1998; Hamby, 1974). EBCT is also useful in ruling out obstructive coronary disease, as demonstrated by several studies of asymptomatic and symptomatic men and women who underwent both angiography and EBCT (Budoff, 2002; Keelan, 2001; Schmermund, 1998). A study of 5500 patients showed that the

negative predictive value of coronary calcium levels was greater than 95%, thereby giving NPs a high degree of confidence that a patient with no coronary calcium (ie, a score of 0) has no obstructive angiographic disease (Shaw, 2003).

A few research studies have compared EBCT with one of the stress testing modalities. One study compared EBCT with exercise stress testing and found that EBCT had a greater sensitivity (80%) relative to the exercise stress test (61%) in asymptomatic persons (Greenland, 2003). Four studies compared EBCT and nuclear stress testing and found that the specificity of regional wall motion abnormalities that would indicate obstructive CHD in at least one major vessel was significantly better in with EBCT in all age groups (Budoff, 1998) but particularly in persons >45 years, (Yao, 2000; Yao, 2004) with the sensitivity of the two tests being similar. The sensitivity and specificity was found to be 100% and 73% for EBCT and only 69% and 36% for nuclear stress testing (Ravipati, 2008).

# Advantages and Disadvantages of Each Test

Current noninvasive tests used for stratifying women according to CHD risk have certain advantages and disadvantages (Table 2)(Redberg, 1998). Among screening tests, the exercise stress ECG test has been in use the longest, is easily accessible, and is the least expensive. However, this test has several disadvantages that limit its accuracy in women. The test has high false-positive rates in women and is less accurate in patients with MVP, LBBB, LVH, or digitalis use—all of which affect the ECG tracing and make interpretation of any ischemic changes difficult.

Table 2. Advantages and Disadvantages of Noninvasive Testing in Women

Test	Advantages	Disadvantages	*Cost
Exercise ECG	Low cost	Less reliable in	\$1960
		presence of MVP,	
		LBBB, LVH, digitalis	
		use	
		High false-positive rate	
Nuclear stress	Higher sensitivity	Breast attenuation	\$2110
	than exercise ECG	Radiation exposure	
	Not solely dependent	More expensive	
	on ECG interpretation	Not widely studied in	
	Additional	women	
	information of EF		
Stress	Higher sensitivity and	Limited by pulmonary	\$3631
echocardiography	specificity than other	disease and obesity	
(echo)	tests		
	Not solely dependent		
	on ECG interpretation		
	Provides information		
	on EF and valve		
	function		
Pharmacologic testing	For persons who	Provides less functional	**Adenosine
(nuclear or echo)	cannot exercise or	data	\$140
	reach target heart rate	Side effects of	Dobutamine
		hypotension, flushing,	\$5
		and bronchospasm	
Electronic beam	Highly correlated	Not widely available	\$400
computed	with angiography	Not widely studied in	
tomography	Excellent spatial	women	
	resolution		
	Not affected by other		
	co-morbid conditions		

ECG = electrocardiography; MVP = mitral valve prolapse; LBBB = left-bundle branch block; LVH = left ventricular hypertrophy; <math>EF = ejection fraction.

Redberg RF, Wenger NK. *Cardiology Clinics*. Philadelphia, Pa: W.B. Saunders Company; 1998. Permission received.

The nuclear stress test has a higher sensitivity than the exercise stress test alone and it also evaluates profusion abnormalities and provides information about the LVEF.

<sup>\*</sup> Cash cost without insurance coverage (average taken from 3 area hospitals)

<sup>\*\*</sup> Additional drug cost to test (Wholesale cost)

Disadvantages of this test include the risk of radiation exposure and the greater cost.

Also, breast attenuation may lead to false-positive results.

Compared with the exercise stress test and the nuclear stress test, stress echo has several advantages in women. This test has higher sensitivity and specificity in women and is not solely dependent on ECG interpretation because it provides information on LVEF and valve function. Stress echo may be used with pharmacologic agents in persons who cannot exercise or reach target heart rate. Disadvantages of stress echo include its minimal usefulness in persons with pulmonary disease or obesity, which makes the results difficult to interpret. In addition, the use of pharmacologic agents poses a risk of side effects such as hypotension, flushing, and bronchospasm.

The EBCT is a newer test for risk assessment that is not as widely available and has not been widely studied in women. However, the advantages are notable. EBCT has excellent spatial resolution, gives information about the extent of coronary calcium present to risk stratify a patient and is highly correlated with angiographic coronary stenosis. EBCT is free of side effects.

#### Conclusion

Several noninvasive tests are available for CHD risk stratification in women, including the exercise stress test, the nuclear stress test, stress echo, and EBCT. Use of traditional noninvasive testing in women has been controversial because of diminished accuracy, the limited number of women in many research studies, and technical limitations that compromise accurate interpretation of the results. NPs evaluating women with risk factors indicative of CHD face the challenge of choosing the appropriate screening test.

Accurate and safe screening tests for CHD in women provide a crucial link to subsequent optimal prevention and management of CHD risk factors. Therefore, a more accurate noninvasive test to evaluate women for CHD risk is imperative—the EBCT scan may fulfill this need. Further research must be conducted to evaluate the use of this test as a cost-effective primary screening tool for risk stratification in women. Current literature suggests that EBCT is highly correlated with angiography, the gold standard for diagnosing CHD.

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Chapter 5

Methodology

### Methodology

This chapter provides a description of the research design, setting, and sample, study variables as well as the protocol for data collection for this study. The final section describes the plan for data management, and analysis.

This descriptive cross sectional study compares the perceived and actual risk of coronary heart disease (CHD) in women. Research questions for this study are: (1) what is the knowledge of women about CHD risk factors and heart attack symptoms? (2) what is the self- reported presence of CHD risk factors in women? (3) what is the proportion of women who discussed risk factors of CHD with their HCP? (4) how do women perceive prevention strategies of CHD? and (5) how does perceived risk compare to actual 10-year CHD risk in women? Hypothesis for this study are that: (1) Women's perceived risk will be lower than actual risk score; and (2) Greater CHD knowledge is associated with more accurate perceived risk.

# Study Variables

The predictor variables of this study are knowledge and actual risk which is defined as low, medium or high risk. The outcome variable for this study is perceived risk, which is defined as low, medium or high risk. Covariates include age, race, family history of CHD, education level, income, number of children in home, occupational status, marital status, and having received personal counseling from health care provider about CHD. Risk factors, such as high blood pressure, high total cholesterol and low HDL cholesterol, smoking, and age are variables that were collected to calculate the Framingham risk score for actual risk.

# Setting and Sample

Setting

Subjects who met the inclusion criteria and agreed to participate in the study were recruited from three different sites in the Bay area. Each of these sites was receptive and supportive of nursing research and expressed an interest in taking part in a study of women and heart disease prevention. Letters of support were provided by each site (Appendix G, H, I).

Site A. Portola Valley Women's Health Clinic (Portola Valley, CA) is a part of the Palo Alto Medical Foundation for Health Care, Research and Education. It is a not-for-profit health care organization that specializes in well-woman care, obstetrics, gynecology, fertility, laparoscopic surgery and menopause. They provide care to approximately 40 patients a day and employ five physicians and two nurse practitioners.

Site B. First Baptist Church (Los Altos, CA) is a community church with approximately 500 members, 300 of whom are women. They provide small group Bible study called Life Groups for various age groups. This is where the data collection took place.

Site C. Mission Hospice (San Mateo, CA) is a community-based hospice organization supported by an expert professional staff and dedicated volunteers. Mission Hospice serves those living with an advanced illness or condition, their caregivers and their loved ones. They employ approximately 25 people and have 40 volunteers, 50 of whom are women.

Sample

A convenience sample of 100 women from the Santa Clara and San Mateo County were invited to participate voluntarily in the study. Inclusion criteria for the subject to participate in the study were: age 30 years or greater, no previously diagnosed CHD (defined as angina or myocardial infarction), no previous CHD intervention (i.e. angiography or bypass surgery), and spoke English.

The potential parameters to be considered are age, race, education level, income, number of children in home, occupational status, marital status, knowledge level, and risk factors (high blood pressure, high total cholesterol, low HDL cholesterol) will be estimated as predictors of risk. Approximately 100 subjects will be sufficient to answer all research questions.

#### Instrumentation

Two instruments and two physiological measures were used for this study. The Women's Health Study Survey (Appendix C) was used to determine perceived risk of CHD as well as knowledge of CHD women. It consists of 5 sections: Screening and Demographics (6 questions); General Awareness of Women's Health issues (3 questions); Perception and Behaviors related to Heart Disease Prevention (17 questions); Knowledge of Heart Disease in Women (4 questions); and Heart Disease Prevention (1 question). This questionnaire was used in Mosca's (2000, 2004) research on women and heart disease awareness in conjunction with the American Heart Association in a national phone survey. The questionnaire has substantial face validity of awareness, perception and knowledge of CHD in women. The reliability and validity has not been otherwise reported in the literature.

The Framingham Risk score (FRS) was used to determine actual 10 year CHD risk. This calculation is determined through a series of calculations computed by the Framingham risk score available online at

http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof. However, this equation was written into the SPSS syntax to run with the collected data. Investigators with the Framingham Heart Study developed CHD risk equations to be used by health care providers in predicting the development of CHD (Kannel, 1967; Grundy, 1998). The FRS was developed to help HCP estimate actual risk of an individual patient developing clinically manifest CHD within 10 years and has been used as a screening tool to determine those that have multiple risk factors and need primary care prevention.

To calculate the FRS, age, gender, LDL cholesterol, HDL cholesterol, smoking status, systolic blood pressure and whether or not they are taking medication for high blood pressure is required. Two readings were taken and averaged for the final documented reading as recommended by the American Heart Association (2008) and the Joint National Committee 7 (2004) guidelines. Blood pressure was obtained on all subjects at all sites by an Omron blood pressure automatic machine. A full lipid profile was obtained by a fingerstick blood sample and analyzed using the Cholestech LDX portable system. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CLIA waived tests are recognized by the FDA to be so simple to use and so accurate that there is little risk of error. The Cholestech LDX system is the only portable cholesterol machine that has met has this waiver. In adition, results from the Cholestech machine have been shown

to meet the NCEP criteria for having accuracy and precision error of > 3% (Shepherd, 2007; Santee, 2002; Issa, 1996; Rogers, 1993)

### Procedures for Data Collection

Site A- Clinic

Women who present for their appointment at Portola Valley Women's Clinic were invited by the Principle Investigator (PI) or trained Research Assistant (RA) to consider taking part in the study and were given an information flyer (Appendix A) that described the study. They could also be referred by their physician or nurse practitioner to the PI or RA. Those women who were interested in the study received a more detailed explaination and were invited to have their questions answered. They were then asked to sign a written informed consent (Appendix B) if they were eligible for the study. If they agreed to participate, a packet was given to them by the PI or RA. They were first asked to answer a short perception questionnaire (AHA-Women's Health Study Survey) at the clinic to determine perception of their personal risk. A cholesterol screening test was taken (fingerstick) and a blood pressure measurement was completed at the clinic by the PI or research assistant.

After completion of all data collction the subjects were given standard AHA information about risk factors and the were encouraged to contact their primary care provider if they have any further questions. They also received a booklet that they could keep with their cholesterol and blood pressure results entered for them as well as a \$5 Starbuck's gift card as a token of appreciation for their participation.

# Site B & C- Church and Hospice

The same procedures where followed for Sites B & C except for all of the subject contact was done by the PI alone. Flyers (Appendix D) were disstributed prior to data collection for women to review and consider taking part in the study. Informed consent was signed (Appendix E). At site B, data collection occurred in a different Life Group each week. At Site C, two days were set up for data collection at times convienient for the subjects who worked there.

#### **Ethical Considerations**

The Committee on Human Research approval was obtained from the University of California San Francisco (Appendix F) for all sites as well as Palo Alto Medical Foundations Internal Review Board approval for Site A. The major risk for this study is the loss of confidentiality, thus this was a top priority to ensure that subjects confidentiality is maintained. Personal contact information is separated from data collection forms and unlinked with a study subject's ID. All data collection forms were securely transported from the data collection site to a secure fireproof filing box with access only to the research team.

The PI/Co-PI or RA was available to review the purpose, nature, risks and benefits of the study with the participants before their consent is obtained. All subjects received a copy of the consent form. Subject's participation was voluntary. Every effort was made to ensure the subjects did not feel coerced by the PI/Co-PI or RA to take part in the study. Questionnaires were returned in a sealed envelope that only the PI/Co-PI will open for scoring.

### Data Management

Perceived and Actual Risk scoring

Perceived risk of CHD as well as knowledge of CHD in women was scored by the PI using SPSS (Statistical Package for Social Sciences) from the Women's Health questionnaire. A Framingham Risk score was completed by SPSS to determine the actual CHD risk of each woman after data was collected. This was calculated by taking the subjects age, total cholesterol, HDL cholesterol, smoking status, systolic blood pressure and if they were on medication for their blood pressure. Percentage of 10-year CHD risk was calculated by the Framingham Risk score written in SPSS from data provided by the National Heart Lung and Blood Institute (NHLBI).

A phone contact was made to the subject to provide results of their perceived and actual test scores. If the subjects results show a high risk for CHD, they were advised to contact their primary care provider directly by phone call and to provide them with a copy of their test results for follow up.

#### Statistical Analysis

Statistical analysis was planned in regards to each research question. Frequencies were run on all variables that were ordinal, dichotomous or categorical with SPSS. Mean, median and standard deviations were run on continuous variables. Crosstabs were completed for RQ 6 to compare actual versus perceived risk.

RQ 1. What is the knowledge of women about CHD risk factors and heart attack symptoms? The knowledge scores for the women are presented in percentages.

- RQ 2. What is the self-reported presence of CHD risk factors in women? The percentages of women who report having each of the CHD risk factors are reported.

  RQ 3. What is the proportion of women who discussed risk factors of CHD with their HCP? The women's self reported account of counseling are reported in percentages.

  RQ 4. How do women perceive prevention strategies of CHD? The women's self reported perception of preventative strategies are reported as an average percentage of correct responses.
- RQ 5. How does perceived risk compare to actual CHD risk scores of women? A cross-tab analysis was done to evaluate the perceived risk against actual risk.

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Chapter 6

Results

#### Results

Data collection was collected between February 14, 2008 and May 11, 2008. The number of women recruited from each site were: Site A (Women's Health Clinic) = 20; Site B (First Baptist Church, Los Altos) = 75; and Site C (Mission Hospice) = 11. Sample characteristics

Table 1 gives the demographic information. The mean age (s.d.) of this sample of women is 53 ( $\pm$  15) ranging from 30 to 87. Sixty-eight percent of the women are Caucasian, 75 % are married or living with a partner, and 61 percent are employed. This group of women is highly educated and affluent with 69% being college educated or more and report a mean annual household income of \$75,000-\$99,999.

# General awareness and perception

Table 2 shows the women's awareness of the leading cause of death in women. A total of 65% identified heart disease as the leading cause of death with 16% identifying breast cancer as the second most common cause. When broken down by age groups, 49% of older women (age 45 - 87) versus 16% of younger women (age 30-44) identified heart disease as the leading cause of death.

Figure 1 identifies how informed the women perceive themselves to be about CHD. Only 29% identified themselves as being "very well" or "well" informed. The majority identified themselves as being "moderately well informed (61%) and 10% perceived themselves "not at all informed". A Spearman's Rho was completed between greater knowledge of CHD and a more accurate perceived risk to determine if there was a correlation. There was a positive statistically significantly result (r=0.23;  $p\le 0.01$ ).

Table 1- Demographic Characteristics of the Sample

Table 1- Demographic Characteristics of the Sample	
Characteristics (n=106)	%
Age groups	
30-34	14
35-44	15
45-54	24
55-64	22
65-87	25
Mean age 53 (±15)	
Race groups	
Caucasian	68
African- American	4
Asian	18
Hispanic	7
Other	3
Marital Status	
Single, never married	7
Married or cohabiting	71
Separated or divorced	17
Widowed	5
<u>Education</u>	
Some high school or less	1
High school graduate/Some college	30
2-yr college	11
4-yr college	30
Postgraduate	28
Income categories	
<20,000	2
20000-49999	18
50000-99999	36
100000-199999	32
≥200000	10
Employment status	
Yes	61
No	39
Number of children at home	
None	54
One	18
Two	23
Three	5

Table 2- Perception of the Leading Cause of Death in Women

Response	%
Breast Cancer	16
Heart Disease	65
Cancer (general)	14
Other	3

Figure 1- Perception of How Informed Women are About Heart Disease

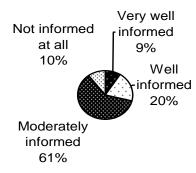
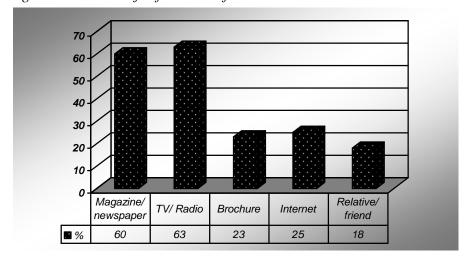


Figure 2 identifies the sources of information about heart disease in women. The two top sources that the women reported to have acquired information were from a magazine or newspaper (60%) and from TV or radio (63%). The internet (25%), brochures (23%), and relative or friend (18%) were additional sources of information.

Figure 2- Sources of Information for Heart Disease in Women



RQ 1. What is the knowledge of women about CHD risk factors and heart attack symptoms?

Table 3 provides percentages of correctly identified CHD risk factors in women. A majority of women knew the major risk factors CHD are family history (96%), overweight (90%), high blood pressure (83%), high cholesterol (83%), smoking (76%) and not exercising (71%). However, only 56% cited diabetes, menopause (20%) or racial heritage (40%) as a major risk factor in women.

Table 4 provides the percentage of correctly identified heart attack symptoms in women. The most often recognized was chest pain (92%), followed by pain across the shoulders, neck or arm (88%) and tightness in chest (88%). Fatigue and nausea were chosen by approximately half the women (55%). Approximately 77% of the sample chose the correct responses to this question.

Table 3- Knowledge of Heart Disease Risk Factors

Response (n=106)	% correct answer
Family history	96
Aging	46
Overweight	90
Diabetes	56
Drinking alcohol	68
High blood pressure	83
High cholesterol	83
High triglycerides	41
Low levels of estrogen	16
Menopause	20
Not exercising	71
Smoking	76
Stress	69
Racial heritage	40

Table 4- Knowledge of Heart Attack Symptoms

Response (n=106)	% correct answer
Chest pain	92
Fatigue	55
Nausea	56
Pain across shoulders and neck or arms	88
Shortness of breath	84
Tightness in chest	88

RQ 2. What is the self-reported presence of CHD risk factors in women?

Table 5 gives the self-reported risk factors of the sample. High blood pressure was reported by 18%, high cholesterol 32%, family history 24%, diabetes 7% and current smoking 3%. Table 6 reports the percentage of women who knew their actual numbers. A high percentage (91%) knew their blood pressure readings, but only 29% knew their total cholesterol number, 14% know their HDL and 14% knew their LDL number.

Table 5- CHD Risk Factors of the Sample

There is of the sample	
Self Reported Risk Factors (n=106)	%
High Blood Pressure	18
High Cholesterol	32
Smoking	3
Diabetes	7
Family History	24

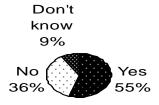
*Table 6 – Knowledge of Risk Factor Numbers (% who knew)* 

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Self Reported Risk Factors (n=106)	%
High Blood Pressure	91
High Cholesterol	29
HDL	14
LDL	14

RQ 3. What is the proportion of women who discussed risk factors of CHD with their HCP?

Figure 3 identifies the percentage of women in this sample that have discussed heart disease with their health care provider (HCP); 55% stated they had, 36% stated they had not and 9% did not know. When asked if they "felt comfortable talking with their HCP about prevention and treatment options", 94% stated that they were comfortable. When asked if they "would like their HCP to talk about prevention" with them, 91% stated they would like to but only 55% stated that they had talked about prevention.

Figure 3- Has Discussed Heart Disease with Their Health Care Provider



# RQ 4. How do women perceive prevention strategies of CHD?

Table 7 provides percentages of correct and incorrect prevention strategies chosen by this sample. Exercise (95%) was correctly chosen most often, followed by quitting smoking (88%), losing weight (85%) and reducing stress (84%). Conversely, taking hormone replacement and aromatherapy were not chosen, indicating that the women knew these were not preventative strategies for CHD. Approximately 71% of this sample chose correct responses to all the prevention strategy questions.

Table 7- Perception of Heart Disease Prevention Strategies

Perception of heart disease prevention strategies	(% correct)	
(correct strategies)		
Quit smoking	88	
Exercise	95	
Losing weight	85	
Reducing dietary cholesterol intake	79	
Reducing animal products in diet	70	
Incorrect strategies		
Taking vitamins	24	
Reducing stress	84	
Taking hormone replacement therapy	14	
Reducing salt in diet	70	
Aromatherapy	6	

RQ 5. How does perceived risk compare to actual CHD risk scores of women?

Table 8 compares perceived risk of CHD versus actual 10-year risk of CHD in this sample; for 55% of the women the perceived and actual risk matched; 38 % overestimated their risk and 7 % underestimated their 10 year risk of heart disease.

Table 8- Comparison of Number of Women Reporting Perceived Coronary Heart Disease Risk Versus Actual 10-year Coronary Heart Disease Risk According the Framingham Risk Score\*

	Act	ual Risk		
		Low	Moderate	High
Perceived Risk	Low	51	7	0
	Moderate	29	6	0
	High	9	2	0

<sup>\*</sup>None had actual high risk on FRS.

# Chapter 7

Discussion and Implications for Practice and Future Research

Discussion and Implications for Practice and Further Research Discussion

This study is unique in that it describes women's perceived compared to actual risk, as estimated using the Framingham Risk Score (FRS), of heart disease in women. In February, 2004 a large national campaign was launched by the American Heart Association called "GO Red for Women" to alert the public about the importance of recognizing that heart disease is a leading cause of death for women. The European Society of Cardiology followed suit with their campaign "Women at Heart" in March, 2005.

Thus, this is one of the first reports since those campaigns. The weather and health conscious culture of Northern California would suggest a higher level of awareness of healthy lifestyle than other parts of the U.S. and the year round opportunity for outdoor physical activity.

The women in this sample were mostly Caucasian, middle aged, married, well educated, employed, and had annual household incomes in the 75,000 to 100,000 dollar range. Forty-six percent had one or more children living at home. This data is slightly higher than the Bay area statistics (2004) of income for San Mateo (Site A & C) county of \$65,400 Santa Clara (Site B) \$ 68,800. Education was also higher (58%) in this study as 40% have a bachelors or higher in San Mateo and Santa Clara counties (US census bureau quick facts).

The most important new findings of this study is the comparison of women's perception of their heart disease risk versus estimated 10 year risk of CHD as calculated by FRS. More than half of the women (55%) accurately perceived their CHD risk; 7 % underestimated and 38% overestimated their risk. This finding contradicts the original

hypothesis that perceived CHD risk would be lower than actual risk of CHD. This could be explained by several factors including (1) the high education level of the sample; (2) the national campaign of Go Red for Women has occurred in the past few years, increasing women's awareness and knowledge of heart disease; (3) the women may have interpreted their perceived risk as their lifetime risk instead of a 10 risk as the FRS measures; and (4) the FRS does not include family history (FH) in the calculation, and 24% of this sample reported a FH. The second hypothesis was supported in that greater knowledge was significantly correlated with a more accurate perceived risk score  $(r=0.23; p \le 0.5)$ . This means that as knowledge about women and CHD increases, the women's perceived risk is more accurate.

In this study, women's knowledge, perception and awareness of CHD in women was compared to Mosca (2006, 2004) national surveys as they are the most recent studies that have evaluated the same areas. Mosca's sample was much larger (n=1024), from all over the country, had lower annual income and were not as highly educated. However, they were similar in age, race, marital status, and number of children in the home. Mosca's study is the most recently published report that has evaluated women's knowledge, perception and awareness of CHD in women. They compared their finding to previous surveys from 2000 and 1998 that showed that all three of these areas continued to improve.

More women in this study reported risk factors of high blood pressure and high cholesterol then in Mosca's (2004) study. However, a lower level of knowledge was seen of their actual LDL numbers (14% compared to 29%) and HDL numbers (14% compared to 26%). In this study, higher knowledge levels about heart disease being the leading

cause of death in women (65%) compared to Mosca (2006) that reported 55%. Interestingly, women in this study feared heart disease most (42%) compared to Mosca (16%), then breast cancer second (29%) compared to Mosca (48%). The findings of this study show a higher proportion that more accurately reflects factual information about CHD, but considerable further improvement is needed.

All responses to knowledge of heart attack symptoms in women were better in this sample; chest pain (92% compared to 62%), pain across shoulders, neck or arms (88% compared to 59%), shortness of breath (84% compared to 59%), tightness in chest (88% compared to 17%), nausea (56% compared to 16%) and fatigue (55% compared to 8%). Women who perceive pain to be a critical aspect of symptom recognition may fail to recognize a heart attack that is not accompanied by pain in the chest or upper torso regions.

Answers in the area of perception of heart disease prevention strategies were interesting. Responses that were preventative strategies were chosen less often than in Mosca's (2004) study, however, responses that were not proven preventative strategies (taking vitamins, taking hormone replacement therapy, reducing salt in diet, and aromatherapy) were chosen less in this study, indicating that this sample of women knew that they were not beneficial.

The women in this study reported that they did not feel they were as well informed; 29% compared to 40% who chose "very well" or "well" informed. The same number of women stated that they felt comfortable talking with their HCP about prevention and treatment options (93%), and encouragingly, an increased number of women stated they had discussed heart disease with their HCP (55% compared to 38%).

Clearly the proportion of women (45%) who have not discussed CHD risk with their primary HCP, leaves considerable room for improvement in primary prevention.

Limitations

This study has a number of limitations; this was a convenience sample obtained from two northern California counties, making generalizability limited to regions beyond Santa Clara and San Mateo county as this area of the country are well educated and an above average household annual income making these results skewed; in addition, 68% of subjects were Caucasian, therefore all ethnic groups were not represented equally; a cross sectional study design, while useful for describing the current level of perception and knowledge, does not allow for causal conclusions about observed relationships; protocol constraints at the Women's Health Clinic made it difficult to recruit as subjects could only be approached after their appointment resulting in some declining to participate due to prior commitments; and the outcome question asked in the questionnaire was ambiguous, not specifically stating that the women should answer in regards to their 10-year CHD risk and no their lifetime CHD risk.

#### Strengths

One the important new findings of this study is the comparison between the women's perception of their heart disease risk versus estimated 10 year risk of CHD as calculated by the FRS. It also shows a significant relationship between knowledge of CHD in women and correctly perceived risk. This is an important fact as educating women and providing them with resources to prevent CHD can make a difference. This study also continues to add to the research for women and heart disease.

*Implications for practice and research* 

The present study shows that knowledge, awareness and perception of CHD in this sample of women were in many aspects better than previously reported. One can reasonably hypothesize that this is in part due to the increased public education efforts launched in the news and television media. Confirmation of this impression would warrant a longitudinal prospective study design or at least a large national random sampling of women to be more representative of the population. This study also shows that opportunities for patient-HCP discussions could be increased. Providing nursing and medical education to increase assessment of women's risk in all settings is warranted as well. Continued education and awareness for women about heart disease being the leading cause of death, risk factors for CHD and atypical heart attack symptoms is essential at the national level as well as in the clinical setting. Sources of information for CHD in women that this sample cited most often in this study were magazines and newspapers, TV and radio. This implies that HCP can be active in public education by writing articles in women's journals and by speaking at public health information forums. In addition, effort to provide aggressive public education for women through the "GO RED FOR WOMEN" campaign should be supported and continued to make additional strides forward.

Even though this study has shown better knowledge levels, research needs to continue to evaluate knowledge, awareness and perception of CHD in women.

Reproducing this study in other ethnic groups, lower income groups and especially in those who are known to be at high risk is needed. Investigating confounding factors that contribute to the lack of knowledge about personal risk factors and heart disease in

general will continue to be necessary, especially when CHD is still the leading cause of death in women. Further research needs to also continue to determine barriers as to why some areas are not improving in prevention of CHD in women. Lastly, investigating reasons for under and over-estimation of risk would be essential as well to target education and risk factor modification.

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Appendix

# YOU ARE INVITED

# WOULD YOU LIKE TO KNOW MORE ABOUT YOUR RISK FOR HEART DISEASE?



### IF YOU ARE:

- A WOMAN
- 30 YEARS OLD OR GREATER
- HAVE NO HISTORY OF A HEART ATTACK
- HAVE NO HISTORY OF AN ANGIOPLASTY OR BYPASS SURGERY

THIS RESEARCH WILL ASSESS THE NEEDS OF WOMEN AND DIRECT FUTURE PROGRAMS FOR PREVENTION OF HEART DISEASE IN WOMEN.

WE WOULD LIKE TO ASK YOU TO TAKE A SHORT 10 MINUTE QUESTIONNAIRE WHILE YOU ARE HERE AT THE CLINIC.

A \$5 STARBUCK'S GIFT CARD AND A FREE CHOLESTEROL AND BLOOD PRESSURE TEST WILL BE GIVEN TO YOU FOR YOUR PARTICIPATION.

If you have any questions about the study, please feel free to contact research investigator Patience McCoy at 650-814-3221 (University of California, San Francisco

# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Perceived versus Actual Risk of Coronary Heart Disease in At Risk

This is a research study about comparing the difference between women's perception of their risk for heart disease and their actual risk for heart disease. The study researchers, Dr. James McCarrick III, MD and Patience McCoy, RN, ACNP, PhD graduate student from the University of California, San Francisco Department of Nursing will be conducting this research project.  Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.  You are being asked to take part in this study because you are over 30 years old, do not have documented coronary heart disease, and may/may not have risk factors associated with coronary heart disease.  Why is this study being done?  The purpose of this study is to understand more about women's perception of their coronary heart disease risk as well as their knowledge about coronary heart disease. This will provide information to health care providers to improve primary prevention in women who may be at risk for coronary heart disease.  It is a personally funded study without financial or proprietary interests to the researchers.  How many people will take part in this study?  About 90 women will take part in this research study?  If you agree, the following procedures will occur:  You will sign this consent form and answer a short perception questionnaire (American Heart Association (AHA)-Women's Health Study Survey) after your visit with your health care provider at the clinic.  Your consent form and questionnaire will be placed in the envelope provided and scaled after completed for privacy.  A chart review will be completed for varification of your risk factors (laboratory	Wome Are yo	n u participating in any other research studies?	□ Yes	□ No	
make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.  You are being asked to take part in this study because you are over 30 years old, do not have documented coronary heart disease, and may/may not have risk factors associated with coronary heart disease.  Why is this study being done?  The purpose of this study is to understand more about women's perception of their coronary heart disease risk as well as their knowledge about coronary heart disease. This will provide information to health care providers to improve primary prevention in women who may be at risk for coronary heart disease.  It is a personally funded study without financial or proprietary interests to the researchers.  How many people will take part in this study?  About 90 women will take part in this study who are volunteers from the Portola Valley Women's Clinic.  What will happen if I take part in this research study?  If you agree, the following procedures will occur:  You will sign this consent form and answer a short perception questionnaire (American Heart Association (AHA)-Women's Health Study Survey) after your visit with your health care provider at the clinic.  Your consent form and questionnaire will be placed in the envelope provided and sealed after completed for privacy.  A chart review will be completed for varification of your risk factors (laboratory	their ri Dr. Jan from th	their risk for heart disease and their actual risk for heart disease. The study researchers, Dr. James McCarrick III, MD and Patience McCoy, RN, ACNP, PhD graduate student from the University of California, San Francisco Department of Nursing will be			
have documented coronary heart disease, and may/may not have risk factors associated with coronary heart disease.  Why is this study being done?  The purpose of this study is to understand more about women's perception of their coronary heart disease risk as well as their knowledge about coronary heart disease. This will provide information to health care providers to improve primary prevention in women who may be at risk for coronary heart disease.  It is a personally funded study without financial or proprietary interests to the researchers.  How many people will take part in this study?  About 90 women will take part in this study who are volunteers from the Portola Valley Women's Clinic.  What will happen if I take part in this research study?  If you agree, the following procedures will occur:  You will sign this consent form and answer a short perception questionnaire (American Heart Association (AHA)-Women's Health Study Survey) after your visit with your health care provider at the clinic.  Your consent form and questionnaire will be placed in the envelope provided and sealed after completed for privacy.  A chart review will be completed for varification of your risk factors (laboratory	make y	our decision about participating, and discuss your decis	ion with your f		
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tests, physical exam results, medical history)	*	(American Heart Association (AHA)-Women's Healt visit with your health care provider at the clinic. Your consent form and questionnaire will be placed in sealed after <b>completed</b> for privacy.	th Study Survey	y) after your rovided and	

SUBJECT'S INITIALS\_\_\_\_

- \* The researchers will assess your risk of developing coronary heart disease.
- \* A phone contact will be made to provide you with your results of your perceived and actual test scores.
- \* If you are concerned about the results that are given to them, they will be given standard AHA information about risk factors and encouraged to contact your primary care provider if you have any questions.
- \* If your results show a high risk for coronary heart disease, we will give this information directly to your primary care provider, who can then follow up with you.

**Study location:** All these procedures will be done at your visit at Portola Valley Women's Clinic

# How long will I be in the study?

Participation in the study will take a total of about 15-20 minutes to complete a questionnaire, and about 10 minutes for the follow up phone call to inform you of your results.

### Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

# What side effects or risks can I expect from being in the study?

- Some of the questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer.
- For more information about risks and side effects, ask one of the researchers.

# Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about women's perception of their heart disease risk and how health care professionals can improve on heart disease prevention in women.

# What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

SUBJECT'S INITIALS
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### Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will **not** be used. Your information will be coded and kept in a secure, locked file with access only to **the researchers**. In the case of unanticipated loss of confidentiality of the research records, your insurability might be placed at risk.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include UCSF's Committee on Human Research.

### What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

# Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be given a \$5 Starbuck's coffee gift-card for taking part in this study. You will also receive an informational handout published by the American Heart Association on Women and Heart Disease.

# What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

# Who can answer my questions about the study?

You can talk to the researcher(s) about any questions or concerns you have about this study. Contact the researcher Patience McCoy at 650-814-3221 or <a href="mailto:patience.mccoy@ucsf.edu">patience.mccoy@ucsf.edu</a>. If you have any questions, comments, or concerns about taking part in this study, first talk to the researcher (above). If for any reason you do not wish to do this, or you still have concerns after doing so, you may contact the office of the Committee on Human Research, UCSF's Institutional Review Board (a group of people who review the research to protect your rights). You can reach the CHR office at 415-476-1814, 8 am to 5 pm, Monday through Friday. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

SUBJECT'S INITIALS\_\_\_\_\_

#### CONSENT

You have been given a copy of this consent form to keep.

If you wish to participate in this study, you should sign below.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

#### \*PATIENT BILL OF RIGHTS:

As a human subject, you have the following rights. These rights include but are not limited to the subject's right to:

- 1. Be informed of the nature and purpose of the experiment.
- 2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- 3. Be given a description of any attendant discomforts and risks reasonably to be expected.
- 4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- 5. Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits.
- 6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.
- 7. Be given an opportunity to ask questions concerning the experiment or the procedures involved.

- 8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice.
- 9. Be given a copy of the signed and dated consent form.
- 10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

\*YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Date

\*Person Obtaining Consent

Signature of Participant

I attest that the participant has been provided with the Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any

risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent	Date	
*Approval Date:February 14, 2008	Expiration Date:_February 14, 2009	

SUBJECT'S INITIALS\_\_\_\_\_

<sup>\*(</sup>To be filled in by investigator. See Approval Letter for dates.)

# American Heart Association WOMEN'S HEALTH STUDY

# **SUBJECTS FOR QUESTIONNAIRE**

	Screening and Demographics	S	
Section 2:	General Awareness of Wome	en's Health Issues	
Section 3:	Communications and Behaviors Related to Heart Disease Prevention		
Section 4:	Knowledge of Heart Disease	Among Women	
Section 5:	Heart Disease Prevention		
Estimated Sur	rvey Duration:	10-15 minutes	
SECTION 1: S	SCREENING		
information yo	ou have provided. <i>Please be a</i>	classification purpose to help us interpret the assured that all the information is collected be connected to you in any way.	
NAME:	CONTA	CT NUMBER:	
DOCTOR'S N			
DOCTOR'S P	HONE NUMBER (if known	) and/or CLINIC NAME:	
-	s your main ethnic or racial his LIST AND RECORD ONL		
-	LIST AND RECORD ONL  1 Caucasian		
-	LIST AND RECORD ONL  Caucasian  African-American		
-	LIST AND RECORD ONL  1 Caucasian 2 African-American 3 Asian		
-	1 Caucasian 2 African-American 3 Asian 4 American Indian		
-	1 Caucasian 2 African-American 3 Asian 4 American Indian 5 Hispanic		
-	1 Caucasian 2 African-American 3 Asian 4 American Indian		
Now I would I the information	1 Caucasian 2 African-American 3 Asian 4 American Indian 5 Hispanic 6 Other ike to ask you a few question you have provided. <i>Please</i>		
Now I would I the information collected for re	1 Caucasian 2 African-American 3 Asian 4 American Indian 5 Hispanic 6 Other ike to ask you a few question you have provided. <i>Please</i>	y ONE RESPONSE)  s for classification purpose to help us interpret  be assured that all the information is	

Q103	What is your current marital status?
	01 Single, never married
	02 Now married
	03 Living together, not married
	04 Divorced
	05 Separated
	06 Widowed
Q104	How many children do you have under the age of 18 living at home?
	01 None
	02 One
	03 Two
	04 Three
	05 Four
	06 Five
	07 Six
	08 More than six
Q105	What is the highest level of education you have completed?
	01 Some high school or less
	02 High school graduate
	03 Some college
	04 2-year college graduate
	05 4-year college graduate
	06 Post graduate study
Q106	What is the total annual income before taxes of everyone living in the household?
	01 Under \$20,000 a year
	02 \$20,000 to less than \$35,000
	03 \$35,000 to less than \$50,000
	04 \$50,000 to less than \$75,000
	05 \$75,000 to less than \$100,000
	06 \$100,000 to less than \$150,000
	07 \$150,000 to less than \$200,000
	08 \$200,000 or more a year

# SECTION 2: GENERAL AWARENESS OF WOMEN'S HEALTH ISSUES

[SINGLE RESPONSE]

**Q001** What do you think is the one greatest health problem facing women today?

	01	AIDS
	02	Alzheimer's
	03	Breast cancer
	04	Cancer (general)
		Diabetes
	06	Drug addiction/alcoholism
		Heart disease/heart attack
	08	Lung cancer
		Osteoporosis
		Smoking
		Stroke
		Other
		Don't know
O002	As far as y	you know, what is the leading cause of death for all women?
•	-	RESPONSE]
		Accidental death
	_	AIDS
	_	Alzheimer's
	04	Breast cancer
		Cancer (general)
		Diabetes
	07	Drug addiction/alcoholism
		Heart disease/heart attack
	09	Lung cancer
		Osteoporosis
		Smoking
	12	Stroke
	13	Violent crime
	99	Don't know
Q003	Please place	ce in order which disease you worry most about (1-5).
	a	Heart disease or heart attack
	b	Breast cancer
	c	Lung cancer
	d	Stroke
	e	Diabetes

# SECTION 3: COMMUNICATIONS AND BEHAVIORS RELATED TO HEART DISEASE PREVENTION

I would now like to ask you several questions about heart disease.

# **Q004** HAVE YOU SEEN, HEARD, OR READ INFORMATION ABOUT WOMEN AND HEART DISEASE WITHIN THE PAST 12 MONTHS?

Have you seen, heard, or read information about heart disease within the past 12 months?

- 01 Yes
- 02 No
- 99 Don't know
- \*\* IF YOU HAVE SEEN, HEARD, OR READ INFO ABOUT HEART DISEASE WITHIN PAST 12 MONTHS CONTINUE.
- \*\* ALL OTHERS JUMP TO Q007.

### <u>HAVE SEEN, HEARD, OR READ INFORMATION ABOUT HEART DISEASE</u> <u>WITHIN PAST 12 MONTHS</u>

Q005 Where did you see, hear or read this information? MULTIPLE RESPONSES okay

- 01 In a magazine
- 02 On the radio
- 03 In a book
- 04 On TV
- 05 Information in a brochure
- 06 Provided by physician, nurse or other healthcare professional
- 07 In a newspaper
- 08 On the Internet or World Wide Web
- 09 From a friend or relative
- 10 Library
- 98 Other
- 99 Don't know

**Q006** Have any of your doctors ever discussed heart disease with you when discussing your health?

- 01 Yes
- 02 No
- 99 Don't know

Q007	How inform	ned are you about heart disease in women? Would you say you are:
	01	Very well informed
		Well informed
		Moderately informed
		Not at all informed
	99 ]	Don't know
Q008	In the past 1	18 months, have you had your blood pressure checked?
	01	Yes
	02	No
	99	Don't know
** IF ]	HAVE HAD	BLOOD PRESSURE CHECKED IN PAST 18 MONTHS
	ΓINUE	
** AI	LL OTHERS	JUMP TO Q010
HAVI	F HAD RLO	OD PRESSURE CHECKED IN PAST 18 MONTHS
	E HAD BEO	OD I RESSURE CHECKED IN LAST IS MONTHS
Q009	When you h	nad it checked last, were you told the result was normal, too high, or
too lov	w?	
		(please write in Blood pressure)
	01	Normal
		Too high on medication
		Γοο high not on medication
		Γοο low
	99	Don't know
Q010	In the past 1	18 months, have you had your cholesterol level checked?
	01	Yes
	02	No
	99	Don't know

- \*\* IF HAVE HAD CHOLESTEROL LEVEL CHECKED IN PAST 18 MONTHS CONTINUE
  \*\* ALL OTHERS JUMP TO Q015

# HAVE HAD CHOLESTEROL LEVEL CHECKED IN PAST 18 MONTHS

Q011 too low	When you had it checked last, were you told the result was normal, too high, or ?
	<ul> <li>01 Normal</li> <li>02 Too high on medication</li> <li>03 Too high not on medication</li> <li>04 Low</li> <li>99 Don't know</li> </ul>
Q012	Do you know what your <b>total cholesterol</b> level is?
	01 Yes(please write in) 02 No 99 Don't know
Q013	Do you know what your <b>HDL</b> or "good" cholesterol level is?
	01 Yes(please write in) 02 No 99 Don't know
Q014	Do you know what your <b>LDL</b> or "bad" cholesterol level is?
	01 Yes(please write in) 02 No 99 Don't know
	Are you currently taking HRT (hormone replacement therapy) or ERT (estrogen ment therapy)?
	01 Yes 02 No 99 Don't know
	OT CURRENTLY TAKING HRT/ERT GO TO Q016. COTHERS JUMP TO Q017.

#### NOT CURRENTLY TAKING HRT

- **Q016** Why did you stop taking HRT (hormone replacement therapy) or ERT (estrogen replacement therapy)? **MULTIPLE RESPONSES okay** 
  - 01 My doctor recommended I stop taking it
  - 02 The risks of complications were greater than the benefit
  - 03 Heard about new research showing no benefit and it may be harmful
  - 04 I decided to stop taking it
  - 05 Couldn't afford the long-term costs of the therapy
  - 06 Side effects
  - 07 Worst of menopausal symptoms have passed/no longer need the therapy
  - 08 Switched to other medications
  - 09 Taking herbal remedies instead
  - 10 I never started taking it
  - 96 Other
  - 98 Don't know
  - 99 Refused
- **Q017** Have you been diagnosed with diabetes?
  - 01 Yes
  - 02 No
  - 99 Don't know
- **Q018** Have you ever had a heart attack?
  - 01 Yes
  - 02 No
  - 99 Don't know
- **Q019** Below is a list of statements about smoking cigarettes. Please tell me which best describes your experience with smoking cigarettes.
  - 01 I have never smoked
  - 02 I used to smoke, but successfully quit
  - 03 I smoke, but not every day
  - 04 I smoke less than 10 cigarettes a day
  - 05 I smoke 10 or more cigarettes, but less than 1 pack a day
  - 06 I smoke 1-2 packs of cigarettes a day
  - 07 I smoke more than 2 packs a day
  - 99 Don't know

**Q020** Do you have a close family member (parents, brother, sister) that has had coronary heart disease or a stroke before the age of 55 (male) or 65 (female)?

01 Yes

02 No

99 Don't know

# SECTION 4: KNOWLEDGE OF HEART DISEASE AMONG WOMEN/BEHAVIORS ASSOCIATED WITH PREVENTION

Q021 For each one, please tell me whether you believe the statement is true or false.

RECORD ONE RESPONSE FOR EACH NEXT TO THE STATEMENT

	1 2 99	
	True False Don't know	
a	Heart disease is the leading cause of death in women	
b	Once men are diagnosed with heart disease, they are more likely than women to become seriously ill or die.	
c	The loss of estrogen is a significant contributor to the development of heart disease in women following menopause.	
d	Heart disease develops gradually over many years and can easily go undetected	
e	Black women are more likely than white women to die from a heart attack or stroke	
f	Men are more likely than post menopausal women to have heart attacks	
g	Men and women experience the same symptoms of a heart attack.	
h	Women are more likely than men to have unusual or atypical symptoms of a heart attack	
i	In the first few hours after the onset of heart attack or stroke symptoms treatments exist that can take care of the blood clots to reduce the damage	٠,

**Q022** Please tell me if you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with each statement.

### RECORD ONE RESPONSE FOR EACH NEXT TO THE STATEMENT

1	2	3	4	99	
Strongly	Agree	Disagree	Strongly	Don't know	
Agree			Disagree		
a	a When I think of heart disease, I most often think of someone h heart attack and dying quickly.				
b	l information about				
<ul> <li>c By taking estrogen replacement therapy, I can help reduce m heart disease.</li> <li>d There is nothing I can do to help prevent myself from getting disease.</li> <li>e I am comfortable talking with my health care provider about preventive and treatment options regarding my health.</li> <li>f. I would like for my health care provider to talk with me about prevention of heart disease.</li> </ul>				elp reduce my risk for	•
				from getting heart	
				with me about	
g.	I am at low risk fo	r a heart attack	or stroke for a	woman my age.	
Rased on v	what you know wh	at warning sign	s do vou assoc	riate with having a	

**Q023** Based on what you know, what warning signs do you associate with having a heart attack?

# MULTIPLE RESPONSES okay

- 01 Chest pain
- 02 Fatigue
- 03 Nausea
- 04 Pain that spreads to the shoulders, neck, or arms
- 05 Shortness of breath
- 06 Tightness of the chest
- 98 Other
- 99 Don't know

# Q024 Based on what you know, what are the major contributors to heart disease? MULTIPLE RESPONSES okay

- 01 A family history of heart disease
- 02 Aging
- 03 Being overweight
- 04 Diabetes
- 05 Drinking alcohol
- 06 High blood pressure
- 07 High cholesterol
- 08 High triglycerides
- 09 Low levels of estrogen
- 10 Menopause
- 11 Not exercising
- 12 Smoking
- 13 Stress
- 14 Stroke
- 15 Your racial heritage
- 98 Other
- 99 Don't know

#### **SECTION 5: HEART DISEASE PREVENTION**

**Q025** Which of the following activities do you believe can prevent or reduce the risk of getting heart disease?

### **MULTIPLE RESPONSES okay**

- 01 Quitting smoking
- 02 Getting physical exercise
- 03 Taking special vitamins like E, C or A
- 04 Losing weight
- 05 Reducing dietary cholesterol intake
- 06 Reducing stress
- 07 Taking hormone replacement therapy
- 08 Reducing sodium or salt in the diet
- 09 Reducing animal products in your diet (such as meat, whole milk, butter and cream)
- 10 Aromatherapy
- 11 None of the above
- 99 Don't know

# YOU ARE INVITED

#### **WOULD YOU LIKE TO KNOW MORE ABOUT YOUR RISK FOR HEART DISEASE?**



#### IF YOU ARE:

- A WOMAN
- 30 YEARS OLD OR GREATER
- HAVE NO HISTORY OF A HEART ATTACK
- HAVE NO HISTORY OF AN ANGIOPLASTY OR BYPASS SURGERY

THIS RESEARCH WILL ASSESS THE NEEDS OF WOMEN AND DIRECT FUTURE PROGRAMS FOR PREVENTION OF HEART DISEASE IN WOMEN.

WE WOULD LIKE TO ASK YOU TO TAKE A SHORT 10 MINUTE QUESTIONNAIRE IN YOUR LIFE GROUP. ANNOUNCEMENTS WILL BE MADE IN THE UPCOMING WEEKS. IF YOU DO NOT PARTICIPATE IN A LIFE GROUP AND ARE INTERESTED IN THE STUDY, PLEASE CONTACT PATIENCE MCCOY.

A \$5 STARBUCK'S GIFT CARD AND A FREE CHOLESTEROL AND BLOOD PRESSURE TEST WILL BE GIVEN TO YOU FOR YOUR PARTICIPATION.

If you have any questions about the study, please feel free to contact research investigator Patience McCoy at 650-814-3221 (University of California, San Francisco)

### UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** Perceived versus Actual Risk of Coronary Heart Disease in At Risk Women

This is a research study about comparing the difference between women's perception of their risk for heart disease and their actual risk for heart disease. The study researchers, Dr. Erika Froelicher, RN, PhD and Patience McCoy, RN, ACNP, PhD graduate student from the University of California, San Francisco Department of Nursing will be conducting this research project.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers. You are being asked to take part in this study because you are over **30** years old, do not have documented coronary heart disease, and may/may not have risk factors associated with coronary heart disease.

#### Why is this study being done?

The purpose of this study is to understand more about women's perception of their coronary heart disease risk as well as their knowledge about coronary heart disease. This will provide information to health care providers to improve primary prevention in women who may be at risk for coronary heart disease.

It is a personally funded study without financial or proprietary interests to the researchers.

#### How many people will take part in this study?

About 90 women will take part in this study who are volunteers from the First Baptist Church Los Altos and Mission Hospice.

# What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- \* You will sign this consent form and answer a short perception questionnaire (American Heart Association (AHA)-Women's Health Study Survey) after the study is fully explained to you by Patience McCoy.
- \* Your consent form and questionnaire will be placed in the envelope provided and sealed after completed for privacy.
- \* A cholesterol screening test (fingerstick) and a blood pressure will be completed for those who have not had one by the researchers who are registered nurses.
- \* The researchers will assess your risk of developing coronary heart disease.
- \* A phone contact will be made to provide you with your results of your perceived and actual test scores.
- \* If you are concerned about the results that are given to them, they will be given standard AHA information about risk factors and encouraged to contact your

1-15-08

- primary care provider if you have any questions.
- \* If your results show a high risk for coronary heart disease, we will give this information directly to your primary care provider, who can then follow up with you.

**Study location:** All these procedures will be done at your visit at First Baptist Church Los Altos or Mission Hospice.

**How long will I be in the study?** Participation in the study will take a total of about 15-20 minutes to complete a questionnaire, and about 10 minutes for the follow up phone call to inform you of your results.

**Can I stop being in the study?** Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

### What side effects or risks can I expect from being in the study?

- Some of the questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer.
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Will information about me be kept private? We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your information will be coded and kept in a secure, locked file with access only to the researchers. In the case of unanticipated loss of confidentiality of the research records, your insurability might be placed at risk.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include UCSF's Committee on Human Research.

1-15-08

What are the costs of taking part in this study? You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study? In return for your time, effort and travel expenses, you will be given a \$5 Starbuck's coffee gift-card for taking part in this study. You will also receive an informational handout published by the American Heart Association on Women and Heart Disease.

What are my rights if I take part in this study? Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

### Who can answer my questions about the study?

You can talk to the researcher(s) about any questions or concerns you have about this study. Contact the researcher Patience McCoy at 650-814-3221 or <a href="mailto:patience.mccoy@ucsf.edu">patience.mccoy@ucsf.edu</a>. If you have any questions, comments, or concerns about taking part in this study, first talk to the researcher (above). If for any reason you do not wish to do this, or you still have concerns after doing so, you may contact the office of the Committee on Human Research, UCSF's Institutional Review Board (a group of people who review the research to protect your rights).

You can reach the CHR office at 415-476-1814, 8 am to 5 pm, Monday through Friday.
Or you may write to: Committee on Human Research, Box 0962, University of
California, San Francisco (UCSF), San Francisco, CA 94143.

#### **CONSENT**

You have been given a copy of this consent form to keep.

If you wish to participate in this study, you should sign below.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

Date	Participant's Signature for Consent	
Date	Person Obtaining Consent	1-15-08

COMMETTEE ON HUMAN RESEARCH
104 ICE OF RESEARCH, INSURA UNIVERSITY OF CALTICATIA, SAN BRANCESCO WHYDROGRAD, ASIGN SCIENA, INJURY APPROVED ASIGN SET (H 25 of 24) (H 24-75-1811)

#### CHR APPROVAL LETTER

TO: Prika 5, Prodictor, Ph.D., R.N.

Perfence McCoy, Pn D Box 9806

Box 0610

RE: Perceived versus Actual Risk of Coronary Heart Disease in Women

The Committee on Human Research (CFR) has reviewed and approved this application to involve humans as research subjects. This included a review of all decuments attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents: Consent Form, Dated 11/13/07

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates, UCSF holds Office of Haniar, Revench Protections Pederalwide Assurance number I'W A00000568. See the CHR website for a list of other applicable FWA/s

**APPROVAL. NUMBER:** H7556-3]8<u>60-01</u>. This combes is a UCSF CTR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: February 1, 2008 EXPIRATION DATE: December 18, 2008 Expedited Review

GENERAL CONDITIONS OF APPROVAL: Please refer to covernessero most led with Approval Conductor for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration fate if work is to confinue. Also, prior CUR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (4SCFR164) and Common Rule (4SCFR46-116(d)): This study has been greated a waiver of consent-authorization for research for use and/or disclosure of Prosected Has life for intraction (PHI).

Signardy,

Diane W. Wara, MD

Vice Chair, Committee on Human Research

cc: Carrier Mattheward Control

#### PALO ALTO MEDICAL FOUNDATION RESEARCH INSTITUTE

Ames Building, 795 El Camino Real, Palo Alto, CA 94301 - (650) 853-4825 - Fax 850-853-2805

#### Institutional Review Board

#### Approval Notification

Rende Strond PhD

To: James McCarrick, M.D., Principal Investigator

From: Rita French. Ph.D., Chair Institutional Review Board

Cc: Patience McCoy, Ph.Dc., Cc-Investigator

Barbara Anderson, Clinical Research Manager

Date: February 20, 2008

Re: Protocol #08-2: "Perceived versus Actual Risk of Coronary Heart Disease in

Women."

The Committee reviewed and approved the initial submission of the above referenced protocol at its meeting on February 14, 2008.

This protocol and the informed consent(s), and if applicable, questionnaires or other attachments, have been approved for a period of <u>12</u> months.

Expiration Date of approval: February 14, 2009

Sponsor/ Funding Agency: No External Funding

If this proposal is used in conjunction with any other human experimentation, or if it is modified in any way, it must be re-approved for these special circumstances. Note that the following should be reported to the IRB: 1) all serious adverse events occurring here or at other institutions, regardless of whether or not the events are thought to be study related; 2) any unanticipated problems; and/or 3) any injuries to subjects enrolled here.

All continuing projects and activities must be reviewed and reapproved at least annually by the Committee. If this project is to continue beyond the expiration date, the investigator must submit a renewal request for approval by the Committee prior to the expiration date. In any event, no new patients may be enrolled in a study for which the approval date has expired.

At the completion of the project or study, a termination report must be filed with the Committee, in order to comply with FDA regulations.



# First Baptist Church

Mrs. Patience McCoy.

I am writing to offer my support for Mrs. McCoy's research proposal. Her work is significant and highly important. The findings from this study have the potential to significantly improve the cardiovascular health of women. I and my staff will offer our full support to Mrs. McCoy. We have approximately 100 women in our church who are 30 years or older that will help Mrs. McCoy to be able to obtain the sample size she needs.

Sincerely-

Pastor Randy Wilson

Senior Pastor

Mission Hospice 1900 O'Farrell Street Ste. 200 San Mateo, CA 94403 650-554-1000

Mrs. Patience McCoy,

I am writing to offer my support for Mrs. McCoy's research proposal. Her work is significant and highly important. The findings from this study have the potential to significantly improve the cardiovascular health of women. Myself and my staff will offer our full support to Mrs. McCoy.

Sincerely-

Linda Wohlrabe Executive Director

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