UNIVERSITY OF ALBERTA

Cardiovascular Risk Factor Management - Current Practice

by:

Marion Barnes

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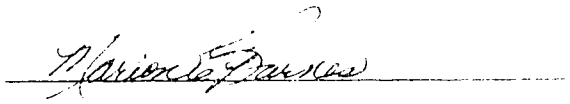

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled "Cardiovascular Risk Factor Management - Current Practice" submitted by Marion E. Barnes in partial fulfilment of the requirements for the degree of Master of Science in Nutrition and Metabolism.

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ABSTRACT

Previous research has suggested the existence of gender bias in the investigation and management of coronary heart disease (CHD). This study investigated and compared current patterns of practice for assessment and management of cardiovascular risk factors in female (n=198) and male (n=199) subjects with clinically manifest coronary heart disease (CHD) using retrospective analysis of medical records. Subjects were from one hospital-based and four community-based outpatient clinics in the greater Edmonton area. Physician-generated portions of the medical record over a consecutive 12 month period between 1991 and 1993 were reviewed for documentation of CHD risk factors, serum lipid evaluations, and evidence of lipid-lowering activities and other CHD risk-factor interventions as recommended by national consensus guidelines. The primary null hypothesis of no difference in documented CHD risk factor assessment and intervention rates between females and males was tested by univariate and multivariate statistical techniques.

Overall, results revealed documentation of risk factors to be inconsistent and infrequently complete. Forty-six percent of charts contained no mention of lipid status; references to the presence or absence of diabetes or of a family history of cardiovascular disease were absent in 34% of cases. Contrary to the primary null hypothesis, however, risk factors were documented with approximately equal frequency for female and male subjects. In contrast, risk factors were documented significantly less often for subjects aged ≥70 years than for younger subjects.

On multivariate analysis, significant predictors of lipid-lowering diet and/or drug interventions were male gender, younger age (<70 years), and a positive history of dyslipidemia. Documented utilization of lipid-lowering and other risk factor interventions, however, was low. Smoking cessation counselling was noted for 24%

of current smokers, lipid-lowering dietary and drug therapy were documented for only 43% and 21% of subjects, respectively.

The results of this study indicate comprehensive risk factor assessments are infrequently documented for patients with established CHD and at high risk of subsequent vascular events. The data further suggest use of risk management strategies, as recommended by expert consensus panels, is suboptimal. Moreover, the results reveal age-based differences in patterns of care which are inconsistent with current consensus guidelines. Confirmation of these initial patterns of practice is required in a broad patient base. If confirmed, direct interventions, for example, explicit guidelines developed in cooperation with practitioners at the local level, are indicated to improve risk management practices and enhance patient outcomes.

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CHAPTER I

INTRODUCTION

Cardiovascular diseases (CVD), including ischemic heart disease, stroke, and peripheral vascular disease, continue to be the leading cause of death in Canada and other Western industrialized societies. Recent figures indicate that 75,089 Canadians, (36,266 women and 38,823 men), died as a result of CVD in 1990, 39% of all deaths in that year [1]. Ischemic heart disease, the largest single component of CVD, was responsible for 23% of total mortality, only slightly less than the proportion attributable to all forms of cancer combined (27%) [1]. The major clinical manifestations of ischemic heart disease, most often a result of coronary atherosclerosis, are also major contributors to morbidity and to the total costs of illness, accounting for approximately 37% of all CVD-related hospital admissions, and 60% of disability pensions for CVD paid to individuals up to age 65 [1,2].

Although ischemic heart disease morbidity and mortality rates in North America remain high [3], death rates for both women and men have been declining in Canada and the United States since the mid-1960s [1,3,4,5]. Whether this is due to a true decrease in the incidence of acute ischemic events, to improved short- and longer-term survival post-event, or to a combination of the two remains controversial [6-10]. According to recent estimates however, between 50% and 70% of the observed reduction in ischemic heart disease mortality may be attributed to modification of risk factors for coronary atherosclerosis and atherosclerotic coronary

heart disease (CHD), particularly the major modifiable risk factors: smoking, dyslipidemia, and hypertension [11-15].

That modification of risk factors for CHD can influence the process of atherosclerosis to delay or prevent first or recurrent cardiovascular events is supported by congruent data from descriptive and observational epidemiologic studies, animal and experimental research, and randomized clinical trials [16-21]. In recognition of the strength and consistency of the accumulated evidence, expert panels have developed consensus documents which summarize the rationale for reducing risk factor levels, and define recommended practices for a patient-based approach to the identification, evaluation and management of CHD risk factors [22-29].

While not all consensus groups have endorsed the concept of universal risk factor screening, particularly of serum cholesterol levels, there is agreement that targeted screening and more aggressive management of high risk population groups are warranted [22-29]. Patients with established CHD are recognized as being at greatest risk for future cardiovascular events, as their relative risk is five to seven times higher than for individuals of similar age without a history of CHD [36,37]. Furthermore, a history of prior CVD doubles risk for dying of an acute cardiovascular event. As a consequence of this high risk status, individuals with CHD are identified in Canadian [23], and other consensus reports [24, 26-35] as a priority target for comprehensive risk factor evaluation and intensive intervention efforts [23-26].

During the last decade, reports of the major North American consensus

conferences [24-26], and implicit practice guidelines formulated by other groups [27-35], have been widely disseminated and promoted within the medical community [38-41]. Substantial increases in physicians' awareness of the importance of CHD risk factors, and knowledge of recommended risk factor management practices have occurred in association with these promotional efforts [42,43], yet the true impact of published recommendations on routine clinical practice remains unclear. This is particularly true with respect to management of risk factors among patients with proven CHD. Anecdotal experience and patterns of practice studies completed up to two years after release of the major consensus recommendations suggest a continuing lack of attention, by both specialist and generalist physicians, toward potentially modifiable risk factors in this high-risk patient group [37,44-47]. While it can be argued that these studies reflected the early part of the learning curve, or slow dissemination of consensus recommendations, investigations into the impact of consensus recommendations in other areas of medicine have demonstrated that significant gaps between actual physician practices and published guidelines persist over time, despite physicians' stated acceptance of the concepts contained in guidelines [48]. Whether such gaps between knowledge and practice continue to exist for management of risk factors in patients with CHD is currently unknown. Also unknown is whether specialist physicians, typically responsible for episodic care of patients with CHD, and generalist physicians, more often responsible for continuing care, differ in the extent to which they apply published recommendations for CHD risk factor management.

Characteristics of the patient may also influence physicians' practice

patterns. In particular, the patient's gender may colour a physician's perception of risk for adverse CHD events, and can affect patterns of investigation and therapy [11]. Gender-bias has been cited as a contributing factor in several studies where coronary disease was investigated and/or treated differently in women as compared to men [49]. To date, no studies have specifically examined the issue of gender-based differences in the assessment and management of coronary risk factors among patients with CHD. In view of existing evidence that both women and men with proven CHD can derive substantial benefits from aggressive risk lowering interventions [46,50], it is important to investigate the level of priority physicians ascribe to the evaluation of risk factors in both female and male patients, and assess whether all patients at risk are provided equal access to therapeutic options.

A. FACTORS OF RISK AND THEIR MODIFICATION

The risk factor concept has evolved largely from epidemiological evidence relating suspected predisposing factors to the subsequent development of CHD and other atherosclerotic diseases [51]. As proposed in the Framingham study, "factors of risk" are those factors associated with the occurrence of a disease or condition, and which are suspected of playing causal roles [51,52].

Factors associated with increased risk for first and subsequent CHD events can be classified as non-reversible determinants of risk, i.e. age, gender and genetic predisposition, and modifiable risk factors. The latter include the "established major risk factors," i.e. smoking, dyslipidemia, and hypertension [53,54], and important secondary or contributing factors, including diabetes, obesity,

and physical inactivity. These modifiable risk factors have been shown to be responsive to clinical interventions, and are identified in the consensus recommendations as major targets for risk reduction efforts [23,24]. Recently, the importance of estrogen status to risk for CHD events in women has also been recognized [50].

Non-reversible Determinants of Risk

Increasing Age

Of all factors known to be associated with overt atherosclerotic coronary disease, advancing age is the strongest predictor of CHD morbidity and mortality [55,56]. This holds for both genders and all population groups studied [1]. However, while the aging process itself cannot be significantly altered, the fact that the recent decline in North American CHD mortality rates has included the oldest age groups suggests overt CHD is not an inevitable consequence of aging [56-58].

Kannel [56] has suggested the higher incidence of cardiovascular events associated with increasing age may be due to a longer exposure to modifiable CHD risk factors, coupled with a diminished physiologic capacity to cope with these factors. In this case, decreased lifetime exposure to modifiable risk factors may reduce rates of CHD morbidity and mortality from those currently seen in the older age groups. There is also evidence that risk factor modification, even when initiated late in life, may reduce the risk for adverse cardiovascular events and need for hospitalization, [59-61], thereby prolonging "active life expectancy" [62] and maximizing quality of life [57].

Gender

Male gender is considered a significant risk factor for overt CHD, particularly "premature" CHD, traditionally characterized as symptom onset prior to age 55-60 years [63]. In all populations studied, the age-standardized CHD mortality rates for men are higher than those for women [1,64], with the highest degree of gender difference occurring among those under age 55 [1].

Despite higher age-standardized CHD mortality rates for men, in absolute terms, CHD kills or disables nearly as many women as men, due a narrowing of the gender gap in incidence and mortality with increasing age [65], and the higher proportion of women in the oldest age groups [1]. It also must be recognized that the relative immunity to CHD for younger women is not universal; premature menopause, [66], the presence of diabetes [67,68], and cigarette smoking [69,70] may significantly diminish or abolish the CHD risk differential between women and men in the younger age groups. The occurrence of AMI also negates the relative advantage associated with female gender; women and men have a similar prognosis post-infarction [50].

Genetic Factors / Family History

Genetic predisposition is widely accepted as a strong determinant of risk for CHD development [71-73]. Although some investigators [74-75] have suggested the tendency for CHD to cluster within family groups is a result of "cultural heritability," i.e. the sharing of environmental factors within family groups, rather than specific high-risk genes, studies in twins and pedigrees indicate that one-fifth

to one-half of the variability in atherogenic traits, including serum lipids, blood pressure, and obesity, may be attributable to genetic factors [76].

Williams and colleagues [77] have determined that men aged 20-39 with a strong family history of early CHD (two or more first-degree relatives with CHD onset prior to age 55) have a relative risk of 12.7 for development of CHD compared to those without this family history. In women aged 40-49, this family history is associated with a relative risk for CHD of 12.9. While only 2%-6% of adults in the general population are estimated to have such a strong genetic predisposition, they appear to account for up to 50% of early CHD events [77]. Aggressive interventions to control modifiable cardiovascular risk factor levels can delay the onset and progression of clinical CHD even in these genetically predisposed individuals [77,78].

Modifiable Risk Factors

Cigarette Smoking

The association between cigarette smoking and adverse coronary events in men has been recognized for many years [79]. Early observational studies of male subjects indicated smokers to have a 70% greater risk of CHD death compared to nonsmokers, with the heaviest smokers (two or more packs per day) experiencing CHD mortality rates 200%-300% higher than those who have never smoked [80,81]. More recent studies have confirmed that a positive relationship also exists between smoking and CHD in women, with risk for CHD events among those who regularly

smoke being generally comparable to those of men [82-85]. The association between smoking and cardiovascular risk also appears to persist into the older age groups. Data from the Established Populations for Epidemiologic Study of the Elderly, involving people over age 65, indicate the relative risk of cardiovascular mortality associated with regular smoking is 2.0 and 1.5 among male and female smokers respectively [86].

The health benefits of smoking cessation have been demonstrated repeatedly both for individuals without known CHD [82,87], and among those with manifest disease [88-91]. Intervention studies in subjects with established CHD have reported a 40%-50% reduction in risk for recurrent coronary events and CHD mortality for individuals who quit smoking following a coronary event relative to those who quit only temporarily, or continued to smoke [88,89].

Although the prevalence of smoking has been declining since the mid-1960s, the Canadian Heart Health Surveys, completed in 1990, indicate smoking continues to be a widespread health-risk behaviour among Canadian adults. Twenty-nine percent of adults surveyed reported regular cigarette smoking; another 4% admitted to occasional smoking [92]. Prevalence rates were similar between men and women, although men reported a higher average daily cigarette consumption [92]. According to U.S. estimates, 70%-75% of smokers visit a physician at least once a year, and, on average, every American adult has five physician contacts per year [89]. Thus, physicians potentially represent an important channel for smoking cessation interventions. A number of trials have demonstrated that physician-delivered interventions can successfully modify smoking behaviour, particularly

when the antismoking message is repeated and positive behaviour changes reinforced over a period of time [93-98]. Physicians' antismoking counselling efforts have been associated with smoking cessation rates ranging from 6.6% in the general population [99], to 50% to 60% among post-MI patients or individuals newly diagnosed with CHD [100-102] Maintaining physicians' motivation to counsel patients however, has often been cited as a problem [99].

Serum Cholesterol

Data from observational studies, animal experiments, studies in molecular biology and genetics, and clinical trials [21,103-112] support the hypothesis that increased serum concentrations of total cholesterol and low-density lipoprotein (LDL) cholesterol, and reduced levels of high-density lipoprotein (HDL) cholesterol, are important etiological factors in the pathogenesis of coronary atherosclerosis and development and progression of CHD [28]. Prospective studies have further shown that cholesterol levels are exponentially related to risk for CHD; higher cholesterol levels are associated with increased CHD risk [113,114]. This relationship is not confined to individuals with cholesterol levels exceeding a certain threshold, rather it appears continuous over a range of initial cholesterol levels [115]. Inversely, favourable effects on CHD risk have been demonstrated by randomized, controlled clinical trials of lipid-lowering interventions [112,116]. Strong associations have been found between CHD endpoints and elevated serum triglycerides in some studies; however, a causal relationship has not been conclusively demonstrated [117].

Impact of Lipid Lowering Therapy

Aggregate data from recently published randomized clinical intervention trials indicate changes in lipid concentrations, particularly reductions of serum LDL cholesterol levels and increase in HDL cholesterol concentrations, are accompanied by reductions in risk for CHD events. Although individual trials show variable results, taken overall, the effect of lipid-lowering interventions appears consistent with a beneficial effect on the process of atherosclerosis, both in ostensibly healthy individuals (primary prevention), and in those with established CHD (secondary prevention) [118-122]. In trials with angiographic endpoints [123-129], sustained reductions in LDL cholesterol levels among actively treated subjects have been associated with a reduced frequency of progression of atherosclerotic lesions relative to control subjects; regression of existing lesions, defined as an increase in arterial lumen diameter at a point of atherosclerotic narrowing [130] has also been observed in a small proportion of subjects [123-129]. Even though the absolute magnitude of arteriographic changes has, in most studies been small, significant reductions in clinical events have been recorded for actively treated, versus control, subjects [124]. Analysis of these angiographic trials indicates that increasing benefits in terms of CHD risk reduction accrue from larger, and longer, reductions in serum cholesterol levels [119]. In most of the earlier trials, a sustained period (2 or more years) of reduced cholesterol concentrations was required for detectable changes in lesion progression or CHD event rates to occur [131]. More recent studies using HMG-CoA reductase inhibitors to lower serum LDL cholesterol concentrations raise the possibility that substantial reductions in CHD events may

be achieved much more rapidly, possibly in as short a period as 6 months [132,133]. The mechanism for such a rapid response has not been determined, but may involve the reestablishment of normal endothelial cell function as LDL cholesterol concentrations fall [133].

Clinical trials have also demonstrated that the method used to achieve cholesterol reduction, whether diet or drug therapy, alone or in combination, [123-127,129], or a surgical intervention [128], is a less critical factor than the degree and duration of lipid lowering attained [119].

The impact on CHD event risk of therapy which increases serum levels of HDL cholesterol has not yet been specifically demonstrated in a randomized trial, although several studies have reported associations between reductions in coronary event rates and changes in the ratio of HDL cholesterol to total and/or LDL cholesterol [129,133,134]. The issue is of considerable importance, particularly in relation to secondary prevention of CHD, as a low level of HDL cholesterol is the primary lipid abnormality in an estimated 20% to 30% of individuals with established coronary disease [136]. At least two randomized, placebo-controlled clinical trials designed to evaluate the effect raising HDL cholesterol levels on CHD event risk are currently underway: the High-Density Lipoprotein Cholesterol Intervention Trial (n=2500) [137], and the Bezafibrate Infarction Prevention Study (n=3000) [138]. The final results of these studies however, will not be available before 1998.

Effectiveness of Lipid Lowering Therapy

While there is extensive support from clinical trials data for the efficacy of

lipid-lowering interventions to reduce CHD risk, only a few studies have assessed the effectiveness of lipid-lowering interventions in the context of routine clinical practice. The Clinical Experience Network [139] recently reported that combined diet, exercise and pharmacologic interventions achieved significant decreases in total cholesterol and LDL cholesterol values, and an increase in HDL cholesterol levels, among 641 dyslipidemic patients drawn from a heterogeneous family practice population. A second study, involving 543 patients with high-risk lipid profiles from a large cardiology practice, demonstrated that a lipid management program based on the U.S. National Cholesterol Education Program (NCEP) guidelines [24] can effectively lower serum lipid levels in a private specialty practice setting [140].

Lipid-lowering Interventions in Women

Considerable emphasis has been placed on the fact that women (and the elderly, many of whom are women) have not been included in the major primary prevention trials; women have also been largely excluded from secondary prevention studies. This has led some practitioners to conclude that lipid-lowering therapy is less important for women than for middle-aged men. As emphasized by LaRosa, however, a relative lack of data cannot be equated with negative findings [141]. Although limited, the available trials data demonstrate that the impact of intensive lipid-lowering therapy on serum cholesterol levels is similar in women and men, as is the reduction in coronary mortality [142]. Recent data also indicate the response of elderly individuals to lipid-lowering interventions is similar to that of

younger individuals [143].

Hypertension

Elevated blood pressure, either systolic or diastolic, has repeatedly been shown to be associated with increased risk for CHD [144,145]. In the Multiple Risk Factor Intervention Trial, systolic and diastolic blood pressure were each associated with CHD mortality risk over 11.6 years of follow-up, independent of other major risk factors. Approximately 49% of excess deaths in the entire cohort were attributable to systolic blood pressure levels higher than optimal (120 mmHg) [146]. For individuals with both systolic and diastolic values in the upper quintiles, the CHD death rate was five times greater than for subjects with both values in the lowest quintile. Synergistic interaction with other major risk factors was also evident. The significant impact of elevated blood pressure on CHD risk has also been observed among other cohorts of younger and older men [147] and women [148,149].

Sustained control of hypertension, through non-pharmacologic means (weight reduction, exercise, dietary modification) or, more commonly, with antihypertensive drug therapy, has been shown to substantially reduce the risk for stroke, with less dramatic effects on development of CHD [150]. In the context of secondary prevention, evidence suggests treatment of elevated blood pressure reduces total mortality [151,152].

Diabetes

In epidemiologic studies, both insulin dependent diabetes (IDDM), and non-

insulin dependent diabetes (NIDDM) have been shown to independently contribute to CHD risk [52,153]. This relationship is particularly strong in women [50,153]. Data from the Framingham study showed the relative risk for CHD events among diabetic versus nondiabetic subjects is 5.1 versus 2.4 in women and men, respectively [154], while the 14-year follow-up of the Rancho Bernardo study found the relative risk of CHD mortality was 3.3 in diabetic women and 1.8 in diabetic men compared to non-diabetic individuals [155,156]. CHD risk is somewhat higher in subjects with IDDM relative to those with NIDDM, possibly due to the earlier onset and more severe metabolic disturbances associated with IDDM [153].

At the present time, there is no conclusive evidence that normalization of glucose levels will delay or prevent development of CHD, or reverse existing coronary atherosclerosis in diabetic subjects [157]. Preliminary data from the Diabetes Control and Complications Trial suggests tight glycemic control may be of some benefit in reducing risk for major cardiovascular events in individuals with IDDM [158]. The long-term impact of this form of therapy however, is unknown.

Other atherogenic traits, including dyslipidemia, hypertension, and obesity have also been found to occur more frequently among individuals with diabetes, particularly those with NIDDM, than among non-diabetic individuals. This clustering of risk factors substantially amplifies risk for CHD events above that associated with diabetes alone; the interaction of smoking and diabetes appears to be particularly detrimental [159]. Reduction or elimination of these modifiable risk factors should be a priority for all diabetics [160].

Obesity

Epidemiologic studies relating obesity to risk for CHD events and mortality have produced inconsistent results [161]. Many studies, however, have been limited by small sample sizes and insufficient length of follow-up [162], while in others, the impact of obesity may have been underestimated due to the effects of confounding factors, such as physical inactivity, smoking status, and dietary habits [163]. Larger, well-designed studies indicate general obesity is an important CHD risk factor both in women and men [164-169], although its effects may be partially mediated through other factors, including hypertension, dyslipidemia, and diabetes [165].

Abdominal obesity, as opposed to generalized obesity, appears to represent a stronger risk factor for CHD [170]. In older women, a positive association between abdominal obesity and angiographically confirmed CHD has been demonstrated [171], and cross-sectional studies support the relationship between a centralized distribution of body fat and a number of possible CHD risk factors, including hyperinsulinaemia, insulin resistance, and elevated fibrinogen levels [172].

The Canadian Heart Health Surveys confirmed obesity as a prevalent problem among Canadian adults; 35% of men and 27% of women surveyed had body mass index (BMI) measurements (kg/m^2) equal to or greater than 27, a level associated with excess morbidity and mortality [173]. In addition, a rise in the prevalence of abdominal obesity, reflected by a high waist-hip ratio ($\geq$0.8 for women, $\geq$0.9 for men), was noted with increasing age in all BMI categories, a trend particularly common among men. The coexistence of other risk factors, notably

dyslipidemia, diabetes, and hypertension in the higher BMI categories was also noted. The survey investigators emphasized that measurement BMI and waist-hip ratio are essential to diagnose abdominal obesity, and recommended the incorporation of these measurements into the routine examinations, and to evaluate overall CHD risk [174].

Extensive research into the treatment of obesity has failed to identify an optimal strategy to achieve sustained weight loss [175,176]. Evidence suggests that traditional approaches utilized by many physicians, including provision of verbal dietary advice, generic low-energy diet sheets, and recommendations for increased exercise, are seldom successful in the long term [177]. The most effective therapies utilize a multidisciplinary approach, and combine nutrition education, behaviour modification, and aerobic and resistance exercise training [175-177].

Physical Inactivity

A number of population studies have suggested a link between high levels of physical activity and lower CHD rates [178-180]. In a review of 43 published epidemiologic studies on the health effects of regular physical activity, Powell et al [180] found that two-thirds of studies documented a strong inverse association between physical activity and CHD risk. Moreover, in individuals who were physically inactive, the relative risk for CHD was 1.9 (CI_{95} 1.4-2.5) compared to persons who were categorized as active. A more recent meta-analysis concluded the available evidence supports an independent role of physical activity in the primary prevention of CHD [181].

There is also evidence that increased physical activity is of benefit to individuals who have already suffered a CHD event [182]. A recent meta-analysis of 22 trials where patients were randomized to cardiac rehabilitation programs post-MI reported a 20% reduction in overall mortality [183]. The physiologic changes that occur with regular aerobic exercise also reduce symptoms of ischemic heart disease due to an increase in the ischemic threshold [183,184].

Although information on the exercise habits of Canadians is not available, recent reports [185] indicate that 60% of the U.S. population lives a predominantly sedentary lifestyle. Among adults aged 35-54 years, men were more sedentary than women, while women aged $\geq$ 55 years were more sedentary than men.

Estrogen Status in Women

While CHD rates among younger, pre-menopausal women are relatively low, it is the predominant cause of morbidity and death among postmenopausal (PM) women [186]. The precise reasons for the higher risk among PM women have not been conclusively established; however, observational studies indicate an association with the relative estrogen deficiency that follows menopause, and the associated development of a more atherogenic lipid profile, as a significant factor [187-188].

Estrogen replacement therapy appears to have a protective effect against CHD, possibly mediated through combined effects on serum lipids, vascular endothelium, fibrinogen, and prostacyclin-thromboxane balance [189,190]. Nabulsi and colleagues estimated that risk for CHD may be reduced by up to 42% in women

who use estrogen post-menopausally compared to non-users [190], and work by Manolio et al suggests the benefits of estrogen replacement therapy are apparent for women well into their eighth decade [191].

B. GENDER DIFFERENCES IN CHD MANAGEMENT

Although CHD is the predominant cause of death for women as well as men [1], the majority of studies of the etiology, clinical presentation, treatment, and prognosis of CHD have focused on the disease as it occurs in men, particularly middle-aged white men [11,192-194]. As a result, the male experience of CHD defines the normative standard [49]. The emphasis on the male model of the disease has created a significant gender gap in the research [11], which contributes both to a perception that CHD is not a serious health problem for women [192], and, possibly, to inappropriate delays in diagnosis and less aggressive management of CHD in women as compared to men [194].

Diagnosis and Investigation of CHD

A number of studies suggest that physicians' approaches to diagnosis and investigation of CHD in women may be less aggressive than in men. Tobin and colleagues [195] reported that women with positive nuclear exercise tests were significantly less likely than men to be referred for cardiac catheterization to confirm the presence of significant coronary disease (4% of women versus 40% of men). In Tobin's study, physicians also attributed chest pain syndromes to psychiatric or

noncardiac causes twice as frequently in women as in men [195]; prescription of anti-anginal drugs however, was similar across gender. Other investigators have also found significant gender differences in rates for coronary angiography among patients hospitalized with suspected or known CHD, with male-to-female odds ratios 1.15 to 1.28 [193,196]. In the Survival and Ventricular Enlargement (SAVE) trial, involving 2231 patients with recent myocardial infarction recruited from 112 hospital in Canada and the US, multiple logistic regression analysis indicated men were almost twice as likely as women to undergo coronary angiography, independently of other clinical variables, including age, previous infarction, history of angina, and coronary risk factors [197]. Several investigators have suggested the lower utilization of coronary angiography in women may have important repercussions in terms of subsequent treatment decisions and clinical outcome [194]; results of angiography appear to be an important determinant of referral for elective revascularization procedures, which carry a lower risk of mortality than do emergency procedures in patients with severe or unstable ischemic syndromes [192].

Gender differences have also been reported for emergency department (ED) evaluation of acute chest pain. Heston et al [198] found that women presenting to the ED with acute chest pain waited significantly longer for an initial ECG to be obtained, and for evaluation by the physician than did men. The study also found that women with an ED diagnosis of acute myocardial ischemia (ie, AMI or unstable angina) were less often admitted to an intensive care unit than were men with the same diagnosis (56% of women versus 82.6% of men).

Treatment of CHD

Gender-related differences in the use of medical therapy, reperfusion strategies and revascularization techniques for CHD have been found in some, though not all, studies. Data from the Western Washington Recombinant Tissue Plasminogen Activator Trial [199] indicated women with AMI are less likely to receive thrombolytic therapy. Of 221 patients eligible for thrombolysis, 55% of women versus 78% of men actually received therapy. Similar numbers of women and men refused therapy; the reason for thrombolytic therapy not being given to the remaining eligible patients could not be determined.

Studies of patients hospitalized for acute myocardial infarction (AMI) provide additional evidence that female patients are less likely to receive thrombolytic [200-202] and other medical therapy proven to reduce AMI mortality risk, including beta-blockers [201,202] and aspirin [201-203]. Differences in referral patterns for percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG) between women and men with CHD are well-documented [204-209], but the significance of the findings are less well understood. A number of studies suggest there is systematically less access to revascularization procedures for women as compared to men with CHD [207]. In addition, women more often are referred for CABG or PTCA later in the course of disease, and with more severe ischemic symptoms [208]. However, Steingardt [197] found that once women had undergone cardiac catheterization, they were as likely as men with similar

angiographic findings to undergo CABG. A recent Canadian study [209] involving 571 patients referred for revascularization following catheterization however, found that referring cardiologists requested CABG over PTCA more often for men than for women ($p = 0.0009$). Among patients actually accepted for a procedure, men were more likely to actually undergo CABG ($p = 0.0002$).

CHAPTER II

RESEARCH ON PHYSICIANS' PRACTICE PATTERNS

Despite intensive efforts to promote physician recognition, investigation, and management of cardiovascular risk factors among patients with, and without, known or suspected CHD, [24] the extent to which physicians routinely address cardiovascular risk factors is largely unknown. Relatively few studies have explored practice patterns for assessment and management of cardiovascular risk factors, and the majority of previous studies have focused on detection or treatment of a specific risk factor, often hypercholesterolemia, among individuals without clinical or symptomatic evidence of atherosclerosis (primary prevention). Management of cardiovascular risk factors in a high-risk patient population, specifically, among patients with pre-existing CHD, has received little attention.

Previous studies of physicians' practice patterns have utilized three major approaches: physician self-report techniques, including self-administered questionnaires and personal or telephone interviews; population surveys, which attempt to ascertain patients' recall of investigations and/or interventions initiated by their physician; and retrospective examinations of physician-documented risk management activities (i.e. medical records review, or chart audit). Occasionally, a combination of these approaches has been used.

A. SELF-REPORT TECHNIQUES

According to surveys of Canadian [210,211], American [42,43,212], and New Zealand [213] physicians, knowledge of cardiovascular risk factors and recommended screening and treatment strategies has increased steadily since release of the first National Institutes of Health consensus conference report on cholesterol [22]. In a 1990 national telephone survey of US physicians (n=1604) the majority of respondents reported basing their treatment decisions on key features of the National Cholesterol Education Panel Adult Treatment Panel (NCEP ATP) guidelines [24], including use of the mean of at least two cholesterol determinations to diagnose hypercholesterolemia, application of lower cut points in cases of multiple risk factors, and determination of LDL cholesterol to guide therapy selection [43]. The majority of physicians reported placing greater emphasis on serum cholesterol as a risk factor in the post-myocardial infarction patient (**Table 1**). Most respondents in both Canadian and U.S. surveys also reported managing at-risk patients according to published consensus committee recommendations, including allowance of a 6 month trial of dietary management prior to institution of drug treatment [43,210]. Some differences in utilization of treatment guidelines by area of specialty (e.g. cardiology, family practice, endocrinology) had been evident in the earlier U.S. surveys, with cardiologists reporting a more aggressive approach to lowering elevated cholesterol levels than other specialties [6]. By 1990, however, these differences between specialities had largely disappeared [43]. Comparable data to assess practice variation by specialty among Canadian physicians does not

Table 1. Self-reported cholesterol management practices of U.S. physicians[1]

Management Practices (Recommended by NCEP ATP Guidelines)	% Responding (n.= 1604)
Key features used in making treatment decisions:	
• Use more than one cholesterol determination	89
• Apply lower cutoffs when multiple risk factors present	83
• Obtain LDL cholesterol measurement prior to determining mode of treatment	80
• Emphasize cholesterol more with post-MI patients	74
Practices related to dietary therapy:	
• Allow 3 to 6 month trial of diet prior to drug therapy	71
• Assess patients' eating habits frequently	65
• Place the most emphasis on dietary saturated fat	41
• Place the most emphasis on total dietary fat	31
• Always or usually refer to registered dietitians	27

[1] Adapted from Schucker et al. Arch Intern Med 1991;151:666-73.

exist, although there is some evidence that family physicians and general practitioners are more likely than specialists to screen patients for elevated cholesterol on a routine basis [210].

Despite apparently favourable trends in attention to cardiovascular risk factors by physicians, several inconsistencies are apparent in the cross-sectional survey data. For example, although 78% of Ontario general practitioners and family physicians who responded to a telephone survey stated they adhered to published guidelines, responses to specific questions on the management of hypercholesterolemia differed substantially from these recommendations. Only 3% of respondents stated they would initiate formal diet therapy at the level of cholesterol set out in the guidelines (> 6.2 mmol/L), and only 15% of respondents would follow recommendations to begin pharmacotherapy if dietary therapy failed to adequately reduce serum cholesterol after 6 months [214].

Shea et al. [215] also reported physician practices inconsistent with published guidelines for management of hypercholesterolemia. In a survey of New York physicians (n=329), with specializations in internal medicine (54.1%), family practice (24.9%), cardiology (12.8%), and general practice (8.2%), 20.1% of those interviewed indicated they would initiate drug therapy for an asymptomatic, otherwise healthy 40-year-old man on the basis of a single elevated (total) blood cholesterol measurement of 7.8 mmol/L, prior to any trial of dietary management. A further 21.0% would begin drug therapy in such a patient after 1 month of lipid-lowering dietary management. An additional finding of interest in this study was that physicians who were less knowledgeable of the NCEP guidelines and relevant

scientific literature were more likely to view drug company representatives and literature as "very useful" sources of information.

Inadequate investigation of blood lipid abnormalities has also been reported among Canadian physicians. In a nation-wide mail survey of general practitioners and family physicians (n=428), 35% were reported to base treatment decisions on a single total cholesterol test result [211]. A small survey of Edmonton physicians (n=107), also revealed that approximately one-third of respondents did not feel lipid fractionation was needed to guide initial treatment [216].

Results of a cohort study in the US Midwest suggested a more uniform shift towards consensus with national guidelines for management of cardiovascular risk factors among asymptomatic individuals [212]. The study cohort consisted of a random sample (n=396) of all physicians named as personal physicians by participants in the Minnesota Heart Health Program [217]. Most specialized in family practice (44%), or general internal medicine (33%); 8% were cardiologists. Serial telephone surveys two years apart (1987, 1989) assessed changes in physicians' reported preventive practices related to each of four separate cardiovascular risk factors (hypercholesterolemia, cigarette smoking, hypertension, and physical inactivity), with the reference patient being an "otherwise healthy 48-year-old man." Physicians in this cohort consistently reported obtaining at least two to three blood cholesterol measures before labelling a patient as hypercholesterolemic, and there was a notable shift between 1987 and 1989 towards using the NCEP recommended cutoff for identifying a cholesterol value as abnormal. The majority of physicians in 1989 also reported they would institute

dietary therapy at, or near, the cholesterol level recommended in the NCEP guidelines. Practices related to the identification and control of hypertension were also found to be in accord with national standards, and a high proportion (84%) of the physicians reported they "frequently" advised patients to exercise regularly. Eighty-three percent also indicated they actively encouraged smoking cessation for their patients. It may be questionable whether this physician cohort was representative of US physicians in general. The Minnesota Heart Health Program, a community-based primary prevention trial of CVD, was widely publicized, and all members of the study group practised in the area at the time. Although the telephone interviews took place 2 years after the official end of the program, the physicians recruited may have been sensitized to heart health issues to a greater degree than physicians elsewhere in the country.

Surveys of physicians' reported practices provide a feasible, relatively inexpensive way to assess overall trends in attitudes toward and knowledge of cardiovascular risk detection and management procedures. However, such surveys are particularly susceptible to selection bias; physicians who choose to participate may be particularly interested in, or confused by, the topic. Self-reported behaviour may also more closely reflect physicians' perceptions of ideal practice rather than routine behaviours, or may reflect anticipation of "correct" answers [212]. A tendency for physicians to overestimate their use of certain preventive practice strategies has also been demonstrated [218]. In addition, standard survey questions fail to reflect the myriad factors that singly or interactively influence practices related to CV risk management [219].

B. POPULATION SURVEYS

Consistent with the self-reported practices of physicians, surveys of the general public indicate an increasing proportion of adults are being screened for elevations in cholesterol, but show a relatively greater rise in the percentage under active treatment (with diet and/or medication) for hypercholesterolemia. By 1990, 62.1% [220] to 65% [43] of U.S. adults who participated in surveys reported having had a cholesterol determination. A significant percentage (16%) of these determinations, however, may have been completed through public screening initiatives rather than by physicians [43]. Roughly one in four adults reported a diagnosis of high or borderline cholesterol; only one in ten reported a prescribed lipid-lowering diet [43]. Two percent of adults surveyed indicated they had received prescriptions for cholesterol-lowering medications from their physicians. The extent to which recall bias and selection bias may have influenced these surveys is unknown.

C. MEDICAL RECORDS REVIEW

In the outpatient, or ambulatory care, setting the majority of practice analyses using medical records review have focused on physician recognition and treatment of lipid risk factors either among patients selected on the basis of an elevation in serum total cholesterol, [221-225], or among consecutive patients presenting to a clinic within a specified time period [226-231]. The influence that existing CHD, other non-lipid risk factors, and patient characteristics such as age and gender have

on physicians' risk assessment and management behaviours has seldom been explored. Table 2 summarizes the relevant studies in this area published since 1985. All of these studies were conducted in US health care centres; no Canadian studies of this type could be identified.

Overall, the results of medical records review analyses show considerable variation in the frequency with which physicians document elevated serum cholesterol in the medical record, ranging from 8% [226] to 80% [230] of cases. Documentation rates for follow-up investigations of lipid levels, and initiation of interventions to reduce elevated serum cholesterol (diet and/or drug therapy) also vary widely between studies. In general, however, a temporal trend toward higher rates of documentation and treatment of elevated cholesterol after 1988 is suggested, and may be related to the fact that the NCEP guidelines [24] and Canadian Consensus Conference on Cholesterol recommendations [23] became widely available that year. The more recent studies [224,225,229,231] also suggest greater use of repeat total cholesterol testing and lipoprotein analysis than was found prior to 1988 [207,208]. This temporal trend is consistent with the findings of physician self-report surveys [42,43]. Nevertheless, a substantial proportion of patients eligible for cholesterol modifying therapies under current guidelines do not appear to be receiving diet therapy or drug treatment from their physicians [224,229,231].

Whether the relative increase in physician attention to serum cholesterol has been extended to include other risk factors, consistent with the concept of "total risk" [27], cannot be determined from the available data. The presence or absence of

Table 2. Summary of patterns of practice studies of cardiovascular risk factor management in outpatient settings†

Ref.	Study Date & Location	Patient Selection & Characteristics	Physician Characteristics	Parameters Assessed	Results	Comments
Otradovec (1985)	1981-1982. Missouri	**n = 268** - Random sample - Patients aged 10-50 yr - Sample 70% women - First time visits only.	- University hospital - affiliated MDs in family medicine, internal medicine, pediatrics	Documentation of: • TC • Lipid profile • History & non-lipid RF • Physical Exam	*Documentation rates*: Cholesterol 6-18% Lipids ≤ 1% Prior CHD <15% Family hx <20% Hx of HTN ≤ 11% Smoking ≤ 34% Exercise ≤ 28% BP and wt ≤ 97%	- Little evidence of attempts to modify risk factors. - No analyses by age/gender or prior dx CHD
Madlon Kay (1987)	Aug-Sept 1985. Georgia	**n = 217** - Random sample of pts with TC ≥ 6.72 on chemistry panel - Sample 67% women - mean age 56 ± 11 yrs	- Faculty and residents in army Family Practice residency program	MD documentation of: • TC elevation • Diet tx initiated • Drug tx initiated	*Documentation rates*: ↑TC noted 47% Diet tx 29% Drug tx 7% No tx 64%	- No analyses by age/gender or prior dx CHD
Bell & Dippe (1988)	Jan-Jun 1986. Arizona	**n = 93** - All pts with TC ≥ 6.2 mmol/L on chemistry panel or individual test - 59 women (63%) - mean age 59, range 15-86 yrs - 25 pts with known CVD	- Family Practice faculty physicians (n=4) & residents (n=17)	MD documentation of: • TC elevation • Lipid profile ordered • Diet tx • Drug tx	*Documentation rates*: ↑TC noted 66% Lipid profile 22% Diet tx: 46% Drug tx: 6%	- Non-significant trend to lower rates of recognition, investigation & treatment of ↑TC in pts ≥ 70 vs. < 70 yrs of age. - No analysis by gender - No analysis by prior dx CHD
Nichols (1988)	Sept 1985-Aug 1986. California	**n = 88** - Pts with TC ≥ 5.7 mmol/L reported within last 3 years - Ages 30-39 yrs only	- Faculty and residents in university Family Medicine program	MD documentation of: • Investigation of ↑ TC • Counseling/treatment for ↑TC • Hypercholesterolemia on pt. problem list	*Documentation rates*: Repeat testing/ Lipids 36.7% **Any tx 34.1%** • Weight: 56.7% • Exercise: 33.3% • Diet tx: 86.7% • Drug tx: 10.0%	- Incidence of tx increased linearly with increasing TC values - No analysis by pt. age/gender or prior dx CHD
Boekeloo et al (1987)	Time period not stated. Maryland	**n = 80** - Post-MI pts in cardiac rehabilitation program	- Primary care physicians (n=24) of the patients selected	MD documentation of: • Hx of ↑TC or current status • Diet/drug tx	*Documentation rates*: TC 34% Diet tx 4% Drug tx 12%	- Rehabilitation program screening found 26% of pts had TC > 6.72 mmol/L - No analysis by pt. age/gender

Whiteside & Robbins (1989)	Time period not stated. California	**n = 159** - Consecutive pts with TC value recorded within past 3 yr - 90 women (57%) - Mean age 56.2 ± 14.9 yrs	- University-affiliated primary care Internal Medicine clinic staff physicians	MD documentation of: • ↑ TC (>5.17 mmol/L) • Diet counseling/tx • Repeat testing/follow-up • Prescribed drug tx • Assessment of other RF	*Documentation rates*: ↑ TC noted 29% Diet tx 20% Follow-up 17% Drug tx 5%	- Survey of patients indicated high level of awareness of ↑ cholesterol as a health risk; willingness to take remedial action. - No analyses by pt. age/gender or prior dx CHD
Neighbor et al. (1991)	1986-87. NW USA	**n = 1528** - Random sample - Clinic pts; 10 per physician - Age criteria: 20-65 yrs - Asymptomatic for CHD - Sample 72% women - Mean age 36 y; median 34 y	- Family practice residents of Family Practice Residency Network (8 residency sites in 5 cities & 2 states in US Pacific NW)	MD documentation of: • Assessment / counseling CV risk factors over 12 mo period • Cholesterol testing	*Documentation rates*: BP 96% Weight 95% Family hx 52% Smoking 40% Cholesterol 26% Activity 25% Diet analysis 25% *RF counselling:* (pts positive for RF) ↑ Lipids 20% Smoking 45% HTN 96% Obesity 46%	Investigators conclusions: - Pts seen for episodic health care unlikely to have RFs assessed - Pts with one CHD RF identified are unlikely to be assessed for additional factors - Pts having a known RF are often not counseled for that RF - High rates of documentation for weight and BP are due to routine recording by nurses. - No analyses by pt age/gender
Madlon-Kay (1989)	1988 Minnesota	**n = 54** - Pts with TC > 5.17 mmol/L seen in May-Jun 1988. - Sample 73% women - Mean age 64	- Family physicians in one community-based urban outpatient clinic	MD documentation of: • Abnormal cholesterol test • Repeat cholesterol test • Therapy initiated	*Documentation rates*: Elevated TC 74% Repeat test 40% Diet therapy 59% Drug therapy 17%	- Study results are the third review at this centre. Improvement seen over earlier two audits. - Threshold for diet tx, TC = 7.21mmol/L. Threshold for drug tx, TC = 8.28 mmol/L - Mean TC value 7.29 ± 0.91 mmol/L - No analyses by pt age/gender
Hudson et al (1990)	1988 Michigan	**n = 450** - Random samples from 3 Family Practice clinics - Mean age 38.8, range 18-65y - Sample 63% women	- Clinic 1: University -affiliated, 12 family practitioners (FPs) - Clinic 2: 4 (FPs) - Clinic 3: 4 (FPs)	Documentation of: • Lipid measurements • Lipid-lowering tx • Other RF (audited only if abnormal lipids charted)	*Documentation rates*: TC 67% Repeat test 55% HDLC 44% LDLC 28% *Interventions* If TC>5.2 mmol/L 47% TC>6.2 mmol/L 64%	- Variation in practices between clinics noted - Women slightly less likely than men to have cholesterol measures ordered (NS) - 95% of men > 50 years had ↑ TC determination

Schectman et al. (1991)	Jun-Jul 1988. Washington D.C.	**n = 243** - Consecutive pts with TC > 6.2 mmol/L - Mean age 48.9 ± 12.6 y - Sample 67.5% women	- University-affiliated general internists (n=16), primary care residents (n=5); one family practitioner.	Documentation of: • Diet counseling, 1) within 12 mo of index TC; or 2) at any time • Repeat cholesterol test • Lipid profile at any time • Lipid-lowering drug tx	*Documentation rates:* Diet 67% Lipid profile 57% Drug tx 14%	- Magnitude of index TC elevation, # other RFs noted, & type of TC measure (isolated TC or chemistry panel) significantly associated with diet counseling - No analysis by gender - Age not a significant variable in regression analyses
Robinson et al. (1992)	Oct 1-Dec 18 1990. Florida	**n = 817** - Systematic random samples (time series sampling) of pts ≥ 20 and ≤ 70 yrs from 4 Family Practice clinics - Mean age 40.9 yrs - Sample 76.7% women	- Family Medicine residents and faculty physicians	Documentation of: • Initial cholesterol measurement & repeat testing • Lipid profile where indicated by NCEP	*Investigation & documentation* Cholesterol measurement: None women 41.7%* men 34.4% Once women 35.6% men 34.4% Repeat testing: women 22.7%* men 31.2% Lipid profile (% of high risk pts) 23.4%	- 70.7% of pts seen ≥ 4 times by a staff MD - Younger age group (20-29y) less likely than older age groups to have a screening cholesterol measurement - Women less likely than men to have repeat cholesterol test ordered. - No separate analysis by prior hx CHD
Walsh et al. (1993)	Nov. 1990 - Jan. 1991. California	**n = 993** - Random sample of pts with ≥ 1 visit to clinic between July 1988 and Nov. 1990. - 87% > 35 yrs of age - Sample 81% women - 86% high risk (≥ 2 RF or manifestations of CAD)	- Faculty physicians (n=15), internal medicine residents (n=37), and nurse practitioners (n=9) of a general internal medicine group practice.	Documentation of: • Screening TC measure within past 5 years • Lipid profile in high risk patients (according to NCEP recommendations) • Lipid profile orderedprior to lipid-lowering drug therapy	*Documentation rates* TC level 80% Lipids in high risk pts 60% Lipidsprior to drug tx 92%	- In mulivariate analysis, age was the only patient characteristic associated with liklihood of cholesterol screening. - Patients at high risk for CV events no more likely to be screened than those at low risk.

' TC = total cholesterol; LDLC = low-density lipoprotein cholesterol; HDLC = high-density lipoprotetin cholesterol; RF = cardiovascular risk factor; NCEP = National Cholesterol Education Program.

* $p < 0.05$

non-lipid risk factors and/or manifestations of CHD in patients included in these studies has only rarely been described by the investigators. Bell and Dippe [222] indicated 17 of 93 patients in their study group were known to have coronary artery disease, but the subgroup was not mentioned in the discussion of their findings (perhaps due to inadequate numbers for subgroup analysis). Hudson and colleagues [229] reported the likelihood of physician intervention for cholesterol reduction was positively influenced by the recognition of another risk factor (defined to include personal history of ischemic vascular disease); however, no further information on the identification or distribution of non-lipid risk factors in the sample population was provided.

A single study [232] examined records of primary care physician assessment and management of cholesterol as a risk factor in outpatients with documented CHD (post-myocardial infarction). Other risk factors were not evaluated, nor was the age and gender distribution of the study population described. The chart audit demonstrated that the frequency with which physicians documented cholesterol elevations among these post-myocardial infarction patients was similar to rates reported for other patient groups of the same time period [227,228]. In contrast to other studies, however, the frequency of drug intervention exceeded that of documented diet therapy.

Most studies of medical records for cardiovascular risk factor management in ambulatory care settings have examined the behaviours of family practitioners and general internists. The practice patterns of cardiologists, who, according to some, should be leaders in CV risk modification efforts [233,234], have not been

extensively explored. In the only study to specifically look at cardiologists' practices in this area, Cohen et al [234], combined the techniques of medical records review and patient self-report techniques to investigate how hospital-based cardiologists dealt with cholesterol as a risk factor among patients with suspected and/or documented coronary disease. Records of 95 patients referred for coronary angiography, all of whom had fasting cholesterol tests performed, were reviewed at discharge for physician notations concerning the cholesterol test results and lipid-lowering interventions. Forty percent of the subjects were long-term patients of the admitting cardiologist. All patients were contacted by telephone at 1, 12 and 24 months after discharge to determine treatment status. Only 17% of patients with high total- or LDL-cholesterol values were receiving diet or drug treatment at 1 month post-discharge; 1 to 2 years later, only 35% of 69 subjects contacted were under active diet and/or drug treatment. It was noted that essentially all patients had contact with the admitting cardiologist over the 2 year follow-up period, suggesting there were opportunities for risk factors to be addressed. This study suggests specialists in coronary disease treatment are no more likely than generalist physicians to initiate or maintain preventive therapy.

Patient Gender Differences

Gender differences in cardiovascular risk factor management have received little attention in previous practice analyses. Hudson et al [229] reported that women were less likely than men to have an initial cholesterol determination, but no significant difference in screening rate was detected. Walsh and associates [231]

also found patient sex was not associated with cholesterol screening. In contrast, Robinson et al [230] found significantly more women than men had no cholesterol measurement recorded ($p < 0.05$), and that men were significantly more likely than women to have repeat tests ordered ($p < 0.05$).

In view of gender differences found at other points in the process of care for individuals with, or at-risk for, CHD [195-199], the issue of gender differences in the cardiovascular risk assessment and management activities warrants further investigation.

D. METHODOLOGICAL LIMITATIONS

A variety of techniques have been utilized by researchers in the appraisal of the process of medical care, none of which are without limitations. Methods which rely on physician self-report, including mail or telephone surveys are susceptible to recall and response bias. Personal interviews also may be compromised by physicians offering the perceived "correct" response to questions; these studies also may threaten anonymity. Direct observation of the physician-patient encounter, and physician management of simulated cases, are susceptible to this effect. Retrospective chart review, however, has minimal impact on existing behaviour patterns and involves no disruption of the routine process of care within institutions or outpatient clinic settings [229]. Another advantage to this methodology is its flexibility; chart review can be completed any time the medical record is not in clinical use. The limitations of the data available in the patient record, however, must be taken into consideration whenever this retrospective approach is used to

define physicians' practices.

That deficiencies exist in the completeness and accuracy of documentation in the patient record has been recognized for decades [235,236]. The incidence of missing laboratory and diagnostic test results, for example, has been estimated to range from 5% to 20% [235]. A more widespread problem relates to variation in the completeness of the physicians' narrative. In a study of the quality of patient records in five hospital-based outpatient facilities, Tufo and Speidel [237] found the historical and treatment portions of the physicians' narrative summaries to be incomplete in one-quarter to one-third of cases. In approximately 10% of the records, definition of the presenting problem and description of treatment were severely deficient, such that the reviewer was unable to determine either the nature of the problem, or the treatment provided. In some cases, the legibility of patient care documentation has also been recognized as a problem [238].

Hudson et al [229] noted specific areas of omission of documentation in records dealing with assessment of cardiovascular risk management. Based on regional norms, they estimated that 30% of the patient population would be regular cigarette smokers; however, only 6% of the 450 patient records sampled indicated the patient to be a smoker. Deficiencies of documentation of dietary interventions were estimated by assessing the number of known diabetics for whom any dietary advice was recorded, with the assumption that some discussion of diet would occur routinely in this group. Documentation of dietary advice to diabetic patients, however, was found in only 68% of cases.

Other researchers have noted that actual practice is less likely to be recorded

when the information is related to patient history taking or counselling than for more objective aspects of care, such as the physical exam and laboratory test information [228]. Documentation is also less likely to reflect practice when testing or inquiry demonstrates the absence, rather than the presence of a finding [239,240].

While weaknesses in the data obtained from medical records review exist, patient charts represent tangible and accessible evidence of physicians' routine practice behaviours. Provided that the limitations of the data are considered in the interpretation of results, useful insights into current patterns of practice can be obtained using this technique.

CHAPTER III

METHODOLOGY

A. RESEARCH PLAN

Rationale

Current literature supports modification of coronary risk factors as a key co:nponent in the effort to delay or prevent future disabling or fatal coronary events in individuals with established CHD. The efficacy of readily available therapeutic regimes for risk factor reduction in this population has also been demonstrated, particularly with respect to unfavourable serum lipid profiles, and national consensus guidelines for use of these therapies in the context of prevention of CHD events (primary and secondary) have been developed. Yet, despite wide dissemination and extensive discussion of these guidelines in the medical literature, the available research indicates physicians' attention to risk factors has been inconsistent and generally suboptimal in all population groups studied.

Much of the evidence on physicians' practices for risk factor investigation and management, however, was obtained within the two years following the 1988 release of the Canadian and American national consensus guidelines [23,24], and may no longer be representative of current practice patterns. Research in other areas of medicine does indicate that a lag period of up to three years is not uncommon before widespread adoption of consensus recommendations or practice guidelines becomes apparent [241]. If this has been the case for guidelines dealing

with lipid and non-lipid risk factors for cardiovascular disease, current practices may parallel recommended approaches more closely than indicated by a literature review, and the added value of specific educational and other intervention efforts in this area may therefore be minimal.

It is also possible that the methods of dissemination and promotion of recommendations for CHD risk factor management have been relatively ineffective, and that a pattern of inattention to CHD risk factors has persisted over time. This would be particularly detrimental for individuals with established CHD, who, due to their high risk for recurrent CHD events, are most likely to derive substantial benefits from risk modifying therapies. Investigation of physicians' attention to CHD risk factors, focusing specifically on CHD patients, is needed to define existing practice patterns for this high risk patient group and to assess the need for programs to increase application of evidence-based guidelines. Such studies also may provide valuable, though indirect, information on the effectiveness of the overall impact of methods commonly used to disseminate research findings and consensus recommendations to the physician community. This latter issue has previously received little attention from researchers and educators.

In light of previous research suggesting existence of sex bias in the investigation and therapy of AMI and other manifestations of CHD, it is of special importance to examine this issue in the context of CHD risk factor management. National consensus guidelines for risk factor assessment and management do not distinguish between women and men once CHD is established; aggressive attention to serum lipids and coexisting risk factors is recommended for all affected

individuals. To date, however, no studies have specifically explored whether the guidelines are applied equally to women and men.

Objectives

The primary objective of this study is to assess gender-related differences in physicians' practice patterns for outpatient-based management of lipid and non-lipid cardiovascular risk factors in patients is established CHD. Possible reasons for such differences, including the influence of age, will also be explored. Secondary objectives are to characterize and compare risk factor investigation and management patterns of hospital-based versus community-based physicians, and to evaluate the extent to which current risk assessment and intervention strategies parallel national management guidelines [23,24] and knowledge from more recently published clinical trials of risk-modifying therapies. The risk profiles of CHD patients attending hospital- versus community-based outpatient clinics will also be compared.

Hypotheses

The primary null hypothesis is there will be no difference in physicians' practice patterns for assessment, investigation and management of cardiovascular risk factors between women and men with CHD. Principal subsidiary hypotheses are:

1. There will be no differences in patterns of risk appraisal and management

for older (age ≥70 years) versus younger (age <70 years) patients;

2. No differences in hospital-based versus community-based patterns of practice will be demonstrated;
3. Actual practice patterns will not differ from relevant published guidelines for detection and management of cardiovascular risk factors, specifically those which focus on management of serum cholesterol and lipid subfractions; and
4. The risk profiles of patients attending hospital, versus community, outpatient clinics will not differ.

B. STUDY DESIGN

Retrospective primary data review (medical records review) was utilized in this pilot study to determine the prevailing patterns of practice for management of serum lipids and other cardiovascular risk factors by hospital-based specialist, and community-based family and general practice physicians. All study variables, and the response categories for each, were prospectively defined. The principal variables were measures of process, i.e. problem (risk factor) identification, investigation/diagnosis, therapy and follow-up; additional patient-specific variables were included to allow exploration of relationships between possible variations in the process of medical care and patient characteristics.

Hospital-based physicians were staff cardiologists with the Division of Cardiology, University of Alberta Hospitals (UAH), a tertiary care referral centre located in Edmonton (population 600,000). Cardiologists providing regular outpatient clinic services (excluding specialty clinics), were considered to be

participants in the study; the medical records of all adult patients seen by these cardiologists were potentially eligible for review.

Community-based physicians (n = 14) were family practitioners from two university affiliated family medicine centres in Edmonton, one group practice in a rural town, (population 3000), located 140 km south-west of Edmonton, and one solo practice located in a satellite community on the eastern perimeter of Edmonton. Community practice sites were selected on the basis of practitioners' willingness to participate in the study and their ability to identify a representative sample of eligible patient records from the clinic populations. That these community practices may not be representative of general or family physicians in general is acknowledged.

Selection of Records for Review

The study protocol received approval from the Research Ethics Board, Faculty of Medicine, University of Alberta, as a substudy of a multicentre patterns of practice investigation by the Clinical Quality Improvement Network.

Patient records included in the retrospective review were initially identified through computer searches of the patient databases of the Division of Cardiology and community clinics. The initial identification process in one community clinic was done manually. In each clinical setting, the parameters of the computer search selected records of subjects with clinical manifestations of CHD as documented by the physician and subsequently classified, according to International Classification of Diseases - Ninth Revision - Clinical Modification (ICD-9-CM) criteria [242], or equivalent, for entry into the database. The search period extended from January

1, 1991 to March 31, 1993. Identical clinical criteria were applied during the manual search of records in the community clinic without computer search capacity.

Preliminary investigation revealed distinct differences between hospital and community clinics, and between academically affiliated and non-academic community sites, in the manner in which cardiovascular diagnoses were recorded and entered into the patient database. The hospital clinic database was, in general, the most comprehensive, with each patient encounter described by multiple, highly-specific diagnostic codes, often related to acute conditions or cardiac procedures. Databases in the academically affiliated clinics also recorded multiple diagnoses for most patient encounters; however, use of less specific codes, frequently indicating chronic conditions (e.g. chronic ischemic heart disease, unspecified, ICD-9CM 414.9) predominated. Prior cardiac procedures (coronary bypass surgery, angioplasty or angiograms) were rarely recorded in the community clinic databases. Non-academically affiliated community clinics maintained patient databases primarily for billing purposes, and, as a result, only the diagnosis for which reimbursement was claimed was available for any specific patient encounter. To accommodate these and other differences between clinical settings, site specific computer search patterns were developed.

Hospital Clinic Subjects

The search of the Division of Cardiology database was constructed to select records of patients with one or more of the following qualifying conditions or procedures entered into the database between 01 January 1991 and 31 March

1993:

- Acute myocardial infarction ICD-9-CM 410
- Unstable angina ICD-9-CM 411.1
- Angina pectoris ICD-9-CM 413
- Coronary artery bypass grafting ICD-9-CM 36.1
- Percutaneous transluminal coronary angioplasty ICD-9-CM 36.0

Records of subjects identified in the initial search were subsequently reviewed to determine study eligibility based on the following additional inclusion criteria:

- Age > 21 years
- At least one visit to a cardiology outpatient clinic in the six months following the *index visit*, defined as the first physician-patient encounter (inpatient or outpatient) for which one of the qualifying conditions was recorded.

The latter criterion effectively excluded all patients seen by a specialist on a one time basis only. Medical records were also excluded from detailed review if the patient had died within 6 months of the index visit, or if any condition expected to significantly reduce life expectancy was noted (e.g. malignant neoplasm); it was felt aggressive attention to cardiovascular risk factors would probably be inappropriate in such cases. From the remaining sample, the charts of 150 consecutive female and 152 consecutive male subjects were selected for detailed review.

Community Clinic Subjects

In contrast to the hospital clinic setting, where virtually all patients present with a well-defined or suspected cardiac complaint, patients seen in community clinics,

even those with long-standing or severe coronary disease, may present with secondary or unrelated complaints, such as upper respiratory tract infections or musculoskeletal problems. In these cases, any underlying cardiovascular disease may be described in more general terms than generally seen in hospital medical records. The initial computer search was therefore constructed to scan for broad cardiovascular diagnostic categories in addition to specific qualifying conditions/procedures. The final search string included:

- Acute myocardial infarction ICD-9-CM 410
- Unstable angina ICD-9-CM 411.1
- Angina pectoris ICD-9-CM 413
- Coronary artery bypass grafting ICD-9-CM 36.1
- Percutaneous transluminal coronary angioplasty ICD-9-CM 36.0
- Old myocardial infarct ICD-9-CM 412
- History of major cardiovascular surgery ICD-9-CM V48.0
- Coronary atherosclerosis ICD-9-CM 414.0
- Myocardial ischemia, chronic ICD-9-CM 414.8
- Chronic ischemic heart disease, unspecified ICD-9-CM 414.9

The records of subjects identified in the initial search were subsequently reviewed for study eligibility based on study inclusion criteria:

- Evidence of one of the qualifying conditions, (AMI, stable/unstable angina, PTCA, or CABG) occurring within the period 01 January 1991 through 31 March 1993

- Age > 21 years
- At least one visit to the community clinic in the six months following the *index visit*, defined as the first physician-patient encounter for which one of the qualifying conditions was recorded.

Records of patients who had died during the study period, or with conditions expected to significantly reduce life expectancy were excluded, as for the hospital clinic sample.

At each community practice clinic, only a small number of female subjects (range 6-19) were identified for the entire period covered by the computer search, while a substantially greater number of male subjects were found. Therefore, the records of all eligible female subjects per clinic site were included in the review, matched by an equal number of records for randomly selected male subjects from each site. The final community clinic samples consisted of records for 48 female and 48 male subjects; one male subject was subsequently excluded when an older entry in the medical record indicated a terminal illness.

Data Collection

Data collection entailed a detailed audit of physician-generated documentation in the medical record for all patient encounters beginning 6 months prior to the index visit and continuing through the 6 months following that visit (up to 12 months in total). "Physician generated" documentation was defined as information entered directly into the record by physicians (e.g. progress notes), plus other entries arising the physician's actions (e.g. lab test

data). Information entered by nursing staff or health care workers into sections of the chart designated for physicians (e.g. progress notes) was accepted; however, information recorded by these professionals in sections of the medical record not normally reviewed by physicians was excluded. This was relevant primarily for hospital clinic subjects, as the index visit was, in some cases, an inpatient record. References to risk factors and/or interventions contained in documents sent to the physician of record, such as consultation reports and discharge summaries, were subject to review provided there was evidence that the document had, in fact, been seen by the receiving physician. Questionnaires completed by patients were excluded unless specifically referred to by the physician.

Data was collected on site by a single auditor using a standard data collection form (Appendix 1) developed for the project. All information was numerically encoded during initial abstraction; the coded information was subsequently entered into a computer database for analysis.

Demographic Data

Demographic data collected from each record included the patient identification number, clinic site attended, date of birth, and gender. The qualifying diagnosis, dates of the index visit, initial visit (up to 6 months prior to the index visit), follow-up visit (up to 6 months following the index visit), and the total number of physician-patient encounters were also recorded.

Clinical History

Documentation of each subject's personal cardiovascular history, including any of: myocardial infarction, unstable angina, angina pectoris, revascularization procedures, cerebrovascular accident or peripheral vascular disease, was abstracted from any eligible entries in the medical record between the initial and follow-up visits.

Risk Factor Assessment

Each medical record was carefully reviewed for documentation by the physician of efforts to determine the presence **or** absence of cardiovascular risk factors (smoking status, history or treatment of dyslipidemia, history or treatment of hypertension, diabetes, obesity, sedentary lifestyle and family history of cardiovascular disease). The criteria used to define risk assessment for each risk factor appear in Table 3. A family history of cardiovascular disease was defined as the reported presence of CHD or other atherosclerotic vascular disease in one or more first degree relatives.

Risk Factor Management

Evidence of planned or active interventions to reduce or control dyslipidemia, smoking, and/or hypertension was abstracted from the records and classified as one of four types of interventions: smoking cessation counselling\therapy; recommendations for exercise; dietary intervention (for management of

Table 3. Criteria for Assessment of CHD Risk Factors

Risk Factor	Assessment
• Serum lipids	• Chart notation indicating a positive / negative history of dyslipidemia (with or without reference to actual lipid levels) • References to recent lipid test data (within 12 months) as being within or beyond normal range • References to previous or current therapy for dyslipidemia (diet and/or drug therapy), or indication of intent to treat.
• Smoking	• Any reference to, or attempt to determine, smoking history and current status
• Hypertension	• Chart notation indicating a positive / negative history of hypertension, with / without reference to actual blood pressure levels. Documentation of "borderline" hypertension is regarded as positive for hypertension. • References to current blood pressure readings as satisfactory / unsatisfactory • Reference to previous or current therapy for hypertension (weight control, diet, exercise, drug therapy), or indication of intent to treat
• Diabetes	• Chart notation indicating the presence / absence of diabetes mellitus (insulin-dependent or non-insulin dependent). Documentation of "borderline" diabetes is regarded as positive for diabetes. • Indication of satisfaction / dissatisfaction with current level of glycemic control • Reference to current diabetic therapy; indication of intent to treat
• Obesity	• Chart notation indicating the presence / absence of obesity, based on the physician's subjective appraisal of weight status. *Severely overweight* and *obese* are regarded as synonomous; *mildly or moderately overweight* are not considered synonomous with obesity unless confirmed by objective measures. • Reference to an objective measurement of obesity (e.g. BMI, RBW)[1]. Obesity is defined as a BMI > 27 or RBW > 120%
• Sedentary behaviour	• Chart notation indicating the presence / absence of a sedentary behaviour pattern based on the physician's subjective appraisal of the patient's habitual activity patterns.

[1] BMI = body mass index (kg/m^2); RBW = relative body weight

dyslipidemia), and pharmacologic therapy of dyslipidemia and/or hypertension. For female subjects, prescription of estrogen replacement therapy was also noted.

Recognizing that a substantial amount of health-related counselling can occur within the context of informal discussions between the physician and patient, and that these discussions may not be recounted in detail in the medical record, a relatively liberal interpretation of references to diet, exercise, and smoking cessation counselling was applied. The major criteria used to define risk factor interventions are shown in Table 4. Not accepted as evidence of CHD risk interventions were, for diet, recommendations for dietary change without mention of total or saturated fat intake, and for physical activity/exercise, advice for "activity as tolerated" or recommendations pertaining to progressive increases in activity level following surgery or injury.

C. Sample Size Calculations

Preliminary data from the Clinical Quality Improvement Network multicentre study was used to determine the sample size required the present study. Sample size calculations were based on the following assumptions:

1) Type I error (α) = 0.05 (two tailed), and a study power of 80% (β = 0.20);
2) In the community outpatient setting, 60% of medical records for male patients with CHD are expected to show physician documentation of the presence or absence of the major established risk factors (dyslipidemia, smoking,

Table 4. Criteria for CHD Risk Factors Interventions

Risk Factor	Interventions
• Serum lipids	• Any indication of dietary advice/recommendations for a lipid-lowering, low fat, low-fat/low-cholesterol diet. • Referral to a dietitian, other health professional, or organized program for lipid-lowering diet counseling • Recommendations to increase exercise/physical activity level to promote correction of lipid risk factors • Documentation of intent to treat with lipid-lowering drugs; initiation of drug therapy, or adjustment of existing drug regime • Indication of satisfaction with existing drug regime with reference to current lipid levels
• Smoking	• Any reference to smoking cessation advice / counseling • Referral to another health professional or organized program for assistance with smoking cessation • Prescription of a nicotine patch to promote smoking cessation
• Hypertension	• Documentation of intent to treat with antihypertensive medication, initiation of drug therapy or adjustment of existing drug regime • Indication of satisfaction with existing drug regime

hypertension); 40% of charts for female patients are expected to contain documentation of these factors.

3) Approximately 95% of records for male and 85% of female patients managed by hospital-based specialist physicians (cardiologists) are expected to contain documentation of the presence or absence of dyslipidemia, smoking, and hypertension.

Sample size estimates are shown in Appendix 2. Samples sizes were calculated for rates of risk factor assessment in male subjects (control group) from 40% to 80%, with rates for female subjects (experimental group), calculated at 15%, 20%, 25% and 30% less than the rates specified for the control group.

Based on these calculations, a study sample size of approximately 400 patients (50% females) was selected. This sample size would allow a relative difference of 20% in risk assessment rates between female and male subjects to be detected with a power of 90%, assuming an overall risk factor assessment rate of 75% for male subjects.

D. STATISTICAL ANALYSIS

The frequency with which risk factor and clinical history variables were assessed by the physician as either present (positive) or absent (negative) were calculated for the overall population and for the gender, age, and clinic setting subgroups using the SAS statistical package [243]. The frequency of non-documentation for each of these variables (no mention of the variable by the physician) was similarly calculated. Intervention rates, for diet, exercise, and

lipid-lowering drug therapy were also determined for the total group, and the gender, age and clinic setting subgroups. Statistically significant differences between risk assessment and intervention rates were tested with chi-square analysis.

The relationship between demographic and risk factor variables, as independent variables, and the utilization of lipid-lowering diet and/or drug interventions, as dependent variables, was investigated using multivariate regression analysis.

CHAPTER IV

RESULTS

A. SUBJECT CHARACTERISTICS

The demographic profile and clinical characteristics of the 397 subjects selected in the computer search and included in the medical records review are shown in Table 5. Of the total, 76% (n = 302; 150 women, 152 men), were patients seen in outpatient clinics of the Division of Cardiology, University of Alberta Hospitals, and 24% (n = 95; 48 women, 47 men) were drawn from the four participating community family practice clinics. The mean age of the entire cohort was 65 ± 11.5 years (range 34 to 90); 36% of subjects were aged 70 or older at the time of their qualifying event. This older age group was predominately (65%) female and approximately evenly distributed between the two clinical settings, comprising 36% of hospital clinic, and 33% of community clinic subjects.

Angina was the most common qualifying event overall (42% of cases) followed by AMI (31%) (**Table 5**). As expected, the majority (68%) of subjects identified through the hospital cardiology database qualified for study entry on the basis of recent myocardial infarction, coronary artery bypass grafting (CABG), or percutaneous transluminal angioplasty (PTCA); only 32% of this group had angina as the qualifying event. In contrast, most community clinic patients (73%) entered the study with a qualifying diagnosis of angina, reflecting

Table 5. Demographic profile and clinical characteristics of patients identified for medical records review (n = 397)

	n (%)
Clinical setting	
Hospital clinic	302 (76)
Community clinic	95 (24)
Gender	
Female	198 (50)
Male	199 (50)
Age	
≥70 years	141 (36)
<70 years	256 (64)
Qualifying Event	
Acute myocardial infarction	122 (31)
Coronary artery bypass graft	61 (15)
Percutaneous transluminal coronary angioplasty	49 (12)
Angina	165 (42)

the different presentation of CHD between the two clinical settings.

Quantitative measures of risk factors were not available for all subjects; the mean values (± SD) based on available data for total, LDL, and HDL cholesterol, triglycerides, systolic and diastolic blood pressure, and body mass index are shown in Table 6. While the average serum total cholesterol value (5.94 mmol/L, n = 242) for this group of subjects was close to the mean values for male (5.52 mmol/L) and female (5.93 mmol/L) subjects aged 65-74 in the Alberta Heart Health Survey (AHHS) [244], 38% of subjects in the current study had total cholesterol values in the high risk range (≥ 6.2 mmol/L), compared to only 19% of those aged 35-74 years in the provincial survey. Similarly, 72% of study subjects had recorded cholesterol values above the commonly accepted "desirable" level (· 5.2 mmol/L) whereas 54% of the population aged 35-74 years in the Alberta survey had cholesterol readings in the borderline-high to high range (Figure 1). Obesity, defined as a BMI of 27 or greater, also was more prevalent in this group of subjects with established CHD than in the Alberta population in general. Based on available clinic measurements of height and weight (n=295), more than half of subjects in this study (52%) could be classified as obese (BMI ≥ 27). In the Alberta survey, 33% of the total population, and 42% of those aged 35-74, had a BMI of 27 or greater (**Table 7**).

Although the study protocol allowed review of all physician-generated entries in the medical record over a period of up to 12 months (from 6 months before to 6 months after the index event), the median number of documented physician-patient encounters actually available for review was 3, (range 2 to 30). Relatively

Table 6. Mean (SD) values for selected risk variables among subjects with documented measurements

Variables	n	mean ± SD	Q1	Q2	Q3
Serum Cholesterol (mmol/L)					
Total cholesterol	242	5.94 ± 1.29	5.09	5.89	6.57
LDL cholesterol	117	3.82 ± 1.09	3.10	3.60	4.40
HDL cholesterol	127	1.09 ± 0.30	0.89	1.10	1.30
Triglycerides	157	2.54 ± 2.89	1.42	1.90	2.60
Blood Pressure (mmHg)					
Systolic	380	137 ± 20	124	136	150
Diastolic	380	78 ± 11	70	80	85
Body Mass Index (kg/m^2)	295	27.8 ± 4.9	24.3	27.2	30.9

Q1 = 25th percentile; Q2 = 50th percentile; Q3 = 75th percentile

Figure 1. Percent distribution of serum total cholesterol (TC) values (n=242)

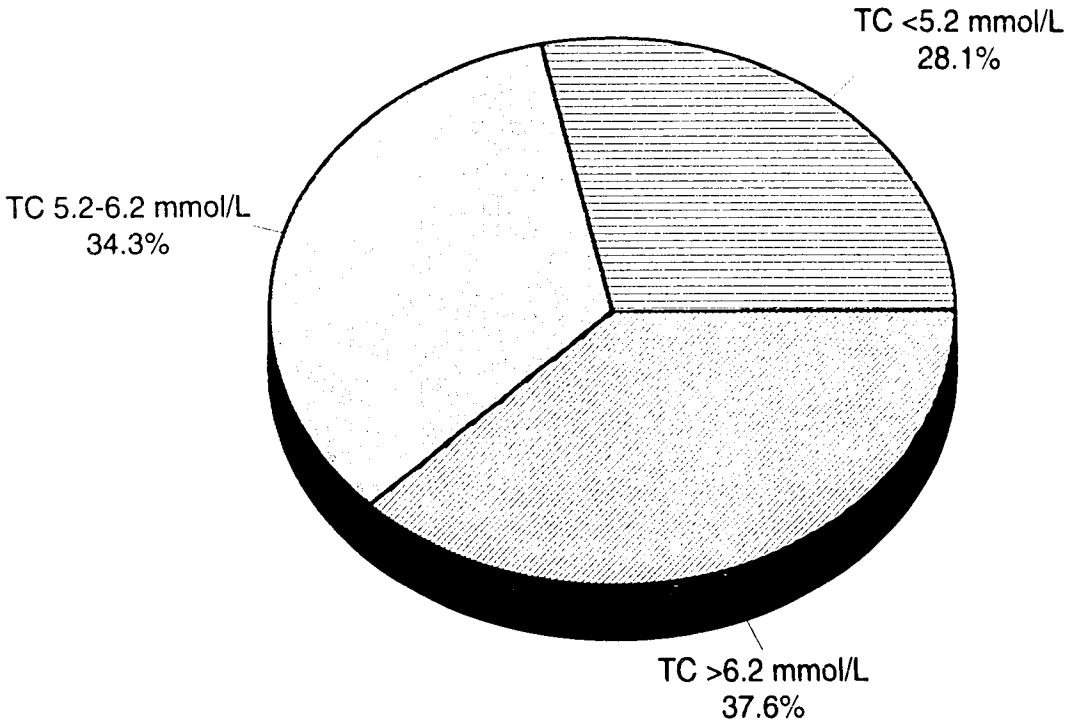


Table 7. Percent distribution of selected risk factors for study subjects (n=397) and Alberta Heart Health Survey (AHHS) sample.

Risk Factor	Current Study	AHHS[1]
	(%)	(%)
Current smoking[2]	27	23
Hypertension	52	25
Hyperlipidemia (total cholesterol ≥ 6.2 mmol/L)	38	19
Diabetes[3]	21	5
Obesity (documented BMI ≥ 27)	52	42

[1] Cohorts aged 35 - 74 years
[2] Subjects identified as smoking regularly at the time of interview
[3] AHHS data based on self-reported diabetes

few of these high-risk patients appeared to have frequent, regular contact with their physician on an outpatient basis. However, the study was not designed to assess whether, or how often, subjects were seen by other physicians during this time period.

B. DOCUMENTED CLINICAL HISTORY

Audit of physician-generated entries in the medical records indicated 78% of all subjects had a known history of AMI or unstable angina, 63% had undergone coronary revascularization (CABG or PTCA), and 83% were identified as having a history of angina **(Table 8)**. References to the presence of other atherosclerotic vascular disease (CVA or PVD), were found in 15% of charts reviewed. AMI or unstable angina and previous revascularization procedures were more frequently noted for patients from the hospital clinics than for community clinics subjects ($p < 0.001$), while a history of CVA or PVD was more commonly indicated for subjects who visited community clinics ($p < 0.05$). A slightly greater proportion of males than females had a history of coronary bypass or angioplasty, although the difference was not significant ($p<0.06$). The pattern of documented cardiovascular events was otherwise similar between gender groups. Comparison of older (age $\geq$ 70 years) and younger (age < 70 years) subjects revealed no differences in the prevalence of documented history of AMI, unstable angina or angina pectoris. Older subjects were however, less likely to have had coronary bypass or angioplasty, (57% versus 67%, age < 70

Table 8. Percent of patients with a positive history of selected cardiovascular events as documented by the physician (n = 397 medical records)

	Gender		Age		Clinic Setting		Total
Event	Female n=198	Male n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
AMI/UA	75	80	77	78	82	63‡	78
CABG/PTCA	58	68	57	67§	73	32‡	63
Angina	86	81	81	85	81	89	83
CVA/PVD	17	14	21	12†	13	22§	15

AMI=acute myocardial infarction; UA = Unstable angina; CABG=coronary artery bypass grafting; PTCA=percutaneous transluminal coronary angioplasty; CVA=cerebrovascular accident; PVD=peripheral vascular disease.
§ $p<0.05$; † $p<0.01$; ‡ $p<0.001$

years; $p < 0.05$) and more likely to have documented histories of CVA or PVD, (21% versus 12%, age < 70 years; $p < 0.001$).

The true prevalence of cardiovascular events among study subjects may be underestimated by the above data since, for each clinical variable, a proportion of patient charts did not contain any references to either a positive or negative history. As shown in Table 9, the frequency of non-documentation for clinical variables was relatively low for those related to cardiac history, but reached 73% for mention of either CVA or PVD. The study protocol did not require specific notation of the absence of a history of coronary revascularization; if there was no mention of CABG or PTCA, a "no" response was recorded.

C. ASSESSMENT OF CARDIOVASCULAR RISK FACTORS

Documented Risk Factors

The prevalence of major and contributing cardiovascular risk factors, as documented by physicians, appears in Table 10. Considering the three major risk factors, 27% of these high-risk subjects were identified as smokers, (smoking within the past 12 months), 31% had a reported history of dyslipidemia, and 52% had diagnosed hypertension. Forty-five percent of all subjects were positive for at least one of these risk factors; 24% had two major risk factors, and for 6% the presence of all three risk factors was documented.

The documented occurrence of other risk factors in the study population was: diabetes, 21%; family history of cardiovascular disease, 45%; obesity, 35%; and

Table 9. Percent of patients without documentation of a positive or negative history of cardiovascular events (n=397 medical records)

	Gender		Age		Clinic Setting		Total
Event	Female n=198	Male n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
AMI/UA	12	8	12	9	8	17	10
Angina	5	5	6	4	6	2	5
CVA/PVD	71	68	62	74	68	73	70

AMI=acute myocardial infarction; UA = unstable angina; CVA=cerebrovascular accident; PVD=peripheral vascular disease.

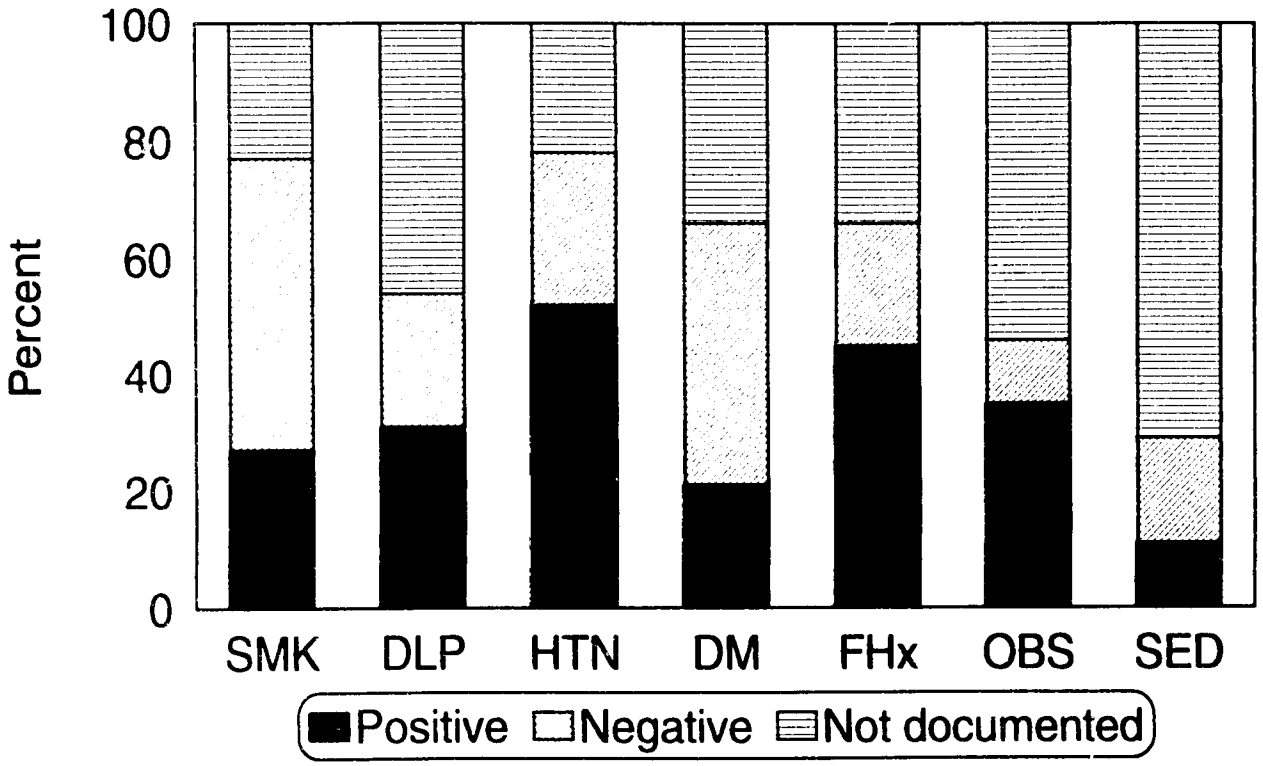
sedentary lifestyle, 11%. In only 9% of cases were none of the specified risk factors documented as positive; multiple risk factors were identified by physicians for two thirds of the study population.

In the cohort of female subjects with CHD, neither menopausal status nor use of estrogen replacement therapy were consistently documented. Although the 25th percentile for age was 59 years, suggesting at least 75% of women were potentially eligible for hormone replacement, estrogen therapy was documented for only 10 subjects.

Non-documentation of Risk Factors

Non-documentation of the presence or absence of risk factors ranged from 20-35% for smoking, hypertension and family history of cardiovascular disease, while records of approximately 45% of subjects contained no mention of diabetic or lipid status. In over 50% of cases, the physician of record made no reference to the presence/absence of obesity; more than 70% of patient records were devoid of any mention of habitual activity patterns (Figure 2). While all these factors may, in fact, have been ascertained by the physician and used to guide decision-making, the lack of medical record documentation allows speculation that, in a large percentage of cases, the presence of risk factors, and potential for risk reduction, did not figure prominently in the management plan.

Figure 2. Risk factor assessment (n=397 medical records)



SMK=Smoking; DLP=dyslipidemia; HTN=hypertension; DM=diabetes; FHx=family history of CVD; OBS=obesity; SED=sedentary lifestyle

Influence of Gender

Risk factor assessments were documented for similar proportions of female and male subjects (**Table 10**). In both groups, nearly 30% were smokers, approximately one-third had a reported history of dyslipidemia, and roughly half carried a diagnosis of hypertension.

With respect to the other risk factor variables, the only significant gender difference evident from physicians' documentation was a higher prevalence of predominantly sedentary behaviour among female subjects ($p<0.01$). However, given the high rate of non-documentation for this variable overall, (approximately 70%), no valid conclusions concerning gender differences in activity patterns, or physicians' attention to this risk factor, can be inferred. Non-documentation of risk factors was common, and did not differ significantly between gender groups, with one exception; family history of cardiovascular disease, whether positive or negative, was less likely to be mentioned in the records of female subjects ($p < 0.05$).

Influence of Age

Smoking, history of dyslipidemia, diabetes, family history of cardiovascular disease, and obesity were documented as positive for a significantly higher proportion of younger than older subjects (**Table 10**). However, due to the higher rates of non-documentation of dyslipidemia ($p<0.001$), family history of cardiovascular disease ($p<0.01$), and obesity ($p<0.001$) among subjects ≥ 70

Table 10. Assessment of coronary heart disease risk factors by gender, age, and clinic setting (n = 397 medical records)

	Gender		Age		Clinic Setting		Total
Risk Factor	Female n=198	Male n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Smoking status							
Assessment documented[1]	73	80	74	78	77	75	77
Present[2]	28	27	15	34‡	26	32	27
History of dyslipidemia							
Assessment documented	50	58	43	61‡	55	52	54
Present	31	32	16	40‡	29	40	31
History of hypertension							
Assessment documented	79	77	80	78	77	82	78
Present	56	48	55	50	48	65	52
Diabetic status							
Assessment documented	66	67	64	68	72	50‡	66
Present	24	18	16	25§	20	24	21
Family history of CVD[3]							
Assessment documented	61	72§	57	71†	68	62	66
Present	40	49	37	49§	45	45	45
Obesity							
Assessment documented	47	44	33	53‡	44	50	46
Present	37	32	19	43‡	34	37	35
Sedentary behaviour							
Assessment documented	29	30	27	30	25	43	29
Present	16	7†	10	12	12	10	11

[1] Presence or absence of risk factor documented by the physician
[2] Number of subjects with presence of risk factor documented/subjects per group
[3] Cardiovascular disease in a parent or sibling
§ p<0.05; † p<0.01; ‡ p<0.001

years of age relative to those <70 years old, it is uncertain whether the available data reflect true differences in risk factor prevalence. The results do suggest, however, that physicians are less likely to consider the influence of these factors on overall cardiovascular risk when the patient is 70 years of age or older.

Influence of Clinic Setting

A history of hypertension or dyslipidemia was more frequently noted for community clinic than hospital clinic subjects ($p < 0.01$ and $p < 0.05$, respectively) (**Table 10**). The documented prevalence of other risk factors was similar between the two groups. Non-documentation rates were also similar between clinical settings with the exception of diabetic status, which was less likely to be described in community clinic records (50% of records without mention of diabetic status versus 28%, hospital clinic, $p < 0.001$). It may be that community physicians routinely record diabetic status only if it is positive, and that this is an accepted practice. However, lack of documentation does introduce an element of uncertainty as to whether the possibility of this disease, particularly non-insulin dependent diabetes, has been considered and ruled out.

D. INVESTIGATION AND MANAGEMENT OF RISK FACTORS

Smoking Intervention

Evidence of smoking cessation counselling or other attempts by the physician to assist patients to reduce or eliminate smoking were noted for 24% of those

subjects who had smoked within the previous 12 months (n=109) (**Table 11**). Given that smoking is a notoriously difficult behaviour to alter, repetition and reinforcement of the stop smoking message is universally recommended. However, in this study, repeated smoking intervention efforts were evident in the records of just 13% of subjects who smoked.

No significant differences in smoking intervention efforts related to gender or clinic setting were evident. A higher proportion of younger than older subjects were offered interventions to reduce smoking, but the small number of older subjects who were classified as smokers (n=21) precludes any reliable conclusions of the impact of age on the probability of smoking intervention efforts by the physician.

Exercise Intervention

Evidence of discussions with patients regarding the benefits of increased physical activity, or any mention of specific exercise recommendations, were present in only 17% of medical records reviewed (**Table 11**). Evidence of interventions to improve physical activity levels were found more frequently in records of community than hospital clinic subjects (28% versus 14%, $p < 0.001$), and for subjects <70 years of age (23% versus 7%, aged 70 years, $p<0.001$). Equally low rates of exercise intervention were recorded for female and male subjects (15% and 20%, respectively).

Table 11. Non-pharmacologic interventions for risk factor reduction documented by physicians

Intervention Documented	Gender		Age		Clinic Setting		Total
	Female n=198	Male n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Smoking cessation[‡]							
Once only	11	19	14	26[†]	12	22	24
More than once	7	10	10	14	6	13	13
Exercise counseling							
Once only	15	20	7	23[‡]	14	28[‡]	17
More than once	5	7	2	8[†]	5	9	6

[‡] Among patients identified as current smokers, n=109

[§] $p < 0.05$; [†] $p < 0.01$; [‡] $p < 0.001$

Investigation of Serum Cholesterol Levels

In this group of high risk subjects with known CHD, results of at least one total cholesterol and/or lipoprotein cholesterol analysis between January 1, 1988 and the end of the study review period were available in 61% of medical records (**Table 12**). A second or subsequent serum lipid analysis, however, was found in only 21% of charts reviewed. Subjects who were identified as having a history of dyslipidemia (n=125) were more likely to have a cholesterol test result on file (78%); however, for only 38% of those with previously diagnosed lipid abnormalities was there a repeat lipid analysis available in the medical record.

Lipid test results were found with approximately equal frequency for female and male subjects; older subjects however, were much less likely than their younger counterparts to have either a single test result ($p < 0.0001$), or repeat determinations ($p < 0.001$) documented. Results of both single and repeat lipid determinations were found with greater frequency in the records of patients from community clinics than in those of hospital clinic subjects ($p < 0.001$) (**Table 12**). Roughly 50% of subjects who visited physicians in community clinics had two or more lipid determinations on file, while only 12% of hospital clinic records contained more than a single cholesterol test result. Approximately half the records from the hospital clinic setting did not contain even a single, random total cholesterol result. Thus, physicians working in the hospital clinics may have been unaware of their patients' blood cholesterol status in about 50% of cases.

Table 12. Documented investigation and management of lipid risk factors

Documented Actions	Gender		Age		Clinic Setting		Total
	Females n=198	Males n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Cholesterol testing							
At least one test[1]	58	64	45	70‡	53	87‡	61
More than one test	20	22	12	26‡	12	49‡	21
Lipid lowering therapy							
Dietary intervention							
• Once	37	49†	35	48†	43	42	43
• More than once	13	18	11	17	13	21	15
Drug therapy	19	24	11	27‡	22	21	21
Intent to monitor / follow-up on serum lipids	25	36§	15	39‡	28	38	31

[1] Full or partial lipid profile analyzed between January 1, 1988 and end of follow-up period.
§ $p<0.05$; † $p<0.01$; ‡ $p<0.001$

Lipid-Lowering Dietary Therapy

Evidence of dietary advice or counselling, or even casual discussions with the patient concerning dietary modification for reduction of serum lipid levels, was found in fewer than half (43%) of all charts reviewed (**Table 12**). Repeated dietary counselling or discussions of diet were recorded in the charts of only 15% of patients. Notations suggesting dietary intervention were slightly more common in the records of subjects who had a documented history of dyslipidemia (n=125) than for the overall study population (54% versus 43%), but even in this subgroup, review or reinforcement of dietary recommendations was evident in just 22% of cases.

No difference in the frequency of dietary counselling was found between clinical settings. Female subjects and those aged ≥ 70 years however, appeared to have been offered dietary counselling less often than males and those aged < 70 years ($p < 0.01$ for both).

Lipid Lowering Drug Therapy

Treatment, or the intent to treat, above optimal lipid levels with hypolipidemic agents was documented in the records of 21% of subjects overall, increasing to 53% of those subjects with a documented history of dyslipidemia (n=125). Lipid-lowering agents were utilized for 35% of the 91 subjects with documented lipid values > 6.2 mmol/L, (with or without a documented history of dyslipidemia), the threshold level for consideration of pharmacologic intervention according to

published recommendations [23,24]. No differences in utilization of drug therapy between hospital and community clinic settings or between male and female subjects were evident. Individuals aged 70 years and older however, were less likely to have been prescribed lipid-lowering therapy than individuals less than 70 years of age ($p < 0.001$).

Follow up Plan for Lipid Management

A specific, written plan indicating the physician's intent to follow-up and actively manage above optimal lipid levels was found in 31% of medical records overall, and occurred more frequently in the charts of male subjects and individuals under age 70 years than in those of female and older subjects ($p < 0.05$ and $p < 0.001$, respectively). A trend toward more frequent documentation of an intent to actively manage serum lipids was seen in charts from the community clinics (38%) as compared to hospital clinics records (28%), but the difference did not reach statistical significance ($p < 0.08$).

As was the case for lipid testing and diet or drug interventions, record of a follow-up management plan was most common for those subjects with a documented history of dyslipidemia (n=125). For 59% of these subjects, the physician had recorded a clear statement of intent to monitor or treat unsatisfactory serum lipid levels.

Multivariate Analyses

Logistic regression (backward elimination) models were used to evaluate the relationship of demographic and selected risk factor variables to the probability of medical record documentation of recommended lipid-lowering therapies (diet and/or drug intervention). Eight variables were entered into the model, including gender (female, male), age (≥70 years, < 70 years), clinic setting (hospital, community), and five risk factor variables: history of dyslipidemia, history of hypertension, current smoking, diabetic status, and family history of cardiovascular disease. Cholesterol values were not entered as a variable due to the large number of missing values. Obesity and sedentary behaviour were omitted from the multivariate analysis, due both to the low level of documentation and subjective nature of these variables. The remaining risk factor variables were converted to dichotomous responses (yes, no/not documented), under the assumption that the documented presence of a risk factor (positive history), as opposed to no documented presence (i.e. documented negative history or no documentation) would be the primary influence on decisions regarding lipid-lowering therapy.

In the first analysis, the probability of definite lipid-lowering diet and/or drug interventions was shown to be significantly related to only three variables: age, gender, and history of dyslipidemia. In this analysis, subjects <70 years of age, males, and those with a documented history of dyslipidemia were more likely to have dietary or drug therapy documented than older subjects, females and those without a previously documented history of dyslipidemia (**Table 13**). History of

Table 13. Pharmacologic interventions for risk factor reduction documented by physicians

Medication Prescribed	Gender		Age		Clinic Setting		Total
	Female n=198	Male n=199	≥70 y n=141	<70 y n=256	Hospital n=302	Community n=95	n=397
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Lipid-lowering agents	17	21	9	24‡	20	15	19
ACE inhibitors	32	30	37	27	33	24	31
Antihypertensives[1]	88	89	89	88	93	74	88

[1] Beta blockers, calcium channel blockers, diuretics

§ p <0.05: † p <0.01; ‡ p <0.001

dyslipidemia was a highly significant predictor; subjects with a positive history were nearly 4 times more likely than those without such history to have an intervention documented in the medical record. A second multivariate analysis with drug intervention as the only dependent variable also revealed a documented, positive history of dyslipidemia to be strongly associated with lipid-lowering drug treatment (OR 13.9, $p<0.0001$). Age < 70 years was again associated with likelihood of drug treatment (OR 2.0, $p<0.05$) in this analysis; gender however, did not remain in the final model.

Since the initial multivariate model assumed equivalence of documentation of the absence of a risk factor (negative history) and non-documentation, the analyses were performed a second time with the risk factor variables dichotomised as *documented* (positive or negative) versus *not documented*. Under this model, diet and/or drug therapy were shown to be significantly related to age, with subjects <70 years more likely to receive therapy than those aged 70 years and older (OR 2.12, $p<0.008$), and was also related to documentation of dyslipidemia (**Table 13**). Either a positive or negative history of dyslipidemia, as recorded by the physician, increased the likelihood of diet and/or drug treatment (OR 2.78, $p<0.0001$) in this model. When only lipid-lowering drug therapy was considered, age and history of dyslipidemia remained significant; however, a third variable, family history of cardiovascular disease, was also retained. Based on this analysis, documentation of family history of cardiovascular disease, whether positive or negative, is significantly related to lipid-lowering drug therapy (OR 2.15, $p<0.01$). It may be that physicians who inquire about family history

are more likely to perform comprehensive risk factor assessments, and thereby identify patients at high risk, who may benefit from drug treatment, despite a negative family history.

CHAPTER V

DISCUSSION

This study focused on the assessment and management of well known cardiovascular risk factors in a group of 397 subjects (50% female) readily identifiable, on the basis of clinically manifest CHD, as being at high risk for future cardiovascular events. All subjects included in the review were seen by a physician on a minimum of two occasions; individuals for whom aggressive risk factor interventions might deemed inappropriate, due to the presence of debilitating disease or terminal illness, were excluded. The results therefore, reflect the probability that, for high risk subjects, comprehensive risk factor assessments will be documented within a defined period of time (12 months), and interventions to reduce risk factor levels indicated in the medical record, either as a management plan, or actions implemented.

It had been assumed, for purposes of determining the sample size, that the major risk factors, (smoking, dyslipidemia, and hypertension), would be well documented by physicians, given the strength of the evidence supporting the role of these factors in CHD events, and proven benefits of their modification. An overall assessment rate of 75% in male subjects and approximately 60% for females was projected, and a sample size to allow detection of a 20% relative difference in the assessment rate for female subjects with approximately 90% power was obtained. Although the actual frequency of documentation of

dyslipidemia was lower than anticipated (58% for males), documentation rates for smoking and hypertension for male subjects were slightly higher than anticipated levels, (80% and 77%, respectively), giving an overall documentation rate for the three factors of 72%. Thus, the study would have had sufficient power to detect gender differences of ≥20% in rates of documentation of major risk factors, if such differences had existed. However, the frequency of documentation of the major risk factors for female patients (73%, smoking; 50%, dyslipidemia; 79%, hypertension), was, at 67%, higher than the anticipated rate (60%), and was in fact similar to the risk factor documentation rate for males. Nonetheless, a number of other interesting findings were revealed.

Major Findings

The results this retrospective study indicate that, for patients with diagnosed CHD seen in outpatient clinics, 1) the documented prevalence of major cardiovascular risk factors (smoking, dyslipidemia, hypertension) is high relative to the general Alberta population; 2) comprehensive risk factor assessments, encompassing both major and contributing risk factors, are infrequently recorded by physicians; 3) risk factors are assessed and treated less often in older (aged ≥70 years) than younger individuals; and 4) based on medical records documentation, physicians' use of recommended strategies for reducing risk factor levels is suboptimal.

Risk Factor Assessment and Status

Despite the uncertainty introduced by the absence of references to major or contributing risk factors in many patient records, the prevalence of diagnosed dyslipidemia, hypertension, diabetes and obesity in this group of subjects with known CHD was substantially higher than reported for the general Alberta population [244], a finding consistent with other studies [245], and supportive of the targeted approach to risk factor management advocated by some experts [37]. Since this tendency for patients with CHD to have additional atherogenic traits which further increase cardiovascular risk has been recognized for many years [245, 246], it is disquieting to find that comprehensive risk factor assessments were not, as far as can be ascertained, completed in a substantial number of cases. While it may be argued that some risk factors, such as smoking status or obesity, may be routinely evaluated, but not recorded, by the physician, it is much harder to accept that a physician can be aware of a patient's lipid status in the absence of any laboratory test results. The Canadian Consensus Conference recommendations clearly identify measurement of total cholesterol, HDL cholesterol, triglyceride, and LDL cholesterol (derived) concentrations as the minimum for determining lipid risk factor status, and further target persons with known CHD as the highest priority for cholesterol testing [23]. Yet, for 39% of subjects in this study, there was not a single serum cholesterol value on record, even when records from 2 or more years prior to the index visit were included in the review, while just 21% of subjects had more than an isolated lipid determination available. Among patients with dyslipidemia by

history, (almost one-third of the total study population), 22% had no accessible serum lipid values to confirm or rule out a lipid abnormality. These results strongly suggest that either lipids are not perceived to be an important influence on patients' overall risk for subsequent CHD events, or possibly, that these physicians do not feel interventions to reduce lipid levels are within their scope of expertise and/or responsibility.

Risk Factor Management

A second important finding of this study is that the documented utilization of interventions to reduce risk factor levels, particularly serum cholesterol concentrations, was disappointingly low overall. Lipid-lowering dietary intervention, the recommended first step to controlling serum cholesterol [23,24], was, even when very broadly defined (**Table 4**), recorded for only 43% of the study population, despite the fact that 78% of subjects with available lipid tests results (n=242) had serum cholesterol values above the "desirable" level (5.2 mmol/L) specified by Canadian and U.S. national guidelines [23,24]. For this group of subjects, the recommended minimum intervention would have included discussion of the American Heart Association Step I diet or equivalent. Subjects with cholesterol levels above 6.2 mmol/L and/or LDL cholesterol values exceeding 3.4 mmol/L would have been appropriate candidates for referral to a registered dietitian for assistance with shifting toward a Step II dietary pattern. With the exception of one community-based practice, however, referrals for

professional dietary counselling were infrequently encountered in patients' records.

Although some researchers suggest that dietary modification for patients who have experienced a CHD event should be regarded as a secondary strategy only, with immediate prescription of a lipid-lowering drug as the primary intervention [247], the recently updated National Cholesterol Education Program Adult Treatment Panel II guidelines [26] continue to emphasize the centrality of the lipid-lowering diet in management of patients with established atherosclerotic disease. Further evidence in support of dietary intervention as a integral component of risk reduction has come from angiographic trials. Watts et al [248] recently reported intake of saturated fatty acids to be correlated with progression of coronary artery disease as measured by changes in coronary luminal dimensions. Conversely, a reduction of saturated fat intake to 8% of total energy intake, which approximates Step II diet recommendations, and is achievable with the assistance of a dietitian, was associated with favourable effects on angiographic endpoints [248].

Other recommended lifestyle modifications to help control risk factor levels also appeared to be used with less than optimal frequency. Interventions to promote increased physical activity/exercise levels were seldom documented (17% of cases), and smoking cessation advice or counselling was recorded for only one quarter of patients identified as current smokers. While the observed utilization rates for non-pharmacologic interventions (diet, exercise, smoking cessation) are disappointingly low, all may have been utilized by physicians

without being recorded in the permanent record. The results, therefore may simply reflect inadequate documentation, rather than possibly inappropriate therapy.

With respect to pharmacologic lipid-lowering interventions, the scarcity of lipid test results to confirm definitely elevated levels does not allow evaluation of the number of subjects for whom drug treatment might actually have been warranted based on persistently elevated serum total cholesterol (· 6.2 mmol/L) [25]. Thirty-eight percent of subjects with documented test results, however, had a value ≥ 6.2 mmol/L on at least one occasion, while only 19% of the total study group were currently taking, or had previously taken, a lipid-lowering agent. Since previous studies indicate that medications are, in general, well documented in medical records [240], this finding suggests that lipid-lowering drug therapy for this high-risk patient population with CHD may be underutilized.

Gender Differences

The presence of systematic gender differences in risk factor assessment practices could not be confirmed by this study. Although family history was less often recorded (positive or negative) for female subjects, other risk factors, notably those factors amenable to modification, were documented for a similar proportion of female and male subjects. Frequency of investigation of lipid risk factors, indicated by laboratory test results, was also similar between genders. However, an intent to monitor and/or treat serum lipids was less often documented for female subjects. Multivariate analysis also indicated female

subjects with CHD were less likely than males to receive lipid-lowering therapy in the form of dietary counselling and/or drug treatment. This relationship was not found when drug therapy alone was considered as the dependent variable, suggesting that physicians may be less likely to consider or specifically recommend dietary modification for female compared to male subjects, a conclusion supported by the significantly greater proportion of males for whom evidence of dietary intervention was documented.

Few other studies that have examined risk factor assessment and management practices have analyzed data for male and female patients separately. One previous study did report that gender was not a predictor of investigation of lipid risk factors, either for an initial screening total cholesterol, or for subsequent lipoprotein analysis [231]; a second investigation [229] reported a lack of association between patient gender and the likelihood of a documented lipid-lowering intervention. In contrast, Robinson et a [230] found that follow-up monitoring of cholesterol levels, in the form of multiple lipid measurements, was more common for male than female subjects; women also were more likely to have no cholesterol level available on the chart.

The current study is somewhat at variance with these previous reports, as females underwent lipid investigations as often as did males, but did not appear to be offered lipid-lowering dietary counselling as frequently as were their male counterparts. Drug treatment for elevated lipids however, was utilized in a similar proportion of females as males.

Age-related Differences

In contrast to the rather limited evidence of gender-based differences in practice patterns, more consistent and significant age-related differences in both risk factor assessment and management practices were revealed. Compared to subjects under the age of 70, subjects aged ≥70 years were less likely to have any mention of lipid status, family history of cardiovascular disease, or obesity documented in the medical record. Risk modifying interventions, including lipid-lowering diet and/or drug therapy, exercise recommendations, and smoking cessation counselling were also documented less often in the files of the older cohort.

None of the previous studies of practices in risk factor management have included significant numbers of subjects older than age 70, most in fact, have deliberately omitted older age groups from the analysis [229]. The few studies which have examined the influence of age on risk factor evaluation and management have reported that rates of investigation and active treatment increase with age, but the upper age limit of 65 years applied in these studies makes than noncomparable with the current investigation. Studies of practice patterns for management of AMI however, are consistent with results of this project, in that older subjects have been shown to receive less of the proven therapies than do younger individuals [201].

Clinic Setting

In the present study, few differences were found in documented assessment of risk factors between clinic settings. This was somewhat unexpected, as a number of the hospital based patient records for the study period spanned inpatient admissions, which require a full history and physical exam. In addition, many of the hospital clinic outpatient records contained outgoing letters of consultation by the specialist physician, providing an ideal opportunity to review cardiovascular risk factors and summarize options for interventions.

Some differences in treatment practices were found however, as community based family physicians were more likely than hospital based practitioners to document use of non-pharmacologic interventions, particularly recommendations for increased exercise/physical activity. A tendency toward more frequent attention to smoking cessation counselling was also evident in community clinic records. This may reflect the growing emphasis on preventive care and healthy lifestyle counselling that has emerged in the primary care literature in recent years [249].

Comments

This project was designed as a pilot study to a larger investigation assessing the feasibility and efficiency of using retrospective medical records review to evaluate and compare patterns of practice for management of cardiovascular risk factors between patient subgroups and clinic settings. Although it was

recognized that problems exist with retrospective medical records review as a method of investigation, chart audits are a valuable tool for initially defining, and monitoring changes in, practice patterns. Some of the specific problems and issues encountered in this study, however, require mention. First, the unexpected difficulties in locating community clinics able to identify appropriate patients through a computer database search, and differences in the identification and coding of cardiovascular diagnoses between community and hospital clinics, required use of different screening strategies among the various sites. Particularly for those clinics without computer search capability, this may have resulted in a biased sample, as all potentially eligible patients may not have been identified.

Second, the high rate of non-documentation of risk factors, and therefore missing data points, required use of assumptions in data analysis that may not have been accurate. It cannot be stated with certainty, for example that the absence of documentation of a risk factor is equivalent to a negative response, given that negative responses were specifically recorded in a substantial proportion of cases.

A third issue relates to the 12 month time period covered by the chart audit. It was expected that these high risk patients would be seen by their physician on multiple occasions over the span of a year, allowing ample time for evaluation of overall risk and development of a risk factor management plan. In reality, however, only a minority of patients were seen frequently; the median number of physician-patient encounters was 3 and the mode 2. Ideally, risk factors levels

would be assessed, and appropriate risk reduction measures taken, within a one year period as was encompassed in this study. However, the nature of the presenting complaint, (cardiovascular versus other), time constraints imposed by the physician's caseload, and patient preferences may make deferral of risk factor assessment and management reasonable and/or necessary for one or more visits. Thus, a relatively narrow time frame may not have adequately captured physicians' full range of risk management activities.

Future Directions

Several issues raised by this pilot study warrant additional and more detailed investigation. The observed differences in patterns of investigation and management of cardiovascular risk factors between older and younger individuals requires confirmation in a larger study, given that the older age group in this study comprised only 141 subjects. In future studies, it may also be useful to identify an upper age limit, beyond which aggressive attention to cardiovascular risk factors may not be considered appropriate on a routine basis; however, the value of potentially preventing debilitating cardiovascular events, and maintaining functional independence in the elderly must also be considered.

Some evidence of gender-related differences in management of lipid risk factors was demonstrated in this study, and should be investigated further. The lower utilization of dietary therapy, and less frequent documentation of an intent to monitor risk status in women as compared to men, may reflect a perception that women with CHD are at lower risk for future cardiovascular events than are

men, as has been suggested by other investigators [63]. On the other hand, women, even those who have diagnosed coronary disease, may feel themselves less vulnerable to cardiovascular events than men, and therefore be less likely to accept the need for risk reduction strategies. In this case, measures to enhance utilization of lipid-lowering and other risk modifying strategies may need to target both patients and physicians.

The major issues for future work highlighted by this pilot study however, were the inadequacy of medical record documentation, and barriers to identification of specific patient populations in community clinic settings. Clearly, the lack of documentation of risk management activities impedes efforts to define current practices, and prevents an accurate assessment of the need for physician education or critical path management programs in this area. Studies to evaluate, and enhance, the degree of correspondence between the content of physician-patient encounters, and medical record documentation are needed.

The difficulty in accessing specific patient populations in the majority of community clinics is another critical area to be addressed in future work. Although there is movement towards computerized patient databases in many clinics, these may or may not be suitable for extracting information for research purposes. Development of systems to identify patient groups on a prospective basis may be one option to investigate. It may also be feasible to develop research-oriented computer databases could be offered to community clinics as an alternative to more conventional systems designed, primarily, for billing purposes. Since current estimates indicate that primary care physicians manage

26% of all patients with coronary heart disease [250], efforts to define and/or alter overall practice patterns for management of lipid and non-lipid risk factors in this patient population must extend beyond in-hospital or hospital-based care to include practitioners in primary care settings. Opportunities for further research across clinical settings and medical specialities should be actively pursued.

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APPENDIX 1

Data Collection Form

CV RISK FACTOR MANAGEMENT DATABASE

DEMOGRAPHIC DATA

Sub-grp	Subject ID#	AHC#	D.O.B	Gender
___	_____	_____	___/___/___	___

QUALIFYING CRITERIA

Index Event	Event Date	Initial Record	Follow-up Record	# MD Contacts
___	___/___/___	___/___/___	___/___/___	_____

DOCUMENTED RISK APPRAISAL

Hx MI/UA	Hx Angina	Hx CABG/PTCA	Hx CVA/PVD	Hx DM	Hx HTN
___.___	___.___	___.___	___.___	___.___	___.___

Hx Abn Lipids	+ve Fhx	Hx Sedentary	Obesity/OW	Smoking	(♀) Estrogen
___.___	___.___	___.___	___.___	___.___	___.___

RISK MANAGEMENT

INTERVENTIONS

↓ Smoking	FU	↑ Activity	FU	Δ Diet	FU	Date	Lipid ↓Rx	Date
___.___	___.___	___.___	___.___	___.___	___.___	___/___	___.___	___/___

MEDICATION PROFILE

Rx 1	*dose*	Rx 2	*dose*	Rx 3	*dose*	Rx 4	*dose*	Rx 5	*dose*	Rx 6	*dose*
___.___	___	___.___	___	___	___	___.___	___	___.___	___	___.___	___

PHYSICIAN FOLLOW-UP OF LIPID RISK FACTORS ___

RISK PROFILE

LIPID VARIABLES

Date	TC	TG	LDLC	HDLC	Tx	MD
___/___/___ *First available*	___.___	___.___	___.___	___.___	___	___
___/___/___ *Most recent*	___.___	___.___	___.___	___.___	___	___

OTHER RISK VARIABLES *(first available outpatient measures)*

SBP	DBP	BMI
___	___	___

COMMENTS:

_____

_____

_____

_____

_____

CV Risk Factor Management Database
DATA CODING KEY

DEMOGRAPHIC DATA

Subgroup	10 = UAH: Cardiologist followup 11 = UAH: Cardiologist + Cardiac Rehab. 20 = Misericordia Clinic: FP follow-up 21 = Misericordia Clinic: FP + Cardiac Rehab. 22 = Misericordia Clinic: Shared Care 30 = Royal Alex Clinic: FP follow-up 31 = Royal Alex Clinic: FP + Cardiac Rehab. 32 = Royal Alex Clinic: Shared Care 40 = Drayton Valley Clinic: FP follow-up 41 = Drayton Valley Clinic: FP + Cardiac Rehab 42 = Drayton Valley Clinic: Shared Care 50 = Sherwood Park Clinic: FP follow-up 51 = Sherwood Park Clinic: FP + Cardiac Rehab 52 = Sherwood Park Clinic: Shared Care
ID #	up to 8 characters (alpha-numeric ± dash)
Alberta Health Care #	11 characters
D.O.B.	dd/mm/yy
Gender	1 = Female 2 = Male
M.D.	Specialty of most responsible physician 1 = Cardiology 2 = Family Practice 3 = Other

QUALIFYING CRITERIA

Index event/dx	First qualifying coronary event/diagnosis on record on or after 01 Jan 91. 1 = MI 2 = CABG 3 = PTCA 4 = Angina
Index event date	dd/mm/yy
Initial record	Date (mm/dd/yy) of first risk screening opportunity ≤ 6

months prior to index record.

Follow-up record — Final record eligible for review; ≥ 6 months after date of index record.

DOCUMENTED RISK APPRAISAL

For the following:

1 = Yes (*presence* of risk factor documented)
2 = No (*absence* of risk factor documented)
Extensions to codes 1 & 2:
.1 = noted by MD
.2 = noted by RN/RD only
.3 = noted by MD and RN/RD
3 = Risk factor status *not documented*

Myocardial infarction (MI) or Unstable Angina (UA)
Angina (stable)
CABG/PTCA
CVA/PVD
Diabetes (IDDM, NIDDM)
Dyslipidemia
Hypertension (HTN)
Overweight/obesity (BMI ≥ 27)
Positive family history
Sedentary lifestyle

Smoking status
1 = Current
2 = Never smoked
3 = Quit recently (< 1 yr)
4 = Former smoker (quit ≥ 1 yr)
5 = Smoking status not documented

- Female pts: estrogen
1 = Pre-menopausal status
2 = Post-menopausal without ERT
3 = Post-menopausla with ERT
4 = Status not documented

RISK MANAGEMENT

Interventions

- Smoking cessation — **1** = Advice/counseling
Extensions:

.1 = by physician
.2 = by RN/RD
.3 = by MD & RN/RD

2 = No intervention effort recorded

3 = Not applicable (non-smoking pts)

- Follow-up

1 = Repeat advice/monitoring
.1 = by physician
.2 = by RN/RD
.3 = by MD + RN/RD

2 = No follow-up recorded

- ↑ Activity/Exercise

1 = Advice/counseling
.1 = by physician
.2 = by RN/RD
.3 = by MD & RN/RD

2 = No intervention effort recorded

3 = Not applicable (pt unable to increase physical activity for health-related reasons)

- Follow-up

1 = Repeat advice/monitoring
.1 = by MD
.2 = by RN/RD
.3 = by MD & RN/RD

2 = No follow-up recorded

- Diet modification

1 = Recommendations/counseling
.1 = by physician
.2 = by RN/RD
.3 = by MD & RN/RD

2 = No diet intervention effort recorded

- Start date

mm/yy of first formal intervention effort, if known

- Follow-up

1 = Repeat recommendations/monitoring
.1 = by physician
.2 = by RN/RD
.3 = by MD & RN/RD

2 = No follow-up recorded

- Lipid-lowering Rx

  1 = Intention to treat/new Rx recorded
  2 = Rx maintained/adjusted
  3 = Rx discontinued
  Extensions:
  .1 = current lipid levels noted
  .2 = lipid status not noted
  4 = No documentation

- Start date — mm/yy first lipid ↓ drug prescribed, if known

Medication Profile

- lipid-altering agents

  1 = Nicotinic acid/niacin
  2 = Cholestyramine (Questran)
  3 = Colestipol (Colestid)
  4 = Gemfibrozil (Lopid)
  5 = Fenofibrate (Lipidil)
  6 = Clofibrate (Atromid-S)
  7 = Lovastatin (Mevacor)
  8 = Simvastatin (Zocor)
  9 = Pravastatin (Pravachol)
  10 = Probucol (Lorelco)

  dose — total mg/d

- other medications

  11 = ACE Inhibitor
  12 = Antioxidants
  (Vit. E, C, β-carotene, selenium)
  13 = Diuretic
  14 = Beta blocker
  15 = Calcium channel blocker
  16 = Estrogen replacement therapy

  extensions (for all medications)
  .0 = New Rx; initiated on after index event
  .1 = Continuing Rx, initiated pre-index event
  .2 = Discontinued Rx

Physician monitoring/ follow up of lipid risk factors

1 = Intent documented
2 = No notation

RISK PROFILE

- Lipid Levels

  - first available (after 1988)
  - interim (within 1 yr of CAD dx)
  - most recent

  total cholesterol (TC) mmol/L (__.__)
  triglyceride (TG) mmol/L (__.__)
  LDL-cholesterol (LDLC) mmol/L (_.__)
  HDL-cholesterol (HDLC) mmol/L (_.__)

treatment (tx)

1 = Pt on lipid ↓ agent when specimen drawn
2 = No lipid ↓ Rx when lipids

requesting MD:

1 = Hospital physician, during pt. admission
2 = Hospital physician, at outpatient visit
3 = Community physician, at outpatient visit
4 = Unknown

- Other Risk Markers

(assessed after CAD dx)

(___) Systolic blood pressure mmHg

(___) Diastolic blood pressure mmHg

(__._) Body mass index (BMI) kg / m^2

APPENDIX 2

Sample Size Estimates

Sample Size Estimates[1]

Comprehensive Risk Factor Appraisal[2]		*Total Patients Required (2N)*
Males	Females	80% Power
0.40	0.36	4644
	0.32	1130
	0.30	712
	0.28	486
	0.24	262
0.50	0.45	3144
	0.40	774
	0.375	490
	0.35	336
	0.30	182
0.55	0.495	2598
	0.44	646
	0.4125	410
	0.385	282
	0.33	154
0.60	0.54	2144
	0.48	538
	0.45	344
	0.42	236
	0.36	130
0.70	0.63	1430
	0.56	368
	0.525	238
	0.49	166
	0.42	92

---

1 $p = 0.05$ (2-tailed)

2 Assessed for presence/absence of: current smoking, dyslipidemia, hypertension.