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The Population Effects of the Global Cardiovascular Risk Model in United States Adults: Findings from The National Health and Nutrition Surveys 2005–2006

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Abstract

Background—The Framingham Global Cardiovascular Disease (FRS-CVD) risk assessment is a proposed alternative to assessing hard coronary heart disease (FRS-CHD) event risk. Beyond heart attack and death, FRS-CVD risk adds the endpoints of cerebrovascular disease, angina, heart failure and peripheral vascular disease.

Objective—We sought to estimate the population impact of using FRS-CVD instead of FRS-CHD risk prediction on U.S. adults.

Methods—We analyzed FRS-CHD and FRS-CVD risk in men age 45–74 and women age 55–74 without cardiovascular disease or diabetes, using the National Health and Nutrition Examination Survey 2005–2006. We stratified the population into 10-year risk categories: low: <6%, moderate ≥ 6 - <10%, moderate high ≥ 10 - <20% and high ≥ 20 % by both risk models, assessing change in risk category distribution and achievement of lipid goals.

Results—We analyzed 1,020 subjects who statistically represent about 50 million U.S. adults. Using FRS-CVD, 63% of men and 74% of women increase at least one risk category compared to FRS-CHD. Overall, the low risk population drops from 52% to 16% and the high-risk group increases from 4% to 20%. Of the subjects changing risk categories, 30% will now fail to meet their new corresponding lipid goals.

Conclusions—FRS-CVD endpoints are more comprehensive, yet the population implications of such a change may be profound. Utilizing a FRS-CVD risk model significantly increases the intermediate and high-risk groups, thus increasing the number of individuals eligible for novel risk assessment tools such as hs-CRP, coronary calcium scoring and more frequent use of pharmacotherapy.

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Disclosures

The authors report no conflicts.

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Keywords

NHANES; epidemiology; primary prevention; risk factors; risk models

INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of mortality in the United States. More than 1 in 3 Americans live with one or more types of CVD.¹ Currently, risk assessment centers around the calculation of a Framingham Risk Score that is incorporated within the National Cholesterol Education Program Adult Treatment Panel III (ATP III) guideline,² which assesses the ten year risk of developing the hard endpoints of myocardial infarction or cardiac death. Risk stratification by the Framingham Risk Score for “hard” coronary heart disease events (FRS-CHD) guides physicians in setting cholesterol goals based on a patient’s cardiovascular risk category. The Framingham score has well documented limitations, but remains a low cost method of combining many risk markers that are commonly available in the patient record. In an effort to improve risk assessment, alternate multivariate cardiovascular risk models have been developed.^{3–5} These models vary in the endpoints tested and risk markers utilized for risk assessment. In 2008, a multivariate risk model that estimates a patient’s global cardiovascular risk was developed and validated in the Framingham cohort. This Framingham global cardiovascular risk model (FRS-CVD) represents the broadest range of endpoints yet, including a patient’s 10-year risk of developing: coronary heart disease, (CHD) (myocardial infarction, coronary insufficiency, new angina, coronary death), cerebrovascular disease, (ischemic, hemorrhagic stroke or transient ischemic attacks), peripheral vascular disease (intermittent claudication) and heart failure. Clinicians now have the option to calculate a FRS based on CHD or CVD and assign treatment intensity based on this assessment. Given the multiple event endpoints, it is not surprising that in most patients, their FRS-CVD is greater than their FRS-CHD score. In 2009, the Canadian Cardiovascular Society released their updated guidelines for the diagnosis and treatment of dyslipidemia, which endorses the use of the FRS-CVD instead of the FRS-CHD.⁶ The original ATP III guideline is now nearly a decade old and the Adult Treatment Panel IV is currently meeting with the expected release of new guidelines in 2011. It is unknown what risk assessment model will be recommended and to what role risk assessment will be assigned.

The aim of this cross sectional study is to define the changes in risk category distribution and corresponding changes to lipid goal achievements U.S. clinicians will encounter if they use FRS-CVD instead of FRS-CHD for routine cardiovascular risk assessment of primary prevention patients.

METHODS

The National Center for Health Statistics performs the National Health and Nutrition Examination Survey (NHANES) surveys⁷ in two-year increments with the objective being to define the health and nutritional status of the United States population. The NHANES surveys are composed of a home health interview and a health examination that is performed in a mobile exam center (MEC). Participants undergo a home interview process administered by a trained interviewer. Subsequently, participants undergo a health assessment in a MEC. The MECs are comprised of a health team consisting of one physician, one dentist, two dietary interviewers, three certified medical technologists, 5 healthcare technicians, one phlebotomist, two interviewers and one computer data manager.

The NHANES utilizes complex, stratified, multistage sampling techniques based on demographic and geographical data, assigning subjects a weight such that the sum represents a statistical model of the entire civilian non-institutionalized United States population. Methods involve identification of primary sampling units, within which, clusters of households are identified with each person in the household screened for demographic characteristics. The NHANES database has been used to develop national health standards,⁸ assess disease prevalence,^{9–11} identify risk factors for disease development and management,^{12–14} and assess the health of the nation.¹⁵ Detailed information on NHANES data collection is published and available at <http://www.cdc.gov/nchs/nhanes.htm>.

The NHANES data sets from 2005–2006 were downloaded and imported into Microsoft Excel (version 11.2 for Macintosh, Microsoft Corp, Redmond, Wash). Please see Appendix A for a list of utilized NHANES item codes and descriptions. The data set was also imported into SAS version 9.1 (SAS Institute, Cary, NC). Standard error calculation was performed using PROC SURVEYMEANS in SAS to account for the complex survey design. In the present paper, we refer to both individual NHANES participant counts that are presented as integers without ranges and also the statistically modeled populations that are presented as represented millions of United States individuals with 95% confidence intervals.

Inclusions/Exclusions

We included men aged 45–74 and women aged 55–74 years free of CVD who completed a mobile examination in the 2005 to 2006 NHANES surveys. (N=1,361) The upper limit of age of 74 for both genders matches the population in which the FRS-CVD was validated. We selected men starting at age 45, women starting at age 55 as the FRS-CVD is a ten year risk model and these aforementioned ages have been denoted in ATP III as conferring a risk factor for age.² Because men accrue a risk factor for age at 45 years of age, and women accrue a risk factor for age at 55 years of age this will result in a larger population of men eligible for this cross sectional analysis. Subjects were excluded if they had diabetes mellitus (N = 230) as the ATP III risk score assigns patients with diabetes mellitus as a risk equivalent, making calculation of the absolute FRS-CHD not valid, thus limiting the comparison of the risk models. Subjects missing cholesterol (N=77) or necessary blood pressure data (N=34) were also excluded. The final study population included 1,020 subjects representing approximately 50 million United States adults in need of primary prevention.

Low-density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald equation¹⁶ and was used to determine attainment of treatment goal. Subjects with triglycerides ≥ 400 mg/dL, missing triglyceride data or with a fasting time < 8 hours, lipid goal attainment was assessed using the corresponding non HDL-C goals set forth by ATP III.²

Definitions

High Risk Criteria—Because use of both risk models were not intended for use with subjects who have CHD or equivalent high-risk medical conditions, the following definitions were used within the NHANES data to exclude those subjects with CVD or diabetes mellitus. Coronary heart disease is defined by subjects reporting they were told by a health care professional that they had a myocardial infarction, coronary heart disease or angina pectoris. Cerebrovascular disease is defined by subjects reporting a history of stroke. Heart failure is defined by subjects reporting that they were told by a health care professional that they had congestive heart failure. Diabetes mellitus is defined by subjects being told by healthcare professional that they had diabetes mellitus, reporting taking oral hypoglycemic or insulin, or they had an 8-hour fasting glucose ≥ 126 mg/dL or a random

glucose ≥ 200 mg/dL. Peripheral vascular disease is defined as an ankle brachial index of < 0.9 in either leg.

Risk Stratification—Subjects underwent risk classification by the FRS-CHD and the FRS-CVD into the following risk categories.

- High risk: score $\geq 20\%$
- Moderate high risk: score between $\geq 10 - < 20\%$
- Moderate risk: score between $\geq 6\% - < 10\%$
- Low risk: score $< 6\%$

Subjects for whom the FRS-CVD reclassified to a different category compared to the FRS-CHD were given a new LDL-C goal based on their FRS-CVD classification. We defined a clinically significant reclassification as one where the new LDL-C goal would warrant a change in clinical recommendations. To determine if an individual was currently on lipid lowering pharmacotherapy we utilized the questionnaire portion of the NHANES survey RXQ_DRUG, which lists the generic names within specific therapeutic classes of the subject's current pharmacotherapy. The National Center for Health Statistics utilizes Lexicon Plus®, a comprehensive database of all prescription drug products available in the U.S. drug market to assist in the data collection, editing and release of pharmacotherapeutic agents. Pharmacologic agents are classified using the Multum Lexicon Therapeutic Classification Scheme. Lipid lowering agents are grouped under “metabolic drugs” and divided within six subclasses based on mechanism of action. Each lipid lowering agent fit into one of the following six classes: HMG-CoA-reductase inhibitors, fibric acid derivatives, bile acid sequestrants, cholesterol absorption inhibitors, antihyperlipidemic combinations and miscellaneous antihyperlipidemic agents. Individuals were documented as being on lipid lowering therapy if they were currently taking any pharmacologic agent within one of the following six classes: HMG-CoA-reductase inhibitors, fibric acid derivatives, bile acid sequestrants, cholesterol absorption inhibitors, antihyperlipidemic combinations and miscellaneous antihyperlipidemic agents. In this study, individuals were considered candidates for either initiation or intensification of lipid lowering therapy if the FRS-CVD score reclassified risk category, and their current LDL-C did not meet the new LDL-C goal of their new reclassified risk level. These categories of treatment need were compared between use of FRS-CHD and FRS-CVD assessment tools.

RESULTS

Subject Characteristics

Men—A total of 663 men representing 32.8 million U.S. men ages 45–74 met inclusion criteria. The mean age of the included men was 55.1 years (SD 7.9 years), mean LDL-C was 120.3 mg/dL (SD 37.3), mean systolic blood pressure was 125.4 mmHg (SD 16.1 mmHg), mean diastolic blood pressure was 73.8 mmHg (SD 11.2 mmHg), mean HDL was 50.5 mg/dL (SD 14.6 mg/dL), and the mean total cholesterol was 204.9 mg/dL (SD 36.2 mg/dL). Of the included male subjects, 26% were tobacco users, 16% had a positive family history of premature coronary heart disease and 24% were on blood pressure medications.

Women—A total of 357 women representing 17.2 million U.S. women ages 55–74 met inclusion criteria. The mean age of the included women was 63.1 (SD 5.7), mean LDL-C was 128.6 mg/dL (SD 36.1), mean systolic blood pressure was 129.9 mmHg (SD 21.2 mmHg), mean diastolic blood pressure was 70.5 mmHg (SD 13.2), mean HDL was 62.3 (SD 17.5), and the mean total cholesterol 220.3 mg/dL (SD 39.3). Of the included women 17%

were tobacco users, 11% had a positive family history of premature coronary heart disease and 42% were on blood pressure medications.

Baseline Lipid Characteristics

Baseline analysis of lipid levels of all 1,020 subjects representing approximately 50 million United States adults resulted in 4.8% of the population with LDL-C levels <70 mg/dL, 16.6% of the population between 70 mg/dL and <100 mg/dL, 32.7% of the population between 100 mg/dL and less than 130 mg/dL, 26.7% of the population between 130 mg/dL and less than 160 mg/dL, 14.3% of the population between 160 mg/dL and less than 190 mg/dL and 4.9% of the population greater than or equal to 190 mg/dL. Of the population with LDL-C <70 mg/dL 37% are on lipid lowering pharmacotherapy, of those between 70 and <100 mg/dL 32% are on lipid lowering pharmacotherapy, of those between 100 mg/dL and < 130 mg/dL 20% are on lipid lowering pharmacotherapy, of those between 130 mg/dL and <160 mg/dL, 7% are on lipid lowering therapy, of those between 160 mg/dL and <190 mg/dL 7% are on lipid lowering therapy, and of those subjects with an LDL-C >190 mg/dL 11% are on lipid lowering therapy.

Risk Reclassification

Baseline evaluation of the 1,020 subjects statistically representing approximately 50 million United States older adults was undertaken by first applying the FRS-CHD model. Applying the FRS-CHD to the 663 male subjects representing 32.8 million men results in: 36.7% (30.2%-43.2%) of the weighted population at low risk, 25.6% (22.1%-29.0%) at moderate risk, 31.6% (26.5%-36.8%) at moderate high risk, 6.1% (4.1%-8.2%) at high risk. Applying the FRS-CVD to this same population of men results in: 11.5% (8.9%-14.2%) at low risk, 27% (20.7%-33.4%) at moderate risk, 36.7% (30.6%-42.9%) at moderate high risk and 24.6% (21.5%-27.8%) at high risk. Overall, applying the FRS-CVD to older U.S. men free of CVD and diabetes mellitus results in 63.2% (58.4%-68.0%) increasing risk category, while 0.1% (0-0.3%) decrease risk category. (Table 1, Figure 1)

Applying the FRS-CHD for baseline assessment of the 357 women representing approximately 17.2 million women results in 81.8% (77%-86.7%) of the weighted population at low risk, 12.6% (8.9%-16.4%) at moderate risk, 4.7% (2.3%-7.0%) at moderate high risk and 0.8% (0-2%) at high risk. Applying the FRS-CVD to this same population of women results in 25.1% (19.2%-30.9%) at low risk, 31.3% (26.3%-36.3%) at moderate risk, 33.2% (28%-38.3%) at moderate high risk, and 10.5% (7.1%-13.9%) at high risk. Overall, applying the FRS-CVD model to U.S. women free of CVD and diabetes mellitus results in 74.1% (67.9%-80.3%) increasing risk category, while no women experience a decrease in risk category. (Table 2, Figure 2)

Lipid Goal Achievement

To further analyze the clinical impact of risk reclassification, we next evaluated lipid goal achievement in the group of men and women who experienced risk category reclassification with the FRS-CVD model. Overall, 432 subjects representing approximately 20.8 million U.S. men experienced risk category reclassification to an increased risk level. Of those men increasing risk category, 29.7% (24.6%-34.7%) will not meet the new corresponding lipid goal for their new risk category classification. Turning to the women, 277 subjects representing approximately 12.7 million older U.S. women experienced a risk category reclassification to a higher level of risk. Of these women increasing risk, 30.3% (22.5%-38.1%) will not meet their new corresponding lipid goals for their new risk category reclassification.

Population Estimates of New Lipid Lowering Pharmacotherapy Prescriptions

In the population that ascended to a higher risk category and did not meet their new corresponding lipid goals, the clinician is now faced with a clinical decision: either to initiate lipid-lowering pharmacotherapy or intensify existing lipid lowering pharmacotherapy. We next assessed the population estimates of individuals who increase risk category with the FRS-CVD, fail to meet their new lipid goals and currently are not taking a lipid-lowering agent. This analysis is the potential number of new prescriptions for lipid lowering therapy when the FRS-CVD is utilized nationally. Of the 6.2 million (4.4M–7.9M) men who increase risk and do not meet their new corresponding lipid goals, approximately 4.8M (3.4M–6.3M) men are on no lipid lowering pharmacotherapy and are eligible for initiation of new therapy. Of the 3.8M (2.5M–5.2M) women who increase risk and do not meet their new corresponding lipid goals, 3.1M (2.0M–4.3M) are on no lipid lowering therapy and are eligible for initiation of new pharmacotherapy.

DISCUSSION

Primary Findings

The present cross sectional analysis represents the first report to define risk reclassification distributions and corresponding changes to lipid goal achievements clinicians will encounter if they shift their risk assessment practice from the FRS-CHD to the FRS-CVD for routine cardiovascular risk assessment. Overall there were three significant findings. First, we found with the routine use of the FRS-CVD model nearly two thirds (63%) of U.S. men aged 45–74 and three quarters (74%) of U.S. women aged 55–74 increase to a higher risk category. Overall use of the FRS-CVD model depletes the low risk individuals, net change –25.1% for men, –56.7% for women, while significantly increasing the classification of moderate, moderate high and high-risk older adults. Second, of the men and women increasing to a higher risk category, approximately 30% will not meet the new corresponding lipid goals of their new risk classification. Finally in those men and women reclassified to a higher risk category and not meeting the new lipid goals, 78.5% of men and 81% of women are not currently on lipid lowering therapy. Thus, use of the FRS-CVD could result in approximately 16% of the population of U.S. men aged 45–74 and women aged 55–74 requiring new prescriptions for lipid lowering therapy.

Risk Reclassification and Treatment of CVD Endpoints

Current guidelines recommend specific lipid goals based on CHD risk level category. Given the overall increase to a higher risk category demonstrated in this cross sectional analysis, many more (16%) of U.S. men aged 45–74 and women aged 55–74 will now be eligible for lipid lowering therapy. When shifting to the routine use of the FRS-CVD risk assessment model, the clinician must also consider the specific endpoints of this model and the differing risk reductions lipid lowering pharmacotherapy has on each endpoint. Use of lipid lowering therapy for primary prevention of CHD is associated with an approximate 30% reduction in CHD mortality¹⁷, while use of HMG-CoA-reductase inhibitors confer estimates of 14–21%^{18, 19} relative risk reduction in stroke. For the other endpoints, however, the literature is less clear. The magnitude of risk reduction HMG-CoA-reductase inhibitors confer in the primary prevention of heart failure is unclear with some estimates around 26%²⁰; however, HMG-CoA-reductase inhibitors do not seem to be as beneficial in the treatment of existing ischemic systolic dysfunction²¹. In peripheral vascular disease, favorable data exist for treatment of diagnosed peripheral vascular disease in patients with concomitant CHD or cerebrovascular disease, however estimates for lipid lowering therapy solely to prevent peripheral vascular disease remains unclear.

Study Limitations/Strengths

The limitations of this study are inherent to the NHANES survey, including sampling and non-sampling errors. Many questionnaire elements are self reported and thus subject to misunderstanding and recall bias. While the NHANES dataset is a complex multistage statistical representation of the entire civilian, non institutionalized U.S. population, one limitation intrinsic to the dataset encountered in analyzing narrow subsets of statistically weighted subjects is that some subsets can be small, which results in wide confidence intervals when translating the impact to the national population. A limitation intrinsic to the FRS-CVD risk model is this model has been validated in adults up to age 74. We appreciate that there is a large population above the age of 74 where risk assessment may be applicable. In the NHANES 2005–2006 surveys adult men and women over the age of 74 eligible for primary prevention risk assessment include 257 subjects representing 7.7 million adults.

Despite these limitations, this cross sectional analysis has numerous strengths. The NHANES are large heterogeneous data samples that utilize complex, multistage sampling techniques to develop a representation of the entire non-institutionalized civilian United States population. This database is ideal to nationally quantify the category distribution change, change in lipid goal achievements and population estimates of new pharmacotherapy when instituting a new multivariate risk model.

CONCLUSIONS

It remains uncertain whether the ATP IV writing group will continue to recommend multivariate risk assessment, and if so, which risk assessment model should be used. Clinicians however, should be aware that shifting nationally to routine calculation of global CVD risk does have implications. Use of the FRS-CVD risk assessment model greatly increases both the number of individuals classified as “intermediate risk” (FRS between 6–20%), and high risk (FRS $\geq$ 20%) while markedly decreasing the low risk population (FRS $<$ 6%). Since the “intermediate risk” individuals become eligible for further risk stratification modalities such as hs-CRP and coronary calcium scoring to better characterize risk and clinically move individuals toward either low risk or high risk, and the high risk individuals are eligible for initiation and intensification of pharmacotherapy, the risk reclassification distribution merits close economic and disease management evaluation.

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List of Abbreviations

CVD	Cardiovascular disease
CHD	Coronary heart disease
ATP III	Adult Treatment Panel III
FRS-CHD	Framingham Risk Score for coronary heart disease events
FRS-CVD	Framingham global cardiovascular risk model
NHANES	National Center for Health Statistics performs the National Health and Nutrition Examination Survey

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Figure 1. Risk Category Distributions in Men Aged 45–74 Using Both Risk Models

The Gray bars demonstrate the distribution of the population using the FRS-CHD risk model. The black bars display the change in distribution that occurs when applying the FRS-CVD to this same population.

Figure 2. Risk Category Distributions in Women Aged 55–74 Using Both Risk Models
The Gray bars demonstrate the distribution of the population using the FRS-CHD risk model. The black bars display the change in distribution that occurs when applying the FRS-CVD to this same population.

Table 1

The Changes in Risk Distribution using the FRS-CVD Risk Model in Men Aged 45–74

Risk Category	FRS-CHD		FRS-CVD		Net Effect of using FRS-CVD	
	Subjects	Weighted Population (in millions)	Subjects	Weighted Population (in millions)	Net Change (%)	Net Change (%)
Low 0% -<6%	191	12.0 (8.9–15.2)	62	3.8 (2.8–4.8)	–25.1% (–31.4, –18.8)	
Moderate ≥6%–<10%	164	8.4 (6.5–10.3)	136	8.9 (6.2–11.6)	1.5% (–7.3, 10.2)	
Moderate-High ≥10%–<20%	256	10.4 (7.5–13.3)	244	12.1 (8.9–15.2)	5.1% (0.3, 10.0)	
High ≥20%	52	2.0 (1.3–2.7)	221	8.1 (6.0–10.2)	18.5% (15.1, 21.9)	

(95% confidence intervals)

Table 2

The Changes in Risk Distribution using the FRS-CVD Risk Model in Women Aged 55–74

Risk Category	FRS-CHD		FRS-CVD		Net Effect of using FRS-CVD Net Change (%)
	Subjects	Weighted Population (in millions)	Subjects	Weighted Population (in millions)	
Low 0% -<6%	278	14.1 (10.3–17.7)	77	4.3 (2.7–5.9)	–56.7 % (–64.8, –48.8)
Moderate ≥6%–<10%	56	2.2 (1.4–2.9)	113	5.4 (3.9–6.9)	18.6 % (12.0–25.3)
Moderate-High ≥10%–<20%	20	0.8 (0.3–1.2)	122	5.7 (4.0–7.4)	28.4 % (22.5–34.5)
High ≥20%	3	0.1 (0–0.3)	45	1.8 (1.0–2.6)	9.6 % (6.6–12.6)

(95% confidence intervals)

Appendix A

NHANES Item ID and Descriptions.

NHANES Item ID	Description
SEQN	Respondent sequence number
RIDSTATR	Interview/Examination Status
RIAGEYR	Age at Screening
RIAGENDR	Gender
WTMEC2YR	Two year MEC sample Exam Weight
Questionnaire	Description
BPQ050A	Currently taking prescriptions for high blood pressure
DIQ010	Doctor told you have Diabetes
DIQ050	Taking insulin now?
DIQ070	Take diabetic pills to lower blood sugar?
MCQ160B	Ever told you had congestive heart failure?
MCQ160C	Ever told you had coronary heart disease?
MCQ160D	Ever told you had angina/angina pectoris?
MCQ160E	Ever told you had heart attack?
MCQ160F	Ever told you had a stroke?
SMQ020	Smoked at least 100 cigarettes in life?
SMQ040	Do you now smoke cigarettes?
RXDDRUG	Generic Drug Name
Examination	Description
BPXSY*	Systolic blood pressure
BPXDI*	Diastolic blood pressure
Laboratory Assessment	Description
PHAFSTHR	Total length of fast in hours
LBXTC	Total cholesterol (mg/dL)
LBXSTR	Triglycerides (mg/dL)
LBDHDL	HDL-C- cholesterol (mg/dL)