ARIC Manuscript Proposal #2178

PC Reviewed: 7/9/13	**Status: A**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Title: Prevalence and control of hypertension and hyperlipidemia and use of preventive cardiovascular medications in a US cohort; the Atherosclerosis Risk in Communities Study

b. Abbreviated Title: Prevalence and control of hypertension and hyperlipidemia

2. Writing Group:

Writing group members: Michael Miedema, Michael Blaha, Salim Virani, Joe Coresh, Christie Ballantyne, OTHERS WELCOME, Aaron Folsom

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. **MDM**

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3. Timeline: Project will hopefully be completed within 6-9 months.

4. Rationale:

Preventive cardiovascular medications, such as antihypertensive medications, lipid-lowering medications, and aspirin, are typically reserved for individuals with elevated cardiovascular risk or known cardiovascular disease. Much of the recent decline in coronary heart disease mortality[1] has been attributed to improved utilization of these preventive medications as well as smoking cessation[2,3]. NHANES data from 2008 estimated the prevalence of hypertension in the US to be 29.0% (95% CI 27.6%-30.5%) with 50.1% of hypertensive individuals having controlled blood pressure (systolic <140mmHg and diastolic <90mmHg)[4]. NHANES data for lipids in 2005-2006 estimated the prevalence of elevated low-density lipoprotein at 21.2% by ATP III guidelines with an estimated 13.4% of the population taking lipid-lowering medications[5]. In 2007-2008, 47% and 22% of individuals, age 65-79, with and without known cardiovascular disease were taking aspirin[6].

The prevalence and control of hypertension and hyperlipidemia and rates of use of preventive cardiovascular medications are very relevant for the elderly, where CHD rates are high, and may be changing over time. Recent concerns about an increase risk of diabetes associated with statin use may lead to less frequent use of lipid-lowering therapy[7]. Additionally, rates of aspirin use may be changing, especially in primary prevention given the increase focus on the impact of the increase in bleeding associated with aspirin use[8]. Conversely, recently employed large-scale cardiovascular prevention programs, such as the American Heart Association's "Life's Simple 7", may be leading to improved control of cardiovascular risk factors in the US[9].

Current guidelines for the treatment of both hypertension and lipids in primary prevention are primarily target-based, with treatment decisions largely based on blood pressure measurement and LDL levels[10-11]. Many experts feel that the bulk of the evidence supports an approach more centered on absolute cardiovascular risk[12-14]. Therefore, the prevalence and control of CVD risk factors at various levels of absolute risk is also of importance. The aim of our study is to provide contemporary estimations on the prevalence of hypertension and hyperlipidemia, the utilization rates of preventive medications, rates of control of hypertension and hyperlipidemia, and the impact of CVD and absolute CVD risk on rates of control in older Americans in the ARIC cohort. This knowledge will provide insight into the current state of cardiovascular prevention in the US and potentially aid the development of more optimal prevention strategies.

5. Main Hypothesis/Study Questions:

Objective #1: To determine the prevalence of hypertension, the utilization rates of antihypertensive medications, and the percentage of hypertensive individuals with blood pressure measurements that meet the current JNC VII guidelines (or JNC VIII if available) in a contemporary US cohort.

Objective #2: To determine the prevalence of hyperlipidemia, the utilization rates lipid-lowering medications, and the percentage of individuals with LDL levels that meet the current ATP III guidelines (or ATP IV in available) in a contemporary US cohort.

Objective #3: To determine the utilization rates of preventive cardiovascular medications (antihypertensive, lipid-lowering, and aspirin) stratified by prevalent CVD and absolute CVD risk thresholds (in individuals without known CVD) in a contemporary US cohort.

6. Design and analysis

Study Design

The study design will be a cross-sectional analysis of the sample of ARIC participants who participated in the 5th visit (2011-2013)[15].

Hypertension, Antihypertensive Medications, and Hypertensive control

Sitting blood pressure was measured after a 5-minute rest 3 times for each participant with a Omron HEM907XL automated device by trained technicians following a standardized protocol. The average of the second and third readings will be used for this analysis.

Hypertension will be defined as systolic blood pressure (SBP) >= 140 mm Hg, diastolic blood pressure (DBP) >= 90 mm Hg, or self-reported use of antihypertensive medications. Individuals on antihypertensive medications will be defined as controlled if systolic blood pressure < 140 mm Hg and diastolic blood pressure < 90 mm Hg or SBP < 130 mm Hg and DBP < 80 mm Hg for individuals with diabetes and chronic kidney disease.

Hyperlipidemia, Lipid-lowering Medications, and Lipid control

A detailed account of the measurement of lipids in ARIC have been previously reported[16,17]. Briefly, blood samples were collected at the each visit after a fast of at least 8 hours. Samples were sent to the ARIC Central Lipid Laboratory for processing. Total plasma cholesterol and triglycerides were determined by enzymatic methods, HDL cholesterol was measured after dextran-magnesium precipitation. LDL cholesterol was calculated by the Friedewald equation in those with triglyceride levels < 400 mg/dl.

The use of lipid-lowering medications was self-reported and confirmed by reviewing medications brought to each visit by the patient. Lipid lowering medications were divided into 2 categories: statins and other lipid medications. Included in the "other" category were niacin (vitamin B3), bile sequestrants, fibrates, and other lipid-lowering agents. ATP III guidelines will be used to define thresholds for control of hyperlipidemia[9], with an LDL goal of <100mg/dl for individuals with known CHD, other CVD, diabetes, or a 10-year CHD risk of >20%, an LDL goal of <130mg/dl for individuals with 2 or more major CVD risk factors, and an LDL goal of <160mg/dl in individuals with 0 to 1 risk factor.

Other Covariates

Age, ethnicity, sex, study center, education level, diabetes status, BMI, cigarette smoking status, chronic kidney disease, and use of aspirin.

Analysis Plan

Baseline characteristics of the sample will be presented stratified by prevalent CVD. Categorical variables will be presented as *n* (%) and continuous variables as mean (SD). The prevalence, rate of medication utilization, and rate of control will be presented for hypertension and hyperlipidemia using the entire sample. The results will then be stratified by prevalent CHD and absolute 10-year CHD risk thresholds (<6%, 6-10%, 11%-20%, > 20%, and individuals with diabetes) in individuals without known CHD. The ATP CHD risk calculator will be used to calculate absolute CHD risk. A sensitivity analysis will analyze results using the ARIC CHD risk calculator as well as analyzing results by prevalent CVD and absolute CVD risk using the ATP CVD risk calculator. Utilization of aspirin will also be analyzed in individuals with and without known CVD. Additional analyses will look at age-stratified results as well as the impact of race and sex. Current control levels according to clinical guidelines will also be compared with the latest NHANES data. Finally, logistic regression will be used to determine independent predictors of having controlled hypertension as well as hyperlipidemia.

7.a. Will the data be used for non-CVD analysis in this manuscript?
____ Yes __X_ No

8.a. Will the DNA data be used in this manuscript?
____ Yes __X__ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: http://www.cscc.unc.edu/ARIC/search.php

X Yes _____ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? ____ Yes _X__ No

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.

12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is **your responsibility to upload manuscripts to PUBMED Central** whenever the journal does not and be in compliance with this policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to Pubmed central.

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