
b. **Abbreviated Title (Length 26 characters)**: CVD risk in MHS and ARIC

2. **Writing Group**: Kristen M. George, Aaron Folsom, Lyn Steffen, Lynne Wagenknecht, and Thomas Mosley

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. **_KMG_** [please confirm with your initials electronically or in writing]

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3. **Timeline**: Finish analysis by November 2017 and manuscript by December 2017

4. **Rationale**:  

There are well established regional differences in cardiovascular disease (CVD) risk and mortality in the United States. [1][2] These geographic disparities involve sociodemographic and
racial factors that are complex and often overlooked when studying CVD, particularly within subpopulations. [3]

African Americans in the ARIC study were primarily enrolled from Jackson, MS or Forsyth County, NC while whites were enrolled from the northwestern suburbs of Minneapolis, MN, Washington County, MD, as well as Forsyth, NC. [4] Mississippi and North Carolina are areas of the southeast with some of the highest rates of CVD morbidity and mortality, especially among black Americans, whereas Minnesota has some of the lowest rates of CVD. [2][5][6] Due to the lack of African Americans from Minnesota and Maryland in the ARIC cohort, the question of whether geographic differences in CVD persist among blacks has not been answered.

The Minnesota Heart Survey (MHS) enrolled a population based sample African Americans living in the Minneapolis-St. Paul metropolitan area. [7] These participants were of similar age to ARIC participants and baseline measures of cardiovascular risk factors were taken in 1985. Using national death index records for CVD death and total mortality, we can assess whether CVD-related mortality risk differed by geographic area between two relatively comparable cohorts.

5. Main Hypothesis/Study Questions:

We hypothesize that African American participants in MHS will have a lower absolute risk of CVD mortality and a lower prevalence of CVD risk factors compared with African Americans in the ARIC cohort, reflecting geographic differences in CVD risk. We will also compare hazard ratios (HRs) for CVD risk factors in MHS vs. ARIC.

6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).

Exclusions: Participants in both studies who are not African American as well as black participants in ARIC not from Jackson, MS or Forsyth County, NC.

Exposures: Exposures include sex, age, total cholesterol, HDL cholesterol, systolic blood pressure, self-report of anti-hypertensive medication use, self-report of diabetes, current smoking, and body mass index (BMI) at baseline.

Outcomes: CVD-related mortality identified using national death searches and ICD codes (CVD-related: ICD10 “I” codes and codes 390-459 for ICD9)

Analysis: (1) Poisson regression will be used to calculate and compare incidence rates of CVD death stratified by sex, study, and study center (only applicable to ARIC). (2) Risk factor means and prevalences will be compared among sites to determine if they explain CVD death rate differences. Risk factors shall include sex, age, total cholesterol, HDL cholesterol, systolic blood pressure, anti-hypertensive medication use, self-report of diabetes, current smoking, and BMI. (3) Study-specific Cox proportional hazards models will be used to assess HRs of major risk factors for CVD death, including an analysis with competing risk of non-CVD related death. HRs will be compared among the sites. A sensitivity analysis will be run using the full MHS sample and excluding those outside of the visit 1 age range of ARIC (45-65 years old).

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

   b. If Yes, is the author aware that the file ICTDER03 must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used? ____ Yes  ____ No

   (This file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

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

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER03 must be used to exclude those with value RES_DNA = “No use/storage DNA”? ____ Yes  ____ 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

   ____ Yes  ____X____ 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)?

None.

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

11.b. If yes, is the proposal
   ____ A. primarily the result of an ancillary study (list number)* __________
   ____ B. primarily based on ARIC data with ancillary data playing a minor role
       (usually control variables; list number(s)* __________  __________  __________)

*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

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.

13. Per Data Use Agreement Addendum, approved manuscripts using CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication. Approved manuscripts should be sent to Pingping Wu at CC, at pingping_wu@unc.edu. I will be using CMS data in my manuscript ___ Yes ___ No.

References:
