ARIC Manuscript Proposal #2402

PC Reviewed: 8/12/14 **Status: A** **Priority: 2**
SC Reviewed: _____ **Status: _____** **Priority: ____**

1.a. Full Title: The Prevalence of CHF stages in African Americans and their relation to mortality and incident CV events

b. Abbreviated Title: Prevalence of CHF stages in AA and relation of stage to mortality and incident CV events.

2. Writing Group:
Writing group members:

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

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ARIC author to be contacted if there are questions about the manuscript and the first author does not respond or cannot be located (this must be an ARIC investigator).

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3. Timeline:

Analysis	July-August, 2014
Manuscript Writing	September- October 2014
Initial Draft	October, 2014
Editing- Final Draft	November 2014
Draft Submitted to P and P Committee	December, 2014
Submission to Journal for Publication	January 2015

4. Rationale:

African Americans (AA) are at an exceptionally high risk of developing heart failure (CHF), an increased susceptibility that is multifactorial and incompletely explained by the higher prevalence of standard risk factors, i.e., hypertension (HTN), obesity and diabetes (DM). AA seem to have a higher prevalence of CHF with a normal (HFPEF) vs. a reduced ejection fraction (HFREF). However, no prior study has comprehensively evaluated the prevalence of AHA-ACC CHF stages nor how these stages in this group are related to incident cardiovascular events and death. The current application will bridge this gap using data from the ARIC Study accompanied by mentoring of minority young scientists.

5. Main Hypothesis/Study Questions:

Specific Aim: To describe the prevalence of AHA-ACC CHF stages in approximately 1800 AA participants who were part of Exam 3 and received echocardiogram.

Hypothesis: We postulate that AA will have high prevalence of CHF stages B-D, and few people will be categorized as CHF class 0. We hypothesize that advanced CHF stages, including even Stage B, is associated with greater risk of mortality on follow-up.

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).

Risk Factor and Echo Parameter Data from ARIC Visit 3

Risk Factors = age, sex, diabetes, hypertension, lipid profile, fasting glucose, systolic and diastolic BP, BMI, total cholesterol, HDL, LDL, waist circumference, premenopausal status, lipid lowering meds, antihypertensive meds, hormone replacement medications, diet, urinary Na from Visit 3.

Echo parameters = LV mass, LV ejection fraction and LV fractional shortening, (also for determination of CHF stage - mitral inflow velocity E, A) from Visit 3.

Prevalent heart failure will be defined hospitalization with ICD-9 code for HF (428.x) listed at discharge between visit 1 and 3 (n=34).

Incident Events and Death

Adjudicated Events (CHD, ischemic stroke and CHF events) from 1993 forward

Adjudicated death

Table. Definitions of CHF stage and Key Domains of Risk factors	
ACC-AHA Stage (modified)	Components
0	Without risk factors, abnormal LV structure or function, no symptoms.
A	Presence of HTN, DM, Obesity, CHD, no abnormal LV structure or function.
B	Abnormal LV structure or function
C/D	Overt CHF. C1: symptoms present but does not fulfill FHS CHF criteria; C2: fulfills FHS CHF criteria. Both C1 and C2: Class II-III symptoms. D: Class IV symptoms.

Statistical Analysis: We will estimate the proportions of AAs individuals in Exam 3 in each stage of ACC-AHA CHF as:

$$\frac{\text{Cases of CHF stage at Exam 3}}{\text{Population at Exam 3}}$$

The estimated prevalence of ACC-AHA CHF stages will be used in a Cox proportional hazards regression analysis to predict 20-year risk of incident CVD events and death, adjusting for age and sex at the minimum. ACC-AHA CHF Stage 0/A will be considered as a reference group.

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

__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)?
None: This proposal utilizes additional HF case ascertainment from ancillary study data collection retrospectively to visit 3 and relates stages of CHF to incident events and mortality.

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

11.b. If yes, is the proposal

__x__ A. primarily the result of an ancillary study (list number* 2012.25 Validation of Heart Failure Hospitalizations in African Americans with Echocardiography **)**

___ 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.

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(12)WRITING COMMITTEE, Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevenson LW, Yancy CW. 2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults. Circulation 2009;119:e391-e479.

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