

ARIC Manuscript Proposal # 1697

PC Reviewed: 9/14/10
SC Reviewed: _____

Status: A
Status: _____

Priority: 2
Priority: _____

1.a. Full Title: Functional status and cardiovascular disease

b. Abbreviated Title (Length 26 characters): Functional status and CVD

2. Writing Group:

Writing group members: Anna Kucharska-Newton, Randi Foraker, Kathryn Rose, Wayne Rosamond, Beverley Gwen Windham, Corey Kalbaugh , others welcome

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

Analyses to start immediately following proposal acceptance. Abstract(s) originating from this work to be presented at national meetings including AcademyHealth and AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke.

4. Rationale:

Although CVD is the leading cause of premature disability, with coronary heart disease (CHD) representing 19% of all Social Security disability disbursements(1), few prospective studies have examined the effect of functional status and quality of life, among persons with CVD-related events. Even fewer have reported repeated measures of functional status over time and examined their trajectories in relation to cardiovascular events (2; 3).

Functional status is usually defined as the “ability to perform self-care, self- maintenance and physical activities.” Numerous scales of functional status have been designed to evaluate the degree to which that ability is compromised (4). Evaluation of functional status can identify risk of frailty and mobility disability that is independent of disease status as well as the impact that a disease may have on a person’s lifestyle and measure a person’s need for care. As such, it is an essential component in the delivery of optimal healthcare.

Most of the knowledge of the association of functional impairment or disability with CVD pertains to physiological impairment resulting from disease-related pathology (5; 6). Existing studies of functional status impairment across gender, race, age, and socioeconomic (SES) strata may be used to inform programs on improvements in quality of life and strategies for self-care among those with CHD. Lacking is an understanding of functional status across the continuum of disease trajectories, including the time prior to the development of clinically detectable symptoms that could inform preventive strategies.

The ARIC study will be conducting an assessment of the functional status of the cohort survivors at Visit 5. With that in mind, we propose to examine the trajectory of functional status in the ARIC study cohort over the years of follow-up preceding the planned Visit 5. Our objective is to quantify the trajectory of repeated measures of self-reported functional status for the ARIC cohort members with a variety of CVD related conditions assessed during the annual telephone follow-up interviews. We propose to examine functional status trajectories prior to and after the incidence of fatal CHD, non-fatal CHD, stroke, and heart failure. We will examine the effect of age, race, gender, and SES on the observed functional status trajectories.

5. Main Hypothesis/Study Questions:

Among ARIC cohort participants with incident fatal and nonfatal CHD, stroke, and heart failure:

1. Describe and compare the trajectory of functional status prior to and following the incident event (functional status among fatal events will only be assessed prior to death)
2. Evaluate the effect of age, gender, race, self-rated health, income, education, and marital status on the observed functional status trajectories
3. Determine whether the presence or absence of chronic diseases or conditions at baseline (CHD, stroke, heart failure diabetes, obesity, or hypertension) modifies the observed functional status trajectories.
4. If average functional status declines post-event, determine how much of this decline is due to deaths.

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).

Information on functional status will be obtained from the annual follow-up questionnaires. Functional status was assessed in versions D through K of the AFU form, which were administered in the years 1993-2007. The functional status questions assessed the ability to perform physical activities, including usual activities and the ability to go to work. The questions, most of which required a “Yes” or “No” answer, remained the same throughout the entire time that they were administered. The outcome of interest for this study will be the percent of cohort members responding to individual questions (e.g. “Are you able to perform heavy housework?”) in a way that indicates diminished functional ability. Since the existing questions do not form a validated functional status instrument, we will evaluate them as separate entities.

Following are the functional status questions that are present in the ARIC study annual follow-up (AFU) forms D-K:

1. Are you able to do heavy work around the house, like shoveling snow or washing windows, walls or floors without help? Y/N
2. Are you able to walk up and down stairs to the second floor without help? Y/N
3. Are you able to walk half a mile without help? That’s about 8 ordinary blocks. Y/N
4. Are you able to go to work? Y/N/NA
5. During the past 4 weeks have you missed work for at least half a day because of your health? Y/N
6. Are you able to do your usual activities, such as work around the house or recreation? Y/N
7. During the past 4 weeks have you had to cut down on your usual activities (such as work around the house or recreation) for half a day or more because of your health? Y/N

We are interested in evaluating trajectories of functional status, measured as the proportion of those with decreased functional abilities, over time prior to and following a cardiovascular event. Age, race, gender, and ARIC study center adjusted functional status trajectories will be centered on the index event. We will evaluate all responses as individual categories. Marital status, socioeconomic status (income and education), self-rated health, and nursing home admission status will be evaluated as potential effect measure modifiers of the observed trajectories.

The ARIC cohort has experienced little loss to follow-up, therefore, we anticipate being able to estimate (i.e. interpolate) missing functional status data, with the exception of data missing due to death, from data collected before and after the missing functional status assessment. Since missingness of functional status data may be due to impaired function, we will perform a sensitivity analysis to evaluate functional status trajectories under the assumption of functional status data missing not at random (data are missing in very impaired individuals), data missing at random (not impaired individuals), or data completely missing at random.

We will use the method of Diehr et al (7) to determine if the functional status trajectories differ from trajectories that would be expected due to aging. Utilizing a comparison group, selected as a random sample of all cohort members regardless of their disease status, we will determine if the functional status trajectories differ from the trajectories that would be expected due to aging. This method will also take into account the extent to which the decline in average functional status in the cohort post-event may be due to deaths.

To eliminate potential bias due to prevalent disease we will stratify the analyses by the presence or absence at baseline of the following disease conditions: coronary heart disease, heart failure, hypertension, obesity, and diabetes. To account for multiple statistical comparisons, the Bonferroni correction will be employed in analysis of variance testing.

7.a. Will the data be used for non-CVD analysis in this manuscript?

☐ Yes ☒ No

b. If Yes, is the author aware that the file ICTDER02 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 n/a

(This file ICTDER02 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 ☒ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = "No use/storage DNA"?

☐ Yes ☐ No

7.a. Will the data be used for non-CVD analysis in this manuscript? ☐ Yes

☒ 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 ICTDER03 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.csc.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)?

Ms# 1462: Foraker et al. "Socioeconomic Status (SES) and the Trajectory of Self-Rated Health (SRH): Before and After a Heart Failure Event" Drs. Foraker, Rose, and Rosamond have been contacted and are co-authors of this proposal.

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.csc.unc.edu/aric/forms/>

12. 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.

References:

1. Boulton C, Altmann M, Gilbertson D, Yu C, Kane RL: Decreasing disability in the 21st century: the future effects of controlling six fatal and nonfatal conditions. *Am J Public Health* 86:1388-1393, 1996
2. Haas S: Trajectories of functional health: The 'long arm' of childhood health and socioeconomic factors. *Social Science & Medicine* 66:849-861, 2008
3. Lunney JR, Lynn J, Foley DJ, Lipson S, Guralnik JM: Patterns of functional decline at the end of life. *JAMA* 289:2387-2392, 2003
4. Applegate WB, Blass JP, Williams TF: Instruments for the functional assessment of older patients. *N Engl J Med* 322:1207-1214, 1990
5. Burnette D, Mui AC, Zodikoff BD: Gender, Self-Care and Functional Status Among Older Persons with Coronary Heart Disease: A National Perspective. *Women & Health* 39:65 - 84, 2004
6. Barbareschi G, Sanderman R, Kempen GJM, Ranchor AV: The Mediating Role of Perceived Control on the Relationship Between Socioeconomic Status and Functional Changes in Older Patients With Coronary Heart Disease. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences* 63:P353-P361, 2008
7. Diehr P, Johnson LL, Patrick DL, Psaty B: Methods for incorporating death into health-related variables in longitudinal studies. *J Clin Epidemiol* 58:1115-1124, 2005