UNC SCHOOL OF MEDICINE
DEPARTMENT OF MEDICINE
Division of Cardiology

March 13, 2009

Josef Coresh, M.D., Ph.D.
Chair, ARIC Publications Committee
Johns Hopkins University
Bloomberg School of Public Health
Departments of Epidemiology, Biostatistics, and Medicine
2024 E. Monument, Suite 2-600
Baltimore, MD 21205

Dear Dr. Coresh:

On behalf of the manuscript writing team, I am submitting the attached manuscript proposal entitled "Surveillance of heart failure hospitalizations requires more than just the ICD-9 code: rates of acute decompensation versus chronic disease in the ARIC Study." All coauthors have reviewed and approved this proposal. Please contact me if you need any additional information (919-843-4069 or pchang@med.unc.edu).

Thank you for your consideration of our proposal.

Sincerely yours,

Patty
Patricia P. Chang, MD MHS
Assistant Professor of Medicine

CB 7075 ♦ Burnett-Womack Building ♦ 160 Dental Circle ♦ 6th Floor ♦ Chapel Hill, NC 27599-7075
(919)966-5201 phone ♦ (919)966-1743 fax

ARIC Manuscript Proposal #1489

PC Reviewed: 03/17/09	**Status: A**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title: Surveillance of heart failure hospitalizations requires more than just the ICD-9 code: rates of acute decompensation versus chronic disease in the ARIC Study.

b. Abbreviated Title (Length 26 characters): Surveillance Acute vs Chronic HF

2. Writing Group:
Writing group members
Wayne Rosamond
Eyal Shahar
Alain Bertoni
Stuart Russell
Tandaw Samdarshi
Lloyd Chambless
Others welcomed

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

First author: Patricia P. Chang, MD, MHS, FACC
Address: Division of Cardiology, CB 7075
160 Dental Circle, 6th Floor Burnett-Womack Building
The University of North Carolina at Chapel Hil
Chapel Hill, NC 27599-7075

Phone: 919-843-4069 Fax: 919-966-1743
E-mail: patricia_chang@med.unc.edu

Corresponding/senior author (if different from first author correspondence will be sent to both the first author & the corresponding author):
As above

3. Timeline: Analysis to begin fall-winter 2009 (after 2 years of surveillance data of 2005 and 2006 heart failure events), first draft within 3 months of data analysis.

4. Rationale:

Heart failure (HF) is a growing epidemic, with an incidence of approximately 10 per 1000 in the population age >65 years and estimated prevalence of 5.7 million in American >20 years old.[1] Although most cases of HF are managed in the outpatient setting, hospitalizations for HF have increased steadily each year, with over 1 million in 2006.[1] But these rates are based on discharge diagnoses codes (ICD-9 codes) and may overestimate the number of hospitalizations for which the primary diagnosis is acute decompensated heart failure, unless the cases are reviewed. Moreover, approximately half of overt heart failure is systolic heart failure (SHF) and the other half is heart failure with preserved ejection fraction (HFpEF),[2] but it is less clear which type of heart failure is represented in these estimates of hospitalized heart failure. Most population-based cohort studies have reported incidence rates for HF overall (that is not further differentiated),[3-4] but only a few have reported various incidence, prevalence, and survival rates of SHF and HFpEF.[5-8]

ARIC surveillance prospectively collects data from hospitalizations for heart failure in the ARIC cohort and the communities beginning in 2005, based on a list of pre-specified ICD-9 codes for HF or HF-related condition which prompts chart abstraction. Cases are subsequently classified after ARIC physician review as either acute decompensated heart failure (definite/possible), chronic stable heart failure, no heart failure, or unclassifiable.

We propose to describe the estimates of hospitalized HF events based on 2 years experience of prospective ARIC surveillance using the ARIF HF classification. We will describe these events in terms of the incidence of new acute heart failure, hospitalization rate of acute decompensation compared to chronic stable heart failure, and case-fatality rates. These estimates will be presented for all of heart failure as well as separately for SHF and HFpEF, and according to common demographics (age, gender, race) and clinical characteristics/comorbidities (coronary heart disease, hypertension, diabetes). Consideration and possible modification of this current protocol may be made in the analytic approach to the study questions of this manuscript proposal.

5. Main Hypothesis/Study Questions:

1. What is the incidence of acute decompensated heart failure, defined as first diagnosed hospitalized event?
2. What is the hospitalization rate of acute decompensated heart failure compared to chronic stable heart failure?

3. What is case-fatality rate for patients with chronic stable heart failure and for patients with acute decompensated heart failure?
4. What is each of these estimates for all HF cases, and separately for SHF and HFpEF?
5. What is the relationship of each of these estimates to the ICD-9 codes most commonly used for case identification?
6. What is the relationship of each of these estimates to common demographics (age, gender, race) and clinical characteristics (risk factors for heart failure or common comorbidities, such coronary heart disease, hypertension, diabetes)?

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).

Data from hospitalized heart failure record (HFA) abstraction and HF MMCC review (HDX) will be used. Demographic and clinical variable of interests will include (but may not be limited to): race, gender, age, type of heart failure, heart function (i.e., left ventricular ejection fraction, diastolic dysfunction, right ventricular contractile function), pre-existing comorbidities (e.g., coronary heart disease, hypertension, diabetes, atrial arrhythmias, chronic kidney disease), symptoms and physical exam findings of volume overload (e.g., dyspnea, crackles, edema, JVD, S3), health insurance status, and field center. Estimation of frequencies will account for the stratified random sampling design.

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 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
(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 ___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 ICTDER02 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)?

927 Loehr LR, et al: Heart failure incidence and survival (From the Atherosclerosis ARIC study).
#1331 - Rosamond WD, et al: Comparison of Hospitalized Heart Failure Diagnostic Criteria

The proposed paper will differ from manuscript #1331 in that we will be describing estimates of the different ARIC HF categories according to ICD-9 codes, common demographic and clinical characteristics. The lead author and several co-authors of that manuscript are also co-authors of this proposal and have agreed with this proposal. There is no overlap with manuscript #927 in which HF cases were identified from 1987-2002 based on non-validated ICD-9 codes.

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/

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. Lloyd-Jones D, Adams R, Carnethon M, et al. Heart disease and stroke statistics -- 2009 update: a report from the American Heart Association

Statistics Committee and Stroke Statistics Subcommittee. Circulation 2009;119(3):480-6.
2. Redfield MM, Jacobsen SJ, Burnett JC Jr, Mahoney DW, Bailey KR, Rodeheffer RJ. Burden of systolic and diastolic ventricular dysfunction in the community: appreciating the scope of the heart failure epidemic. JAMA 2003;289(2):194-202.
3. Schellenbaum GD, Heckbert SR, Smith NL, et al. Congestive heart failure incidence and prognosis: case identification using central adjudication versus hospital discharge diagnoses. Ann Epidemiol 2006;16(2):115-22.
4. Ni H. Prevalence of self-reported heart failure among US adults: results from the 1999 National Health Interview Survey. Am Heart J 2003;146(1):121-8.
5. Roger VL, Weston SA, Redfield MM, Hellermann-Homan JP, Killian J, Yawn BP, Jacobsen SJ. Trends in heart failure incidence and survival in a community-based population. JAMA 2004;292(3):344-50.
6. Owan TE, Hodge DO, Herges RM, Jacobsen SJ, Roger VL, Redfield MM. Trends in prevalence and outcome of heart failure with preserved ejection fraction. N Engl J Med 2006;355(3):251-9.
7. Bhatia RS, Tu JV, Lee DS, et al. Outcome of heart failure with preserved ejection fraction in a population-based study. N Engl J Med 2006;355(3):260-9.
8. Vasan RS, Larson MG, Benjamin EJ, Evans JC, Reiss CK, Levy D. Congestive heart failure in subjects with normal versus reduced left ventricular ejection fraction: prevalence and mortality in a population-based cohort. J Am Coll Cardiol 1999;33(7):1948-55.