ARIC Manuscript Proposal # 1490

1.a. Full Title: Utilization of optimal medical therapy for hospitalized heart failure and outcomes: the ARIC Study.

  b. Abbreviated Title (Length 26 characters): HF optimal therapy outcomes

2.   Writing Group:

Writing group members
Wayne Rosamond
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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]**

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    As above

3.   Timeline: Analysis to begin winter 2009-2010 (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] Guidelines for the care of patients with chronic heart failure have been in place since 1995, with the most recent ACC/AHA version in 2005.[2] Although standard therapy is better understood for systolic heart failure (SHF), what is considered standard therapy for heart failure with preserved ejection fraction (HFpEF) is less well understood. Despite these guidelines, heart failure is still undertreated.[3-5] Medications are often not optimized, especially to target doses, and life-saving devices such as defibrillators are underutilized. However, published reports to date about optimal therapy have been based on hospital registries which have been based on patient "volunteers" (e.g., OPTIMIZE-HF and ADHERE registries)[3-4] or hospital "volunteers" (Get With the Guidelines-HF registry)[5] rather than a population sample. Some of these registries[5] do not have follow-up data and all of these registries are biased by the fact that someone at that institution has enough of an interest in heart failure to participate.

ARIC surveillance prospectively collects data from hospitalizations for heart failure in the multiracial ARIC cohort and the communities beginning in 2005. We propose to describe estimates of the use of standard therapy for both SHF and HFpEF during the first 2 years of surveillance (2005-2006), according to common demographics (age, gender, race), regional differences (urban vs. rural, community vs. university hospital), health insurance status, and clinical characteristics/ comorbidities (coronary heart disease, hypertension, diabetes). We will also examine the relationship of optimal treatment and outcomes, such as hospitalization and rehospitalization for acute decompensation, length of stay, and death. 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 frequency of appropriate medical therapy for SHF (e.g., ACE-inihibitors/ARBs, beta blockers, aldosterone-antagonists, defibrillators, cardiac resynchronization therapy)?
2. What is the frequency of similar medical therapy for HFpEF (e.g., ACE-inihibitors/ARBs, beta blockers, aldosterone-antagonists, diuretics, digoxin)?
3. For HF that cannot be differentiated as SHF or HFpEF, what is the frequency of medication types used for SHF?
4. What is the relationship of each of these estimates to common demographics (age, gender, race, regional differences), health insurance status, clinical characteristics (common comorbidities, such coronary heart disease, hypertension, diabetes, chronic kidney disease)?
5. What is the relationship of each of these estimates to outcomes, such as hospitalization for acute decompensation, length of stay, and death?

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, kidney disease), symptoms and physical exam findings of volume overload (e.g., dyspnea, crackles, edema, JVD, S3), health insurance status, and field center. The frequency of appropriate medical therapy will be assessed at time of hospital admission and also at time of hospital discharge. 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)?

#1331 - Rosamond WD, et al: Comparison of Hospitalized Heart Failure Diagnostic Criteria.
#1489 – Chang PC, et al: Surveillance of heart failure hospitalizations requires more than just the ICD-9 code: rates of acute decompensation versus chronic disease in the ARIC Study.
   There is no significant overlap with these manuscripts.

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. Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society. Circulation. 2005 Sep 20;112(12):e154-235 (also J Am Coll Cardiol. 2005 Sep 20;46(6):e1-82).

3. Fonarow GC, Stough WG, Abraham WT, et al. Characteristics, treatments, and outcomes of patients with preserved systolic function hospitalized for heart failure: a report from the OPTIMIZE-HF Registry. J Am Coll Cardiol 2007;50(8):768-77.

4. Fonarow GC, Heywood JT, Heidenreich PA, Lopatin M, Yancy CW; ADHERE Scientific Advisory Committee and Investigators. Temporal trends in clinical characteristics, treatments, and outcomes for heart failure hospitalizations, 2002 to 2004: findings from Acute Decompensated Heart Failure National Registry (ADHERE). Am Heart J 2007;153(6):1021-8.

5. Shah B, Hernandez AF, Liang L, Al-Khatib SM, Yancy CW, Fonarow GC, Peterson ED; Get With The Guidelines Steering Committee. Hospital variation and characteristics of implantable cardioverter-defibrillator use in patients with heart failure: data from the GWTG-HF (Get With The Guidelines-Heart Failure) registry. J Am Coll Cardiol 2009;53(5):416-22.