ARIC Manuscript Proposal #2071

PC Reviewed: 2/12/13	**Status: A**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title: Lifetime Risk of Venous Thromboembolism

b. Abbreviated Title (Length 26 characters): Lifetime Risk of VTE

2. Writing Group:

Writing group members: Aaron Folsom, Pam Lutsey, Mary Cushman, Saonli Basu, Susan Heckbert, Donald Lloyd-Jones

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

F**irst author**: **Aaron Folsom**
Address:

Phone: Fax:
E-mail: folso001@umn.edu

3. Timeline: hope to finish by summer 2013

4. Rationale:

Lloyd-Jones and others have reported the lifetime absolute risk (probability) of several cardiovascular diseases. A recent paper that included ARIC indicated that lifetime risk of CVD was 60% for men and 56% for women (1). Although age-specific rates of venous thromboembolism (VTE) have been reported, including by us for the LITE study (2), no estimates of lifetime VTE probability exist. Having such estimates may be clinically useful, as would be estimates within various strata, e.g., sex, obesity status, race, and other characteristics.

We will address this in the LITE study, combining VTE event data from ARIC and CHS.

5. Main Hypothesis/Study Questions:

1. What is the lifetime risk of VTE?
2. What is the lifetime risk of VTE for people with or without various risk VTE factors.

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).

Study group: combined ARIC and CHS cohorts

Events: incident VTEs after baseline

Main analysis: time to event, e.g. as per Lloyd-Jones (1, 3), use Kaplan Meier analysis that incorporates competing risks, with deaths from other causes as competing events. One of the assumptions of this competing risk model is that each failure mechanism leading to a particular type of failure (i.e., failure mode) proceeds independently of every other one, at least until a failure occurs.

We will also report simple age-specific rates of VTE.

Risk factors for stratification: (age), race, sex, BMI, factor V Leiden and prothrombin mutations.

References

1. Wilkins JT et al. JAMA 2012;308:1795-1801.
2. Cushman M et al. Am J Med 2004;117:19-25.
3. Lloyd-Jones DM, Larson MG, Beiser A, Levy D. Lifetime risk of developing coronary heart disease. Lancet. 1999;353(9147):89-92.

7.a. Will the data be used for non-CVD analysis in this manuscript? ____ Yes _xx___ 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?
__xx__ 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 ICTDER03 must be used to

exclude those with value RES_DNA = "No use/storage DNA"?
_xx___ 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

___xx___ 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)?**

Ref 2 above.

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

11.b. If yes, is the proposal
__xx_ A. primarily the result of an ancillary study (list number* _2006.16_)
___ 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/