

ARIC Manuscript Proposal #2423

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

Status: A
Status: _____

Priority: 2
Priority: _____

1.a. Full Title: Life's Simple 7 (ideal CV risk) and venous thromboembolism

b. Abbreviated Title (Length 26 characters): Simple 7 & VTE

2. Writing Group:

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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]

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3. Timeline: Start summer 2014

4. Rationale:

The American Heart Association has recently promoted primary prevention of cardiovascular disease (CVD) by recommending Americans follow "Life's Simple 7." The Simple 7 identify ideal, intermediate and poor levels of CVD risk factors or behaviors (namely, smoking, body mass index, physical activity, diet, total cholesterol, blood pressure, and fasting serum glucose).¹ The Atherosclerosis Risk in Communities (ARIC) Study reported that the number of ideal factors achieved is associated strongly and inversely with subsequent incidence of cardiovascular disease and cancer.^{2,3}

Although some arterial CVD risk factors (e.g., high BMI) increase risk of venous thromboembolism (VTE), others have little apparent association (e.g., total cholesterol). Yet, the REGARDS Study recently reported that a higher Life's Simple 7 score is inversely associated with VTE occurrence.⁴ We sought to replicate this finding in the ARIC Study.

We expect this to be a brief report.

5. Main Hypothesis/Study Questions:

Adherence to Life's Simple 7 is associated inversely with VTE incidence.

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).

Design: cohort

Endpoint: time to VTE incidence

Exposure: Components of Life's Simple 7

We will categorize Life's Simple 7 in two ways for analysis. Firstly, we will count the number of ideal Life's Simple 7 components a participant meets. Secondly, as done in REGARDS (5), we will create a score in which each component was given points of 0, 1, or 2 to represent poor, intermediate, or ideal health categories, respectively, and these were summed to yield a Life's Simple 7 score. This score will be categorized as inadequate (0-4), average (5-9), or optimal (10-14) for cardiovascular health.

Exclusions: VTE prior to visit, anticoagulant use, missing Simple 7 data.

Main covariates: age, race, sex

Analysis: We will calculate incidence rates of VTE and 95% confidence intervals using Poisson regression, and calculate hazard ratios (HR) and 95% confidence intervals of incident VTE using Cox proportional hazards models. We compute cumulative incidence of VTE according to the Simple 7 score, using Kaplan-Meier methods.

We will also explore the association of each Simple 7 component with VTE incidence, to see which might explain any overall association.

REFERENCES

1. Lloyd-Jones DM, Hong Y, Labarthe D, et al., on behalf of the American Heart Association Strategic Planning Task Force and Statistics Committee. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's Strategic Impact Goal through 2020 and beyond. *Circulation*. 2010;121:586-613.
2. Folsom AR, Yatsuya H, Nettleton JA, Lutsey PL, Cushman M, Rosamond WD, for the Atherosclerosis Risk in Communities (ARIC) Study Investigators. Community prevalence of ideal cardiovascular health, by the American Heart Association definition, and relationship with cardiovascular disease incidence. *J Am Coll Cardiol*. 2011;57:1690-1696.

3. Rasmussen-Torvik LJ, Shay CM, Abramson JG, Friedrich CA, Nettleton JA, Prizment AE, Folsom AR. Ideal cardiovascular health is inversely associated with incident cancer: The Atherosclerosis Risk in Communities Study. *Circulation*. 2013;127:1270-1275.
4. Olson NC, Cushman M, Lutsey PL, McClure LA, Judd S, Tracy RP, Folsom AR, Zakai NA. Inflammation markers and incident venous thromboembolism: the REasons for Geographic And Racial Differences in Stroke (REGARDS). Submitted to *Arterioscler Thromb Vasc Biol*. 2014.

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 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 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>

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

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data?

Yes No

11.b. If yes, is the proposal

- 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.csc.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.csc.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.