ARIC Manuscript Proposal # 3325

PC Reviewed: 1/8/2019	**Status: _____**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title: Income changes across federal poverty level, change in American Heart Association's Life's Simple 7 score, and incident cardiovascular disease: The ARIC study

b. Abbreviated Title (Length 26 characters): **income change, LS7, CVD**

2. Writing Group:
Writing group members: Stephen Y. Wang, Andy S. L. Tan, Brian Claggett, Alvin Chandra, Ichiro Kawachi, Pamela Lutsey, Anna Kucharska-Newton and Scott D. Solomon; Others welcome.

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

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3. Timeline: Analysis will begin following proposal approval with the aim of completing analysis and a manuscript within 12 months.

4. Rationale:

Link and Phalen argued that socioeconomic status (SES) is a "fundamental cause" of disease.[1] No matter the health threat, higher SES individuals have greater access to resources to protect their health.[1] Since socioeconomic status is difficult to directly measure, a common method of operationalizing socioeconomic status is income.[2] Prior studies have shown that higher income at baseline is associated with healthier behaviors, such as beneficial smoking behaviors,[3-5] greater adherence to dietary guidelines,[6,7] and higher intensities of exercise.[8]

Although the literature has described the association of income with health behaviors in relative depth, the literature is limited regarding the association of change in income with health behaviors in adults. One Canadian study found that individuals whose incomes increased above the federal poverty level (FPL) were more likely to be non smokers than those whose incomes remained below the FPL.[9] A study by Rehkopf et al. observed participants <50 years old who received earned income tax disbursements and found that participants who received the tax credits had both positive and negative changes in various health behaviors, but overall had a greater number of positive health behaviors.[10]

However, income changes in general may even lead to worse overall health, as one study showed an increase in BMI with earned income tax credit benefits.[11] Due to the potentially contradictory positive and negative health effects of changes in income, more research is required in the effects of changes in income on health behaviors. In addition, there has been no previous study in the literature on income change and long-term follow up of health outcomes, which includes incident cardiovascular events.

Because the relationship between income and health may be logarithmic, that is, the rate of benefit of additional income on health diminishes with higher income levels,[12] we would like to examine changes in income at lower baseline income values, thus the federal poverty level (FPL) will be used as a reference point. FPL as reference point has been used in other studies of change in income.[9,13] This study will assess the relationship of change in income across the FPL in midlife as a dynamic variable to examine associations with change in the American Heart Association (AHA) Life's Simple Seven Score (LS7) in ARIC participants. The LS7 are health behaviors and health metrics that are part of the goals of the AHA, scored on a scale from 0 to 14,[14] and adherence to the LS7 has been shown to reduce incidence of CVD.[15-18] Lastly, we will examine the effect of changes in income on long-term risk of incident cardiovascular disease.

5. Main Hypothesis/Study Questions:

Hypotheses:

- We hypothesize that an increase in income above the FPL will be associated with an increase in the LS7 score.
- We hypothesize that a decrease in income below the FPL will be associated with a decrease in the LS7 score.
- We hypothesize that LS7 scores would not change in adults that either remained above FPL or remained below FPL.
- We hypothesize that compared to the group that remained above FPL, the group that fell under FPL would have a significantly greater decrease in LS7 score.

- We hypothesize that compared to the group that remained below FPL, the group that rose above FPL would have a significantly greater increase in LS7 score.
- We also hypothesize that compared to adults who remain above FPL, those who rise above FPL will have similar or decreased rates of incident cardiovascular disease, while a 6-year change in income level from that above FPL to below FPL will be associated with higher rates of incident cardiovascular disease.

Our aims are as follows:

1. To examine the association between the Visit 1 and Visit 3 changes in income bidirectional across FPL with changes in LS7 score
2. To examine the association between the Visit 1 and Visit 3 change in income bidirectional across FPL to below and above FPL with CVD (MI, stroke, HF) 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).

Study design: We plan to examine change in income between visit 1 and visit 3 with regards to the federal poverty level (FPL). The 1989 FPL will be used for visit 1 FPL (87-89) and the 1995 FPL will be used for visit 3 FPL (93-95). We will calculate FPL for both visits 1 and 3 using information on household income and the number of household occupants. We will compare each individual's FPL with their household income to determine the income change categories. When a household's theoretical FPL level was within the household's income category, we will designate that category as below FPL. Since this was an arbitrary distinction, sensitivity analysis will also be conducted by designating that category as above FPL.

Four categories of FPL will be created. Category 1 remained in poverty, category 2 went into poverty, category 3 rose out of poverty, and category 4 stayed above the poverty level. We will attempt to determine the relationship between these changes in income and concurrent changes in AHA LS7 score.

Below are the methods which will be used to calculate the LS7 score.[18] Each ideal health metric is worth 2 points, intermediate health metric is worth 1 point, and poor health metric is worth 0 points, for a total of 0-14 points for the 7 health metrics:

- Smoking: There is self-reported smoking status in every ARIC visit. Ideal smoking status is defined as never smoker or quit >12 months ago. Intermediate smoking status is defined as a former smoker who smoked <=12 months ago. Poor smoking status is defined as current smoker.
- Healthy diet score: A 66-item semi-quantitative food frequency questionnaire was completed during visit 1 and visit 3. For each visit, we will use this questionnaire to divide up each individual by the number of AHA ideal diet items completed,[19] which include: 1) ≥4.5 cups/day of fruits and vegetables (approximated as ≥4.5 servings/day in the ARIC study); 2) ≥3.5 oz servings/week of fish (approximated as ≥2 3- to 5-oz servings/week); 3) ≥3 1-oz servings/day of whole grains (approximated as ≥3 servings/day); 4) sodium (<1,500 mg/day); and 5) ≤36 oz/week of sugar-sweetened

beverages (approximated as ≤4 glasses/week).[15] Each individual will be placed in a category of low (1 item), intermediate (2-3 items) or ideal (4-5) diet for each visit.

- Physical Activity: Exercise behavior was surveyed using the validated Baecke questionnaire in ARIC visits 1 and 3.[20] Our exercise score will use the questions in the questionnaire to determine minutes per week of moderate or vigorous exercise, categorized by recommended guidelines.[15,21] Each individual's exercise score will be divided up into poor (no exercise) or intermediate (defined as either intermediate exercise which is 1-149 min/week of moderate or 1-74 min/week of vigorous or 1-149 min/week moderate + vigorous exercise), or ideal exercise (defined as >=150 min/week moderate or >=75 min/week vigorous or >=150 min per week moderate + vigorous exercise).[15]
- BMI: BMI was calculated through measured weight in scrub suit and standing height in ARIC visit 1 and visit 3. BMI will be divided into poor (>=30kg/m^3), intermediate (25-29.99kg/m^3), and ideal (<25kg/m^3).
- Glucose: Serum glucose was measured in mg/dL with a hexokinase/glucose-6-phosphate dehydrogenase method. Serum glucose will be divided into poor (>=126mg/dL), intermediate (100-125mg/dL or treated to <100mg/dL), or ideal (<100mg/dL without medication).
- Blood Pressure: Sitting blood pressure was calculated with three measurements from a random-zero sphygmomanometer after a 5-min rest, and the average of the last two measurements was used. Blood pressure is divided into poor (SBP>=140 or DBP>=90 mmHg), intermediate (SBP 120-139 or DBP 80-89 or treated to <120/<80mmHg) or ideal (<120/<80 mmHg without medication) categories.
- Total Cholesterol: Fasting plasma total cholesterol was measured by enzymatic methods. Cholesterol was divided into poor (>240mg/dL), intermediate (200-239mg/dL or treated to <200mg/dL), or ideal (<200mg/dL without medication) categories.

AHA LS7 score will be calculated at visit 1 and visit 3. Change in LS7 score will be analyzed as the outcome, with income change categories as the predictor. We will parameterize the change in our model with one-unit changes in the LS7 score. Adjustment will be conducted for age, gender, education level, race and center, and employment, all at visit 1. Change in individual components of the LS7 will also be analyzed separately.

Lastly, we will analyze associations between income change at midlife and incident CVD, in follow-up through older adulthood. Our primary outcome will be the composite outcome of definite or probable MI, fatal coronary heart disease, incident HF, or definite or probable stroke. Components of this composite outcome will also be analyzed individually. The group that remained above FPL will be used as the reference category since it will likely have the largest sample size.

Inclusion/exclusion criteria: We will exclude individuals with missing values for income at visit 1 and/or visit 3. In addition, we will exclude individuals if they are missing values for smoking status, if they are missing variables to calculate Baecke leisure sports activity score, if they are missing variables to calculate components of ideal diet score (whole grains consumed, fish consumed, fruits and vegetables consumed, sugary beverages consumed, and sodium levels), and if they are missing blood pressure, total cholesterol, blood glucose and BMI values at v1 and v3. Other exclusions will be if participants were missing information on the number of persons in

their household. Additionally, individuals who are not black or white and blacks from MN and MD will be excluded due to small numbers.

Key variables of interest:

1. Exposure: Income at visits 1 and 3,
2. Covariates: age, sex, gender, education level, race and study center, employment status.
3. Outcomes:
    a. Behavior variables: At visits 1 and 3, smoking status, variables to calculate physical activity based on Baecke sports leisure activity, food frequency questionnaire items to compute ideal health score (whole grains consumed, fish consumed, fruits and vegetables consumed, sugary beverages consumed, and sodium levels).
    b. Composite outcome of definite or probable MI or fatal coronary heart disease
    c. Incident definite or probable incident stroke from ICD-9 and ICD-10 codes.[22]
    d. Incident heart failure identified from ICD-9 and ICD-10 codes.[23]
    e. Composite incident cardiovascular disease
    f. Follow-up for incident cardiovascular events will be through December 31, 2018.

Data analyses:

1. Descriptive statistics will be used to analyze demographic variables within each of the income change categories. We will use global chi square tests and anova to compare categorical and continuous variables, respectively.
2. We will conduct a linear regression, using as outcome the change in LS7 score between v1 and v3. Income change category will be the predictor. Multivariable modeling will also be conducted to adjust for demographic variables (age, sex, gender, education level, employments status, and race-center).
3. The primary outcome (incident CVD) and each separate component of the primary outcome will be analyzed using a Kaplan-Meier curve using the 4 income change categories as the predictor and Cox multivariable modeling with adjustment for demographic variables (age, gender, sex, education level, race and center, with group staying above FPL as reference). Since income is dynamic and may change after visit 3 (Ie. Retirement), sensitivity analysis will also be conducted with follow up truncated at 10 years for the CVD outcomes, which is around half the total follow-up time. A time less than 10 years was not chosen since differences in outcomes from changes in income will likely take many years to manifest.

Limitations:

1. Temporality may be an issue. There is no way to know exactly when incomes were changed in between visits 1 and 3, or when behaviors were changed between visits.
2. We do not have exact income levels, only income categories.
3. Income is dynamic as we observed and may change after visit 3.
4. Income was self-reported and may not be completely reliable.
5. There may be unmeasured confounders.

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 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.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)?

None

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/

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.cscc.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.

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