ARIC Manuscript Proposal # 1813

PC Reviewed: 7/12/11 Status: A Priority: 2
SC Reviewed: _________ Status: _____ Priority: ____

1.a. Full Title: Twenty-year changes in smoking behaviors and secondhand smoke exposures in a longitudinal cohort: the ARIC Study

b. Abbreviated Title (Length 26 characters): 20-year changes in smoking

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

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3. Timeline:
This is an analysis of existing data. We expect to complete the manuscript <24 months after approval.
4. **Rationale:**

Cigarette smoking is an important risk factor for cancer, heart disease, respiratory disease, and stroke and tobacco use is among the most preventable causes of morbidity and mortality in high income countries such as the United States (World Health Organization 2004). In North America, 22% of cardiovascular mortality has been attributed to smoking (Ezzati et al. 2005) and tobacco smoke remains the most important risk factor for chronic obstructive pulmonary disease (Mannino and Buist 2007).

At the time of the baseline ARIC exam, 42% of the ARIC cohort identified themselves as lifetime non smokers and 58% reported current (26%) or former (32%) cigarette use. ARIC study participants likely developed their smoking habits in the 1950s and 1960s, when smoking rates and tobacco consumption were rising in the United States. However, tremendous changes in the prevalence of smoking have occurred over the past several decades; smoking prevalence peaked in the 1960s and has steadily declined since the publication of the 1964 Report on Smoking and Health by the Surgeon General of the U.S. Public Health Service (Office of the Surgeon General 1964). Regulations, including the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969, and vigorous public health efforts have also led to significant changes in smoking behaviors, particularly among men (Garrett et al. 2011).

Analysis of National Health and Nutrition Examination Survey (NHANES III) data (1988-1994) provide evidence of considerable variation in the prevalence of cigarette smoking by gender, race, and employment status, with the highest prevalences observed among unemployed persons (43%), and those working in transportation occupations (46%), as waiters and waitresses (45%), and as construction laborers (42%); lowest prevalences were reported among persons employed in education (14%) and sales (19%) (Bang and Kim 2001). More recent data indicate that 21% of adults in the United States currently smoke, and that the prevalence varies widely across categories of age, education, employment status, ethnicity, gender, and race (Pleis et al. 2009; Garrett et al. 2011).

Data from the ARIC study provide an opportunity to evaluate changes over time in smoking behaviors and secondhand smoke (SHS) exposure in a large, population-based, longitudinal cohort of adults. Most notably, the ARIC study includes detailed smoking history and related information obtained from questionnaires administered at visits 1-4. Smoking status updates were also included in annual follow-up data collection since 1998, making available the possibility of identifying periods of quitting between the detailed visit questionnaires. Information about smoking status, types of products used, smoking behaviors (e.g., amount smoked, extended periods of quitting, smoke inhalation habits), and SHS exposure will provide valuable information about changing smoking behaviors and SHS exposure among African-American and white men and women in the United States.

Questionnaire data from the ARIC study provide unique information about the smoking history of the ARIC cohort during the last 20 years. Smoking histories will be used to describe populations with specific profiles (e.g., lifetime non smokers, light/moderate/heavy smokers, incident/remitting/intermittent/persistent smokers) and those whose smoking-related habits and SHS exposures have changed over time. Information about changes in tobacco use, smoking
behaviors, and SHS exposure across categories of employment status and occupation will be used to describe potential interactions between smoking and occupational inhalation exposures. Information about such changes across categories of age, education, employment status, gender, health insurance status, income, literacy, marital status, occupation, race, respiratory disease (asthma, chronic bronchitis, emphysema) history, and study center will be used to develop hypotheses about populations that may benefit from targeted tobacco cessation messages and protection from involuntary SHS exposures. The results will be used to develop and refine hypotheses about the contribution of tobacco use and SHS exposures to the progression of respiratory disease in the ARIC cohort.

5. **Main Hypothesis/Study Questions:**

There are two main objectives of this proposed paper:

1. To characterize baseline status and subsequent changes in participants’ tobacco use, smoking behaviors, and SHS exposure
2. To evaluate patterns of tobacco use, smoking behaviors, and SHS exposure across categories of age, allergy history, body mass index (BMI), education, employment status, gender, health insurance status, income, literacy, marital status, occupation, race, respiratory disease (asthma, chronic bronchitis, emphysema) history, and study center

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**

The proposed characterization of baseline status will be a cross-sectional analysis of data collected during visit 1. The proposed analyses of changes in tobacco use, smoking behaviors, and SHS exposure will use data collected during visits 1 through 4 and in annual follow-up contacts.

**Inclusion/Exclusion Criteria**

Participants with RES_OTH=“CVD Research” will be excluded.

**Independent Variables**

Age, allergy history, BMI, education, employment status, gender, health insurance status, income, literacy, marital status, occupation, race, respiratory disease (asthma, chronic bronchitis, emphysema) history, and study center will be considered independent variables.

Age – Age at each data collection point will be calculated based upon the participant’s date of birth and the date of data collection.

Allergy history – Responses to the following question will be used as an indicator of allergy history, “Has a doctor ever told you that you had hay fever?” This question was included at visit 4, and will be used to indicate a lifetime allergy history.

BMI – Weight and height measurements at each ARIC visit will be used to calculate BMI at each time point.
Education – Highest educational attainment reported at visit 1

Employment status – Categories of employment status will be developed using data from each of the study visits. Major categories will include homemaker/no other job reported, employed (continuously, intermittently), unemployed, self-employed, and retired; sub-categories will be created, as necessary.

Gender – Reported at visit 1

Health insurance – Reported at study visits 1 and 2 in response to the following question: “Do you have health insurance, such as Medicare, or a medical plan, such as an HMO, which pays part of a hospital, doctor’s, or surgeon’s bill?” Reported at visits 3 and 4 in response to “To help pay for your medical care, do you NOW have:” followed by the options: “Health insurance or a health plan, such as Blue Cross/Blue Shield or an HMO”, “Medicare”, “Medicaid”, “Other.”

Income – Income group used to define total combined family income during the last 12 months will be used to describe each participant’s socio-economic status (SES). Changes across visits 1 through 4 will be used to identify trajectories in SES and to categorize total family incomes as increased, decreased, or stable.

Literacy – Literacy will be categorized using responses provided by interviewers at visit 1 to the survey item “Is the respondent able to read and write?” (yes/no/unsure).

Marital status – As reported in visits 1 and 2 (married, widowed, divorced, separated, never married) and in annual follow-up forms (beginning with form D). Sub-categories of changes in marital status will be created, as necessary.

Occupation – Occupational categories based on baseline self-reported occupation information were created for previous analysis (Mirabelli et al. under review) and will be used again for these proposed analyses. The categories were created using each participant’s current employment status, most recent occupation, and self-employment status. The primary categorization of occupation will be based on existing categorization of respondents’ current/most recent occupations (at visit 1) into the 15 broad occupational groups, which are based on the 1977 Standard Occupational Classification (SOC) coding system and shown in ARIC Manual 2 Visit 1 Appendix III (pp. A18-A24). Changes in employment status, including retirement, following visit 1 will be based on changes reported at study visits 2-4.

Race – Reported at visit 1.

Respiratory disease – History of asthma, chronic bronchitis, and emphysema will be based on responses to broad questions (e.g., Have you ever had asthma? Has a doctor ever told you that you have chronic bronchitis) included at each of the four study visits. A positive history of asthma will be categorized as childhood asthma (≤age 16) or adult-onset (>16). Among smokers, any history of respiratory disease will be categorized as occurring before or after the age participants began smoking.
Study center – Study center will be used to assess the influence of geographic region and other unmeasured variables associated with geographic region. Of particular interest is the evaluation of whether participants in Forsyth County, North Carolina, a region with strong historical and cultural ties to tobacco production, show distinctly different patterns of tobacco use, smoking behaviors, and SHS exposures.

**Dependent Variables**
Dependent variables will be created to characterize smoking status, tobacco use, and SHS exposure.

Smoking status (cigarettes) – Questionnaires administered at study visits 1-4 include detailed information with which to characterize smoking status (lifetime non-smoker, former smoker, current smoker) at each time point. These data will be used to categorize participants in the following categories:

- **Lifetime non smoker:** Non smokers at visits 1-4 and in all annual follow-ups.
- **Former smoker:** Indicated former smoking status at visits 1-4 and reported not currently smoking in all annual follow-ups.
- **Incident smoking:** Non smokers at visit 1, current smoking indicated in any subsequent contact and in all contacts after the initial reporting of smoking.
- **Rermitting smoking:** Current smoking reported at visit 1, followed by non smoking status in any subsequent contact and in all contacts after the initial report of non smoking status.
- **Intermittent smoking:** Starting and/or stopping smoking more than once throughout the ARIC study contacts.
- **Persistent smoking:** Current smoking in all ARIC study contacts.

Smoking status was also included in annual follow-up calls (beginning with form G) using the question “do you now smoke cigarettes?” Although the primary analysis will be conducted using the questionnaire data from visits 1-4, these data will be used to categorize participants with missing data and those whose smoking history requires additional detail (e.g., respondents who report lifetime non-smoking followed by former smoking).

Smoking status (other tobacco products) – Questionnaire data about the use of pipes, cigars, chewing tobacco, snuff, nicotine gum, and nicotine patches were included to varying degrees of detail in questionnaires administered at visits 1-4. We will create dichotomous indicators of use of each of these at each of the four visits.

Tobacco Use – Smoking patterns will be evaluated for former and current smokers. For example, data about the ages at which they started/stopped smoking, the length of time during which they quit, the intensity of their smoking (e.g., pack-years of cigarettes), and whether they inhale the smoke will be used to create variables for each of the 4 study visits. In addition to the descriptive variables describing lengths of time as a smoker, years since quitting, lifetime pack-years of smoking, and smoke inhalation, participants’ tobacco use will be categorized as having increasing, decreasing, or stable over the course of the all four study visits.
Secondhand smoke (SHS) – Participants who identified themselves as non-smokers were each asked the following question: During the past year, about how many hours per week on the average, were you in close contact with people when they were smoking? For example in your home, in a car, at work, or other close quarters? (yes/no).

Statistical Methods
The statistical methods will be largely descriptive. First, using data from ARIC visit 1, descriptive statistics (i.e., prevalences, means, medians, ranges) will be used to characterize the smoking variables for the entire study population and for sub-populations categorized by age, allergy history, BMI, educational attainment, employment status, gender, health insurance status, income, literacy, marital status, occupation, race, respiratory disease (asthma, chronic bronchitis, emphysema) history, and study center.

Second, using data from ARIC visits 1-4, the descriptive statistics will be presented for all four visits in order to present changes in smoking status, tobacco use, and SHS exposure over time. Using these data, participants will also be described according to their change in smoking status (lifetime non smoker and incident, intermittent, remittent, and persistent smoking status), tobacco use, and SHS exposures. Smoking variables will be presented for the entire study population and for the categorized sub-populations listed above. Participants will be included in analyses until death or last available visit.

Finally, multivariate analyses will be used to evaluate predictors of each smoking status category. These analyses will use binomial regression to evaluate associations between the independent variables and each smoking category in separate models. Associations will be presented as relative risks (RRs) with 95% CIs.

Limitations
The main limitation to this analysis will be misclassification of smoking status, tobacco use, and SHS exposure. The misclassification is expected to arise, in part, due to under-reporting of smoking behaviors and SHS exposures. If smoking data were systematically under-reported by any of the demographic, geographic, social, health related, smoking, or other variables included in our analysis, then our analyses may incorrectly attribute changes in smoking variables to strata in which smoking was not under-reported. The use of ARIC data collected at multiple time points will enable us to evaluate contradictions in the reporting of smoking status.

Additional misclassification is expected to arise due to our classification of participants into a few broad categories of smoking status (e.g., incident, remittent, intermittent smokers). Our evaluation of pack-years of smoking, dates of starting/stopping, and other tobacco use behaviors will enable us to provide a more thorough description of the smoking behaviors of participants in these broad categories.

Another limitation of the analysis is that a long list of other factors affecting smoking status, tobacco use, and SHS exposure will not be considered here. The potential for social factors (e.g., alcohol use, economics, stress), medical factors (e.g., adverse health conditions of the participant or his/her family, medication use, surgical procedures) and other related factors (e.g., smoking cessation programs) to affect smoking habits will be acknowledged.
References


7.a. Will the data be used for non-CVD analysis in this manuscript?  _X__ 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?  _X__ 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](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)?

There are currently no ARIC manuscripts using tobacco use, smoking behaviors, or SHS exposures as dependent variables. The following each use cross-sectional data about smoking status (at visit 1) as independent variables or important covariates. Our manuscript proposal builds upon these by describing longitudinal changes in tobacco use, smoking behaviors, and SHS exposures.


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* _________)
- 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/](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.