1.a. Full Title: Prevalence and associated factors of anosmia

b. Abbreviated Title (Length 26 characters): Prevalence of anosmia

2. Writing Group:
Writing group members:

(Currently in alphabetical order): Alonso, Alvaro; Chen, Honglei; Huang, Xuemei; Mosley, Thomas H; for the ARIC analysis

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

First author: Chen, Honglei
Address: 111 T.W. Alexander Dr. PO BOX 12233,
Mail drop - A3-05 Research Triangle Park, NC 27709

Phone: 919-541-3782 Fax: 919-541-2511
E-mail: chenh2@mail.nih.gov

ARIC author to be contacted if there are questions about the manuscript and the first author does not respond or cannot be located (this must be an ARIC investigator).

Name: Mosley, Thomas H
Address: 2500 North State Street, Jackson, Mississippi 39216-4505
Phone: 601-984-2763 Fax: 601-815-3422
E-mail: tmosley@umc.edu

3. Timeline: Manuscript submission by July 2015

4. Rationale: Anosmia or the loss of the sense of smell affects up to 25% of the US older adults and adversely impacts their safety and quality of life. More importantly, recent evidence suggests that anosmia may be one of the earliest symptoms of Parkinson’s disease and possibly an early symptom of Alzheimer’s disease. It has been hypothesized that research on anosmia helps to identify high risk populations for neurodegeneration and to understand early disease etiology. Despite its potential importance, little is known about anosmia in the general elderly population, for example, its prevalence by age, gender, and race and potential risk factors. In the ARIC study, the sense of smell was measured with the 12-item Sniffin’ Sticks test as part of the
neurocognitive study (NCS) and clinical visit 5 in 2011-2013. Study participants were asked to smell and identify 12 daily odorants with a score of 0-12, one for each correctly identified odorant. The test was validated and widely used in clinical and epidemiological research. We therefore propose to examine the prevalence of anosmia and associated factors in ARIC, more specifically to 1) define the age-, gender-, and race- specific prevalence of anosmia among community based US elderly; 2) understand demographic and lifestyle factors that are associated with anosmia. We are conducting similar research in the Health ABC study (HABC: 3,075 participants, ~40% African Americans) which has very similar participant characteristics and exposure and outcome assessment. The HABC used the Brief Smell Identification Test (BSIT, score 0-12) to measure the sense of smell. This method is very similar to the Sniffin’ Stick, which allows us to define anosmia the same way in both cohorts. We plan eventually to combine data from these two cohorts for publication purpose.

5. Main Hypothesis/Study Questions:

To estimate the prevalence of anosmia in the elderly; we hypothesize that the prevalence of anosmia increases with age and is higher in men than in women and in African Americans than in Caucasians. We will also examine anosmia prevalence in relation to diet, lifestyle, and health conditions.

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: Cross-sectional analyses primarily using data from the neurocognitive study.

Study Description: Our goal was to estimate the prevalence of anosmia among the elderly and examine associated factors. The analyses will be cross-sectional among participants of the ARIC neurocognitive study who had valid data on the sense of smell score. Participants with race other than black and white will be excluded.

General Analysis Approach: Multivariate logistic regression model. Analyses will be conducted first by race (blacks versus whites), gender (men versus women), and cohort (ARIC versus HABC) and then pooled.

Major Phenotype to Analyze: Anosmia defined as the sense of smell score ≤6.

Exposures of interest / main covariates: Exposures/covariates will be primarily from the NCS/visit 5 data, including age, sex, education, smoking status, alcohol drinking, cognitive score (MMSE), use of Parkinson’s medication, self-reported poor sense of smell, running nose in the past two weeks, depression (CESD), snoring, general health status, and BMI. Additional data will be from the 2012 semi-annual follow-up call (daytime sleepiness, acting out of dreams, self-reported Parkinson’s disease), and clinical visit 4 (head injury).
Limitations: While this will be the largest and most comprehensive analysis on the sense of smell and anosmia, we do not have information on important risk factors such as sinus problems, deviated nasal septum, and nasal polyps.

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 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  __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)?

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

11.b. If yes, is the proposal
__X__  A. primarily the result of an ancillary study (list number* 2010.17 Evaluation of olfactory dysfunction in the Atherosclerosis Risk in Communities (ARIC) study )

__  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.

Understand

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.