1.a. Full Title: Dementia, Hearing Loss, & Hearing Healthcare among Older Adults

b. Abbreviated Title (Length 26 characters): Dementia and Hearing Care

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

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3. **Timeline:**
Analysis and manuscript will be completed within 6 months.

4. **Rationale:**

The number of older adults with Alzheimer’s disease and related dementias (ADRD) will double by 2050, but few therapeutic options exist. Age-related hearing loss is highly prevalent among older adults and may exacerbate behavioral symptoms of dementia and caregiver burden. Preliminary evidence supports the use of amplification to reduce neuropsychiatric symptoms (NPS) and depression. Access to communication is fundamental to daily functioning and quality of life, and hearing care may represent an often neglected, yet key, mechanism for strengthening the communication and psychosocial function of older adults with ADRD.

Disparities in hearing health care exist based on race/ethnicity and socioeconomic position. Barriers to traditional hearing care, which involves multiple visits to multiple providers and out-of-pocket costs of $4700 for hearing aids, not covered by Medicare, present additional challenges to older adults with ADRD living at home and their caregivers. Few studies examine the co-occurrence of ADRD and age-related hearing loss and the potentially synergistic impact of hearing loss and ADRD on the health and function of older adults with ADRD. Clinic-based convenience samples from outpatient memory disorders clinic find the prevalence of hearing loss from 60% to over 90% among patients with cognitive impairment. Caregivers often underestimate the presence of hearing-related communication difficulties. Although hearing loss is increasingly recognized as a potentially modifiable risk factor for cognitive decline and incident dementia, little is known regarding the role of unaddressed communication impairments and the use of existing models of hearing care among older adults with ADRD, particularly minority older adults.

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

Within a biracial cohort with adjudicated cognitive impairment (mild cognitive impairment or dementia), what is the prevalence of hearing loss, communication impairment, and hearing aid use among older adults with cognitive impairment compared to those with normal hearing?

Aim 1: To describe the prevalence of audiometric hearing loss among older adults with cognitive impairment compared to participants who are cognitively normal.
Hypothesis 1: We hypothesize that the prevalence of audiometric hearing loss is greater among older adults with cognitive impairment compared to participants who are cognitively normal.

Aim 2: To describe the prevalence of communication impairment, as reported by the participant, among older adults with cognitive impairment compared to participants who are cognitively normal.
Hypothesis 2: The prevalence of communication impairment is higher among older adults with cognitive impairment compared to participants who are cognitively normal.
Aim 3: To describe the prevalence of hearing aid use among older adults with cognitive impairment and hearing loss compared to older adults with hearing loss who are cognitively normal.
Hypothesis 3: Adjusting for the severity of audiometric hearing loss, prevalence of hearing aid use is lower among older adults with cognitive impairment as compared to older adults with normal cognition.

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 study of ARIC visit 6 participants.

Study Population: The analytical cohort will include older adults with audiometric data and neurocognitive testing, specifically those with a global cognition score. Participants with missing audiometric frequencies at 0.5, 1, 2, or 4 kHz will be excluded. Participants with missing cognitive status (normal vs mild cognitive impairment vs dementia) will also be excluded.

Outcomes:

1. Audiometric hearing loss: Hearing loss will be defined as better hearing ear speech pure tone average (0.5, 1, 2, 4 kHz) greater than 25 dB HL based on the WHO classification, collected at visit 6.

2. Communication impairment: Communication impairment will be based on the total score from the Hearing Handicap Inventory for the Elderly (HHIE; form HHI). The variable will be explored continuously (total score: 0-40) as well as categorizing the variable by severity of impairment (0-8: no impairment, 10-24: mild-moderate impairment, 26-40: significant impairment).11

3. Hearing aid use: Self-reported hearing aid use among ARIC visit 6 participants, collected via the HNE form, offered to all participants at visit 6.

Exposure: The primary independent variable is cognitive status from visit 6, which will be defined as cognitively normal, mild cognitive impairment, and dementia, as previously described in the ARIC-NCS cohort.12 The variable will be explored as an ordinal variable (normal cognition, mild cognitive impairment, dementia) as well as a dichotomous variable (non-demented vs demented) and continuous variable using the composite Z-score.

Covariates: We will include demographic and individual-level socioeconomic position variables. For race/ethnicity, we will include a derived variable for self-identified race/ethnicity-center given the strong association between race/ethnicity and center within the ARIC cohort. For variables related to individual-level socioeconomic position, we will include the following categorical variables as individual variables: education level (HOM54 from visit 1), annual household income (PHX1 from visit 6), self-reported financial situation (PHX3 from visit 5), and
supplemental insurance (AQC2 from visit 5). For Aim 3, hearing related variables will be utilized in the analysis to control for the degree of hearing loss and only those with clinically significant hearing loss (PTA > 25 dB), who may benefit from hearing aids, will be included in these analyses. We will utilize pure tone air-conduction audiometry, specifically speech PTA from the better hearing ear based on thresholds obtained at 0.5, 1, 2, and 4 kHz (WHO categorization) and will test its inclusion as a continuous variable or as a categorical variable (i.e., mild, moderate, severe, etc.). Regarding demographics, we will include age as a continuous variable given the prevalence and severity of age-related hearing loss varies by age as well as sex as a categorical variable.

**Statistical Analysis:** Exploratory data analysis with graphical displays and frequency distributions, and cross-tabulations will be used. In describing the cohort by cognitive status, continuous variables will be presented as means and categorical variables as percentages and compared using t-tests and chi-squared tests. Univariate and multivariate logistic regression as well as multinomial logistic regression will be used to estimate the association between cognitive status and hearing loss, communication impairment, and hearing aid use. In examining cognition as a continuous variable through the composite Z-score, linear regression will be utilized. Models will be adjusted for age, sex, severity of hearing loss, race-center, and education as appropriate.

**Limitations:** A potential limitation relates to the possibility of missing or inaccurate data from either participants or proxies of participants with cognitive impairment, particularly for communication impairment and self-report hearing aid use. Given the potential for missing or inaccurate data from participants with dementia, we will also explore restricting analyses to those with mild cognitive impairment vs normal cognition. We will exclude participants who do not have audiometric data, which may exclude those well enough to the testing. The analytical cohort will likely include older adults with less severe cognitive impairment and will limit the generalizability of the results.

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.)

N/A

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

N/A
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/mantrack/maintain/search/dtSearch.html

___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)?

#2327 - Hearing impairment and cognitive performance in the Atherosclerosis Risk in Communities Neurocognitive Study (ARIC NCS): cross-sectional and longitudinal results

#2417 - Cross-sectional Association of Hearing Impairment and Region-Specific Brain Volumes in the Atherosclerosis Risk in Communities Hearing Pilot Study

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* _2008.06___)

____ 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 https://www2.cscc.unc.edu/aric/approved-ancillary-studies

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.

References:


