1.a. **Full Title:** Analyses of Hearing Impairment and Healthcare Satisfaction: A Pilot Study

b. **Abbreviated Title (Length 26 characters):** Hearing Satisfaction

2. **Writing Group (alphabetical):**
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I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal.

NSR [please confirm with your initials electronically or in writing]

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3. **Timeline:**
Manuscript will be completed in 6 months.

4. **Rationale:**
Hearing impairment is highly prevalent, impacting two-thirds of adults over the age of 70 in the United States\(^1,2\). Moreover, the prevalence of hearing impairment is projected to rise given the United States’ aging society\(^3\). Recent studies have found associations with hearing impairment and negative health outcomes in older adults, including cognitive decline and dementia\(^4-7\). Despite its high prevalence, addressing hearing impairment via hearing aid uptake is low (<20%)\(^8\).
Patient satisfaction has long been a goal and marker of quality of care in the healthcare system\textsuperscript{9-12}. Higher satisfaction among patients has been previously linked to decreased odds of emergency department visits and lower risk of 30-day readmission\textsuperscript{13,14}. There is increasing pressure to improve satisfaction in the U.S. healthcare system as Medicare has tied reimbursement to patient satisfaction surveys\textsuperscript{15}.

While many factors contribute to patient satisfaction, communication likely plays an underappreciated key role. Patient-provider communication has been associated with important healthcare quality measures including treatment adherence and, importantly, patient satisfaction\textsuperscript{11,16-20}. Health literacy, the ability to access and understand healthcare information, is limited by hearing impairment\textsuperscript{21}. Despite these observations\textsuperscript{21}, there is a paucity of research exploring hearing as a factor in health literacy, patient-provider communication, and/or patient satisfaction\textsuperscript{20,22,23}. Notably, a recent study of a convenience sample from an outpatient clinic showed that self-reported hearing impairment was associated with poorer perceived patient-provider communication\textsuperscript{22}. Importantly, self-report of hearing impairment is known to underestimate its prevalence\textsuperscript{24,25} and to be related to factors that may also influence patient-provider communication (age, sex, race) (cite our paper comparing the 2 hearing measures)

Exploring sensory impairments’ impact on patient-satisfaction has implications for public health and clinical care planning. Herein, we propose to leverage objectively-measured hearing data from the pilot study at V5 to report exploratory analyses and describe the association between hearing impairment and patient-satisfaction.

This pilot exploratory analysis will inform future analyses and studies from ARIC and ACHIEVE data.

5. **Main Hypothesis/Study Questions:**
We hypothesize that objectively measured hearing impairment is associated with poorer patient satisfaction with health care. Our aims are:

**Aim 1:** To describe the association of hearing impairment and overall patient satisfaction with health care

**Aim 2:** To describe the association of hearing impairment with other factors related to patient satisfaction with health care, including access to care, delaying care, perceptions of provider actions (listening, respect, time allotment)

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:** Pilot Cross-sectional study of 253 participants who underwent audiometric testing as part of a hearing pilot study at Washington County who also completed a patient satisfaction survey at visit 5.

**Outcomes:**
**Primary:**
Self-reported patient satisfaction with medical care received from their health care providers over the past 12 months (AQC form), reported as an ordinal variable (very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied). The AQC form was offered to all ARIC participants presenting at their clinic visit.

**Secondary:**
Self-reported questions on perceived difficulty getting to appointments on short notice, difficulty discussing medical problems over the phone, delaying care, and perception of how well providers listen carefully, explain procedures, show respect, and spend time with patients. All variables are reported on ordinal scales.

**Exposure:** At the end of ARIC visit 5, a sub cohort of 307 participants at Washington County were offered hearing measured as part of a hearing pilot study when they presented for their regular ARIC clinic visit. 255 completed the measurement. Pure tone air-conduction audiometry and speech perception testing were conducted in a sound-treated booth within a quiet room meeting ANSI standards. Pure tone audiometry is the gold-standard test to determine the faintest tones that a person can detect for a range of pitches. We will calculate a speech frequency PTA using audiometric thresholds at 0.5, 1, 2, and 4 kHz in the better-hearing ear in accordance with the World Health Organization definition of hearing impairment. The primary analysis for PTA will categorize hearing impairment using a clinically defined ordinal variable for hearing impairment (normal: <25 dB HL, mild: 26-40 dB HL, moderate or greater >40db HL) in line with clinical standards. We will also model PTA as a continuous analysis.

Because only 2 of the 255 participants were non-white, they were dropped to restrict analysis to all self-reported white cohort. Of 253 participants, 73 (29%) had no hearing impairment, 95 (37%) had mild hearing impairment, and 85 (34%) had moderate or severe hearing impairment. Mean age at the time of the hearing assessment was 76.9 (SD, 5.4) years, and 58.9% of participants had a high school education or less. On average, participants with moderate/severe hearing impairment were older (79.4 years) and more likely to be male (54%) and to have hypertension at baseline (33%) than participants with mild or no hearing impairment. Notably, pilot participants were older at visit 5 (77.1 years, SD=5.4 vs 75.7 year, SD=5.3, p<0.01) and more likely to have a high school education or less (60% vs 46%, p<0.01) than the rest of the ARIC cohort.

**Statistical analysis:** Multivariable logistic regression will be used to estimate the association of hearing impairment and patient satisfaction (primary outcome). Subsequent multivariable logistic regression models will be used to estimate the relationship between hearing impairment and secondary outcomes. Models will adjust for demographics (age, sex, and education), recent self-report hospitalization, and summary comorbidity score (count), Medicaid insurance status, usual source of care, and provider seen most frequently covariates which may confound the relationship between hearing impairment and patient satisfaction with health care. Depending on distributions, stratification may be used to explore outcomes. We will explore for possible statistical interactions of age and sex with hearing impairment by stratification and inclusion of interaction terms in the models. We acknowledge a prior that limited sample size will limit statistical power to assess interactions and this analysis is exploratory in nature. Further, inference will have limited generalizability (hearing pilot study was conducted at Washington County only and relatively small sample size) and relatively small sample size, but will add to the
literature given the lack of studies quantifying the relationship between objectively measured hearing impairment and patient satisfaction with health care.

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 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  __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

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.csc.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)?

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

Proposal #2880 - A Randomized Pilot Trial of Hearing Treatment for Reducing Cognitive Decline: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) 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* __2016.03______)
___ 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.cscce.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.cscce.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.

13. Per Data Use Agreement Addendum, approved manuscripts using CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication. Approved manuscripts should be sent to Pingping Wu at CC, at pingping_wu@unc.edu. I will be using CMS data in my manuscript _____ Yes _X___ No.
References
