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Demographic and Audiological Characteristics of Candidates for Over-the-Counter Hearing Aids in the United States

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Objectives: This report presents descriptive data on the demographic and audiological characteristics of US adults with perceived mild-to-moderate hearing loss, the primary candidates for over-the-counter (OTC) hearing aids.

Design: The analyses are descriptive and present population-weighted responses for various self-reported demographic and audiological variables for adults with mild or moderate perceived hearing trouble. Results of pure-tone audiometry and immittance measures are also presented. Nationally representative datasets from the National Health and Nutrition Examination Surveys (NHANES) for 2011 to 2012, 2015 to 2016, and 2017 to 2020, the three most recent NHANES datasets with audiological information, were used.

Results: The NHANES datasets indicated that there are 49.5 million adults in the United States with perceived mild-to-moderate hearing trouble. Results indicated that OTC hearing-aid candidates are most frequently 50 to 69 years of age, married, and identify as non-Hispanic White race/ethnicity. Most of these individuals graduated from high school, had several risk factors for hearing loss, had not had a hearing test in the past 5 years, and had never used hearing aids or assistive listening devices previously. The typical audiometric profile was a bilaterally symmetrical sloping hearing loss with slight to mild hearing loss above 2000 Hz. Group data showed normal immittance measures and absence of otoscopic abnormalities except for the presence of excessive (not impacted) cerumen in about 13% of the OTC hearing-aid candidates.

Conclusions: Tens of millions of US adults have perceived mild-to-moderate hearing trouble but have not pursued assistance, either through obtaining a hearing test or acquiring prescription hearing aids.

Key words: Hearing aids, Perceived hearing trouble, Epidemiology.

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INTRODUCTION

The focus on improved affordability and accessibility of hearing healthcare in the United States (US) over the past 15 years (Donahue et al 2010; NASEM 2016) has changed the hearing healthcare landscape for millions of adults. These efforts led to the over-the-counter (OTC) Hearing-Aid Act of 2017 and the implementation of new regulations for OTC hearing aids by the Food and Drug Administration (FDA) in its final rule on hearing aids which took effect October 17, 2022. Hearing aids can now be acquired directly by adults with "perceived mild-to-moderate hearing loss."

What do we know about adults with "perceived mild-to-moderate hearing loss?" To answer this question, one must first define what this expression means. Typically, degrees of "hearing loss" are defined audiometrically and are not based on the individual's perception. "Hearing difficulty" or "hearing trouble," on the other hand, are based on perception and sometimes include response scales that use terms close to "mild" and "moderate" to represent the amount of trouble experienced. One of the most widely used surveys of this type, due mainly to its use in large epidemiological studies of adults living in the United States, is a question about one's general condition of hearing. This question has been included for many years in the National Health and Nutrition Examination Survey (NHANES) and the National Health Interview Survey (NHIS), as well as in several state datasets (Marrone et al. 2019; Dillard et al. 2022). The responses to this query about one's condition of hearing include "a little trouble" and "moderate trouble" hearing. These response categories are considered here to be representative of those with "perceived mild-to-moderate hearing loss," the primary candidacy requirement for OTC hearing aids per the FDA.

With this question used to identify those with perceived hearing trouble of varying degrees, several studies over the past 5 to 10 years have examined how those with perceived hearing trouble (≥"a little trouble hearing") differ from those without such trouble (Zelaya et al. 2015; Spankovich et al. 2018; Marrone et al. 2019; Dillard et al. 2022; de Gruy et al. 2023; Humes 2023b). However, those with the two greatest amounts of hearing difficulty, corresponding to responses of "a lot of trouble" or "deaf," have usually been included in these analyses but were not the intended targets for OTC hearing aids. Rather, in accordance with the new FDA regulations, these individuals would most likely be candidates for follow-up with hearing healthcare professionals to determine their candidacy for prescription hearing aids.

The purpose of the present report was to provide the demographic and audiological characteristics of those US adults who self-report "a little" or "moderate" hearing trouble, that is, the primary candidates for OTC hearing aids. This report makes use of data from several recent NHANES surveys which include the most recent and extensive data available for US adults with perceived mild-to-moderate hearing loss. An added advantage for the use of these datasets is that population-weighted estimates for the United States can be generated. NHANES also includes a large volume of audiological information to better characterize the audiological characteristics of those with perceived mild-to-moderate hearing loss. Although the primary interest is in those with a little or moderate trouble hearing, for comparison

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purposes, data are also presented for those with self-reported excellent or good hearing as well as those who reported a lot of trouble hearing or indicated that they were deaf.

MATERIALS AND METHODS

The NHANES Datasets

This report makes use of three NHANES datasets. All three datasets are fully described and openly available online (https://www.cdc.gov/nchs/nhanes/index.htm). NHANES is overseen by the National Center for Health Statistics (NCHS) of the US Centers for Disease Control and Prevention. NHANES is comprised of both interview and examination components, the latter completed in mobile examination centers (MECs) and is completed typically in 2-year cycles. The three most recent datasets, NHANES 2011 to 2012, 2015 to 2016, and 2017 to 2020 with audiological data, were used in these analyses, and all made use of the same question regarding the self-reported condition of hearing, including identical response alternatives. For NHANES, all study participants answered the question about general condition of hearing, along with questions about demographics, general health, and other broad information. For each NHANES cycle, all participants were interviewed at home and then scheduled for follow-up interviews and examination in the MEC with about half of those assessed in the MEC selected for audiological evaluation.

For all three NHANES surveys combined, demographic and general-health data were available for a total sample size of 35,287. Of these, NCHS assigned nonpositive weights to the data from 2105 individuals for a variety of reasons, excluding those data from consideration and resulting in a total sample size of 33,182 individuals available for analyses. Here, because the FDA guidelines for OTC hearing aids are to be applied to adults only, the analyses were restricted to those 20 years of age or older which corresponds to a frequently used age limit for NHANES audiometric measurements. Limiting the sample to those ≥20 years of age resulted in data from a total of 19,337 individuals between 20 and 80+ years of age included in the present analyses. For protection of participant identity, NCHS top coded the ages of those over the age of 80 with a value of 80 for NHANES.

These data formed the basis for the description of the general demographic characteristics of those with perceived mild-to-moderate hearing loss, the candidates for OTC hearing aids. The demographic characteristics examined here included sex, age, race/ethnicity, birth in the United States, marital status, family income, education level, and several hearing-related risk factors such as cigarette smoking, high blood pressure, and diabetes. Many of these variables were included because they have been demonstrated previously to affect the risk for audiometric hearing loss or self-reported hearing trouble (Hoffman et al. 2017; Spankovich et al. 2018; Humes 2023a, b). All these variables were available in the NHANES datasets with only minor differences in the survey questions and responses across surveys. Specific details about how each of these variables was defined here can be found in Humes (2023a).

For the NHANES datasets, in addition to household interviews, most were both interviewed and examined at the MEC. A question answered by all sample persons pertains to the general condition of one's hearing and is identified in NHANES as question AUQ054. Specifically, AUQ054 asks, "Which statement best describes your hearing (without a hearing aid or other listening device)? Would you say that your hearing is excellent, good, that you have a little trouble, moderate trouble, a lot of trouble, or are you deaf?" The focus here is on those who responded that they had "a little trouble" or "moderate trouble," interpreted as equivalent to perceived mild-to-moderate hearing loss. Those responding "excellent" or "good" as well as those responding "a lot of trouble" of "deaf" represented two additional groups formed from this single question about hearing. These two groups were included solely for reference purposes to compare results to those of the primary group of interest: those with a little or moderate trouble hearing.

In NHANES 2011 to 2012 and 2015 to 2016, 9082 adults aged 20 to 69 years of age completed additional hearing-related interview questions and audiological measures. This is shown in the flow diagram in the upper panel of Figure 1. It is important to note that NCHS decided apriori that only 20 to 69-year-olds included in NHANES 2011 to 2012 and 2015 to 2016 would answer these questions and receive the audiological examination. These 9082 20 to 69-year-olds represent about 48% of the full sample of 18,882 individuals included in these two NHANES surveys. In NHANES 2017 to 2020, NCHS had apriori designated the 6 to 19-year-olds and those 70 to 80+ years of age as the targets for completion of these extra questions and audiological measures. Of the total available of 14,300, 1493 adults 70 to 80+ years of age, as shown in the lower panel of Figure 1, completed these additional interview questions and audiological measurements. Audiological information acquired during the MEC interviews of all three NHANES surveys included in these analyses dealt with topics of history of middle-ear disease, tinnitus, hearing aid use, noise exposure, and similar measures. Again, for each item analyzed in this report, Humes (2023a) provided extensive details about the specific NHANES interview questions used and the treatment of the responses to those questions.

Last, the results of pure-tone audiometry and immittance measurements from the three NHANES datasets were also examined for this report. To be considered here, the audiogram status had to be designated as "complete" in NHANES (rather than "partial" or "not done"). When immittance measurements were considered, the tympanogram quality had to have been judged by the supervising audiologist to be of "adequate" or "good" quality. Further details about the audiometric and tympanometric measures have been provided elsewhere (Humes 2023a, c). As shown in Figure 1, for NHANES 2011 to 2012 and 2015 to 2016, complete audiometric data were available from 7729 adults between the ages of 20 and 69 years. Of these 7729 sample persons with complete audiograms, 7550 had tympanograms of good or adequate quality in both ears. In NHANES 2017 to 2020, complete audiometric data were available for 1066 adults 70 to 80+ years of age and 1012 of these sample persons also had tympanograms judged by NHANES staff to be of adequate or good quality in both ears. The adequacy of the tympanograms only was taken into consideration for the analyses of the immittance measurements completed in these analyses of the NHANES datasets.

NHANES also recorded the reasons for incomplete audiograms and the top reasons for both "partial" and "not done" categories from the three NHANES surveys included in these analyses are summarized in Table 1. As noted, the NHANES 2011 to 2012 and 2015 to 2016 surveys planned to complete

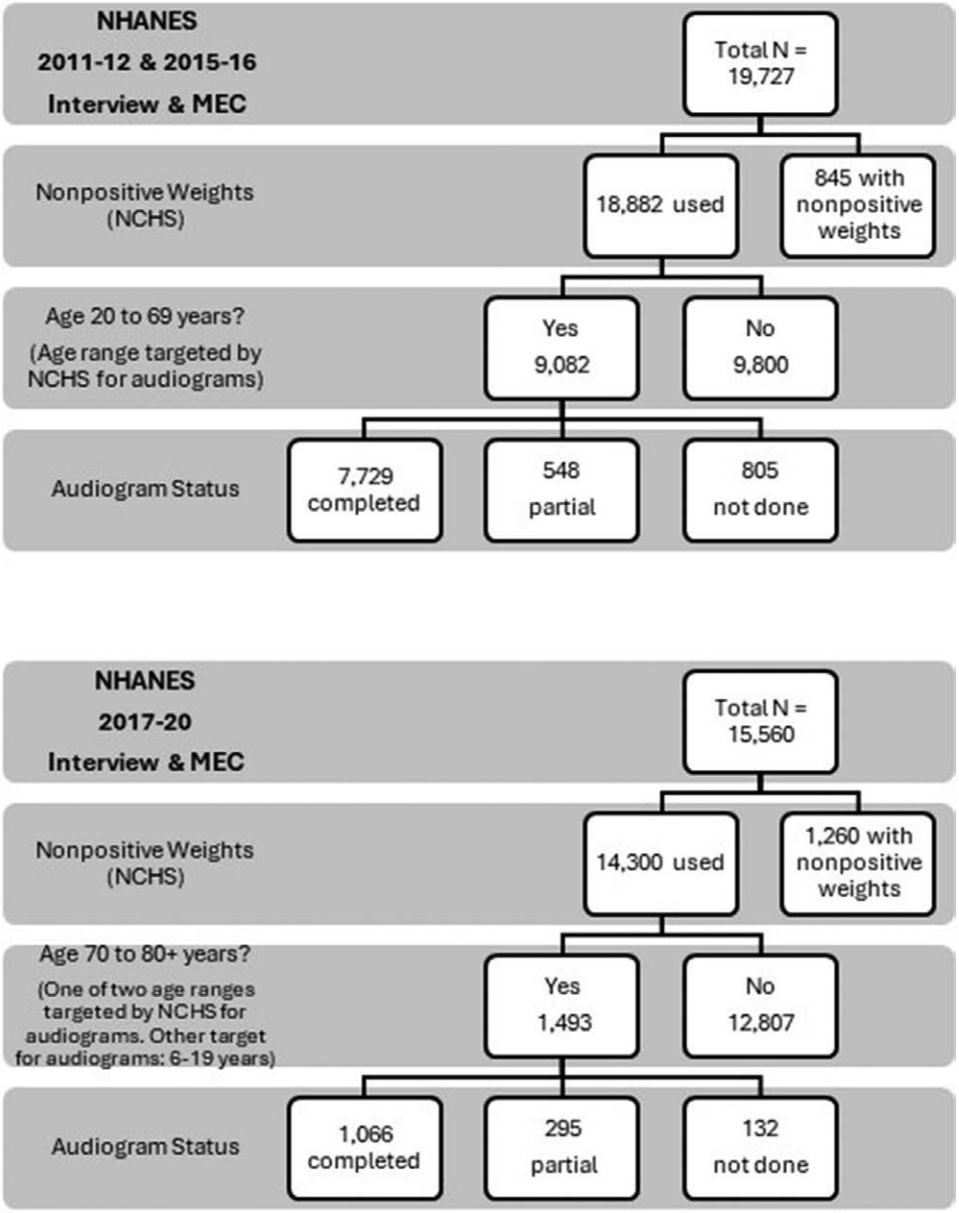

Fig. 1. Flow diagrams showing the culling of data for various analyses for the NHANES 2011 to 2012 and 2015 to 2016 datasets (top) and the NHANES 2017 to 2020 dataset (bottom). MEC indicates mobile examination center; NCHS, National Center for Health Statistics.

audiological measures on 20 to 69-year-olds and NHANES 2017 to 2020 targeted adults 70 to 80+ years of age for audiological measurements (as well as children and adolescents, 6 to 19-year-olds). Aside from "other" reasons noted in NHANES 2011 to 2012 and 2015 to 2016, the most frequent reason for partial completion of an audiogram was a physical limitation of the sample person which was the cited reason for partial completion among 21.2% of the 20 to 69-year-olds and 53.0% of those 70 to 80+ years of age. One of the cases of physical limitation noted in the NHANES procedure manual is the inability of the sample person to independently remove his or her hearing aids before attempting the audiogram. This may explain the much higher prevalence of this reason for partial audiograms among the older age group. Equipment failure and error together represented another 21.8 to 23.2% of the reasons for partial completion of audiograms in both age groups. Regarding reasons that the audiogram was not done at all, the top reason for both age groups was that the survey participant arrived late, left early, or both. As shown in Table 1, when this is combined with "no time," about two-thirds of the time the audiogram was not attempted because of insufficient time for both age groups.

To examine the impact of restricting analyses to only those with completed audiograms, two groups were formed for the 20 to 69-year-olds in NHANES 2011 to 2012 and 2015 to 2016 and for those 70 to 80+ years of age in NHANES 2017 to 2020. One group consisted of those with audiometry designated as "complete" (C) and the other group was designated here as incomplete (I) and was comprised of those whose audiograms were designated "partial" or "not done" in NHANES. Table 2 shows the population-weighted percentages for each of several demographic and audiological variables for each of these groups. The left half of Table 2 includes the percentages for the

TABLE 1. Top reasons for audiograms being designated as either "partial" or "not done" in NHANES surveys

Reason for Partial Completion	NHANES 2011–2012 and 2015–2016 N = 548 % (Unweighted)	NHANES 2017–2020 N = 295 % (Unweighted)
SP physical limitation	21.2	53.0
Equipment failure	12.3	13.7
SP unable to comply	(Not included)	14.4
Error (technician/ software/supply)	10.9	8.1
SP refusal	10.3	4.2
Other	32.9	1.8
Reason Not Done	**NHANES 2011–2012 and 2015–2016 N = 805 % (Unweighted)**	**NHANES 2017–2020 N = 132 % (Unweighted)**
SP came late/left early	64.5	53.8
Child with SP	12.7	(not included)
No time	2.8	12.9
Other	4.0	10.6

Unweighted percentage of time a reason was listed for 20 to 69-yr-olds in NHANES 2011–2012 and 2015–2016 and for those 70–80+ yrs for NHANES 2017–2020. To be listed, at least 10% occurrence in one of the two datasets was required.
SP, survey participant.

20 to 69-year-olds from NHANES 2011 to 2012 and 2015 to 2016 and the right half for those 70 to 80+ years of age from NHANES 2017 to 2020. If there was no overlap of the corresponding 95% confidence intervals (CIs) for the estimated percentages of each of the two groups for a given variable listed in Table 2, these were considered notable differences. Such notable differences between the percentages and CIs of the complete and incomplete groups appear in bold font in Table 2. Overall, among the 32 measures listed in Table 2, few differed notably between the complete-audiogram and incomplete-audiogram groups.

For the 20 to 69-year-olds in the left-hand portion of Table 2, a notably higher percentage of the incomplete group had less than a ninth-grade education and a family income-to-poverty ratio less than 1 compared with the group with complete audiograms. Several of those in the incomplete-audiogram group with partial audiograms had sufficient data to compute four-frequency pure-tone average (PTA4) values for each ear. When doing so, the tendency was for those with partially completed audiograms to have notably higher percentages with audiometric hearing loss (PTA4 ≥20 dB HL) compared with those with completed audiograms. It is important to note, however, that there were no differences between those with completed audiograms and those with incomplete audiograms for self-reported

TABLE 2. Comparison of several variables for those with complete vs. incomplete audiograms in the NHANES 2011–2012 and 2015–2016 dataset (six left columns) and NHANES 2017–2020 (six right columns; age 70–80+ yrs only)

Variable	% C	L95	U95	% I	L95	U95	% C	L95	U95	% I	L95	U95
Male	49.2	48.0	50.4	46.3	43.1	49.6	41.8	38.8	44.8	48.4	39.6	57.2
Race/Ethn, MA	8.9	5.9	11.9	9.7	6.2	13.1	2.8	1.5	4.2	2.9	1.0	4.8
Race/Ethn, OH	6.6	4.6	8.6	8.5	5.0	11.9	4.3	2.2	6.4	8.0	4.5	11.5
Race/Ethn, NHW	64.0	58.1	69.9	58.0	51.8	64.2	78.1	72.6	83.5	70.8	62.5	79.0
Race/Ethn, NHB	11.8	8.5	15.0	12.9	9.0	16.7	7.8	4.9	10.7	9.4	6.0	12.8
Race/Ethn, NHA	5.5	3.9	7.1	7.4	5.0	9.8	4.0	1.9	6.0	5.4	2.4	8.4
Race/Ethn, NHO	3.2	2.7	3.6	3.6	1.4	5.8	3.0	1.5	4.6	3.4	1.2	5.7
Age, 20–29 yrs	21.8	19.5	24.1	18.5	14.6	22.3	—	—	—	—	—	—
Age, 30–39 yrs	19.8	18.1	21.6	21.8	19.1	24.6	—	—	—	—	—	—
Age, 40–49 yrs	20.8	19.1	22.6	20.0	16.5	23.5	—	—	—	—	—	—
Age, 50–59 yrs	21.5	20.0	23.1	21.1	17.0	25.2	—	—	—	—	—	—
Age, 60–69 yrs	16.0	14.6	17.5	18.7	15.5	21.8	—	—	—	—	—	—
Age, 70–79 yrs	—	—	—	—	—	—	**71.9**	**68.2**	**75.6**	**52.7**	**46.2**	**59.2**
Age, 80+ yrs	—	—	—	—	—	—	**28.1**	**24.4**	**31.8**	**47.3**	**40.8**	**53.8**
Educ, <9th Grd	**4.4**	**3.3**	**5.4**	**9.9**	**7.7**	**12.1**	**4.1**	**2.9**	**5.3**	**9.4**	**5.6**	**13.1**
Educ, 9–11th Grd	9.2	7.3	11.0	11.3	8.9	13.7	9.0	6.5	11.5	11.2	7.7	14.6
Educ, HS Grad	19.7	17.9	21.6	19.5	16.1	22.9	32.0	28.4	35.7	25.4	18.0	32.9
Educ, some Coll	33.5	31.2	35.8	28.7	25.3	32.0	27.3	23.5	31.1	26.2	20.8	31.6
Educ, Coll Grad	33.2	29.0	37.4	30.6	25.3	36.0	27.6	22.1	33.1	27.8	21.0	34.7
Diabetes	9.3	8.3	10.4	9.0	6.9	11.2	29.5	25.6	33.3	23.3	18.1	28.5
Hypertension	31.7	30.1	33.3	34.4	30.2	38.5	73.6	70.5	76.7	69.5	62.7	76.2
Smoking	27.1	25.8	28.4	26.4	23.0	29.7	25.0	22.0	27.9	21.0	15.3	26.7
Income, FIPR <1	**15.6**	**13.1**	**18.0**	**24.6**	**21.2**	**28.0**	6.7	4.8	8.7	11.0	6.7	15.2
Income, FIPR 1–2	19.6	17.4	21.8	20.1	16.8	23.5	23.4	19.7	27.1	28.1	20.7	35.5
Income, FIPR 2–3.5	21.6	19.1	24.0	16.3	12.6	20.1	30.2	23.1	37.3	26.2	18.5	33.8
Income, FIPR 3.5–4.99	**17.0**	**14.9**	**19.1**	**11.7**	**8.8**	**14.6**	16.3	11.9	20.8	13.2	7.6	18.8
Income, FIPR = 5	26.2	22.3	30.2	27.2	21.9	32.5	23.3	16.7	30.0	21.5	13.0	30.0
Excellent/good	80.7	79.0	82.4	80.3	76.6	83.9	51.1	45.7	56.6	41.9	35.1	48.6
A little/moderate	17.8	16.3	19.4	17.3	13.7	20.9	40.3	35.7	45.0	46.0	38.3	53.7
A Lot/deaf	1.5	1.0	1.9	2.5	1.3	3.6	8.5	5.8	11.3	12.1	8.2	16.0
PTA4 R ≥20 dB HL	**18.3**	**16.6**	**20.0**	**31.1**	**25.6**	**36.6**	**74.6**	**71.2**	**78.1**	**84.0**	**78.5**	**89.6**
PTA4 L ≥20 dB HL	**20.1**	**18.2**	**21.9**	**31.0**	**24.9**	**37.2**	79.9	76.1	83.7	84.1	77.9	90.3

All values shown are population-weighted percentages. Percentages in bold font indicate non-overlapping 95% confidence intervals for the estimated percentages of the groups with complete vs. incomplete audiograms.
C, complete-audiogram group; Coll, college; dB HL, decibels hearing level; Educ, education level; Ethn, ethnicity; FIPR, family income-to-poverty ratio; Grad, graduate; Grd, grade; I, incomplete-audiogram group ("partial" and "not done" combined); L, left ear; L95 and U95, lower and upper 95% confidence intervals for percentage estimates; MA, Mexican American; NHA, non-Hispanic Asian; NHB, non-Hispanic Black; NHO, non-Hispanic other; NHW, non-Hispanic White; OH, other Hispanic; PTA4, four-frequency pure-tone average; R, right ear.

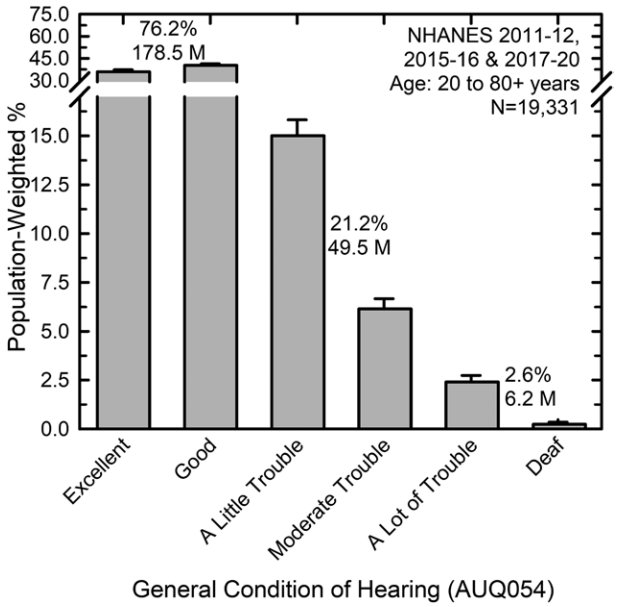

Fig. 2. Population-weighted percentages of each response to the NHANES question about general condition of hearing (AUQ054) for 19,331 adults 20 to 80+ yrs of age. Error bars are 95% confidence intervals of the percentage estimates. M indicates million; NCHS, National Center for Health Statistics.

hearing trouble with similar percentages of each group reporting excellent or good hearing, a little or moderate trouble, or a lot of trouble or deafness.

For those 70 to 80+ years of age in NHANES 2017 to 2020, shown in the right-hand portion of Table 2, there were fewer notable differences between the complete-audiogram and incomplete-audiogram groups. A higher percentage of the incomplete-audiogram group was in their 80s and had less than a ninth-grade education compared with the complete-audiogram group. In addition, a higher percentage of the incomplete-audiogram group had audiometric hearing loss (PTA4 ≥20 dB HL) in the right ear compared with those with completed audiograms in this same age group. Again, it is important to note that there were no notable differences between these two groups in the percentages for each severity of self-reported hearing difficulty.

All told, for both age groups, there were relatively few differences observed between those with complete or incomplete audiograms, whether partial or not done. As a result, those with complete audiograms are considered representative of the entire sample.

The surveys used in NHANES and NHIS were approved by the National Center for Health Statistics Institutional Review Board, and all participants provided written consent. For NHANES, the audiometry examination was conducted by trained health technicians and included otoscopy, tympanometry, and air-conduction pure-tone audiometry. As noted, the entire NHANES and NHIS protocols, including the survey instruments and data-coding procedures, and the complete datasets are publicly available online.

Statistical Analyses

All prevalence estimates, percentiles, and statistical analyses were performed in accordance with National Health and Nutrition Examination Survey: Analytic Guidelines, 2011–2014 and 2015–2016 published online on December 14, 2018, by the NCHS and National Health and Nutrition Examination Survey, 2017–March 2020 Prepandemic File: Sample Design, Estimation, and Analytic Guidelines (Akinbami et al. 2022). Statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC). This included the use of masked strata and cluster variables for the design and the use of the adjusted sample weights provided for each participant by the NCHS. In addition, as recommended by the NCHS, the lowest common denominator guided the choice of which set of sample weights to use and, given the focus on audiometric data attained in the MEC, the MEC sample weights were used here. The use of sample weights may be important both for measures of central tendency and variability.

For all analyses, the full dataset was included with restrictions to subgroups accomplished via domain or table specifications in the SAS analyses. Variance estimation used the recommended Taylor-series linearization method. All prevalence estimates in this report meet the NCHS standard of reliability (relative SE less than or equal to 30%). Population-weighted percentiles and corresponding 95% CIs for the percentiles were those generated by SAS 9.4 based on SEs estimated by linear interpolation of a normal distribution [i.e., standard error = $((p \times q)/N)^{1/2}$, where p is the proportion of interest, 0.5 for the median, and $q = 1 - p$, also 0.5 for the case of the median, and N is the number of cases].

Distribution-free medians represent the primary measure of central tendency used in the descriptive analyses of audiometric and tympanometric data. In all population-weighted analyses, missing data for variables included in each analysis were treated as not missing completely at random in the SAS analyses, as recommended by the NCHS.

RESULTS AND DISCUSSION

Demographic Characteristics of OTC Hearing-Aid Candidates

The prevalence of each response to the NHANES question about the general condition of hearing, AUQ054, is shown in Figure 2 for 19,331 sample persons (6 had missing data). As noted, these responses were used to form three groups: excellent or good hearing, a little or moderate trouble hearing, and a lot of trouble hearing or deaf. The population-weighted prevalence of each of these three groups is also shown in Figure 2 along with the estimated number of US adults in each group. Those adults with a little or moderate trouble hearing represent the group targeted by the FDA for OTC hearing aids. This group constitutes 21.2% (95% CI: 20.0 to 22.3%) of US adults 20 to 80+ years of age, or an estimated 49.5 million individuals. Clearly, there are many more adults with self-reported excellent or good hearing, 76.2% (95% CI: 75.0 to 77.4%) or 178.5 million, as expected, but the group targeted for OTC hearing aids is nonetheless quite substantial.

Figure 3 summarizes the demographic characteristics of those in each of the three groups differing in degree of self-reported trouble hearing for the 19,331 with complete data in NHANES 2011 to 2012, 2015 to 2016, and NHANES 2017 to 2020. Despite some minor differences in questions or responses in some cases, the pattern of results across datasets is very similar. Focusing first on the data for all those with a little or

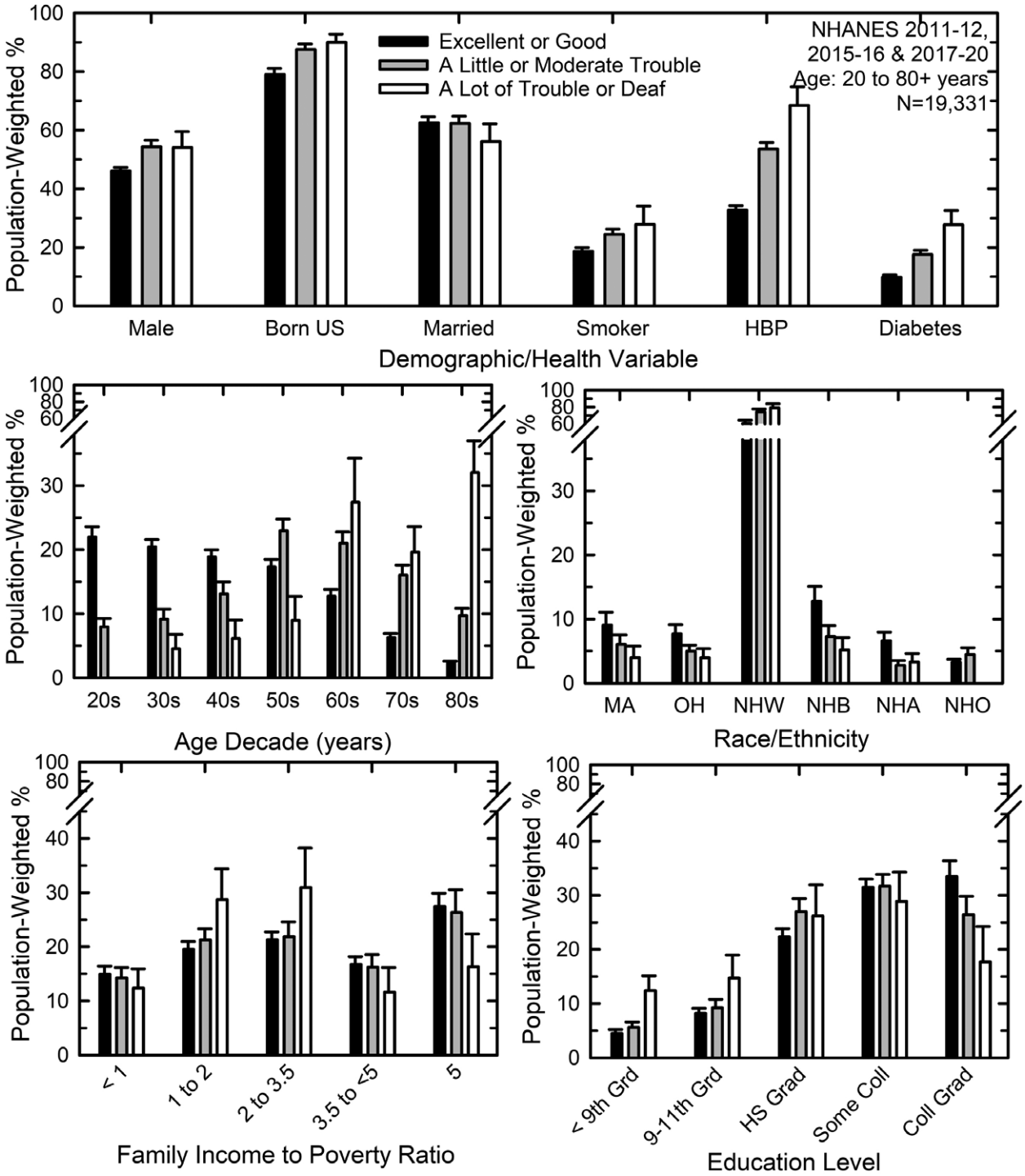

Fig. 3. Population-weighted percentages for the responses of 19,331 sample persons to various demographic questions for each of three groups derived from their self-reported hearing trouble: excellent or good (black bars); a little or moderate trouble hearing (gray bars); and a lot of trouble hearing or deaf (white bars). Coll indicates college; Grad, graduate; Grd, grade; HBP, high blood pressure; HS, high school; MA, Mexican American; NHA, non-Hispanic Asian; NHB, non-Hispanic Black; NHO, non-Hispanic other; NHW, non-Hispanic White; OH, other Hispanic.

moderate hearing trouble (gray bars), about 55% of the targeted OTC hearing-aid candidates were male, about 88% were born in the United States, and about 64% were married or living with a partner. This intermediate group, moreover, was similar either to those with better self-reported hearing (% married) or to those with more hearing trouble (% males, % born in the United States). The three right-most variables in the top panel of Figure 3 show the prevalence of several general-health risk factors for hearing loss for each of the three groups. The percentages of those with a little or moderate hearing trouble who are smokers, have high blood pressure, or have diabetes typically fall midway between those with either less or more self-reported hearing trouble. This is consistent with risk factors for hearing trouble identified via binary logistic-regression

analyses in these same NHANES datasets (Humes 2023a) or from the NHIS (Humes 2023b).

The left-middle panel in Figure 3 shows the age distribution for potential OTC hearing-aid candidates. Results are shown in age decades, but it should be recalled that the oldest decade included those with top-coded ages such that 80 was the highest age entered for the NHANES datasets. For the NHANES datasets, the median age for the 80+ group was 85 years as reported by the NCHS. Focusing on the data for all participants with mild-to-moderate hearing trouble first (gray bars), about 40 to 45% of OTC hearing-aid candidates ranged in age from 50 to 69 years. Another 15% or so of those with little or moderate hearing trouble were found in each of the adjacent age decades (40 to 49 and 70 to 79 years), slightly more 70 to 79-year-olds than 40 to 49-year-olds. As a result, about three-fourths of OTC hearing-aid candidates are 40 to 79 years old. As expected, compared with those with a little or moderate trouble hearing, the distributions of those with excellent or good hearing (black bars) is shifted toward younger ages and toward older ages for those who consider themselves to have a lot of hearing trouble or to be deaf (white bars).

Regarding the race/ethnicity of those with a little or moderate hearing trouble (middle-right panels), about 80% of OTC hearing-aid candidates were non-Hispanic White adults with non-Hispanic Blacks comprising the next most prevalent race/ethnicity at a much lower prevalence of about 7%. Generally, the percentages of non-Hispanic Whites increased slightly as the degree of self-reported hearing difficulty increased which was also reflected in an opposite pattern for all other race/ethnicities. Overall, there were small differences in the racial/ethnic composition of each of the three perceived hearing trouble groups with each being predominantly non-Hispanic White.

The population-weighted prevalence estimates for each education level are shown in the lower-right panel of Figure 3. These results indicate that about 85% of prospective OTC hearing-aid candidates had at least a high-school diploma or equivalent with about 27% having a college degree. Among those who considered themselves to have a lot of hearing trouble or to be deaf (white bars), higher percentages had less than a high-school education compared with the other two groups.

The lower-left panel of Figure 3 presents information about annual family income. When the NCHS released the data for the NHANES 2017 to 2020 dataset, income information was presented only as family income relative to the Federal poverty income level, the family income-to-poverty ratio, with poverty threshold established each year based on the size of the family and the number of related children under age 18 in the family. Ratios <1 indicate that the family is below the poverty level in the United States for that year. Because this was the only income metric available in NHANES 2017 to 2020, it was also used for the earlier NHANES datasets included in these analyses. The lower-left panel of Figure 1 indicates that about 15% of prospective OTC hearing-aid candidates (gray bars) were below the Federal poverty level with another 26 to 27% at the other extreme; having annual family income that was five times greater than the poverty level. For the NHANES 2011 to 2012 and 2015 to 2016 datasets, however, annual family income in US$ was provided in addition to the income-to-poverty ratios. For these two datasets, 17.9% (95% CI: 15.4 to 19.9%) had annual family incomes <$20,000, 32.4% (95% CI: 24.8 to 40.0%) had annual family incomes of $75,000 or more, and the remainder, about half, fell between these two extremes. The distribution of annual family income for those with excellent or good hearing was not notably different from the data for those with a little or moderate trouble. Too few data were available to generate reliable estimates of annual income in NHANES 2011 to 2012 and 2015 to 2016 for those who had a lot of trouble or considered themselves to be deaf.

Last, prior active-duty military service was another demographic variable included in the two earlier NHANES datasets but not in NHANES 2017 to 2020. When analyzed for NHANES 2011 to 2012 and 2015 to 2016 combined, 13.4% (95% CI: 10.4 to 16.5%) of those with a little or moderate trouble hearing had previously served in the military. This percentage was not notably different for those who had a lot of trouble hearing or considered themselves to be deaf. A notably smaller percentage, 5.8% (95% CI: 4.8 to 6.9%), of those with excellent or good self-reported hearing had served in the military.

Audiological Characteristics of OTC Hearing-Aid Candidates

Self-Report Measures • As noted, by design, about half of those who completed the MEC interview and examination for NHANES have audiological assessments. Further, whereas the interviews cover a wide range of ages for adults from 20 to 80+ years, the audiological information from the MEC interview and exam is constrained to the 20 to 69-year-old age range in NHANES 2011 to 2012 and 2015 to 2016 and to an age range of 70 to 80+ years in NHANES 2017 to 2020.

Figures 4 and 5 summarize the responses to several interview questions for participants aged 20 to 69 years in NHANES 2011 to 2012 and 2015 to 2016 (Fig. 4) and those aged 70 to 80+ years in NHANES 2017 to 2020 (Fig. 5). The top panel in each of these figures summarizes information from the MEC interview pertaining to the presence of tinnitus during the past year, ever having more than two ear infections, and ever having tubes inserted in the ears. For each of these questions regarding otologic history, those with excellent or good hearing have the lowest prevalence. Those with a little or moderate hearing trouble have a notably higher prevalence than those with self-reported excellent or good hearing which, in turn, is either lower than (Fig. 4) or the same as (Fig. 5) that observed among those with at least a lot of trouble hearing. Generally, all the prevalence estimates for these questions about otologic history are lower in the top panel of Figure 5 for 20 to 69-year-olds compared with that of Figure 4 for those 70 years of age and older. This could reflect cohort differences in treatment and identification of ear infections at younger ages or, if in fact, these were childhood experiences, could reflect age-related differences in recall of those early otologic events.

The middle-left panel of Figures 4 and 5 shows the number of years passed since the participant's last hearing test. "Hearing test" was defined in NHANES very generally as a test "…that is done in a sound-proof booth or room, or with headphones [and may be given by] audiologists, ear nose and throat doctors, and trained technicians or occupational nurses." For those with self-reported excellent or good hearing, it has been 5 or more years since the last hearing test for about 80% of all adults 20 to 80+ years of age. For those with a little or moderate hearing trouble, it has been 5 or more years since the last hearing test for about 69% of 20 to 69-year-olds (Fig. 4)

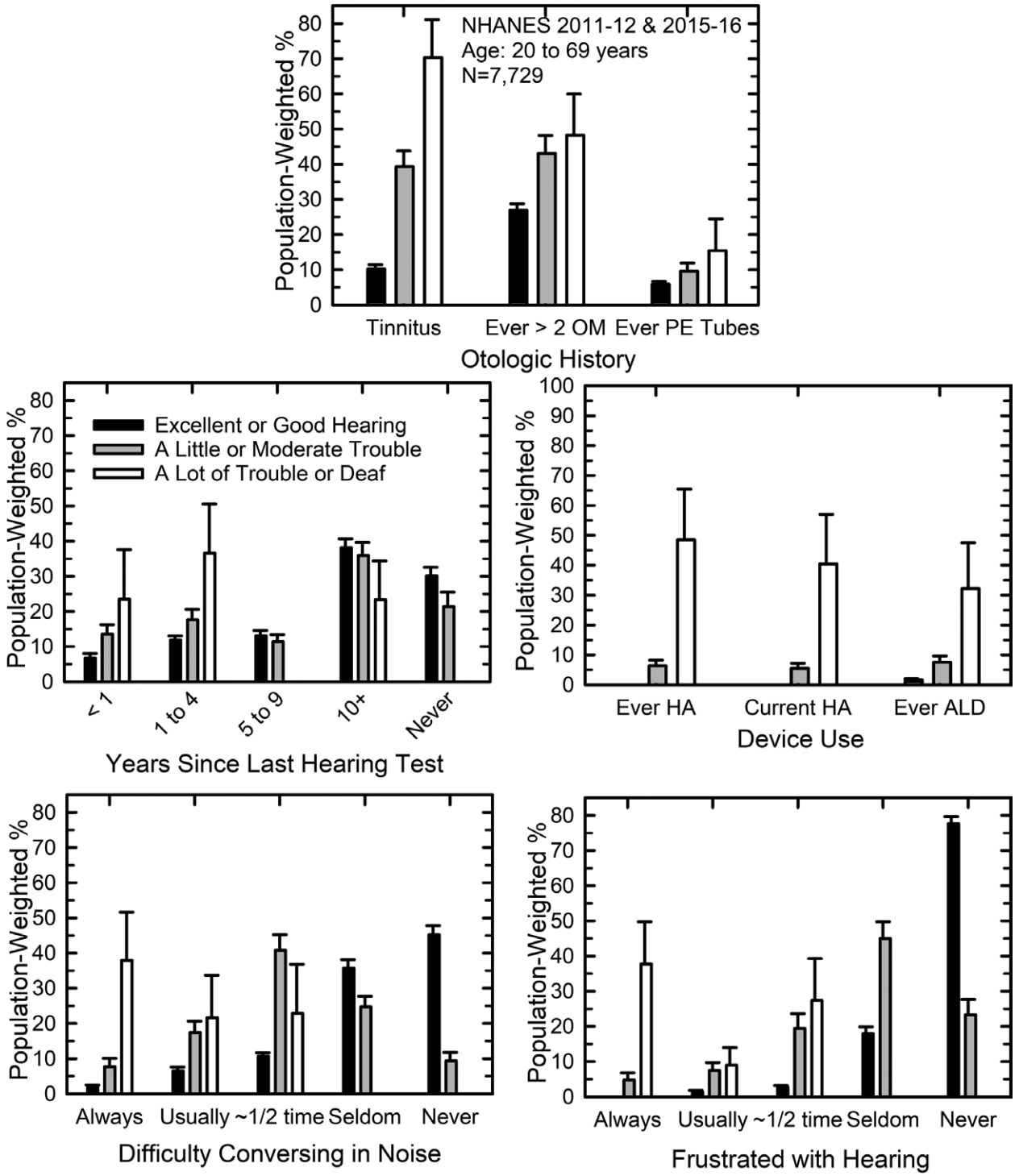

Fig. 4. Population-weighted responses of those with excellent or good self-reported hearing, a little or trouble hearing, and a lot of trouble or deaf for 7729 adults 20 to 69 yrs of age in the NHANES 2011 to 2012 and 2015 to 2016. ALD indicates assistive listening device; HA, hearing aid; NHANES, National Health and Nutrition Examination Survey; OM, otitis media ("ear infections"); PE, pressure-equalization.

and for about 53% of those 70 to 80+ years of age (Fig. 5). The latter data for potential hearing-aid candidates compare favorably to those from Nash et al. (2013) and Zelaya et al. (2015), both finding over 50% had not had a hearing test in the past 5 years, although those data were for all those with any trouble hearing (all those with at least a little trouble hearing). Despite reporting a little or moderate trouble hearing, regardless of age group, 50 to 70% of potential OTC hearing-aid candidates had not had a hearing test from a specialist in the past 5 years. Obtaining a hearing test can be considered the key to access hearing healthcare in the prevailing healthcare system and it has been adopted as such for consumers in general, including those interested in OTC hearing aids (American National Standards Institute 2023). As a result, failure to obtain

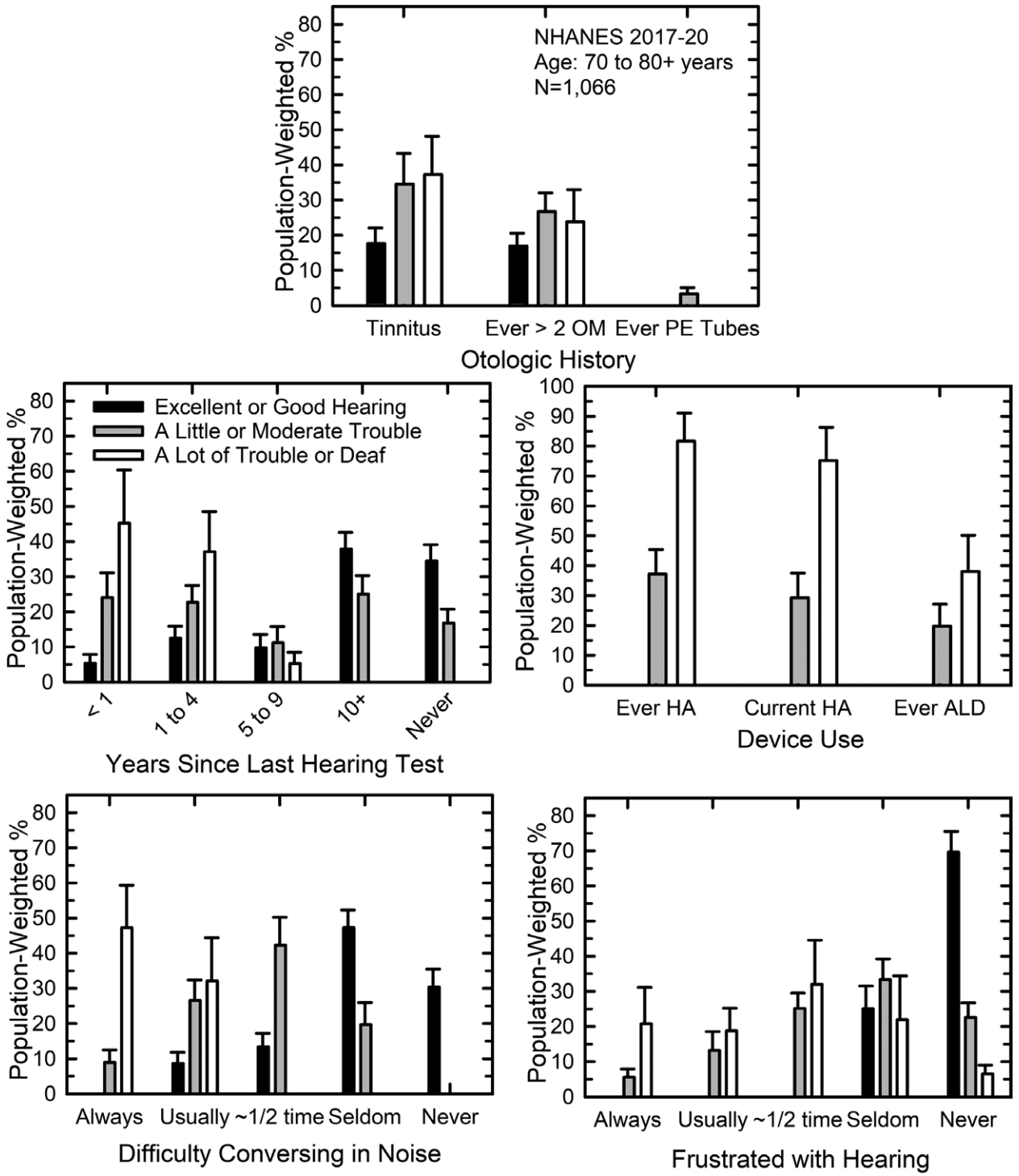

Fig. 5. Population-weighted responses of those with excellent or good self-reported hearing, a little or trouble hearing, and a lot of trouble or deaf for 1066 adults 70 to 80+ yrs of age in the 2017 to 2020 NHANES dataset. ALD indicates assistive listening device; HA, hearing aid; NHANES, National Health and Nutrition Examination Survey; OM, otitis media ("ear infections"); PE, pressure-equalization.

a hearing test may deny many with perceived hearing trouble access to hearing healthcare.

The data in the middle-right panel in Figures 4 and 5 show the prevalence of hearing-device use for the NHANES datasets and may offer support for the assumed limited access to hearing healthcare in the prevailing healthcare system. This panel shows the prevalence of current hearing aid use, ever using hearing aids, and ever using assistive listening devices. These data are for those using what would be considered today by the FDA to be "prescription hearing aids." For all NHANES datasets and each of the three device categories, the prevalence estimates for those with excellent or good hearing were too low to be estimated reliably (except for ever using assistive listening devices in Fig. 4). For those with a little or

moderate trouble hearing, about 5% of 20 to 69-year-olds had used hearing devices (Fig. 4) whereas this was 20 to 35% of those 70 to 80+ years of age (Fig. 5). When the middle-right panel of Figure 4 is compared with that of Figure 5 the effect of age on hearing-device uptake is striking. Despite having the same perceived hearing trouble, four to five times as many adults 70 to 80+ years of age have used hearing devices compared to adults 20 to 69 years of age. This could again be a cohort difference sampling adults from different generations. It could, however, also be interpreted in the context of an "ageism" stigma associated with hearing aid use (Erler & Garstecki 2002; Wallhagen 2010). In this case, it is hypothesized that younger adults with a little or moderate hearing trouble do not wish to appear old by wearing hearing aids whereas older adults are already old and may care less about appearing old. Stigma may prove to be an important consideration for the adoption of OTC hearing aids by those 20 to 69 years of age who have a little or moderate hearing trouble. Last, the other clear effect observed in the middle-right panels of Figures 4 and 5 is that the uptake of hearing devices by those with a lot of hearing trouble or who consider themselves to be deaf is much greater than that for those with better self-reported hearing. Note, however, that this is still just 30 to 50% of 20 to 69-year-olds (Fig. 4) and about 40 to 80% of those 70 to 80+ years of age (Fig. 5) among those with at least a lot of trouble hearing. Many of these individuals have unmet hearing healthcare needs (Nash et al. 2013; Humes 2023a, b).

The bottom two panels of Figures 4 and 5 show the participants' responses to two separate queries about how often the respondent had difficulty following a conversation with noise (other speech) in the background and how often the respondent's hearing caused frustration when talking to family or friends. For conversing in noise, shown in the lower-left panel of Figures 4 and 5, the distribution of responses for those with a little or moderate hearing trouble (gray bars) is centered at "about half the time" whereas the response distribution is shifted more toward "seldom" or "never" for those with excellent or good hearing (black bars) and toward "always" for those with more severe self-reported trouble hearing (white bars). Overall, in both Figures 4 and 5, about 66 to 78% of those with a little or moderate trouble hearing indicated that they had trouble conversing in noise at least half the time. For those with excellent or good hearing, the results in Figures 4 and 5 show that the percentage of those having trouble conversing in noise was 19 to 22% whereas it was 82 to 94% among those with more severe self-reported hearing trouble.

For frustration with hearing difficulty, the lower-right panel in Figures 4 and 5, the response distributions are broad with slightly more responses of "seldom" for those with a little or moderate trouble hearing. The vast majority of those with excellent or good hearing, 70 to 80%, report never feeling frustrated with hearing problems whereas about half of those with a lot of trouble hearing or who consider themselves deaf reported being usually or always frustrated with their hearing. For those with a little or moderate trouble hearing, the presumed OTC hearing-aid candidates, 32 to 44% were frustrated with their hearing at least half the time. Frustration is an emotional reaction to the hearing difficulty and represents a more significant concern regarding negative impact of this difficulty on the individual's emotional wellness and overall well-being (Caputo & Simon 2013; Freedman et al. 2017).

Responses to several questions about noise exposure from NHANES 2011 to 2012 and 2015 to 2016 for adults 20 to 69-year-old and from 2017 to 2020 for adults 70 to 80+ years of age are presented in Figures 6 and 7. Generally, the relative distributions of responses in each panel of Figure 6 are similar to those in Figure 7, although more 20 to 69-year-olds reported exposure to very loud work noise and off-work exposure to very loud noise than those who were 70 to 80+ years of age (top left panel of Figs. 6 and 7). Examples given for the off-work exposures included "power tools, lawn mowers, farm machinery, cars, trucks, motorcycles, motorboats, or loud music." For those who ever used firearms, the distribution of responses to the number of rounds fired in one's lifetime (top right panels) is similar in Figures 6 and 7, with about 30 to 50% indicating fewer than 100 rounds had ever been fired. The distributions of exposure durations for those exposed to loud work noise (middle-left panels) or to very loud work noise (middle-right panels) indicate that, for those exposed to such noise at work, 40 to 60% worked in such noise for 15 or more years. It is important to note that only those who indicated that they had been exposed to loud noise at work were then asked whether they had been exposed to very loud noise (and, if so, for how long). Overall, although fewer adults 70 to 80+ years of age reported ever working in loud or very loud work noise compared with adults 20 to 69-year of age (top left panels of Figs. 6 and 7), when the older group worked in such noise, a higher percentage worked in that noise for 15 or more years compared with adults aged 20 to 69 years (middle panels of Figs. 6 and 7). Focusing on those with a little or moderate trouble in the middle panels Figures 6 and 7, about 50 to 65% had been exposed to loud noise at work for 10 or more years.

The bottom two panels of Figures 6 and 7 show responses to questions about the use of hearing-protection devices when using firearms (bottom left panels) or in very loud noise, at work and off-work, over the past 12 months (bottom right panels). In the latter case, the not-applicable responses indicate that the person had not been in such noise over the past 12 months, and this was the case about 20 to 30% of the time. About 50 to 60% of those 20 to 69-year of age reported using hearing-protection devices less than half the time whereas this was about 65 to 75% for those 70 to 80+ years of age. These percentages did not vary appreciably with the level of self-reported hearing difficulty.

There were slight differences in the wording of the questions, including the definitions of "loud" and "very loud" noise exposures, across the NHANES surveys examined here. Generally, loud noise was tied to the need to speak "in a raised voice to be heard" but this was qualified by adding "by someone three feet away when not using hearing protection" in NHANES 2015 to 2016 only. Those who responded affirmatively about exposure to "loud" noise were then asked about exposure to "very loud" noise with "very loud" noise defined as "so loud you have to shout to be understood by someone standing 3 feet away from you." NHANES 2015 to 2016 again added "without the use of hearing protection." Humes and Moore (2022) found that these wording differences did not significantly alter the response distributions when the data for NHANES 2011 to 2012 were compared with those from NHANES 2015 to 2016.

It is generally the case that, for a speaker-listener distance of 3 feet, a noise level of 80 to 85 dBA requires a raised voice to communicate whereas the need to shout typically does not arise until noise levels approximate 90 dBA (Miller 1974; Robinson & Casali 2000; Ahmed et al. 2004; Neitzel et al. 2009). Self-report

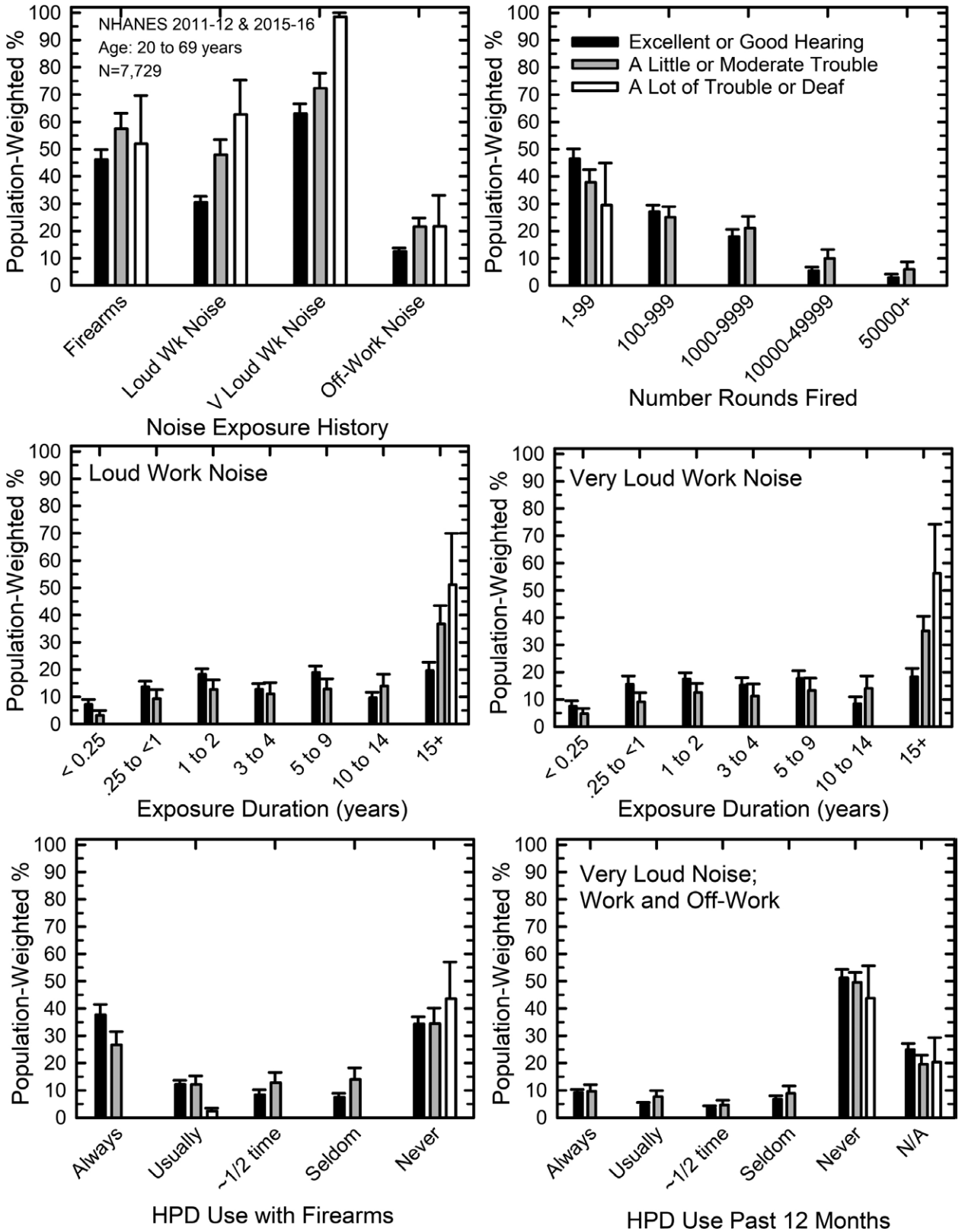

Fig. 6. Population-weighted responses of the three groups with varying degrees of hearing trouble for 7729 adults 20 to 69 yrs of age in the NHANES 2011 to 2012 and 2015 to 2016. HPD indicates hearing-protection device; NHANES, National Health and Nutrition Examination Survey; V, very; Wk, work.

ratings of noise levels using raised or shouted speech compare favorably to those measured acoustically (Neitzel et al. 2009; Schlaefer et al. 2009). The combinations of noise exposures, together with the general lack of use of HPDs, suggests that many prospective OTC hearing aid candidates have experienced noise exposures that put their hearing at risk.

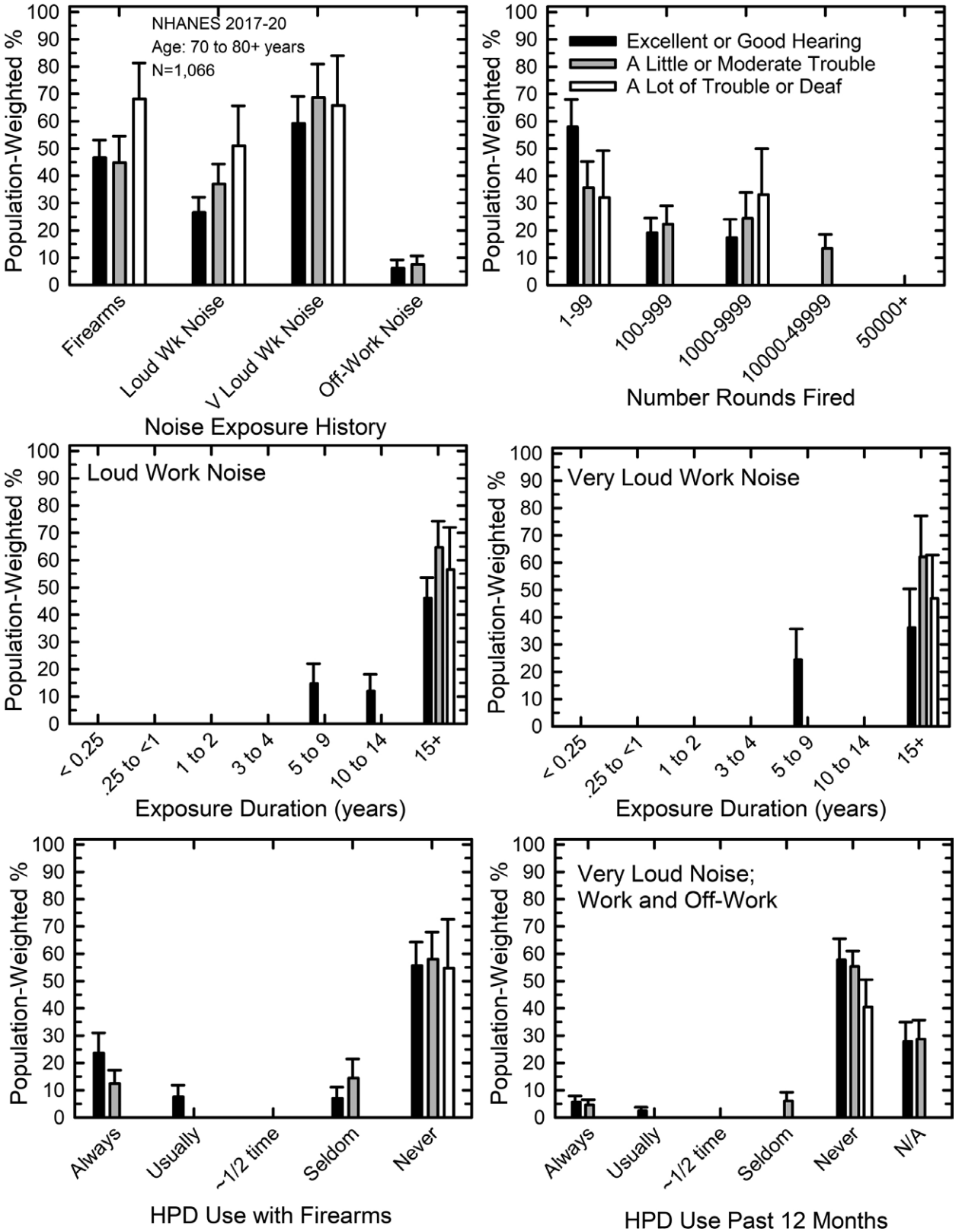

Fig. 7. Population-weighted responses of the three groups with varying degrees of hearing trouble for 1066 adults 70 to 80+ yrs of age in the NHANES 2017 to 2020. HPD indicates hearing-protection device; NHANES, National Health and Nutrition Examination Survey; V, very; Wk, work.

Audiometric and Tympanometric Measures • Figure 8 shows the median audiograms for those adults with self-reported excellent or good hearing (top), a little or moderate trouble hearing (middle), and a lot of trouble hearing or deaf (bottom), for 20 to 69-year-olds from NHANES 2011 to 2012 and 2015 to 2016 (left panels) and ages 70 to 80+ years from

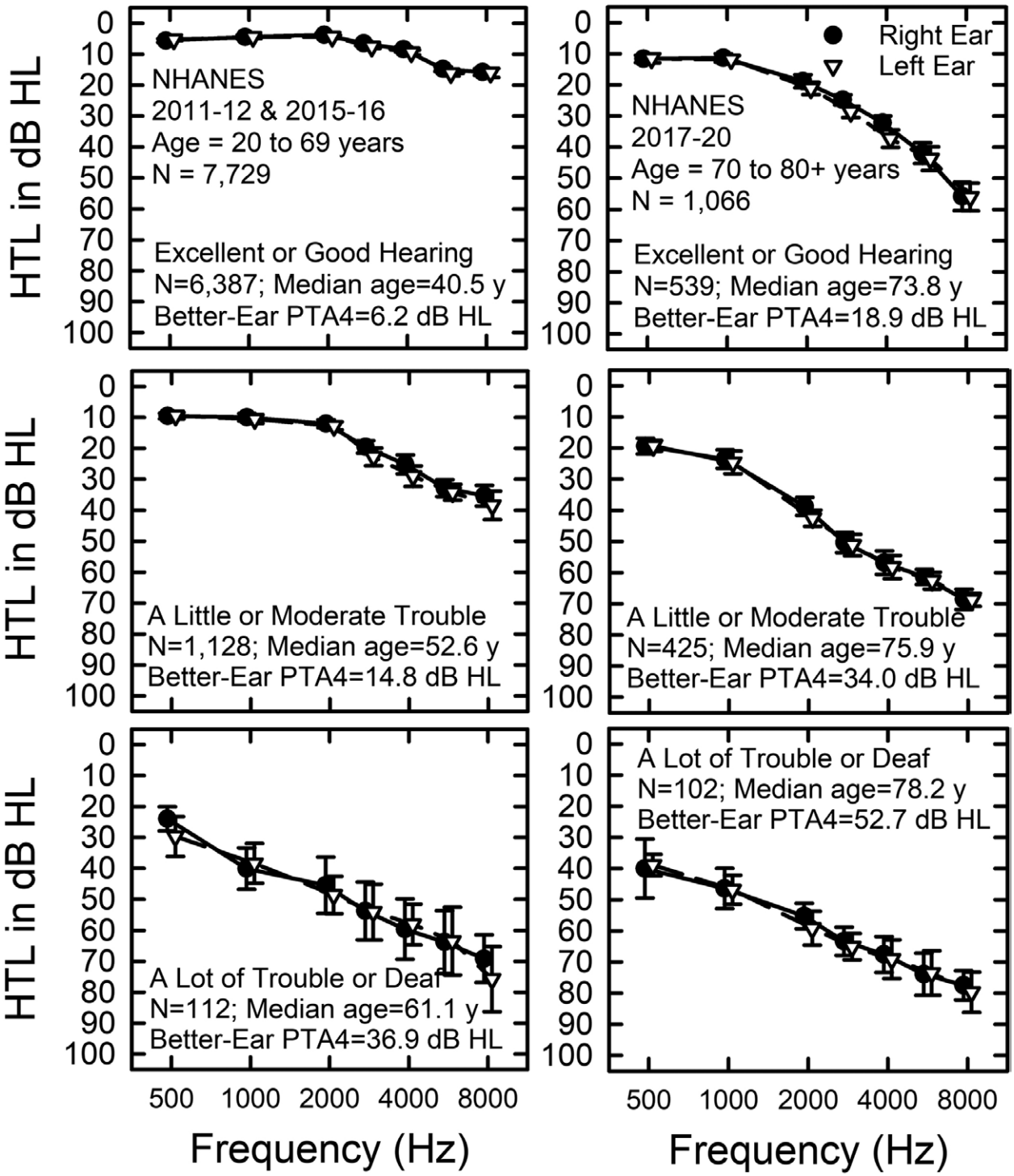

Fig. 8. Population-weighted medians and 95% confidence intervals (error bars) for the HTLs in dB HL for the right (circles) and left (triangles) ears. Data for the 20 to 69-yr-old adults in NHANES 2011 to 2012 and 2015 to 2016 appear in the left column and for the adults 70 to 80+ yrs of age in NHANES 2017 to 2020 in the right column. The top panels show the audiograms for all those with excellent or good self-reported hearing, the middle panels for those with a little or moderate hearing trouble, and the bottom panels for those with a lot of trouble hearing or deaf. The sample sizes (Ns), median ages, and median PTA4s for the subgroups in each panel are also provided. dB HL indicates decibels hearing level; HTLs, hearing threshold levels; NHANES, National Health and Nutrition Examination Survey; PTA4s, four-frequency pure-tone averages; y, years.

NHANES 2017 to 2020 (right panels). The median thresholds shown were not adjusted for the midpoint convention as has sometimes been suggested (Dobie 2006; Hoffman et al. 2010). Many statistical software packages, including SAS 9.4 used here, generate medians by default that correspond to an upper limit of the interval containing the value for which 50% of the ranked cases fall below this value. HTLs in NHANES were established, however, using 5-dB step sizes and finer 1-dB

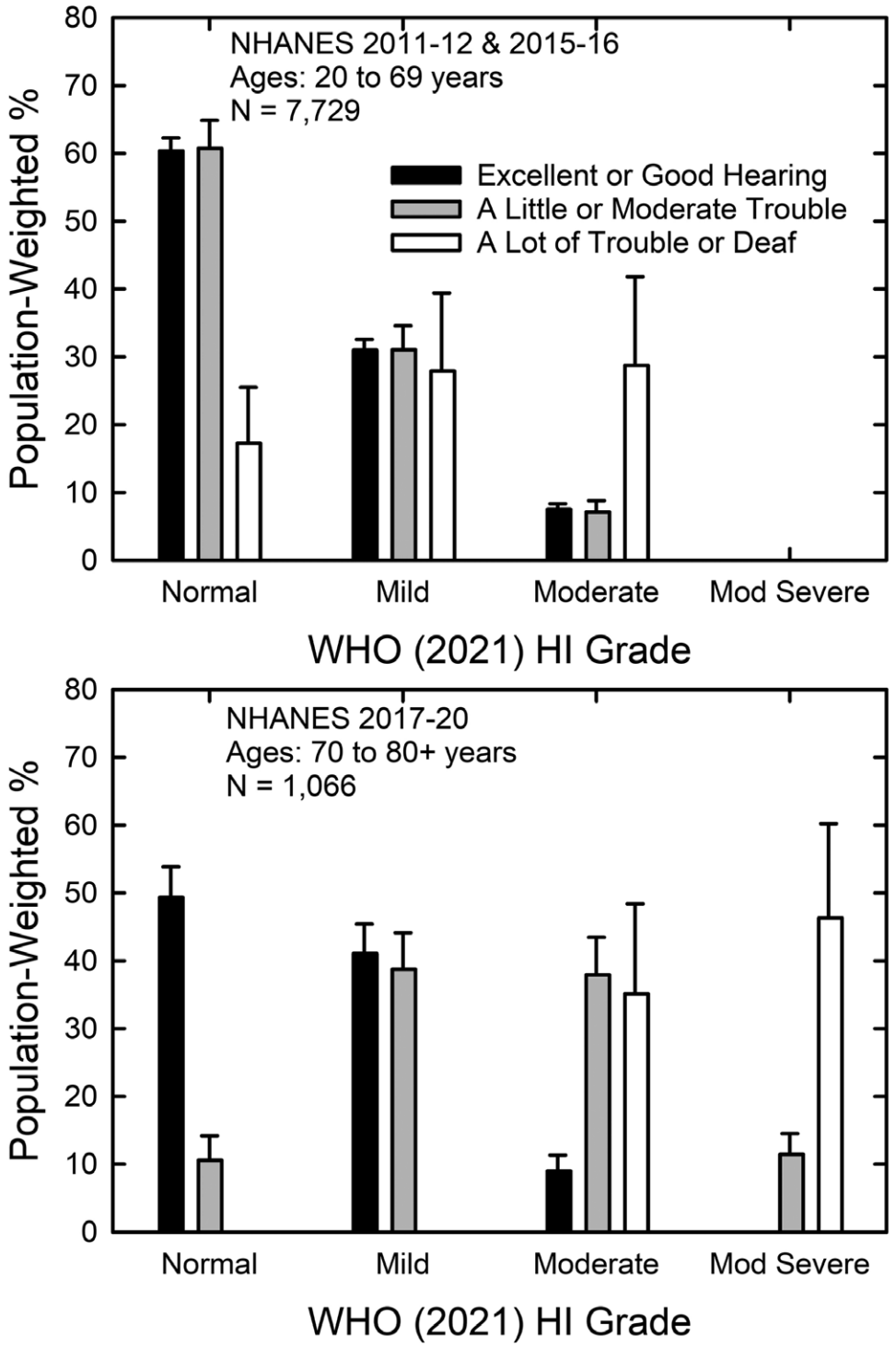

Fig. 9. Population-weighted distributions of WHO HI grades for the 7729 20 to 69-yr-olds in NHANES 2011 to 2012 and 2015 to 2016 (top) and those 1066 sample persons 70 to 80+ yrs of age in NHANES 2017 to 2020 (bottom). Results are shown for those with excellent or good self-reported hearing (black bars), a little or moderate trouble hearing (gray bars) and a lot of trouble or def (white bars). Error bars represent 95% confidence intervals for each population-weighted prevalence estimate. HI indicates hearing-impairment; NHANES, National Health and Nutrition Examination Survey; WHO, World Health Organization.

steps may better represent the underlying distribution of HTLs in the population and generate a more appropriate estimate of the median than the default upper-limit approach. Dobie (2006) and Hoffman et al. (2010) demonstrated that the conventional upper-limit medians provided by default in many statistical software packages can be adjusted by adding half the step size, or 2.5 dB, to the default upper-limit medians. As a result, midpoint adjusted median HTLs could be established for the audiograms in Figure 8 by adding 2.5 dB to all values.

All the audiograms in Figure 8 depict bilaterally symmetrical sloping hearing loss, configurations commonly observed in aging. For both age groups, those with a little or moderate

TABLE 3. Population-weighted estimates for several audiological measures from NHANES 2011–2012 and 2015–2016 (NH 1112–1516) or NHANES 2017–2020 (NH 1720) for the left and right ears of those with a little or moderate hearing trouble

		NH 1112–1516	NH 1112–1516	NH 1112–1516	NH 1720	NH 1720	NH 1720
Ear	Measure	Median	SE	N	Median	SE	N
Left	PTA4	18.08	0.96	1187	38.68	1.10	398
	TPP	–4.93	0.99	1123	–9.35	1.39	370
	V_{ec}+	1.40	0.02	1187	1.25	0.04	397
	TTW+	83.06	1.45	1123	82.10	2.75	372
	Y_{tm}+	0.70	0.02	1170	0.56	0.03	373
Right	PTA4	17.73	0.77	1187	36.69	0.98	398
	TPP	–5.19	0.60	1123	–8.04	1.27	373
	V_{ec}+	1.44	0.02	1187	1.28	0.04	396
	TTW+	79.77	1.48	1127	80.61	2.96	373
	Y_{tm}+	0.70	0.01	1172	0.60	0.04	372

The + demarcation for the immittance measures denotes the use of a +200 daPa reference pressure at measurement onset.
N, number of adults; PTA4, pure-tone average in dB Hearing Level for 500, 1000, 2000, and 4000 Hz; TPP, tympanic peak pressure in dekaPascals (daPa); TTW+, tympanometric width in daPa; V_{ec}+, equivalent ear-canal volume in cm^3; Y_{tm}+, peak-compensated static admittance in mmho.

hearing trouble (middle panels) have more audiometric hearing loss than those with self-reported excellent or good hearing (top panels) and less audiometric hearing loss than those with more severe hearing difficulty (bottom panels). Comparing across age groups, the biggest differences are clearly for those with excellent or good hearing (top panels) or a little to moderate trouble hearing (middle panels). In both cases, the younger group (left) manifests less high-frequency hearing loss compared with the older group (right) with the same perceived hearing difficulty. The results for the NHANES 2011 to 2012 and 2015 to 2016 closely parallel those published recently by de Gruy et al. (2023) for the same datasets. The focus of the analyses by de Gruy et al. was on the mapping of a little trouble hearing and moderate trouble hearing to audiometric test results, especially various pure-tone averages. By including the data from NHANES 2017 to 2020 for those aged 70 to 80+ years in the present analyses, it is apparent that the mapping of perceived hearing trouble to audiometric hearing loss varies with age. As shown in the middle panels of Figure 8, those 70 to 80+ years of age with a little or moderate hearing trouble have more underlying audiometric hearing loss than those 20 to 69 years of age with equivalent perceived hearing trouble. This is also the case for those with self-reported excellent or good hearing (top panels).

This is reflected as well in Figure 9 which depicts the prevalence of the World Health Organization's (2021) hearing-impairment grades for each of the three groups differing in perceived hearing trouble. The WHO hearing-impairment grade is based on the better-ear pure-tone average for 500, 1000, 2000, and 4000 Hz (PTA4). The top panel of Figure 9 shows the results from NHANES 2011 to 2012 and 2015 to 2016 for 7729 adults 20 to 69-year of age and the bottom panel from NHANES 2017 to 2020 for 1066 adults ranging in age from 70 to 80+ years. Whereas 60% of those with a little or moderate hearing trouble, the presumed OTC hearing-aid prospects, between the ages of 20 and 69 years have hearing classified as "normal" by World Health Organization this is true for only about 10% of those 70 to 80+ years of age. On the other hand, nearly 40% of the older group has audiometric hearing loss classified by World Health Organization to be of moderate severity whereas this was only the case for about 7% of the 20 to 69-year-olds.

Historically, the WHO considered only those with at least a moderate PTA4-based hearing-impairment grade, better-ear PTA4 ≥35 dB HL, to have "disabling hearing impairment" which made them the primary candidates for (prescription) hearing aids (World Health Organization 1991, 2023). World Health Organization (2021), however, acknowledged that there may be many individuals with PTA4-based hearing loss at lower grades (normal or mild) who have hearing difficulties and need assistance of some type. Figure 9 shows that over 90% of those 20 to 69 years of age and half of those 70 to 80+ years of age with a little or moderate hearing trouble have PTA4-based hearing-impairment grades of normal or mild, lower than those typically considered to be candidates for hearing aids in the past. Little is known about the hearing-specific needs of these individuals and how hearing aids should be adjusted to best meet those needs. The audiograms in Figure 8 suggest that relatively low amounts of gain would be needed above 2000 Hz to improve audibility. Given that most expressed difficulty communicating in noise (Figs. 4 and 5), improvements in the signal-to-noise ratio acoustically through technology (e.g., noise reduction algorithms, directional microphones) or behaviorally through training may be paramount to success for OTC hearing-aid candidates. Even established clinical procedures, such as the details of widely used gain and output prescription formulas for conventional prescription hearing aids, should be carefully considered. For example, the widely used NAL-NL2 prescription formula was finalized using data obtained from 189 adults, none of whom had PTA4 values less than 20 dB HL, a WHO HI grade of "normal" (Keidser et al. 2012). The same is true for the validation of the Desired Sensation Level method (Scollie et al. 2005), another widely used method for setting prescription hearing aids.

Table 3 shows the PTA4 and immittance results for the left and right ears of those in each NHANES dataset with a little or moderate hearing trouble. These data are only provided for the presumed OTC hearing-aid prospects, those with a little or moderate trouble hearing. The 20-dB differences in PTA4 values for each ear for the two datasets reflect the wide separation of audiograms shown previously in the middle panels of Figure 8 for these two age groups. The median immittance values, moreover, reflect healthy middle ears, on average, among those with a little or moderate hearing trouble which is consistent with prior reports on immittance findings from these same NHANES datasets (McManus et al. 2022; Humes 2023c).

In addition, not shown in Table 3, about 84% of the 20 to 69-year-olds and 79% of those 70 to 80+ years of age with mild-to-moderate hearing trouble had normal otoscopy. When otoscopy was not judged to be normal, in >90% of the cases it was due to the presence of excessive cerumen (less than 50% of the eardrum visible) rather than impacted cerumen (0% of the eardrum visible). These otoscopic findings are consistent with analyses of the full NHANES datasets (McManus et al. 2022; Humes 2024). There do not appear to be outer ear or middle-ear contraindications for the pursuit of OTC hearing aids by those adults 20 to 80+ years of age with a little or moderate hearing trouble.

Summary and General Discussion

This report provided descriptive information from NHANES US National datasets about the demographic and audiological profiles of the nearly 50 million adults with a little or moderate hearing trouble, representing the presumed OTC hearing-aid candidates with "perceived mild-to-moderate hearing loss." Most OTC hearing-aid candidates were found to be between 50 and 69 years of age with the next largest age groups being 70 to 79 and 40 to 49 years. However, as has been noted elsewhere (Humes 2023a, b) and was observed here, the prevalence of hearing-aid use increases with age such that those 40 to 69 years of age represent the group having the most prevalent perceived difficulty and unmet hearing healthcare needs. Most OTC hearing-aid candidates were high-school graduates and had annual family incomes more than twice the income-to-poverty ratio with about half having annual incomes over $50,000. Over 80% of OTC hearing-aid candidates identified themselves as non-Hispanic Whites.

Many OTC hearing-aid candidates in the United States had health conditions that increased their risk for hearing loss including, high blood pressure (60%), smoking at least 20 pack years (~25%), and diabetes (15 to 20%). Use of firearms and exposure to loud noise at work were additional risk factors for hearing loss commonly experienced by 40 to 60% of those with a little or moderate hearing trouble. Compounding the risk of hearing loss from noise exposure, most of the candidates used hearing-protection devices in noise less than half the time. All these factors increase the odds for both audiometric hearing loss and self-reported hearing trouble (Humes 2023a, b) and none would be expected to be addressed through the acquisition of an OTC hearing aid by adults who have a little or moderate hearing trouble. Optimization of their hearing health or auditory wellness (Humes 2021) should not only permit candidates to self-select and fit OTC hearing aids but should also provide them with access to education and information about the importance of the maintenance of good hearing to their overall well-being.

Over 70% of OTC hearing-aid candidates did not use prescription hearing aids or other devices for assistance despite over 60% having trouble conversing in noise at least half of the time and 30 to 40% being frustrated with their hearing during conversation. Over 50% had not had a hearing test in over 5 years. Clearly, the prevalence of unmet hearing healthcare needs is high among those with a little or moderate hearing trouble. That about one-third of those with a little or moderate trouble hearing indicated that they had an emotional reaction to their hearing trouble (frustration) is worrisome as such a reaction negatively impacts wellness and overall well-being (Caputo & Simon 2013; Freedman et al. 2017).

Despite 40 to 50% having a history of at least three ear infections, the immittance data suggested healthy middle ears, on average, and otoscopy found few with impacted cerumen or other outer-ear abnormalities that would be contraindications for OTC hearing aids. The audiometric hearing loss underlying a little or moderate hearing trouble revealed a bilaterally symmetrical loss with slight to moderate amounts of hearing loss at and above 3000 Hz. Fifty to ninety percent of adults with a little or moderate perceived hearing trouble had WHO hearing-impairment grades of "normal" or "mild." As such, it is likely that many would not be considered viable candidates for prescription hearing and those in the "normal" range of audiometric hearing loss would not be considered candidates for consumer-selected devices according to recent guidelines American National Standards Institute (2023).

Last, this study is not without limitations. These limitations include those inherent to the NHANES datasets, such as the few questions that inquired about perceived hearing difficulties. Here, responses to a single question about the sample person's general condition of hearing (AUQ054) were used to classify the respondents into the three groups of hearing difficulty and the resulting categories of hearing difficulty were used for the remainder of these analyses. Validation of this classification into three groups, however, was apparent through systematic variations across groups in other outcomes, such as self-reported difficulty in noise and frustration with hearing, as well as audiometric hearing loss. Another possible limitation is that the analyses of audiological variables were focused on those with audiograms designated as complete by NHANES. Overall, it was demonstrated here that the demographic and audiological characteristics of those with complete audiograms were very similar to those with incomplete audiograms but there were some differences observed which could have biased the analyses when confining the analyses solely to those with complete audiograms.

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The entire NHANES protocols, including the survey instruments and data-coding procedures, and the complete dataset are publicly available online at https://www.cdc.gov/nchs/nhanes.

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