APPENDIX

A Re-Examination of Risk Estimates from the NIOSH Occupational Noise and Hearing Survey (ONHS)*

---

*Reprinted with permission of the American Institute of Physics from *The Journal of the Acoustical Society of America*, Volume 101, Issue 2, February 1997, pages 950–963. Further reproduction is prohibited without permission of the copyright holder.

A re-examination of risk estimates from the NIOSH Occupational Noise and Hearing Survey (ONHS)

Mary M. Prince, Leslie T. Stayner, Randall J. Smith, and Stephen J. Gilbert
*Education and Information Division, National Institute for Occupational Safety and Health,
4676 Columbia Parkway, Cincinnati, Ohio 45226*

(Received 13 July 1994; revised 9 April 1996; accepted 20 September 1996)

This paper describes a new analysis of data from the 1968–72 National Institute for Occupational Safety & Health (NIOSH) Occupational Noise and Hearing Survey (ONHS). The population consisted of 1172 (792 noise-exposed and 380 "controls") predominately white male workers from a cross section of industries within the United States. The analysis focused on how risk estimates vary according to various model assumptions, including shape of the dose-response curve and the amount of noise exposure among low-noise exposed workers (or controls). Logistic regression models were used to describe the risk of hearing handicap in relation to age, occupational noise exposure, and duration exposed. Excess risk estimates were generated for several definitions of hearing handicap. Hearing handicap is usually denoted as an average hearing threshold level (HTL) of greater than 25 dB for both ears at selected frequencies. The frequencies included in the biaural averages were (1) the articulation-weighted average over 1–4 kHz, (2) the unweighted average over 0.5, 1, and 2 kHz, and (3) the unweighted average over 1, 2, and 3 kHz. The results show that excess risk estimates for time-weighted average sound levels below 85 dB were sensitive to statistical model form and assumptions regarding the sound level to which the "control" group was exposed. The choice of frequencies used in the hearing handicap definition affected the magnitude of excess risk estimates, which depended on age and duration of exposure. Although data were limited below 85 dB, an age-stratified analysis provided evidence of excess risks at levels ranging from 80 to 84 dB, 85–89 dB, and 90–102 dB. Due to uncertainty in quantifying risks below 85 dB, new data collection efforts should focus on better characterization of dose-response and longitudinal hearing surveys that include workers exposed to 8-hour time-weighted noise levels below 85 dB. Results are compared to excess risk estimates generated using methods given by ANSI S3.44-1996. [S0001-4966(97)01102-8]

PACS numbers: 43.50.Qp, 43.64.Wn [GAD]

INTRODUCTION

The most common goal for protecting workers from the auditory effects of occupational noise has historically been the preservation of hearing for speech discrimination. With this protection goal in mind, the National Institute for Occupational Safety and Health (NIOSH) defined hearing handicap as a *biaural average* of hearing levels exceeding 25 dB at the audiometric test frequencies of 1, 2, and 3 kHz and 0.5, 1, and 2 kHz (NIOSH, 1972). Here, the term "biaural average" is used to identify the mean value for the left and right ears. Using these definitions, NIOSH (1972) estimated the excess risk of hearing handicap as a function of age, sound levels and duration of occupational noise exposure. Excess risk, also known as percentage risk, is defined as the percentage of individuals with hearing handicap among individuals exposed to daily 8-hour occupational noise exposure after subtracting the percentage of individuals who would typically incur such a handicap due to aging in an unexposed population. For a 40-year lifetime exposure to average daily (8-hour) noise levels of 80, 85, and 90 dB in the workplace, NIOSH (1972) estimated the excess risk to be 3%, 15%, and 29%, respectively for the biaural average over 1, 2, and 3 kHz. [Unless otherwise noted, "dB" implies an A-weighted 8-hour time-weighted average sound level.] Table I compares the NIOSH (1972) excess risk estimates for the biaural average over 0.5, 1, and 2 kHz to those developed by other organizations at approximately the same time.

Since the publication of the 1972 NIOSH Criteria Document, statistical methods for analyzing categorical data outcomes have been improved to assess risk of disease (Breslow and Day, 1980a). The aim of this paper is to reevaluate the models used to generate excess risk estimates from data collected for the NIOSH 1968–72 Occupational Noise and Hearing Survey (ONHS) (Lempert and Henderson, 1973). Using these newer statistical methods, the paper examines the relationship between exposure to noise and risk of noise-induced hearing handicap (NIHH) and highlights areas of uncertainty in estimating risks. These results will be compared to the 1972 NIOSH analysis (NIOSH, 1972) and to the ANSI S3.44 (ANSI, 1996) standard, which adopted the methods developed by the International Standards Organization (ISO 1971, 1990). The data collected in the NIOSH survey are of continuing interest since they were obtained before hearing protection devices were widely used in the U.S. Observations by NIOSH investigators during sound level surveys and management's impressions of their respective plants did not indicate that participating companies had policies *requiring* hearing protection use. Use of protectors, if available at all, were left to the discretion of the workers. No mass use of hearing protectors was noted in any of the

TABLE I. Comparison of excess risk estimates by organization.[a]

Average daily exposure level (dB)	Excess risk estimates (%) Hearing handicap defined as HTLs > 25 dB for the average of 0.5, 1, 2 kHz		
	NIOSH (1972)	ISO 1999 (1971)	EPA[b]
80	3	0	5
85	15	10	12
90	29	21	22.3
95	43	29	not available

[a]These excess risk estimates are for a 40-year lifetime exposure to noise.
[b]From Federal Register, Vol. 39, No. 244, 1974.

companies surveyed (Cohen, personal communications, 1996).

I. RELEVANCE TO COMPARABLE STUDIES OF NOISE-INDUCED HEARING LOSS

Several investigators (Robinson and Sutton, 1975; Royster and Thomas, 1979; NCHS, 1965; Robinson, 1970; Yerg *et al.*, 1978) have examined the relationship of noise-induced permanent threshold shift (NIPTS) and occupational noise exposure. Studies similar to the NIOSH 1968–72 Noise Survey with respect to time period and methods of data collection include Baughn (1973), Passchier-Vermeer (1968) and Burns and Robinson (1970). These studies will be the main focus of our review of the relevant noise and hearing surveys from this period. These studies have been used by ISO 1999 (1971) and ANSI S3.44 (ANSI, 1996) to estimate the risk of NIHH or NIPTS. Table II presents major study characteristics of each of these studies.

As shown in Table II, only the Baughn (1973) study did not screen their workers for otologic abnormalities. These studies report that their populations were restricted to workers with daily constant levels of steady state noise exposure for the entire length of employment. A review of these studies' limitations has been addressed by Ward and Glorig (1975) and Yerg *et al.* (1975). They include possible contamination of non-steady state noise exposure in the population and small sample sizes for subjects exposed to continuous steady state for daily sound levels below 90 dB. The Passchier-Vermeer report (1968) reviewed published studies and was not specifically designed to address criteria for a noise standard. The NIOSH study (Lempert and Henderson, 1973) was specifically designed to examine risk of noise-

TABLE II. Overview of selected noise and hearing studies used to assess risk of hearing handicap.

Study	Population examined in risk analysis	Exposure characteristics	Screening of subjects
NIOSH ONHS study[a]	1172 predominately white males from a cross section of industries within the U.S. *792 noise-exposed* *380 low noise-exposed*	Workers exposed to steady state noise for up to 41 years of exposure to daily noise levels from 80–102 dB. Workers exposed to impact or impulse noise were excluded.	Workers were excluded if they had previous noisy jobs, significant firearm exposure (military or recreational), ear disease or other otologic abnormalities, incomplete job histories or unknown noise exposures.
Baughn, 1973	6,835 audiograms on Caucasian male employees from a Midwestern auto parts plant: 1960–65. Stable work force, light turnover. Employees drawn from surrounding farming-industrial community. Age range: 18–68 yrs.	Workers assigned to three 8-hour TWA exposure levels: 78, 86, and 92 dB: *N=852–78* dB *N=5150–86* dB *N=833–92* dB Age used as uniform measure of exposure duration.	No Otological screening of subjects. 2/3 of available tests were excluded due to significant known or unknown exposures.
Passchier-Vermeer, 1968	4557 Caucasian workers from an industrial population in The Netherlands: *4096 males* *461 females*	Include only workers with constant noise exposure levels for an 8-hour shift for all exposure years considered.	Workers excluded if they had previous noise exposure during other jobs, otologic abnormalities.
Burns & Robinson, 1970	759 noise-exposed workers and 97 non-noise exposed controls from a variety of occupations. Subjects were volunteers. *422 males* *337 females*	Exposed daily to steady state noise for periods of up to 50 years.	Excluded individuals with existing or previous ear disease or abnormality, exposure to firing weapons, workers whose noise exposure could not be quantified, and those with language difficulty.

[a]Lempert and Henderson, 1972.

induced hearing handicap as a basis for establishing health based occupational standards. The following summary of the study methods is from a NIOSH technical report by Lempert and Henderson (1973).

II. STUDY METHODOLOGY

A. Survey population

In 1968, the U.S. Public Health Service undertook a nationwide study, called the Occupational Noise and Hearing Survey (ONHS). The study was continued and completed by NIOSH in 1972. The aim of the survey was "to characterize noise exposure levels in a variety of industries, to describe the hearing status of workers exposed to such noise conditions, and to establish a relationship between occupational noise exposure and hearing handicap that would be applicable to general industry." Subjects for the study were recruited through notices at industrial hygiene conferences and through the regional offices of the U.S. Public Health Service. All companies interested in participating were considered if certain priority considerations applied. These included (1) existence of a factory or occupational noise conditions having noise levels relevant to developing noise standards and criteria, and (2) a work force with a wide range of years of exposure to such noise levels.

The data collected in the survey included noise measurements, personal background information, medical and otological data and audiometric examinations. Noise level measurements (using Bruel-Kjaer Sound Level Meters) were taken at different areas of each plant and tape recordings were used for laboratory analysis of noise characteristics. A questionnaire was used to obtain information on each worker's job history, military service, hobbies, and medical history pertinent to ear abnormalities and hearing difficulty. An otoscopic inspection of the ears was also made, usually after the completion of the questionnaire. Measurements of hearing levels (using a Rudmose RA-108 audiometer) for pure tone frequencies of 0.5, 1, 2, 3, 4, and 6 kHz in the right and left ears of the workers were conducted in a Rudmose audiometric travel van (model RA-113). Workers from noisy workplaces were always tested at the beginning of their work shift.

For plants with less than 500 employees, the entire work force was tested. For larger plants, a random sample was selected. Individuals from each plant who worked in offices or other quiet work areas were also included in the survey to provide control data.

B. Screened population for analysis

The survey population was "screened" to exclude individuals with prior noise exposure (from occupational and non-occupational sources) and medical or otologic conditions that might affect a person's risk of hearing loss, independent of occupational noise levels at the time of the survey. Criteria for data exclusion included (1) uncertainty in the noise exposure history or validity of audiometric tests and (2) evidence that hearing loss might have been caused by factors other than occupational noise exposure (e.g., military history, other non-occupational noise exposures, head trauma, other audiological/otologic medical conditions). Workers exposed to noise that was not continuous (e.g., discrete impact sounds or noise with highly variable and unpredictable levels) and all maintenance workers were also excluded. Due to the relatively small number of females in the survey population, all analyses were limited to 1172 males (792 noise-exposed and 380 controls).

C. Variable definitions

1. Definition of hearing handicap

The major outcome of interest is hearing handicap, defined as a biaural average hearing threshold level of greater than 25 dB for a selected set of frequencies. In this analysis, the set of frequencies includes (a) 0.5, 1, and 2 kHz, (b) 1, 2, and 3 kHz and (c) 1, 2, 3, and 4 kHz (herein denoted as 1–4 kHz). The 1–4 kHz frequency average was recommended by an American Speech-Language-Hearing Association (ASHA) Task Force (ASHA, 1981), which focused on the need to include frequencies most affected by noise exposure. The ASHA Task Force recommended that percentage formulas should include hearing threshold levels for 1, 2, 3, and 4 kHz, with low and high fences of 25 and 75 dB, representing 0 percent and 100 percent hearing handicap boundaries, respectively (ASHA, 1981). In this analysis, the ASHA recommendation was modified by calculating a weighted average across frequencies rather than an arithmetic average over the test frequencies of 1, 2, 3, and 4 kHz. Weights were assigned according to frequency specific articulation indexes (ANSI, 1969). The articulation index (AI) is a weighted fraction representing (for a given listening situation) the effective proportion of the speech signal that is available (above a masking noise level or hearing threshold) to a listener for conveying speech intelligibility (ANSI, 1969).

Average hearing threshold levels ($\mathrm{HTL_{avg}}$) using the articulation indexes as weights were calculated [Eq. (1)] and then averaged over both ears:

$$\mathrm{HTL_{avg}}=\frac{\mathrm{HTL}_{1k}W_1+\mathrm{HTL}_{2k}W_2+\mathrm{HTL}_{3k}W_3+\mathrm{HTL}_{4k}W_4}{W_1+W_2+W_3+W_4}, \tag{1}$$

where, $W_1=0.24$, $W_2=0.38$, $W_3=0.34$, and $W_4=0.24$ are the weights at 1, 2, 3, and 4 kHz, respectively. This definition will be referred to as the "1–4 kHz AI average" definition of NIHH.

2. Measurement of noise exposure

Daily 8-hour time-weighted average (TWA) noise exposure was estimated for each worker or worker group using (1) area survey samples, (2) interviews with workmen and supervisors to establish typical workday patterns and (3) time-study charts. These charts segmented the workday into a succession of exposures at specific noise levels and for specified durations. Discussions with both management and workmen were necessary to determine changes in noise exposure over the course of many years. Consideration was given to variations in occupational noise conditions due to placement or relocation of machinery and as well as changes in workers' work routine and locations. The reported noise

TABLE III. Covariates considered for inclusion in the analysis of the NIOSH survey.

Variables	Coding conventions
Age at examination	Continuous variable: age in years Categorical:[a] 17–27 years 28–35 years 36–45 years 45–54 years >54 years
Duration of noise exposure	Continuous variable: duration in years Categorical:[a,b] 0–1 years 2–4 years 5–10 years 11–20 years > 20 years
Sound level, L_{NE}, A-weighted 8-hour, time-weighted Average (TWA) sound level—dB, where L_{NE}=*average sound levels for exposed workers;* L_0=*average sound levels for control population*	Continuous variable "Centered" at L_0, dB: $(L_{NE}-L_0)$ L_0 was initially fixed to 79 dB but then estimated in models presented in the text.

[a] Categories were the same as NIOSH, 1972.

[b] In the 1972 NIOSH analysis, those exposed to noise for less than 6 months were coded as "0" for duration of exposure. In the current analysis, controls were coded as "0" for duration of exposure and exposed individuals with less than 6 months of exposure were given a value of 0.25.

levels for the study population represent A-weighted eight hour TWA sound levels calculated assuming a 5 dB exchange rate (i.e., 5 dB increase in sound level is exchanged against a factor of 2 in duration within the workday). All levels were measured with sound level meters set to "slow" response. The A-weighted daily noise levels were available on the 792 noise-exposed individuals but not available for the 380 controls. Although sound levels for the control population were not recorded, they were reported to be below 80 dB (Lempert and Henderson, 1973).

3. Other covariates

Other covariates of interest in this paper were age and duration of exposure in years. The risk of hearing handicap was examined in relation to the covariates defined in Table III. For models that included categorical variables for age (reference: 17–27 years) and duration (reference: 0–1 years), four indicator variables were created for different levels of age and duration exposed (Table III). For models that included continuous variables for duration exposed, all controls were reassigned a duration value of zero because it was assumed that duration has no effect on the hearing of the controls. Exposed individuals with less than six months were coded as 0.25 years (midpoint between 0 and 0.5 years).

D. Statistical models

Logistic regression models were used to analyze hearing handicap, defined as the proportion of individuals whose biaural hearing level is greater than 25 dB for averages over selected frequencies. These logistic regression models were fit using the SAS LOGISTIC procedure (SAS Institute, Inc., 1989) and the nonlinear minimization (NLMINB) routine in S-PLUS (Statistical Sciences, Inc., 1993).

Stratified contingency table analyses (Breslow and Day, 1980a) were performed to assess these data for qualitative evidence of hearing handicap due to exposure to noise after controlling for age. The 2×2 contingency tables were stratified by one year age groups and the prevalence of hearing handicap among the three noise-exposed categories of 80–84 dB, 85–89 dB, and 90–102 dB were contrasted to the prevalence among controls. One-sided tests for detecting increased risks were computed using Mantel–Haenszel methods. Further details of this method are found in Breslow and Day (1980a).

The quantitative relationship between hearing handicap and the covariates (defined below) was modeled using logistic regression methods (Breslow and Day, 1980b). These models can be expressed as

$$p=\Pr(Y=1|X)=\frac{e^{F(X;\alpha,\beta,\phi,L_0)}}{1+e^{F(X;\alpha,\beta,\phi,L_0)}}, \tag{2}$$

where, p=the expected proportion with average hearing level greater than 25 dB (indicated by $Y=1$), given **X**. ($Y=0$ indicates an average hearing level is less than or equal to 25 dB);

X =a vector of explanatory variables containing information on age, sound level, and duration of exposure;

$$F(X;\alpha;\beta;\phi,L_0)=\alpha+\beta_1(\text{Age})+[\beta_{2j}(L_{NE}-L_0)^{\phi}], \tag{3}$$

where

L_{NE}=A-weighted 8-hour TWA sound level for noise-exposed workers in dB;

L_0=parameter for nominal TWA sound level in control population in dB;

ϕ=shape parameter on dB effect;

α=intercept parameter;

β_1 =slope coefficient for age effect;

β_{2j}=the slope coefficient for the jth duration of exposure (years) interval, where $j=1,2,3$ represent exposure intervals of 2–4 years, 5–10 years, and >10 years of exposure, respectively.

1. Model development

The first step in the analysis was to fit several hierarchical logistic regression models and compare nested models using likelihood ratio tests (LRTs) to identify which parameters significantly improved the fit to the data (Fienberg, 1987). The fit of the model to the data was evaluated using a likelihood ratio test and examining the log likelihood statistic, G, which is defined by the expression

$$G=-2\Sigma\{Y\log p+(1-Y)\log(1-p)\}, \tag{4}$$

where the summation is over all individuals in the sample (Breslow and Day, 1980b).

In general, the lower the value of G, the better the fit between the model and the data. Differences in G statistics for nested models may be interpreted as chi-squares (Breslow and Day, 1980b).

To be consistent with the methodology used in the 1972 NIOSH Noise Criteria Document (NIOSH, 1972), the model was initially fit assuming that the sound level for the control population (L_0) was 79 dB and the shape parameter (ϕ) was 1. This was accomplished by first fitting models with main effects only and then adding interaction terms between (a) duration exposed and daily TWA sound level (L); (b) duration exposed and age; and (c) age and sound level. These interaction terms tested whether there should be allowance for differing slopes by levels of other variables. Models with linear main effect of age, duration exposed, and sound levels were fit with an assumption that all control 8-hour TWA sound levels (L_0) were 79 dB. This assumption was made because individual noise exposure data for controls were unavailable but were known to be less than 80 dB (Lempert and Henderson, 1973). Other models with categorical main effects of age and duration were also examined. The final steps of the analysis involved further model refinements that included (1) assuming there is a nondecreasing relationship of prevalence with sound level and duration; (2) refitting functional forms identified by the LRT strategy accordingly; (3) assuming more flexible models for incorporating the effects of sound level by permitting the shape parameter (ϕ) to vary; (4) permitting the control sound level (L_0) to vary from 79 dB; and (5) conducting sensitivity analyses of the impact of critical assumptions.

A final form of the model was fit such that all the parameters (including L_0 and ϕ) were solved for simultaneously. This model form was fit with the following restriction: the control level, L_0, was bounded at 55 dB and 79 dB. For the final model, a two-sided 90 percent confidence interval was calculated for several noise levels using the parametric percentile bootstrap method (Efron and Tibshirani, 1986; Efron, 1982). The same restrictions on L_0 were applied to 1000 bootstrap samples generated to obtain the confidence limits for excess risk. Graphical displays of bootstrap-based confidence limits were smoothed using localized linear regression smoothers in S-PLUS (Statistical Sciences, Inc., 1993).

2. *Excess risk estimation*

Excess risk for a particular age is defined as the difference between the risk of hearing handicap for the noise-exposed population, given exposure duration, and the exposure sound level, L_{NE} (where $L_{NE} > L_0$), and the risk of hearing handicap among controls. The excess risk associated with exposure to noise evaluated at a given age was estimated from logistic models using the following relationship:

$$\text{Excess Risk} = \Pr[Y=1 \mid \text{age, duration, and intensity of exposure}] - \Pr[Y=1 \mid \text{age, control}]. \quad (5)$$

Hence, excess risk is assumed to be equivalent to the increase in risk of hearing handicap associated with noise exposure.

3. *Sensitivity analyses*

Sensitivity analyses were performed to examine how model assumptions may affect the results (i.e., excess risk estimates). Assumptions evaluated in this analysis included (1) the shape of the dose-response relationship; (2) the sound level, L_0, for the control population; and (3) the effect of using different definitions of hearing handicap. The first two issues were addressed during model development, where each assumption was varied while the other remained fixed.

A comparison of how excess risk estimates varied with different definition of hearing handicap was also examined in this analysis. The new definition (1–4 kHz AI average) was compared to definitions previously used by NIOSH (1972)—biaural hearing levels averaged over 1–3 kHz and 0.5–2 kHz. The analyses of different hearing handicap definitions were based on our final model for each definition of hearing handicap: the model in which the control sound level (L_0) and shape parameter (ϕ) were simultaneously estimated.

III. RESULTS

Figure 1 shows the hearing threshold level distributions (10th, 50th, 90th percentiles) for different frequencies by age and sound level categories for exposed and control workers. All hearing thresholds shown are averages over the left and right ears. Data are classified into five age groups and three noise exposure categories (80–87 dB, 88–92 dB, 92–102 dB). The boundaries for the age and sound level categories were selected to provide adequate sample size (i.e., at least 30) in each cell. Sample sizes for the noise-exposed [$n(NE)$] groups are provided for each graph with median exposure duration. The sample sizes for the controls [$n(C)$] are the same within age groups (shown in top panel of each column). The graphs show similar exposure durations within each age cell and increasing trends for median hearing threshold levels with age and sound level. In all cases, control hearing threshold levels are lower than the noise-exposed population. The tendency of median hearing thresholds to increase with increasing age and sound level is also illustrated. The spread of the distribution (given by the 10th and 90th percentiles) is most marked at 3 and 4 kHz.

A scatter plot of the ONHS data showing years of duration versus TWA sound level, L_{NE}, is presented in Figure 2. The vast majority of the data points are at sound levels above 85 dB. Almost 50% of the noise-exposed population had 8-hour TWA sound levels between 85 and 89 dB, while only 27% were exposed below 85 dB. There are also very few data points corresponding to 40 or more years of noise exposure. This lack of data in the low exposure region (80–84 dB) and among workers with long duration of exposure (> 40 years) imposes limitations for quantifying the risks for workers exposed to noise throughout their working lifetime (e.g., 45 years, assuming a worker starts work at 20 years of age and ends at 65 years).

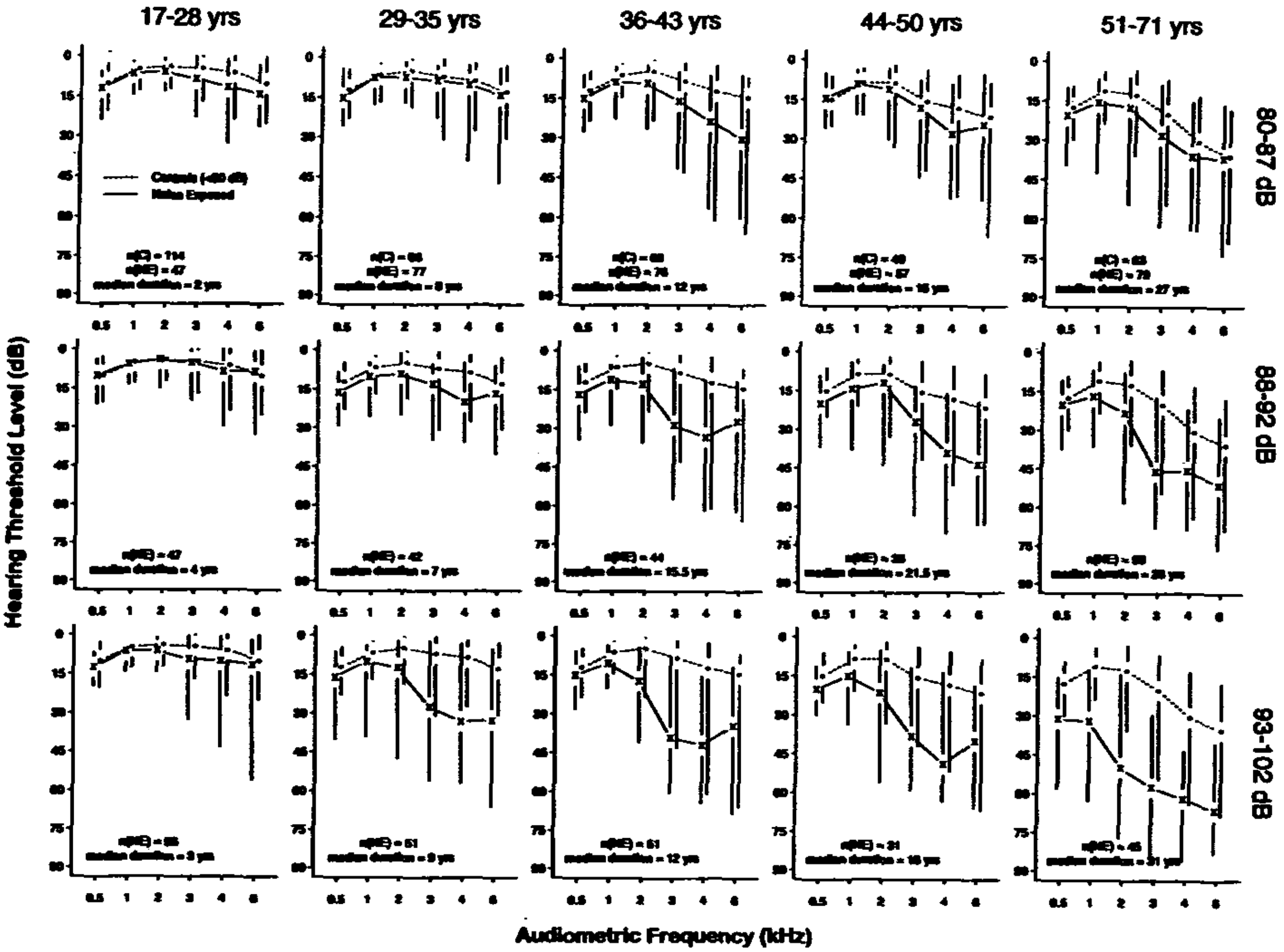

FIG. 1. Distribution of hearing levels (10th, 50th, and 90th percentiles) by age and average daily sound level (L_{NE}) categories from the NIOSH 1968–72 survey.

Despite the limited amount of data in the low exposure region, the Mantel–Haenszel age-stratified analysis provided evidence of positive excess risk associated with sound levels ranging from 80 to 84 dB ($p=0.02$), as well as 85 to 89 dB ($p=0.02$) and 90 to 102 dB ($p<0.001$).

Age was found to be a highly significant predictor of hearing handicap due to noise whether it was modeled using a continuous variable ($\chi^2=211$, $df=1$) or a set of categorical variables ($\chi^2=213$, $df=4$). The fitted categorical effects for age suggested a linear trend (data not shown). This trend was also apparent when models including sound level and duration were fit. Therefore, the simpler models with linear effects for age (as a continuous variable) were subsequently considered in the final models. The addition of either years of exposure or sound level (L_{NE}) significantly improved the fit of the model containing age. The addition of both terms further increased the goodness of fit. A statistically significant interaction ($\chi^2=29.6$, $df=4$) was observed between sound level and categories of years of exposure. No significant interactions between age and duration exposed, nor age and sound level were observed in this data set.

Based on this preliminary analysis, the best fitting linear model is a function of continuous age, categorical levels of duration of exposure, and sound level. However, this model initially appeared to be inappropriate for risk assessment because the excess risk of hearing handicap predicted by this model decreased over limited ranges of sound level and duration of exposure. For example, the parameter estimates of this model suggested that the risk of hearing handicap was lower for individuals with greater than 20 years of exposure than it was for individuals with 11–20 years of exposure when the sound level was above 90 dB. We found no statistically significant difference between the fit of the model that combined the two highest duration categories (11–20 years and > 20 years combined to > 10 years) and the model with separate parameters for each duration category. This suggested that risks remain essentially flat after 10 years of exposure, and that these two categories could be combined. This initial model was further refined to describe predicted risks of hearing handicap as a nondecreasing function of exposure duration and sound level. The models also assume that the effects of sound level depend on durations greater than or equal to two years.

To test whether a linear sound level effect ($\phi=1$) adequately described the relationship between noise exposure and risk of hearing handicap, higher order terms for the sound level effect were tested in the analysis. Using a quadratic sound level term for exposure ($\phi=2$) appreciably im-

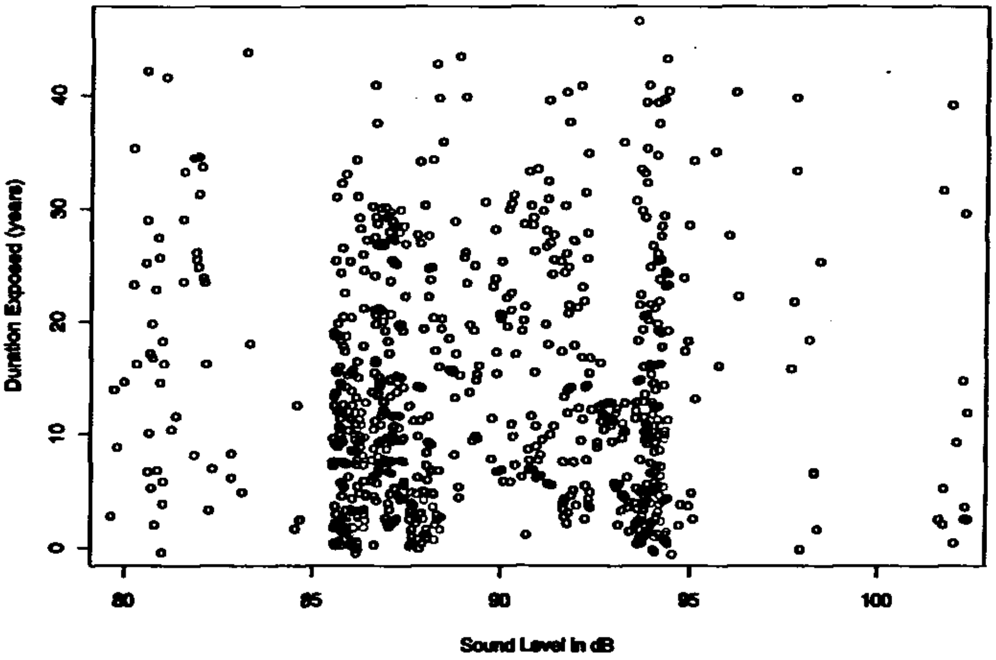

FIG. 2. Scatter plot of exposure sound levels (L_{8hE}) versus exposure duration of 792 noise-exposed workers from the NIOSH 1968–72 survey.

proved the goodness of fit of the model relative to the linear model. Using a cubic sound level term ($\phi=3$) resulted in only a slight improvement in the goodness of fit over the quadratic model. The final results from fitting models with linear, quadratic, or cubic sound level terms and assuming control sound levels, L_0, of 79 dB are presented in Table IV. Also shown are the results from fitting a final model in which the control value and the shape parameter were found to be 73 dB and 3.4, respectively (model 4, Table IV). Model 4 is denoted as the "best fitting model," because it produced the best fit to the data. These results indicate considerable variability in excess risk estimates depending on model form and is likely due to lack of data at lower sound levels. This was most marked at average daily sound levels less than or equal to 85 dB. Figure 3 presents excess risk estimates with smoothed 90 percent confidence limits for 65-year-old males with greater than 10 years of exposure as a function of sound level for the "best fitting model" (model 4).

A. Sensitivity analyses

1. Assumption regarding control 8-hour TWA sound levels

To examine the sensitivity of risk estimates to the assumed sound level for the control group, the value of L_0 was varied from 60 to 79 dB and optimum values of the shape parameter, ϕ, were estimated. As L_0 is varied, there is very little variation in the log likelihood statistic, G, whereas the excess risk estimate for noise exposure at a level of 80 dB varies between 0.06 and 2.9 (Table V). The results also show that the optimum value of ϕ decreases considerably as the assumed value of L_0 increases. This analysis suggests that information regarding the distribution of occupational sound levels within the control population is important in estimating the risk of noise-induced handicap in noise-exposed populations. The variability of excess risk estimates below 85 dB seen in Fig. 3 may be attributed to the lack of accurate

TABLE IV. Excess risk percent of noise-induced hearing handicap for workers aged 65 with 10 or more years of noise exposure at various time-weighted average sound levels for linear, quadratic, cubic, and best fitting models.

Exposure sound level (L_{8hE}) in dB	Excess risk estimates for various models				
	Quadratic (model 2) $\phi=2$	Cubic (model 3) $\phi=3$	Best fitting (model 4)[a] $\phi=3.4$	Linear dB models ($\phi=1$)	
				Present analysis	NIOSH (1972)
80	0.2	0.02	1.2	3.4	3
85	8.3	3.2	7.6	19.6	15
90	24.5	17.8	22.3	32.2	29
95	28.5	36.2	38.3	40.6	43
100	44.1	41.2	44.0	45.5	56

[a] Risk estimates can be generated using the following equation: *Logit* $[Pr(Y > 25 \text{ dB HL})] = -5.0557 + 0.0812(\text{Age}) + [\beta_j (\text{Duration}=1)]^{*}[(L_{8hE}-L_0)/(102-73)]^{\phi}$, where, β_j = 2.6653, 3.989, and 6.4206, respectively, for the *j*th duration of exposure for 2–4 years, 5–10 years, and >10 years, respectively and Y is the AI-weighted biaural average over 1–4 kHz. For the best fitting model, ϕ was estimated to be 3.4 and L_0 = 73 dB. The term *(102–73)* in the denominator of the coefficient describing the effect of duration and sound level, standardizes the exposure term such that the maximum exposure equals one. This was done for ease of comparison to models with differing estimates for L_0 and ϕ.

TABLE V. Excess risk percent of hearing handicap from logistic regression models assuming different sound level values for controls with corresponding shape parameters: Male workers aged 65 with duration exposure greater than 10 years.

Exposure sound level (L_{NE}) in dB	Control sound levels (L_R) in dB and corresponding shape parameters (ϕ) 60 (ϕ=5.46)	65 (ϕ=4.67)	70 (ϕ=3.88)	75 (ϕ=3.10)	79 (ϕ=2.49)
80	2.9	2.4	1.8	0.8	0.06
85	9.6	9.1	8.3	7.0	5.2
90	23.4	23.2	22.8	22.1	21.0
95	39.2	39.0	38.6	38.1	37.3
100	45.2	44.9	44.4	43.6	42.6
Log likelihood statistic, G	*1039.794*	*1039.715*	*1039.645*	*1039.631*	*1039.754*

sound level data among control subjects and the sparseness of the data for workers exposed at sound levels below 85 dB.

2. Definition of hearing handicap

To examine whether excess risk estimates varied by the definition of hearing handicap used, we compared the 1–4 kHz AI average definition to two other definitions using the same fence (> 25 dB HL), the unweighted biaural frequency averages of 0.5–2 kHz and 1–3 kHz. All three definitions were examined using a model that included age and a dose metric effect defined as $(L_{NE}-L_0)^{\phi}$ times duration categories (e.g., 2–4, 5–10, and >10 years). The resultant estimated shape parameters for the 0.5–2 kHz and 1–3 kHz biaural averages were 4.5 and 4.9, respectively, with L_0 equal to 55 dB for both.

Under these models, excess risk estimates were affected by both the definition of hearing handicap and the age of the worker. We also found that changing from the articulation index to a simple average of 1–4 kHz did not substantially affect excess risk estimates (results not shown). For workers aged 65 years (with > 10 years of exposure), excess risks for the 1–3 kHz definition are higher than excess risk for the new definition, particularly for sound levels above 85 dB (Fig. 4A). However, among workers aged 45 with similar years of exposure, excess risk estimates are similar for all sound levels for the 1–3 kHz definition and the new definition (Fig. 4B). For younger workers (aged 30 years) with 5 to 10 years of exposure, excess risk estimates for the definitions that included 3 kHz and/or 4 kHz, are similar for all sound levels (Fig. 4C).

IV. DISCUSSION

The results of these analyses indicate that there is an excess risk of noise-induced hearing handicap (NIHH) at 8-hour time-weighted average (TWA) sound levels greater than or equal to 85 dB. The excess risk below 85 dB was not well defined in our analysis. However, the Mantel–Haenszel test result suggests that there is a positive and statistically significant excess risk at levels between 80 and 84 dB.

These findings also indicate two major areas of uncertainty for quantifying the risk of noise-induced hearing handicap. The first concerns the sensitivity of the analysis to the assumed sound level for the control group (L_0). The second relates to the shape of the dose-response relationship between the sound levels among the noise-exposed group (L_{NE}), duration exposed, and the risk of NIHH. Risk estimates were found to vary considerably for values of L_{NE} below 85 dB, depending on the assumed control sound level (L_0), and the shape parameter (ϕ) for the sound level effect (e.g., linear, quadratic, or cubic) in the models.

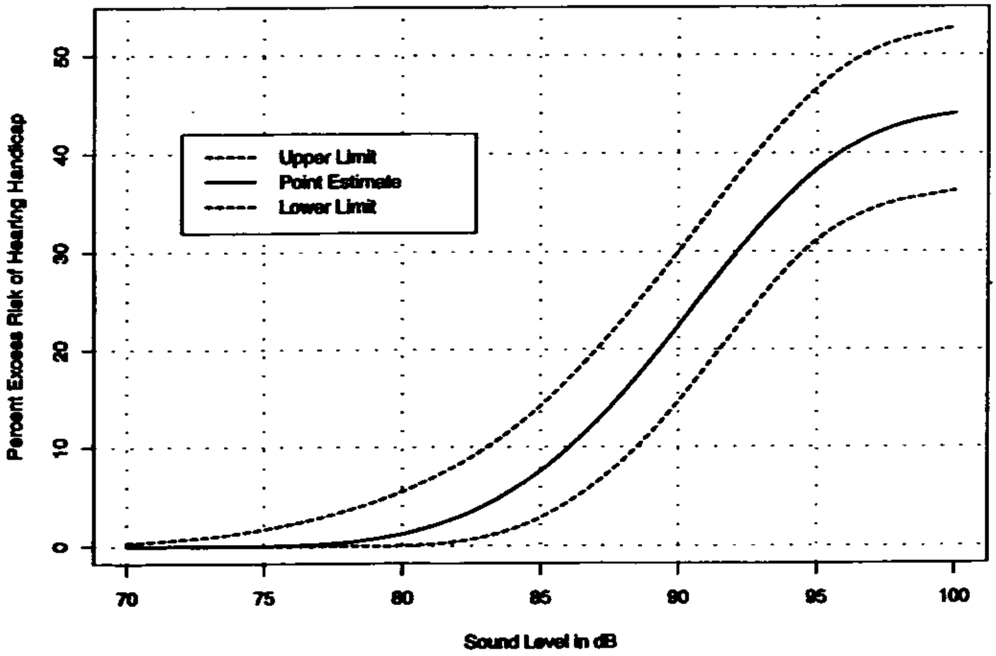

FIG. 3. Excess risk (percent) of hearing handicap (*AI*-weighing, 1–4 kHz) and bootstrap-based 90% confidence limits from model 4 (Table IV) for 65-year-old males exposed for greater than 10 years to varying levels of noise (L_{NE}).

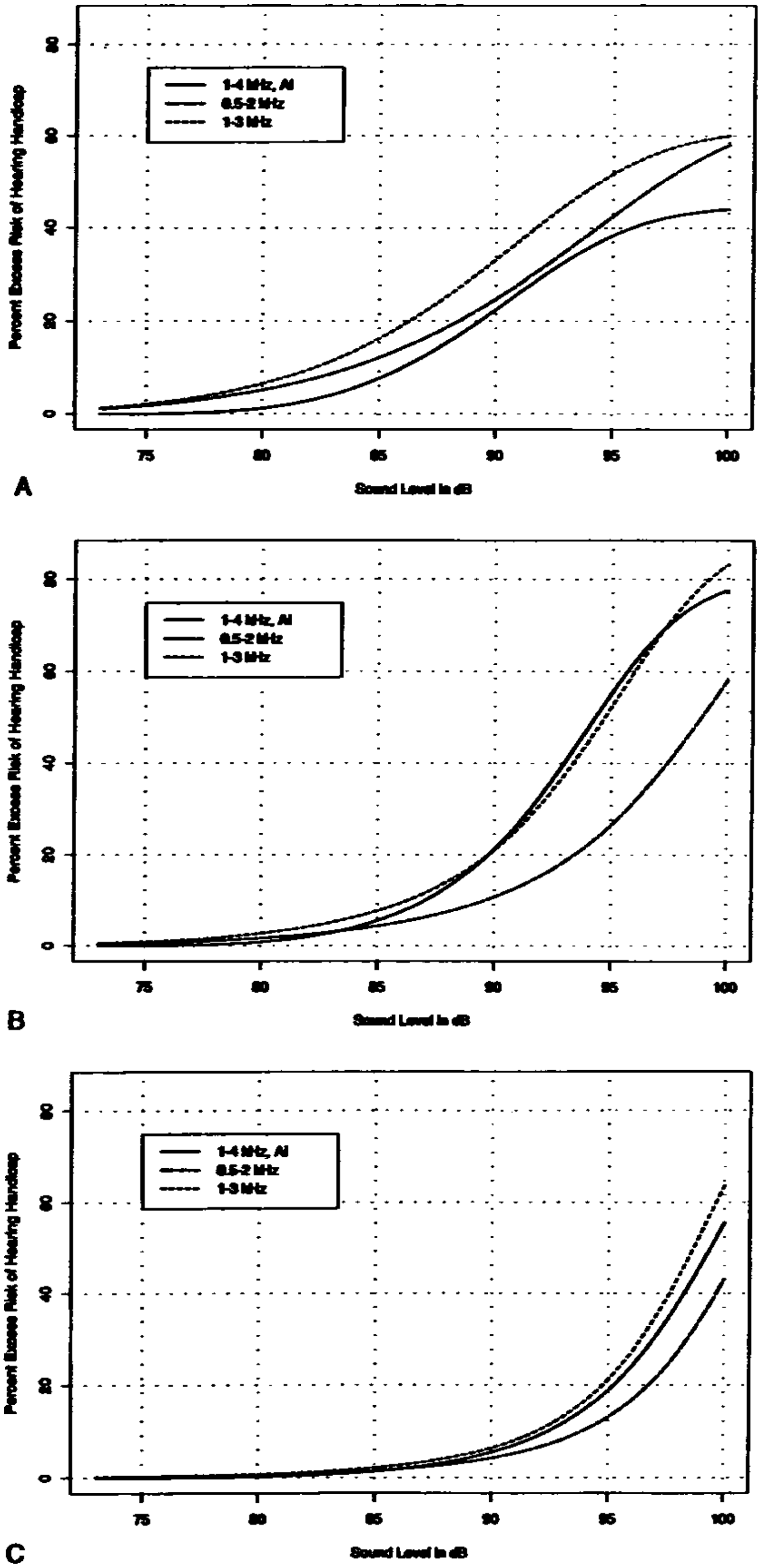

FIG. 4. Excess risk percent from model 4 (Table IV) as a function of varying sound levels (L_{Aeq}) for different definitions of hearing handicap. Panel A: A
65 years, duration exposure >10 years. Panel B: Age 45, duration exposure >10 years. Panel C: Age 30 years, duration exposure 5–10 years.

The previous NIOSH (1972) estimate of excess risk for a 40-year working lifetime of exposure to noise was approximately 15 percent at 85 dB. A linear regression model of log hearing levels was used in the previous analysis (NIOSH, 1972) to estimate the risk of hearing handicap. NIHH was defined as an average biaural hearing level greater than 25 dB based on unweighted averages of 0.5–2 kHz or 1–3 kHz. The model described in the 1972 NIOSH criteria document (NIOSH, 1972) is mathematically equivalent to a probit model in which the risk of a hearing level greater than 25 dB is of interest. The results from the previous NIOSH analysis (NIOSH, 1972) also appear to be consistent with the assumption that the control group was exposed to sound levels near 79 dB.

It is clear that models which include a quadratic or cubic effect for the sound level effect fit significantly better than the linear effect model and produce lower excess risk estimates for sound levels below 85 dB than similar models used in the 1972 NIOSH analysis (NIOSH, 1972). As shown in Table IV, the point estimates of excess risk at 85 dB from the quadratic and cubic models are 8 percent and 3 percent, respectively. The quadratic and cubic models fit better than the linear model, mainly due to the effect of sound level in the low exposure region. For sound levels less than or equal to 90 dB, the excess risk estimates from fitting a linear model (Table IV) are slightly higher than those in the NIOSH (1972) analysis. Thus, the disparity in excess risk estimates presented in Table IV may be attributed primarily to the different functional forms (i.e., shape of the sound level effect) of the fitted models. The logistic model used in this analysis assumes the existence of a plateau in risk after 10 years of exposure duration.

The analysis comparing different indicators of NIHH show that patterns of excess risk as a function of average daily sound level depend on age. Differences in excess risk were nominal for the 1–4 kHz average, irrespective of whether HTLs were weighted by the frequency-specific articulation indexes. These differing results by age may be attributable to the fact that the effect of aging on risk of hearing handicap may overshadow any incremental increases in excess risk due to noise exposure. In the upper range of duration and sound level, the dose-response curve shows signs of a plateau effect. The analysis also suggests that the effect of sound intensity and duration of exposure is dependent on frequency. Hearing damage at 3 and 4 kHz is expected to occur sooner than loss at lower frequencies (0.5, 1, or 2 kHz). Definitions that exclude the higher frequencies tend to be less sensitive to noise damage and may require longer durations of exposure to a given sound level to see significant excess risks in the population.

Figure 4A and B suggests that the most suitable definition of hearing handicap may depend on the population characteristics, such as age, exposure duration, and degree of hearing handicap already accrued, as well as whether one chooses to identify preclinical or later stages of hearing handicap. The addition of the most sensitive frequencies to a hearing handicap definition is a valid option if the goal is to have a measure that addresses both prevention and identification of hearing handicap.

A. Data limitations

The cross-sectional design of this study presented limitations for estimating the risk of noise-induced hearing handicap. For example, the 8-hour TWA sound levels, L_{NE}, were determined at one point in time and are assumed to be representative of exposure over the entire length of an employee's job experience. This may have introduced a substantial source of error in the estimation of L_{NE}. As a means of reducing this error, the screened ONHS population included only workers who remained in the same job for the entire time that they worked at the study facility. These workers were then assigned an 8-hour TWA sound level based on noise measurements and job activities at the time of the survey. It is possible that larger errors in estimating 8-hour TWA sound levels over a long period of time may have occurred for workers with longer durations of exposure. It is also possible that the workers with long durations included in this study represented a population which may have been less sensitive to the adverse effects of noise on hearing. This may have contributed to the observed decrease in risk with increasing sound level, L_{NE}, for durations greater than 20 years. Hence, the cross-sectional design of the survey introduces areas of concern for predicting NIHH risks over a working lifetime.

B. Modeling caveats

The data limitations described above also placed limitations on the modeling approach and interpretations presented in this paper. One data limitation with implications for modeling the risk of noise-induced hearing handicap, was the lack of information on the distribution of 8-hour TWA sound levels among the control population. This is a crucial omission because all excess risk estimates depend on the risk of handicap among workers with low levels of occupational noise exposure (in this study, defined as exposure to sound levels less than 80 dB).

Due to this lack of data, a very simplistic assumption was made: sound levels in the control population could be represented by a single number. This is problematic in terms of model interpretation. First, it ignores the possibility that there may be a distribution of sound levels below 80 dB for this population. Second, this assumption results in a model that implies that the estimated value (L_0) is a threshold sound level at which no excess risk of noise-induced hearing handicap is predicted regardless of the duration of exposure. Hence, the statistical criteria used in model development are valid only if all of the controls were below a defined threshold.

These modeling issues underscore the fact that all models are likely to be dependent on assumptions used to account for uncertainty in the available data. This analysis did not model hearing threshold levels as a continuous variable. Therefore, calculation of NIPTS using these models are not possible. The analysis also did not extensively explore other possible shapes for the sound level function other than $(L_{NE}-L_0)^{\phi}$. Furthermore, modeling exposure duration as a categorical variable limits finer examination of the relationship of duration of exposure on risk of hearing handicap.

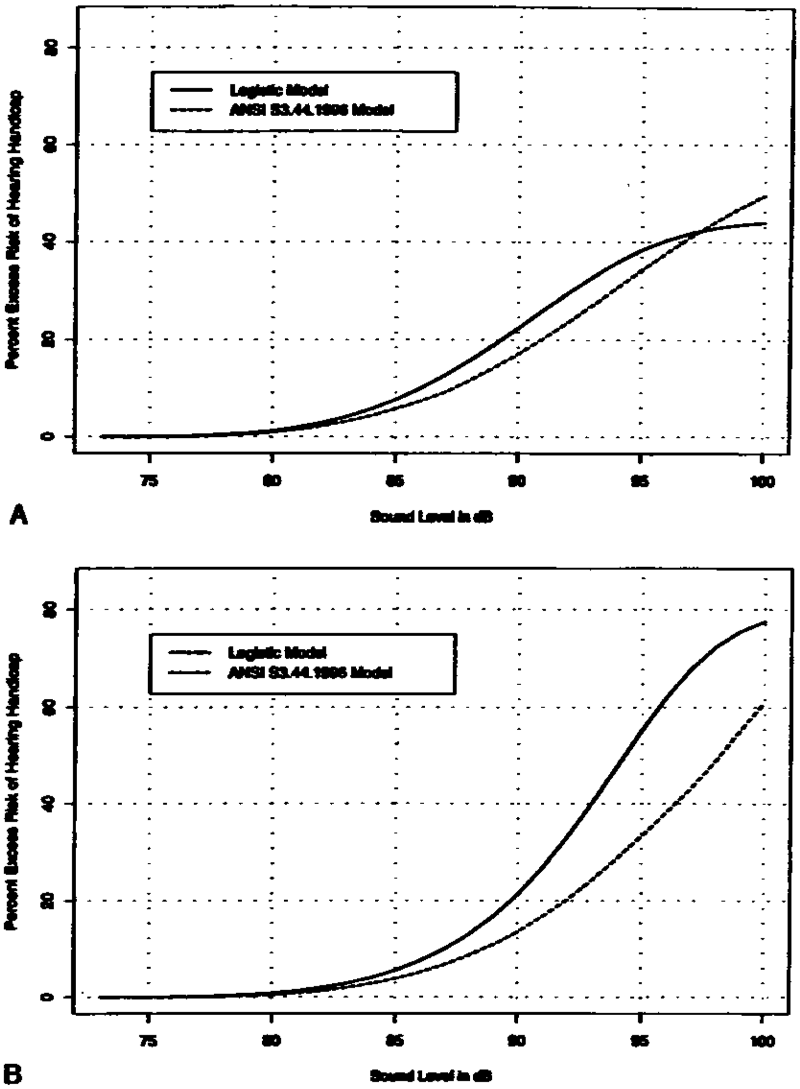

FIG. 5. Excess risk (AI-weighting, 1–4 kHz) as a function of sound level (L_{eq8}) according to model 4 (Table IV), in comparison with curves derived from ANSI S3.44.1996 using Annex A database. Panel A: age 65 years, exposure duration 45 years. Panel B: age 45 years, exposure duration 25 years.

The models described in this paper were developed on the basis of this particular data set. Inferences based on the ONHS data set are also limited by its cross-sectional nature and the fact that exposure data was absent for the control population exposed to 8-hour TWA sound levels below 80 dB. As a result, the use of this model for other data sets with differing characteristics and different methods of data collection would not necessarily provide similar results.

C. Comparison of new risk estimates to ANSI S3.44

Given this updated analysis of the NIOSH (1972) data, it is of interest to compare these results to estimates generated using methodology developed by the International Standards Organization (ISO 1971, 1990), which was adopted in the ANSI S3.44 standard (ANSI, 1996). This standard was issued to provide a more accurate and more generalized model of the relationship between NIPTS and occupational noise exposure for people at different ages and duration of exposure. ANSI S3.44 (ANSI, 1996) provides mathematical procedures for estimating hearing handicap due to noise exposure for populations free from auditory impairment (other than that due to noise).

The data from studies by Passchier-Vermeer (1968) and by Burns and Robinson (1970) are the basis of the ANSI S3.44 (ANSI, 1996) standard for estimating NIPTS. As with the NIOSH (1972) study, most of the noise-exposed workers were exposed to daily noise levels ranging from 85 to 95 dB.

The Passchier-Vermeer (1968) and Robinson (1970) models are represented by different mathematical equations which include an aging (non-noise) component in dB and a NIPTS component in dB. For each model, the equation for NIPTS was determined by age correcting the noise-exposed workers' hearing threshold levels to get the NIPTS component. An empirical equation was developed for NIPTS in terms of noise level and exposure time. For each model, the aging and NIPTS components were combined to compute total hearing threshold level in dB (ANSI, 1996). A simple arithmetic average of the NIPTS values of Passchier-Vermeer and Robinson are used to predict NIPTS for ANSI

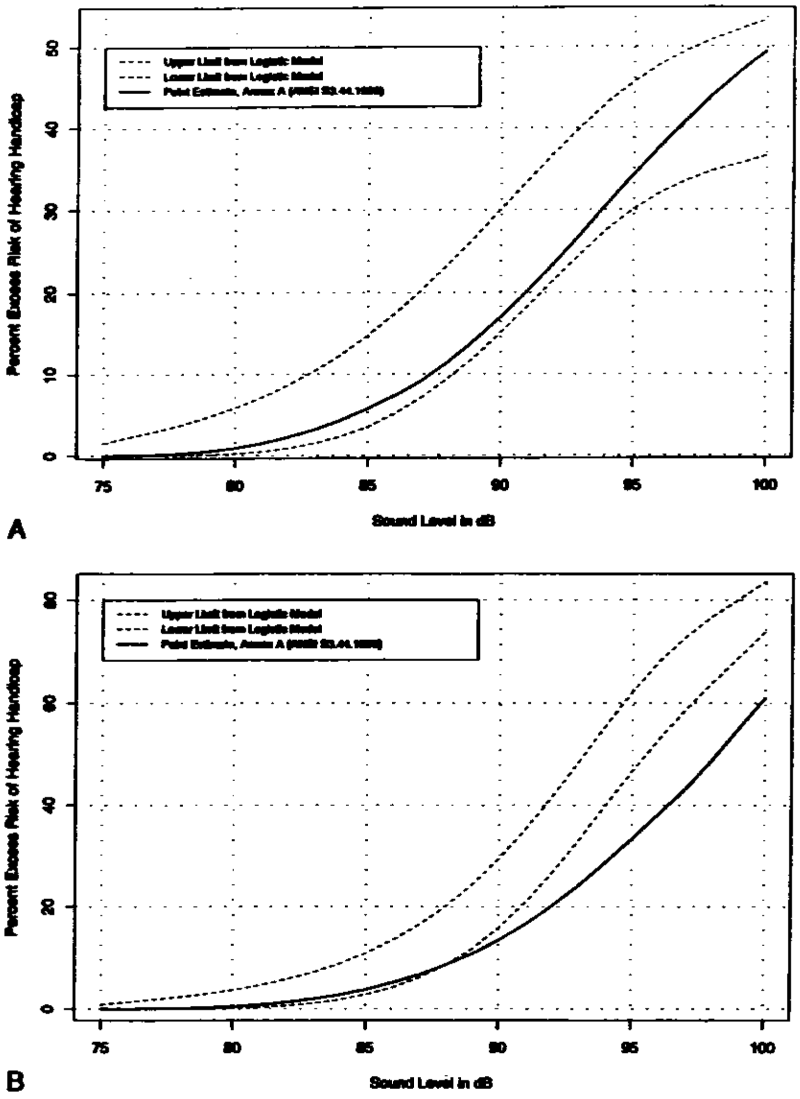

FIG. 6. Bootstrap-based 90% lower and upper confidence limits for excess risk (AI-weighting, 1–4 kHz) as a function of sound level (L_{NE}) according to model 4 (Table IV), in comparison with curves derived from ANSI S3.44.1996 using Annex A database. Panel A: age 65 years, exposure duration 45 years. Panel B: age 45 years, exposure duration 25 years.

S3.44 (ANSI, 1996). Johnson (1978) provides the methodology used to develop risk percent calculations using the percentage of the population expected to exceed a specific hearing threshold level (e.g., 25 dB) for a given population.

The excess risks generated from our analysis of the 1–4 kHz AI definition are compared to excess risk estimates generated using the ANSI S3.44 (ANSI, 1996) methodology and Annex A as the unexposed population. Annex A was chosen over Annex B since the NIOSH study population was highly screened. Hence, the Annex A highly screened control population is the most appropriate comparison to our study population. As shown in Fig. 5, excess risk estimates from our best fitting model are similar to those estimated by ANSI S3.44 (ANSI, 1996) for workers aged 65 years with 45 years of exposure. However, among workers aged 45 years with 25 years of exposure, excess risk estimates at sound levels greater than 90 dB are higher for this analysis as compared to ANSI S3.44 (ANSI, 1996). These results particularly in the range of 80–90 dB are not surprising given the similarities in study design, data collection and time period for all of these studies. Although these are qualitative comparisons, the differences in estimates of lifetime excess risk between ANSI S3.44 (ANSI, 1996) and this analysis do not appear to be substantial. This is illustrated in Fig. 6, which shows that excess risk estimates generated from ANSI S3.44 are located between the bootstrap-based 90% upper and lower confidence limits from the best fitting logistic model. At age 45 years and 25 years of exposure, excess risk estimates below 89 dB are within the lower bound of the confidence limits from the logistic model. Thereafter, point estimates from ANSI S3.44 are found to be lower, particularly at sound levels greater than 92 dB.

For other definitions of hearing handicap (0.5–2 kHz and 1–3 kHz), ANSI S3.44 estimates of excess risk are considerably lower at 85 dB for workers aged 65 years with 25 years of exposure. For the 0.5–2 kHz definition, excess risks at 85 dB from our logistic model and ANSI S3.44 (ANSI, 1996) are 12% and 1%, respectively. For the 1–3 kHz definition, the values are 16% for our model and 4% using ANSI S3.44 (ANSI, 1996) methods. At 80 dB, ANSI S3.44 generates excess risks of 0% for both definitions, while estimates from this analysis are 5% and 6% for the 0.5–2 kHz and 1–3 kHz definitions, respectively. Some of the divergent results may be due to differences in population characteristics of the studies used to generate excess risks. The NIOSH data set represented a heterogeneous population of workers from a variety of geographic regions and worksites within the United States. The study populations used to develop the ANSI S3.44 (ANSI, 1996) models were likely to be more homogeneous with respect to industry, demographic and socioeconomic (e.g., access to medical care) characteristics.

D. Future directions and data needs

This analysis indicates a need to collect and analyze data from populations exposed to noise at sound levels below 85 dB to learn more about the shape of the dose-response relationship below 85 dB. Like similar studies conducted in the late 1960 and early 1970's, the screened ONHS data set had few subjects with exposures at levels below 85 dB. This contributed to a high degree of instability in the risk estimates as the modeling assumptions were varied. Although logistic modeling techniques were used in this analysis, other methods for evaluating excess risks can reasonably be applied to these data. Nonetheless, it seems plausible that the observed instability below 85 dB would persist using other modeling methods. Risk estimates in the range of 88–95 dB are probably more reliable than the estimates for the lower ranges of sound level. More recent longitudinal data sets may be useful in examining risk below 85 dB. To examine whether noise-induced hearing handicap remains a problem for workers enrolled in OSHA-mandated hearing conservation programs (Department of Labor, 1981a,1981b), we are currently examining appropriate longitudinal audiometric databases. The present analysis indicates that new studies should be implemented to (1) characterize noise exposure for presumably "non-noise" or low noise populations (including populations exposed to nonoccupational sources of noise); and (2) examine dose-response relationships for noise and hearing handicap among workers exposed to noise levels below 90 dB.

ACKNOWLEDGMENTS

The authors wish to thank Dr. John Franks for his useful comments and advice in the development of this work and Barry Lempert for supplying an electronic version of the data for this analysis.

ANSI (1969). ANSI S3.5-1969, "American National Standard Methods for the Calculation of the Articulation Index (American National Standards Institute, New York).

ANSI (1996). ANSI S3.44-1996, American National Standard Determination of Occupational Noise Exposure and Estimation of Noise-Induced Hearing Impairment (American National Standards Institute, New York).

ASHA (1981). American Speech-Language-Hearing Association Task Force on the Definition of Hearing Handicap, "On the definition of hearing handicap," Asha 23, 293–297.

Baughn, W. L. (1973). "Relation between daily noise exposure and hearing loss as based on the evaluation of 6835 industrial noise exposure cases," AMRL-TR-73-53, Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio.

Breslow, N. E., and Day, N. E. (1980a). "Classical Methods of Analysis of Grouped Data," in *Statistical Methods in Cancer Research: Vol. I– The Analysis of Case-control Studies (International Agency for Research on Cancer, Lyon, France), IARC Publication No. 32, Chap. 4, pp. 140–148.*

Breslow, N. E., and Day, N. E. (1980b). "Unconditional Logistic Regression for Large Strata," in *Statistical Methods in Cancer Research: Vol. I–The Analysis of Case-control Studies* (International Agency for Research on Cancer, Lyon, France), IARC Publication No. 32, pp. 192–247.

Burns, W., and Robinson, D. W. (1970). *Hearing and Noise in Industry* (Her Majesty's Stationary Office, London).

Cohen, A. (1996). Personal communication. August 1996.

Department of Labor (1981a). 46 Fed. Reg. 11, "Occupational noise exposure; Hearing Conservation amendment, rule, and proposed rule, part III," pp. 4078–4179.

Department of Labor (1981b). "Final regulatory analysis of the hearing conservation amendment," Report number 723-860/752 1-3, U.S. Government Printing Office, Washington, D.C.

Efron, B. (1982). *The Jackknife, the Bootstrap and Other Resampling Plans (Society for Industrial and Applied Mathematics, Philadelphia, PA).*

Efron, B., and Tibshirani, R. (1986). "Bootstrap methods for standard errors, confidence intervals, and other measures of Statistical Accuracy." Stat. Sci. 1(1), 54–77.

Federal Register (1974). "Environmental Protection Agency comments on Proposed OSHA Occupational Noise Exposure Regulation," Vol. 39, No. 244, pp. 43802–43809.

Fienberg, S. E. (1987). *The Analysis of Cross-Classified Categorical Data* (MIT, Cambridge, MA).

ISO 1999 (1971). "Assessment of occupational noise exposure for hearing conservation purposes," First Edition, International Organization for Standardization, ISO/R 1999–1971.

ISO 1999 (1990). "Acoustics—Determination of occupational noise exposure and estimation of noise-induced hearing impairment," International Organization for Standardization.

Johnson, D. L. (1978). "Derivation of presbycusis and noise induced permanent threshold shift (NIPTS) to be used for the basis of a standard on the effects of noise on hearing," AMRL-TR-78-128, Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio.

Lempert, B. L., and Henderson, T. L. (1973). "Occupational Noise and Hearing 1968 to 1972: A NIOSH Study," U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, Division of Laboratories and Criteria Development, Cincinnati, OH.

NCHS (National Center for Health Statistics) (1965). "Hearing Levels of Adults by Age and Sex, United States, 1960–72," Vital and Health Statistics, Public Health Service Publication No. 1000-Series 11-Np. 11, U.S. Government Printing Office, Washington, D.C.

NIOSH (1972). "NIOSH criteria for a recommended standard: occupational exposure to noise," Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHSS(NIOSH) Publication No. HIM 73-11001.

Passchier-Vermeer, W. (1968). "Hearing loss due to exposure to steady-state broadband noise," Report No. 35 and Supplement to Report No. 35, Institute for Public Health Engineering, The Netherlands.

Robinson, D. W. (1970). "Relations between hearing loss and noise exposure," in *Hearing and Noise in Industry*, edited by W. Burns and D. W. Robinson (Her Majesty's Stationary Office, London), pp. 100–151.

Robinson, D. W., and Sutton, G. O. (1975). "A comparative analysis of data on the relation of pure-tone audiometric thresholds to age," NPL Acoustics Report AC84, England, April 1978.

Royster, L. H., and Thomas, W. G. (1979). "Age effect hearing levels for a white non-industrial noise exposed population (NINEP) and their use in evaluating hearing conservation programs," Am. Ind. Hyg. Assoc. J. **40**, 504–511.

SAS Institute, Inc. (1989). "SAS/STAT User's Guide," Version 6, Fourth Edition Volume 2. SAS Institute, Cary, NC, pp. 1071–1125, pp. 1135–1193.

Statistical Sciences, Inc. (1993). *S-PLUS for Windows Users Manual, Version 3.1* (Statistical Science Inc., Seattle).

Ward, W. D., and Glorig, A. (1975). "Protocol of inter-industry noise study," J. Occup. Med. **17**(12), 760–770.

Yerg, R. A., Sataloff, J., Glorig, A., and Menduke, H. (1978). "Inter-industry noise study," J. Occup. Med. **20**(5), 351–358.

*U.S. Government Printing Office: 1998 - 652-939