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Abstract:
During the grant period, a large audiometric data set was analyzed to determine whether risk factors for noise induced hearing loss could be identified among the employees. Originally, the data set from one aluminum smelter was analyzed. Later, the analysis was expanded to other Alcoa audiometric sets. Linkage was made with an industrial hygiene data set to improve noise exposure assessments. The annual rate of hearing loss in employees was calculated, and this was compared with other metrics of hearing loss, such as the proposed ANSI standard for evaluation of hearing conservation program effectiveness. Progress occurred on the development of an audiometric case definition; a board of experts was convened, and these experts performed analysis on a set of audiograms. Risk factors for noise induced hearing loss were evaluated through both a case-control and a prospective approach using a cox-proportional hazards model.

Publications
Rabinowitz PM: Noise-Induced Hearing Loss. American Family Physican, Vol 61:9 2749-2756, 2000

Rabinowitz PM, Sparer J: Noise-Induced Hearing Loss. Occupational Airways, 6:2 2-4

FINAL PERFORMANCE REPORT

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IDENTIFYING RISK FACTORS FOR NOISE INDUCED HEARING LOSS

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Abstract:

This report describes research on the audiometric data set of Alcoa which the principal investigator has carried out with funding from a KO1 SERCA between 1998 and 2001. During the grant period, a large audiometric data set was analyzed to determine whether risk factors for noise induced hearing loss could be identified among the employees. Originally, the data set from one aluminum smelter was analyzed. Later, the analysis was expanded to other Alcoa audiometric sets. Linkage was made with an industrial hygiene data set to improve noise exposure assessments. The annual rate of hearing loss in employees was calculated, and this was compared with other metrics of hearing loss, such as the proposed ANSI standard for evaluation of hearing conservation program effectiveness. Progress occurred on the development of an audiometric case definition; a board of experts was convened, and these experts performed analysis on a set of audiograms. Risk factors for noise induced hearing loss were evaluated through both a case-control and a prospective approach using a cox-proportional hazards model.

Significant Findings with Respect to Specific Aims:

Aim 1a: Determine the rate of noise-induced hearing loss occurring at the study site, using the method currently employed at the study site (age corrected rate of OSHA standard threhold shifts)

Previous analysis of the Alcoa data set has indicated that a significant amount of hearing loss is occurring in the worker population.

In 1990, it was noted that at one aluminum smelter, among individuals working in noise levels greater than or equal to 85 dBA, 22% had hearing impairment by AMA criteria (threshold average of at least 25dB at the frequencies of 500, 1000, 2000, and 3000 Hz). Reducing the rate of new cases of hearing loss is one of the health and safety priorities for the company.

Using the OHM Audiometric database (see above) annual rates of Standard Threshold Shifts (OSHA STS); i.e. change in average hearing thresholds of 10dB from baseline at 2000,3000, and 4000 Hz, were calculated for one of the Alcoa aluminum smelters. At this smelter, approximately 1000 workers were in the hearing conservation program.

Methods:

The audiometric files from the OHM medical surveillance database were exported to SAS. A program was written to choose the best of initial audiograms as a reference baseline. Subsequent audiograms for each individual were used to calculate shifts in hearing thresholds from baseline. A standard threshold shift was defined as a 10dB shift in audiometric average at 2000, 3000 and 4000 Hz in either ear on two subsequent tests.

Results:

Table 1: Annual Rates of Standard Threshold Shifts in Hearing at an Alcoa Aluminum Smelter

Year	**Rate of Noise Exposed Workers Showing A Standard Threshold Shift (STS)**
1988	7.8%
1989	14.5%
1990	8.6%
1991	5.88%

1992	7.89%
1993	9.25%
1994	7.51%
1995	9.19%
1996	7.38%
1997	5.96%

The results of these studies have been shared with management at Alcoa. There is an ongoing effort in the company, resulting in part from such data collection, to further reduce hearing loss through improved engineering controls and training of workers in proper use of PPE. It is hoped that these efforts will lead to decreased hearing loss occurring in the workforce.

At the same time, these data indicate that despite hearing conservation measures, a significant amount of hearing loss has occurred in the recent past among Alcoa workers exposed to noise.

Aim 1b: Compare this measure to rates of several other potentially more sensitive outcome measures of noise-induced hearing loss as well as draft standards of the American National Standards Institute for the evaluation of hearing conservation program effectiveness.

Research into this aim is summarized in the attached poster presentation: **Applications of Draft ANSI S12.13 (Evaluating the Effectiveness of Hearing Conservation Programs) to an Audiometric Database: Issues of Choosing a Restricted Population (Rabinowitz PM, Dixon-Ernst C).** A key finding of this research was that the draft ANSI measures were very sensitive to choice of reference population. Recommendations were made for guidelines for the draft measures.

Aim 2a.
Improve exposure assessments through a plant visit and review of company records.

After reviewing noise exposure records in the audiometric data set, it was found that the range of recorded noise exposures was restricted, possibly due to the fact that it was being used for medical surveillance purposes, not research. Therefore, the focus shifted to analyzing an entirely separate data set of industrial hygiene measurements maintained by the company. These measurements were felt to have the most accurate readings of noise exposures.

Records of noise exposure measurements appearing in the Hygenius database were examined to determine the frequency and distribution of recorded noise exposures. Table

4 shows the distribution of the 90th percentile for noise measurements for different Similar Exposure Groups (SEGS). As Table 4 demonstrates, approximately 180 SEGs have noise measurements where the 90th percentile is equal to or exceeds 85dBA.

Temporal trends in noise exposures:
A preliminary analysis of a number of SEGS where noise exposures exceeded 85dBA indicates that over the past 15 years, there has not been a significant change in noise levels.

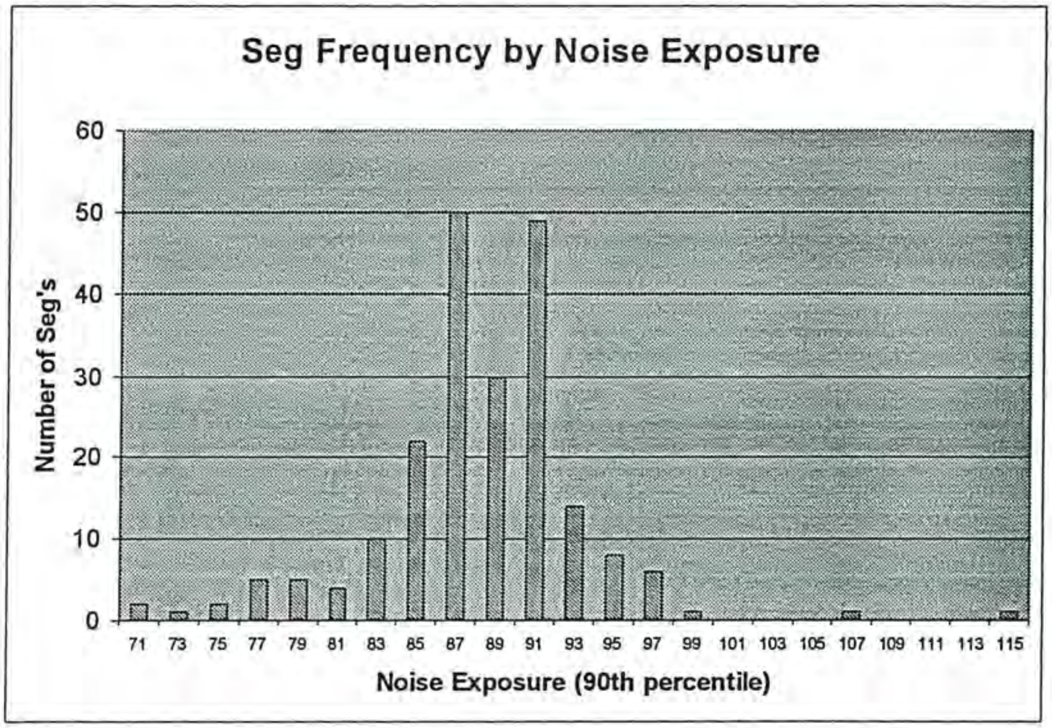

Figure 1. Noise Exposures (90th percentile) and Number of SEGS* Exposed
*note: SEG=Similar Exposure Group; multiple persons exposed in each SEG

In summary, it appears that a large number of exposure groups are exposed to noise levels exceeding 85dBA, and that these exposures have been continuing during the past 20 years. The results of these preliminary analyses have been shared with the company, and have led to increased efforts to reduce exposures. At the same time, these data indicate that the Alcoa database is a reasonable place to explore historical exposures to noise and their impact on hearing loss.

Aim 2b: Identify Risk Factors at pre-placement for loss of hearing during the first five years of employment using a nested case control design.

This research is summarized in the poster presentation: **Predictors of Hearing Loss in A Noise- Exposed Population** (see attached). An association between noise induced hearing loss and older age and worse hearing at baseline was found. Cases were more likely than controls to complain of difficulty hearing at baseline. There was no excess risk associated with reporting history of hunting, shooting, or a previous job in noise.

Aim 2c: Assess the relative importance of these risk factors through a longitudinal cohort study.
Aim 2d: Test the risk factor estimate in the larger data set.

Work on these aims was delayed by the need for better noise exposure assessment data, which was eventually achieved using the Hygenius data base. Linkage between the data sets was necessary to accomplish this. A Cox-proportional hazards model has now been constructed, and results are expected soon.

Aim 3a: Identify early audiogram changes for individuals during the first five years of employment which predict risk of hearing loss over the next ten years through a nested case control design.
Aim 3b: Assess the relative validity of these indicators through a longitudinal cohort study.
Aim 3c: Test the risk factor estimate in the larger Alcoa data set.

See above: Aims 2a-d. Audiometric evidence of hearing loss at baseline was associated with a risk of hearing loss later in employment.

Aim 4a. Develop and validate a case definition for noise-induced hearing loss based on audiometric records of an individual.
Aim 4b: Correlate the case definition with expert diagnosis of audiograms in order to create a case definition with optimal sensitivity and specificity for clinically significant noise-induced hearing loss.
Aim 4c: Using this new case definition, perform a repeat analysis of the studies for rates of hearing loss, risk factors for hearing loss, and early indicators described in aims 1-3.

Work on creating a validated case definition is summarized in the attached poster presentation: **Change in audiometric configuration helps to determine whether a standard threshold shift is work-related (Dobie RA, Rabinowitz PM).** An advisory panel has been assembled and has performed preliminary analysis on a set of audiograms. Dr. Robert Dobie, a recognized expert in NIHL, and the PI have collaborated on a preliminary scoring metric for NIHL. This scoring metric is being tested in the cohort analysis now in progress.

Other publications:
During the grant period, the PI published several general papers on the topic of noise induced hearing loss. These are attached.

2. FINANCIAL STATUS REPORT

See attached.

3. EQUIPMENT INVENTORY:

No equipment was purchased under this grant.

4. FINAL INVENTION STATEMENT:

No inventions were conceived under this grant.

Applications of Proposed ANSI S12.13 to an Audiometric Database: Issues of Choosing a Restricted Population

Poster Presentation for the 1999 NHCA Conference

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ABSTRACT:

The Draft ANSI standard for the evaluation of hearing conservation effectiveness (ANSI S12.13) has not been used extensively in industry to date. With the increasing availability of computer software for managing audiometric databases, however, there is the potential for increased incorporation of the proposed ANSI measures. In this descriptive study, ANSI methods of audiometric data base analysis were applied to a data set of audiograms from workers in an aluminum smelter and lignite mine. It was found that the choice of methods used to select the restricted population for analysis had a marked effect on the percentage of audiograms "captured" for analysis each year. The restrictiveness of the selection method also appears to affect the sensitivity of the ANSI measures to detect deficiencies in the hearing conservation program. These findings highlight the importance of minimizing selection bias and maximizing sensitivity and specificity when applying the ANSI measures.

BACKGROUND:

The draft ANSI standard for evaluation of the effectiveness of hearing conservation programs (ANSI S12.13) was first published in 1991 and is currently under revision. While the standard has been widely distributed, its actual implementation in industry has been limited. There are three basic steps to applying the standards: choosing a population to study, calculating the ANSI audiometric database analysis (ADBA) measures, and using the results to assess hearing conservation program adequacy. With increasing use of computer software to manage audiometric databases, there is a potential for greater use of these methods in the future. If the ANSI standard is to be successfully employed, a consistency of application will be necessary if results are to be compared between programs. This paper will explore issues related to the choice of "restricted population" which were faced by the investigators in applying the draft standard to a relatively large audiometric database.

STUDY HYPOTHESIS:

The study had the following hypotheses:

Hypothesis 1. The current ANSI ADBA standard provides considerable flexibility in terms of the choice of a restricted population.

Hypothesis 2. Using different methods to choose the restricted population could produce different results in terms of both the size of the restricted population and the magnitude of ANSI measures.

METHODS OF SELECTION IN THE PROPOSED REVISIONS TO ANSI S12.13:

The proposed revisions to the ANSI standard (ANSI S12.13-199X) give the following guidelines for selecting a restricted population for analysis. (Note: these revised guidelines differ in several ways from the original published standard).
In section 1.3.2.2 (Constant Restricted Population), the revised standard stipulates that the user must restrict the population to a constant group, consisting of the same individuals. In 1.3.2.3, the minimum number of audiograms for the restricted population is defined as two or greater.

In 1.3.2.4 (Representative Restricted Population), it is stated that ideally the restricted population should include all employees who have received the minimum number of audiograms, but if it is necessary to reduce the size of the group for analysis, the selected group should be representative of the total.

In 1.3.2.5, a minimum of 30 persons per restricted group is suggested.

In 5.1 (Selecting the restricted database) the standard states that the evaluator must keep audiograms from the same years together, restricting the database to those employees whose desired audiogram occurred in the same year. Section 5.1 also states that the restricted database must have constant group membership, without dropouts or new employees added. Only 1 audiogram per year should be included in the data base. In 5.11, the standard states that the data base should be restricted to the largest number of employees who have received the maximum number of annual audiograms all beginning in the same calendar year, with the latest audiogram occurring in the most recent year of testing.

In 5.1.2, the standard revision says that if the data set has many years of data available, the evaluator can "decide what type of restricted database can yield the desired information. It might be appropriate to restrict the data base to the first N tests for all employees with at least N annual tests (8 or 10 for example) and whose first test was in a selected year." 5.1.2 also states that for an HCP with a very large number of audiograms, the evaluator might want to consider only the most recent few years of data for all employees with at least N tests, providing the first of the most recent tests is 4 or higher. This allows for some "lumping" of later test sequential tests together. In summary, although some general guidelines for selection of a restricted population are given, there is considerable room for interpretation of these guidelines.

DESCRIPTION OF DATABASE ANALYZED:

ALCOA has maintained audiometric records for employees in their US facilities for approximately 40 years. For the purposes of this study, the audiometric data from one aluminum smelting facility was chosen. The collection of audiometric data has been under the direction of a single company audiologist for the past 15 years. The database begins in 1958, although regular follow-up testing did not begin until 1979. In 1988, workers in an adjacent lignite (coal) mine were added to the database. For the purposed of this study, only audiograms coded as being performed on employees working in noise (N=4701) were included.

STUDY METHODS:

A SAS computer program was written to analyze the dataset, which had unique identifiers removed for confidentiality. The SAS program allowed the investigators to apply ANSI measures of hearing conservation effectiveness by individual year. The revised Draft ANSI standard for hearing conservation effectiveness (Proposed ANSI S12.13-199X) was used to select a restricted population. Using the general guidelines as stated above, three different methods were used to choose the restricted population.

Method I: Only Employees with Annual Tests (Most Restrictive Method)
This method used some of the most restrictive options to select a population:
1. Only the first test each year for an individual was retained for analysis (Section 5.1: "only one audiogram per year per employee should be included..."
2. For each year of analysis, a search was made for employees who had had annual audiograms each year, with the final audiogram during the year of analysis. For example, for the year 1985, eligible employees would include those with a first audiogram in 1981, second in 1982, third in 1983, fourth in 1984, and fifth in 1985. It would also include those with a first audiogram in 1982, second in 1983, third in 1984, etc.

Method II: Only Employees with two tests in the past two years. (Moderately Restrictive Method)
1. For each year of the study, any employee who had had tests on two consecutive years (with the second of the two consecutive tests occurring during the year of analysis) was counted. For example, in 1985 this would include people with the second test in 1985 and the first in 1984 (1-2 sequential), as well as those with the third test in 1985 and the

second in 1984(2-3 sequential), etc., regardless of whether their tests prior to the last two years had been on an annual basis.

Method III: All Employees with N tests, Most Recent Test in Year of Analysis, Maximum Average Between Tests 2 Years (Least Restrictive Method)
For this method, an employee was eligible for analysis if the most recent test occurred during the year of analysis, and the employee had had at least N tests in 2N years. For example, in 1985, an employee was eligible if he had the third test in 1985, and at least 3 tests in the past six years.

For each of the three methods described, the total number of audiograms eligible for analysis each year in each test sequential (from 1-2 to 9-10) was calculated. This was divided by the total number of audiograms performed on noise-exposed employees that year to give a "percentage of follow-up audiograms captured" by each method.

For the year 1995, the restricted populations chosen by the three methods were used to calculate ANSI measures of hearing conservation program adequacy, and the magnitude of the measures compared between methods.

RESULTS:

Year	# Tests in Noise	%Capt-ured (Method I)	%Capt-ured (Method II)	%Capt-ured (Method III)
1985	82	11%	13.4%	20.7%
1986	56	25	30.4	32.1
1987	106	14.2	17	41.5
1988	329	7	9.4	12.8
1989	377	34.5	36.3	38.7
1990	538	32.7	35.1	50.6
1991	720	33.5	43.6	51.7
1992	645	33.2	49.1	66.8
1993	430	27.4	53.3	77.4
1994	324	22.2	67.9	81.5
1995	314	18.2	66.6	83.1
1996	293	10.2	54.3	68.9
1997	218	4.6	36.2	56.9
1998	269	5.9	25.3	53.9

TABLE I: Percent of Tests Captured, By Method

Table I shows the number of audiograms "captured" by each of the selection methods for the years 1985-1998. The number of tests performed on noise exposed employees increased in the first few years, as OSHA compliance increased and the adjacent lignite mine was added to the HCP. As expected, the most restrictive method consistently captured the fewest audiograms, and the least restrictive captured the most. Reasons for incomplete capture are related to the fact that not all employees in the hearing conservation program had annual audiograms during the years of analysis. The reasons for this could include: low compliance with annual testing on the part of employees or HCP personnel, and employees switching in an out of noise areas during their employment.

Table II shows the ANSI statistics %Worse Sequential (Ws%) and % Better Worse Sequential (BWs%) for the year 1995, using each of the three methods. In this analysis, test sequentials 1-4 were lumped together to get an "early test" sequential measure, while test sequentials 5-10 were lumped together to get a "late test" sequential measure. As this illustrates, there is a considerable difference in the magnitude of the estimates.

Statistic	**Method I**	**Method II**	**Method III**
%Captured	18.2%	66.6%	88.2%
%Worse (Test1-4)	35.3%	38.1%	42.6%
%Worse(Test5-10)	28.9%	41.1%	44.2%
BWs% (Test 5-10)	34.2%	53.4%	55.8%

Table II: ANSI Measures, 1995 Analysis, by Method

Furthermore, the most restrictive method (method I) tends to produce the lowest measure estimates, while the least restrictive method (III) consistently produces the highest measure estimates. This suggests that if optimal sensitivity to detect problems with an HCP was desired, method III would be the most sensitive method.

DISCUSSION:

In using available records to assess the health of a population or the adequacy of a health program, methods of sampling should avoid, whenever possible, sources of bias which can lead to invalid conclusions. The issue of selecting a restricted population for application of ANSI methods for evaluating the effectiveness of a hearing conservation program illustrates this dilemma. As Table I illustrates, the selection method used can result in markedly different sizes of restricted populations. While one of the assumptions of the ANSI standard is that the restricted population is representative of the entire HCP population, this assumption could be questioned if:

1. The workers in the restricted population differed by noise exposure, compliance with hearing protection, degree of pre-existing loss, and predisposition to NIHL from the rest of the population.

2. The numbers of workers to be analyzed was too small for statistical validity.
Since the larger number of audiograms "captured" would tend to minimize statistical bias, the least restrictive method would seem to be the most appropriate one to use in a population like this where compliance with annual audiograms was less than optimal.

Table II suggests that a more liberal method of choosing the restricted population would also increase the sensitivity of the ANSI measures. This would appear desirable, since a major purpose of audiometric database analysis is to flag an unacceptable program before significant hearing loss occurs in the workers.

CONCLUSION:

The current proposed revisions to the Draft ANSI standard for Evaluation of HCP effectiveness (ANSI S12.13) provide considerable flexibility in choosing the restricted population for analysis. As this descriptive study indicates, the choice of method for choosing the population could influence the size of the population and the magnitude of the ANSI measures. If the ANSI measures begin to be incorporated into software programs for use by hearing conservation professionals, a uniform method of population selection will maximize comparability of measures between programs, as well as the sensitivity and specificity of the measures. This paper suggests that the least restrictive methods of choosing a study population may result in the greatest sensitivity to flag ineffective hearing conservation programs.

Predictors of Hearing Loss in a Noise Exposed Population: Preliminary Results of a Case Control Study

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Abstract:

Susceptibility to noise-induced hearing loss varies between individuals and remains poorly understood. If risk factors for subsequent hearing loss could be identified at the time of employment, hearing conservation programs could be more effective. This study looked at longitudinal audiometric data from an aluminum smelter where a hearing conservation program has been in place since the 1960's. 106 cases of individuals developing a confirmed OSHA Standard Threshold Shift during their first fifteen years of employment were compared to 225 controls with similar noise exposures who did not exhibit significant threshold shifts over the same duration of follow-up.

The average age at the time of hire was slightly greater for cases compared to controls. Average initial hearing thresholds at 2000, 3000 and 4000 Hz were higher for cases than controls with the difference being more significant in the left ear. No significant difference in risk was associated with race or sex, although the number of females in the sample was small.

Odds ratios were calculated for risk factors identified by questionnaire at the time of initial testing. Compared to controls, cases were more likely to have complained of difficulty hearing at their first exam. There was no significant risk associated with hunting or shooting, or a previous job in noise.

Introduction:

In industrial settings where engineering controls cannot completely eliminate significant noise exposure, workers are at risk of noise-induced hearing loss. Despite a hearing conservation program being in place, certain workers may show an accelerated pattern of hearing loss due to noise. It has been observed that in apparently similar exposure situations, some individuals lose more hearing than others due to noise. Presumably this represents an interaction of noise exposure, compliance in use of hearing protection, function of hearing protection devices, other concomitant exposures and individual differences in susceptibility. In this way, noise-induced hearing loss appears to resemble other chronic diseases such as cardiovascular disease which have multifactorial causes, some environmental, some genetic and behavioral. Despite the prevalence of noise-induced hearing loss, the relative importance of these factors remains poorly understood. While damage-risk criteria for environmental noise exposures have been extensively investigated, the role of host factors such as age, sex, race, hereditary predispostion and underlying disease remains controversial. If risk factors for increased susceptibility to subsequent hearing loss could be identified at the time of hire or early in employment, it would enhance the efforts of hearing conservation personnel in prevention of noise-induced hearing loss.

In this study, the audiometric records of an aluminum smelter where cases of noise-induced hearing loss have occurred are being reviewed as part of an ongoing effort to maximize the effectiveness of the hearing conservation program at the plant. This review of cases has provided an opportunity to characterize individual risk factors for noise-induced hearing loss at the study site.

Methods:

Description of the Database:

The audiometric database used in this study consists of the computerized results of periodic audiograms performed on workers at the smelter as part of the plant's hearing conservation program. At present, the database consists of over 24,000 observations on over 2000 individuals recorded over a thirty year period. At the time of testing, hearing thresholds are recorded for each ear, and the employee completes a questionnaire asking about hearing symptoms as well as non-occupational exposures, medications, and medical diseases predisposing to hearing loss. The results of an otological examination for structural abnormalities is also included in the computerized record, as are the most recent sound levels recorded for the employee's work station and the type of hearing protection worn.

Definition of the Exposed Population- Selection Criteria:

For this study, cases were identified from the population of smelter workers who had had at least 3 audiograms over a fifteen year period, and whose minimum time between date of service and most recent test was eight years. At least one of the tests must have been done during the first five years of employment. To be considered a noise-exposed employee, an individual must have had a recorded exposure, as noted in the audiometric records at the time of testing, of at least 85 dB, as well as an average exposure over the first fifteen years of employment of at least 82dB.

Case Definition:

A case was defined as an individual who, on two consecutive occasions, had a documented average shift from baseline, in either ear, of at least 10dB at frequencies of 2000, 3000 and 4000 Hz (confirmed OSHA Standard Threshold Shift). The baseline was determined to be the average of the first three tests performed in the first five years of employment, in order to account for test variability and the "learning effect" which has been seen in audiometric databases.

Definition of Controls:

Controls were defined as individuals who during a similar period of follow-up never experienced even one 10dB average threshold shift from baseline at 2000, 3000 and 4000 Hz.

Variables Studied:

Demographic information regarding age, sex and race, noted at the time of the initial medical examination, was compared between groups. The mean exposure for an individual over the study period, as well as the initial average of hearing thresholds at 2000, 3000 and 4000 Hz, were also compared.

Responses to the detailed questionnaire regarding hearing difficulties, as well as non-occupational and medical risks, were also compared for cases and controls.

Statistical Analysis:

All data were analyzed using SAS software. For this preliminary data analysis, mean noise exposures, age at time of hire, hearing thresholds at time of initial testing, and average duration of follow-up were compared between groups using t-tests for significance. The frequency of responses to questionnaire items was compared using Chi-square and Odds Ratios.

Results:

Using the selection criteria described above, 106 cases and 225 controls were identified.

Variable	Cases	Controls	Significance
Sex:			
Male	105 (99.1%)	215 (95.6%)	p=.19
Female	1 (0.9%)	10 (4.4%)	
total:	106 (100.0%)	225 (100.0%)	
Race:			
White	69 (65.1%)	137 (60.9%)	p=.27
Black	21 (19.8%)	62 (27.6%)	
Hispanic	16 (15.1%)	26 (11.5%)	
total:	106 (100.0%)	225 (100.0%)	
Average age at time of hire:	28.5 years	27.3 years	p=.047

Table 1: Demographic Variables

Table 1 lists demographic characteristics of the two groups. Only 11 females were present in the sample, and the increased risk of hearing loss associated with male sex was not statistically significant. Race was also not significantly associated with the risk of hearing loss. Although cases were more likely to be White or Hispanic and less likely to be Black compared to controls, this difference was also not statistically significant. The average age of cases at the time of hire was greater than that of the controls, and this difference was significant at the 95% confidence level.

Variable	Cases	Controls	Significance
Initial average hearing threshold at 2,3,4 KHz:			
Left Ear	20.1dB	17.2dB	p=.04
Right Ear	16.9dB	15.6dB	p=.06
Time from date of hire to most recent test	13.6 years	13.2years	p=.30
Mean noise exposure	84.9dB	84.9dB	p=.31

Table 2: Exposure Variables and Initial Hearing Levels:

Table 2 compares duration of exposure, level of exposure and hearing levels on the first test for both cases and controls. There was no significant difference between the groups in duration of exposure or mean exposure during the study period. However, hearing threshold averages at 2000, 3000 and 4000 Hz were greater for cases than controls, with the difference being more significant in the left ear.

Item	**Cases**	**Controls**	**Odds Ratio (Confidence Interval)**	**Significance**
Do you have difficulty hearing? Yes No	 12 (11.3%) 94 (88.7%)	 3 (1.3%) 222(98.7%)	9.4 (3.2-27.9)	p=.001
Do you hunt or shoot? Yes No	 8 (7.6%) 98 (92.4)	 24 (10.7%) 201(89.3%)	0.68 (.29-1.57)	p=.37
Have you previously had a noisy job? Yes No	 10(9.4%) 96 (90.6%)	 31(13.8%) 194(86.2%)	0.65 (.31-1.38)	p=0.26

Table 3: Responses to Hearing Questionnaire: Initial Test

Table 3 compares employee responses to several of the items on the initial hearing questionnaire. Cases were nine times more likely than controls to have complained of hearing difficulty at the initial examination. On the other hand, being a hunter or having previously worked in a noisy job was not associated with an increased risk of hearing loss.

Discussion:

This study was limited by relatively small numbers of cases and controls, and by its retrospective approach. At the same time, it was able to make use of the extensive information compiled on individuals in the database and to identify areas worthy of further study using a cohort design. For example, hunting and shooting as a hobby, often considered to place an individual at high risk of hearing loss, was in this study not more frequent among cases compared to controls, and in fact was associated with a decreased risk of hearing loss which was not statistically significant. The association between increased age and greater risk of loss early in employment also deserves further study.

Summary:

A case-based approach to the audiometric records of noise-exposed employees may yield useful information for hearing conservation programs. This study suggests that in the study population, older age and hearing difficulties on the first exam may be associated with an increased risk of future hearing loss during the first fifteen years of employment, while hunting as a hobby is apparently not associated with an increased risk of noise-induced loss.

CHANGE IN AUDIOMETRIC CONFIGURATION HELPS TO DETERMINE WHETHER A STANDARD THRESHOLD SHIFT IS WORK-RELATED

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ABSTRACT

As of October 2001, OSHA continues to consider a rule that would require standard threshold shifts (STSs) to be recorded on the OSHA 300 Log, unless determined not to be work-related. If this rule is implemented, determination of work-relatedness will become more important than it has been, because the number of potentially recordable shifts will rise dramatically. Audiometric configuration, especially the "noise notch," has always been an important factor in these determinations, but **change** in configuration may become even more useful. Noise-induced STSs usually demonstrate more shift for the 2, 3, 4 kHz pure-tone average (PTA-234) than for the 1, 8 kHz average (PTA-18). A notch index (PTA-234 minus PTA-18) quantitates the "notchiness" of an audiogram, and a positive change in this index suggests that an STS is noise-induced, and possibly work-related. Use of the notch index will be illustrated with examples from a hearing conservation program.

THE PROBLEM

Recording Criteria (OSHA 300 Log)

Since 1991, the Occupational Safety and Health Administration (OHSA) has required threshold shifts of 25 dB or greater, for the 2, 3, 4 kHz pure-tone average (PTA-234), to be recorded as occupational injuries or illnesses, unless determined not to be work-related. Age correction and confirmatory retests have been optional. In January 2001, OSHA announced its intention to change the recording criterion, effective one year later, to 10 dB, i.e., every standard threshold shift (STS) would be potentially recordable. In October 2001, under new leadership, OSHA announced that the effective date of this change would be postponed to January 2003, at the earliest, and that they would "continue to evaluate" the changes planned by their predecessors. Obviously, a criterion of 10 dB would result in many more recordable cases than the currently effective 25 dB criterion. Since cases recorded on the OSHA 300 Log (formerly Form 200) may be seen as failures of the hearing conservation program (HCP), employers, managers, and HCP service providers understandably wish to minimize them. Age correction, confirmatory retesting, and clinical evaluation of work-relatedness remain available under the new proposed rules, and each of these will reduce the number of shifts that need to be recorded. If the 10 dB recording criterion takes effect, all of these will become more important, but our focus in this paper is on the one that is probably least used at present: determination of work-relatedness.

While assessing the work-relatedness of 10 dB shifts has always been part of an OSHA HCP, the proposed rules would focus more attention onto the 10 dB shift audiogram. If an STS is truly due to noise exposure, it is important to recognize this and take steps to both protect the worker and reduce noise exposures. If an STS is truly not related to noise exposure, it is important to recognize this as well and take appropriate action.

Work-Relatedness

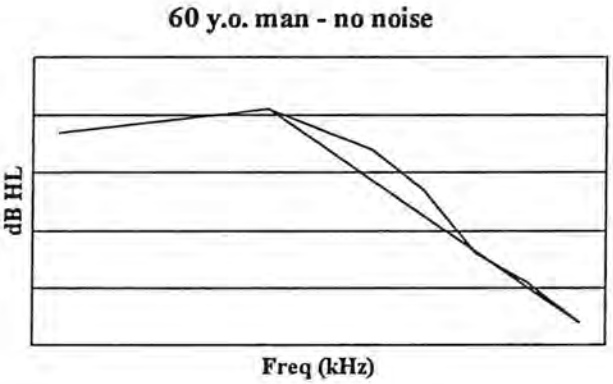
The January 2001 Rule (suspended at least until 2003) includes a special definition of work-relatedness for hearing loss: work-relatedness is presumed if noise dose is 50% or greater, but that presumption can be overturned "if a physician or other licensed health care professional determines that the hearing loss is not work-related or has not been significantly aggravated by occupational noise exposure." For other types of occupational illness and injury, a much different standard is used: "if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness," the condition is work-related. Non-work-related conditions (other than hearing loss) are those that "result **solely** from a non-work-related event or exposure that occurs outside the work environment." A plausible interpretation of the difference between the two standards is that, in cases of hearing loss, clinicians are not required to determine whether occupational noise exposure contributed to the loss, only whether it was the predominant cause. The term "significantly aggravated" modifies this simple requirement: elsewhere in the document, OSHA states that significant aggravation exists only when death, loss of consciousness, loss of work time, or medical treatment has occurred because of the change.

Most clinicians will make such judgments using different types of data, e.g., occupational and non-occupational noise exposure history, audiometric history, medical history, and, when necessary, physical examination and special tests. In this paper we discuss only one such factor: audiometric configuration and particularly changes in configuration, showing how a simple statistic derived from the pure-tone audiogram can assist in determining whether a shift is noise-induced, and thus possibly work-related.

AUDIOMETRIC CONFIGURATION

Age-Related Hearing Loss (ARHL)

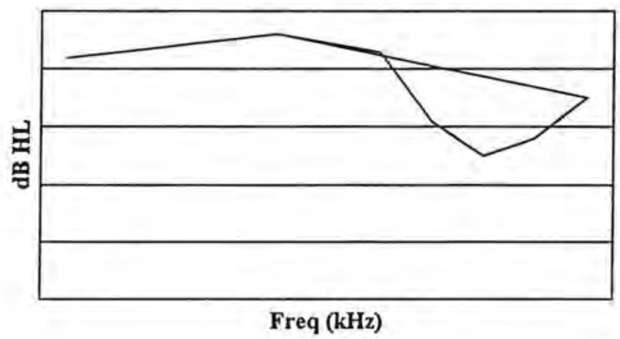
The pure-tone audiogram in "pure" ARHL (excluding people with significant noise exposure, ear infections, etc.) is usually down-sloping: the higher the frequency, the worse the threshold. Between 1 kHz and 8 kHz, the audiogram may look like a straight line going downward, but more often there is a curvature that can be described as convex upward. In other words, if you draw a straight line between the thresholds at 1 and 8 kHz, thresholds at the intervening frequencies (2, 3, 4, and 6 kHz) are likely to be above that line (as in Figure 1, below). [Figures 1 – 3 represent median audiograms (0.25 - 8 kHz, 0 – 50 dB HL) for men of different ages and durations of noise exposure, with age-related thresholds from Coles at al. (2000) and noise-induced shifts from Passchier-Vermeer (1971), combined according to ISO-1999 (1990).]



The "Notch" of Noise-Induced Hearing Loss (NIHL)

NIHL in a very young person almost always creates a notch in the audiogram, as in Figure 2 (next page). Typically, a "noise notch" means thresholds at 3, 4, or 6 kHz that are substantially worse than thresholds both at lower frequencies (0.5 and 1 kHz) and at 8 kHz (where a "recovery" is said to take place). Obviously, if we draw a line between the 1 and 8 kHz thresholds (it will be a nearly horizontal line in most young people), most of the intervening thresholds will be below that line, in sharp contrast to the pattern in ARHL. This is another way of saying that the curve is concave upward.

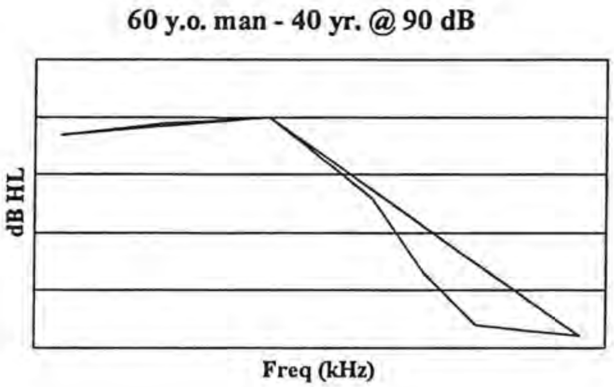
30 y.o. man - 10 yr. @ 90 dB



Despite being considered almost pathognomonic for NIHL, the noise notch has not been clearly defined. There is no currently accepted standard for describing or quantitating the "notchiness" of an audiogram. Even "experts" do not always agree: for example, McBride and Williams (2001a) recently reported that a panel of three experts agreed less than 50% of the time about whether an audiogram was notched. Meanwhile, some have tried to quantitate the presence of a notch. Methods included a parabolic approximation (Gates et al., 2000) and an algebraic curve fitting technique (Cooper and Owen, 1976).

Combination of ARHL and NIHL

In middle-aged and older people, the effects of ARHL and NIHL are often commingled. NIHL is the predominant factor early in most persons' careers, while ARHL becomes more important in later years. The notch that was apparent early on may be effaced by age-related threshold shifts, especially at 8 kHz, but the effects of NIHL may still be visible as what Coles (2000) calls an audiometric "bulge," and we have called a concavity. Even when 8 kHz is worse than all other frequencies (as in Figure 3, next page), a straight line drawn between 1 and 8 kHz may still lie above the thresholds for the intervening frequencies.



The Notch Index

A simple "notch index" (NI) can be calculated as the difference between PTA-234 and the average threshold at 1 and 8 kHz (PTA-18). When the audiogram between 1 and 8 kHz is a straight line (assuming the usual logarithmic axis for frequency), NI will be exactly zero. If the thresholds for 2, 3, and 4 kHz lie above the line connecting the 1 and 8 kHz thresholds, as is typical in ARHL, NI will be negative (NI is equal to –3.17 dB in Figure 1). If these thresholds lie below the line, as typical for NIHL, NI will be positive (NI is +7.5 dB in Figure 2). Note that a positive NI detects an audiometric bulge or concavity even when there is no recovery at 8 kHz, as in Figure 3, where NI equals +6.67 dB.

The choice of PTA-234 as the first term in the notch index could be debated. Certainly, the earliest and largest changes in NIHL occur at 3, 4, and 6 kHz, but the exclusion of 6 kHz and the inclusion of 2 kHz make sense for several reasons:

1. Thresholds at 6 kHz are both less valid and less reliable than those at lower frequencies (McBride and Williams, 2001b; Williams, 1996; Dobie, 1983);
2. Noise-induced changes at 2 kHz are both substantial and important in cases of long exposure at high levels;
3. OSHA defines STS based on 2, 3, and 4 kHz (because of reasons 1 and 2), so we already have PTA-234 calculated for us.

The choice of PTA-18 as the second term is then fairly easy; by spacing our "anchor points" exactly an octave above and below the STS region, we have the convenient result that NI describes exactly the average deviation of the audiogram (excluding 6 kHz) from the straight line connecting 1 and 8 kHz.

CHANGE IN CONFIGURATION

So far, we've seen how NI can help to diagnose the cause of a person's hearing loss, but for OSHA purposes we are asked to diagnose not the total hearing loss but the **change** in hearing. The question posed in this study is whether NI can help here, too. The thesis is a simple one: **change** in NI helps to determine whether an STS is noise-induced.

While there have been several attempts to define notches, less attention has been focused on the change in configuration between subsequent audiograms. Almost all of our understanding of the progression of the audiogram in noise-exposed individuals is extrapolated from cross-sectional studies such as Taylor's classic study of weavers. Few studies have followed noise-exposed workers longitudinally to quantitate the progression of the audiogram. Neither cross-sectional nor longitudinal studies have assessed the changes in audiometric configuration in individual subjects; rather, they have reported distributions for thresholds (or changes in thresholds) at individual audiometric frequencies.

In order to study this problem further, it would be helpful to find ways to quantitate the change in the audiometric configuration over time. One way to do this is to look at the change in NI from baseline to STS, without age-correcting the audiograms. This approach is demonstrated by looking at Figures 2 and 3, assuming they represent the same man at two points in his career (age 30 and age 60). NI has changed from 7.5 dB to 6.67 dB during this 30-year interval, during which both age and noise exposure may have contributed to his progressive hearing loss. Although NI is still positive, reflecting primarily the effects of the first 10 years of noise exposure, the negative change in NI (-0.83 dB) suggests that aging may have been the more important factor in the subsequent years. Indeed, for the databases used to construct Figures 2 and 3, the median age-related change in PTA-234, from age 30 to age 60, is 18 dB. In contrast, median change in PTA-234 attributable to the period from year 11 to year 40 of noise exposure at 90 dBA is only 3.3 dB.

The above examples represent hypothetical cases constructed from cross-sectional samples. How does a measure such as the notch index described above behave in the real world?

METHODS

From an anonymous database abstracted from an industrial hearing conservation program, 100 cases of standard threshold shift were randomly selected (50 right ear cases, 50 left ear cases). For each case, the baseline audiogram and the audiogram showing a 10 dB or greater STS were entered onto a Microsoft Excel spreadsheet (without age correction), and a graphical audiogram produced, with a standard logarithmic frequency axis. The following data were also recorded for individuals: age at time of STS, period of time between baseline and STS, sex, and estimate of industrial noise exposure (dBA). For each case, NI (PTA-234 minus PTA-18) was calculated for both the baseline and STS audiograms. A notch progression (NP) statistic was calculated by subtracting the baseline NI from the STS audiogram NI.

The STS audiograms were reviewed by two physicians with experience in the diagnosis of NIHL. Looking only at the audiograms (not at the NI scores), the reviewers scored each case as consistent or not consistent with NIHL. In a separate analysis, reviewers examined both the baseline and STS audiograms to make a judgment whether the progression of the audiogram was consistent or not consistent with causation by noise. Again, the review was performed without reference to the NI or NP scores.

RESULTS

NI values ranged from –25 to +38.3 dB, with a mean value of 9.26 dB. One reviewer scored 81% of the STS audiograms as NIHL, while the other observer scored 79% as NIHL. The two observers agreed on 90% of cases (75 NIHL, 15 not NIHL), and the kappa statistic for inter-observer agreement was 0.69 (generally considered good to very good agreement). NI was highly correlated with reviewer judgments for the 90 consensus cases: 72 out of 75 cases with NI greater than –6 dB were judged as NIHL, while 12 out of 15 cases with NI less than –6 dB were judged not to be consistent with NIHL (chi-square = 53.5, $p < 0.001$). Overall accuracy was 93% (84/90).

NP values ranged from –15.8 to 20 dB, with a mean value of 5.0 dB. One reviewer scored 65% of the changes from baseline to STS as noise-induced, while the other considered 78% to be noise-induced. There were 71 consensus cases, and the kappa statistic was 0.30 (considered fair agreement). NP was highly correlated with reviewer judgments for the 71 consensus cases: 56 out of 59 cases with NP greater than 1 dB were judged to represent noise-induced change, while 11 out of 12 cases with NP less than 1 dB were judged not to represent noise-induced change (chi-square = 57.3, $p < 0.001$). Overall accuracy was 94% (67/71).

DISCUSSION

Both NI and NP correlated well with consensus clinical judgments. Statistics like these may be helpful to clinicians making judgments of work-relatedness in at least two ways:

1. Relatively inexperienced clinicians may find quantitation of audiometric shape useful in their "learning curve" of developing clinical judgment.

2. Audiometric shape statistics may facilitate more efficient analyses of large numbers of STSs, even for more experienced clinicians. This might be especially true when results are presented in tabular rather than graphical format.

Of course, it must be emphasized that determination of work-relatedness is a complex clinical judgment often requiring the integration of multiple lines of evidence with clinical experience and judgment. Statistics like NI and NP can be at best adjunctive to that process. In particular, one must remember that a diagnosis of NIHL is not equivalent to a determination of work-relatedness; for the latter, both occupational and non-occupational exposures must be considered.

One might have expected an NI value of 0 dB to have separated the cases into those that clinicians would judge as NIHL (NI > 0) and those judged not to be NIHL (NI < 0). Instead, the best criterion value was –6 dB. There were six audiograms with negative NI values that received consensus judgments of NIHL: four of these had notches limited to 6 kHz, while two had shallow notches at 4 kHz coupled with up-sloping audiograms below 2 kHz. It is certainly possible that different methods of notch estimation would perform better; for example, a statistic defined as PTA-346 minus PTA-28 would have yielded positive values for five of these six cases. Whether this statistic (or other statistics) would have performed better than NI overall is a subject for future research.

NP, on the other hand, performed more nearly as expected: the best criterion separating consensus cases into noise-induced and non-noise-induced categories was close to zero (1 dB). Additional research should compare NP and other quantitative methods to clinical judgment, to determine the most useful statistics for measuring audiometric progression.

It would not be surprising if the best methods for notch detection and for audiometric progression used different frequency combinations or even completely different algorithms. Some of the problems in notch estimation (e.g., up-sloping audiograms in lower frequencies, notches that begin their downward slopes at different "corner" frequencies) might require the use of complex curve fitting (Gates et al., 2000; Cooper and Owen, 1976) for best agreement with clinician judgment. These problems may not be as important for estimation of audiometric progression, because we are not interested in the initial or final configuration of the audiogram, but in the change in configuration. For this purpose, simple statistics such as NP may work as well or better than more complex methods.

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