FINAL PROGRESS REPORT

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Abstract (500 words or less)

Overview:

Noise induced hearing loss remains one of the most prevalent occupational conditions in industrialized and developing countries. In many countries, workplaces have instituted hearing conservation programs (HCPs) to reduce the occupational risk of NIHL. Despite existence of checklists to assess HCP quality and effectiveness, there remains no consensus regarding how to assess effectiveness of HCPs or the most effective program components. To seek an evidence-based approach to this issue we conducted a multi-site, mixed-method assessment of HCPs.

Setting and Worker Groups:

The Hearing Conservation Effectiveness study took place in a number of manufacturing facilities involved in primary aluminum production as well as secondary aluminum fabrication. At each facility, we examined the noise exposure and hearing loss experience of the hearing conservation program.

Approaches: The study accomplished the following aims:

Aim 1: Recruit 15 manufacturing facilities willing to assess their hearing conservation programs (HCPs).

Aim 2: For each facility, perform quantitative analyses using a number of measures including test-test variability based on draft ANSI Standard S12.13, STS rates and rates of “early flag” audiometric indicators.

Aim 3: For each facility perform qualitative on-site assessments of hearing conservation components using interviews, observations and focus groups. Use these data to determine compliance scores for each HCP component and gather contextual information about each hearing conservation program.

Aim 4: Employ mixed methods to compare the quantitative measures of hearing outcomes (Aim 2) with the qualitative program assessments (Aim 3) to explore correlations among measures and observed vs. expected high frequency hearing loss (Aim 1).

In addition to these aims, we analyzed relationships between noise levels and injury, as well as noise levels and hypertension, and also analyzed the costs of different components of the hearing conservation programs.

Key Findings:

Only a few items from the manager and health professional interviews correlated with hearing loss rates. For the employee survey, management commitment to hearing loss prevention and being counseled about hearing during annual hearing testing showed a strong association with hearing loss rates, and also reflected comments from the focus groups. Some of the focus group comments regarding management commitment also correlated with hearing loss rates.

These findings indicate that while program managers are often the ones assessing HCPs, querying workers may yield greater value regarding program effectiveness. Our analysis suggests that management commitment and counseling of workers about hearing loss may be key factors in program effectiveness. A combination of qualitative and quantitative assessments appears to be useful for assessing program effectiveness. Expenditures on hearing conservation varied between sites, and expenditures on certain components such as fit testing may be relatively cost-effective.

Additionally, this study found that noise exposures were declining over time in these manufacturing facilities. We also found that the cost of hearing conservation programs was significant, but that investments in particular aspects such as fit testing may be beneficial. Finally, we found an association

between noise exposure and injury risk, but did not find significant association between noise exposure and hypertension.

Section 1 of the Final Progress Report (2-page limit)

Significant or Key Findings.

While program managers are often the ones assessing HCPs, querying workers may yield greater value regarding program effectiveness.

We found that when we modeled data from our site assessments to determine associations with facility level risk of hearing loss, what the employees said about the hearing conservation during a short survey showed greater predictive power than the responses of hearing conservation managers to program audit-type questions.

Management commitment and counseling of workers about hearing loss may be key factors in program effectiveness

In particular, locations where a high proportion of surveyed workers reported being counseled about hearing loss during audiometric testing, and locations where a high proportion of workers reported "high" or "exceptional" management commitment had lower rates of hearing loss.

A combination of qualitative and quantitative assessments appears to be useful for assessing program effectiveness.

There were some questions on the manager survey that showed some association with hearing loss rates. Asking about hearing conservation cost data was also worthwhile (see below). In general, our study supported the value of a "mixed methods" type of program assessment.

Hearing Conservation costs are important

The average expenditure on hearing conservation programs was, according to our findings, approximately $310 per person per year. We found significant variability between facilities in this per capita expenditure level, and also variability in which aspects of the program received a greater proportion of the funding. Investments in fit testing programs appeared to correlate with reduced hearing loss rates for the facility, in unadjusted models.

Hearing loss, tinnitus, and noise exposure may be risk factors for occupational injury.

We found, in analyses of Alcoa workers at a number of facilities (including some that were not included in the program effectiveness survey), that increased noise exposure was associated with an increased risk of injury. In addition, tinnitus (more than hearing loss) also appeared to be a risk factor for injury.

Ambient Noise exposure levels do not predict incident hypertension

Using the Alcoa cohort, we were able to assemble a retrospective inception cohort of workers and determine whether noise exposure was associated with an increased risk of new onset hypertension. We were unable to find any such association. However, the variable attenuation of exposure that individuals may receive from their hearing protective devices could obscure such a relationship.

Noise exposures in manufacturing may be decreasing

Using longitudinal data from the Alcoa industrial hygiene database including more than 10,000 noise measurements, we examined temporal trends in noise exposure, and found that noise exposure levels appear to be decreasing.

Translation of Findings.

This study has a number of research to practice implications.

- First, it shows the importance of systematically assessing hearing conservation program effectiveness
- Specifically it demonstrates that surveying workers is important
- Third, it demonstrates the importance of gathering quantitative and qualitative data as well as cost data.
- Fourth it supports the consideration of the cost-effectiveness of different HCP components
- It also shows the importance of including considerations of injury risk in hearing conservation, including whether the use of hearing protective devices could increase injury risk.

Research Outcomes/Impact.

This project can potentially lead to improvements in hearing conservation programs. The emphasis on management commitment and counseling of employees may also enhance workplace safety culture. It is possible that these measures could reduce costs of hearing conservation programs. There is also the possibility that enhanced hearing conservation programs that take into account the injury risk of noise exposure could lead to better prevention of occupational injury in noisy workplaces.

SCIENTIFIC REPORT: ASSESSING HEARING CONSERVATION EFFECTIVENESS

Background

<u>Noise induced hearing loss as a critical occupational health problem</u>

Noise induced hearing loss (NIHL), the sensorineural hearing loss due to over exposure to noise, is one of the most prevalent occupational illnesses (1). Occupational NIHL accounts for a significant amount of adult hearing loss worldwide (2). And almost thirty years since the promulgation of the 1983 Occupational Safety and Health Administration (OSHA) hearing conservation standard (3), occupational hearing loss continues to occur among US workers (4, 5). Therefore, there is a critical need to better understand and prevent this prevalent condition. The 2005-6 NIOSH National Occupational Research Agenda (NORA) strategic planning process identified basic and applied research on noise induced hearing loss as a top priority need, and Strategic Goal 4 of the 2010 National Manufacturing Agenda developed by the NORA Manufacturing Sector Council is to: "reduce the incidence of occupationally induced hearing loss in the manufacturing sector"(6). The Agenda's specific activities and outputs to achieve this goal included:

Activity/Output Goal 4.1: "Implement surveillance activities to identify and reduce sources of noise exposures, conduct longitudinal analyses of hearing outcomes, implement hearing protection usage guidelines…",

Activity/Output Goal 4.3: "Implement research and development activities for personal hearing protection devices, effective means of fit-testing protectors, guidance, and educational materials for use of hearing protection in the workplace."

Activity/Output Goal 4.4 "Implement research activities to identify hearing loss risk factors for impulsive noise in manufacturing", and,

Activity/Output Goal 4.6: Implement research activities to develop metrics of intervention effectiveness for hearing loss to validate consensus standards, and to publicize or assess the effectiveness of hearing conservation programs."

<u>Assessing the effectiveness of occupational hearing conservation programs</u>.

During the late 20th century, hearing conservation programs (HCPs) were introduced in many workplace settings, often under regulations such as the 1983 OSHA Hearing Conservation Amendment (3), which mandated HCPs in worksites where exposures met or exceeded OSHA's Action Level of 85 dBA on an 8-hour Time Weighted Average (TWA). Under the OSHA regulation, an HCP includes five key elements: assessment and control of noise exposure; training of workers in the importance of protecting their hearing; provision of hearing protection devices at no cost to the worker; performance of annual audiometric surveillance of noise exposed workers; and record keeping.

Despite the existence of such programs, NIHL remains one of the most prevalent occupational conditions in the US (7) and other industrialized countries, and constitutes an even greater burden of adult hearing loss in developing countries (2).

A possible explanation for the continued excess loss of hearing among noise-exposed workers is that many workplaces, especially in less formal but noisy occupational settings such as construction, entertainment, and farming, may not have formal HCPs. Another explanation is that even when a worksite has an HCP, that program may not be sufficiently effective in preventing hearing loss.

In 2006, the National Academy of Sciences recommended devoting greater research attention to the challenge of determining the effectiveness of HCPs (8). Despite the fact that analysis of a number of individual programs has shown benefits from hearing conservation efforts (9, 10) a number of recent systematic reviews have noted the paucity of rigorous evidence regarding the impact of preventive programs on hearing loss risk (11, 12). At the same time, anecdotal reports of successful hearing conservation efforts in particular settings continue to appear in the literature (9). Given the considerable expense and effort now devoted to hearing conservation in many industries, it is important to continue to develop improved methods to assess the effectiveness of such programs (13). At present, there remains no consensus regarding the assessment of program effectiveness or the components or activities of a program that are most responsible for improving effectiveness. While several decades ago a proposed draft national standard for hearing conservation effectiveness, based on methods for audiometric database analysis (ADBA) and focused in large part on the year-to-year variability of sequential audiograms, was considered by the American National Standards Institute (ANSI), it was never formally adopted, due in part to concerns about both feasibility and reliability (14). Even if it had been adopted, the proposed method would have addressed only one lagging indicator of HCP effectiveness (i.e., trends in audiometric testing results). To the best of our knowledge, no comprehensive methodology for assessing HCP effectiveness is currently under formal consideration as a standard.

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A recent evidence-based review of industrial hearing loss prevention programs (HLPPs) concluded that, "there is contradictory evidence that HLPPs are effective in the long-term." The authors of the review state that "even though case studies show that substantial reductions can be achieved, there is no evidence that this is realized in practice.

At the same time, anecdotal reports of successful hearing conservation efforts in particular settings continue to appear in the literature (9). Given the considerable expense and effort now devoted to hearing conservation in many industries, it is important to continue to develop improved methods to assess the effectiveness of such programs (13). At present, there remains no consensus regarding the assessment of program effectiveness or the components or activities of a program that are most responsible for improving effectiveness. While several decades ago a proposed draft national standard for hearing conservation effectiveness, based on methods for audiometric database analysis (ADBA) and focused in large part on the year-to-year variability of sequential audiograms, was considered by the American National Standards Institute (ANSI), it was never formally adopted, due in part to concerns about both feasibility and reliability (14). Even if it had been adopted, the proposed method would have addressed only one lagging indicator of HCP effectiveness (i.e., trends in audiometric testing results). To the best of our knowledge, no comprehensive methodology for assessing HCP effectiveness is currently under formal consideration as a standard.

In the absence of agreed-upon methods of assessing program quality and effectiveness, managers of HCPs may rely on program audit checklists such as that developed by the National Institute for Occupational Safety and Health (NIOSH) (15). They can also compare their program elements with the requirements of regulations such as those of the Occupational Safety and Health Administration (OSHA) to determine whether the program is in regulatory compliance. Additional ways to assess programs include tracking the annual occurrence of hearing loss indicators such as standard threshold shifts (a change from baseline of at least 10dB in the average of hearing thresholds at 2,3, and 4000 Hz) (12) or assessing changes in noise levels over time (16, 17). Use of lagging rather than leading indicators of hearing loss to measure program effectiveness, however, is far from ideal, since by the time a standard threshold shift has occurred, affected workers already exhibit significant degrees of hearing loss (18). Similarly, assessment of noise exposures alone does not consider health impacts of exposure. For this reason, other approaches have been proposed, such as looking at the rate of audiometric "early flags" for hearing loss (earlier changes in an audiogram prior to development of an STS) (19) or using worker focus groups (facilitated group sessions with employees to qualitatively explore attitudes regarding hearing conservation) to assess program component quality (20). Better implementation and reinforcement is needed. Better evaluations of technical interventions and long-term effects are needed.

Specific Overarching Study Aims

The overarching aim of the study was to explore the relative value of different components of an HCP in preventing hearing loss. Secondarily, we sought to characterize the usefulness of tools to evaluate HCP effectiveness as well as examine the cost of programs and other interventions to prevent loss.

Specific aims were as follows:

Aim 1: Recruit 15 manufacturing facilities willing to assess their hearing conservation programs (HCPs). For each facility, calculate the rate of high frequency hearing loss that is occurring compared to the expected rate based on demographics and measured ambient noise exposures
Aim 2: For each facility, perform quantitative analyses using a number of measures including test-test variability based on draft ANSI Standard S12.13, STS rates and rates of "early flag" audiometric indicators.
Aim 3: For each facility perform qualitative on-site assessments of hearing conservation components using interviews, observations and focus groups. Use these data to determine compliance scores for each HCP component and gather contextual information about each hearing conservation program.
Aim 4: Employ mixed methods to compare the quantitative measures of hearing outcomes (Aim 2) with the qualitative program assessments (Aim 3) to explore correlations among measures and observed vs. expected high frequency hearing loss (Aim 1).

In addition, we examined the costs of hearing conservation programs, and also performed analyses of the association between noise exposure, hearing loss, and injury, as well as noise exposure, hearing loss, and hypertension.

Study #1: Assessing Hearing Conservation Effectiveness: Results of a multi-site assessment.
(Rabinowitz PM, Cantley LF, Galusha D, Trufan S, Swersey A, Dixon-Ernst C , Ramirez V, Neitzel R; JOEM 2017 in press: the following contains quotes from the manuscript in press)

Methods

Site selection and recruitment

The study took place at multiple, geographically dispersed plant locations of a large metal manufacturing company in the United States. The company, at the time of the study, had approximately 40 plant locations in the US. Plant selection criteria included having workers enrolled in an HCP and availability of noise measurement and audiometric data for at least five years prior to the site visit. The study team contacted all company facilities meeting these criteria (N-15) and requested permission to perform site visit assessments. Fourteen plants agreed to site visits. Three of the facilities were engaged in primary metal production, while the others were engaged in some form of metal fabrication. We used one site as a pilot site to pilot test the assessment tools. Management at each site was informed that the information about the site and their HCP would be kept confidential, not be released to the company or other facilities in an identifiable manner, and that no individual-identifying information would be collected. Following site visits, the study team provided site management with a consultation report based on the site assessment and analysis of location specific audiometric and noise exposure data. The study team also requested feedback to correct any items noted in the report as an additional quality control step. Complete site visit data was available for 13 of the 14 plants. One plant participated only in the management survey and noise-sampling aspects of the site visit (without worker survey or focus groups); therefore, we excluded this plant from further analysis.

Site visits

The study team performed site visits of 2 – 3 days' duration between 2012 and 2015. Assessments included plant walkthroughs, administration of a standardized in person interview to HCP managers and medical providers, a short written survey of workers (self-administered during meetings and work breaks), personal dosimetry measurements of noise levels, and worker focus groups. All study procedures were pilot-tested at a single company site, which is not included in the analysis presented here. The study protocols were reviewed and approved by the Yale University School of Medicine Human Investigation Committee (Protocol # 0509000588) to assure protection of the rights of research subjects.

The management survey was adapted from the NIOSH Hearing Conservation Program checklist on the NIOSH website (15), and consisted of over 100 items encompassing program components including general program administration, worker training, noise assessment and control, hearing protection devices, audiometric testing, and record keeping. Also included were questions about the costs of program administration; these data will be described in detail elsewhere (manuscript in preparation). This survey was constructed with input from experts in HCPs, and pretested with plant managers and health and safety professionals in the study company prior to being finalized. The survey is included as an appendix (see supplementary materials). Responses to surveys were entered into the Research Electronic Data Capture (REDCaP) platform (21) for further analysis.

The anonymous employee survey consisted of eight questions that employees could answer in approximately one minute. These questions covered worker perception of risk and management commitment to preventing hearing loss. As an incentive to complete the survey, workers received a raffle ticket for gift cards. The study team distributed surveys directly to the workers during meetings, meal breaks, and other worker gatherings, and collected them immediately after completion. The goal during each site visit was to have at as many of the workers in the HCP as possible complete the survey, although actual worker completion percentages varied between facilities. The worker survey is included as an appendix (see supplementary materials).

Focus groups, led by members of the research team, were conducted in groups of 4-12 volunteers, and lasted between 15 and 40 minutes. Participants received a cash incentive ($20 USD). Company management was not permitted to be present during the focus groups. During a typical site visit 8-10 focus groups were conducted, and in each facility, the number of groups conducted was more than sufficient to reach theme saturation (22). Audio recordings of each group were transcribed and the transcripts reviewed to identify salient themes. These data were entered into ATLAS-ti (version 7.5.6) for further analysis. With input from the plant health and safety manager during each site visit, full-shift personal noise dosimetry (DoseBadge®, Cirrus Research, North Yorkshire, UK) was performed on a representative sample of workers during plant visits, with a focus on high noise areas and areas that were in the opinion of the local health and safety management a noise control priority. Sampling measurements took place across day, night, and swing shifts. The number of dosimetry measurements varied between plants based on the size of the noise-exposed workforce. All dosimeters were configured to the OSHA hearing conservation requirements (3), and were calibrated pre- and post-measurement. Results were compared to the OSHA action level of 85 dBA TWA. We calculated the average noise levels for each facility as the average of results from the onsite dosimetry performed during study site assessment visits.

Calculation of Hearing loss rates and audiometric test variability for study locations

Under a longstanding research agreement between the company and the study team, company data sets including audiometric surveillance data were available for analysis. Details of the research agreement have been described previously (18). For each facility, we calculated the average annual rate of high frequency hearing loss, defined as the annual rate of change in the binaural average of hearing thresholds for individuals at the noise-sensitive frequencies of 3, 4, and 6 kHz, for all individuals in the location who had at least three audiograms over a five year or greater time period over the previous 10 years. We corrected these values for age using ANSI standard S3.44 (23). For each facility, we also calculated the annual rate of standard threshold shifts (age-adjusted 10dB change from baseline in the average of hearing thresholds at 2, 3, and 4 kHz) for the previous ten years, using age correction tables from the OSHA Hearing Conservation Standard (3). We then calculated annual average test-test variability for the previous ten years as well; this metric was based on previously published audiometric database analysis (ABDA) methods (24). The test-test variability statistic involved comparing sequential audiometric tests for individuals at each facility and determining the annual percentage of audiometric tests in that facility showing either sequential improvement or worsening of hearing thresholds of 15 dB or more in any of the frequencies from 1-6000 Hz.

Statistical Analysis for predictors of hearing loss

Since the data for this study are naturally nested, with multiple workers associated with each facility, multilevel regression models were used to assess the independent association between hearing loss and both the worker and facility characteristics (Table 4). This strategy separates within-facility variation from between-facility variation and models the assumption that underlying differences in the quality of the hearing conservation program lead to systematic differences among facility hearing loss rates. We performed this modeling using the Generalized Linear Mixed Model (GLIMMIX) procedure in SAS statistical software V.9.4 (SAS Institute, Cary NC). The model used as the outcome each individual's annual rate of change in the binaural average of hearing thresholds for 3, 4, and 6 kHz over the previous 10-year period (see above). We included in the model, as individual-level fixed effects, worker age, race/ethnicity, sex, baseline hearing threshold level and presence of tinnitus. Categorical responses to the management survey items as well as grouped response rates (by facility) to each of the employee survey items - dichotomized at the 50th percentile for participating plants - were examined as plant-level fixed effects in models adjusted for the individual level fixed effects. Separate preliminary models, adjusted only for the fixed effects of age, race/ethnicity and gender, examined contribution of other individual level and plant level variables, Items were retained for inclusion in the fully adjusted model if statistical significance of 0.1 or less was reached in the preliminary models. Average noise exposure levels, STS rates, and audiogram test-test variability were also examined as plant-level fixed effects in preliminary models adjusted for age, gender, and race/ethnicity. We retained variables for inclusion in the fully adjusted model if their statistical significance reached 0.1 or less. To account for unmeasured between-site variation, we included “plant” as a random effect in the fully adjusted model.

Results

Recruitment:

Table 1 shows the demographics of the workers enrolled in hearing conservation programs at the study facilities and overall plant characteristics. The participating facilities had an average of about 600 workers, but ranged substantially in size, from 165 to 1,425 workers. The number of personal noise dosimetry measurements per site ranged from 28 to 44 (total N=513), and the average noise exposure across the 13 participating plants was 83.1 dBA (standard deviation across sites 3.1 dBA, range 78.5 – 87.5). At the plant level, between 18 and 75% of dosimetry measurements exceeded the OSHA Action Level of 85 dBA TWA. Overall, 168 (32.7%) of the 513 individual dosimetry measurements exceeded 85 dBA. The test-test variability statistic for a plant location (i.e. how many periodic audiograms showed significant improvements or worsening of 15dB or more at one or more frequencies between sequential tests) ranged between 31.3 and 44.5% (mean=37.0). This represented the average over the previous 10-year period. The mean annual age corrected raw STS rate (regardless of work relatedness determination) was 3.5± 2.0%. Hearing conservation program cost averaged nearly $300 per worker.

Table 1. Plant and Worker Characteristics

Characteristic	mean/n	sd/%
Plant characteristics (n=13)		
No. of workers - mean, sd	617.5	445.4
Noise levels - mean,sd (dBA)	83.1	3.0
Test-test variability statistic- mean, sd (%)	37.0	3.6
Annual overall STS rate - mean. sd.	3.5	2.0
Annual cost of HCP ($USD/worker) - mean, sd	$294	$62
Employee characteristic (n=8,028)		
Age - mean,sd	42.8	9.6
Gender - n,%		
Male	6589	82.1
Female	1439	17.9
Race/Ethnicity - n,%		
White	6080	75.7
Black	916	11.4
Hispanic	813	10.1
Other	219	2.7
Hearing at baseline (binaural average of hearing thresholds at 3,4,6KHz) - mean,sd	21.7	16.4
Annualized hearing loss rate in avg 3,4,6KHz (dB/yr) – mean,,sd	0.61	0.78

The average age of workers in the HCP at the participating sites was approximately 43 years at time of entry into our study cohort (age at their first audiometric test included in our study). Workers in our study cohort were predominantly white, and had a hearing threshold of approximately 22 dB HL at the binaural average of 3, 4, and 6 kHz for the first audiometric test included in the study. Slightly more than 18% of workers reported tinnitus at some point during the follow up period (data not shown).

Figure 1 shows average rates of hearing loss, in dB per year for the average of hearing thresholds at 3, 4, and 6 kHz, for workers enrolled in HCPs in each of these facilities. Negative numbers for the corrected rate implies that in general, individuals at the plant were losing less hearing than predicted by age by the ANSI 3.44 formula.

(FIG 1 Here)

<u>Management and employee surveys</u>

Table 2 shows the distribution of responses to manager survey items retained for inclusion in the fully adjusted model. These included questions about timing of hearing testing, type of noise sampling performed, whether a professional supervisor (physician or audiologist) determined work relatedness, requiring hearing protection for full-shift exposures >85 dBA, and whether workers were complaining about work interference by hearing protectors. Notably, for many questions on the manager survey, including some of the items shown in Table 2, the plant managers answered in the same way, demonstrating little response variability between plants. Table 3 shows the results of responses to the employee survey, averaged across all facilities, as well as the range of response rates across plants. Overall, more than 80 percent of workers reported that during the annual hearing test process, they received counseling about their hearing. This percentage ranged between 56% and 92% for different locations. Similarly, while 68% of workers overall rated management commitment to hearing loss prevention as "High or exceptional", the rates varied from a low of 45% to a high of 87% percent. More than 50% of employees expressed high or extreme concern about hearing loss, while over 40% also expressed concern about the potential for accidents related to noise or the use of hearing protection. Less than 50% of workers reported "never" removing their hearing protectors to communicate during a work shift.

Table 2. Responses to selected items in Manager Survey

Survey Item	Yes		No	
	n	%	n	%
Annual audiograms conducted before workshift (vs during/after)	1	7.7	12	92.3
Hearing protection devices required when noise levels exceed 85dBA (vs >90 or other criteria)	7	53.8	6	46.2
Noise monitoring conducted using personal measurements only (versus both personal and area measurements)	2	15.4	11	84.6
Work-relatedness of hearing loss determined by Professional supervisor (Physician or Audiologist) vs other professional	9	69.2	4	30.8
Have any workers complained that HPDs interfere with their ability to do their jobs at your facility	8	61.5	5	61.5

Table 3. Employee Survey: percentage of employees in each facility with certain responses

Question	mean	sd	Minumum	Maximum
When you had your most recent hearing test, did anyone talk to you about your hearing? (% answering “yes”)	82.5	9.3	56.0	92.0
When you had your most recent hearing test, did anyone talk to you about how to best use your hearing protective device? (% answering “yes”)	74.9	10.3	55.0	92.0
What percentage of time does your supervisor wear his/her hearing protective device while on the floor?(% answering “76-100%”)	82.9	17.1	39.0	96.0
In areas where hearing protection is required, how often do other workers wear their hearing protective devices? (% answering “always”)	68.8	15.7	43.0	87.0
How would you rate the level of commitment to preventing hearing loss at your workplace? (% answering “high or exceptional”)	68.7	10.3	45.0	87.0
How much of a personal concern do you have about losing your hearing because of on the job noise exposure? (% answering “ high or extreme”)	54.8	8.4	41.0	75.0
How much of a personal concern do you have about injuries or accidents occurring because of noise, hearing loss or wearing hearing protective devices? (% answering “high or extreme”)	43.7	5.2	35.0	53.0
On average, how many times during each work day do you have to remove your hearing protective device in order to communicate? (% answering “never”)	45.7	11.2	29.0	64.0

Focus groups

Across the 13 plants participating in all study components, we conducted 126 focus groups, with a range of 6 to 14 groups per site for a total of 767 participants. Major themes included the perceived level of management commitment to hearing conservation; the extent to which a variety of HPDs were available and accessible; and whether or not workers were encouraged to take hearing protectors home for use when exposed to non-occupational sources of noise. In the majority of plants visited, focus group participants described a high level of management commitment to the HCP and high levels of personal commitment to protecting hearing on the job. In contrast, in less than half of the study sites did focus group participants report a strong personal investment in protecting hearing off the job.

Predictors of hearing loss

Table 4 shows the variables achieving statistical significance of p=.10 or less in preliminary analyses (adjusted for age, race/ethnicity and gender) that were retained in the fully adjusted models as well as the results of the fully adjusted models of individual and plant level predictors s for high frequency hearing loss among employees at the study facilities.

Significant individual-level factors predictive of hearing loss in the fully adjusted model included age, sex, race, ethnicity, tinnitus, and baseline hearing (with worse baseline hearing associated with lower risk of further hearing loss). Plants for which at least 85% of employees surveyed reported receiving counseling during their annual hearing test experienced less hearing loss, and plants for which at least 70% of workers reported the highest levels of workplace commitment to preventing hearing loss showed lower rates of hearing loss among workers. Each of these variables retained significance in the fully-adjusted model. Manager survey items remaining in the fully-adjusted, final multilevel model included: the timing of annual audiograms; whether noise sampling included personal sampling vs. personal and area sampling; and whether or not workers complained about HPDs interfering with work. Plants that conducted annual audiometric testing during or after work shifts compared to before work shifts showed higher rates of hearing loss. Plants for which noise-monitoring efforts included both personal and area sampling showed lower rates of hearing loss. Finally, plants in which managers had received worker complaints that HPDs interfered with their ability to perform their jobs had higher rates of hearing loss. Neither measures of test-test audiogram variability mean plant noise levels, nor hearing conservation program size (number of persons in HCP), or annual per capita expenditures on the hearing conservation program were significant plant level predictors of hearing loss after adjusting for age, gender, and race/ethnicity.

Table 4. Predictors of high frequency hearing loss

Variable	Adjusted for Age, Gender, Race*		Fully Adjusted Multilevel Model (only significant variables included)**	
	estimate	**p-value**	**estimate**	**p-value**
Employee Variables				
Age	0.016	<.0001	0.018	<.0001
Male (vs female)	0.174	<.0001	0.183	<.0001
Race/Ethnicity				
Black (vs white)	-0.196	<.0001	-0.202	<.0001
Hispanic (vs white)	-0.087	0.0133	-0.089	0.009
Tinnitus	0.197	<.0001	0.216	<.0001
Tinnitus unknown	-0.083	0.0008	-0.083	0.001
Baseline hearing (mean 3,4,6KHz)	-0.002	0.0058	-0.003	<.0001
Location level Variables				
Employee survey responses				
When you had your most recent hearing test, did anyone talk to you about your hearing? (% yes >=85%)	-0.142	0.0361	-0.191	<.0001
Workplace level of commitment to HL (high or exceptional >=70%)	-0.124	0.0944	-0.119	0.001
Manager survey responses				
Annual audiograms conducted before workshift (vs during/after workshift)	-0.363	0.0027	-0.300	0.003
Hearing protection devices required when noise levels exceed 85dBA (vs >90 or other criteria)	-0.174	0.0110		
Noise monitoring conducted using both personal and area measurements (compared to personal measurements only)	-0.181	0.0747	-0.158	0.025
Work-relatedness of hearing loss determined by Professional supervisor (Physician or Audiologist) vs other professional	-0.145	0.0903		
Have any workers complained that HPDs interfere with their ability to do their jobs at your facility (yes vs no)	0.153	0.0244	0.094	0.006
Other location level variables				
Annual Hearing conservation cost per employee (per $100)	0.044	0.2856		
Number of employees in Hearing Conservation Program	-0.004	0.6775		

Study #2: Sayler SK, Rabinowitz PM, Cantley LF, Neitzel RL. Costs and Effectiveness of Hearing Conservation Programs. Int J Audiology In press

Objective

Given the gaps in available knowledge regarding the cost-effectiveness of US HCPs, this study sought to characterize costs associated with HCPs by evaluating overall costs and costs associated with individual program elements and examining the association between these costs and several metrics of noise-induced hearing loss.

Design

We conducted structured interviews with health and safety personnel and reviewed records to collect HCP cost information at 14 metals manufacturing facilities operated by a single company. We also conducted up to 45 full-shift personal noise measurements on workers for comparison to the ten-year average of noise measurements made by each facility, which we obtained from the company's noise database. Hearing outcomes, also obtained from the corporate health database, included rates of standard threshold shifts, rates of high-frequency hearing loss, and prevalence of hearing impairment for each participating facility. We used linear regression models to identify per-person HCP cost variables that best predicted the four hearing health outcomes.

Study Sample

Our study evaluated 14 US metal manufacturing facilities operated by a single company.

Results

Annual HCP costs at the facilities ranged from roughly $67,000 to $400,000, with an average annual cost of $308±80 per person. Study noise measurements (mean 83.1 dBA) showed good agreement with measurements made by the facilities (mean 82.6 dBA). The mean hearing impairment prevalence rate was about 15% across all facilities. Program management expenses represented about 30% of total HCP costs on average. Higher training costs and hearing protector fit-testing costs were significantly associated with reduced STS prevalence among the participating facilities. Higher training costs were also related to reduced hearing impairment prevalence and lower high-frequency hearing loss rates.

Conclusions

HCP program costs were substantial and variable across the participating facilities. Increased spending on training and fit-testing may help minimize noise-induced hearing loss in the workplace.

Additional Results:

Table 2. Descriptive statistics for program costs (in US dollars) and noise and hearing loss rates at metals manufacturing facilities in the US (N=14).

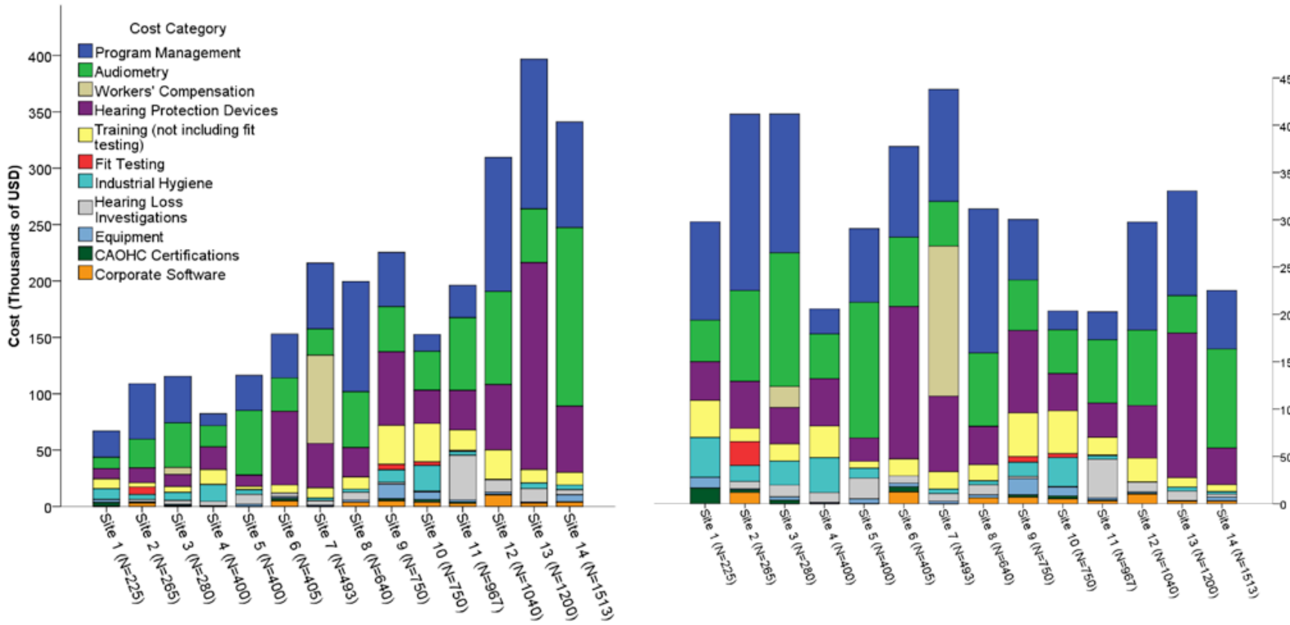
		Overall Cost (USD)				Per Person Cost (USD)			
Cost Variables	N plants reporting costs	Mean	SD	Min	Max	Mean	SD	Min	Max
Total costs	14	191,417	99,542	67,016	396,638	308	80	203	438
Cost by wages vs. non-wages									
Wages	14	118,474	54,013	51,610	231,329	199	63	101	333
Non-wages	14	72,943	58,513	15,406	196,400	108	57	56	253
Cost by program element									
Program management	14	56,270	39,010	10,600	132,725	94	50	20	186
Audiometry	14	48,670	36,969	9,876	158,205	76	35	40	143
Workers Comp Claims	2	42,218	50,893	6,231	78,204	90	96	22	159
HPDs	14	44,559	45,077	9,175	183,500	64	43	25	161
Training	14	15,136	11,306	2,819	39,249	25	15	7	52
Training only	14	14,045	10,436	2,819	34,600	23	13	7	46
Fit testing	4	3,818	2,460	825	6,656	9	11	0.9	25
Industrial hygiene	13	7,102	6,149	483	22,822	15	14	0.4	42
Hearing loss investigation	13	7,814	10,174	701	39,620	11	10	0.9	41

Table 3. Unadjusted models for predicting percentage of age-corrected and non-age-corrected standard threshold shifts (STS) at metal manufacturing facilities in the US (N=14).

Per Person Cost (USD)	Age-corrected STS[1] (%)			Non-Age-Corrected STS[1] (%)			High-Frequency Hearing Loss Rate[2] (dB/year)			Hearing Impairment[3] (%)		
Variables	β	SE	*P*	β	SE	*p*	β	SE	*p*	β	SE	*p*
Total costs	0.001	0.005	0.782	-0.003	0.008	0.716	0.001	0.001	0.207	0.027	0.024	0.263
Cost by wages vs. non-wages												
Wages	0.002	0.006	0.692	-0.001	0.010	0.892	<0.001	0.001	0.827	0.003	0.032	0.926
Non-wages	0.000	0.006	0.961	-0.004	0.012	0.719	0.001	0.001	0.120	0.050	0.033	0.130
Cost by program element												
Program management	0.004	0.007	0.577	0.002	0.013	0.875	0.001	0.001	0.141	0.039	0.039	0.313
Audiometry	0.000	0.011	0.999	0.025	0.018	0.158	<0.001	0.002	0.908	-0.010	0.058	0.861
Workers Comp Claims	-0.001	0.009	0.930	-0.006	0.016	0.675	0.002	0.001	0.191	0.012	0.048	0.803
HPDs	-0.001	0.009	0.945	-0.011	0.015	0.454	0.001	0.001	0.604	0.090	0.041	0.026*
Training	-0.023	0.024	0.332	-0.098	0.035	0.006**	-0.007	0.003	0.029*	-0.283	0.111	0.011*
Training only	-0.004	0.027	0.871	-0.063	0.047	0.178	-0.006	0.004	0.112	-0.274	0.133	0.040*
Fit testing	-0.095	0.048	0.045*	-0.239	0.074	0.001**	-0.010	0.007	0.161	-0.339	0.285	0.233
Industrial hygiene	0.028	0.025	0.259	-0.002	0.046	0.964	0.001	0.004	0.749	-0.133	0.138	0.333
Hearing loss investigation	-0.021	0.035	0.549	0.031	0.063	0.619	-0.005	0.005	0.333	0.150	0.190	0.428
Equipment	0.018	0.077	0.813	-0.034	0.140	0.805	-0.12	0.011	0.280	-0.605	0.398	0.128
CAOHC[4] certifications	0.204	0.063	0.001**	0.147	0.146	0.314	0.010	0.012	0.379	-0.125	0.462	0.788

[1]Standard Threshold Shift as defined by the Occupational Safety and Health Administration average over the preceding ten years.

Figure 2. Hearing Conservation Program (HCP) costs by cost category for 14 metals manufacturing facilities in the US, where N represents the number of individuals enrolled in the associated HCP at the time of the study.



Study #3: Cantley et al: Workers' perceptions of hearing loss prevention programs: an analysis of focus group findings in a manufacturing cohort. In preparation

Our aim for this paper is two-fold: 1) To describe how focus groups were used to gather information regarding workers' perceptions of effective and less effective program components, organizational and individual commitment to hearing loss prevention, and opportunities for program enhancement as part of a comprehensive study designed to assess HLPP effectiveness (Rabinowitz, et al JOEM 2017, in press); and 2) to detail common themes arising from the focus groups, the variation in themes across plants, the degree to which information gleaned from focus groups matched or diverged from information gleaned from structured interviews with management personnel, and explore whether focus group themes predicted hearing loss rates among the plants studied.

Study #4: Tessier-Sherman B et al: Noise exposure and hypertension: in resubmission, American Journal of Industrial Medicine

Abstract

Background: Community noise exposure has been shown to increase the risk of hypertension; however, the relationship between occupational noise exposure and hypertension is less clear.

Methods: Using an inception cohort of workers in a specialty metals manufacturing company, we retrospectively assessed occupational noise exposure, hearing acuity, and incident hypertension diagnoses using administrative datasets. Time-weighted average noise exposure levels were assigned to employees based on their job histories. Cox proportional hazards models were performed to determine the association of noise exposure with risk of incident hypertension.

Results: The adjusted hazard ratio (HR) of incident hypertension did not significantly differ between groups by cumulative continuous or categorized noise exposure metric.

Conclusion: We found no increased risk of incident hypertension with exposure to occupational noise among workers. Further assessment examining workers' use of hearing protection devices is warranted.

<u>Study #5:</u> Cantley LF, Galusha D, Cullen MR, Dixon-Ernst C, Tessier-Sherman B, Slade MD, Rabinowitz PM, Neitzel RL. Does tinnitus, hearing asymmetry, or hearing loss predispose to occupational injury risk? Int J Audiol. 2015 Feb; 54 Suppl 1:S30-6. doi: 10.3109/14992027.2014.981305. Epub 2014 Dec 30. PMID: 25549168

<u>Abstract</u>

OBJECTIVE: To determine the relative contributions of tinnitus, asymmetrical hearing loss, low frequency hearing loss (pure tone average of 0.5, 1, 2, 3 kHz; PTA.5123), or high frequency hearing loss (pure tone average of 4, 6 kHz; PTA46), to acute injury risk among a cohort of production and maintenance workers at six aluminum manufacturing plants, adjusting for ambient noise exposure and other recognized predictors of injury risk.

DESIGN: Retrospective analysis.

STUDY SAMPLE: The study considered 9920 workers employed during 2003 to 2008. The cohort consisted of 8818 workers (89%) whose complete records were available.

RESULTS: Adjusting for noise exposure and other recognized injury predictors, a 25% increased acute injury risk was observed among workers with a history of tinnitus in conjunction with high-frequency hearing loss (PTA46). Low frequency hearing loss may be associated with minor, yet less serious, injury risk. We did not find evidence that asymmetry contributes to injury risk.

CONCLUSION: These results provide evidence that tinnitus, combined with high-frequency hearing loss, may pose an important safety threat to workers, especially those who work in high-noise exposed environments. These at risk workers may require careful examination of their communication and hearing protection needs.

<u>Study #6:</u> Cantley LF, Galusha D, Cullen MR, Dixon-Ernst C, Rabinowitz PM, Neitzel RL. Association between ambient noise exposure, hearing acuity, and risk of acute occupational injury. Scand J Work Environ Health. 2015 Jan;41(1):75-83. doi: 10.5271/sjweh.3450. Epub 2014 Aug 19. PMID: 25137556

<u>Abstract</u>

OBJECTIVE: This study aimed to examine the associations between acute workplace injury risk, ambient noise exposure, and hearing acuity, adjusting for reported hearing protection use.

METHODS: In a cohort of 9220 aluminum manufacturing workers studied over six years (33 300 person-years, 13 323 person-jobs), multivariate mixed effects models were used to estimate relative risk (RR) of all injuries as well as serious injuries by noise exposure category and hearing threshold level (HTL) adjusting for recognized and potential confounders.

RESULTS: Compared to noise <82 dBA, higher exposure was associated with elevated risk in a monotonic and statistically significant exposure-response pattern for all injuries and serious injuries with higher risk estimates observed for serious injuries [82-84.99 dBA: RR 1.26, 95% confidence interval (95% CI) 0.96-1.64; 85-87.99 dBA: RR 1.39, 95% CI 1.05-1.85; ≥88 dBA: RR 2.29, 95% CI 1.52-3.47]. Hearing loss was associated with increased risk for all injuries, but was not a significant predictor of risk for the subset of more serious injuries. Compared to those without hearing loss, workers with HTL ≥25 dB had 21% increased all injury risk (RR 1.21, 95% CI 1.09-1.33) while those with HTL 10-24.99 dB had 6% increased risk (RR 1.06, 95% CI 1.00-1.13). Reported hearing protection type did not predict injury risk.

CONCLUSION: Noise exposure levels as low as 85 dBA may increase workplace injury risk. HTL was associated with increased risk for all, but not the subset of serious, injuries. Additional study is needed both to confirm the observed associations and explore causal pathways.

<u>Study #7:</u> Neitzel RL, Galusha D, Dixon-Ernst C, Rabinowitz PM.
Methods for evaluating temporal trends in noise exposure.
Int J Audiol. 2014 Mar;53 Suppl 2:S76-83. doi: 10.3109/14992027.2013.857438.
PMID: 24564696

<u>Abstract</u>

OBJECTIVE: Hearing conservation programs have been mandatory in many US industries since 1983. Since then, three program elements (audiometric testing, hearing protection, and training) have been the focus of much research. By comparison, little has been done on noise exposure evaluation.

DESIGN: Temporal trends in time weighted average (TWA) exposures and the fraction of measurements exceeding 85 dBA were evaluated by facility, by exposure group within facility, and by individual worker within facility.

STUDY SAMPLE: A large dataset (> 10 000 measurements over 20 years) from eight facilities operated by a multinational aluminum manufacturing company was studied.

RESULTS: Overall, exposures declined across locations over the study period. Several facilities demonstrated substantial reductions in exposure, and the results of mean noise levels and exceedance fractions generally showed good agreement. The results of analyses at the individual level diverged with analyses by facility and exposure group within facility, suggesting that individual-level analyses, while challenging, may provide important information not available from coarser levels of analysis.

CONCLUSIONS: Validated metrics are needed to allow for assessment of temporal trends in noise exposure. Such metrics will improve our ability to characterize, in a standardized manner, efforts to reduce noise-induced hearing loss.

Conclusions

This study provided an unprecedented opportunity to study hearing conservation programs and determine metrics to assess their effectiveness. The cooperation of the plant locations, the variety and depth of the data sources, and the number of plants evaluated sets this study apart from previous studies. The study provides important guidance for future efforts to set standards for evaluation of hearing conservation program effectiveness and cost-efficiency.

The study's related investigation also shed important light on the relationship between noise exposure and injury.

Publications

2017

Rabinowitz PM, Cantley LF, Galusha D, Trufan S, Swersey A, Dixon-Ernst C , Ramirez V, Neitzel R Assessing Hearing Conservation Effectiveness: Results of a multi-site assessment. JOEM (in press)

Sayler SK, Rabinowitz PM, Cantley LF, Neitzel RL. Costs and Effectiveness of Hearing Conservation Programs. Inl Jl Audiology. In press (2017)

Cantley et al: Workers' perceptions of hearing loss prevention programs: an analysis of focus group findings in a manufacturing cohort. In preparation 2017

Tessier-Sherman B et al: Occupational Noise Exposure and Risk of Hypertension in an Industrial Workforce. AJIM. In revision 2017.

<u>2016</u>

Cantley LF, Galusha D, Cullen MR, Dixon-Ernst C, Tessier-Sherman B, Slade MD, Rabinowitz PM, Neitzel RL. Does tinnitus, hearing asymmetry, or hearing loss predispose to occupational injury risk? Int J Audiol. 2015 Feb;54 Suppl 1:S30-6. doi: 10.3109/14992027.2014.981305. Epub 2014 Dec 30. PMID: 25549168

<u>2015</u>

Cantley LF, Galusha D, Cullen MR, Dixon-Ernst C, Rabinowitz PM, Neitzel RL.
Association between ambient noise exposure, hearing acuity, and risk of acute occupational injury.
Scand J Work Environ Health. 2015 Jan;41(1):75-83. doi: 10.5271/sjweh.3450. Epub 2014 Aug 19.
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<u>2014</u>

Neitzel RL, Galusha D, Dixon-Ernst C, Rabinowitz PM.
Methods for evaluating temporal trends in noise exposure.
Int J Audiol. 2014 Mar;53 Suppl 2:S76-83. doi: 10.3109/14992027.2013.857438.
PMID: 24564696

Other:

1) Cumulative Inclusion Enrollment Table:

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Assessing Hearing Conservation Effectiveness

Total Planned Enrollment: 4000

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	16	139	155
Not Hispanic or Latino	400	3445	3845
Ethnic Category: Total of All Subjects *	416	3584	4000
Racial Categories			
American Indian/Alaska Native	11	88	99
Asian	10	87	97
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	35	305	340
White	360	3104	3464
Racial Categories: Total of All Subjects *	416	3584	4000

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

2) Inclusion of Gender and Minority Study Subjects:

Alcoa Inc. has women and minorities working in noise exposure areas. Recruitment has been blind as to race, ethnicity and gender, therefore we have included both women and minorities in the study population (see Targeted Enrollment Table). However, at some study sites, the number of minorities were limited.

Our research plan includes a plan to conduct multivariate analyses that determine, as covariates, the effect of gender and/or racial ethnic subgroup. We have examined these factors in the results presented.

3) Inclusion of children: We anticipated that some workers may be between 18 and 21 years old, but that this would be a very small minority. We have not excluded any such children from the study.

4) Materials available for other investigators.

We have created an online risk calculator based on our results. This allows hearing conservation program managers a set of tools to evaluate their program. We include a survey for employees in order to assess their opinion about management commitment, as well as cost calculator.
We have created a webpage to highlight the program materials: available at
http://deohs.washington.edu/hearing-loss

This is also linked to by the NIOSH website.
We are also creating a deidentified data set that will be available to other researchers upon request.

Equipment Inventory Report:
NA

Final Invention Statement:

We have created the web-based tools described above. These are freely available to the public.

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