Perspectives on "Efficacy of the U.S. Army Policy on Hearing Conservation Programs"

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INTRODUCTION

We wish to respond to the recent article published in this journal by Drs. Oestenstad, Norman, and Borton, "Efficacy of the U.S. Army Policy on Hearing Conservation Programs."[1] Although, as is discussed below, we disagree with the methodology and conclusions presented by Dr. Oestenstad and his colleagues, we firmly appreciate their efforts to examine the hearing conservation program (HCP) at the Anniston U.S. Army Depot. The field of hearing conservation is well recognized for the healthy debates associated with the development of hearing damage risk criteria and the subsequent promulgation of hearing conservation standards. Consider that over 10 years elapsed from the initial notice of proposed rule making for the Occupational Safety and Health Administration (OSHA) noise exposure standard and the promulgation of the current OSHA Hearing Conservation Amendment. The authors of the present manuscript hope that the issues addressed herein will form the basis for continued discussions on best practices for preventing occupational hearing loss.

In the spirit of the history of this debate, let us begin by stating that we do not agree with Oestenstad et al. that (1) 675 employees were "unnecessarily" and "unjustifiably" added to the hearing conservation program, and (2) using an 85-dBA time weighted average (TWA) as measured with a 3-dB exchange rate is an "excessively" conservative criterion. Our concerns with the manuscript presented by Oestenstad et al. fall into the following four topical areas: (1) study design, (2) use of the ANSI S3.44[2] Annex A and Annex B databases as control populations, (3) analysis of noise-induced permanent threshold shifts (NIPTSs), and (4) conclusions regarding the 3-dB exchange rate. Each of these will be discussed in turn, below.

(1) Comments Regarding Study Design

The stated purpose for the study in question was to determine whether a group of 675 workers at the Anniston Army Depot had incurred occupational noise-induced hearing loss between 1987 and 2001. The implied purpose was to determine whether the application of an 85-dBA TWA criterion as measured with a 3-dB exchange rate is "overly restrictive" and that these criteria provide "no appreciable benefit in the prevention of hearing loss." Their expressed concern was that money was being unnecessarily spent on hearing conservation.

The manuscript by Oestenstad et al. was not a case study. Rather, it was intended to provide conclusions that could be used to make generalized statements about criteria for determining when a worker should be included in a hearing conservation program. As such, it is the responsibility of the researchers to demonstrate the results that will have sufficient statistical power to make such conclusions. No such power analysis was provided. Although 675 employees were eligible to participate in the study, only 231 volunteered. Such a high nonresponse rate may have compromised the generalizability of the study. Further, 186 of the volunteers either withdrew or were excluded for other reasons. The remaining 45 subjects actually used in their study were not randomly selected, and it is unknown whether they are truly representative of the target population. The lack of randomly selected subjects combined with a very small sample size pose serious constraints on the conclusions that were drawn.

The workers in the study were not enrolled in an HCP between 1987 and 2001. However, all subjects were previously enrolled in an HCP, and would have had regular hearing tests, annual health education briefings, knowledge of their occupational noise exposures, and would have been provided with hearing protection.[3] The investigators assumed the workers were not at all influenced by their previous enrollment in an HCP, and received no benefit from previous training and education about conserving their hearing. They also must have

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assumed workers would have universally eschewed the use of hearing protectors when they were not formally enrolled in the HCP even though their jobs and noise exposures had not changed. There was no apparent attempt to study/analyze workers' hearing loss prevention beliefs and behaviors, and it is unknown whether all workers actually stopped using hearing protectors. Without accounting for such variables, it is not possible to assume the workers did not functionally (informally) participate in hearing conservation techniques in the intervening years.

(2) Comments Regarding the Use of the ANSI S3.44 Annex A and Annex B Databases as Control Groups

When analyzing subjects' hearing threshold levels (HTLs), Oestenstad et al. chose to rely upon Annex B of American National Standards Institute ANSI S3.44-1996 (R2001) as the reference control group. Annex B represents the HTLs for an unscreened population. This is in contrast to Annex A, which represents "persons in a normal state of health who are free from all signs or symptoms of ear disease and from obstructing wax in the ear canal, and who have no history of undue exposure to noise." In addition to representing an unscreened population, Annex B hearing levels may also have been affected by industrial noise exposure. It should not be surprising that the hearing levels in Annex A are lower (i.e., better hearing) than those in Annex B. According to Oestenstad et al., not only work histories, but also medical histories were available for each of the 45 subjects used in this study. However, the subjects' medical histories were not addressed in the article. With such a small sample size, it should not have been difficult to review the medical histories and determine whether the subjects were otologically normal. If so, the subjects' HTLs also should have been compared against Annex A HTLs, and not just those in Annex B. This is important because the differences in HTLs would have been greater had Annex A been used as the reference database. Additionally, there is more uncertainty in Annex B HTLs than in Annex A. The larger uncertainty makes it more difficult to identify true differences in a small subject pool. Without addressing the available medical history data, it is not possible to rule out the possibility that Annex A is the more appropriate reference database.

(3) Comments Regarding the Analysis of NIPTSs

As noted above, it was reported that all of the subjects in this study had been enrolled in a hearing conservation program before 1987. It was also reported that work histories for each subject were available. Thus, the subjects would have had true baseline hearing tests (i.e., audiograms taken before incurring any noise exposure), and there would have been a record of the total number of years workers were exposed to noise. Unfortunately, pre-1987 HTLs and noise exposure histories were not reported. This is a critical oversight. It is generally accepted (and clearly documented in ANSI S3.44 Annex E) that the growth of NIPTSs follow a predictable trajectory. Specifically, a NIPTS grows most rapidly in the first 10 years of exposure. Subsequent changes are notably smaller and occur much more gradually. Since the youngest age group in 1987 had a mean age of 31.2 years (median = 32 years), it is likely most of these workers would already have had noise exposures longer than 10 years. All of the remaining subjects almost certainly would have had exposures in excess of 10 years. The data plotted in Figure 1 and Figure 2 are taken from ANSI S3.44 Annex B, and illustrate the growth of NIPTSs for the 10th percentile (i.e., the 10% with the most NIPTSs) for workers exposed to an equivalent continuous A-weighted sound pressure level of 85 and 90 dB, respectively, for a nominal 8-hour exposure. It should be noted that these data are based on unprotected ears and that exposures were calculated using a 3-dB exchange rate. Filled symbols indicate the NIPTSs for each audiometric test frequency for exposures of 10, 20, 30, and 40 years. These figures demonstrate how, for affected frequencies (3, 4, and 6 kHz), the growth of occupational hearing loss decelerates after about 10 years of exposure. Even the most sensitive ears show comparatively little additional NIPTS after the initial 10 years of exposure. Therefore, to conclude that these workers did not need to be enrolled in a hearing conservation program because there was no substantial (i.e., clinically meaningful) NIPTS between 1987 and 2001 is to totally ignore both pre-1987 noise exposures and the trajectory by which NIPTS grows. In other words, it should have been predicted that there would have been little additional change in HTLs after 1987 unless the noise exposure level significantly increased.

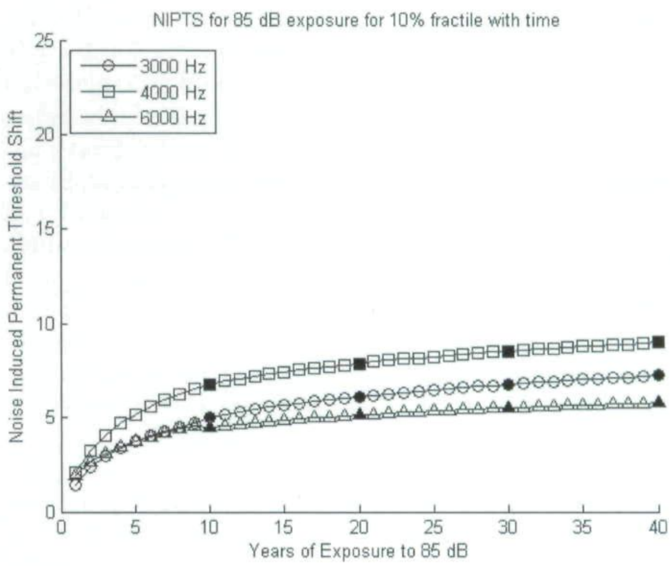

FIGURE 1. Noise-induced permanent threshold shift (NIPTS) over time for the 10% most sensitive persons exposed to an equivalent continuous A-weighted sound pressure level of 85 dBA for a nominal 8-hr work day. (Drawn from ANSI S3.44 Annex B.)

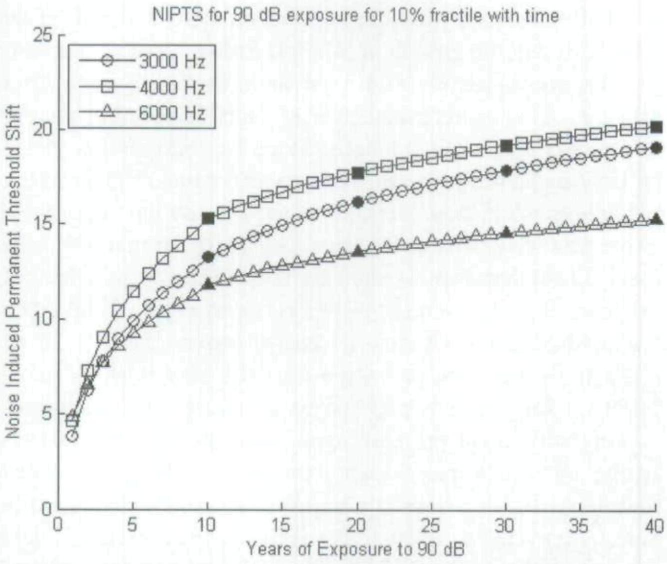

FIGURE 2. Noise-induced permanent threshold shift (NIPTS) over time for the 10% most sensitive persons exposed to an equivalent continuous A-weighted sound pressure level of 90 dBA for a nominal 8-hr work day. (Drawn from ANSI S3.44 Annex B.)

When discussing median HTLs and hearing threshold levels associated with age (HTLAs), the original manuscript failed to appropriately address the mean HTL and HTLA values shown in their Table II. Monitoring audiometry characteristically identifies isolated cases in which there appears to be an excessive change in hearing threshold. These isolated cases could easily influence mean HTLs, particularly when dealing with small sample sizes. Consider the mean hearing levels shown in their Table II for 1987. The mean HTL–HTLA differences are substantially greater than the comparable median differences shown in their Table III. This strongly suggests some of the subjects' hearing was considerably worse than would be predicted from age-related changes alone. Indeed, this is borne out by the data for maximum HTLs shown in their Table II. In other words, at least some of the subjects had evidence of significant pre-existing hearing loss at the beginning of this study. With a sample of only 45 subjects, this factor could have fatally confounded attempts to determine whether additional exposure durations were associated with subsequent hearing changes, particularly when the exposure levels in question would be likely to result in relatively small threshold shifts. Furthermore, since Oestenstad et al. reported that audiometric data were screened, and many potential subjects were excluded from participating in this study, it is difficult to understand why persons with significant pre-existing hearing loss were included in this study.

Concerns about pre-existing hearing loss in some subjects bears additional scrutiny. As shown in Table II of the original article, the maximum 1987 HTLs at 500, 1,000, and 2,000 Hz were 25, 20, and 50 dB, respectively. Hearing levels of this magnitude at these frequencies are very unlikely to be associated exclusively with the noise exposures reported by the Anniston Army Depot. Such hearing thresholds, however, could be associated with mixed (conductive and sensorineural components) or some component of a nonorganic hearing disorder. By their very nature, any conductive impairment can function as a built-in earplug, and would be most effective at attenuating ambient noises. At the noise levels to which these subjects were exposed, any conductive hearing loss could have effectively precluded the affected person from incurring a noise-induced hearing loss. As mentioned previously, Oestenstad et al. never mentioned the medical histories of these subjects.

There are also issues associated with the maximum 1987 HTLs shown in Table II for 3,000, 4,000, and 6,000 Hz (the frequencies most affected by noise) which are 70, 75, and 85 dB, respectively. Such hearing losses are classified as severe. It is difficult to understand what purpose is served by including subjects with pre-existing severe hearing loss in a study purported to be looking for small changes in NIPTS. Additionally, with HTLs of this magnitude, the presence of ceiling effects is a distinct possibility.

The presence or absence of a standard threshold shift (STS) is one of the most important metrics in an HCP. OSHA defines an STS as a change from baseline hearing of an average of 10 dB or more at 2,000, 3,000, and 4,000 Hz in either ear for a specific worker.[4] The article in question should have addressed this metric, particularly in light of the audiometric data presented in their Table III. The median group HTLs at 2,000, 3,000, and 4,000 Hz demonstrate an average change of 11.7 dB, thus exceeding the OSHA STS criteria. It should be noted that this compared 2001 HTLs against 1987 HTLs. The differences would certainly have been even greater had the 2001 HTLs been compared against the true baseline audiograms. The use of group data to the exclusion of any individual changes is inappropriate in determining the presence of an occupational hazard. Thus, we do not know the number of these workers who had an STS, and we also do not know how many of these would have met the criteria to be recorded on the OSHA Form 300—Log of Work-Related Injuries and Illness.

Oestenstad et al. noted that Figure 2 and Table III of their manuscript demonstrate positive values for HTL–HTLA. In fact, for all but 500 Hz, the HTL–HTLA differences are greater in 1987 than in 2001. However, since the differences were not clinically significant (i.e., greater than 5 dB) these differences were dismissed, and Oestenstad et al. concluded, "These results suggest that it is unlikely that the changes in HTL between 1987 and 2001 were caused by occupational noise exposure." It is not clear why the authors chose to summarily dismiss the possibility that small changes could have been caused by noise. While it is true that 5-dB changes are the minimum changes considered to be reliable in individuals tested under good clinical conditions. This is not the case for aggregate data. With aggregate data, smaller changes may be reliable indications of valid changes. Appendix F in ANSI S3.44 clearly demonstrates that noise exposures of the magnitude and durations reported by the authors would result in small changes.

Perhaps the most unjustified conclusion made by Oestenstad et al. was that these workers should not be included in the Anniston HCP. Even if their methodology yielded valid HTLs, this conclusion is not warranted given the near certainty that a number of these subjects would have had an STS. In fact, even if there were no STSs, the authors failed to present a cogent rationale for excluding these workers from an HCP. The purpose of an HCP is to identify individual workers and intervene before hearing changes become significant and permanent.[5,6] According to the data presented, at least some permanent hearing changes were observed. Thus, the authors are apparently recommending that hearing conservation efforts be abandoned on the basis of the concept of prevention, and advocate enrolling only those workers at risk for incurring the largest hearing losses. The justification for this position appears to be based solely on the costs of administering a hearing conservation program. While the authors cited data on the estimated cost of administering an HCP, it is interesting to note that they did not quote the costs of worker compensation that might be incurred if an occupational hearing loss resulted from the work-related noise exposures.

Failure to mention hearing loss compensation costs in the Oestenstad et al. article is notable because these costs reveal the false economy of their justification. Moreover, compensation costs were the original driving force for Anniston's involvement in this study and their request for a waiver from the 3-dB exchange rate. The following chronology of events over the study period (1987–2001) should clarify these assertions.

Before the Army's implementation of the time-weighted criteria (using a 3-dB exchange rate) in 1995, enrollment in the hearing conservation program for steady state noise was generally based on routine exposures over 85 dBA regardless of the actual exposure duration. The 85 dBA time-weighted criteria with a 5-dB exchange rate could also be used, and was more practically employed for Department of the Army civilians. To Anniston's credit (and eventual undoing) in 1995 they had comprehensive time-weighted noise exposure data on their employees using a 5-dB exchange rate. In 2000, 5 years after the Army had changed to the 3-dB exchange rate, a newly assigned occupational health physician intervened to implement the 3-dB exchange rate at Anniston Army Depot (Dr. Douglas W. Ohlin, personal communication).

During this 15-year study period, 588 workers were awarded $8,389,167—an average of $14,267 per hearing loss claim.[7] The highest number of claims (128) was awarded in 2001. In the previous year, over 600 workers had been added to the program rolls because of the delayed implementation of the 3-dB exchange rate. When their periodic hearing tests were compared to reference audiograms conducted many years earlier, there was a spike in the number of STSs. As a result of follow-up and referral procedures, reference audiograms were re-established and compensation filings were initiated. The 128 hearing loss claims awarded in 2001 were four times the average annual claim count over the previous 14 years. Anniston's almost singular focus of noise hazard evaluation to limit program enrollment continues to reveal the false economy of this approach. In the last year in which worker injury statistics are currently available (July 2007–June 2008) 47 workers at Anniston Army Depot were awarded $926,998—an average hearing loss claim of $19,723.[7] Thus, occupational hearing loss remains a major problem, and to suggest current criteria for inclusion in the Army HCP are excessive is, at best, unwarranted and completely unsubstantiated by the data presented by Oestenstad et al.

(4) Additional Comments Regarding the 3-dB Exchange Rate

In their discussion section, the authors state, "Although there are no 3-dB doubling rate data to compare to the 5-dB doubling data available for this study, it can be expected that the TWA values would be much higher." We take strong exception to this conclusion, as it is inappropriate to make such a broad assumption with no direct evidence to support such a claim. It is true that, in general, intermittent exposures will generate higher TWAs when using 3-dB vs. 5-dB exchange rates. However, as the authors mentioned, this can vary widely. Thus, the authors should not have stated that with the present study a 3-dB exchange rate would have resulted in "much higher" values. The fact that this is debated at all is somewhat puzzling. Virtually all noise dosimeters can make at least two independent TWA measurements. Given that their article is attempting to address Army policy, the authors should have made every effort to obtain data to support their conclusions and recommendations. With such a small number of subjects, the authors could easily have fit dosimeters on each of the subjects and obtained TWAs measured with both 3-dB and 5-dB exchange rates. Nevertheless, the issue is not which exchange rate will lead to larger or smaller TWAs, but which exchange rate is best suited for characterizing hazardous noise exposures. The authors make the simple assertion that because a 3-dB exchange rate may yield higher TWAs, the 5-dB exchange rate would be more appropriate to use for purposes of determining inclusion in a hearing conservation program. This line of reasoning ignores the extensive body of evidence that supports the 3-dB exchange rate as the most effective single exchange rate for determining noise levels associated with hearing hazards.[5,8–10]

CONCLUSION

The purpose of this article was to respond to a previously published article in *Military Medicine* by Drs. Oestenstad, Norman, and Borton, "Efficacy of the U.S. Army Policy on Hearing Conservation Programs" (Volume 173, No. 10, pp. 992–998). Using data collected from 45 civilian workers at the Anniston U.S. Army Depot, they concluded that the U.S. Army hearing conservation program would be better served by adopting a permissible exposure limit of 90 dBA with a 5-dB exchange rate. This article evaluated the methods, assumptions, and analyses employed by Oestenstad et al. to arrive at their conclusions. Specifically, we identified and discussed (1) shortcomings in the study design employed by Oestenstad et al., (2) errors in their application of ANSI S3.44, and (3) analytical and procedural errors in determining noise-induced permanent threshold shifts of their study population. We therefore, disagree with the conclusions put forth by Oestenstad et al. We believe that the Anniston U.S. Army Depot has not unnecessarily enrolled workers in its hearing conservation program. Moreover, we believe that the U.S. Army is well served by its current policy of using a 3-dB exchange rate and an 85-dB permissible exposure limit.

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