Assessment of the Proposed Draft American National Standard Method for Evaluating the Effectiveness of Hearing Conservation Programs

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Using audiometric data, this study assessed the Draft American National Standard ANSI S12.13-1991 (DANS) method for evaluating the effectiveness of hearing conservation programs by comparing it against a standard epidemiologic method. Although the hearing conservation program of the study population was rated as "acceptable" (scale: acceptable, marginal, unacceptable) using the DANS method, the epidemiologic method found a 130% increased risk of hearing loss (relative risk = 2.3, 95% confidence interval = 0.8 to 6.5). In addition, study workers who were excluded from analyses for failing to comply with the DANS criteria were found to be at significantly increased risk of hearing loss (relative risk = 9.1, 95% confidence interval = 3.4 to 24.2). These data indicate that the DANS method may overestimate the effectiveness of hearing conservation programs and systematically exclude workers at high risk of hearing loss from analyses.

Noise-induced hearing loss is one of the most common problems in industry worldwide[1-3] and affects many occupations, both civilian and military.[4-19] In the United States, occupational hearing loss is among the 10 leading occupational diseases.[5] It is estimated that occupational noise exposure greater than 90 dBA affects 2.9 to 3.4 million workers, and 5.2 to 8.9 million are affected at the 85 to 90 dBA range.[4]

Noise-induced hearing loss is very expensive. In a Canadian compensation board study from 1979 to 1983, the average cost per hearing loss claim was estimated at $14,106.[6] Office of Workers' Compensation Program costs for US federal agencies from hearing loss claims for fiscal year 1990 totaled $27,451,585.[7] Moreover, US Veterans Administration hearing loss compensation costs for calendar year 1990 were $205,733,820.[7]

Many studies have been published of hearing loss in noise-exposed worker populations,[9-18] but few have evaluated noise-exposed worker populations enrolled in a comprehensive hearing conservation program (HCP).[2] Recently, audiometric data base analyses techniques have been developed for evaluating industrial hearing conservation programs.[22-28] Based on these techniques, the American National Standard Institute (ANSI) Working Group S12/WG12 recommended the publication of the Draft American National Standard ANSI S12.13-1991 (DANS) for Evaluating the Effectiveness of Hearing Conservation Programs.[29] This Draft

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Standard has been approved by Accredited Standards Committee S12 for trial use, comment, and criticism before acceptance as an American National Standard. However, quantitative assessments of the DANS method are lacking. Thus, the aim of this study was to assess the validity of the DANS method in its capability to evaluate hearing conservation programs.

Methods

Study and Reference Populations

The study population was drawn from 2317 utility company employees who were enrolled in the HCP from 1979 to 1989. The criterion for entry into the HCP was exposure to a noise level of ≥85 dBA 8-hour time-weighted average (TWA), the Occupational Safety and Health Administration's action level. Exposure was determined by a Dupont MK-1 personal dosimeter twice a year.[31,32] All workers enrolled in the HCP were required to use personal protective devices (PPDs) consisting of ear plugs with a noise reduction rating ≥ 24 and/or ear muffs with a noise reduction rating ≥ 21. Reportedly, the use of PPDs was enforced by designated local shop safety personnel and nonuse of PPDs where required constituted grounds for disciplinary action. In addition, study workers were required to receive annual audiograms. Audiometric tests were performed according to the Council for Accreditation in Occupational Hearing Conservation guidelines[33] using audiometric booths meeting ANSI[34] and OSHA guidelines.[20] Hearing threshold levels were obtained at 0.5, 1, 2, 3, 4, and 6 kHz. Before the annual audiogram, at a work site, workers in the HCP completed a questionnaire that included identifying information. Data on race were not obtained.

The reference population was 105 tobacco company employees who had TWA noise exposures of approximately 87 dBA, reportedly wore PPDs consistently, and were followed from 1972 to 1984. This population was one of the control data bases used to develop the DANS standards.[29]

Subject Selection

Cohort restrictions as specified in the DANS method excluded a large number of the study population. Only 5% (112 of 2317) of the study workers had at least 4 annual audiograms complying with the DANS specified criteria. Each worker had four annual tests from 1984 to 1987, and the 1984 audiometric test was the first. Of the 112 employees who qualified for the analyses, only three were women. Therefore, the analyses was restricted to the 109 men only. Similarly, 94 of the 105 reference employees met the DANS criteria; 93 were men. They all had their first test in 1972, and had a total of four annual tests from 1972 to 1975. Therefore, in the initial comparison of study and reference workers, the results presented are based upon 109 study men and 93 reference men observed for approximately 3 years.

Because many of the study workers were excluded from analyses for failing to comply with the DANS criteria, we examined their risk profiles. The procedure by which we studied those who were excluded by the DANS was as follows: First, the 1984 to 1987 study cohort selected according to the DANS criteria described above was further observed until 1989 for a total of 5 years of follow-up resulting in 97 study workers (study cohort 1). This extended follow-up was made to allow more time for the development of a standard threshold shift (STS). Second, we selected 273 study workers who had a first test and a follow-up test 5 years later during 1984 to 1989, regardless of the number of audiograms received during this period (study cohort 2). Finally, study cohort 3 was formed by subtracting study cohort 1 from study cohort 2, resulting in 176 male study workers observed for 5 years, but who were excluded from analyses for failing to comply with the DANS criteria for annual audiometric evaluations. We were able to observe all 93 members of the reference cohort for approximately 5 years (1972 to 1977).

Data Analysis

The analysis of data employed the DANS method and a standard epidemiologic approach that we refer to here as the "risk ratio" method. The DANS method utilized the percent worse and standard deviation procedures for both individual and averaged test frequencies. The percent worse procedure computes the proportion of subjects whose hearing worsened by ≥15 dB between two sequential audiograms at test frequencies of 0.5 to 6 kHz in either ear. The standard deviation procedure computes standard deviation of the average binaural differences both for individual and averaged frequencies. The results from these procedures were then compared against a table of acceptable criteria recommended by the Draft ANSI S12.13-1991.[29] Using the standards, the HCP was then classified as being "acceptable, marginal, or unacceptable."

In the risk ratio method, the STS was used as a measure of hearing loss and was defined as a change of 10 dB or more in hearing threshold in the average of 2, 3, and 4 kHz in either ear.[20] Thus, a worker in this study was considered to have experienced hearing loss if the mean of the difference between the first and last audiograms at 2, 3, and 4 kHz was greater than or equal to 10 dB in either ear. For both the study and reference populations, the cumulative incidence of hearing loss was computed by dividing the number of subjects who developed hearing loss by the total number of subjects at risk.[36] The cumulative incidence of hearing loss in the study population divided by the cumulative incidence in the reference population gave the risk ratio (RR).[36] The RR provides the probability (likelihood) of developing hearing loss among the study population relative to that of the reference population. The age-adjusted RR was calculated by means of a stratified analysis using the method of Mantel-Haenszel.[37]

Results

Age Distribution

The age distributions for study and reference workers at baseline (ie, at first audiogram) were generally similar (Table 1). The average age at baseline for the study and reference pop-

ulations was 34.4 and 35.0 years, respectively.

Draft American National Standard Method

Based upon the percent worse sequential procedure of the DANS rating scale, the HCP of the study population received "acceptable," "marginal," and "unacceptable" ratings on comparisons of audiometric tests 1-2, 2-3, and 3-4, respectively (Table 2). Overall, the HCP was rated as "marginal" using this method.

The performance of the HCP was further evaluated using the standard deviation of the differences between tests 1 and 2, 2 and 3, and 3 and 4 for each audiometric test frequency. Using this method, the HCP received "acceptable" ratings for all test comparisons and frequencies except for 1-2 test comparison at 0.5 kHz, where the rating was "marginal" (Table 3). Thus, this method rated the HCP as "acceptable" in 17 of 18 (ie, 94%) test comparisons. In addition, the HCP received "acceptable" ratings for all test comparisons when the standard deviation of the average binaural differences for averaged frequencies were used (Table 4). Overall, using the percent worse and the standard deviation procedures for both individual and averaged frequencies, the DANS method rated the HCP as "acceptable."

Risk Ratio Method

The incidence of hearing loss for study workers rose with age from 2.8% in the 30 to 39 age group to a peak of 36.4% in the 50 to 59 age range (Figure). In this population, workers in the 50 to 59 age range had more than 5 times the risk of developing hearing loss when compared with those under 30. In contrast, reference workers had relatively lower incidences ranging from 0% in the under 40 age group to 28.6% in the 50 to 59 age group. The incidence of hearing loss for the study workers was consistently higher than for the reference workers at every age group.

Study workers had 2.6 times the risk of developing hearing loss as reference workers for all ages (Table 5). Because the incidence of hearing loss for the reference population below the age of 40 was zero, the association between worker status and the development of hearing loss was examined after stratification by age in those under 50 years of age and those 50 years and over. The risk ratio increased to 3.5 for study men under the age of 50. However, the ratio diminished to 1.3 for those over the age of 49 years. After age adjustment, the study population had a 130% increased risk of

TABLE 1
Age Distribution at Baseline of Study and Reference Workers

Age, y	Study Workers, N = 109 (%)	Reference Workers, N = 93 (%)
<30	42 (38.5)	28 (30.1)
30–39	36 (33.0)	37 (39.8)
40–49	20 (18.3)	21 (22.6)
50–59	11 (10.1)	7 (7.5)

TABLE 2
Summary of Percent Worse Sequential Computations with Associated Hearing Conservation Program (HCP) Ratings for Male Industrial Workers (N = 109)

Test Computation	Total	Percent Worse Sequential	HCP Rating*	Range†
1–2	109	29.4	Marginal	20–30
2–3	109	19.3	Acceptable	<20
3–4	109	31.2	Unacceptable	>30

* Draft ANSI Standard S12.13-1991 rating scale.[29]
† Draft ANSI Standard S12.13-1991 recommended criterion ranges.

TABLE 3
Standard Deviation of the Average Binaural Differences with Associated Hearing Conservation Program (HCP) Ratings by Audiometric Frequency for Male Industrial Workers (N = 109)

Frequency (kHz)	Test 1–2			Test 2–3			Test 3–4		
	SD	HCP Rating*	Range†	SD	HCP Rating*	Range†	SD	HCP Rating*	Range†
0.5	6.0	M	6–7	4.5	A	<6	5.3	A	<6
1	4.2	A	<6	4.2	A	<6	4.5	A	<6
2	4.9	A	<6	3.9	A	<6	5.1	A	<6
3	5.2	A	<7	4.6	A	<7	5.3	A	<7
4	6.4	A	<7	5.9	A	<7	6.9	A	<7
6	8.1	A	<9	6.2	A	<9	8.8	A	<9

* Draft ANSI Standard S12.13-1991 rating scale. M = marginal, A = acceptable.
† Draft ANSI Standard S12.13-1991 recommended criterion ranges.

TABLE 4
Standard Deviation of the Average Binaural Differences with Associated Hearing Conservation Program (HCP) Ratings by Averaged Frequencies for Male Industrial Workers (N = 109)

Frequency Averaged (kHz)	Test 1–2			Test 2–3			Test 3–4		
	SD	HCP Rating*	Range†	SD	HCP Rating*	Range†	SD	HCP Rating*	Range†
0.5, 1, 2, 3	3.8	A	4.5	3.5	A	4.5	4.3	A	4.5
2, 3, 4	4.6	A	5.5	4.2	A	5.5	5.2	A	5.5
3, 4, 6	5.2	A	6	4.3	A	6	5.7	A	6

* Draft ANSI Standard S12.13-1991 rating scale. A = acceptable.
† Draft ANSI Standard S12.13-1991 recommended criterion range.

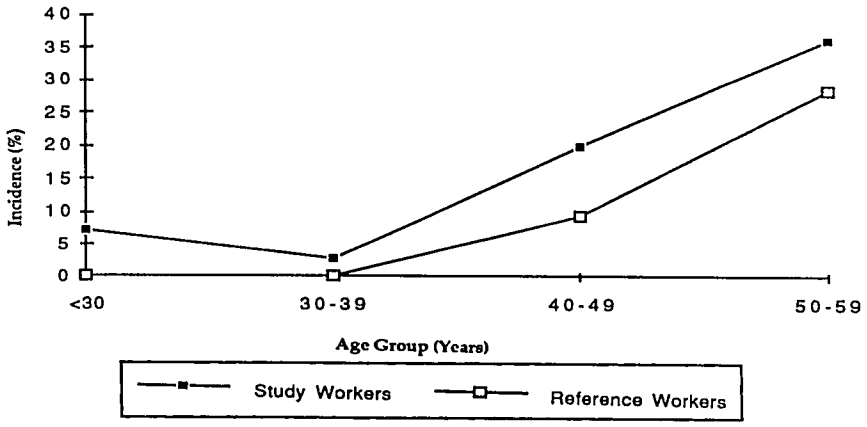

Figure. Incidence of hearing loss by age in study and reference workers.

TABLE 5
Incidence of Hearing Loss and Risk Ratio in Study and Reference Workers According to Age

Age, y	Reference and Study Populations	No. with Hearing Loss	No. at Risk (Cumulative Incidence, %)	Risk Ratio (95% CI)
All ages	Reference	4	93 (4.3)	1.0
	Study	12	109 (11.0)	2.6 (0.9–8.9)
<50	Reference	2	86 (2.3)	1.0
	Study	8	98 (8.2)	3.51 (0.8–16.1)
≥50	Reference	2	7 (28.6)	1.0
	Study	4	11 (36.4)	1.3 (0.3–5.1)
	Age-adjusted risk ratio RR_{MH} (95% CI) = 2.3 (0.8–6.5)			

developing hearing loss compared with the reference population (risk ratio [RR_{MH}] = 2.3, 95% confidence interval [CI] = 0.8 to 6.5).

After selection in accordance with the DANS criteria and extending the follow-up period from 3 to 5 years, the risk ratio for study cohort 1 relative to the reference cohort was 2.2 (95% CI = 0.7 to 6.8) (Table 6). This ratio was not substantially different from the calculated risk ratio of 2.6 (95% CI = 0.9 to 8.9) when the original study and reference cohorts were compared (Table 5). For study cohort 2 (ie, workers meeting the risk ratio criteria, but not necessarily meeting the DANS criteria) the risk ratio was 6.7 (95% CI = 2.5 to 18.3) (Table 6). Because the DANS method selected only 5% of the original study cohort, we determined the risk characteristics of those excluded. Accordingly, when we compared the incidence of hearing loss of the study population that was excluded from analyses (study cohort 3) by the DANS method to that of the reference population, a statistically significant ($P < .001$) high risk ratio was observed (RR = 9.1, 95% CI = 3.4 to 24.2).

Discussion

In this paper we present an assessment of the proposed Draft American National Standard for Evaluating the Effectiveness of Hearing Conservation Programs (Draft ANSI S12.13-1991).[34] The assessment was made by comparing results of the proposed standard with an epidemiologic method of comparing risks in study and reference populations.[36] Overall, the proposed standard rated the HCP as "acceptable" (scale: acceptable, marginal, unacceptable) for men in the study population. In contrast, the risk ratio method revealed that for all men the age-adjusted risk of developing hearing loss was 2.3 times that of the reference population. Although a larger sample size is needed to make the estimate of the RR more precise, we believe that a HCP in which study workers had more than a twofold increased risk of developing hearing loss should not be rated as "acceptable." Ideally, this ratio would be expected to approach 1.0 if study workers did not experience noise-induced hearing loss. As noted above, the reference population used in this study was one of the control data bases used to develop the Draft American National Standard. Members of this reference population were industrial workers. Even though reference workers were reportedly well protected in a work environment with TWA noise exposures of approximately 87 dBA, it is possible that their incidence of hearing loss exceeded that of a nonindustrially noise-exposed population. An increased incidence of hearing loss in the reference population would have reduced the magnitude of the risk ratios calculated for the study worker populations. In other words, the age-adjusted risk ratio may have been greater than 2.3-fold for all men had we used a nonindustrial worker group as a reference population. Therefore, the data presented indicate that the proposed Draft ANSI Standard may overestimate the effectiveness of a HCP.

The study workers who did not comply with the restrictive proposed Draft ANSI Standard criteria for inclusion in the analyses were found to be at more than 800% increased risk of hearing loss (RR = 9.1, 95% CI = 3.4 to 24.2) compared with reference workers. Hence, the proposed DANS method appears to exclude systematically workers at high risk of hearing loss from the analyses. This could lead to an underestimation of the adverse effect of industrial noise exposure on hearing loss, giving a spurious impression of program effectiveness.

A major limitation of this study is the appropriateness of the reference population stemming from the unavailability of certain potential confounding variables such as race, chronic ear disease, middle-ear infections, hereditary hearing loss of progressive nature, head trauma, and noise exposure outside the work en-

TABLE 6
Incidence of Hearing Loss and Risk Ratios in Four Different Male Cohorts

Reference and Study Workers	No. with Hearing Loss	No. at Risk (Cumulative Incidence, %)	Risk Ratio (95% CI)
Reference cohort*	4	93 (4.3)	1.0
Study cohort 1†	9	97 (9.3)	2.2 (0.7–6.8)
Study cohort 2‡	78	273 (28.6)	6.7 (2.5–18.3)§
Study cohort 3‖	69	176 (39.2)	9.1 (3.4–24.2)§

* Cohort selected according to Draft ANSI Standard but with extended follow-up to 5 years (1972–1977).

† Cohort selected according to Draft ANSI Standard but with extended follow-up to 5 years (1984–1989).

‡ Cohort followed for 5 years with audiometric tests in at least the first and fifth years (1984–1989).

§ $P < .0001$.

‖ Cohort excluded by Draft ANSI criteria = study cohort 2 minus study cohort 1.

vironment. Thus, the true risk ratio may be underestimated or overestimated if the frequency of occurrence of these potential confounders were different in the study and reference populations.

This study has raised a serious question as to the applicability of the proposed DANS method in evaluating hearing conservation programs designed to protect all workers from industrial noise-induced hearing loss. Similar investigations using other data bases appear warranted to confirm these findings before the proposed standard can be seriously considered for approval as an American standard. In addition, a concerted effort needs to be made to establish several data bases of nonindustrial noise-exposed populations for use as reference populations.

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Change: the Ultimate Concern

I am concerned, as is obvious, with an image—the image of our species as a vast, featureless mob of yahoos mindlessly trampling this planet's most ancient and delicate harmonies. This image, which is on its way to becoming an article of faith, is not a completely inaccurate description of present conditions in some parts of the world, but it portrays the human presence as a sort of monolithic disaster, when in fact *Homo sapiens* is the crown of creation, if by creation we mean the explosion of earthly vitality and particularity long ago ignited by a weak solution of amino acids mixing in sunlit waters. Change—dramatic, wholesale change—is one of the most reliable constants of this story. To say that the changes we have brought, and will continue to bring, are somehow alien to the world, and are within a half inch of making its "natural" continuance impossible, displays some contempt, I think, for the forces at work, along with a large dose of inverted pride. Who are we, for instance, to say what's possible and what isn't? Have we already glimpsed the end? Where exactly did things go awry? It's useful to remember that just yesterday our main concern was finding something to eat.

—From "The Case for Human Beings" by T. Palmer in *The Atlantic Monthly*, Jan 1992:269:83–88.