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SOME NON-OCCUPATIONAL ASPECTS OF SENSORINEURAL LOSS OF HEARING ACUITY--A PROPOSED DESIGN FOR STUDY

Thomas Varley, B.S., M.D.
The University of Texas
Health Science Center at Houston
School of Public Health, 1985

Supervising Professor: Martin D. Werner

Although the adverse effects of occupationally associated noise on hearing have been well documented, review of the recent literature revealed few studies which have carefully measured the role of non-occupational loud sound in sensorineural hearing loss. This proposed study will measure the strength of association of sensorineural deafness and avocational noise by calculating the odds ratio in a case-comparison design. The prevalence of avocational loud noise activities of a group of 200 cases diagnosed as having sensorineural deafness at retirement from the United States Air Force will be compared with the prevalence of avocational loud noise activities of a group of non-deaf Air Force retirees who have been matched for age, service occupation, family history of hearing loss, personal history of hearing loss and known causes of otic dysfunction.

Limitations of the study and anticipated results are
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By

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DESIGN FOR STUDY

by

Thomas Varley, B.S., M.D.

APPROVED:

________________________
Martin D. Werner, Ph.D.

________________________
Clayton W. Eifler, Ph.D.
DEDICATION

This work is dedicated to my advisers, Drs. Martin D. Werner and Clayton W. Eifler. They showed an inordinate amount of patience and consideration throughout this entire undertaking. Clinical training and experience do not necessarily shed much insight on the microworld of research and hence I came to this project pretty green. If they were exasperated they never let it show.
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PROJECT
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SCHOOL OF PUBLIC HEALTH
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Turning over new ground is a more forbidding task if one is obliged to undertake it alone. Fortunately for me there were people who contributed time and talent so that this paper would not be a lonely, solo production. Their help extended to current, unpublished information. I want to extend thanks to Harrell C. Sutherland, Jr., and Roy Danford, Jr., both of the USAF Hearing Conservation Laboratory; to Colonel J. Wiley, Captain Rebecca Caraway and Ricardo Diaz—all at the USAF Manpower Personnel Center, to Major Charles L. Mannix of Bolling Air Force Base and Georgetown University School of Law; and to the staff of the medical libraries at Brooks Air Force Base and the University of Texas at San Antonio. All gave unstintingly and I am grateful to them.
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INTRODUCTION

Every case of sensorineural loss of hearing acuity noted upon retirement of United States military members, unless acquired frivolously, is considered to have occurred in the line of duty. Thus, sensorineural hearing loss is generally assumed to be due to loud noise on the job unless the loss can be documented to be the result of ear disease or other trauma (AFOSH 161-17, 1982). If the retiree has 30% or more hearing loss in at least one ear, then a commensurate part of the pension is given tax-free as a medical disability (AFR 160-43, 1979). According to Veterans Administration figures this amounts to nearly 13 million dollars each month, accounting for all military retirees receiving pension money for hearing disability (Sutherland, Personal communication, 1985).

Periodically all procedures and reports concerning hearing problems are reviewed and new means of hearing conservation are considered and adopted when feasible. This reviewing process includes amending policies such as the type of required protective gear to be worn by all personnel known to be exposed to loud occupational noise. Such improvements are made consistent with state-of-the-art technology. Surveillance of noise problems continues incessantly. There is no good reason to suppose that persons exposed to pathologic levels of job noise are not being looked after optimally in the military (Sutherland, Personal communication, 1985). During the last twelve months only one person was retired from the U.S. Air Force solely due to hearing loss (Caraway, Personal interview, 1985). Sensorineural hearing loss noted upon re-
tirement after 20 years of Air Force service is reported to be about 15 per cent, but no one is certain of this information because a) most hearing-impaired people are kept on active duty until retirement using hearing aids and b) the computers at Medical Retirements Section at Randolph Air Force Base keep only the first three diagnoses and only rarely is one of them sensorineural hearing loss (Wiley, Personal communication, 1985).

No study has been done which was designed to examine whether persons not exposed to sufficiently traumatic on-the-job noise to cause hearing loss do get significant sensorineural hearing loss from loud noise suffered off the job. If significant numbers of these non job-exposed people are losing part of their hearing from loud noise off the job, then perhaps some specific causes might be identified and/or eliminated. Different strategies might suggest themselves to those concerned with hearing conservation. Additional revision of the current Air Force policy of compensation for cases of sensorineural hearing loss might be justified. From the preceding, then, questions arise. Is there an association between sound heard off the job and significant sensorineural loss of hearing acuity? If non-occupational noise is associated with hearing loss then how strong and how stable is the association? This study is designed to begin to answer these questions.
REVIEW OF LITERATURE

Hearing, sensorineural hearing loss, hearing loss secondary to noise, and the awful cost of lost hearing which is not reversible—are all areas which have attracted considerable attention and study. One hundred and seventy-four articles and chapters have been published in English on the subject of human noise-induced hearing loss since 1970. Ninety-seven of them have been published since 1980, possibly a reflection of increased interest in the field.

To the researcher, there is a problem of selecting the material most germane to a specific topic from the many available. While the hearing loss secondary to noise is sensorineural, one finds the literature under the heading "Hearing Loss Noise-Induced". Perhaps owing to the potential difficulty in financing studies which might not pay off in industry, there is a clear preponderance of studies of hearing lost in the workplace as opposed to hearing lost off the job. One article by two members of the Jefferson Medical College ENT faculty points out that hearing loss due to occupational noise is our most prevalent industrial disease (Sataloff, 1984). They claim that 8 million people have suffered noise-induced hearing loss in American industry. They are counting only those people who were still employed at the writing of the article, not people who have been impaired during the history of U.S. industry. A somewhat sweeping claim which should be given some consideration is that neglect of prevention of this noise-induced loss has resulted in human and economic consequences which
affect virtually every American household. The authors consider this especially regrettable since noise-induced hearing loss is "almost completely preventable at relatively little cost". No specific mention is made of costs or what should be done to prevent further such occupational loss.

Of singular value to my own undertaking, however, is the warning that all people should be made aware of the dangers of non-occupational noise exposure, such as that associated with using chain saws, firearms, motorcycles and snowmobiles (Sataloff, 1984).

An United States Army researcher shows that among three career fields (Infantry, Armor, Artillery) 20-30% of personnel with two or more years of service show clinically significant hearing loss (Hefler, 1984). He notes that in these same fields after 15 years of service more than 50% of soldiers demonstrate the same losses. A Rumanian group has examined parallels between changes in long bone and deafness in operators of pneumatic hammers (Ghibus, 1984). Establishment of a dose-bioeffect relationship in long-term exposure to occupational noise has been reported in the USSR (Muhkin, 1984). High peak pressure, the single-burst effect which can result in permanent damage after one exposure was investigated by a team in West Germany (Pfander, 1984). They have attempted to seek out the significance of high peak pressure in acoustically-induced hearing loss by determining levels of auditory fatigue after acoustic stress with peak pressures. Their findings could ultimately be of non-occupational importance because high peak pressures can be encountered unexpectedly while simply
talking into a cordless telephone as the next article mentioned indicates (Singleton, 1984). OSHA maximum industrial noise levels have been lowered from 90 decibels to 85 decibels for workers employed over an eight-hour day (Harmon, 1984). In order for workers to stay in sound levels higher than 85 decibels, approved hearing protective gear must be worn at all times. It is significant to observe that the same specific trauma concerns investigators on both sides of the Atlantic at the same time.

The study which deals with the threat to hearing said to be inherent in some cordless telephones might be of interest to anybody (Singleton, 1984). Fifteen patients seen in the same clinic presented with significant sensorineural loss reportedly caused by having cordless telephones accidentally ring in their ears. Several (8) of these patients had pre-existing sensorineural loss said to be secondary to occupational trauma. According to the authors, who did post-trauma Audiograms to match the ones they had taken prior to the telephone trauma, these 8 patients had extended their losses by the telephone incidents. The standard of the Electronic Industries Association for maximum peak acoustic power is 130 decibels, the study points out. Maximum workplace exposure for impulse noise (that which occurs in single bursts as opposed to protracted sound over longer increments of time) is 140 decibels, according to the authors. The phones used by each patient were brought to the clinic and measured by the same standardized gear and they were found to be in excess of the maximum impulse standard, some by as much as 12 decibels. The authors advise all physicians and audiologists
to make their patients aware of dangers inherent in cordless telephones. The reported hearing damage done is mid-frequency loss associated with a high-intensity low-frequency ringing device located in the earpiece (Singleton, 1984). While small, the study is mentioned because it is reported on in detail and deals with one area of noise seldom mentioned in the American literature at the present time, the impulse loss.

A similar finding which points to parallel trauma but occurring over longer time frames is the object of a letter by a group in Boston (Katz, 1982). Stereophonic earphones, they claim, have the potential of inducing permanent sensorineural hearing loss. They tested two portable FM radios and one stereo cassette player and reported that sound levels in excess of 115 decibels can be reached on all three sets. Each set was tested on the same instruments. In view of the OSHA standard of 85 decibels maximum level for long-term (8-hour) noise one can see why the authors were concerned. They advised that there can be no doubt that these sets have the potential for causing permanent bi-lateral sensorineural hearing loss when worn for extended periods. No fault, it seems is found with the radios-cassette players until teamed with the earphones.

Few correlations could be demonstrated in Sweden between hearing loss and specific leisure time activities among 538 boys between 17-20 years old, but the study was designed to examine whether the same subjects were suffering noise-induced hearing loss during vocational classes (Axelsson, 1981). The authors claim that 15 per cent of the group demonstrated a 20 per cent
hearing loss, but they provided no data to substantiate that figure. While one study does not deal with hearing loss in any form, it establishes the doctrine that children up to age 12 may be more susceptible than adults to communication interference (Dejoy, 1983). This study indicates that 45 decibels is the maximum desirable level for environmental noise while classes are being conducted. Beyond this the children cannot concentrate well on the information being given orally (Dejoy, 1983).

A group in North Carolina compares the hearing acuity of unscreened black subjects who have not been exposed to industrial noise to four previously established data bases (Driscoll, 1984). The data bases show hearing losses by age and sex, among whites and among industrial workers, respectively. The data bases were established by separate, but similar, studies which began in 1969 and were done serially. Following the same study design, Driscoll's findings suggest that there are at least potential differences among races in sensitivity to noise. The authors advise that these differences should be considered during development of national standards for dangerous noise. The group stresses that these racial differences should be especially considered if hearing conservation groups are to be maximally effective (Driscoll, 1984).
THE NATURE OF SOUND

The molecules which make up air have two qualities without which there could be no noise to deafen people but no sound for them to hear. The qualities are inertia and elasticity, which allow the small particles to bump together and then bounce apart. The bumping together is called compression and the bouncing apart is called rarefaction. If this sort of bumping and bouncing is conceived of as going on through a huge wall of particles (which is what air really is) then it could be plotted as in Figure 1A. Any action requires time to occur and waves of sound are plotted in parts of seconds. A sound wave is the distance an impulse travels during one complete cycle of compression through a period of rarefaction back to the beginning of the next period of compression (Gasoway, 1979).

An often-used term of reference is "frequency". Frequency is the number of cycles per second at which a wave passes from a mid-point of a period of compression through a period of rarefaction up to the mid-point of the next period of compression. Frequency is measured in units called Hertz. One cycle per second is one Hertz. The relation of wave length to frequency is shown in Figure 1B.

The other chief unit of measurement in sound is called the decibel. It is used to express the intensity or magnitude of a given sound generates at a given point in space. One might tend to think of a decibel as an absolute measure of something, such as a centimeter, but it is not. Common noise generates a tremendous
FIGURE 1

Wave Length and Frequency and Their Relationship to Harmonic Motion

1A.

_wave length_ (distance from one compression to another)

1B.

WAVELENGTH IN AIR VS. FREQUENCY

WAVELENGTH (λ) IN FEET

<table>
<thead>
<tr>
<th>100</th>
<th>50</th>
<th>20</th>
<th>10</th>
<th>5</th>
<th>2</th>
<th>1</th>
<th>0.5</th>
<th>0.2</th>
<th>0.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>20</td>
<td>50</td>
<td>100</td>
<td>200</td>
<td>500</td>
<td>1000</td>
<td>5000</td>
<td>10,000</td>
<td></td>
</tr>
</tbody>
</table>

FREQUENCY IN Hertz (Hz)

Taken from Section III Audiology and Hearing Conservation
range of sound power, so many levels that the human mind cannot keep accurate track of them. So a scale was worked out on logarithmic ratios which group together large groups of levels (Gasoway, 1979). This scale sets up a notion called a sound pressure level and makes the absolute minimum threshold of human hearing equal to 0 decibels. Sound pressure itself is measured in Newtons per square meter and is not really germane to this study, but Figure 2 illustrates the relationship between sound pressure and sound pressure levels. While 0 decibels is the absolute threshold of human hearing, no one can hear 0 decibels. The actual hearing threshold of many people might be a soft whisper at five feet. That sound is measured at roughly 20 decibels (Figure 2).

These concepts are fundamental to understanding hearing and hearing loss. The preceding information was taken from Section III of Audiology and Hearing Conservation.
FIGURE 2
Relationship of Sound Pressure to Sound Pressure Levels

<table>
<thead>
<tr>
<th>Pressure in Newton/m²</th>
<th>Sound Pressure Level (in dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000</td>
<td>160 F-4E w/AB, Take-Off, 45° at 100'</td>
</tr>
<tr>
<td>1000</td>
<td>140 Threshold of pain (human hearing)</td>
</tr>
<tr>
<td>10</td>
<td>120 Noisy factory</td>
</tr>
<tr>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>0.1</td>
<td>80 Noisy business office</td>
</tr>
<tr>
<td>0.1</td>
<td>60 Average voice at 3'</td>
</tr>
<tr>
<td>0.01</td>
<td>40 Ambient noise in an average home</td>
</tr>
<tr>
<td>0.00002</td>
<td>20 Soft whisper at 5'</td>
</tr>
<tr>
<td>0</td>
<td>0 &quot;Absolute&quot; threshold of human hearing</td>
</tr>
</tbody>
</table>

Taken from Section III Audiology and Hearing Conservation
The normal human ear has a remarkable range of sensitivity. It can discriminate frequencies from 20 Hertz to 20,000 Hertz. Receiving these sounds in the form of waves is the job of the outer and middle ears, which together actually are an antenna and conduction mechanism. Impulses are picked up from the air by the ear drum and passed on to a structure in the inner ear called the cochlea. It is in the cochlea that the process which people understand as "hearing" actually occurs (Gasoway, 1979).

Other structures in the inner ear are ignored here because the crux of hearing is the cochlea, which has two parts. Of these the bony cochlea is mentioned only because it houses the real nerve center of hearing, the membranous cochlea, in which is located the organ of Corti.

By looking at Figure 3 it can be noted that the human cochlea makes two and three-fourth turns from beginning (base) to end (apex). Figure 3 shows these turns and also indicates various amplitudes for pure tones. This makes it clear that higher frequencies, such as 20,000 Hertz are represented at the basilar end of the cochlea and the very lowest frequencies, such as 20 Hertz are represented at the other, apical end. This is important when understanding sensorineural hearing loss (Gasoway, 1979).

Within the organ of Corti is a structure called the tectorial membrane, as can be seen schematically in Figure 4. Further, it can be noted that hair cells protrude from this membrane. What cannot be seen is that smaller hair-like cells called microcilia protrude from these hair cells. Each organ of Corti, before
FIGURE 3

The Cochlea, Showing Frequencies Represented from Higher to Lower.

Regions of maximum amplitude for pure tones

Taken from Section III Audiology and Hearing Conservation
FIGURE 4
Schematic View of the Organ of Corti

Tectorial membrane

Inner hair cells

Outer hair cells

Basilar membrane

Taken from Section III Audiology and Hearing Conservation

14
any damage occurs, starts out with about 35,000 microcilia (Schubert, 1980). The function of the organ of Corti is known to be the changing of physical sound impulses into electrochemical signals and then sending them toward the brain via the acoustic portion of the VIIIth Cranial nerve. Just how this is accomplished is not fully known (Price, 1983). There is more information in the source from which this material was taken, which is ET Handout No. 15, Audiology and Hearing Conservation.
HOW NOISE INDUCES HEARING LOSS

While no one knows exactly how microcilia change physical impulses into electrochemical signals, much can be told if microcilia are absent. In experimental animals and also in man, microcilia are seen in multitudes when no hearing loss has occurred but are in fewer numbers following hearing loss (Jurger, 1981).

There are really two types of hearing loss. One is conductive, which usually takes place when calcium-like deposits grow over a window-like structure in the middle ear. This condition is often reversible through means of a surgical procedure. It is important to note that in pure conduction deafness, the lesion is at the middle ear and the cochlea is unharmed. The microcilia are not a part of or even near the site of conductive deafness (Sataloff, 1980). Noise-induced deafness does affect the cochlea, and more specifically the microcilia. Moderately loud noise breaks parts of some microcilia off; if rested they regenerate completely almost overnight (14 hours) and resume full function. There may be no limit to the number of times one of these cells can regenerate if it is partly broken (Sataloff, 1980).

At very loud noise or at sustained levels greater than 84 decibels over a time frame which varies with the person, entire microcilia disintegrate. Sometimes even the membrane beneath them is traumatized. If the entire microcilia is destroyed it never regenerates. When this happens to large numbers of microcilia then sensorineural hearing loss occurs. This loss is not rever-
sible (Gasoway, 1979).

An experimental operation begun at Mt. Sinai School of Medicine in New York and now being done at six centers holds out some possible future hope for those who will become impaired due to cochlear trauma. While primitive at present the surgical procedure, called a cochlear implant, has provided nearly 50 per cent of patients with enough acuity to hear a telephone ring. It does not (at least at present) permit the patient to distinguish between shouted sounds. The same implant has been used in several selected patients who were born without normal cochlear function with approximately the same results. If the implant improves a great deal in sensitivity it would provide the first hope in medical history for the noise-damaged patient (Parisier, 1984).

There seem to be differences in the damage caused by equally loud noises. For example, in experimental animals differences in microcilia were found in those who have been exposed to the report of a cannon than were found in those who have been exposed to the report of a rifle although both reports were of equal loudness (Price, 1985). Permanent damage can occur from one very loud burst of noise or from chronic exposure to less loud but still stressful noise levels. At higher than 140 decibels, which is the noise level produced by the crowd when a touchdown is scored at the Kingdome in Seattle, only one burst of sound can produce permanent sensorineural damage (Mueller, 1985, Gasoway, 1982). Another mode of sensorineural trauma is chronic exposure to stressful noise levels over periods of weeks to years. For example, most people stay safely at noise levels up to 84 decibels for
8 hours a day for indefinite periods (AFR 161-35, 1982). The same people in a discotheque at a distance of 10-15 feet from the sound source would be in danger of permanent damage after 2 minutes and 23 seconds. Were these normal people to leave that same discotheque after a visit of several minutes and then have no re-exposure to stressful levels of sound overnight, then no permanent damage is likely to result. Were these same people to visit the same discotheque for several hours each night over a period of months, the likelihood of ultimate permanent damage would be high (Danford, 1985).

Noise levels from several common sources are given on Table 1.
TABLE 1
Noise Levels from Some Common Sources (From Danford, 1981)

**Safe Levels**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Decibels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flushing of a Toilet (initial flush)</td>
<td>70-75</td>
</tr>
<tr>
<td>Typical Home Hair Drier</td>
<td>70</td>
</tr>
<tr>
<td>Typical Human Voice from 3 feet away</td>
<td>70</td>
</tr>
<tr>
<td>Home Vacuum Cleaner (to its operator)</td>
<td>70</td>
</tr>
</tbody>
</table>

**Unsafe Levels**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Decibels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Lawn Mower</td>
<td>87-96</td>
</tr>
<tr>
<td>Typical Discotheque</td>
<td>105</td>
</tr>
<tr>
<td>(75 feet from sound source)</td>
<td></td>
</tr>
<tr>
<td>The Level of Pain</td>
<td>140</td>
</tr>
</tbody>
</table>
STUDY DESIGN SELECTION

While persons have become permanently deaf from having been exposed to one great burst of noise, most loss of acuity to chronic noise levels takes five years to manifest and sometimes much longer. These losses are not reversible (Price, 1983). They are due to permanent damage to structures in the inner ear (Gasoway, 1985). Consequently surveillance for periods up to 20 years is a desirable plan if one has the time because more loss is likely to have become manifest and measurable after this time period.

A confounding variable which could enter as a result of using so long a time frame is presbycusis, the hearing loss associated with aging. But if every subject in the study were less than 50 years old the detectable presbycusis would affect fewer than 2 per cent of them (Tables of Vital and Health Statistics, 1965). The majority of enlisted people enter the Air Force at ages 18-20 years, hence retirement after 20 years would begin at 38 (Diaz, Personal communication, 1985). Most officers enter the Air Force upon graduation from college at 21-23 years and retirement for them after 20 years begins at 41 (Diaz, Personal communication, 1985). People who stay in the service longer than 20 years will not be a part of this study. Since the population pool from which all subjects in this study are selected is 39-43 years, no age varies from any other by more than six years.

There are factors in favor of choosing a retrospective case-comparison design over a prospective cohort analytic design.
A minimum time frame of ten years would be required to show manifest hearing loss due to the intensity of noise exposure of interest in the study. More power would be inherent in a 20-year surveillance. Such delay resulting from the use of a prospective design may be reasonable at times. However, in terms of potential gained for reducing disease earlier, getting the results sooner through use of the retrospective design is to be desired. The lower cost of a retrospective study is also a consideration. The technique for measuring hearing loss in this study, the Audiogram, has been used on every military recruit since 1959 and this investigation would draw from a pool dating back only to 1965, so each subject will have had one upon entering service and another upon retirement. No difference has been measured in the performance skills of audiological technicians (Audiographers) during that time. Consequently, Audiograms done on each subject at induction into the Air Force can be compared with Audiograms done upon retirement (Sutherland and Danforth, Personal communication, 1985).

To summarize, the retrospective case-comparison design is more sensitive than the analytic cohort design in measuring strength of association of non-occupational noise and hearing loss. It is also a less costly design and can be obtained in a shorter period of time, hence it is chosen to be employed.
SELECTION OF SAMPLE SIZE

Sample sizes for this study were arrived at by the use of equations taken from the work of James J. Schlesselman (1982). His work is the basis for sample size programs on computer at the University of Texas School of Public Health at San Antonio.

The number of controls per case, as a determinant in sample size, depends on the power required by the study. In this case 3 controls per case are chosen because more (for example, 4) would provide only marginally more power, yet require much larger numbers of subjects with its attendant number of negative aspects. The following statistical equations were used to determine sample size in this study:

\[
[1] \quad n = \frac{Z_a \sqrt{\left(1 + \frac{1}{c}\right)\bar{p}\bar{q}} + Z_b \sqrt{P_0Q_1 + \frac{P_0Q_1}{c}}}{(P_1 - P_0)^2}
\]

In which:
- \(n\) = sample size (subjects)
- \(c\) = number of controls per case
- Odds Ratio = 2 (approximately equal to relative risk)
- \(z_a(\alpha) = 1.645\)
- \(z_b(\beta) = 1.282\)
- Alpha error = 0.05 One-sided Test
- Beta error = 0.01
- \(p_o\) = frequency of exposure among controls
\[ \bar{Q}_0 = 1 - P_0 \]
\[ Q_1 = 1 - P_1 \]
\[ \bar{Q} = 1 - \bar{P} \]

\[ [2] \quad P_1 = \frac{P_0 R}{1 + P_0 (R-1)} \]

\[ [3] \quad \bar{P} = \frac{P_1 + C P_0}{1 + C} \]

These equations yield 201 cases.
THE STUDY

About eleven hundred members of the United States Air Force retire each month (Diaz, Personal communication, 1985), of which approximately 10 per cent have documented significant sensorineural hearing loss (Sutherland, Personal communication, 1985). This study attempts to measure the strength of association between deafness and non job-related noise in some of these retirees. In order to do so, subjects will be divided into two groups. The first will be called the case group. Each case member has a sensorineural hearing loss of at least 30 decibels in at least one ear. About 201 cases will be required.

The second group will be called the control group. No member of the control group could have lost a significant amount of hearing during the 20 years of military service. Since no loss greater than 15 decibels in one ear was the minimum standard required for enlistment, that will be the standard for a control for this study (AFR 160-43, 1979). Control subjects number 603. Only 20 year retirees will be selected for either group. All subjects included in both groups are otherwise similar. They have parallel work experience, none have been exposed to on-the-job noise loud enough to have caused hearing trauma and all must be between 39 and 43 years of age.

Not all sensorineural hearing loss is associated with noise. Such loss can be due to inflammatory or tumorous otic disease, medications such as antibiotics and other iatrogenic factors. Genetic causes can be responsible as well as other forms of...
trauma and such loss is associated with aging (Sataloff, 1980). All subjects will be screened for all known causes of significant sensorineural loss by an otolaryngologist at the respective Air Force base of retirement. Those who could have had loss due to any of those causes will be eliminated from the study. The specialist will examine each subject, review each medical record and then administer the questionnaire. The first duty of the otolaryngologist will be to screen for confounding causes of hearing loss whether occupational or other and reject unsuitable subjects. The second duty will be to separate cases from controls. The third duty will be to administer the questionnaire (Appendix B) in such a way that the specialist is satisfied that he can decide in each subject whether there has been sufficient exposure to off-the-job noise to cause hearing loss. At that point the primary selection of subjects is made by the otolaryngologist.

Central to determining the amount of harmful sound to which all subjects have been exposed is a definition of pathologic noise. First, the Air Force has a great many persons exposed to the sounds of airplane engines and other noise and has been dealing with those associated problems for many years. Air Force Regulation 161-35, last reviewed in 1982, designates 84 decibels as the maximum level at which a person may stay full-time without suffering hearing loss due to the noise level. Even while there is no known precise minimum level at which all people suffer loss, those working for the Air Force must wear approved protective gear at 84 decibels and at greater levels. Consequently for purposes of this study 84 decibels will be considered the threshold of
noise which causes damage to hearing. The current NIOSH standard for maximum loud noise is 85 decibels (Harmon, 1984).

This study's concern, however, is with off-the-job noise. Hence it is obligatory to set up a level of sound which is not measurably injurious to human hearing. Then it might be postulated that persons working at or below that safe level cannot have lost any significant amount of hearing from that exposure.

In a search for that level one notes that hand-held decibelmeters designed to measure safe and harmful levels of sound begin calibrated measurement at 70 decibels (Realistic, 1983). Home vacuum cleaners average 70 decibels as do home hair dryers and the flush of toilets. The sound of a busy business office is 70 decibels and every one of those mentioned must meet NIOSH standards (Danford, 1981). The critical level of exposure to non-occupational noise for this study will be set at 70 decibels which is conservative compared to U.S. Air Force and OSHA standards. Consequently the subjects of this study have been questioned about levels of noise louder than 70 decibels and will have replied that they have not been exposed to it at work for periods longer than an eight-hour day five times a week for more than four weeks (i.e., 160 total hours) in their lives whether in service or at any other job. The responsibility for making this decision rests with the administering otolaryngologist.

Every otolaryngologist at every Air Force base from which these subjects are retiring will be instructed by his chief to consider carefully every retiring member and to reject all subjects who do not fall within the qualifications of the study. Se-
lection of subjects is to be continued until sufficient suitable ones are found. Attrition subjects added are 25 cases and 50 controls. Each questionnaire is accompanied by and will be placed into an envelope which is pre-stamped, slugged Priority Mail and addressed for the attention of the study chief who will be stationed for the duration of the study at the Repository of Retired Medical Records in St. Louis, Missouri. This enables further checking of records if indicated. The study chief will personally open each envelope and then check in order to see whether subjects have been coded correctly. He will make final selections until the required number of data is at hand, then curtail further selection activity at all bases. A potential problem in unintended bias presents in making selections because selection of cases, for example, might move along faster than that of controls. In case of delay in finding suitable controls in such a situation the qualifications or even the nature of a population might change. However, in this case, fewer than 900 subjects are required and as pointed out earlier 1100 members retire each month. A period of six months is anticipated for selection. No change in the retiring population is prospected during that time, and no change prospected even if selection were to require as much as two years, which is not anticipated.
DATA ANALYSIS

The object here is to make some intelligible meaning of the 804 sheets of data included on the completed, legible questionnaires. The first three questions are a check to rule out confounders which should have been intercepted by the otolaryngologist at the bases of retirement. Each of those answers should be (2) no. Any answer other than that to any of the three questions rejects that questionnaire. Questions A through I are handled as follows:

Answer (3) (I don't know) has no further value to the study and is now rejected. It did give subjects a place to phrase their uncertainty and hence may have kept them from becoming so frustrated that they might otherwise have provided some confused answers instead of valid ones. Since each of the questions has two possible answers and there are two groups (cases and controls), one may set up a 2x2 table:

<table>
<thead>
<tr>
<th></th>
<th>CASES</th>
<th>CONTROLS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

The table for cases will contain A number of yes (1) answers and C number of no (2) answers. The table for controls will contain B number of yes (1) answers and D number of no (2) answers.
DISCUSSION

This proposal was initially undertaken to examine a problem that was by definition complex and difficult. The aim was to uncover an area of probable harm to many people which had attracted relatively little quantitative exploration. Faced with such a problem I decided it is probably better to deal with it and then allow for inherent weaknesses than to reject the project out of hand as unsuitable for research. The study was designed to result in an odds ratio of 2. Hopefully a stronger association might be produced.

Obtaining a figure of 2 or higher might ultimately lead to several alterations. First, future Air Force retirees might have to prove that their sensorineural hearing loss was received in line of duty in order to receive compensation, which is not the case now. There might well be fewer military retirees who need disability money for reasons of hearing loss if changes in lifestyle are brought about. Certainly one might expect that strategies of hearing conservation specialists might be re-directed to include more stress on care taken during avocational activities. A new regulation on off-duty noise in barracks and other dwellings is not hard to conceive.

Interpretation of results would be made after careful consideration of several factors, but mostly after examining those elements of weakness inherent in the study. A cardinal point is the questionnaire. It relies on the recall of each subject and even though it enlists the specialized help of qualified ENT spe-
cialists in making key decisions the results are subjective interpretations. While the Audiogram itself remains widely accepted after more than 25 years, it is not a totally objective tool and hence somewhat less than optimal. Among the subjects there might be wide differences in interpretation for many reasons. For example, a person without hearing loss might answer the same question differently from a person with hearing loss because the latter might be looking for excuses.

So much subjectivity can hardly strengthen a study. Were there more objective measurement available, I would think that an odds ratio of 1.5 might be indicative of off-the-job hearing loss.

It is not necessary, however, for this study to resemble a stonework landmark in order to have value. Showing that avocational trauma might be important could be significant in motivating others to investigate such trauma. Elements of safer leisure-time activity could interest firms manufacturing avocational equipment because safer items might sell better and unsafe equipment can be taken off the market. This proposal does deliver the potential of identifying specific areas of possible avocational trauma. If exposing any of these areas were to stimulate an investigator to take up where this research left off, then a worthwhile job will have been done.
TWX From the Surgeon-General to all Hospital/Clinic Commanders,

All commands, Special emphasis to ENT Chiefs:

Your attention is directed to a study being conducted over the next months by the Department of Occupational Medicine. The program will concern all active duty members retiring honorably after 20 years of service who are between the ages of 39-43 years.

Responsibility will be relegated to each ENT department chief who will then relegate to a staff specialist or keep it himself. Beginning when the envelopes arrive at your facility no potential retiree will be rejected unconsidered until the study is concluded. Cases, each of which will be coded A, will consist of members who have never been exposed for a definitive period of time to occupational noise louder than 70 decibels but who have a significant (APR 161-35, 1982) sensorineural hearing loss.

Controls, each of which will be coded B, will likewise never have been exposed to occupational noise louder than 70 decibels for a definitive period but will have no significant hearing loss whatever. Any history or evidence of current inflammatory, iatrogenic, conductive, presbycutic, obstructive or other otic disease will cause immediate rejection from the study, a determination to be made at that time by the respective doctor.

Phase 1 of the program ends when cases have been selected. Phase 2 ends when controls have been selected. The study requires three controls for each case. You will be notified in
writing at the conclusion of each phase.

The selected otolaryngologist will examine each selectee, review each respective medical record, administer the questionnaire, then code each selectee A or B on the basis of significant sensorineural loss only. All other hearing loss persons or those in questionable areas by history or examination are to be rejected by the respective doctor. This same doctor will determine, after administering the questionnaire, whether each subject's exposure to off-the-job noise is sufficient to have caused hearing loss and select subjects accordingly.

Each questionnaire selected for the study will be placed in the appropriate envelope which has been stamped and addressed and will be sent PRIORITY MAIL as it says on the envelope. Each step is to be conducted without delay. Your cooperation is appreciated.
APPENDIX B

Questionnaire

Code ____ Name __________________________ Social Security Number ____
Sex ____ Age ____ Race ____ Career Field (AFSC) __________ Other AFSCs
during career ______________ Marital Status ____ Total Years Active
Military Service ______

The following questions are an attempt to determine the amount of exposure to loud noise that you have had during your entire lifetime. What we mean by "loud noise" is any noise LOUDER THAN the initial flush of a toilet, the sound of a vacuum cleaner from 3 feet away or having to work in noise loud enough so that you had to raise your voice in order to be heard by a normal-hearing person 3 feet from your lips. By "exposure" we mean that you were subjected to sound LOUDER THAN THAT for the equivalent of five full eight-hour days for at least four weeks of your life (i.e., 160 hours of total exposure).

If your answer to a question is Yes, then write the number 1 in the box to the right. If your answer is No, then write the number 2 in that same box. If you don't know, then write the number 3 in that same box. All answers are kept strictly confidential. There are no wrong answers. Don't leave any box blank.

Have you now or have you ever had any hardness of hearing? ☐

Has anyone in your family ever had any hearing 34
problem? □

Have you ever worked around "loud noise" so that you were exposed as defined above? □

A. Do you listen to music which is "loud noise"? □
   More than one hour per week? □
   More than two hours per week? □
   More than three hours per week? □

B. Have you been "exposed" to "loud noise" at discotheques? □
   More than one hour per week? □
   More than two hours per week? □
   More than three hours per week? □

C. Have you ever raced autos (not models) or attended motorcar races at which you were "exposed" to "loud noise"? □
   More than one hour per week? □
   More than two hours per week? □
   More than three hours per week? □

D. Have you ever been "exposed" to the "loud noise" of motorboats? □
   More than one hour per week? □
   More than two hours per week? □
   More than three hours per week? □

E. Have you ever been "exposed" to the "loud noise" of snowmobiles? □
   More than one hour per week? □
   More than two hours per week? □
   More than three hours per week? □

F. Do you now or have you ever fired weapons or been "exposed"
to the "loud noise" of fired weapons? □
More than one hour per week? □
More than two hours per week? □
More than three hours per week? □

G. Do you use or have you ever used a chain saw or band saw or been "exposed" to those sounds as "loud noise"? □
More than one hour per week? □
More than two hours per week? □
More than three hours per week? □

H. Do you now or have you ever flown in such aircraft or practiced parachute jumping from aircraft that you might have been "exposed" to "loud noise"? □
More than one hour per week? □
More than two hours per week? □
More than three hours per week? □

I. Do you have other hobbies or chores in which you might have become "exposed" to "loud noise"? □
Do you live now or have you ever lived for longer than one month in a house where there was "exposure" to "loud noise" inside or in which "loud noise" entered from without? □

That is the end of the questions. They are part of a study aimed at improving the quality of Air Force life. Thank you for your help.
This document culminates in the informed consent of the undersigned to the use of that person's medical records and participation in the research study known hereafter as "The Study".

First this explains the plan/procedure to be followed and its purpose. Eight hundred and seventy-nine, or fewer, active duty United States Air Force personnel who had normal hearing acuity upon entering service and who have not been exposed to definitive periods of loud noise on the job are now retiring after 20 years. Each will be administered an Audiogram, a standard test of general hearing acuity and will be asked questions from a prepared questionnaire after being briefed about what is meant by "exposure" and by "loud noise".

There is no anticipated benefit other than indirectly, or for example, if a pronounced but heretofore hidden flaw in hearing should be incidentally discovered, then the subject would be referred to an appropriate specialist. Apart from that, the chief benefit is knowing that the subject has participated in sincere medical research, which aims to determine further knowledge of mechanisms of human hearing.

Any inquiries concerning the study or procedures will be answered to the best knowledge of the respective specialist administering the questionnaire or the study chief. The subject or legally authorized representative is free to withdraw consent or...
to discontinue participation at any time without prejudice with respect to such matters as care, education or compensation. The subject is assured of confidentiality in the handling of information or recorded data obtained during the course of the research or activity and of anonymity in any publication or other public disclosure of the data collected.

The subject does not waive or appear to waive any of his/her legal rights, must not be subjected to any exculpatory language and will not release the institution or its agents from liability or negligence. This activity provides no situation which proposes to place any person at risk. This will be a written consent form to be signed by the subject or his representative and an auditor witness to both the oral presentation and affixation of the signature of the subject or his representative and the person obtaining the informed consent (Mannix, 1985).

Witness Date Participant Date
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VITA

Thomas Varley was born in Pawtucket, Rhode Island, on March 17, 1931, the son of Thomas and Annie (Hulme) Varley. After graduating from Pawtucket East High School in 1948 he worked for two years before entering Boston University in 1951, when he completed one year. The next year was done at El Camino College, California, after which he enlisted in the United States Air Force. After separation he began work at the Providence Journal Company, Providence, Rhode Island, as a general assignment reporter while taking classes at Providence College, in pre-medicine in 1959. After three months as a reporter he was made an editor and after two years he became a photo-journalist all with the same newspapers. He also took classes during this time at the University of Rhode Island, College of Liberal Arts, and lectured at the same school on photo-journalism and feature-writing. He resigned from the newspapers in April, 1967 and began studies in Manila. His pre-medical degree was awarded in 1968 and his M.D. in 1972, both from the University of Santo Tomas. Post-graduate work was done at the University of New South Wales, Australia, in 1973 (rotating internship) and one year of residency was completed in August, 1974 at Brown University-Rhode Island Hospital, Providence. Since then he has been a member of the United States Air Force Medical Corps, having done general practice for the first nine years. Divorced, he has a son, Thomas III born in 1976 and a daughter, Rebecca Jane, born in 1979.
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This project was typed by Dianne S. Fortune.