PLANNING REPORT FOR AN
EPIDEMIOLOGICAL STUDY OF
AGRICULTURAL WORKERS EXPOSED TO NOISE

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INTRODUCTION

This report was prepared and submitted in response to the contract requirement to develop a detailed research protocol for an epidemiological study of farm workers exposed to noise. The technical content of the portions of this report entitled Statement of the Problem and Appendix A; More Specific Recommendations for Research Procedure is based upon a paper prepared by consultants to the contractor. The consultants were Aram Glorig, M.D. and W. Dixon Ward, Ph.D.

The report presents a Statement of the Problem, including current understanding of epidemiological factors, relevant work, and needed research; Study Plan; and Resource Requirements.

STATEMENT OF THE PROBLEM

The most important hazard posed by noise is the danger of producing damage to the hair cells of the inner ear, thereby causing a partial loss of hearing. In the presence of noise above about 70 dBA, it is true that the autonomic nervous system does produce certain measurable changes: dilation of the pupils of the eyes, changes in cardiac pattern, and vasoconstriction of the extremeties. But these effects, produced by many other changes in the environment, are temporary and reversible, according to present knowledge. While there is suggestive evidence[1] that steel workers exposed to noise so severe as to produce hearing loss relatively rapidly may also display an incidence of circulatory problems that is significantly higher than in a control group of non-noise-exposed workers, the noise workers concerned were also exposed to higher temperatures and a greater concentration of fumes from the steel-making process. The difference in circulatory problems is at the moment considered to be due primarily to the stress induced by fumes and temperature; although there remains the possibility of a synergistic interaction among the various stressors, this is still speculative. In the absence of conclusive data, such interactive influences shall be ignored in this document. A similar conclusion applies to the combination of noise and vibration, especially in operators of tractors, which is the most ubiquitous source of potentially hazardous noise to American farmers: although some speculation exists that vibration may enhance the effects of a given noise exposure, the evidence is both meager and inconclusive.

Noise may also occasionally be a contributing factor in accidents due to failure to hear warning signals of one sort or another. In the agricultural realm, however, such situations will only seldom arise, so the effect of noise on the communication process may probably be safely ignored.

Finally, although the popular press and some anti-noise extremists have contended that high-intensity noise may impair task performance, possibly increasing the probability of error in judgment on the part of tractor operators, again the evidence is at best equivocal, despite dozens of experiments designed to show such effects, if they existed. By the same token, speculation linking noise with such things as insomnia, mental illness, sexual potency, and the like are not supported by any firm evidence.

Thus, the primary, if not the only, result of noise on the farmer is its effect on hearing. Present evidence indicates that steady exposure 8 hr/day, 5 days/wk, 50 wk/year to industrial noise whose level is 85 dBA and which has an "average" spectrum (not unlike that of a tractor) will just produce, after 10 or more years, a measurable hearing loss -- i.e., a 10-dB hearing loss at the frequency most sensitive to damage by noise, 4000 Hz. If the level is 90 dBA, this loss will be about 20 dB. Inasmuch as noise levels generated by tractors, combines, chain saws, grinding mills, elevators, and most other powered farm implements exceed 90 dBA very often, it is clear that a potential hazard exists. On the other hand, the exposure of the typical farmer is anything but regular. In the spring he may spend 16 or even 18 hours a day on his tractor, but in the winter his weekly exposure to levels of 90 dBA or above may total less than an hour. The eventual effects of such variable exposure have to date not been adequately determined, but there are two extreme points of view: the "integration of microtraumata" and the "critical incident" theories. According to the microtrauma theory, every bit of acoustic energy entering the ear contributes its share to the gradual breakdown of the sensory elements, a situation analogous to that generally assumed to hold for radiation damage. The critical-incident hypothesis, on the other hand, contends that there is a tolerable daily acoustic dose, perhaps peculiar to the ear concerned, below which no lasting effect whatever is produced, so that the hearing losses that accrue over a long period of time can be attributed to a few separate days in which an unusually severe exposure was experienced. Although the Environmental Protection Agency in its so-called Levels Document[2] has accepted the microtrauma theory, no persuasive evidence for its validity has yet been uncovered.

It can be seen that the degree of "hazard", particularly in terms of the number of farmers judged "exposed", depends critically on which of these hypotheses the truth is nearer. If the total-immission (microtrauma) theory is correct, then everyone nearly everywhere -- and of course each farmer -- is "at risk". However, if (as seems more likely), the critical-incident schema is the more accurate, then hazard must be estimated from empirical hearing-loss data obtained on farmers directly.

The overall deterioration of auditory sensitivity with time can be broken into four more or less distinct components:

(1) The loss due to occupational noise, which is what we want to determine;

(2) Sociacusis: hearing loss that can be ascribed to the noises to which an individual voluntarily subjects himself, quite apart from the working situation (gunfire, rock music, power tools, etc.);

(3) Presbyacusis: the hearing loss that is attributed to the general process of aging as such; and

(4) Nosoacusis: the loss in auditory sensitivity caused by diseases, drugs, blows to the head, industrial chemicals, and the like.

The problem then is: How much worse is the hearing of the hypothetical "typical farmer" than that of someone the same age, who is exposed to the same amount of gunfire, recreational noise and otological hazards, but to no occupational noise whatsoever? It is clear that epidemiological studies of farm-noise-induced hearing loss must use exceedingly meticulous controls if a valid result is to be obtained. Merely showing that some farmers have severe hearing losses is of course pointless. Even demonstrating that farmers have worse hearing than city dwellers is not sufficient to establish occupational hazard unless one can also show that their exposure to recreational noise sources is no greater. Finally, fair surveys have been shown to be often misleading, because of both the possibly non-random nature of that group of farmers who are fair-goers and the self-selection processes that influence the determination of who gets tested.

Unfortunately, no large random sample of farmers has ever been studied; most extant data are either based on haphazard selection processes or involve such a small number of farmers that once one breaks the sample into groups with equal years of exposure, comparison with some other non-farm sample is of dubious meaning. There seems little doubt that some farmers have severe hearing losses, and that there are occupational farm noises that <u>could</u> produce such losses. Beyond these general statements little can currently be said with confidence.

Current Understanding of Epidemiological Factors

The current understanding of noise induced hearing loss in farmers in the areas of prevalence, incidence, population at risk, relative rates, and itiology is summarized in the following.

1. Prevalance. Hearing loss is not an all-or-none matter; nearly everyone has some hearing loss, in the sense of a deviation from the norm. Therefore an estimate of "prevalence" must be based on some arbitrary degree of loss. One commonly used criterion is an average HL (Hearing Level -- dB of loss relative to an internationally-approved standard "normal") at 500, 1000 and 2000 Hz of 25 dB. This is the point at which handicap is judged to begin, according to the rule approved by the American Medical Association and hence widely used in this country. While the relative incidence of handicapping loss, in a random sample of the population of the USA, broken down by age decade and sex, has been determined by the Public Health Service[3], no attempt was made in that survey to determine occupation, so its incidence in farmers is unknown. Even in the Fair surveys[4,5,6,7] of hearing of farmers, categorization in terms of this handicap was not attempted.

2. Incidence. Unknown, for essentially the same reasons as the above.

3. Population at Risk. Probably everyone who works long hours with a tractor; some unknown fraction of the total farm population of about 3 million male adults.

4. Relative Rates. Basically unknown. Of the few references that bear on the problem, three[5,6,7] give audiometric data in a form that at least allows comparison of means HLs with those of the random sample of the USPHS survey. They all agree that after 10 to 30 years of work, farmers have 10 to 20 dB more hearing loss in the 4000-Hz range than the average USA male. This substantiates the conclusion that if the samples in the three surveys are representative (which, however, must not be taken for granted), farmers will have a higher incidence than the general population. Of course, nobody argues that the general population is really the appropriate group with which to compare the agricultural group. All persons who have worked in noise over 80 dBA should have been removed from the PHS survey if one is to deduce the effects of noise on any particular noise-exposed group. If this removal were possible, the implied loss due to farm noise would doubtless be somewhat greater, but just how much greater is not known.

5. Severity. As indicated above, an average HL of 25 dB at 500, 1000 and 2000 Hz is taken as the dividing line between "no loss" and "some loss". Complete handicap is assumed to occur when the index reaches 92 dB, with a linear rate of increase from the "low fence" to "full loss" of 1½% per dB. There is some agitation at this time to lower these limits and/or to use 1000, 2000 and 3000 Hz instead of 500, 1000 and 2000 Hz, but such changes will probably not be effected for several years.

6. Etiology. The internal combustion engine (tractors, chain saws, loaders, grinders, etc.) is the main source of noise on the farm. However, one must remember that farmers as a group are also exposed to more gunfire than the average citizen; although gunfire-induced losses are not strictly "occupational", they will of course result in a greater proportion of farmers exceeding the low fence at any particular age. Levels generated at the ear of the operator of many farm implements and tractors are given in reference 8 and in a presentation by W. F. Splinter before the Environmental Protection Agency Office of Noise Abatement and Control Hearings in Denver, Colorado, on October 1, 1971.

Relevant Work

Bozung[5] conducted a study of farmers in 1973 in cooperation with the Department of Audiology and Speech Science of Michigan State University. Of farmers attending Farmers' Week at Michigan State University, volunteers (inducement not stated) were screened against non-farm-related loud-noise exposure (including service in the armed forces), gunfire other than during hunting season, excessive ("more than 2 hours, often") snowmobiling, and tractor noise exposure more than 2 hr. in duration on the preceding day. Air and bone-conduction audiograms were administered to those passing the screening, and individuals with more than a 5-dB air-bone gap were discarded. This left 80 farmers aged 26-65 years with 10 to 39 years of full-time farming. An attempt was made to analyze results for different types of farming (dairy, swine, poultry; area in field crops), but with such small numbers, this was fruitless. When broken down by age groups, HLs are clearly greater than the presbycusis norms advocated by NIOSH[9] at frequencies above 1000 Hz: about 10 dB worse (relatively independent of age) at 2000 Hz, and 25 dB worse at 3000, 4000 and 6000 Hz. About 17 dB worse at 3000, 4000 and 6000 Hz than the PHS medians. Thus hazard appears clearly established; only randomness of the sample is the question.

Dennis[6] reported in 1969 the results of a study where 484 farmers were interviewed and examined at 8 agricultural farms and 2 "mexabitions" (agricultural exhibitions) in Saskatchewan. Subjects were rejected if: exposed to tractors or combines within 18 hours of test (33); over 65 or under 25 in age (19); prior known hearing loss from early childhood (5); audiometric error (10); ear operation (4); or some combination of the foregoing (2). The remaining audiograms (412) were analyzed in terms of: (A) Area of land farmed (tendency for more loss in farmers with more land, but no statistical test for significance; difference less than 5 dB in the aggregate, it appears); (B) shooting habits (no effect); (C) military service (no effect). Breakdown by age shows losses 10 to 15 dB worse than PHS medians at 3000, 4000 and 6000 Hz (no comparisons with controls were made by the author). Sampling is unknown, as is the method of inducement to participate. The only other weakness is the lack of statistical analysis. However, results must be judged inconclusive or negative at best.

A study reported by Willsey[7] in 1972 involved fifty-one farmers from around Lafayette (Indiana) who participated in a special hearing study (method of selection not mentioned) performed at Purdue University Hearing Clinic. Breakdown by age (N in each decade not indicated) shows HLs indistinguishable from the PHS medians at all frequencies except at 4000 Hz. At 4000 Hz, about 10 dB more loss in the 30-39 and 40-49 age groups, but not in the 20-29, 50-59 and 60-69 groups. This study therefore implies very little hazard from occupational farm noises -- no more than exists in the average American occupation.

It should be clear at this point that the extant audiometric data, though in some cases completely reliable and valid, do not unequivocally prove anything except that some farmers have hearing losses, which was really known all along. Although, because farm noises are often greater than 90 dBA, these hearing losses may be attributed to farm noises, the assumption of such a causal relation is gratuitous.

Needed Research

Answers to the questions as listed in the following should be pursued.

1. Do the noises of the modern farm produce a greater average hearing loss in farmers than in the general population? By no means certain.

2. If so, is this loss greater than in the average of those citizens who have not been exposed to supra-90-dBA noises for extended periods of time? The answer is probably affirmative, from the evidence in reference 5; it is difficult to imagine that self-selection processes alone could account for the 25-dB implied difference at 3000, 4000 and 6000 Hz between the farmers that were actually tested and all Michigan farmers. However, the true extent of the increased risk can be determined only if self-seleciton is eliminated. Assuming a positive answer to this question, the next one is:

3. What is the typical noise dose of a farmer? Although the noise levels generated by various farm machines are being measured at the University of Nebraska and elsewhere, not much is known about the typical exposure of the average farmer (some sort of integral over time of the acoustic power entering the ear) in daily, weekly, seasonal or yearly terms. One of the reasons for this is that there is at present considerable disagreement over how the noise dose should be measured -- whether to use a system whereby a reduction of exposure time by one-half will allow an increase in level of 5 dBA, as the present OSHA regulation indicates, or of only 3 dBA, a relation espoused by the Office of Noise Abatement and Control of the Environmental Protection Agency; whether to include exposure to noise levels between 80 and 90 dBA and above 115 dBA in calculating the dose; how the effect of interpolated rest periods is to be treated; how steady noise and impulse noise act jointly; and so on. Until the definition of "noise dose" is settled (if ever), however, it would still be possible to record (on tape for later multiple analyses) sound-level histories over a few days of a group of randomly-selected farmers; this would at least provide an indication of the range of exposures, in a general sense.

4. Do hearing losses really develop gradually, or are particularly severe single exposures responsible? A longitudinal study for 3 to 5 years of a group of randomly-selected farmers, involving audiograms every two weeks, might be able to provide an answer to this question (which, of course may well be "both"). Special attention should be paid to the effects of 14- to 18-hr. exposures to tractor or machinery noises, because in such concentrated work periods not only is the ear being exposed for unusually long times, but the normal recovery period is also being shortened, so that the farmer begins the next day's plowing with a still-fatigued ear.

As a summarization of the foregoing itemized questions there clearly exists the need to determine the extent of hearing damage in farmers and the causal relation between such losses and the cumulative noise dose (or critical-incident history). Someone must be willing to undertake the indicated audiometric studies of an exhaustive or a random population of farmers, both cross-sectional and longitudinal. The brief outline of the beginnings of such a study is included as Appendix A. Studies of the type described and needed require the long-term commitment (from three to six years) of personnel, equipment, and funding. These might best be carried out through agreements with local organizations who are concerned with the problem and are conducting studies of only limited scope in terms of both resources and geographical area. The role of NIOSH would then be one of financial support and coordination of study protocols, and data analysis and interpretation on a national scale.

A much less ambitious study plan than that implicit in the foregoing is proposed in the remainder of this report. It has several recognized shortcomings which may cause the principal results to provide nothing more than the motivation for a commitment to the all-encompassing program suggested above. On the other extreme if the remedies suggested for the shortcomings are successful, the requirements in terms of needed research in this area will be fulfilled to a satisfactory degree and no further investigations need be carried out.

STUDY PLAN

Approach

Logistically, the most difficult aspect of the proposed study lies in getting the agricultural worker to the audiometry test equipment, or converseley, the audiometric test equipment to the farmer. Any plan which involves taking test equipment to the work place will require commitment of equipment and personnel over an extended period of time. This results from the low density of farmers in areas suitable for the study and the requirement for valid results that do not reflect temporary threshold shifts that test candidates not be exposed to high levels of noise for at least sixteen hours prior to the audiometry exam. It seems a conservative estimate that it will require one week to test twenty-five individuals under these constraints. To achieve a sample size of any significance would then require a time commitment of from six months to one year and the accompanying investment of funds this represents. NIOSH owned test equipment would be totally committed during this period of time and/or the cost of a long-term lease arrangement from a private source would have to be borne.

A more logical approach would be to bring the randomly selected agricultural worker to a central equipment location. Proper scheduling under these circumstances would enable the relatively rapid accumulation of results from a large sample size. For example, a representative* of an industrial audiometric testing firm estimates that it is conservatively possible for one of their audiometric test vans to test thirty subjects per hour. Assuming a relatively constant supply, this could result in the gathering of data from up to 250 individuals per day.

The logistics of providing a constant supply of willing subjects at a central location then becomes the real world problem. It is proposed that a workable solution to this problem may exist in the concept of locating audiometric test vans at state fairs in appropriate states, and conducting hearing tests on volunteers and/or preselected and screened individuals.

*Mr. Bert Scott, Environmental Tech. Corp., Cleveland, Ohio.

Several arguements against the gathering of data at state or provincial fairs have been presented in the preceeding. These involve questions regarding the validity of data taken from the population sampled because of possible biases introduced by self-selection processes and inaccuracies in background information. Self-selection biases result both from the non-random nature of the group of farmers who are fair-goers and from individual subject characteristics that influence the determination of who gets tested. Inaccuracies in background information are suspected because of the social environment in which interviews are conducted at the fair, i.e. there is probably a tendency to sacrifice accuracy of responses in order to be done with it.

It can be argued that a self-selection bias will result under even the most favorable conditions in a study of this kind. Assuming that a valid random selection of farmers is made in a particular geographical region, it is not at all certain that all of such a group will consent to cooperate in a hearing study. Some will simply not want to take the time and trouble in completing an interview form and submitting to an audiology test. Thus, a self-selection bias is introduced. The extent of such a bias may or may not be as great as that which results in the less motivated situation which exists on the fair grounds. However, it seems likely that sufficient incentive could be provided in the latter case so as to cause the bias to be more equal in the two situations.

The study plan presented here is comprised of three phases. The nature and extent of phases II and III will depend heavily upon the outcomes of phase I, and phases I and II respectively. It is intended that these decision points be provided so that an all out commitment be avoided of the considerable time and funds implied by a truly random selection and on-site testing of a representative group of farmers. The outcome of this study will, at a minimum, provide a test of the hypothesis that farmers as a group have a greater degree of sensory-neural hearing loss than all other groups taken as a whole.

1. Phase I. Phase I of the study consists of the random selection and survey of a group of farmers within a one to several county area surrounding the site of the state fair in each of four determined states. These four states are Nebraska, Iowa, Illinois, and Kansas. The number of counties for which this is to be accomplished in each case will depend upon how many will be required to bring the size of the random sample to approximately 1,000

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individuals. Assuming a retention/participation rate of 25% this will result in a sample size of 1,000 individuals over the four state area.

The random sample to be surveyed could be identified from a variety of sources. The best is probably the state office of Agricultural Stabilization and Conservation Service. This is a USDA office maintained in each state. Records of the identity of farmers throughout the state are kept via branch offices in each county.

The random sample once identified is to then be surveyed relative to members willingness to cooperate in the study and the possible existence of any disqualifying factors that can be determined directly over the telephone. These may include such elements as hereditary deafness or service in the armed forces. Prior to initial contacts, however, extensive efforts will be made to publicize the study via appropriate groups to which the farmers relate and attempts will be made to gain the support of these organizations on at least a conceptual level. The organizations to be contacted will include the previously mentioned county offices of the Agricultural Stabilization and Conservation Service, the local 4-H Club chapters, the county extension agents, and the farm bureaus and federations.

It is proposed that the surveys in each state be conducted through the use of college students. Preferably these students will be drawn from the agricultural colleges. In two of the states (Kansas and Illinois) this may not be feasible as the agricultural schools are approximately one hundred miles from the site of the state fairs. In these two cases, if appropriate agricultural students are not identifiable, efforts will be made to find suitable college age students in the local area.

Once initial telephone contacts have been made and a group of suitable individuals who are willing to participate in the study have been identified a personal contact and interview will be conducted for each. The interview will attempt to develop information relative to age, work history noise exposure, recreational noise exposure (snow mobiling, hunting), and other possible sources of noise exposure (e.g. chain saws, etc.). It is anticipated that five individuals should be able to accomplish the complete contact and interview process in each state for 1,000 initial individuals. The initial contact should be accomplishable in one month and the follow-up interview process should take no longer than two months.

With interview data available, a final study group of 250 individuals is to be selected with some effort made to adequately represent each decade from 20 to 60 years of age, with an additional single group to include all those over 60 years. Further, if some grouping according to exposure levels to recreational noise sources can be accomplished, this should be done as well.

The final group of study individuals will be asked to attend the local state fair so that an audiology examination can be accomplished. An appropriate inducement for attendance will be provided. This could take the form of a free admission for the study individual and his family or the provision of a specific amount of cash or "fair script" to be spent in any way the person pleases. In any event, the greatest effort reasonable will be made to convince the study subjects to attend the fair so that the study can be concluded in a useful manner. The number who do agree to attend in each state will determine the manner in which phase II of the study will be conducted.

2. Phase II. The objective of this study phase is to conduct audiology examinations on each of the 250 individuals identified as the study group in each state, plus as many randomly selected fair goers as possible. As indicated earlier, it is possible that up to 250 individuals could be tested per day with the resultant potential of 2,500 total for a ten day fair.

The approach proposed will take advantage of the central focal point naturally provided by the state fair. It will attempt to reduce the self-selection bias by independent, random selection of subjects from the fair crowd and the offering of an appropriate inducement to convince them to have their hearing tested. Such an inducement could consist of cash, a particular amount of fair script, or a donation in their name to a local charity; as, for example, to the local childrens speech and hearing clinic. The latter approach may provide the greatest incentive, especially if the individual doing the selection is accompanied by a member of 4-H or the Boy Scouts.

In an attempt to further minimize self-selection bias, and any bias that may be introduced as a result of the test subject providing inaccurate data, the basic study design is proposed to be that of a case-control study. In this situation, the case group will be all those individuals tested who can be demonstrated to have sensory neural hearing loss. The control group will consist of all those individuals who have been tested and found to have "normal" hearing and can be matched on a one-to-one basis with someone in the study group. Assuming this can be accomplished, the question is then asked; is there a statistically significant difference in the number of farmers in the case group than in the control group? The ramifications of a "yes" answer will depend quite heavily upon the extent to which members of the case and control group can be matched.

Ideally, of course, the desired approach is to be able to identify a farmer group of representative size (ranging from 20 to 50 depending upon the sensitivity of the extent of hearing loss it is desired to detect) for each cell of a three dimensional matrix involving age, annual noise exposure, and recreational noise exposure. If such selection and assignment is done carefully, then the results should provide, as indicated in the Appendix A text, evidence relative to the growth of hearing loss as a function of exposure to the annual cycle of work related noise (probably tractors) and recreational noise (probably gunfire).

Certainly with the sample sizes suggested, 5,000 to 10,000 individuals over four states, an adequate number of farmers should be available to fill each slot of the estimated 100 element matrix with a sufficiently large group. The overriding concern is that the population tested be representative of the farming population at large. It is to resolve this concern that the 250 study individuals are to be randomly selected for testing in each state. These will provide a group for comparison with the farmer group which results from the selection process on the fair grounds. If essentially all of the preselected group show up at the fair for testing, then an excellent comparison will be possible at all levels. If a significant percentage of this group do not follow through and come to the fair for testing, then only a limited comparison will be possible, but none the less, one that will be useful. Any differences detected between the study group and the case group selected on the fair grounds can be used to introduce corrective factors in data analysis and interpretation.

It is intended that the process of selecting individuals on the fair grounds as candidates for testing will be accomplished with the students employed in the previously described phase I. It would seem that the most appropriate inducement to consent to participation would be to provide a cash contribution in the volunteers name to a relatable charity. This inducement would be enforced if a 4-H person or Boy Scout were to accompany the selecting individual. Once the volunteer is brought to the audiology test site, the same questionnaire will be administered that is to be used in phase I. Again, students employed in phase I can assist in this function.

Actual audiometric testing can be accomplished either utilizing the existing NIOSH capability or leasing from organizations which provide this service on a commercial basis. Use of the NIOSH equipment would be most desirable from the points of view of cost and positive control over operator expertise and consistency and appropriate equipment calibration. A binaural test will be administered requiring approximately 10 minutes.

It is suggested that a test also be administered to each volunteer that measures the impedance of the middle ear. The time required is on the order of 5 minutes and equipment is minimal. The test results provide an indication of possible middle ear pathology and thus if any hearing loss is sensory-neural in origin. This will provide a clinically acceptable alternate to an exam by an otologist and can be administered by a trained technician. To insure the validity of results, equipment will be calibrated when it first arrives on location at the fair grounds and at one week later.

3. <u>Phase III</u>. This study phase attempts to address the problem of measurement of noise impinging on the agricultural worker and hopefully of providing some degree of correlation with demonstrated existence or lack of hearing loss. It is proposed that this effort be one of a long-term nature, utilizing the results of the previously described phases I and II.

It seems certain that the data provided in phases I and II will enable an identification of "representative" farmers in each of the recognized segments of the agricultural industry (e.g. dairy farm, feedlot operation, grain farm, confinement housing). Cooperation of a small group of these farmers (approximately six) will be obtained for each segment for both hearing loss and no hearing loss categories. It would then be a relatively straightforward matter to instrument the selected individuals with appropriate recording equipment as they proceed through a "typical" work day in an identifiable phase of a yearly work cycle.

A crucial element in this type of endeavor is the valid identification of typical phases in the yearly work cycle of the particular agricultural segment under consideration. This will be accomplished in collaboration with the appropriate staff of the agricultural college in the state of concern and with the cooperating farmers. Once phases have been validly identified, then several days can be randomly selected during these periods for instrumentation of the cooperating farmers. Useful data should then be obtainable over a one year study period. Thus, a one year study involving the measurement of noise impinging on the farmer is a logical follow on to the physiological effects study.

Instrumentation is readily available to enable either of two approaches to actual measurement of noise exposure. These are the recording and later spectral analysis of the analog signal in the sound frequency range of interest or the utilization of wearable noise dosimeters which simply provide an on-demand readout of total noise exposure (integration of intensity over time) from some established point in time.

The recording of analog noise signals can be readily achieved using commercially available personal tape recorders. Such recorders are routinely used in a number of medical applications such as continuous EKG monitoring. In the event commercially available equipment is not suitable as a result of extreme requirements for wide variation in signal amplitude or resistance to impact, devices developed for NASA manned and unmanned space programs would most certainly be appropriate and should be readily available to NIOSH for this type of study.

Several commercial organizations currently market personal dosimeters for noise exposure*. These devices are relatively inexpensive but provide only a reading of accumulated exposure referenced to permissible OSHA exposure levels. They can operate over a 24-hour period and provide an output either directly or via a readout device.

The answer to the question of which approach should be utilized is influenced by the manner in which the data are to be interpreted and used. The analog recording approach would allow the characterization of noise exposure as a function of time over a "typical" work day. However, it would be difficult to correlate this result with a currently existing hearing loss or lack of hearing loss. Any correlation would be strictly inferrential without an extensive time history of noise exposure and hearing degradation.

*General Radio, Concord, MA
Model 1944 Noise Dosimeter

Tracor Medical Instruments Division, Austin, TX
Model SPL-104AB Personal Noise Dosimeter

Use of the noise dosimeter would provide a measure of total noise load over the recording period. This could then be reliably correlated with the extensive existing data relative to hearing loss and exposure levels in the industrial setting. However, given a knowledge only of total noise load over one day, it would be very difficult to determine which noise sourced provided the excessive levels. The best approach would appear to be to utilize an analog recording system in conjunction with a personal noise dosimeter. Ideally, the cooperating farmer would wear only the analog system, and playback would then be monitorable by the dosimeter for an indication to total noise load. A more sophisticated, and faster, approach would be to play the analog recording back into a computer at a much faster speed than signals were recorded. Appropriate computer analysis and scaling could then be readily accomplished to provide an output of both noise intensity as a function of time and total noise load over the recording period.

Data Analysis and Interpretation

Data will be returned on each test subject in the form of responses to requested information on the interview form and results of the audiometric examination on standard audiogram forms. These latter forms will have a visual indication of the test subjects hearing threshold at either six or ten pure tone frequencies. It is anticipated that thresholds will be determined for both ears at ten frequencies (.25, .5, .75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0, 8.0 K Hertz). However, the minimum of six which are a subset of the listed ten may be used depending upon the actual equipment employed.

The interview and audiometric data will be converted to a keypunch form so that they can be conveniently input to a computer system for tabulation and statistical processing. The kinds of analyses it is expected will be accomplished on the data will utilize relatively standard software capabilities such as are available in the SPSS and BMD packages. Beyond this any sorting or categorization capabilities that are required can be rather easily and quickly generated in some higher level language (e.g. Fortran IV). For the purposes of this study protocol it is assumed that the NIOSH computer system will be utilized.

As indicated previously, the most fundamental analysis that will be performed is that of a case-control study. It is assumed that all individuals inappropriate to the study will have been eliminated (e.g. those who were extensively exposed to gunfire in the armed forces, or those with demonstrated middle ear pathology). All those with identified hearing loss will be specified to be in the case group. An attempt will then be made to accomplish a defensible matching of individuals in the hearing loss group with those having no detectable hearing loss. This matching will be accomplished on the basis of a number of characteristics including age, race, and length of exposure to recreational noise. The matched subgroups of cases and controls will then be compared to determine if there is a larger percentage of farmers in the former than the latter. If there is, the difference can only be attributable to the areas where a matching was not accomplished. One area where this will be intentionally true is in occupation.

Hence, assuming no other complicating factors, it can be determined with some reasonable assurance, that farmers do, or do not have greater hearing loss than their non-farmer counterparts. One potentially significant complicating factor is the characteristic of the farmer who will go to fairs. As described in the earlier section on Approach, an attempt will be made to control for this by means of the study group to be identified a priori in each state. It can be argued that the self-selection process will be at work in the a priori study group as well. All efforts will be made to overcome any such tendency. In all probability it will at least be detectable and the interview data will be available for the entire group, providing some insight and control of the problem.

The ideal approach as presented in Appendix A text is to define a three dimensional matrix with each cell representing a particular vector point defined by age, annual noise exposure in the work environment, and cumulative exposure to recreational noise. Each cell would then be filled with a group large enough to provide statistical validity (20 to 50 individuals). Once the matrix is completely filled, requiring some unique kinds of individuals at the end points, audiometric tests are given to all individuals in each cell. The overall study proposed here falls somewhat short of this exhaustive process. However, because of the large sample size anticipated it is possible that a similar kind of analysis can be accomplished, albeit on a somewhat limited basis, and results which can be of considerable value obtained.

The data analysis will proceed by breaking the data down in varying degrees of fineness. The first analysis to be performed (for each fair) will be a simple chi square analysis to determine if there is a relationship between farmers and non-farmers and whether an individual has a hearing loss or not. The contingency table used to perform this analysis is displayed below.

OCCUPATION	HEARING LOSS: Yes	HEARING LOSS: No
Farmers		
Non-Farmers		

The next stage will use a Mantel Haenszel chi square[10] to determine if there is a relationship between occupation and degree of hearing loss. A sample table to be used in this analysis follows:

OCCUPATION	HEARING LOSS: None	Mild	Moderate	Severe
Farmers				
Non-Farmers				

Since age plays such an important role in hearing loss, it will be necessary to perform this analysis for different age groups (e.g., for individuals in each decade from 20 to 60, and those over 60) and then use a summary Mantel-Haenszel chi square to see if there is over-all significance. By using this particular technique on either of the above tables, it is possible to determine if there is a relationship at any particular age and then if there is an overall summary effect controlled for age.

Since more than one fair is involved, the above analysis can be performed for each and then a summary Mantel-Haenszel chi square can be accomplished including the results of all fairs. Hence, if control is provided for both age and fair, the summary chi square will be summed over both age groups and different fairs.

Since there will be different types of farmers involved it should be possible to obtain an idea of whether there is a difference in the amount of hearing loss among different types of farmers. In order to determine this, a regular chi-square analysis is performed using tables as displayed below.

		OCCUPATION			
		Non-Farmer	Farmer "A"	Farmer "B"	Farmer "C"
HEARING LOSS	YES				
	NO				

Utilizing the data collected from the questionnaire, further appropriate analyses can be performed. Some examples of these follow. A Mantel-Haenszel chi square can be performed with one variable as degree of hearing loss and another variable as some categorical breakdown of certain kinds of farming or recreational activities, ordered for possible degree of noise severity. The sample table to do this would look as follows:

		HEARING LOSS			
		None	Mild	Moderate	Severe
NOISE SEVERITY	MILD				
	MODERATE				
	SEVERE				

If it is supposed that degree of hearing loss is related in some rather regular fashion to noise insult (e.g., polynomial), regressions can be run to determine if there is a significant relationship between degree of hearing loss and degree of noise in the occupation or recreational activity.

In order to perform the initial analysis more carefully, certain other aspects (e.g., recreational hearing insult) can be introduced as controlling variables in the Mantel-Haenszel analysis. The way this is accomplished is to group the individuals involved by the amount of time they spend hunting (i.e., none, moderate and extensive). The analysis is then run for each of these groups of individuals and a summary chi square test performed over all classes of gun noise exposure. As analysis of the large quantity of data anticipated proceeds, other significant questions will be developed and useful approaches to interpretation will become obvious. These will be pursued and employed as appropriate to provide the most comprehensive and realistic view of the physiological effects of noise on the farming population.

Problem Areas

The most serious and potentially invalidating problem areas in this study have been presented and discussed at some length in the preceeding text. These are dominated by the possibility that the sample obtained will not be truely representative of the agricultural work force. Possible precautionary measures have been proposed which can correct for these biases and represent an integral part of the study design.

A further significant problem area concerns the willingness, or lack thereof, of the farmer to cooperate in the study. This is a very real consideration that must be dealt with effectively if a meaningful study is to result. It is proposed that the investigators interact extensively with farmer organizations, such as cooperatives and federations, the local representatives of the USDA offices, the extension agents, and the 4-H Clubs. Further, action will be taken through these organizations/individuals rather than independently whenever possible. The questionnaire to be administered to each of the study participants represents a vital source of data which is basic to the success of the study. Appropriate care will be taken in its design to insure that the intended meaning is conveyed by the wording, and provisions are made to enable an accurate and useful answer to be given. Additionally, the questionnaire will be kept as short as possible to encourage its completion in as accurate a manner as is reasonable under the real world circumstances.

Accuracy and consistency in the actual performance of the audiometry tests must be a primary consideration. This will be obtained by using the same technicians for testing in all locations and by frequent calibration of the test equipment. Technicians are to be trained in a well qualified school for audiometry technicians and frequent contact will be maintained with a professional audiologist throughout the testing period. In general, data recording, handling, and transcribing must be planned and conducted so as to minimize the probability of introducing errors.

There are a myriad of problems that will arise and must be considered simply in the logistics involved in conducting a study of the magnitude proposed. As an example; waiting time must be minimized and/or made more pleasant if the greatest participation is to be achieved and maintained. These can only be recognized and dealt with as effectively as possible as more detailed plans for the study are developed and implemented.

Schedule

The schedule of events for the study proposed here is shown on the following page. It assumes that phases I and II will be the only portions to be addressed and will be concluded in one year. The final products will be an extensive data base and a final report. The report will contain a description of the study as it was actually implemented and carried out and will deal with the data base itself in terms of its form, content, possible limitations, and interpretation along with any underlying assumptions.

It is not known at this point in time when the proposed study will be initiated. The most obvious constraining factor is the actual timing of the state fairs. In the four-state area involved, these fairs are scheduled each year so as to follow each other in the fall in an essential non-overlapping sequence over about a seven-week period. This is to allow common attractions such as livestock shows, travel time to appear at all four events. The schedule shown in the following is keyed to the fair schedule for 1975 if it is assumed that month 1 correlates with January of 1975. Actual fair dates and attendance records for the past two years are as follows:

STATE:	FAIR DATES:	PAST ATTENDANCE FIGURES: 1973	1974
Illinois	August 8 - 17, 1975	701,319	794,000
Iowa	August 15 - 24, 1975	644,000	646,000
Nebraska	August 29 - September 7, 1975	543,000	577,500
Kansas	September 13 - 21, 1975	518,000	512,200

UTAH BIOMEDICAL TEST LABORATORY University of Utah	SCHEDULE TASKS Epidemiological Study of Agricultural Workers Exposed to Noise
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	TASK OR EVENT	Months 1	2	3	4	5	6	7	8	9	10	11	12
1	Identify A Priori Study Groups												
2	Develop Questionnaire												
3	Establish Contacts With Ag Groups												
4	Recruit Student Field Teams												
5	Train Student Field Teams												
6	Initial Screening of Study Groups												
7	Field Interviews of Study Groups												
8	Fair Attendance Follow-Up												
9	Identify and Train Audiology Techs.												
10	Training Follow-Up												
11	Data Gathering: Fair #1												
12	Data Gathering: Fair #2												
13	Data Gathering: Fair #3												
14	Data Gathering: Fair #4												
15	Data Conversion and Validation												
16	Data Analysis and Interpretation												
17	Study Report												
18													

Notes:

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RESOURCE REQUIREMENTS

Manpower loading and budget estimated to be required to carry out the proposed study are summarized in the following three pages. The important underlying assumptions were made that:

- The study will be conducted from Salt Lake City, Utah.
- The NIOSH Audiology Testing Trailer will be used.
- Audiology Techs will be trained in Salt Lake City and sent to the four states involved to conduct testing.
- All required expertise is in-house; i.e., no consultants are used.
- Computer support will be provided by NIOSH.
- Student Field Teams will be trained on-site in the state concerned by the Field Study Coordinator.

It should also be noted that no overhead is included in the personnel cost estimate. This was not done as it is not known at this time who would actually be conducting the study.

UTAH BIOMEDICAL TEST LABORATORY
University of Utah

Revision: 0

Date: 6/26/75

SCHEDULE

MANPOWER

Epidemiological Study of Agricultural Workers Exposed to Noise

	TASK OR EVENT	Months											
		1	2	3	4	5	6	7	8	9	10	11	12
1	Principal Investigator	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	1.0	1.0	1.0
2	Field Study Coordinator	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
3	Epidemiologist	.2	.2	.2	.2				.1	.1	.1	.1	.1
4	Field Interview Teams			2.0	12.0	20.0	20.0	20.0	17.5	5.0			
5	Audiologist	.1	.1	.1	.1	.1	.1	.5	.5	.5	.1	.1	.1
6	Audiology Techs							3.0	3.0	3.0			
7	Data Techs								2.0	2.0	2.0	1.0	1.0
8	Biostatistician										.2	.2	.1
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													

Notes:

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Personnel Costs

Direct Labor:	$116,929.00	
Fringe Benefits @ 19%	22,216.00	
		$139,145.00

Equipment

Middle Ear Impendance Test Equipment		
3 @ $2,000		6,000.00

Supplies

Forms, Pencils, etc.	3,000	
Equipment Maintenance	500	
		3,500.00

Services

Telephone - 4,000 calls @ $5 ea.	20,000	
Reimbursement of fair attendees		
1,000 @ $5 ea.	5,000	
Incentive Cost		
10,000 @ $1 ea.	10,000	
		35,000.00

Travel

Air Fare	11,744	
Per Diem	7,890	
Car/Truck Rental	3,685	
Personal Mileage	11,250	
		34,569.00
TOTAL:		$218,214.00

Travel Back Up

16 r/t to Springfield, Illinois	$ 3,360	
16 r/t to DesMoines, Iowa	2,752	
16 r/t to Lincoln, Nebraska	2,432	
16 r/t to Hutchinson, Kansas	3,200	
		$11,744
Per Diem 263 days @ $30		7,890
Car Rental on 64 trips		2,760
Student Personal Auto Mileage Allowance:		
Assumes 150 mi. r/t for 2 contacts		
Total of 1,000 contacts = 75,000 mi. @ $.15/mi.		11,250
Tractor Charges for Moving Trailer		
Approx. 1,500 mi. over 50 days		
Assumes $14/day + $.15/mile for GSA Tractor		925
		$34,569

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APPENDIX A

APPENDIX A

MORE SPECIFIC RECOMMENDATIONS FOR RESEARCH PROCEDURE

Farmers are exposed to presbyacusic, nosoacusic and sociacusic influences in addition to the noises (chiefly those associated with tractors and tractor-driven machines) of their profession. These influences will be designated P, N, S and T; the hearing losses associated with these factors will then be HL_p, HL_n, HL_s and HL_t. Assuming these are all additive, we thus have

$$HTL = HL_p + HL_n + HL_s + HL_t$$

where HTL is the individual's Hearing Threshold Level (ANSI 1969). Also assumed in this step is that each individual is assumed to have begun with normal hearing. Thus

$$HL_t = HTL - HL_p - HL_n - HL_s$$

In the case of farmers, we may assume that the major source of sociacusis is gunfire (use of chain saws, for example, and perhaps even snowmobiles, which would be a sociacusic noise for most people, would be regarded as an element of a farmer's occupational noise).

Suppose, then, we knew the hearing status of all farmers in America. To determine HL_t (our ultimate goal), we would compare the HTLs of different subgroups. Consider two groups, 1 and 2. $HTL_2 - HTL_1$ would be equal to $HL_{t2} - HL_{t1}$ if HL_{p1} and HL_{p2}, and also HL_{n1} and HL_{n2}, were either equal or both zero. Since HL_p and HL_n cannot be set equal to zero , they must be equated within the groups. Presbyacusis is therefore eliminated as a factor if only equal-age groups are compared. Such a practice will also get rid of differential nosoacusic influences if the groups are large enough, so it will be assumed to be followed below. In this case,

$$HL_t = HTL - HL_s + C$$

so that

$$HL_{t2} - HL_{t1} = HTL_2 - HTL_1 - HL_{s1} + HL_{s2} .$$

With our assumption that the major source of sociacusic differences among farmers is gunfire, so that other sources may be ignored, we must proceed to get farmers with various degrees of exposure to both tractor noise and to gunfire. Each farmer will then be characterized in terms of age, degree of exposure to tractor noise, and degree of exposure to gunfire. Breaking age down into 5 or 6 decades, annual noise exposure into 5 dategories, and cumulative exposure to gunfire into perhaps 4 would give one the order of 100 to 120 cells in the three-dimensional matrix. In order to be able to infer the significance of a 5-dB difference in median HTLs or inferred HL_ts, at least 20 individuals should be assigned to each cell; if information on the most sensitive 10% of ears is to be reliable, then probably 50 would be required. Thus the population examined audiometrically should be at least 2000, with some 6000 needed if the major concern is not with only the average farmer.

Of course, if one were content to show differences only at a single age, assuming that differences among noise and gunfire groups by say age 40-50 will have reached an asymptote, then a population of only 400 to 1000 would be needed. Obviously, however, more than 400 40-50-year-old farmers would have to be <u>contacted</u> before one ended up with 20 in each of the 20 categories (5 degrees of tractor noise, 4 of gunfire), and this applies to the situation with 50 in each group as well. The procedure should be, therefore, to administer the interview (on the basis of which assignment to category is to be made) to a random or exhaustive sample of farmers in the appropriate age range, using a predetermined order; audiometry would then be performed only if the category to which he is assigned has not yet been filled. Upon completion of the 20 or 50 in all categories, the analysis would be performed.

The questionnaire in this case should ask for both age and birth date, as a check against errors that people sometimes make in stating their age, information that will allow assignment to the appropriate noise-exposure group (some integral of level over time), and questions relating to gunfire exposure for categorization in that regard. There is little to be gained by applying various exclusion principles that attempt to eliminate various sources of nosoacusis (head blows with unconsciousness, various diseases, earaches, etc.), so the individual need not be questioned in regard to such things, as long as the main emphasis is on the median.

A possible exception, however, is military service, which confuses the issue in regard to both noise and gunfire, so one might exclude all veterans, or all those with service-connected noise exposure and/or gunfire beyond basic training. At any rate, if the rules of assignment to category are made sufficiently explicit, there need be no delay between interview and test.

The least-exposed group (minimum tractor noise, minimum gunfire) would probably be the Amish farmers, so the study should include an area that contains a group of these individuals, or it might take forever to fill that category properly. In a sense, then, the Amish will serve as a control group for the other 19 categories. If the data are carefully gathered, we would have unequivocal evidence showing the growth of both hearing loss due to tractor noise and that ascribable to hunting in farmers, and also an indication of possible synergistic effects.

The main problem, of course, that still remains is the definition of the category limits for tractor noise and gunfire. A pilot study would probably be necessary to allow an estimate of the range of each so that one did not end up by needing to question 1000 people to get that last individual to fill the maximum-noise maximum-gunfire category. The greater specificity as to exposure that can be gathered, the better, naturally, if one is to correlate some dose measure with the extent of HL_t and HL_s associated with exposure to farm noises.