FINAL REPORT

R01 OH009392

Evaluation of a Hearing Conservation Program for Farm Youth: A 15-Year Follow-Up

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National FarmMedicine Center

October 5, 2012

Maryann P. Monroe
Grants Management Specialist
Acquisition & Assistance Field Branch
P.O. Box 18070
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070

Reference: 5 R01 OH009392

Dear Ms. Monroe:

Enclosed is the final progress report for the above referenced grant entitled *Evaluation of a Hearing Conservation Program for Farm Youth: A 15-Year Follow-Up*. The Financial Status Report, The Final Invention Statement and Certification, and the Equipment Inventory Listing will be submitted separately by the Marshfield Clinic Research Foundation, Office of Sponsored Programs.

Please contact me if you need further information.

Sincerely,

Barbara Marlenga

Barbara Marlenga, PhD

Enclosures

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Closeout Document 1: The Final Progress Report

Abstract (main study)

Background: Agriculture is an industry with among the highest recorded exposures to dangerous levels of noise. Studies have demonstrated an increased prevalence of noise-induced hearing loss among youth who were actively involved in farm work. The Occupational Safety and Health Administration (OSHA) mandates hearing conservation programs in industries where noise levels equal or exceed 85 decibels averaged over eight working hours. However, most agricultural worksites are exempt from OSHA regulations, so alternative strategies to promote hearing conservation among farm youth must be identified and evaluated.

Purpose: We had the rare opportunity to conduct a cluster randomized controlled trial to observe the long-term (16 year) effects of a well-designed hearing conservation intervention for high school students working in agriculture. This trial assessed whether the intervention resulted in: 1) a reduced prevalence of noise-induced hearing loss assessed clinically; and/or 2) sustained use of hearing protection devices.

Methods: In 1992-96, 34 rural Wisconsin schools were recruited and 17 were randomized to receive a comprehensive 3-year hearing conservation intervention. In 2009-10, extensive efforts were made to find and contact all students who completed this original trial. Participants in the 16-year follow-up completed an exposure history questionnaire and a clinical audiometric examination. Rates of noise-induced hearing loss and reported use of hearing protection were compared.

Results: We recruited 392 participants from the original trial, 200 (53%) from the intervention group, and 192 (51%) from the control group. Among participants with exposure to agricultural noise, the intervention group reported significantly higher use of hearing protection compared with controls (25.9% vs. 19.6%; P=0.015), although the use of hearing protection was still quite low. The intervention group also reported significantly higher use of hearing protection when shooting guns (56.2% vs. 41.6%; P=0.029), but similar use of hearing protection in all other contexts. There was no significant difference between groups with respect to objective measures of noise-induced hearing loss.

Conclusion: This novel trial provides objective evidence that a comprehensive educational intervention by itself may be of limited effectiveness in preventing noise-induced hearing loss among young workers. There is a need for creative solutions to protect young people from major sources of noise in both occupational and recreational settings. Potential solutions should focus on environmental modifications and regulations to control noise emissions, because educational solutions on their own may fail to protection many young workers from noise-induced hearing loss.

Abstracts (secondary analyses)

Study 1: Hearing conservation program for agricultural students: Short-term outcomes from a cluster randomized trial with planned long-term follow-up

Objectives. To conduct a contemporary analysis of historical data on short-term efficacy of a three-year hearing conservation program conducted from 1992-1996 in Wisconsin, USA with 753 high school students actively involved in farm work, to establish procedures for assessment of hearing loss for use in a recently funded follow-up of this same hearing conservation program cohort.

Methods. We analyzed a pragmatic cluster-randomized controlled trial, with schools as the unit of randomization. Thirty-four rural schools were recruited and randomized to intervention or control. The intervention included classroom instruction, distribution of hearing protection devices, direct mailings, noise level assessments, and yearly audiometric testing. The control group received the audiometric testing.

Results. Students exposed to the hearing conservation program reported more frequent use of hearing protection devices, but there was no evidence of reduced levels of noise-induced hearing loss.

Conclusion. Our analysis suggests that, since noise-induced hearing loss is cumulative, a three-year study was likely not long enough to evaluate the efficacy of this intervention. While improvements in reported use of hearing protection devices were noted, the lasting impact of these behaviors is unknown and the finding merits corroboration by longer term objective hearing tests.

Study 2: Determinants of early stage hearing loss among a cohort of young workers with 16-year follow-up

Objectives. We had a unique opportunity to study the early impacts of occupational and recreational exposures on the development of noise-induced hearing loss (NIHL) in a cohort of 392 young workers. The objectives were to estimate strengths of associations between occupational and recreational exposures and occurrence of early stage NIHL and to determine the extent to which relationships between specific noise exposures and early stage NIHL were mitigated through the use of hearing protection.

Methods. Participants were young adults who agreed to participate in a follow-up of a randomised controlled trial. While the follow-up study was designed to observe long term effects (up to 16 years) of a hearing conservation intervention for high school students, it also provided opportunity to study the potential aetiology of NIHL in this worker cohort. Study data were collected via exposure history questionnaires and clinical audiometric examinations.

Results. Over the 16-year study period, we documented changes to hearing acuity that exceeded 15 dB at high frequencies in 42.8% of males and 27.7% of females. Analyses

of risk factors for NIHL were limited to males, who comprised 68% of the cohort, and showed that risks increased in association with higher levels of the most common recreational and occupational noise sources, as well as chemical exposures with ototoxic potential. Use of hearing protection and other safety measures, although not universal and sometimes modest, appeared to offer some protection.

Conclusion. Early stage NIHL can be detected in young workers by measuring high frequency changes in hearing acuity. Hearing conservation programs should focus on a broader range of exposures, whether in occupational or non-occupational settings. Priority exposures include gunshots, chainsaws, power tools, smoking, and potentially some chemical exposures.

Study 3: Asymmetry in Noise-Induced Hearing Loss: Evaluation of Two Competing Theories

Objectives. There are competing theories about why patterns of asymmetry are observed in noise-induced hearing loss. We evaluated these theories using an existing cohort of young workers studied over 16 years. Our objectives were to describe and evaluate patterns of hearing loss and asymmetry by gender, exposure to agriculture, and exposure to gunfire.

Design. This is a secondary analysis of data collected from young adults during the follow-up for a randomized controlled trial. The follow-up study was designed to evaluate the long-term effects of a hearing conservation intervention for rural high school students. The sample consisted of 392 of 690 (57%) participants who took part in the original randomized controlled trial from 1992 to 1996 and were successfully located and recruited for a 2009 to 2010 follow-up study. In total, 355 (91%) young adults (aged 28–32 years) completed both an exposure history survey and a clinical audiometric examination at follow-up.

Results. At frequencies above 2000 Hz, males showed more hearing loss, with greater asymmetry and a different pattern of asymmetry, than women. For males with documented hearing loss, there was a trend towards increasing asymmetry with increasing levels of hearing loss. Asymmetry at high frequencies was consistent regardless of the level of exposure to agricultural work. In contrast, asymmetry at high frequencies varied substantially by level of shooting exposure. Although the number of left-handed shooters was small, similar patterns of high frequency asymmetry were seen in right- and left-handed shooters.

Conclusion. While the "head shadowing" theory is accepted as the primary explanation for asymmetric hearing loss in much of the audiology and related public health literature, findings from this study are more consistent with physiological differences as the primary cause of asymmetric hearing loss, with greater susceptibility to noise-induced hearing loss in the left ear of males.

Section 1 of the Final Progress Report

Significant (Key) Findings

1. The hearing conservation program appeared to increase the use of hearing protection devices, but the usage was still quite low.
   - Some study participants reported never wearing hearing protection and most others used hearing protection only a fraction of the time when they were exposed to loud noise.

2. Noise-induced hearing loss is not just a problem of old age.
   - Measurable high frequency hearing loss (10dB or more) was observed in 63% and substantial loss (25dB or more) was observed in 12% of the young adult participants (28-32 years of age).

3. Recreational noise exposures were found to be related to hearing loss, even more so than occupational noise exposures.
   - Noise exposures of particular concern in this study were gunshots, chainsaws, and power tools.

4. With some disappointment, we demonstrated that the hearing conservation program did not make a significant difference in preventing early hearing loss.
   - Education alone cannot be counted on to protect young people from noise-induced hearing loss.

Translation of Findings

Our findings suggest that a comprehensive, well-designed and executed intervention aimed at educating high school students working in agriculture about hearing conservation was ineffective in preventing noise-induced hearing loss. This is particularly notable as this was an early intervention in the lives of these young people, and theoretically such early interventions should be efficacious. There is a need for creative solutions to protect young people from major sources of noise in both occupational and recreational settings. Potential solutions should concentrate on environmental modification and regulations to control noise emissions, as educational solutions on their own are insufficient to protect many young people from noise-induced hearing loss.

A knowledge translation fact sheet was developed for the study participants outlining the key findings from the study and emphasizing the importance of prevention (see Appendix A).

Outcomes/Impact

Potential Outcomes That Could Impact Workplace Risk (if used):

1. Hearing conservation programs should be focused on environmental modification and regulation to control noise emissions.
   - Our findings provide objective evidence that a comprehensive educational intervention by itself had limited effectiveness in preventing early noise-induced hearing loss. Thus, time and money would be better spent making machinery and equipment quieter, rather than relying on young workers to use hearing protection appropriately as the primary means of preventing noise-induced hearing loss.

2. Hearing conservation policies and practices should focus on early detection of noise-induced hearing loss in young workers.
   - Our finding demonstrated that early stage noise-induced hearing loss can be detected in young workers using a sensitive and objective measure of high frequency changes (3, 4, or 6 kHz) on audiogram.
   - Among participants in our study with hearing loss, the audiometric configuration varied substantially, with a minority showing the classic audiometric notch. Using an objective measure of high frequency changes on audiogram, can result in identification of young workers who are on a possible trajectory leading to noise-induced hearing loss as they age and could be efficacious in preventing further irreversible damage.

3. Hearing conservation programs must expand to focus on a broader range of exposures, whether they occur in occupational or non-occupational settings.
   - Recreational noise exposures were found to be related to hearing loss, even more so than occupational noise exposures. Priority exposures include gunshots, chainsaws, power tools, smoking, and potentially some chemical exposures.
   - From the employer's perspective, the costs of an expanded hearing conservation program may be offset by both improvements in employee health and potential reductions in liability.

Section 2 of the Final Progress Report

Scientific Report

Background

From 1992 to 1996, a cluster randomized trial was conducted to evaluate the efficacy of a 3-year hearing conservation program involving junior and senior high school students who were working in agriculture. The original trial was comprised of 34 schools in rural Wisconsin with vocational agriculture programs. Schools were first stratified by projected number of students into smaller and larger schools, and then each school (cluster) was randomized to either the intervention or control group separately within these two strata.

A noise exposure questionnaire was completed at baseline (1992–1993) and again after three years (1995–1996). Audiometric examinations were completed on-site at each school by trained technicians using a truck-mounted mobile testing unit with a specially-designed testing booth. The intervention spanned three years and incorporated elements of the ideal industrial hearing conservation program. The intervention included classroom instruction, fitting and distribution of hearing protection devices, direct mailing of educational materials to students' homes to reinforce hearing protection messages, noise level assessments conducted at the home, and yearly audiometric testing with reinforcement of hearing protection messages. The control group received audiometric testing at baseline and years 2 and 3. Short-term outcomes of this trial suggested that the intervention led to significantly improved rates of hearing protection use at 3-years post-intervention, but no differences were found between intervention and control groups on objective audiometric measures of NIHL.

Specific Aims

The purpose of this study was to evaluate the long-term effectiveness of this 3-year hearing conservation program directed at junior and senior high school youth working in agriculture. The study assessed the role of early intervention in sustaining hearing protection behaviors and preventing noise-induced hearing loss in young workers.

Primary Objectives

1. Evaluate the long-term (16 years after baseline) effectiveness of a 3-year hearing conservation program directed at junior and senior high school students by comparing intervention (hearing conservation program) and control (did not receive the hearing conservation program) groups with respect to:
    a. Self-reported use of hearing protection devices when exposed to high noise levels (above 85 decibels)
    b. Audiometric threshold test results

2. Within the full cohort, compare young adults currently working in agriculture with those in other work settings via: a) audiometric threshold test results, b) self-

reported use of hearing protection devices, and c) noise exposure history (work and recreational).

3. Provide recommendations regarding the long-term effectiveness of school-based hearing conservation programs for young workers.

Methodology

Participants. A total of 690 students completed the original trial (349 intervention, 341 control); this constituted our target cohort for the 16-year follow-up study. There were no specific exclusion criteria.

From March 2009 to March 2010, extensive efforts were made to find and contact all 690 members of the target cohort. These efforts started with matching the original study participant roster with the Marshfield Clinic electronic medical record (EMR). If participants could not be matched to the EMR, telephone directories and internet searches were used to find contact information. If unsuccessful, the parent roster from the original study was matched with Marshfield Clinic's EMR. If parents could not be matched to the EMR, telephone directories and internet searches were used to find parent contact information. Attempts to contact participants were exhaustive. In total, more than1200 recruitment letters were mailed to participants and/or parents and 3252 telephone calls were made.

Exposure assessment. Participants in the 16-year follow-up completed an exposure history questionnaire covering 13 years since the last contact in 1996. The questionnaire focused on high noise level recreational activities, high noise level occupational exposures, and exposure to smoking and chemicals with ototoxic potential. Use of hearing protection devices for each activity and exposure was also recorded. Time-weighted averages were calculated to summarize historical noise exposures and hearing protective behaviors. Part-time (PT) work was weighted as a percent of full-time (FT) for agricultural (38%, based on means of 19.5 hours PT, 51.5 hours FT) and non-agricultural (51%, based on means of 22.7 hours PT, 44.6 hours FT) industries using means for 2009 reported by the U.S. Bureau of Labor Statistics (http://data.bls.gov). Exposure measures are reported in units of mean time exposed over 13 years. Protective behaviors are reported as mean percent of time when hearing protection devices were used during exposure.

Audiometric testing at 16-year follow-up. Participants were scheduled for audiometric examinations at the Marshfield Clinic main campus or one of seven satellite clinics. Examinations were conducted by licensed audiologists in clinical audiology departments under standard operating procedures. An audiology study protocol was developed and reviewed with all 12 audiologists involved in testing before participant enrollment. Audiologists were not informed of individual participants' group membership (intervention, control). Established measures were used to summarize audiogram results.

Primary outcome measures. All outcomes were assessed at the individual participant level. The hearing protection measure was self-reported use of hearing protection devices for each recreational and occupational category examined. Participants responded using a 5-point Likert scale anchored by *never* and *always*.

Audiometric outcome measures were audiometric threshold changes from baseline to the 16-year follow-up in: 1) individual frequencies; 2) OSHA standard threshold shift, representing an increase of $\geq$10 dB in the average for 2000, 3000, and 4000 Hz in either ear (yes or no); 3) low frequency average (500, 1000, and 2000 Hz); 4) high frequency average (3000, 4000, and 6000 Hz); and 5) bulge depth statistic defined as the difference between mean audiometric values at 2000, 3000, and 4000 Hz and mean values at 1000 and 6000 Hz.

Sample size calculations. The goal was to recruit as many original study participants as possible (up to 349 intervention, 341 control). *A priori* power calculations based on the original study data showed estimated power of at least 85% (α=0.05, two-sided test) for the primary outcomes assuming: 1) effect sizes of 22% for absolute difference in use of hearing protection devices and 10 decibels in the standard threshold shift; 2) intra-class correlation (ICC) of 0.06; and 3) 60% recruitment in each group. An interim analysis of conditional power was conducted in November 2009 when it was clear that recruiting 60% of the cohort would be impossible under the existing timeline. Interim estimates of ICC were lower than those used for planning, enough to more than offset the lower recruitment. After all attempts at 16-year follow-up recruitment were exhausted, recruitment ended under the original timeframe (enrollment of 52%).

Statistical methods. Survey responses on use of hearing protection devices and other protective equipment were reported in five ordinal categories: never (0%), sometimes (1–33%), often (34–66%), frequently (67–99%), and always (100%). Before analysis, extreme categories were pooled as necessary to provide at least ten responses per study arm in each category. A cumulative logit parameterization assuming proportional odds was used to model use of protective equipment in those exposed and to test for group differences. A linear model was used to calculate adjusted mean exposures for presentation, but the exposure distributions were skewed, with many zeros and some very high values, so means for exposure are much higher than medians (not shown).

Individual audiogram frequencies were each analyzed as a maximum (left or right) change from baseline using logistic regression to compare study arms. A cumulative logit parameterization assuming proportional odds was fit to the resulting ordinal scale (e.g., 0, 5, 10, 15+) measures. The OSHA standard threshold shift was analyzed using binary logistic regression to compare study arms.

Audiogram summary measures were each analyzed as maximum (left or right) change from baseline using a linear model to compare study arms. The measures were first transformed to provide better approximate normality and improved statistical properties. Statistics were returned to the original scale for presentation.

All statistical models described above were adjusted for randomization by school. A school indicator was included as a random effect in models to estimate and adjust for potential correlation (ICC) among subjects from the same school. As reported previously, the randomized groups differed with respect to the percentage male, and substantial gender differences in hearing have been reported, so all models included gender as a covariate.

Analyses included all available data following intention-to-treat principles. References to statistical significance are based on 5% level of significance ($P<0.05$) in two-sided tests. No adjustment for multiple comparisons was utilized, but it had been decided *a priori* that statistical significance at any one frequency would not be considered definitive without supporting trends in adjacent frequencies.

Results

Recruitment and Participant Flow. A total of 392 participants from the original study were successfully located and recruited; 200 (53%) from the intervention group and 192 (51%) from the control group. An equal number of subjects from each group ($n=149$) did not participate in the 16-year follow-up primarily due to subjects not returning phone calls after multiple attempts (non-committal). Within the non-committal groups ($n=91$ intervention, $n=86$ control), 27 subjects from each group agreed to participate but did not appear for the audiometric examination and/or return the survey. Sixty-four subjects could not be located – 28 from the intervention group and 36 from the control group. Only 47 (8%) of the 616 subjects who were located declined participation. Ten subjects were deceased, with nine from the intervention group ($P=0.046$). This group discrepancy is likely due to differences in availability of follow-up information and is reported for completeness only, since mortality was not a planned outcome. In five cases where cause of death was determined, two were drownings, two were motor vehicle crashes, and one was a homicide. The combined numbers, either known deceased or unable to locate, were identical ($n=37$) in both groups.

Descriptive Data. The median age of participants was comparable between groups; however, consistent with the baseline allocation, the percentage of males was higher in the intervention group at the 16-year follow-up (74% vs. 62%). Thirty-seven participants failed to complete either the survey ($n=3$) or the exam ($n=34$); for consistency, all further analyses will be restricted to the 355 participants completing both the survey and exam.

After adjustment for gender and study design, exposures to occupational and recreational high noise exposures were quite similar in the two groups and showed no significant differences. Smoking history varied somewhat by group ($P=0.044$), with 38% of the intervention group reporting current or previous smoking as compared with 26% of the control group.

Hearing Protection Devices. Intervention group members with agricultural noise exposure reported significantly higher use of hearing protection devices ($P=0.015$) than those exposed in the control group, although the percentage using devices was quite low in both groups (25.9% and 19.6%, respectively). There was a significant difference

between intervention and control groups in use of hearing protection devices when exposed to gunfire (P=0.02), with the intervention group reporting a higher percentage using hearing protection (56.2% and 41.6%, respectively).

Audiometric Threshold Tests. Raw audiometric results showed similar distributions between intervention and control groups in both males and females. The largest group difference was observed at 6000 Hz, where there was a five decibel difference in the 75^{th} percentiles (better hearing in the intervention group).

Group comparisons of audiometric thresholds adjusted for gender showed no significant differences between intervention and control groups, and no consistent trend was observed across thresholds. The group difference at 6000 Hz approached significance (P=0.054) in the direction of less hearing loss in the intervention group (38% with loss ≥10 dB versus 50% in control group). If included as a covariate in this model, smoking (ever/never) was significantly related to the 6000 Hz outcome (P=0.002, with smokers showing more hearing loss), and increased the apparent significance of the intervention effect (P=0.024, OR=0.62). Adjustment for smoking did not result in significant intervention effects at other frequencies.

The standard threshold shift indicator showed no suggestion of group differences (P=0.847). Similarly, no significant group differences were observed with hearing summary measures. Means adjusted for design and gender were very similar by group for the low and high frequency averages and for the bulge depth statistic.

Discussion

Major findings that emerged from this 16-year follow-up of a cluster randomized trial were: (1) by self-report, participants randomized to the hearing conservation intervention reported more frequent use of hearing protection than controls, although this was limited to two contexts – agricultural work and gunfire; and (2) the educational intervention had no convincing effect on NIHL, as assessed via objective audiometric measures.

Long-term increases in use of hearing protection devices among the intervention group were demonstrated as compared to controls. However, this increased use of hearing protection during noisy activities in agriculture was still quite low (25.9%) and similar to rates reported in the general farm population. Even if real, such effects are not adequate to prevent NIHL. The observed increase in use of hearing protection would still have resulted in substantial exposures to potentially damaging noise, as rates of use in numerous noisy occupational and recreational contexts were also low.

The lack of any convincing effect of the intervention on the audiometric test results in this cohort is noteworthy. Although there was some indication of an effect at a single high frequency (6000 Hz), this met significance only upon adjustment for smoking history and was not supported by data at other frequencies, as required *a priori* in our trial protocol for definitive evidence. Studies have shown associations of smoking with

hearing, but these reports have been in older subjects, and there is a strong potential for confounding the effects of smoking with other important factors (gender, age, occupation, etc.). Regardless, by documenting important changes in hearing acuity at high frequencies over time, this study provides objective evidence that a well-organized educational intervention by itself was ineffective at preventing NIHL, both short- and long-term. Hence, other approaches to prevention require consideration.

Conclusion

Our findings suggest that this comprehensive, well-designed and executed intervention aimed at educating rural high school students about hearing conservation was ineffective in preventing NIHL. This is particularly notable as this was an early intervention in the lives of these young people, and theoretically such early interventions should be efficacious. Second, there is a need for creative solutions to protect young people from major sources of noise in both occupational and recreational settings. Potential solutions should concentrate on environmental modification and regulations to control noise emissions, as educational solutions on their own are insufficient to protect many young people from NIHL.

Publications

Berg RL, Pickett W, Fitz-Randolph M, Broste SK, Knobloch MJ, Wood DJ, Kirkhorn SR, Linneman JG, Marlenga B. (2009).
Hearing conservation program for agricultural students: Short-term outcomes from a cluster randomized trial with planned long-term follow-up.
Preventive Medicine, 49 (6): 546-552.

(The purpose of this paper was to present a contemporary analysis of historical data on the short-term efficacy of the 3-year hearing conservation program conducted from 1992 to 1996 and establish procedures for assessment of hearing loss for use in our 16-year follow-up study.)

Marlenga B, Linneman JG, Pickett W, Wood, DJ, Kirkhorn SR, Knobloch MJ, Broste SK, Berg RL. (2011).
Randomized trial of a hearing conservation intervention for rural students: Long-term outcomes.
Pediatrics, 128 (5): e1139-e1146.

(The purpose of this paper was to report the main findings of the 16 year follow-up assessing the sustained use of hearing protection devices and the prevalence of noise-induced hearing loss in this cohort of young workers.)

Marlenga B, Berg RL, Linneman JG, Wood DJ, Kirkhorn SR, Pickett W. (2012). Determinants of early stage hearing loss among a cohort of young workers with 16-year follow-up. *Occupational and Environmental Medicine*, 69 (7): 479-484.

(The purpose of this paper was to estimate the strength of associations between occupational and recreational exposures and early stage noise-induced hearing loss.)

Berg RL, Pickett W, Linneman JG, Wood DJ, Marlenga B. Asymmetry in noise-induced hearing loss: Evaluation of two competing theories. *Ear and Hearing* (submitted August 23, 2012).

(There are competing theories (physiology vs. the physics of noise exposure) about why patterns of asymmetry are observed in noise-induced hearing loss. The purpose of this paper was to describe and evaluate patterns of hearing loss and asymmetry by 1) gender, 2) exposure to agriculture, and 3) exposure to gunfire.)

Inclusion of Gender and Minority Study Subjects

See Inclusion Enrollment Table in Appendix B.

Inclusion of Children

The study was a 16-year follow-up of a randomized controlled trial of a school-based hearing conservation program for children working in agriculture who were in the 7^{th}, 8^{th}, and 9^{th} grades, so the original study participants were children 13-15 years of age. The program was deemed effective in the short term (3 years) in increasing the use of hearing protection devices but the long-term effectiveness had not been assessed. These children were now 28-32 years of age and comprised the proposed study population. So, although none of the study participants were children, the original intervention targeted *children* working in agriculture and the follow-up study findings were used to provide recommendations regarding the effectiveness of this program developed and implemented for *children.*

Materials Available for Other Investigators

Upon request to the principal investigator, data files will be created electronically from the primary study database and will contain all the key subject-level study data, but no subject identifier. Data will include descriptive data (gender, school), questionnaire results, and hearing test results.

Closeout Document 2: The Final Financial Status Report

This document will be submitted separately by the Marshfield Clinic Research Foundation, Office of Sponsored Programs.

Closeout Document 3: The Final Invention Statement and Certification

This document will be submitted separately by the Marshfield Clinic Research Foundation, Office of Sponsored Programs.

Closeout Document 4: Equipment Inventory Listing

This document will be submitted separately by the Marshfield Clinic Research Foundation, Office of Sponsored Programs.

APPENDIX A

Knowledge Translation Fact Sheet for Participants

16 Years Later

Hearing Conservation Program
Follow-up Study

The purpose of the Hearing Conservation Program Follow-up Study was to see if hearing education for rural high school students conducted from 1992 to 1996 resulted in: ❶ less noise-induced hearing loss and/or ❷ continued use of hearing protection devices when participants were recontacted 16 years later. We also took the opportunity to study common work and recreational noise exposures that may affect hearing over time.

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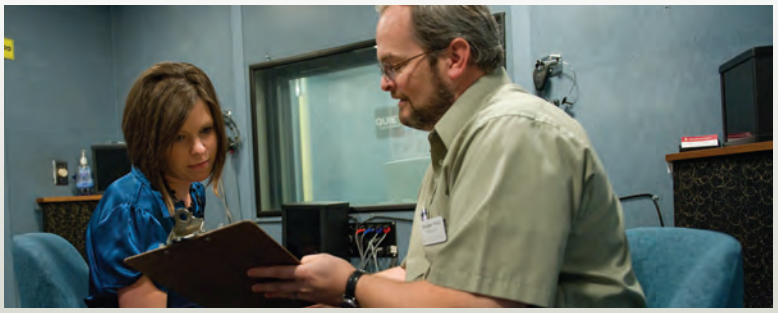

A unique study

- Your participation in this study made a unique and important contribution to clinical medicine and science.
- To the best of our knowledge, this is the only study with hearing assessments conducted on adolescents who were followed into the early years of adulthood.
- This long-term follow-up has allowed researchers to begin seeing when in a person's life noise-induced hearing loss typically begins to emerge and what factors lead to hearing loss.

What we learned

1. The hearing conservation program appeared to increase the use of hearing protection devices, but the usage was still quite low.
   - Some study participants reported never wearing hearing protection and most others used hearing protection only a fraction of the time when exposed to loud noise.
2. Noise-induced hearing loss is not just a problem of old age.
   - Measurable high frequency hearing loss (10dB or more) was observed in 63% and substantial loss (25dB or more) was observed in 12% of the young adult participants (28-32 years of age).
3. Recreational noise exposures were found to be related to hearing loss, even more so than occupational noise exposures.
   - Noise exposures of particular concern in this study were gunshots, chainsaws, and power tools.
4. With some disappointment, we learned that the hearing conservation program did not make a significant difference in preventing early hearing loss.
   - Education alone cannot be counted on to protect young people from noise-induced hearing loss.

What does this mean for you?

Prevention is the key

- Noise exposures are cumulative...
  every exposure increases your risk for hearing loss.
- Nothing can restore or repair hearing loss from noise damage...
  so we all need to do a better job protecting our hearing.
- The best solutions to protect our hearing are environmental modifications...
  making machinery and equipment quieter.
- Use hearing protection devices around every loud noise, every time...
  especially if there is no way to make machinery and equipment quieter.

Fast facts	Participants	Schools Represented	Participants who traveled 100+ miles (round-trip)
Original Study	690	34	0
16-year Follow-up	392	34	114

Schools with the most participants completing a hearing test in the 16-year follow-up:

Marathon 22	Spencer 21	Loyal 19	Gilman 19	Stratford 17
Athens 15	Granton 15	Auburndale 15	Abbotsford 15	

Publications from this study

- *Hearing conservation program for agricultural students: Short-term outcomes from a cluster randomized trial with planned long-term follow-up.* (Berg RL et al.) Preventive Medicine, Volume 49, Number 6 (2009).
- *Randomized Trial of a Hearing Conservation Intervention for Rural Students: Long-term Outcomes* (Marlenga B et al.) Pediatrics. Volume 128, Number 5 (2011).
- *Determinants of early stage hearing loss among a cohort of young workers with 16-year follow-up* (Marlenga B et al.) Occupational and Environmental Medicine, March 23, [Epub ahead of print], (2012).

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16 Years Later

Thank You for your participation

2221-000

APPENDIX B

Inclusion Enrollment Report

Program Director/Principal Investigator (Last, First, Middle): Marlenga, Barbara L.

Inclusion Enrollment Report

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

Study Title: Evaluation of a Hearing Conservation Program for Farm Youth: A 15-Year Follow-Up

Total Enrollment: 392 **Protocol Number:** N/A

Grant Number: 5 R01 OH009392-02

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	3	2	0	5 **
Not Hispanic or Latino	119	235	0	354
Unknown (individuals not reporting ethnicity)	6	27	0	33
Ethnic Category: Total of All Subjects*	128	264	0	392 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	128	260	0	388
More Than One Race	0	0	0	0
Unknown or Not Reported	0	4	0	4
Racial Categories: Total of All Subjects*	128	264	0	392 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	2	0	5
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	3	2	0	5 **

* These totals must agree.
** These totals must agree.