Development of a school based hearing conservation program for use in rural areas

December, 23, 2005

Gregory A. Flamme

Western Michigan University
Department of Speech Pathology and Audiology
Kalamazoo, MI 49008
Greg.flamme@wmich.edu

Co-investigators: Shelby Myers-Verhage, M.A.T.
James A. Merchant, M.D., Dr.P.H.
Ann M. Stromquist, Ph.D.
Craig Zwerling, M.D., Ph.D., M.P.H.

Sponsor: National Institute for Occupational Safety and Health
Grant Number: R21 07707

Start date: 10/1/2002
End date: 9/30/2005

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

HBM:	Health Belief Model
PSu:	Perceived susceptibility
PSe:	Perceived severity
PBen:	Perceived benefits
PBar:	Perceived barriers
CtA:	Cues to action
SEf:	Self-efficacy
ItP:	Intent to protect hearing
DP:	Distortion product
DPOAE:	Distortion product otoacoustic emissions
ROC:	Receiver Operating Characteristic
SPL:	Sound pressure level
dB:	Decibel
dBA:	A-weighted sound pressure, in dB
HL:	Hearing Level
UNS:	Unscreened

ABSTRACT

Issue addressed. This project was designed to develop and evaluate hearing loss prevention programs for use with youth in grades 4 and 7 in rural areas.

Importance of the problem. There is a high prevalence of hearing impairment among adolescents living in rural areas, particularly those with farming backgrounds. The prevalence of hearing impairment among rural adolescents is higher than the prevalence observed in the general United States population, and substantial hearing impairment is observed by the majority of rural residents before age 40. Hearing loss prevention programs are needed to reduce the severity of hearing impairment among those who already have hearing impairments and to prevent the occurrence of hearing impairments among those who have normal hearing. Rural schools are a logical place to provide hearing loss prevention information. These schools have large percentages of students who are regularly exposed to occupational or recreational risk factors for hearing impairment and many of these students will continue or increase these exposures upon entry into the workforce.

Approach. A controlled intervention study with both longitudinal and cross-sectional components was used in each of two grades. Study endpoints included a combination of measurements of hearing status, questionnaire measures of knowledge, attitudes, and health beliefs pertaining to hearing and hearing loss prevention, unobtrusive measures, and participant ratings of program elements.

Key findings. It is possible to develop comprehensive hearing loss prevention programs that address science and health education standards. Both comprehensive and basic hearing loss prevention programs were observed to have long term (9- to 12-month) effects, and the relative merits of these programs can differ with age. Basic and comprehensive hearing loss prevention programs achieved comparable levels of effectiveness among participants in grade 4. A comprehensive hearing loss prevention program was effective for participants in grade 7, but a basic program did not provide substantial benefits.

How the results can be utilized. The results from this developmental/exploratory study suggest that there can be substantial benefit from basic hearing loss prevention programs consisting of audiometric monitoring, and individual consultation for youths in grade 4, but effective programs for youths in grade 7 may need to have a broader scope.

HIGHLIGHTS/SIGNIFICANT FINDINGS

Long term (9- to 12-month) effects of hearing loss prevention programs were observed in this study.

Basic and comprehensive hearing loss prevention programs achieved comparable levels of effectiveness among participants in grade 4.

A comprehensive hearing loss prevention program was effective for participants in grade 7, but a basic program did not provide substantial benefits.

TRANSLATION OF FINDINGS

These results suggest that basic and comprehensive hearing loss prevention programs can have effects that last one year, and that there are additional benefits to comprehensive hearing loss prevention programs. Future work in this area should be targeted at replicating these results with other rural populations and with a different sample in this rural population, and efforts should be made to assess the long-term (e.g., 2- to 5-year) impact of basic and comprehensive hearing loss prevention programs.

OUTCOMES/RELEVANCE/IMPACT

Among rural youth in grade 4, either basic (hearing testing and individual consultation) or comprehensive hearing loss prevention programs (hearing testing and individual consultation, classroom presentation, supporting take-home materials) were beneficial. Among youth in grade 7, more comprehensive interventions seem to be required to show substantial benefits.

SCIENTIFIC REPORT

Background

The prevalence of hearing impairment among 18-27 year old rural Iowa males is over 40% (Mudipalli 1999), which indicates that by the time many rural males enter the workforce, they already have significant hearing impairments. Flamme, Mudipalli, Reynolds, Kelly, Stromquist, et al. (2005) showed that the prevalence among adolescents is higher than the U.S. national prevalence among children aged 12 to 19.

Conventional wisdom holds that most of the hearing impairments observed in rural youth are due to excessive noise exposure. Noise levels produced by farm machinery (Simpson and Deshayes 1969; Solecki 1995; Holt, Broste, and Hansen 1993) and woodworking and metalworking machines (Roeser, Coleman, and Adams 1983) are sufficiently high to produce permanent hearing damage. Noise exposure during recreational activities is also a potential cause of hearing impairment. The sound levels produced by many recreational noise sources (e.g. snowmobiles, ATVs, firearms) are also sufficient to cause permanent hearing impairment (Axelsson, Jerson, Lindberg, and Lindgren 1981). People living in rural areas are more likely to engage in both farming and recreational activities that put them at risk for hearing impairment (Nondahl, Cruickshanks, Wiley, Klein, Klein, and Tweed 2000).

In addition to excessive noise exposure, additional risk factors for acquired hearing impairment have been identified (e.g., smoking (Barone, Peters, Garabrant, Bernstein, and Krebsbach 1987; Cruickshanks, Klein, Klein, Wiley, Nondahl, and Tweed 1998; Itoh, Nakashima, Arao, Wakai, Tamakoshi, Kawamura, and Ohno 2001; Mudipalli 1999; Nomura, Nakao, and Morimoto, 2005; Siegelaub, Friedman, Adour, and Seltzer 1974; Virokannas and Anttonen 1995). In two rural population-based studies (Cruickshanks and others 1998; Mudipalli 1999), the odds of hearing impairment among smokers are approximately double those of non-smokers.

Permanent hearing impairment has serious psychosocial consequences. Hearing impairment is associated with increased depressive symptoms, reduced feelings of mastery, reduced self efficacy, feelings of loneliness, reduced self-esteem, and smaller social networks (Anonymous 1999, Bess, Dodd-Murphy, and Parker 1998; Kramer, Kapteyn, Kuik, and Deeg 2002). Hearing impairments described as "mild" using conventional audiological nomenclature result in substantial disabilities and handicaps in the areas of speech understanding in noise and the ability to locate the source of a sound (Flamme 2001; Kramer, Kapteyn, Festen, and Tobi 1996; Kramer, Kapteyn, and Festen 1998).

Despite known high levels of noise exposure, few people living in rural areas use hearing protection devices (Merchant and others 2001). Hearing conservation training should begin during childhood and schools represent a logical place to conduct this training (Anonymous, 1990; Chermak and Peters-McCarthy 1991; Montgomery and Fujikawa 1992; Niskar, Kieszak, Holmes, Esteban, et al. 2001; Blair, Hardegree, and Benson 1996;

Roeser 1980; Lass, Woodford, Lundeen, Lundeen, and Everly-Myers 1986; Brookhouser, Worthington, and Kelly 1992; Dobie 1995).

Few school-based hearing conservation programs have been systematically evaluated. However, there is evidence to suggest that hearing conservation programs can be beneficial. Chermak and Peters-McCarthy (1991) observed a 23% improvement in knowledge and attitudes regarding hearing protection in third and fourth grade students, measured two weeks after the administration of a hearing conservation program. In a subsequent study with fourth grade students, Chermak et al. (1996) found a 25% improvement in knowledge of hearing and noise-induced hearing impairment, measured one week after the administration of a hearing conservation program. Despite short follow-up periods, these studies demonstrate that students are able to learn about hearing and hearing protection.

The Marshfield program (Knobloch and Broste 1998) was developed for use in adolescent agricultural populations. This program included classroom-style education, reminders or cues to action intended to motivate students to engage in hearing protection behavior, noise level assessments, convenient access to hearing protection devices, and hearing evaluations. In a 3-year longitudinal study, this program increased the use of hearing protection devices in secondary school students from below 25% at baseline to a final level above 87%.

The development of the Marshfield program elements was informed by the Health Belief Model (see Strecher and Rosenstock, 1997) and the Theory of Self-Efficacy (Bandura 1977). In the substantive area of hearing conservation, the Health Belief Model holds that, before engaging in behaviors intended to protect hearing, a person must perceive that he/she is susceptible to hearing damage (Perceived Susceptibility, or PSu), that hearing damage has severe consequences (Perceived Severity, or PSe), and that the protective behavior will be beneficial (Perceived Benefits, or PBen). In addition, the person must also be aware of and reduce the potential physical or social/psychological barriers to the activities of hearing protection (Perceived Barriers, or PBar), and be regularly reminded to protect their hearing (Cues to Action, or CtA). The supporting construct of the Theory of Self-Efficacy (SEf) holds that the person must be confident that he/she has the ability to successfully implement hearing protective behaviors before he/she will engage in these behaviors.

Through student ratings of program components, the investigators discovered that most influential aspect of the Marshfield program was the availability of free hearing protection devices, which could indicate that availability and/or cost of hearing protection devices constitute a substantial barrier to the implementation of hearing conservation procedures. *Cues to action* like annual hearing evaluations, mailings to participants, teacher influence, and classroom instruction also influenced students' use of hearing protection devices (Knobloch and Broste 1998).

Many hearing loss prevention programs have been developed for use with children and youth (see Folmer, Griest, and Martin, 2002) but these programs rarely have been developed with specific guidance of health communication theory or evaluated in terms of long-term effectiveness. If a hearing loss prevention program is to be effective, it must support long-term changes in beliefs and behaviors. An effective hearing conservation program would have considerable benefits (e.g. reduced hearing impairment, reduced need for hearing aids and other rehabilitative treatments, reductions in psychosocial sequelae of hearing impairment). However, if hearing conservation programs are ineffective, the resources used to conduct the programs (e.g., supplies, personnel expenses, lost classroom time), will be wasted. It is not sound to assume that untested programs will motivate students to engage in protective behaviors. Also, it is uncertain that the added complexity and cost of more comprehensive programs will result in better outcomes than a simpler, cheaper alternative.

School administrators and teachers could successfully argue that hearing loss prevention programs require time and resources that could be better used to meet more fundamental learning objectives (science, mathematics, health, etc.). These objectives could be integrated with a hearing loss prevention program in such a way that both goals are met. To this end, the hearing loss prevention programs developed for this project were designed to address appropriate national science and health education standards.

<u>Significance.</u> We implemented the recommendations of the NIH Consensus statement (Anonymous, 1990), including the use of individual hearing protection devices, education programs beginning with school-age children, increased awareness of noise exposure, guidance in estimating hearing damage risk, and hearing conservation programs designed for rural/agricultural occupational settings. This study was a controlled evaluation study ("Stage 3" re: NIOSH, 1999). The outcome of this study will inform the development of a larger longitudinal study of hearing conservation program effectiveness. The results will imply either that there is sufficient effectiveness to justify the inclusion of one or both programs in larger-scale longitudinal assessments of the impact of hearing conservation programs, or indicating that substantial revision and restructuring are necessary prior to such work. Of secondary interest is that the study involved (1) new approaches for people to use in estimating their risk of hearing damage, and (2) objective acoustic measures hearing status (i.e., distortion product otoacoustic emissions), which are not regularly included in current evaluations of hearing conservation program effectiveness.

Specific Aims

The current study was part of a research program to develop and evaluate the effectiveness of hearing conservation programs that can be used in rural areas. Hearing conservation programs are needed in rural areas to reduce the severity of hearing impairment among those who already have hearing impairments and to prevent the occurrence of hearing impairments among those who have normal hearing.

Specific Aim 1. Develop and implement four hearing conservation programs, two (one basic, one comprehensive) for 4th graders and two (one basic, one comprehensive) for 7th graders. The programs will be based on existing programs, with specific refinements intended to enhance program effectiveness and incorporate the recommendations described in the NIH consensus statement (Anonymous, 1990).

Specific Aim 2. Compare the effectiveness of comprehensive and basic interventions to each other and to a reference group receiving no intervention.

Specific Aim 3. Explore the use of Distortion Product Otoacoustic Emissions as an indicator of cochlear damage.

Research Design and Methods

For each age level (grade 4 or grade 7), a three-group design (two intervention groups, one reference group) was used. Pretest-posttest differences were nested within this design to permit measurements of change in knowledge, attitudes, and self-reported exposures during the study period. The follow-up intervals for participants in grades 4 and 7 were approximately 9 months and 12 months, respectively.

Participants. Participants in this study were selected on the basis of their enrollment in targeted school districts. Targeted districts were located in small rural areas surrounding Iowa City, Iowa. Eighteen school districts were approached to participate in one of the three groups, and fifteen agreed to participate. To avoid the diffusion of program components and materials across groups, school districts assigned to the comprehensive group were separated from any districts assigned to the basic group by at least one set of school district boundaries. Fourth graders from fourteen schools participated in this study. These schools had a combined enrollment of 556 students, of which 450 (81%) participated, one hundred fifty-nine of these participants were enrolled in either the comprehensive or basic intervention (N = 84 and N = 73 in each subgroup, respectively). Seventh graders from thirteen schools having a combined enrollment of 668 students and 479 (72%) participated, one hundred fifty of these were enrolled in either the comprehensive or basic intervention group (N = 93 and N = 57 in each subgroup, respectively). A larger number (62%) of the participants in grade 7 received the comprehensive intervention. This was because participation in the study was offered on a school-by-school basis, which meant that enrollments increased in discrete steps rather than on an individual-by-individual basis. Enrollment efforts were discontinued once the total number of participants within a grade reached 150. This level of imbalance was not expected to have substantial effect on the power of statistical analyses (Pocock, 1983). Approximately one half (46%) of the participants were male.

Hearing conservation programs

Basic interventions. Participants receiving the basic intervention received a hearing test followed by individual counseling about appropriate responses to high noise levels and the need to also avoid chemical and smoke exposures. A copy of the hearing test was then sent home with a letter explaining the results of the hearing test. Participants in grade 7 were also notified that earplug dispensers were placed in the students' Science classrooms for easy access to a continuous supply of earplugs throughout the school year for personal use.

Comprehensive interventions. The comprehensive intervention included the same components as the Basic intervention, and class presentations, booster interventions and earmuffs (grade 7 only) were added. The comprehensive intervention for the 4th graders included one 40-minute classroom presentation and two 40-minute classroom presentations were made to the 7th graders. Posters were displayed in the classroom representing sound levels associated with common rural noise sources. The classroom presentation curriculum connected to national standards in Science and Health Education and involved a series of mini-lessons about hearing and hearing loss prevention. The lessons utilized a variety of instructional strategies allowing for hands-on learning, small group activities, handouts, classroom materials, and individual learning components. Students were shown what hearing loss sounds like (using the NIOSH Hearing Loss Simulator) and were given basic information on how sound travels through the ear. We explained how hearing loss occurs, with emphasis on avoiding risk factors of noise, smoke and chemicals and making wise choices when confronted with these exposures.

During the first presentation, students were issued a variety of take home tools that offered reminders about hearing loss prevention, and instructed participants about how to best use them. Participants in grade 4 were given magnets that gave examples of sounds in the "red, yellow and green" exposure zones.

Participants in grade 7 were given bookmarks that represented the dBA scale with common rural noise levels and reminders of the "Roll, Pull, Hold" earplug insertion technique. Seventh graders were also given laminated (wallet-size) noise exposure cards showing the sound levels produced by common rural noise sources and a table showing the permissible exposure times associated with a given sound level. Sound level meters for student use were also distributed to classrooms along with a detailed instruction sheet describing how to use the meter.

Participants in grade 7 were also given a "homework" assignment to complete before the second presentation. Classroom teachers issued the sound level meters to student volunteers who performed simple experiments involving the measurement of the sound levels of noise sources in their daily lives. Students who took home the sound level meters recorded their measurements and reported them to the class during the second presentation. Participants were asked to list the loud sounds encountered during the time between the first and second presentation and estimate the level of those sounds. The second presentation to the 7th graders took place approximately 1 week after the first presentation. The second presentation reviewed the main points of the first presentation, went into more detail about the sound levels produced by common rural noise sources, and the rapid reduction in safe exposure times as a function of increased sound level (i.e., dose accumulation according to a 3-dB exchange rate). During one part of this lesson 7th graders were presented with situations where they would be exposed to risk factors and they had to make group decisions about how to best protect hearing. Participants were shown how to use hearing protectors using: a custom digital recording of an adolescent putting on earmuffs and earplugs, demonstration by the presenters, and with graphics describing the "Roll, Pull, Hold" instruction technique.

In addition to having a hearing test report sent home to parents, students in the comprehensive group were given booster interventions three times (every 2-3 months) during the follow-up period. These interventions were brochures and other informational materials that described seasonal activities and how those related to hearing loss prevention. After the school year was over, 7th grade students were asked if they needed more earplugs since they no longer had access to their dispensers in class and we sent home more earplugs to those students who requested them. We also sent additional bookmarks and noise cards to students in grade 7 to remind them about key points of the program and give them factual information about situations where they might encounter noise or other exposures related to hearing loss.

Study endpoints

Hearing Status. Hearing status measurements were obtained with both intervention groups, but not the reference group. External and middle ear pathology were ruled out using otoscopy and aural immittance (compliance) measures. Pure tone thresholds were obtained using a swept-frequency Bekesy paradigm (Gescheider 1997) and with stimuli meeting ANSI S3.6 (1996) specifications. The Bekesy method was used because it allows the treatment of frequency and intensity as continuous variables rather than as a variable that is sampled in discrete steps. A 5-dB step is conventionally used in clinical audiometry, and this step size was regarded as too large to monitor for small changes in threshold over a relatively small number of listeners. Stimuli were gated pure tones with steady state duration of 200 ms and a 50% duty cycle. Tones were gated on and off using a 25 ms linear ramp. Tone frequency was continuously swept at a rate of 2 octaves per minute across the range of 200 to 8000 Hz for listeners in the 7th grade, (445 to 8000 Hz for listeners in the 4th grade). Tone amplitude was continuously swept at a rate of 160 dB per minute (2.7 dB/second). The tone amplitude was calibrated twice daily, in 1/12-octave steps across the entire frequency range, using an ANSI S1.4 Type I sound level meter system with an HA-2 2cm^3 coupler. Calibration at all frequencies was achieved using a curvilinear regression equation fitted to the reference equivalent threshold SPL values. The error tolerance for this calibration check was 0.5 dB. Errors exceeding this absolute value were automatically corrected in the test software. One-third octave band ambient noise levels were evaluated daily in each test environment (re: ANSI S3.1, 1999), and thresholds were compared with the minimum testable threshold in each environment during testing. One-third octave band sound pressure levels were obtained using a ANSI S1.4 Type 1 sound level meter (Larson Davis System 824) coupled to a high-sensitivity (~45 mV/Pa) one-half inch microphone (Larson Davis Model 2560) and a low noise preamplifier (Larson Davis Model PRM902). A Tucker-Davis Technologies RP2 Real Time Processor was configured to generate the pure tone signals and to monitor listener response switch status. The RP2 was controlled via a USB interface to the M50 workstation using Matlab software. Pure tone signals were passed through a 25 dB attenuation/isolation pad and into ER-3A insert earphones.

Distortion product otoacoustic emissions were measured at upper stimulus frequencies of 1.5, 2, 3, 4, 5, and 6 kHz. Stimulus levels were 65 and 55 dB SPL in a Zwislocki occluded ear simulator at the lower and upper stimulus frequencies, respectively. The cubic difference tone (2F1 – F2) was monitored for the distortion product emission. An Interacoustics MT10 handheld tympanometer was used to evaluate middle ear status.

Data were downloaded directly to a Dell M50 mobile workstation via USB (pure tone threshold) or RS-232 interface (tympanometry and otoacoustic emissions) and displayed using a set of custom MATLAB and executable software routines written specifically for this project (see Appendix for an example printout).

Questionnaires. Two questionnaires were used in this study, one for each grade. These questionnaires were designed to estimate a participant's frequency of exposure to risk factors for hearing damage; knowledge of auditory anatomy, physiology, and risk factors for hearing impairment; health beliefs (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action) and degree of self-efficacy regarding hearing loss prevention; and intent to protect hearing during future exposures to risk factors for hearing impairment. Questionnaire items were written so that they had a Flesh-Kincaid reading level of grade 3 for participants in 4th grade and a grade 4 reading level for participants in the 7th grade. Response alternatives for exposure items followed a nonlinear scale ranging from "Less than 1 time each year or never" to "Nearly every day." Response alternatives for questionnaire items pertaining to HBM components, SEf, and ItP domains were "strongly agree, agree, don't know, disagree, and strongly disagree."

Example questionnaire items are "The more time I spend around noise, the worse my hearing will be." (PSu domain), "If my hearing is harmed, I could hear ringing in my ears all the time." (PSe domain), "Learning is easier when you have normal hearing." (PBen domain), "My friends would tease me if I wore earplugs or earmuffs." (PBar domain), "If I work with chemicals, I should use gloves and wash my hands afterwards." (CtA domain), "I can use earplugs the right way." (SEf domain), and "If earplugs were around when I needed them, I would use them." (ItP domain).

Questionnaires administered at baseline consisted only of items related to exposures and knowledge and attitudes regarding auditory anatomy, physiology, and risk factors for hearing impairment. Exposure items were originally developed for use in this study, and knowledge and attitude items were taken from prior published studies (e.g., Chermak & Peters-McArthy, 1991; Chermak, et al., 1996). Analyses of baseline measures indicated the need for questionnaire revision due to ceiling and floor effects. For example, the preponderance (> 80%) of participants in grade 4 were well aware at baseline of the relationship between noise exposure and hearing impairment and the need to reduce noise exposure in order to protect hearing. Items with this initial response distribution were discarded.

In order to more directly assess the impact of the hearing conservation programs with respect to the components of the HBM, self efficacy, and intent to protect hearing, we developed a new questionnaire consisting of items intended to sample SEf and each domain of the HBM (e.g., PSu, PSe, PBen, PBar, CtA).

A pool of 54 potential questionnaire items that met the item reading level criteria and response alternatives of strongly agree, agree, don't know, disagree, and strongly disagree was developed for participants in grade 4 (66 items for grade 7). Within a given domain (e.g., HBM component, self efficacy), the number of potential items for participants in grade 4 ranged between 5 and 10 (median = 8). For participants in grade 7, the number of potential items per domain ranged between 7 and 14 (median = 9).

Within each grade, the item pool was divided into 7 domains (PSu, PSe, PBen, PBar, CtA, SEf, ItP) and distributed into fifteen separate questionnaire forms. These forms were intended for administration to different segments of the reference group so that the relative value of each item could be assessed. Each questionnaire form included a 14-item exposure profile, all items pertaining to two of the HBM and SEf domains (PSu, PSe, PBen, PBar, CtA, SEf), and all potential items pertaining to intent to protect hearing. Permuted sets consisting of all fifteen unique combinations of the six HBM and SEf domains were included across forms, which meant that each HBM and SEf domain was included in five of the fifteen forms. Participants began completing each form with demographic and exposure items, and then responded to items pertaining to the HBM components, SEf, and ItP. HBM, SEf, and ItP items were randomly mixed throughout each questionnaire form.

Within each grade, each of the fifteen questionnaire forms was administered to one classroom in the reference group, so the number of participants completing each subscale varied depending on the number of students in each classroom. For participants in grade 4, the number of participants completing each subscale ranged between 77 (PBen) and 105 (SEf). For participants in grade 7, the number of complete subscales ranged between 92 (PBar) and 135 (CtA). Items having the highest factor loadings in exploratory principal components analyses of items within each domain were selected for inclusion in the final questionnaire. The number of components extracted in these principal components analyses was based on the eigenvalues obtained during parallel analyses (Horn, 1965). With the exception of the PBar domain in the grade 7 population, each questionnaire subscale was unidimensional (i.e., represented by a single factor). For participants in grade 7, the PBar domain consisted of three dimensions that were labeled comfort, convenience, and personal image.

The final questionnaire used with the grade 4 group included a self-reported exposure assessment containing 17 items, a longitudinal 6-item assessment of knowledge of risk factors for hearing impairment, and a 28-item scale containing items pertaining to the HBM, SEf, and ItP (Total items = 51). The final questionnaire used with the grade 7 group included the same 17-item exposure assessment, a longitudinal 8-item assessment of knowledge and attitudes, and a 47-item scale pertaining to the HBM, SEf, and ItP (Total items = 72). Responses were assigned values of 2, 1, 0, -1, and -2 for responses of strongly agree, agree, don't know, disagree, and strongly disagree, respectively. Subscale scores calculated as the mean response across the times pertaining to a given domain.

<u>Nonreactive measures (Grade 7 only).</u> Hearing Protection Device use were compared between the experimental and reference groups by monitoring the total number of earplugs issued to each school. This type of outcome provides an erosion-type nonreactive (Webb, Campbell, Schwartz, Sechrest, and Grove 1981) measure of hearing protection device use. Students and the classroom teacher were notified that an infinite supply of earplugs was available and that they would be replaced when supplies were low, but only the investigators were aware that replacement rates were being tracked as a program outcome. Earplug use was estimated by the number of earplugs replaced,

divided by the number of months of follow-up time within each school. Earplugs sent to the student during the summer were not considered a part of this endpoint.

Program evaluation (Grade 7, comprehensive intervention only). Participants in grade 7 who received the comprehensive intervention were asked to rank the importance of various components of the program at the end of the study. Participants assigned a number (1 = most important) to each of five program elements, including the classroom presentation, the availability of the sound level meter, earplugs, earmuffs, and the hearing test and individual consultation.

Results

Our first specific aim was to develop and administer two hearing loss prevention programs for each grade. For both grade levels, the basic hearing loss prevention program included audiometric monitoring, individual consultation, and for participants in grade 7 only, easily available earplugs. The comprehensive hearing loss prevention program was informed by the HBM and the Theory of Self Efficacy, and contained elements that meet national standards for science and health education for each grade level.

The main aim of this project was to estimate the effectiveness of the hearing loss prevention programs. The primary outcome for participants in grade 4 was the questionnaire assessment of knowledge, attitude, and beliefs. Results from longitudinal data will be described first and analyses of cross-sectional data shall follow.

Effectiveness: Primary outcomes for grade 4. Responses to the six items included in the longitudinal assessment of knowledge and attitudes were scored "correct" or "incorrect" with respect to hearing protective behavior, and values of "1," "0," and "-1" were assigned to each item showing an improvement, no improvement, or a decrement in knowledge and attitudes, respectively. These values were then summed across the six items to provide an overall estimate of the change in each participant's knowledge of risk factors regarding hearing impairment. The average improvement across participants was 0.48 items. These improvements, however, were not significantly associated with intervention group when the difference was associated using the Mann-Whitney test ($p > .05$). No individual items showed a significant association ($p > .05$) with treatment group using the Mann-Whitney test.

With respect to each program's effectiveness in the domains of the HBM, SEf, and ItP, substantial differences were seen in many domains. Figure 1 illustrates the pattern of belief scores across the three groups in each domain. Except in the PBar domain, more positive belief scores represent beliefs that are more consistent with hearing protective behaviors. In the PBar domain, more positive belief scores represent a greater awareness of the barriers to hearing protective behaviors.

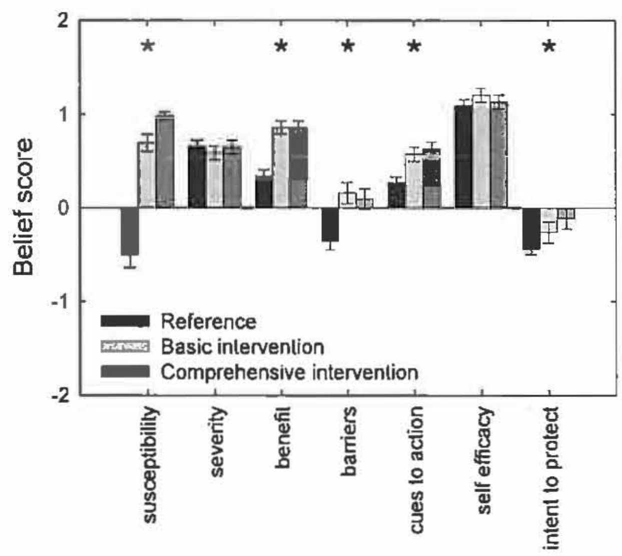


Figure 1: Questionnaire subscale scores, by participant group.
Error bars represent the standard error of the mean, asterisks represent analyses where significant ($p < .05$) main effects were observed using analysis of variance.

The significance of observed differences was evaluated using analysis of variance of scores within each domain and using post hoc comparisons (Scheffe and Student Neuman-Keuls) in cases of significant main effects. In the PSu domain, the main effect of group was significant ($p < .05$) and post hoc tests revealed that all groups were different from each other ($p < .05$). Effect sizes measured using Cohen's d statistic (Cohen, 1988) revealed that the comprehensive intervention group scores were greater than the basic intervention group by 0.55 standard deviation units, and the comprehensive and basic intervention groups were greater than the scores from the reference group by 1.07 and 0.79 standard deviation units, respectively.

In the PSe and SEf domains, no group was shown to have significantly different scores from any other group ($p > .05$), all observed effect sizes were small (~ 0.13 or less).

In the PBen domain, the main effect of group was significant ($p < .05$) and post hoc tests revealed that both intervention groups had significantly higher scores ($p < .05$) than the reference group. In terms of effect sizes, the effect magnitudes were 0.59 and 0.55 standard deviation units for the comprehensive and basic intervention groups, respectively.

Results from the PBar domain revealed a significant main effect ($p < .05$) and post hoc testing suggested that both intervention groups were more aware of barriers to protective

behavior than the reference group (effect sizes 0.32 and 0.40 for the comprehensive and basic groups, respectively).
Similar results were seen in the CtA domain, where the comprehensive and basic intervention group scores were 0.38 and 0.35 standard deviation units greater than the reference group scores.

A significant main effect ($p < .05$) was also observed in the ItP domain, and post hoc comparisons revealed that the group receiving the comprehensive intervention had greater scores (Effect size: 0.31 standard deviation units) than the reference group.

Effectiveness: Primary outcomes for grade 7. The rate of earplug use was monitored via the rates of replacement of earplugs in classroom earplug dispensers. The median earplug replacement rates were 49.2 and 16.5 pairs per month for the comprehensive and basic intervention groups, respectively (overall range: 0 to 52). This corresponds to an effect size of 0.81 standard deviation units, which is a large effect size (Cohen, 1988). The difference was not statistically significant at the .05 level using the Mann-Whitney test.

Change in hearing threshold was also a primary outcome for participants in grade 7. Participants with abnormal middle ear status (i.e., abnormal tympanograms) at baseline or retest were excluded from these analyses because observed changes in these individuals could have resulted from temporary fluctuations in middle ear status. These exclusions resulted in a total sample size of 85 for these analyses. Mean pure tone thresholds for participants meeting these criteria are represented in Figure 2. Similar data for participants in grade 4 are presented for comparison. All mean thresholds are near 0 dB HL, although there was a trend toward better hearing sensitivity in the high frequencies, in right ears, and among participants in grade 4.

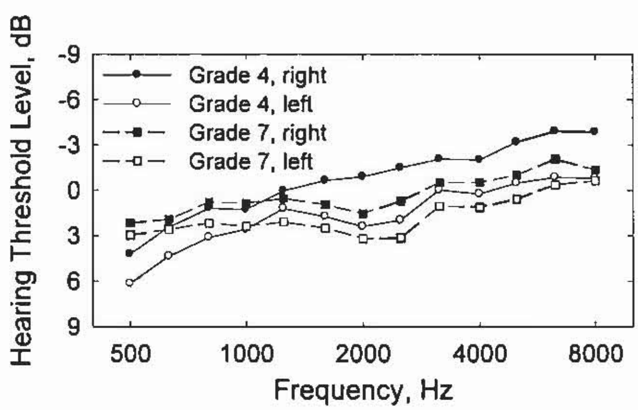


Figure 2: Mean baseline hearing threshold, by grade level and ear.

Change in hearing was evaluated using joint change criteria from both pure tone threshold and distortion product otoacoustic emission results. A substantial change was defined as a 2-dB decrement in distortion product amplitude in the presence of a 5-dB increase in pure tone threshold between the baseline and follow-up test. Differences meeting both criteria occurred between 3 and 11 percent of participants, depending on the frequency tested. The association between change in hearing and intervention status was evaluated using multivariable logistic regression models controlling for gender and modeling a potential interaction between gender and intervention status. The association was evaluated in each ear separately and at each frequency where combined otoacoustic emission and pure tone threshold data were available (i.e., 1.6, 2, 3, 4, 5, and 6 kHz). No significant association between hearing status and intervention status was observed ($p > .05$).

<u>Effectiveness: Secondary outcomes for grade 4.</u> Change in hearing was evaluated using the same criteria and approach as were used with participants in grade 7. No significant association between hearing status and intervention status was observed ($p > .05$).

<u>Effectiveness: Secondary outcomes for grade 7.</u> Responses to the eight items included in the longitudinal assessment of knowledge and attitudes were scored in the same way as for responses from grade 4. The average improvement across participants was 0.86 items. These improvements, however, were not significantly associated with intervention group when the difference was associated using the Mann-Whitney test ($p > .05$). One individual item pertaining to noise exposure from four-wheeler (an all-terrain vehicle) noise exposure showed a significant association ($p < .05$) with treatment group using the Mann-Whitney test. At baseline, 35% and 26% of those receiving the comprehensive and basic interventions (respectively) regarded the noise from these vehicles to be a risk factor for hearing impairment. At the time of follow-up, 65% and 18% of the comprehensive and basic intervention groups considered this noise to be a risk factor.

Substantial differences across groups were seen in HBM components, and in SEf, and ItP. Figure 3 represents the pattern of belief scores across the three groups in each domain. Analyses of variance indicated that there were significant ($p < .05$) differences across groups in all but the comfort and image aspects of the PBar domain.

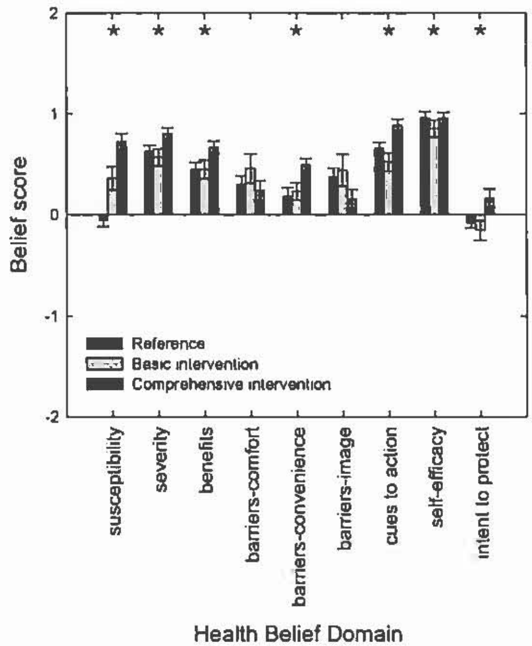


Figure 3: Group differences in Health Belief Model components, self-efficacy, and intent to protect hearing. Error bars represent the standard error of the mean, asterisks represent analyses where significant ($p < .05$) main effects were observed using analysis of variance.

In the PSu domain, post hoc tests revealed that all mean scores were significantly different from each other ($p < .05$). The effects of the comprehensive intervention relative to the basic intervention and the reference group were 0.50 and 1.16 standard deviation units, respectively. The effect of the basic intervention relative to the reference group was 0.63 standard deviation units.

In the PSe domain, scores from the comprehensive group were significantly higher ($p < .05$) than either of the other groups. Effect sizes were 0.44 and 0.29 relative to the basic intervention group and the reference group, respectively.

In the PBen domain, scores from the comprehensive group were significantly higher ($p < .05$) better than the reference group, and scores from the basic intervention group were not significantly different from either of the other groups. The effect sizes for the comprehensive intervention group relative to the basic and reference groups were 0.39 and 0.35 standard deviation units, respectively.

A similar pattern of differences was seen in the PBar-Convenience domain. Participants receiving the comprehensive intervention had significantly higher scores than were obtained with the reference group (effect size: 0.46 standard deviation units). This difference suggests that those who participated in the comprehensive intervention were more aware of the barriers to convenient protection of hearing. A similar effect size

(0.50) was observed between the groups receiving the comprehensive and basic interventions, but this effect did not reach statistical significance.

In the CtA domain, scores from those who received the comprehensive intervention were significantly ($p < .05$) greater than the scores obtained from either of the other groups, and scores from the basic intervention were not significantly different from those obtained from the reference group. The magnitudes of the differences were 0.70 and 0.40 standard deviation units when scores from the comprehensive intervention were compared with those from the basic and reference interventions, respectively.

In the SEf domain, scores from the basic intervention group were significantly ($p < .05$) lower than those from either of the other two groups (effect size = 0.20 standard deviation units).

Scores from the comprehensive intervention group were significantly ($p < .05$) higher than those from the other two groups in the ItP domain. The effect sizes relative to the basic intervention and reference group were 0.46 and 0.32 standard deviation units, respectively.

Rankings of the components in the grade 7 comprehensive intervention indicated that the participants found the hearing test/individual consultation session and the classroom presentations to be the most important elements in the hearing loss prevention program (Figure 4).

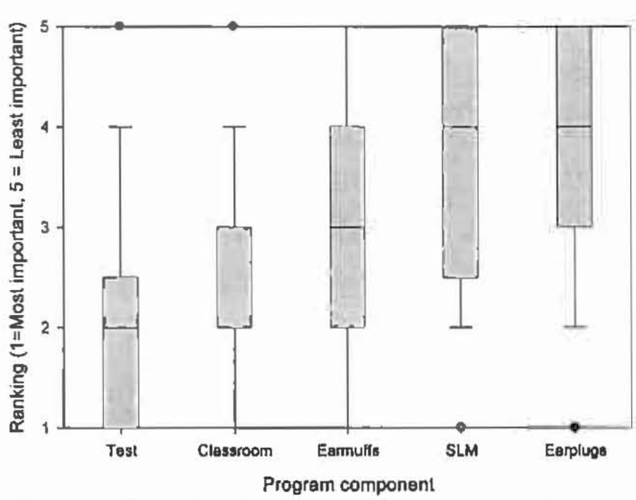


Figure 4: Boxplot of the program component rankings. Shaded regions represent the interquartile range, error bars represent the boundaries between the 2.5 and 97.5 percentiles. Filled circles represent responses falling outside of the 95% confidence interval.

<u>Distortion product otoacoustic emissions results.</u> Two approaches were used to evaluate DPOAE as an indicator of cochlear damage. In the first approach, distortion product amplitude was used to determine the degree of separation between the DP amplitude

distributions for individuals having pure tone thresholds categorized as "normal" or "abnormal" (re: ANSI S3.44 1996). Results were obtained for the left ear only and expressed as the area under the ROC curve for all participants in this study (collapsed across grade levels) and for the subgroup of participants having normal middle ear status at the time of test. The results of these analyses are represented in Figure 5.

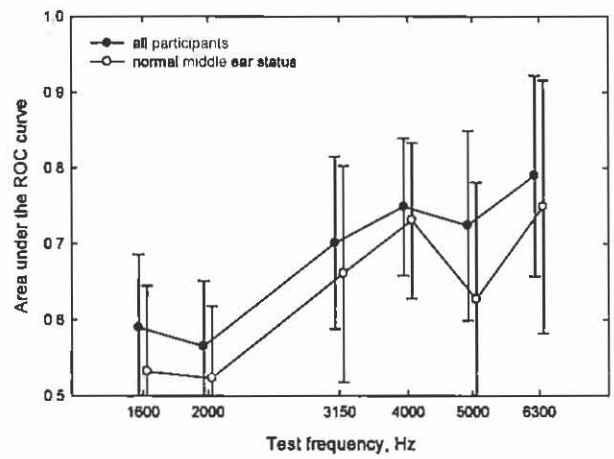


Figure 5: Area under the ROC curve as a function of frequency and group. Filled circles represent results from the left ears of all participants at the baseline test, empty circles represent results from the left ears of only the participants having normal middle ear status at the baseline test. Error bars represent the 95% confidence interval of the estimate. The area is significantly different ($p < .05$) from 0.5 if the lower boundary of the confidence interval is greater than 0.5. See text for details.

These results indicate that there was greater separation of the distributions at frequencies above 3000 Hz, and that diagnostic accuracy is somewhat poorer when middle ear status is controlled. To further explore these results, the sensitivity and specificity functions at 4000 Hz were examined for each group (Figure 6). These functions indicate that equal rates (approximately 35%) of missed cases and false alarms would be obtained with a DP amplitude cutpoint of 1 dB SPL. If an investigator desired sensitivity over 75%, a cutpoint of 2 dB SPL should be used and a false alarm rate of approximately 45% should be expected. Given the observed 14.5% prevalence of abnormal thresholds (using this definition), approximately 20% of participants with positive DP screening results would have had confirmed abnormal hearing thresholds in subsequent tests.

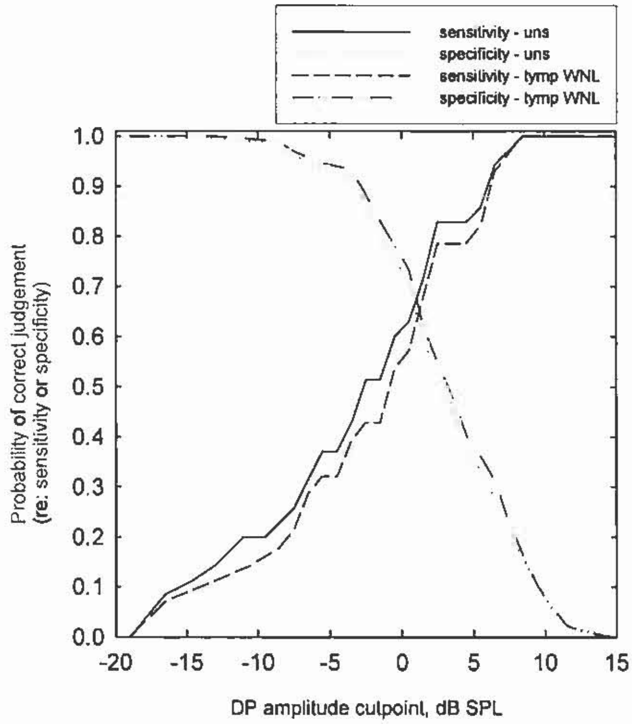


Figure 6: Sensitivity and specificity at 4000 Hz across DP amplitude cutpoints. The upper function in each pair represents results obtained from the unscreened sample (i.e., all participants); the lower function represents results from only the participants having normal middle ear status during the baseline test. See text for details.

The usefulness of monitoring for changes in DP amplitude was assessed by estimating the 95% confidence interval of the test-retest distribution for individuals with thresholds within normal limits (re: ANSI S3.44), normal middle ear status, and self-reported exposures at or below the 20% percentile of the distribution when summed across all risk factors. These criteria resulted in a small sample (N = 22) of participants that represented a sample that was screened to exclude most cases of probable change in DP amplitude. The 2.5, 5, 95, and 97.5% points on this test-retest distribution are represented in Figure 7. These percentile points suggest that large changes (> 5 dB) in DP amplitude commonly occur in a screened sample. This is a matter of concern because DP amplitudes cover an approximate 30 to 40 dB range, so a 10 to 20 dB range of uncertainty can be considered quite broad when attempting to detect changes in response.

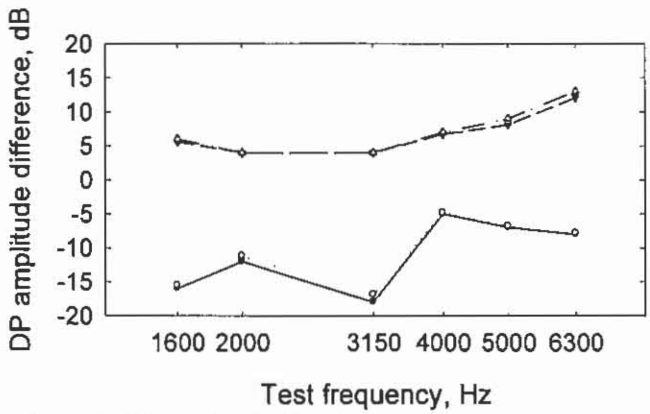


Figure 7: DP amplitude distribution percentiles.

The correlations between DP amplitude at test and retest were also estimated at each frequency for the left ears of participants having normal middle ear status at both test and retest (N = 131). These correlations were significant ($p < .05$) and ranged between .64 and .73, and no clear pattern across frequency was demonstrated. These results suggest that between 40 % and 50 % of the variance in DP amplitude was consistent between test and retest. Note that the corresponding values for pure tone threshold results ranged between 25 % and 36 %, suggests that test-retest correlations for DP amplitude are as good or possibly are better than those for pure tone thresholds. Correlations between change in DP amplitude and change in hearing threshold were weak (maximum absolute $r = .12$) and were not significant at any frequency ($p > .05$), which suggests that change in DP amplitude was not a suitable surrogate for change in hearing threshold in this sample.

Discussion

This developmental/exploratory study involved the development of four hearing loss prevention programs for use in rural areas, two for students in grade 4 and two for students in grade 7. Within each grade, one intervention was basic, involving hearing tests, individual consultation, and for students in grade 7 only, earplugs. The other program in each grade was comprehensive and included all of the elements in the basic intervention, plus classroom presentations, supplemental materials to be taken home, and for students in grade 7 only, earmuffs.

The comprehensive program was informed by the health belief model and it also included lessons and activities that met science and health education standards while also conveying the fundamental message of hearing loss prevention. These elements are important because classroom time is extremely valuable, and the investigators believed if school-based hearing loss prevention programs are to be sustainable, they must facilitate existing educational activities rather than replace them. This program has additional value because, although it was primarily developed for use in science classrooms, it integrates science, health, technology, and math learning objectives while also helping students avoid future hearing impairments.

The notion of including hearing loss prevention education in schools is easy to support, but the specific programs to be implemented must be efficient. That is, they must have evidence that they maximize the effectiveness/cost ratio. Resources absorbed by programs that do not have positive outcomes are wasted, and the additional resources used to implement a comprehensive program may not be justified by correspondingly better outcomes than a simpler program that returns a similar outcome while using fewer resources.

Our preliminary estimates of the cost to administer these programs in rural Iowa suggest that the costs of the comprehensive and basic programs for grade 4 would be approximately $2.20 and $0.90 per student, respectively. The cost of these programs for grade 7 would be approximately $13.40 and $2.00 per student, respectively. The comprehensive programs are approximately 2.4 and 6.7 times more costly than the basic programs. For participants in grade 7, the majority (60%) of the difference is due to the cost of each pair of earmuffs, which were considered by the participants to be a moderately important component of the intervention.

This study is a preliminary step toward determining whether these additional costs are justified. The results of this study suggest that positive outcomes can be obtained from basic and comprehensive hearing loss prevention programs. However, the relative value of each type of program appears to change with the grade level of the participant. The data from 4^{th} graders suggest that members of the comprehensive and basic interventions groups had significantly greater scores than were obtained from the reference group. However, the comprehensive and basic intervention groups were significantly different only in the PSe domain. This pattern of findings suggests that the basic and comprehensive interventions provided similar outcomes and therefore it may not be necessary to expend the additional resources required to administer the comprehensive intervention to participants in grade 4.

A different conclusion was reached the data from participants in grade 7 were examined. In this case, participants receiving the comprehensive intervention had greater scores than participants in the basic intervention and/or the reference group in many domains, but scores from the basic intervention group were only superior to the reference group in one domain (PSu) and they were inferior to the reference group in another (SEf). This pattern of results suggests that outcome of the basic intervention may not be good enough to justify the resources required to administer it, but the positive outcomes obtained from the comprehensive intervention suggest that there may be sufficient benefits to justify the cost of this program.

This study also explored the use of distortion product otoacoustic emissions (DPOAE) as a measure of cochlear damage. This test could be used in two ways. It could be used to identify individuals with pre-existing disorders at the time of enrollment in a hearing loss prevention program, or it could be used to monitor for change in hearing status in an already ongoing program.

For identification purposes, DPOAE results could be used to optimize the use of limited resources for pure tone hearing threshold testing, which requires more time, effort, and instrumentation. In this screening role, the diagnostic accuracy of the test is of key importance. It is reasonable to expect that high sensitivity would be desired from a test used in this way. For a sensitivity of 75%, the results from this study suggest that approximately 4 in 5 positive test results would be classified as "false alarms" (i.e., would not be associated with abnormal hearing thresholds). Thus, the use of this test in a screening role would provide few benefits with respect to increasing the efficiency of hearing test protocols that are primarily concerned with detecting abnormal behavioral pure tone thresholds.

The low correlations between changes in DP amplitude and changes in pure tone thresholds suggest that DP amplitude would not be a suitable replacement for pure tone thresholds in this type of study. The results also suggest that neither DPOAE nor pure tone threshold has ideal test-retest correlations, and the use of pure tone threshold tests as a "gold standard" is questionable. It should be noted that this outcome regarding pure tone thresholds is consistent with prior work (Flamme, 2001) showing that pure tone thresholds are likely to contain substantial method variance, which would have the net effect of reducing the maximum possible correlation across test methods.

Conclusions

The results of this study suggest that basic and comprehensive hearing loss prevention programs can have positive effects that are observable in questionnaire measures 9- to 12-months after the program is administered. Significant differences with respect to hearing status were not observable in this study, perhaps due to slow onset of hearing impairment and/or due to the relatively small number of participants monitored for hearing change (N ~ 150 per grade) within this study.

Basic or comprehensive hearing loss prevention programs are equally effective for rural youth in grade 4, but only the comprehensive hearing loss prevention program was generally effective for participants in grade 7. This suggests that a basic program for 4th graders and a comprehensive program for 7th graders may be needed to achieve an effective use of resources for hearing loss prevention in rural schools.

References

Anonymous: [1990] Noise and hearing loss. Consensus Statement. Jan 22-1990 Jan 24; 8(1):1-24.

Anonymous: [1999] Untreated Hearing Loss Linked to Depression, Isolation in Seniors [Web Page]. 1999 May; Accessed 2001 Dec 19. Available at: http://www.ncoa.org/news/archives/hearing_loss.htm.

American National Standards Institute, Inc. [1999] S3.1: American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms.

American National Standards Institute, Inc. [1996] S3.6: American National Standard Specification for Audiometers.

American National Standards Institute, Inc. [1996] S3.44: American National Standard Determination of Occupational Noise Exposure and Estimation of Noise-Induced Hearing Impairment.

Axelsson, A, Jerson, T, Lindberg, U, Lindgren, F: [1981] Early noise-induced hearing loss in teenage boys. Scandinavian Audiology 10(2):91-96.

Bandura, A: [1977] Self-efficacy: Toward a unifying theory of behavioral change. Psychology Review 84(2):191-215.

Barone, JA, Peters, JM, Garabrant, DH, Bernstein, L, Krebsbach, R. [1987] Smoking as a risk factor in noise-induced hearing loss. Journal of Occupational Medicine 29(9):741-745.

Bess, FH, Dodd-Murphy, J, Parker, RA: [1998] Children with minimal sensorineural hearing loss: prevalence, educational performance, and functional status. Ear and Hearing 19(5):339-354.

Blair, JC, Hardegree, D, Benson, PV: [1996] Necessity and effectiveness of a hearing conservation program for elementary students. Journal of Educational Audiology 4:12-16.

Brookhouser, PE, Worthington, DW, Kelly, WJ: [1992] Noise-induced hearing loss in children. Laryngoscope 102(6):645-655.

Chermak, GD, Curtis, L, Seikel, JA: [1996] The effectiveness of an interactive hearing conservation program for elementary school children. Language Speech and Hearing Services in Schools 27:29-39.

Chermak, GD, Peters-McCarthy, E: [1991] The effectiveness of an educational hearing conservation program for elementary school children. Language Speech and Hearing

Services in Schools 22:308-312.

Cohen, J: [1988] Statistical Power Analysis for the Behavioral Sciences. Hillsdale, New Jersey: Lawrence Erlbaum Associates.

Cruickshanks, KJ, Klein, R, Klein, BE, Wiley, TL, Nondahl, DM, Tweed, TS: [1998] Cigarette smoking and hearing loss: the epidemiology of hearing loss study. JAMA 279(21):1715-1719.

Dobie, RA: [1995] Prevention of noise-induced hearing loss. Archives in Otolaryngology Head and Neck Surgery 121(4):385-391.

Flamme, GA: [2001] Examination of the validity of auditory traits and tests. Trends in Amplification 5(3):111-138.

Flamme, GA, Mudipalli, VR, Reynolds, SJ, Kelly, KM, Stromquist, AM, Zwerling, C, Burmeister, LF, Peng, S-C, Merchant, JA: [2005] Prevalence of hearing impairment in a rural Midwestern cohort: Estimates from the Keokuk County Rural Health Study, 1994 to 1998. Ear and Hearing 26:350-360.

Folmer, RL, Griest, SE, Martin, WH: [2002] Hearing conservation education programs for children: A review. Journal of School Health 72(2): 51-57.

Gescheider, GA: [1997] Psychophysics: The fundamentals. 3rd ed. Mawah, NJ: Lawrence Erlbaum Associates.

Holt, JJ, Broste, SK, Hansen, DA: [1993] Noise exposure in the rural setting. Laryngoscope 103(3):258-262.

Horn, JL: [1965] A rationale and test for the number of factors in factor analysis. Psychometrika 30:179-185.

Itoh, A, Nakashima, T, Arao, H, Wakai, K, Tamakoshi, A, Kawamura, T, Ohno, Y: [2001] Smoking and drinking habits as risk factors for hearing loss in the elderly: epidemiological study of subjects undergoing routine health checks in Aichi, Japan. Public Health 115(3):192-196.

Knobloch, MJ, Broste, SK: [1998] A hearing conservation program for Wisconsin youth working in agriculture. Journal of School Health 68(8):313-318.

Kramer, SE, Kapteyn, TS, Festen, JM: [1998] The self-reported handicapping effect of hearing disabilities. Audiology 37(5):302-312.

Kramer, SE, Kapteyn, TS, Festen, JM, Tobi, H: [1996] The relationships between self-reported hearing disability and measures of auditory disability. Audiology 35(5):277-287.

Kramer, SE., Kapteyn, TS, Kuik, DJ, Deeg, DJH: [2002] The association of hearing impairment and chronic diseases with psychosocial health status in older age. Journal of Aging and Health 14(1):122-137.

Lankford, JE, DeLorier, J, Meinke, D: [2000] Farm safety camp: Hearing loss prevention. NHCA Spectrum 17(4):6-9.

Lass, NJ, Woodford, CM, Lundeen, C, Lundeen, DJ, Everly-Myers, DS: [1986] The prevention of noise-induced hearing loss in the school-aged population: a school educational hearing conservation program. Journal of Auditory Research 26(4):247-254.

Merchant, JA, Stromquist, AM, Kelly, KM, Zwerling, C, Reynolds, SJ, Burmeister, LF: [2002] Chronic disease and injury in an agricultural county: The Keokuk County Rural Health Cohort Study. Journal of Rural Health 18(4):521-535.

Montgomery, JK., Fujikawa, S: [1992] Hearing thresholds of students in the second, eighth, and twelfth grades. Language Speech and Hearing Services in Schools 23:61-63.

Mudipalli, VR: [1999] Hearing loss characteristics in Keokuk County - A cross-sectional analysis, M.P.H. Thesis, University of Iowa.

NIOSH [1999]: A model for research on training effectiveness. Publication 99-142. Cincinnati, OH: National Institute for Occupational Safety and Health.

Niskar, AS, Kieszak, SM, Holmes, AE, Esteban, E, Rubin, C, Brody, DJ: [2001] Estimated prevalence of noise-induced hearing threshold shifts among children 6 to 19 years of age: the third national health and nutrition examination survey, 1988-1994, United States. Pediatrics 108(1):40-43.

Nomura, K, Nakao, M, Morimoto, T: [2005] Effect of smoking on hearing loss: Quality assessment and meta-analysis. Preventive Medicine 40(2):138-144.

Nondahl, DM, Cruickshanks, KJ, Wiley, TL, Klein, R, Klein, BE, Tweed, TS: [2000] Recreational firearm use and hearing loss. Archives in Family Medicine 9(4):352-357.

Pocock, SJ: [1983] Clinical trials: A practical approach. New York: John Wiley and Sons.

Roeser, RJ: [1980] Industrial hearing conservation programs in the high schools (Protect the Ear Before the 12th Year). Ear and Hearing 1(3):119-120.

Roeser, RJ, Coleman, T, Adams, RM: [1983] Implementing an industrial hearing conservation program in the schools. Journal of School Health 53(7):408-411.

Siegelaub, AB, Friedman, GD, Adour, K, Seltzer, CC: [1974] Hearing loss in adults: relation to age, sex, exposure to loud noise, and cigarette smoking. Archives in

Environmental Health 29(2):107-109.

Simpson, EW, Deshayes, IL [1969] Tractors produce ear damaging noise. Journal of Environmental Health 31(4):347-350.

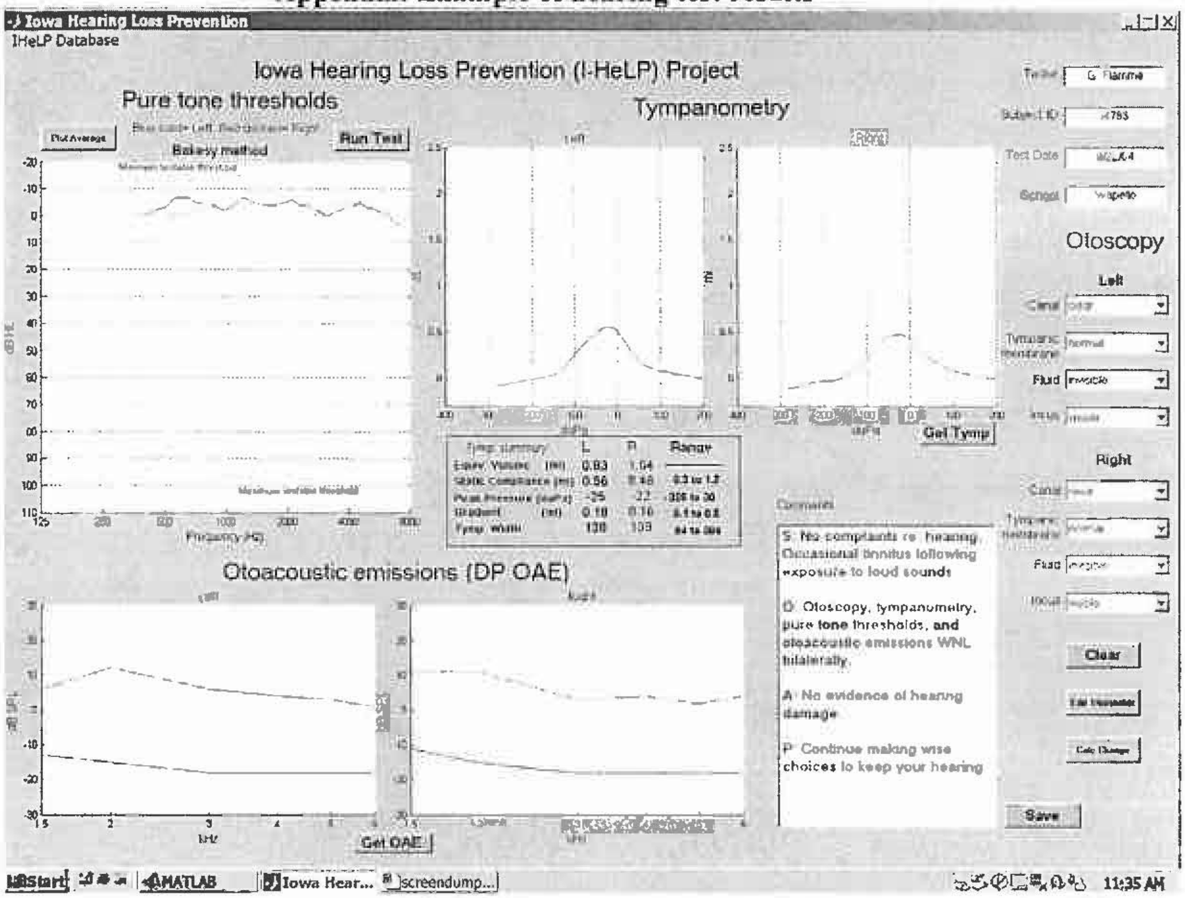
Solecki, L: [1995] Evaluation of occupational exposure to noise among operators of tractors and self-propelled machines. Annals of Agricultural Environmental Medicine 2(2):135-138.

Strecher, VJ, Rosenstock, IM: [1997] The Health Belief Model. In Health Behavior and Health Education. 2nd ed. (eds. Glanz, K, Lewis, FM., Rimer, BK,) San Francisco, CA: Jossey-Bass.

Virokannas, H, Anttonen, H: [1995] Dose-response relationship between smoking and impairment of hearing acuity in workers exposed to noise. Scandinavian Audiology 24(4):211-216.

Webb, ET, Campbell, DT, Schwartz, RD, Sechrest, L, Grove, JB: [1981] Nonreactive Measures in the Social Sciences. Boston, MA: Houghton Mifflin.

Appendix: Example of hearing test results



PUBLICATIONS

To date, no manuscripts associated with this project have been published.

INCLUSION OF GENDER AND MINORITY STUDY SUBJECTS

The PHS Form 2590 Enrollment Report form has been completed. Note that race/ethnicity data were not collected as part of this study, so only gender distributions can be reported on this form.

INCLUSION OF CHILDREN

All participants in this study were children.

MATERIALS AVAILABLE FOR OTHER INVESTIGATORS

Test protocols, hearing loss prevention program materials, and software written for this project (e.g., hearing test functions, data download functions, hearing test display software) are available without warranty or technical support to interested investigators and can be obtained by contacting the principal investigator (greg.flamme@wmich.edu). De-identified data can also be obtained for specific projects by contacting the principal investigator.

Form Approved Through 9/30/2007
OMB No. 0925-0001

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Procedure for Submission of
Final Invention Statement and Certification (For Grant or Award)
Form HHS 568

A Final Invention Statement and Certification (Form HHS 568) shall be executed and submitted within 90 days following the expiration or termination of a grant or award. The Statement shall include all inventions which were conceived or first actually reduced to practice during the course of work under the grant or award, from the original effective date of support through the date of completion or termination. The Statement shall include any inventions reported previously for the grant or award as part of a non-competing application. This reporting requirement is applicable to grants and awards by Department of Health and Human Services in support of research.

The Final Invention Statement and Certification does not in any way relieve the person responsible for the grant or award, or the institution, of the obligation to assure that all inventions are promptly and fully reported directly to the National Institutes of Health, as required by terms of the grant or award. Information regarding the reporting of inventions, including the reporting form to be followed, may be obtained from the Office of Policy for Extramural Research Administration, Division of Extramural Inventions and Technology Resources, 6701 Rockledge Drive MSC 7750, Bethesda, Maryland 20892-7750, Telephone: (301) 435-1986.

The original of the completed Final Invention Statement and Certification is to be returned to the awarding component that funded the grant or award. The entire grant or award number must appear in the designated box on the form. The period covered by the Final Invention Statement is the project period of the grant or award at a particular grantee institution. If no inventions were involved, insert the word "None" in the first block under item Title of Invention. Each Statement requires the signature of: (1) the person responsible for the grant or award concerned, and (2) an institution official authorized to sign on behalf of the institution.

The PHS estimates that it will take from 5 to 10 minutes to complete this form. This includes time for reviewing the instructions, gathering needed information, and completing and reviewing the form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If you have comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing this burden, send comments to: NIH, Project Clearance Office, 6701 Rockledge Drive MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0001). ***Do not send this form to these addresses; they are for comments only.***

Form Approved Through 9/30/2007
OMB No. 0925-0001

Department of Health and Human Services

Final Invention Statement and Certification

(For Grant or Award)

DHHS Grant or Award No.

R21 07707

A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

10/1/2002 through 9/30/2005 .

original effective date — *date of termination*

B. Inventions (Note: If no inventions have been made under the grant or award, insert the word *"NONE"* under Title below.)

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS
	NONE	
(Use continuation sheet if necessary)		

C. First Signature —The person responsible for the grant or award is required to sign (in ink). Sign in the block opposite the applicable type of grant or award.

TYPE OF GRANT OR AWARD	WHO MUST SIGN *(title)*	SIGNATURE
Research Grant	Principal Investigator or Project Director Gregory A. Flamme	
Health Services Grant	Director	
Research Career Program Award	Awardee	
All other types (*specify*):	Responsible Official	

D. Second Signature — This block *must* be signed by an official authorized to sign on behalf of the institution.

Title	Name and Mailing Address of Institution
Typed Name	
Signature / Date	

Privacy Act Statement

The PHS maintains application and grant records as part of a system of records as defined by the Privacy Act: 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship, and Construction Applications and Related Awards." The Privacy Act of 1974 (5 USC 522a) allows disclosures for "routine uses" and permissible disclosures.

Some routine uses may be:

1. To the cognizant audit agency for auditing.
2. To a Congressional office from a record of an individual in response to an inquiry from the Congressional office made at the request of that individual.
3. To qualified experts, not within the definition of DHHS employees as prescribed in DHHS regulations (45 CFR 5b.2) for opinions as part of the application review process.
4. To a Federal agency, in response to its request, in connection with the letting of a contract or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter;
5. To organizations in the private sector with whom PHS has contracted for the purpose of collating, analyzing, aggregating, or otherwise refining records in a system. Relevant records will be disclosed to such a contractor, who will be required to maintain Privacy Act safeguards with respect to such records.
6. To the sponsoring organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.
7. To the Department of Justice, to a court or other tribunal, or to another party before such tribunal, when one of the following is a party to litigation or has any interest in such litigation, and the DHHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party.
   a. the DHHS, or any component thereof;
   b. any DHHS employee in his or her official capacity;
   c. any DHHS employee in his or her individual capacity where the Department of Justice (or the DHHS, where it is authorized to do so) has agreed to represent the employee; or
   d. the United States or any agency thereof; where the DHHS determines that the litigation is likely to affect the DHHS or any of its components.
8. A record may also be disclosed for a research purpose, when the DHHS:
   a. has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;
   b. has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;
   c. has secured a written statement attesting to the recipient's understanding of; and willingness to abide by, these provisions; and
   d. has required the recipient to:

      (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record;

      (2) destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information; and

      (3) make no further use or disclosure of the record, except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the DHHS, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law.

The Privacy Act also authorizes discretionary disclosures where determined appropriate by the PHS, including to law enforcement agencies, to the Congress acting within its legislative authority, to the Bureau of the Census, to the National Archives, to the General Accounting Office, pursuant to a court order, or as required to be disclosed by the Freedom of Information Act of 1974(5 USC 552) and the associated DHHS regulations (45 CFR Part 5).

Principal Investigator/Program Director (Last, First, Middle): Flamme, Gregory Alan

Inclusion Enrollment Report

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

Study Title: Development of a school-based hearing conservation program for use in rural areas

Total Enrollment: 929 **Protocol Number:**

Grant Number: R21 07707

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

Ethnic Category	Sex/Gender: Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)	430	495		925
Ethnic Category: Total of All Subjects*	430	495		925 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported	430	495		925
Racial Categories: Total of All Subjects*	430	495		925 *

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

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

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

1. Federal Agency and Organizational Element to Which Report is Submitted NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH	2. Federal Grant or Other Identifying Number 7R21OH007707-3			
3. Recipient Organization (Name and complete address, including ZIP code) WESTERN MICHIGAN UNIVERSITY WESTERN MICHIGAN UNIVERSITY 1903 W MICHIGAN AVE KALAMAZOO, MI 49008 KALAMAZOO MI 49008	4. Employer Identification Number 1386007327A1 5. Recipient Account Number 25-7007000 6. Final Report ☒ Yes ☐ No		7. Basis ☐ Cash ☒ Accrual	
8. Funding/Grant Period		9. Period Covered by this Report		
From 01/01/2005	To 09/29/2005	From 01/01/2005	To 09/29/2005	
10. Transactions:	Previously Reported	This Period	Cumulative	
a. Total outlays	0.00	46,174.45	46,174.45	
b. Refunds, rebates, etc	0.00	0.00	0.00	
c. Program income used in accordance with the deduction alternative	0.00	0.00	0.00	
d. Net outlays (Line a, less the sum of the lines b and c)	0.00	46,174.45	46,174.45	
Recipient's share of net outlay, consisting of:				
e. Third Party (in-kind) contributions.	0.00	0.00	0.00	
f. Other Federal awards authorized to be used to match this award.	0.00	0.00	0.00	
g. Program income used in accordance with the matching or cost sharing alternative	0.00	0.00	0.00	
h. All other recipient outlays not shown on lines e, f or g	0.00	0.00	0.00	
i. Total recipient share of net outlays (Sum of lines e, f, g and h)	0.00	0.00	0.00	
j. Federal share of net outlays (line d less line i)	0.00	46,174.45	46,174.45	
k. Total unliquidated obligations			0.00	
l. Recipient's share of unliquidated obligations			0.00	
m. Federal share of unliquidated obligations			0.00	
n. Total Federal share (sum of lines j and m)			46,174.45	
o. Total Federal funds authorized for this funding period			49,278.00	
p. Unobligated balance of Federal funds (lines o minus line n)			3,103.55	
Program Income, consisting of:				
q. Disbursed program income shown on lines c and/or g above			0.00	
r. Disbursed program income using addition alternative			0.00	
s. Undisbursed program income			0.00	
t. Total program income realized (Sum of lines q, r and s)			0.00	
11. Indirect Expense	a. Type of Rate	Provisional ☐ Predetermined ☒ Final ☐ Fixed ☐		
	b. Rate	c. Base	d. Total Amount	e. Total Amount Federal Share 7,524.91
	46.00	16,358.50	7,524.91	
Total	46.00	16,358.50	7,524.91	
12. Remarks			Carryover Request 0.00	
13. Authorized Official	Name Tiffany B White Title Contract & Grant Specialist	Telephone (Area code, number, and extension) 269-387-4729	Date Report Submitted 12/02/2005	
14. Approved by	Name		Date Report Accepted	