

PHARMACEUTICAL INTERVENTIONS FOR HEARING LOSS (PIHL)

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EDITORIAL

To our Readers:

It is a noisy world as many of you well know. Noise exposures are pervasive in today's environment. For many, work remains the single largest contributor to daily hazardous noise exposure, but noise can be found in transportation, residential settings and entertainment. Transportation noise sources include engines, reciprocating and turbine; tire noise; mechanical; rail wheel. Work environments include factories and processing plants; buildings; gathering places. Residential settings include items such as yard equipment (e.g., lawnmowers, leaf blowers, weed whackers, power tools, etc.); dishwashers, vacuum cleaners, and garbage disposals. Entertainment includes sports stadiums, movie theaters and personal sound systems. What can we do about it? The first step is understanding the possibilities of noise control, noise measurements, and noise injuries so that the problem can be addressed comprehensively.

To address these challenges, members of the Sound Committee within the HCE Pharmaceutical Interventions for Hearing Loss (PIHL) working group submitted a list of articles/papers addressing noise control engineering, hazardous noise measurements and auditory injuries. The contributions were numerous and expansive. They reflect decades of work and significant research investments. To assist the reader in locating articles of interest, they are organized in three headings: Noise Control, Occupational Noise, and Noise Injuries. In these headings, you will find recommended readings. I chose these to provide the best overview of the topic. Some of these are classic research projects from the early days of auditory research. As these projects were before subject safety protocols were developed, it is not likely that these projects could be repeated today.

Noise control is the primary focus. Noise control, despite being alleged of being black magic, is a systems engineering discipline. Having worked in the noise measurement and design fields for years, I have faced the challenges of incorporating noise control features into ship design. Complicating those efforts in 1994, the US Navy downsized the surface ship acoustic design staff and related research and development budget. As the program manager, I worked over the next several years to ensure the noise control features were archived in a fashion usable to program offices. I have highlighted those works and related works that can be helpful to incorporating noise control. Closely related are hazardous noise measurements and noise injuries articles submitted by my colleagues.

I hope you find this collection informative and useful in planning your future noise control efforts and related research.

~Kurt Yankaskas

NIHL Program Officer, Office of Naval Research, Code 342

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RESEARCH GUIDANCES

Director's Foreword

The Pharmaceutical Interventions for Hearing Loss (PIHL) working group was chartered in 2012 with the purpose of reviewing and maintaining state of the science knowledge that supports translational therapies for the prevention and rescue of noise induced hearing loss. This foundational knowledge was to be used to spotlight minimal functional performance requirements of potential agents, and importantly, to identify the evidence-based laboratory, animal, exposure, and clinical assessment methodologies that underscore best practices and could be used to promote comparability across trials investigating new drug development.

The guidance beginning in this newsletter edition is the culmination of two years of working group discussion, literature review, and open dialogue during two states of the science symposia by the experts working with front-running candidate drugs and actually performing these investigations. All discussion focused on analyzing the issues most relevant to participation in Investigational New Drug (IND) development and translation of the science for the prevention and/or rescue of hearing loss. While these views are not necessarily based on rigorous systematic review, the process of subject matter review, debate and experience, coupled with PIHL advisory consensus to bridge literature gaps in this developing field of research, allows us to confidently recommend appropriate standards and technologies to guide future PIHL studies.

Both Military and Civilian noise threats continue to claim casualties. Degradation of quality of life and limitations in communication, opportunities and performance can be expected to continue to escalate, marginalizing significant portions of the nation. Advancements in the PIHL arena are critical to ebbing this tide. The HCE will continue to facilitate extramural collaborations with Military study populations and by establishing requirements for technology transition to the DOD. Finally, the HCE is happy to continue to coordinate the translational spectrum by recommending and administratively facilitating research methodology for DOD stakeholder implementation.

It has been my privilege to work with a passionate PIHL working group on developing these guidelines and I am honored to endorse the recommendations proposed herein.

I believe in the competitive process, but feel that competition is enhanced by collegial and collaborative rules of engagement. I feel confident that this competing field of experts has defined a functional way ahead that will boost the progress of everyone interested in participating in the advancement of Pharmaceutical Interventions for Hearing loss.

~ Col Mark Packer, USAF, MC, FS

Executive Director, DOD Hearing Center of Excellence

Noise Surveys for Industrial Hygiene and Noise Control

Kari Buchanan, Hearing Center of Excellence

Background

The Department of Defense (DoD) has a lot of noise data on equipment and workplace environments, but the data is in various forms, ranging from area noise surveys, to personal dosimetry, to equipment surveys, as well as design and acceptance testing (engineering detailed measurements). This paper will briefly discuss the differences between the data, uses, limitations, and some new technologies that can assist in assessing and controlling noise exposure.

Per DoD Instruction 6055.12 (2010), hazardous noise levels have been established as sound pressure levels (SPLs) equal to and greater than 85 decibels A-weighted (dBA). The hearing conservation program implemented when personnel are exposed to SPLs at 85 dBA or greater for an 8 hour time-weighted average (TWA) using a 3 decibel (dB) exchange rate or to impulse noise of 140 decibels peak or greater.

Industrial Hygiene Measurements

Industrial hygiene is the “science and art devoted to the anticipation, recognition, evaluation, prevention, and control of those environmental factors or stresses arising in or from the workplace which may cause sickness, impaired health and well-being, or significant discomfort among workers or among citizens of the community” (AIHA, 2014). Industrial hygiene noise surveys are conducted for the purposes of identifying (1) noise hazardous areas, spaces, and equipment; (2) the appropriate hearing protection for the noise hazard; and (3) who to place into the hearing conservation program. Two types of data are typically collected for noise surveys, general noise levels and noise dosimetry. Within DOD, general noise levels are collected and reported as area or equipment surveys using the 85 dBA criteria. This level assumes an 8 hour work day. Dosimetry is collected using an 8 hour TWA and also assumes an 8 hour work day. The

remaining 16 hours in a day are considered audiological recovery time. Since many military operations are longer than 8 hours, systems that are below 85 dBA should be recorded as they may add to the 24 hour noise dose.

Area and Equipment Surveys

- Conducted to determine if the area or equipment is noise hazardous and what type of hearing protection is appropriate.
- Boundaries are used to determine the area in which the SPL is below noise hazardous and therefore, no hearing protection is needed.
- dBA and dBC measurements are taken using a Type II sound level meter (SLM) with the microphone held in the worker's hearing zone.
- Most general surveys do not specify the type of worker in the area, but rather the space name and work center.

It is imperative that accurate notes are taken. The needed items are distance from measured item, operating conditions such as rpm, speed, and any other operating conditions.

Records of area and equipment noise surveys are maintained by the parent command and the command conducting the survey. Outside of DOD, two databases are available on noise levels generated by equipment. The first is a power tool database that is available on the National Institute for Occupational Safety and Health website: <http://wwwn.cdc.gov/niosh-sound-vibration/>. A second database covering outdoor equipment can be found on the European Commission website: http://ec.europa.eu/enterprise/sectors/mechanical/noise-outdoor-equipment/database/index_en.htm.

Personal Dosimetry

- Personal dosimetry may be conducted to determine noise dose as well as determine if someone is to be placed into the hearing conservation program.
- Most noise dosimeters are type II meters which usually only measure dBA and can report dose, average energy, TWA, maximum level, minimum level, peak level, exposure, and run time.
- Instruments have measuring ranges which may be able to be changed for different uses and environments.
 - The range for industrial settings is usually between 70 to 140 dBA with levels below 70 too small to be separated from the noise floor of the instrument and levels above 140 are too high. Measurements below and above the range present rounding errors for dosimetry.
- Dosimetry surveys should list the type of work being conducted and the occupational specialty of the person performing the work.

- Dosimetry results are provided to the person surveyed, the supervisor, and copies placed into medical records.

Personal dosimetry data may be found in a variety of places. DOD has a central repository for industrial hygiene data referred to as DOEHRS-IH, Defense Occupational and Environmental Health Repository System – Industrial Hygiene, however, data pre-dating 2009 may not be contained in the system. Prior to DOEHRS-IH, the Army, Air Force, and Navy maintained separate databases of the industrial hygiene data, however it is unclear how complete the databases are. In addition, the commands conducting the dosimetry, the command the person belonged to, and the person's medical record should all have copies of the dosimetry results.

Uses of General Noise Surveys and Dosimetry

Industrial hygiene surveys are useful in determining hazardous noise sources and areas; placing personnel into the hearing conservation program; and deciding which hearing protection is appropriate. They can be used to determine areas that need further testing for potential noise control.

Limitations of General Noise Surveys and Dosimetry

Due to the nature of the industrial hygiene surveys, they are not useful for noise control purposes. However, they may be useful in determining if evaluations for noise control are needed. Noise surveys also don't contain lists of oto-toxic chemicals, but those may be listed in a full industrial hygiene survey.

Noise Control

Noise control engineering uses acoustic surveys to assess noise. Acoustic surveys are used when developing or accepting new equipment, and when the levels exceed standards. Noise control plans may be used to correct the situation. Noise control plans can be used in several different situations: (1) to decrease levels below the hazardous noise level; (2) to decrease noise levels to levels where hearing protection is protective; (3) when noise interferes with critical communications; (4) develop noise isolation systems and (5) to decrease the effect noise has on sleep. To create a noise control plan, a goal and a variety of measurements, tools, and experienced acoustic engineers are needed.

Noise Control Surveys

To develop a noise control plan, the noise environment must be characterized for how the space is used. Understanding that the noise can be a combination of continuous, intermittent, or impulse drives the type of instrumentation needed to conduct the surveys. A Type I SLM that requires a person to manually switch from one octave band to another is good for an environment with continuous noise sources, but it is not capable of analyzing impulse and other intermittent noise sources with the accuracy

desired. More advanced Type I SLM that perform real-time analysis of 1/1 and 1/3 octave bands is needed for impulse or short-duration intermittent noise sources (Royster, et al. 2003). Advanced engineering noise surveys will include a calibrated recording system along with narrowband and one-third octave band analysis. This type of survey will include multiple sensors (microphones and accelerometers for vibration measurements).

Computer models, such as Designer NOISE® are often needed to predict and control noise. The programs will allow noise control and acoustic engineers to input material factors such the type of walls and floors as well as room height and related factors. The more detailed noise measurements enable more precise design assessments. The models can be used to compare which treatment will work better for the type of noise and space. (Fischer and Komrower, 2012).

Design Criteria Standards

MIL-STD 1474E provides design criteria standards on noise limits for military equipment and platforms. The design criteria standard also contains instructions on how to test equipment for approval under the standard. In most cases, octave band analysis on both the A- and C-weighted scales is required. For impulse noise, the standard allows the use of a computer model to predict the auditory hazard or a noise dose from a single impulsive event (MIL-STD- 1474E, 2014).

Developing technologies

In-the-ear Dosimetry

Dosimeters that measure the external noise dose and the amount of noise that reaches the inner ear have been recently developed. These dosimeters can permit safety professionals, audiologists, and industrial hygienists to monitor the effectiveness of the hearing conservation program and how much protection personnel receive from their hearing protection. Some have been designed to transmit data in real time to allow for quick corrective action when personnel are not wearing protection properly. An additional benefit for industry is the ability to conduct real time monitoring for workers approaching the noise dose and remove the workers from the noise hazardous area before exceeding a daily dose (ATI, 2014).

3-D Acoustic Surveys

For noise control, the recent development of 3-D acoustic noise surveys greatly assists noise control engineering. Complex noise environments are better characterized using a 3-D picture of surfaces and superimposes the acoustic data on the picture. This enables a visual representation of primary noise paths and the frequency range of the noise. This visual depiction allows the development of optimized acoustic treatment plans (Komrower, 2012).

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Damage Risk Criteria for Twenty-Four Hour Noise Exposures

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Disclaimer: The findings and conclusions of this report are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Why it is important?

U.S. Occupational regulations limit the eight hour exposure of workers to noise to 90 dBA or less. The National Institute for Occupational Safety and Health (NIOSH) recommends that workers not be exposed to more than 85 dBA for more than 8 hours per day. The NIOSH Criteria Document (1998) in Table 1-1 lists a Permissible Exposure Level of 80 dBA for 25 hours 24 minutes. There are occupations and situations where workers may be in an environment in which exposures may last 24 hours or even longer.

What is known?

Long term noise exposure research was primarily conducted in the period from 1960-1980 to determine contributing factors to noise-induced permanent threshold shift (PTS). Since it is unethical to induce a PTS in a human all of this research was conducted by

inducing a TTS of 30 dB or less. (Parallel animal PTS research was being conducted at this time.) The overarching assumption is that TTS measured at 2 minutes post-exposure is a predictor of noise-induced PTS. After 8-16 hours of continuous noise exposure temporary threshold measures asymptote producing an Asymptotic Threshold Shift (ATS). The assumption is that because the ear is reacting to acoustical energy the ultimate PTS will not exceed the ATS. It has been suggested that ATS predicts the level of PTS after 10-20 years of constant occupational noise exposure. For a comprehensive review of the logic associated with the ATS research Melnick ([1991](#)) is recommended. In the late 1970's the Air Force in conjunction with EPA and NASA did a series of controlled 24 and 48 hour noise exposures. Nixon et al. ([1977](#)) did long duration (24- and 48-hour) noise exposures of 85 dBA pink noise. They found that in both exposures, ATS occurred at 8-16 hours into the exposure but that recovery from ATS was prolonged in the 48 hour exposure. Based on their data the authors suggest that a noise exposed person should be given the same amount of time to recover in quiet as the time exposed. Based on their exposures they recommend that long-term exposures in excess of 90 dBA should be avoided.

In a second Air Force study Stephenson et al. ([1980](#)) exposed college age males to pink noise for 24 hours at levels of 65, 70, 75, 80 and 85 dBA. They found the level at which ATS was not detectable (less than 5 dB) lies between 75 and 80 dBA. They confirmed the Nixon et al. observation that the recovery time course about matched that of the course to develop asymptotic threshold shift even when ATS levels were lower. In a third Air Force study Johnson et al. ([1976](#)) exposed volunteers for 24 hours to the equivalent of 85 dBA pink noise presented with interruptions. The interruptions were from seconds to minutes. They noted that the time to reach ATS was about the same in all groups but the level of ATS was less than the previous continuous noise level. Again, they found that recovery from TTS required as much time as the initial exposure. In 1974 the Environmental Protection Agency (EPA) in appendix C of their document Information on levels of environmental noise requisite to protect public health and welfare with an adequate margin of safety ([1974](#)) worked through the logic of a 24 hour environmental noise damage risk criterion. These recommendations were predicated on several significant assumptions. The first assumption is the Temporary Threshold Shift assumption described above. (Another Pharmaceutical Intervention in Hearing Loss [PHIL] group is examining the relationship between TTS and PTS.) The second assumption is the Equal Energy Hypothesis. This hypothesis states that the ear integrates sound energy: time and acoustical energy can be interchanged to produce equivalent TTS. Much of the TTS work emphasized 4 kHz because it is more susceptible to both temporary and permanent threshold shift than other audiometric frequencies. The authors use occupational epidemiological data from noise exposed workers. This amounted to a 40 year exposure to 8 hour per day noise with 16 hours of "rest." Based on cross sectional data the EPA determined that a 40 year 8 hour daily maximum exposure level of approximately 73 dBA will protect the population against an NIPTS of more than 5 dB. Intermittency of the noise reduces the noise hazard. The authors

suggest a 5 dB correction factor if the noise, like most environmental noises, drops to 65 dB at least 10% of the time. This produces a maximum exposure level of 78 dBA. Based on the Equal Energy Hypothesis and a number of calculations the EPA determined that a noise level of 71.4 dBA of intermittent noise, 24 hours per day for 365 days per year is a reasonably safe exposure. They rounded to 70 dB for ease.

Based on the Air Force studies, once exposed to noise in an occupational setting, the worker should have a minimum of 8 hours of quiet. How quiet must the rest period be to obtain full recovery? Based on the research of Ward ([1976](#)) and others, consensus was that in order to recover from a noise induced TTS the worker should remain in an environment of less than 65 to 70 dB for 16 hours. This seemed to be the level at which no further TTS was observed and thresholds were returning to pre-shift levels.

In 2012 Flamme et al. ([2012](#)) had 286 civilian volunteers wear noise dosimeters round the clock for durations of 23 hours to 20 days (median 9.8 days). They found the median noise level was 79 dBA with 70% of the sample exceeding the EPA recommendation for acoustic rest. Based on their mid-west U.S. sample the authors concluded that a large proportion of the general public is exposed to noise levels that could result in long-term negative effects on hearing.

NASA ([Goodman 2003](#)) in designing the acoustic environment for the International Space Station had even more stringent guidelines. They allow a 60 dBA acoustical environment while the astronauts are working and 50 dBA limit while the astronauts are resting.

What is not known (research possibilities)?

Kujawa and Liberman's recent studies of TTS in the mouse and guinea pig ([Kujawa and Liberman 2009](#), [Lin, Furman et al. 2011](#)) found that even TTS that resolves to pre-exposure threshold levels result in inner hair cell synaptic changes it is doubtful that any new long-term human laboratory studies inducing a TTS will be allowed in the foreseeable future. Human studies based on occupational exposures may be possible. Exposures in excess of 48 hours: The longest laboratory studies of TTS have been 48 hours. The researchers in those studies indicated a reluctance to exceed 48 hours based on the time required for hearing to return to baseline. In reality there are noise exposures in military and civilian environments which may exceed 48 hours.

Exposures greater than 90 dBA: Johnson et al. ([1976](#)) showed that with intermittent noise exposures levels as high as 100 dB over 24 hours can produce TTS levels which resolve to baseline. Pushing beyond 90 dB is risking producing PTS in humans.

Values for quiet rest levels: Although there have been a number of guesses about the noise level at which rest must be to produce effective resolution of TTS there does not appear to be a definitive study. Levels from 78 dB to 65 dB have been suggested. NASA International Space Station design standards were developed not only to reduce hearing loss but also to reduce psychological and physiological stress ([Goodman 2003](#)).

Can these resting environments be produced by passive hearing protection or active noise cancellation?

Understanding the variability of threshold shift to a noise exposure: One of the big questions in noise-induced hearing loss is: why there is so much variability between individuals? It is often talked about as "iron" and "glass" ears. This variability seems in some respects to be genetic. However, even inbred mice show variability but to a lesser extent. It would allow for much better damage risk criteria if the source(s) of vulnerability to noise could be determined and accounted for.

Can a pharmaceutical intervention either protect or rescue the ear from long term exposures? It would be exciting to be able to reduce the level of ATS, or speed recovery of the ear from TTS by intervention of a pharmaceutical and thereby perhaps reduce PTS.

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Impulsive Noise

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Why are we interested in impulsive noise?

Short duration impulsive noise is typically generated by a release of pressure (impulse) or a collision of solid objects (impact). In animal models these noises have been shown to be more damaging to the ear than continuous noise of equal energy (Hamernik and Henderson 1974, Dunn, Davis et al. 1991, Hamernik, Ahroon et al. 1994). Impulsive noises are common in manufacturing, construction, public service and the military. All police and sheriff officers must qualify annually on firearms which generate impulsive noise.

What is an impulsive noise?

The US Occupational Safety and Health Administration (OSHA) definition of impulsive noise includes noises most researchers do not consider impulsive: "If the variations in noise level involve maxima at intervals of 1 second or less, it is to be considered continuous." That is, if maxima are 1 second or less, noises are considered impulsive. Most researchers would consider a noise impulsive if it is a single pressure peak typically lasting milliseconds to microseconds.

How do we measure impulsive noises?

The use of standard industrial hygiene noise dosimeters to measure impulsive noises is inappropriate (Kardous and Willson 2004). Dosimeter electronics “clip” at high input levels and do not have a fast enough time constant to capture impulses. Many sound level meters may be able to capture peak levels with a peak hold circuit depending upon the microphone and amplifier. For about the past 10 years the National Institute for Occupational Safety and Health (NIOSH) has been developing a portable measurement system to measure firearm discharges and other impulsive noise. The directional nature of impulsive sounds may require multiple sensors to capture the sound. One approach is to use a stand-alone probe with multiple microphones separated by well-known distances in a calibrated capsule such as the G.R.A.S. (Holte, Denmark) sphere. This probe consists of four matched G.R.A.S. ¼”, 40-BH pressure microphones in a 1”-diameter machined aluminum sphere. The four preamplifiers for the microphones are located inside the sphere. However, the sphere itself may affect the measurement.

What to measure for risk analysis?

In the pre-digital days a microphone attached to a storage oscilloscope captured the configuration of the impulsive noise. The dimensions that are easily measured on an oscilloscope screen are peak pressure level and duration. A number of conventions have evolved to characterize impulses: A, B, C and D duration, etc. Although codified into American National Standards Institute (ANSI) and International Standards Organization (ISO) standards and even law, there is little evidence to correlate any of these dimensions with risk of hearing loss. OSHA and NIOSH indicate that no one should be exposed to impulses in excess of 140 dBA.

In recent years a number of additional metrics have evolved for impulsive noises. In 1991 Richard Price and Joel Kalb published the first papers on the auditory hazard assessment algorithm for the human (AHAAH) model (Price and Kalb 1991, 1991). The most recent version of the model is electronically available and has been thoroughly described by Fedele et al. (2013). The model has good face validity. Functional data on the human outer, middle and inner ear have been integrated into a model through which digital representations of impulsive noises could be analyzed. The essence of the analysis is to integrate the square of positive displacements of the basilar membrane measured in microns at 23 locations spanning the frequency range from approximately 250 Hz to 11500 Hz. From this motion the model predicts Auditory Risk Units (ARUs). Based on cat data the authors established limits for the number of ARUs that the ear can be exposed to without producing more than 20 dB permanent threshold shift. Price has published and presented a number of analyses demonstrating the use of the AHAAH model for post-hoc prediction of risk to impulsive noise (Price 2007, 2007). Other researchers have devoted time to validate the AHAAH model. The initial model was written in the Delphi language which is no longer supported. Graduate students at the

University of Cincinnati have re-written the model in C/C++ and in MATLAB to allow continued experimentation with the model. William Murphy at NIOSH has re-analyzed one of Price's analyses: the US Army Blast Overpressure Study. His analysis used three criteria: AHAH, A-weighted 8 hour equal energy (L_{Aeq8hr}) and the Military Design Standard 1474D (Murphy, Khan et al. 2009) [The report is available at <http://www.cdc.gov/niosh/surveyreports/pdfs/309-05h.pdf>]. They found that of the three risk criteria the AHAH model was the worst predictor of threshold shift. The best predictor was L_{Aeq8hr} . The AHAH model is extremely complex and requires a lot of computer resources to calculate. The AHAH model is proposed as one of the accepted methods for calculating acoustic limits under the Military Design Standard 1747E. At this time the standard is undergoing peer review through the ANSI approval process. The Department of Defense is currently in the process of updating the AHAH model to determine if it can better meet the needs of the hearing conservation community.

A risk calculation which seems to be more valuable is measurement of kurtosis of the impulse (Henderson and Hamernik 2012). The mean of a statistical distribution is the first moment; variance is the second moment; skew is the third moment; and kurtosis is the fourth moment. Gaussian noise (white noise) has a kurtosis value of 3. As the noise becomes more impulsive in nature the kurtosis value increases and may reach double digits. Hamernik's group has shown that as the kurtosis of the noise increases the amount of permanent threshold shift increases in chinchillas (Hamernik and Qiu 2001, Hamernik, Qiu et al. 2007) and now in worker populations (Zhao, Qiu et al. 2010, Davis, Qiu et al. 2012).

It has also been shown that when there is exposure to a high level acoustic impulse noise, such as from a weapon, the impulsive noise is transmitted to the cochlea through bone conduction pathways. The amplitude of the responses at the temporal bone and inside the head simulator appears to be linear with peak impulse amplitude. As a result hearing protection that has been designed to reduce the effects of bone-conducted sound for continuous noise exposure can indeed reduce the peak amplitude inside the head as well as the vibrations of the temporal bone. However, a helmet has the effect of increasing the duration of the wave inside the head. It is unknown at this time, whether such vibrations and acoustic levels inside the head can lead to cochlear or neurological damage in the case of repeated exposure. However, it is clear that the impulsive noise is transmitted through the head to the cochlea via bone conduction.

What are the research questions that remain with impulsive noise?

The overarching question is "Can a damage risk criterion be developed for impulsive noise?" The answer is important for workers and warfighters who are exposed regularly or occasionally to impulsive noise.

What is happening inside the cochlea to increase the damaging effect of impulsive noise compared to continuous noise?

Two major contributors exist: 1) The short duration of impulsive noise does not allow the middle ear muscles to contract and reduce the input to the cochlea; 2) Non-linearities in the cochlea may be interacting with the noise to increase the hazard. Some of the nonlinearities include the annular ligament of the stapes footplate, basilar membrane stiffness, organ of Corti structure, and stria vascularis support.

Can tools that produce impulsive noise be re-designed to reduce risk? Are there mechanical ways to change the blast wave of a pistol to make it less risky? Can a nail gun be re-designed to reduce the risk of hearing loss over a 40-year career?

These questions need to be answered. An interesting example is a rivet removal gun that significantly reduced the risk of noise exposure in workers while improving quality: <http://www.ncms.org/index.php/portfolio/fastener-removal-improvement-technology-adoption-frita/>.

Are earplugs and earmuffs adequate for protection from impulsive noise? And how should they be labeled to convey that information? NIOSH has undertaken studies of hearing protection device effectiveness using mannequins exposed to firearm and shock tube impulses. For peak sound pressure levels below about 170 dBA NIOSH has found that the hearing protection devices interact with the blast wave in a non-linear manner and produce more attenuation than what is currently given by the Noise Reduction Rating. However, the bone conducted transmission path appears to remain linear in the presence of impulsive noise and must therefore be taken into account when assessing damage-risk criteria for impulse noise. They have also found that seemingly insignificant differences in test setups can produce significant differences, on the order of 1 to 3 dB, in outcome measurements. NIOSH has been working closely with the U.S. Environmental Protection Agency to develop revised regulation to labeling hearing protection devices for impulsive noises. Unfortunately, the EPA has not yet promulgated the final rule.

The effect of impulsive noise on workers is an important question. In order to make recommendations for a national standard for impulsive noise, audiometric data from workers and accurate assessments of their exposures are necessary. American industry is probably not ideal since the current generation of workers have worked under the OSHA hearing conservation laws (although there is some indication that these regulations may not be protecting hearing (Groenewold, Masterson et al. 2014, Masterson, Sweeney et al. 2014)). It is important to study a population of workers who have not benefited from those protections in order to study the working life effects of impulsive noise. Given these needs our research may have to be conducted outside of the United States in an ethical manner.

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Impact of Noise on Speech Communication

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Fluctuating Versus Steady Noise

Spoken communication between individuals often occurs in a background of noise, which can affect speech intelligibility. Speech intelligibility is traditionally defined (and measured) by the ability to understand speech despite the presence of masking noise. Masking noise is any noise that may potentially cover up (i.e., mask) another sound, such as speech. Steady noise has spectral and temporal characteristics that are essentially constant over time, for example, the background noise created by a fan or an idle vehicle. This type of sound may mask some words more than others because of its spectral content. On the other hand, fluctuating noise has spectral characteristics and levels that change over time, sometimes quite rapidly. Ambient noise often includes both steady and fluctuating noise, but fluctuating noise is the most common type of background noise that people experience. Examples of fluctuating noise include people talking, road traffic, or gusting winds. There are essentially two manners in which fluctuations in the noise can occur: first as a variation in the frequency content of the noise over time (spectral fluctuation), such as the change in pitch of the noise inside a vehicle as it accelerates; second, as a variation in the overall level of the noise over time (temporal envelope variation), such as the sound of a passing vehicle.

Background noise that does not include speech is commonly referred to as energetic masking. In contrast, environmental noise that includes speech is referred to as informational masking because the listener processes the background noise as speech. Examples include noise from multiple talkers (e.g., a crowd where several people are speaking simultaneously in the vicinity of the listener) or from multiple sources of speech (such as multiple radio channels heard in a cockpit communication headset).

Effect of Fluctuating Noise on the Listener

When background noise levels fluctuate over time, the difference in speech intelligibility between normal and hearing-impaired listeners can be significant. Normal hearing listeners benefit from the information available during relatively silent periods in the fluctuating noise. For equal long term average noise levels, normal hearing listeners have better speech intelligibility in fluctuating noise than in steady noise. However many hearing-impaired listeners have difficulty understanding speech in noise even if both speech and noise are well above threshold. Several studies have demonstrated that many older listeners have difficulty understanding speech particularly in the presence of background noise or reverberation (Plomp, 1978; Duquesnoy and Plomp,

1980; Nabelek and Robinson, 1982). In fact, the percentage of the population with problems understanding speech approximately doubles with every decade in age, from 16% for 60-year-olds to nearly 100% for 86-year-olds.

Although age-related hearing loss reduces the audibility of the speech in the background noise as expected, it is thought that other factors lead to significant differences in speech intelligibility across individual listeners with similar audiometric profiles. Some studies also suggest that hearing loss may result in a "frequency-specific" deficit in the contribution of speech information, where individuals with moderate to severe hearing loss may use amplified low-frequency information much better than amplified high frequency information (Ching et al., 1998; Hogan and Turner, 1998; Turner and Cummings, 1999; Amos, 2001). These differences are thought to be caused by deficits related to deterioration of the inner ear, such as reduced temporal and spectral resolution and a loss of normal auditory compression.

Measurement of Speech Intelligibility in Noise

The performance measurement for speech intelligibility in background noise is the speech reception threshold (SRT). It is calculated as the speech level or signal-to-noise ratio (SNR) at which 50% of the speech is understood in the presence of steady background noise.

Predicting Speech Intelligibility in Noise

Several metrics have been developed to predict speech intelligibility in background noise and account for the hearing loss. The first is the articulation index (AI) which evolved into the speech intelligibility index (SII) as part of ANSI S3.5-1997. The SII predicts the speech intelligibility of a particular listener in a noisy background by using the listener's audiometric hearing thresholds and knowledge of the spectral content of the noise. The SII is a generalization of the AI based on the amount of audible speech information relative to noise level (i.e., SNRs) in each of several critical frequency bands and on the importance of each band to speech intelligibility. The contribution of each band is summed, resulting in a SII value that ranges from zero (inaudible speech), to one (fully-audible speech). As a result, the SII is a better predictor of speech intelligibility than hearing thresholds alone, as the calculation takes into account the characteristics of speech, noise, and the listener's hearing thresholds.

However, the SII assumes that the background noise is steady. To overcome this limitation the extended SII (ESII) was developed by Rhebergen and Versfeld (2005) to predict speech intelligibility in fluctuating noise based on the SII. The ESII is calculated with the noise spectrum level analyzed in 'snapshots' as opposed to using a long-term average noise spectrum. Rhebergen et al. (2008) tested the ESII model to predict SRTs in a variety of real-life noises for normal hearing subjects and showed that the ESII model performed better in predicting speech intelligibility rates than SII. The ESII was also successfully used to model the performance in understanding unprocessed and

amplified speech in hearing impaired listeners for continuous and temporally-modulated (10 Hz square-wave) noise (Desloge et al., 2010). Another measure of speech intelligibility in background noise is the speech transmission index (STI). The STI is based on the idea that the reduction in intelligibility caused by noise can be modeled in terms of the reduction in temporal envelope modulations (Steeneken and Houtgast, 1980). The STI metric has been shown to predict the effects of reverberation, room acoustics, and additive noise on speech intelligibility.

Conclusion

Noise, particularly when fluctuating, has a significant impact on speech intelligibility, particularly for listeners with hearing impairments. Interventions for hearing loss and functional performance must take into account speech intelligibility in both fluctuating and steady noise, keeping in mind that fluctuating noise affects hearing impaired listeners more severely than individuals with normal audiograms. Several metrics are available for this assessment, and these are still being refined in order to better address the variable impact of fluctuating noise.

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Rickie R. Davis, Ph.D. Rick Davis has been a hearing researcher for 30 years with the National Institute for Occupational Safety and Health in Cincinnati. He received his Ph.D. in 1981 at the Kresge Hearing Research Lab at the Oregon Health & Sciences University in Portland with Bob Brummett. He then did a post-doc in Bill Stebbins's lab at Kresge at Michigan. His journey included stops at Washington U in St. Louis and UVa in Charlottesville. His areas of interest are the biological bases of noise-induced hearing loss, hearing protector comfort and the history of TTS research. Rick Davis is a Captain in the US Public Health Service and will retire October 31.

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Kurt Yankaskas is the Noise Induced Hearing Loss Program Manager for the Office of Naval Research and leads both the Auditory Fitness for Duty Working Group as well as the PIHL Sound Committee for the HCE. He manages a research portfolio investigating noise induced hearing loss and tinnitus (ringing in the ears), methods to protect Sailors and Marines and how to reduce the noise of military equipment. He has research products that will further the understanding of the mechanisms of noise induced hearing loss and tinnitus, develop micro-acoustic processors for advanced hearing protection, develop the next generation of hearing protection devices with integrated communications/dosimetry and noise control applications for ships and tactical jet engines. He developed a long-term interest in noise-induced hearing loss with his visit to the aircraft carrier, USS GEORGE WASHINGTON in 1996. Kurt Yankaskas graduated from Rensselaer Polytechnic Institute in 1974 with a BS degree in biology and Florida Atlantic University in 1977 with a BS in Ocean Engineering. In his spare time, Mr. Yankaskas has broad interests. He is a certified multi-engine, instrument rated pilot and certified scuba instructor. He has been involved in the International Submarine Races as safety judge and technical director (www.isrsubraces.org). He is also very active in the Boy Scouts of America and serves the National Capitol Area Council as a camp director.

RESEARCH HIGHLIGHTS

Articles determined to be of particular interest as “seminal articles” will be listed with full abstract in “Research Highlights” below, followed by the remainder of the “Relevant Literature.”

NOISE CONTROL: Classics

Acoustic Characteristics of T-AGOS 19 Class SWATH Ships

Naval Engineers Journal, 107(3), 95. (1995).

Yankaskas, K. & Slotwinski, T.

Note: This paper provides specific noise control machinery fixes.

<http://onlinelibrary.wiley.com/doi/10.1111/j.1559-3584.1995.tb03039.x/abstract>
Small Waterplane Twin Hull (SWATH) vessels exhibit superior seakeeping capabilities in rough water, which render them more capable than monohull ships for many missions. SWATH vessels are currently in use for a variety of acoustic missions, including oceanographic research and surveillance, which render it necessary to assess and minimize underwater noise generated by the ship. In addition, potential future missions such as anti-submarine warfare require the development of quiet SWATH ships. A wide range of acoustic and vibration data are needed to support the design and construction of SWATH ships with acoustic missions.

A number of acoustic tests and trials have been conducted on USNS Victorious (T-AGOS 19) Class ships. During these tests, several innovative acoustic and vibration measurement and analysis techniques were used to identify, investigate and correct a number of acoustic deficiencies. This paper provides an overview of these trials and the acoustic-deficiency correction process. Personnel from a variety of organizations worked as a focused team to provide the technical and implementable solutions necessary to improve the acoustic characteristics of the T-AGOS 19 class. Additionally, the results of a diagnostic acoustic trial conducted on the Victorious are prepared and discussed in terms of the unique platform acoustic characteristics found on SWATH ships.

Design Guide for Shipboard Airborne Noise Control

SNAME Technical and Research Bulletin, 3-37. (1983).

Fischer, R., Burroughs, C., & Nelson, D.

Note: This is an early noise control design guide.

<http://www.sname.org/communities1/resources/viewtechnicalpaper/?DocumentKey=3803fd4e-2cb3-47e4-8931-24dc776fa581>

Outline of a shipboard noise control plan is given to assist the designer in formulating approaches to meet the criteria. Guidelines on acoustical design practices are then given, a majority of the guide deals with noise prediction procedures using a source - path - receiver approach. Information on noise control treatments is given and three appendices are provided (see pages 1-5-6).

Supplement to Design Guide for Shipboard Airborne Noise Control

SNAME Supplement, NJ. (2001).

Fischer R., & Boroditsky, L.

Note: This is a supplement to the SNAME Design Guide

<http://www.sname.org/arcticsection/resources/ViewDocument/?DocumentKey=94ec52f2-231c-47ba-887a-28a8857c40fd>

This document was prepared by Raymond Fischer and Leo Boroditsky of Noise Control Engineering, Inc., Billerica, MA 01821. Funding was provided by the U.S. Coast Guard under Contract DTCG40-98-P-60019. Mr. Thomas Gahs was the technical point of contact. This report documents the development of a Supplement to SNAME's T&R Bulletin 3-37, "Design Guide for Shipboard Airborne Noise Control". This information is to be used in conjunction with the original SNAME document. It is not a stand-alone document. The recommendations of this guide are intended to be advisory only, and there is no implication of warranty or assurance by the Society that performance of the procedures recommended addresses all considerations in the acoustical design of merchant ships. Use of this guide will not assure compliance with noise specifications.

Case Study: Application of SEA to Predicting Shipboard Noise

Lloyds Conference on Ship Noise and Vibration, June 20-21, 2005.

Fischer, R., Spence, J. & Boroditsky, L.

Statistical Energy Analysis (SEA) methods have been used to develop an integrated shipboard noise prediction tool. This tool has been used to accurately predict the habitability noise on over twenty-five vessels. It addresses machinery, HVAC, propulsor, and wave induced noise transmitted over airborne, structureborne and secondary structureborne paths. The programs' ship-specific hybrid SEA algorithms allow for elements the size of compartment decks and bulkheads, facilitating rapid model creation. The program can account for most standard shipboard constructions and treatments, including thermal/fire/acoustic insulations, joiner panels, and deck

treatments. The paper will discuss 1) Differences and limitations of SEA, and the hybrid methods implemented by this tool. 2) Speed in which models can be created and iterated, allowing for rapid trade-off and “what-if” studies. 3) Projects where this program has been used to accurately predict noise and model effective treatments.

Reduction of Preventable Noise Exposure, Language for Acquisition Documents

SURVIAC/DSOC, Sept. 2011.

Note: This is an excellent overview of noise control for military systems and related acquisition language.

http://www.public.navy.mil/comnavsafecen/Documents/acquisition/Prev_Noise_Ref.pdf

This presentation by SURVIAC in conjunction with DSOC covers what noise is, simple noise controls, Analysis of Alternatives (AoA), Request For Information (RFI), Request For Proposal (RFP), Capability Development Document (CDD), System Engineering Plan (SEP)/System Engineering Management Plan (SEMP), System Performance Specification (SPS), Programmatic Environmental, Safety, and Health Evaluation (PESHE), contract incentives for noise, cost reimbursement contracts, fixed price contracts, incentive contracts, structuring multiple incentive contracts, value engineering, DoD Noise-Air, DoD Noise-Sea, DoD Noise-Land, standards, and references.

MIL-STD-1474E Noise Limits

dtd 15APR2015

http://quicksearch.dla.mil/qsDocDetails.aspx?ident_number=36905

This standard establishes acoustic noise limits and prescribes testing requirements and measurement procedures for determining conformance to the noise limits stated herein. The standard specifies sound pressure level limits and measurement procedures to promote personnel safety, speech intelligibility, and security from acoustic detection and recognition. Acoustical noise limits for determining conformance to community annoyance requirements are beyond the scope of this standard. Noise limits for community annoyance are covered by local laws and statutes. DOD materiel (motor vehicles, construction and material handling equipment, mobile generator sets, and portable air compressors) may have to comply with these local laws and statutes anywhere in the world they operate.

NOISE CONTROL: Relevant Literature

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(Note: Companion paper to "CVN Flight Operations: Crossing the Aircraft/Ship Interface.")

<http://www.ingentaconnect.com/content/asne/nej/1999/00000111/00000004/art00010>

OCCUPATIONAL NOISE: Classics

Asymptotic behavior of temporary threshold shift and recovery from 24- and 48-hour noise exposures.

Aviat Space Environ Med, 48(4), 311-5. (1977).

Nixon, C.W., Johnson, D.L., & Stephenson, M.R.

<http://www.ncbi.nlm.nih.gov/pubmed/871291>

Temporary hearing loss (TTS) from long-duration noise exposure reaches an asymptote between 8 and 16 h and does not increase further during continued exposure for durations of at least 48 h. Potential auditory hazards of long-duration exposures are examined in terms of growth and recovery patterns of TTS. TTS growth and recovery patterns were compared during 24- and 48-h exposures of humans to continuous pink noise at a level of 85 dB A-weighted. Results indicate similar patterns of acquisition and relatively equal amounts of TTS for the two exposure durations. However, recovery of pre-exposure hearing at 4000 Hz following termination of the 48-h noise exposure differed somewhat from that which followed the 24-h exposure. The implications of these findings for long missions in noisy environments are discussed.

The use of the kurtosis metric in the evaluation of occupational hearing loss in workers in China: Implications for hearing risk assessment.

Noise & Health, 14(61), 330-342. (2012).

Davis, R. I., Qiu, W., Heyer, N.J., Zhao, Y., Yang, Q., Li, N., Tao, L., Zhu, L., Zeng L. & Yao, D.

[http://www.noiseandhealth.org/article.asp?issn=1463-](http://www.noiseandhealth.org/article.asp?issn=1463-1741;year=2012;volume=14;issue=61;spage=330;epage=342;auiast=Davis;type=3)

[1741;year=2012;volume=14;issue=61;spage=330;epage=342;auiast=Davis;type=3](http://www.noiseandhealth.org/article.asp?issn=1463-1741;year=2012;volume=14;issue=61;spage=330;epage=342;auiast=Davis;type=3)

This study examined: (1) the value of using the statistical metric, kurtosis [$\beta(t)$], along with an energy metric to determine the hazard to hearing from high level industrial noise environments, and (2) the accuracy of the International Standard Organization (ISO-1999:1990) model for median noise-induced permanent threshold shift (NIPTS) estimates with actual recent epidemiological data obtained on 240 highly screened workers exposed to high-level industrial noise in China. A cross-sectional approach was used in this study. Shift-long temporal waveforms of the noise that workers were exposed to for evaluation of noise exposures and audiometric threshold measures were obtained on all selected subjects. The subjects were exposed to only one occupational noise exposure without the use of hearing protection devices. The results suggest that: (1) the kurtosis metric is an important variable in determining the hazards to hearing posed by a high-level industrial noise environment for hearing conservation purposes, i.e., the kurtosis differentiated between the hazardous effects produced by Gaussian and non-Gaussian noise environments, (2) the ISO-1999 predictive model does not accurately

estimate the degree of median NIPTS incurred to high level kurtosis industrial noise, and (3) the inherent large variability in NIPTS among subjects emphasize the need to develop and analyze a larger database of workers with well-documented exposures to better understand the effect of kurtosis on NIPTS incurred from high level industrial noise exposures. A better understanding of the role of the kurtosis metric may lead to its incorporation into a new generation of more predictive hearing risk assessment for occupational noise exposure.

Effects of Intense Noise on People and Hearing Loss.

Handbook of Noise and Vibration Control. M.J. Crocker (Ed.), John Wiley & Sons, NJ, Hoboken, 337-342. (2007).

Davis, R. R. & Murphy, W.J.

<http://onlinelibrary.wiley.com/doi/10.1002/9780470209707.ch28/summary>

Crocker's new handbook covers an area of great importance to engineers and designers. Noise and vibration control is one largest areas of application of the acoustics topics covered in the successful encyclopedia and handbook. It is also an area that has been under-published in recent years. Crocker has positioned this reference to cover the gamut of topics while focusing more on the applications to industrial needs. In this way the book will become the best single source of need-to-know information for the professional markets.

Impulse noise: critical review.

Journal of the Acoustical Society of America, 80(2), 569-584. (1986).

Henderson, D. & Hamernik, R.P.

<http://scitation.aip.org/content/asa/journal/jasa/80/2/10.1121/1.394052>

A review of the last 10 years of research on impulse noise reveals certain insights and perspectives on the biological and audiological effects of exposures to impulse noise. First, impulse noise may damage the cochlea by direct mechanical processes. Second, after exposure to impulse noise, hearing may recover in an erratic, nonmonotonic pattern. Third, even though the existing damage - risk criteria evaluate impulse noise in terms of level, duration, and number, often parameters such as temporal pattern, waveform, and rise time are also important in the production of a hearing loss. Fourth, the effects of impulse noise are often inconsistent with the principle of the equal energy hypothesis. Fifth, impulse noise can interact with background continuous noise to produce greater hearing loss than would have been predicted by the simple sum of the individual noises.

OCCUPATIONAL NOISE: Relevant Literature

Davis, R. R., Murphy, W. J., Byrne, D. C. & Shaw, P. B. (2011). **Acceptance of a Semi-Custom Hearing Protector by Manufacturing Workers.** *Journal of Occupational and Environmental Hygiene*, 8(12), D125-D130.
<http://www.tandfonline.com/doi/full/10.1080/15459624.2011.626262#tabModule>

Hayden, C.S. & Zechmann, E. L. (2009). **Relevant test methods for establishing sound power levels of powered hand tools.** *Noise Control Engineering Journal* 57(3), 279-290.
<http://www.ingentaconnect.com/content/ince/ncej/2009/00000057/00000003/art00011>

Hayden, C. S. I., Ford, R. & Zechmann, E. (2012). **Advanced Tools for Buying Quiet Products.** *Proceedings of INCE - Institute for Noise Control Engineers Conference.* New York, NY.
<http://www.cdc.gov/niosh/nioshtic-2/20041543.html>

Henderson, D. & Hamernik, R. (2012). **The Use of Kurtosis Measurement in the Assessment of Potential Noise Trauma. Noise-Induced Hearing Loss: Scientific Advances.** C. G. Le Prell, D. Henderson, R. R. Fay & A. N. Popper (Eds.), New York, Springer. 49, 41-56.
http://link.springer.com/chapter/10.1007%2F978-1-4419-9523-0_4

Kardous, C. A. & Murphy, W. J. (2010). **Noise control solutions for indoor firing ranges.** *Noise Control Engineering Journal*, 58(4), 345-356.
<http://www.ingentaconnect.com/content/ince/ncej/2010/00000058/00000004/art00001>

Kardous, C. A. & Shaw, P.B. (2014). **Evaluation of smartphone sound measurement applications.** *The Journal of the Acoustical Society of America*, 135(4): EL186-EL192.
<http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>

Kardous, C. A. & Willson, R. D. (2004). **Limitations of using dosimeters in impulse noise environments.** *J Occup Environ Hyg*, 1(7), 456-462.
<http://www.tandfonline.com/doi/full/10.1080/15459620490465839#tabModule>

Kirchner, D. B., Evenson, E., Dobie, R. A., Rabinowitz, P., Crawford, J., Kopke, R., Hudson, T. W. (2012). **Occupational noise-induced hearing loss: ACOEM Task Force on Occupational Hearing Loss.** *J Occup Environ Med*, 54, 106-8.
http://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/Occupational%20Noise-Induced%20Hearing%20Loss.pdf

Meinke, D. K., Finan, D. S., Soendergaard, J., Flamme, G. A., Murphy, W. J., Lankford, J. E., & Stewart, M. (2013). **Impulse noise generated by starter pistols**. *International Journal of Audiology*, 52, S9-S19.

<http://informahealthcare.com/doi/abs/10.3109/14992027.2012.745650>

Meinke, D. K., Murphy, W.J., Finan, D. S., Lankford, J. E., Flamme, G.A., Stewart, M., Soendergaard, J. & Jerome, T. W. (2014). **Auditory risk estimates for youth target shooting**. *International Journal of Audiology*, 53, S16-S25.

<http://informahealthcare.com/doi/abs/10.3109/14992027.2013.865845>

Murphy, W. J., Khan, A. & Shaw, P. B. (2009). **An Analysis of the Blast Overpressure Study Data Comparing Three Exposure Criteria**. EPHB Report, Cincinnati, OH, National Institute for Occupational Safety and Health, 1-61.

<http://www.cdc.gov/niosh/surveyreports/pdfs/ECTB-309-05h.pdf>

Murphy, W. J., Stephenson, M. R., Byrne, D. C., Witt, B. & Duran, J. (2011). **Effects of training on hearing protector attenuation**. *Noise and Health*, 13(51), 132-141.

[http://www.noiseandhealth.org/article.asp?issn=1463-](http://www.noiseandhealth.org/article.asp?issn=1463-1741;year=2011;volume=13;issue=51;spage=132;epage=141;aui=1463-1741;year=2011;volume=13;issue=51;spage=132;epage=141;aui=1463-1741)

[1741;year=2011;volume=13;issue=51;spage=132;epage=141;aui=1463-](http://www.noiseandhealth.org/article.asp?issn=1463-1741;year=2011;volume=13;issue=51;spage=132;epage=141;aui=1463-1741;year=2011;volume=13;issue=51;spage=132;epage=141;aui=1463-1741)

OSHA Standard 1910.95 App G: Monitoring Noise Levels non-mandatory informational appendix

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9742

OSHA Standard 1910.95 App A, B, C, D, E, F, G, H, I: Occupational noise exposure

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=9735

NOISE INJURIES: Classics

The effect of impulse intensity and the number of impulses on hearing and cochlear pathology in the chinchilla.

J Acoust Soc Am 81, 1118-1129. (1987).

Hamernik, R. P., Patterson, J. H., & Salvi, R. J.

<http://scitation.aip.org/content/asa/journal/jasa/81/4/10.1121/1.394632>

Forty - one chinchillas, divided into seven groups, were exposed to 1, 10, or 100 noise impulses (one every 3 s) having peak intensities of 131, 135, 139, or 147 dB. Hearing thresholds were measured in each animal before and after exposure using an avoidance conditioning procedure; a surface preparation of the cochlear sensory epithelia was performed approximately 90 days after exposure. There was generally an orderly relation between the amount of permanent threshold shift and the severity of exposure, and a general agreement between averaged histological data and the audiometric data. For the impulses used in this study, there is a range of intensities which is bounded on the high side by the intensity which just produces injury with single impulse exposures and bounded on the low side by a critical intensity below which the injury potential drops precipitously with a reduction of impulse intensity. This region is only about 10–15 dB wide for the exposure conditions of this experiment. Within this region, the threshold of injury is a constant total energy; i.e., 10 - dB change of intensity implies a tenfold change in the number of impulses for threshold injury. Detailed relations between temporary and permanent threshold shift, cochlear pathology, and exposure variables are discussed, as are the implications of these data to the development of exposure criteria.

Blast overpressure induced structural and functional changes in the auditory system.

Toxicology 121, 29-40. (1997).

Patterson, J. H., Jr. & Hamernik, R. P.

<http://www.sciencedirect.com/science/article/pii/S0300483X97036536>

Blast overpressure of sufficient intensity can produce injury to various organ systems. Unprotected ears result in the auditory system being the most susceptible. The injuries to the auditory system include: rupture of the tympanic membrane, dislocation or fracture of the ossicular chain, and damage to the sensory structures on the basilar membrane. All these injuries can be characterized as a form of mechanical damage to the affected structure. Injury to the sensory structures on the basilar membrane leads to temporary and permanent loss of hearing sensitivity. The temporary component of the hearing loss shows a time course after removal from the noise which frequently will include an initial increase in hearing loss followed by a recovery period during which

threshold may return to pre-exposure levels or stabilize at a higher level which represents a permanent loss of hearing sensitivity. This type of recovery function suggests that there are damage processes which continue after the traumatic event and that intervention might mitigate some of the damage and hearing loss.

Damage of the auditory system associated with acute blast trauma.

Ann Otol Rhinol Laryngol Suppl 140, 23-34. (1989).

Roberto, M., Hamernik, R. P., & Turrentine, G. A.

<http://www.ncbi.nlm.nih.gov/pubmed/2497695>

This paper reviews the results of several studies on the effects of blast wave exposure on the auditory system of the chinchilla, the pig, and the sheep. The chinchillas were exposed at peak sound pressure levels of approximately 160 dB under well-controlled laboratory conditions. A modified shock tube was used to generate the blast waves. The pigs and sheep were exposed under field conditions in an instrumented hard-walled enclosure. Blast trauma was induced by the impact of a single explosive projectile. The peak sound pressure levels varied between 178 and 209 dB. All animals were killed immediately following exposure, and their temporal bones were removed for fixation and histologic analysis using light microscopy and scanning electron microscopy. Middle ears were examined visually for damage to the conductive system. There were well-defined differences in susceptibility to acoustic trauma among species. However, common findings in each species were the acute mechanical fracture and separation of the organ of Corti from the basilar membrane, and tympanic membrane and ossicular failure.

NOISE INJURIES: Relevant Literature

Cave, K. M., Cornish, E. M., & Chandler, D. W. (2007). **Blast injury of the ear: clinical update from the global war on terror.** *Mil Med* 172, 726-730.
<http://www.ncbi.nlm.nih.gov/pubmed/17691685>

Du, X., Ewert, D. L., Cheng, W., West, M. B., Lu, J., Li, W., Floyd, R. A., and Kopke, R. D. (2013). **Effects of antioxidant treatment on blast-induced brain injury.** *PLoS One* 8, e80138.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0080138>

Ewert, D. L., Lu, J., Li, W., Du, X., Floyd, R., and Kopke, R. (2012). **Antioxidant treatment reduces blast-induced cochlear damage and hearing loss.** *Hear Res* 285, 29-39.
<http://www.sciencedirect.com/science/article/pii/S0378595512000238>

Fausti, S. A., Wilmington, D. J., Gallun, F. J., Myers, P. J., and Henry, J. A. (2009). **Auditory and vestibular dysfunction associated with blast-related traumatic brain injury.** *J Rehabil Res Dev* 46, 797-810.
<http://www.ncrar.research.va.gov/Publications/Documents/AuditoryAndVestibularDysfunction.pdf>

Garth, R. J. (1994). **Blast injury of the auditory system: a review of the mechanisms and pathology.** *J Laryngol Otol* 108, 925-929.
<http://dx.doi.org/10.1017/S0022215100128555>

Gondusky, J. S., & Reiter, M. P. (2005). **Protecting military convoys in Iraq: an examination of battle injuries sustained by a mechanized battalion during Operation Iraqi Freedom II.** *Mil Med* 170, 546-549.
<http://www.ncbi.nlm.nih.gov/pubmed/16001610>

Hamernik, R. P., Patterson, J. H., and Salvi, R. J. (1987). **The effect of impulse intensity and the number of impulses on hearing and cochlear pathology in the chinchilla.** *J Acoust Soc Am* 81, 1118-1129.

Hoffer, M. E., Balaban, C., Gottshall, K., Balough, B. J., Maddox, M. R., and Penta, J. R. (2010). **Blast exposure: vestibular consequences and associated characteristics.** *Otol Neurotol* 31, 232-236.

http://journals.lww.com/otology-neurotology/Abstract/2010/02000/Blast_Exposure__Vestibular_Consequences_and.12.aspx

Jensen, J. H., & Bonding, P. (1993). **Experimental pressure induced rupture of the tympanic membrane in man.** *Acta Otolaryngol* 113, 62-67.
<http://informahealthcare.com/doi/abs/10.3109/00016489309135768>

Kopke, R., Bielefeld, E., Liu, J., Zheng, J., Jackson, R., Henderson, D., & Coleman, J. K. (2005). **Prevention of impulse noise-induced hearing loss with antioxidants.** *Acta Otolaryngol* 125, 235-243.
<http://informahealthcare.com/doi/abs/10.1080/00016480410023038>

Nageris, B. I., Attias, J., and Shemesh, R. (2008). **Otologic and audiologic lesions due to blast injury.** *J Basic Clin Physiol Pharmacol* 19, 185-191.
<http://www.ncbi.nlm.nih.gov/pubmed/19025030>

Xydakis, M. S., Bebarta, V. S., Harrison, C. D., Conner, J. C., Grant, G. A., and Robbins, A. S. (2007). **Tympanic-membrane perforation as a marker of concussive brain injury in Iraq.** *N Engl J Med* 357, 830-831.
<http://www.nejm.org/doi/full/10.1056/NEJMc076071>

CLINICAL TRIALS

ClinicalTrials.gov was searched using the following search terms: ("noise induced hearing loss" OR "hearing loss" OR tinnitus) AND (pharmaceutical OR drug). "Include only open studies" was selected and the search results, retrieved Oct 2015, derived 120 results. Studies were further eliminated from inclusion based on subjective determination of relevance for a total of 28 studies included below. It should be noted that relevance was considered broadly as any studies of potential interest, including in secondary outcomes listed to any one of the PIHL committee focus areas. An exception to the PIHL focus areas used was the category of noise exposure, to include both measurement and preventative assessments, as this opens such a large category of studies, not all of which would necessarily categorize as a clinical trial nor be required to register in clinicaltrials.gov, and thus inclusion herein would produce an indeterminately incomplete set. In studies where primary or secondary outcomes assessed an intervention for hearing or tinnitus outcomes the studies were included, whereas studies which only captured hearing or tinnitus outcomes as adverse events were excluded. This fine line was most often presented in cancer drug trials studies.

1. Title:	Safety, Tolerability and Efficacy for CGF166 in Patients with Bilateral Severe-to-profound Hearing Loss
Conditions:	Severe-to-profound Bilateral Hearing Loss with Intact Vestibular Function in the Non-operative Ear.
Interventions:	Drug: CGF166
Sponsor/Collaborators:	Novartis Pharmaceuticals Novartis
Phases:	Phase 1 Phase 2
Start Date:	June 2014
Completion Date:	August 2017
Last Updated:	October 13, 2015
Outcome Measures:	Number of patients reported with total adverse events, serious adverse events and death as an assessment of safety and tolerability Change in pure tone audiometry compared to pretreatment values Change in otoacoustic emission (OAE) testing compared to pretreatment values Change in brainstem auditory evoked responses (BAER) compared to pretreatment values effects of CGF166 on various assessments of vestibular function compared to pretreatment values Changes in auditory functions (speech recognition) and vestibular functions before and after IL infusion of CGF166 between the study ear and the contralateral ear
URL:	https://ClinicalTrials.gov/show/NCT02132130

- 2. Title:** **SPI-1005 for Prevention and Treatment of Chemotherapy Induced Hearing Loss**
- Conditions:** Lung Cancer | Head and Neck Cancer | Hearing Loss | Ototoxicity | Tinnitus | Neuropathy
- Interventions:** Drug: SPI-1005 Low Dose | Drug: SPI-1005 Middle Dose | Drug: SPI-1005 High Dose | Drug: Placebo
- Sponsor/Collaborators:** Sound Pharmaceuticals, Incorporated | VA Puget Sound Health Care System
- Phases:** Phase 2
- Start Date:** November 2014 **Completion Date:** December 2015
- Last Updated:** August 26, 2014
- Outcome Measures:** Number of participants with adverse events | Reduction of hearing loss incidence and severity | Reduction of tinnitus incidence and severity.
- URL:** <https://ClinicalTrials.gov/show/NCT01451853>
- 3. Title:** **Prevention of Noise-induced Hearing Loss**
- Conditions:** Noise-induced Hearing Loss
- Interventions:** Drug: Zonisamide | Drug: Methylprednisolone
- Sponsor/Collaborators:** Washington University School of Medicine
- Phases:** Phase 1 | Phase 2
- Start Date:** June 2016 **Completion Date:** January 2019
- Last Updated:** December 16, 2014
- Outcome Measures:** Pure Tone Thresholds | DPOAE | Pure tone thresholds
- URL:** <https://ClinicalTrials.gov/show/NCT02049073>
- 4. Title:** **Treating Tinnitus Using Eutectic Mixture of Local Anesthetics (EMLA) 5% Cream**
- Conditions:** Tinnitus
- Interventions:** Drug: EMLA cream 5% | Other: cetomacrogol cream (lotion cream)
- Sponsor/Collaborators:** HaEmek Medical Center, Israel
- Phases:** Phase 4
- Start Date:** November 2014 **Completion Date:** December 2015
- Last Updated:** October 29, 2014
- Outcome Measures:** Questionnaire results- Beck depression questionnaire | questionnaire results- Pittsburgh sleep quality index | questionnaire results- tinnitus handicap inventory | questionnaire results - Beck depression questionnaire
- URL:** <https://ClinicalTrials.gov/show/NCT02266160>

- 5. Title:** **NAC to Prevent Cisplatin-induced Hearing Loss**
- Conditions:** Neuroectodermal Tumors, Primitive | Liver Neoplasms | Neoplasms, Germ Cell and Embryonal | Osteosarcoma | Other Childhood Cancers Using Cisplatin-based Regimens
- Interventions:** Drug: N-Acetylcysteine
- Sponsor/Collaborators:** Children's Hospital Los Angeles
- Phases:** Phase 1
- Start Date:** October 2015 **Completion Date:** March 2019
- Last Updated:** July 29, 2015
- Outcome Measures:** Target Serum Level NAC | Adverse events during infusion of NAC | NAC Level | Hearing assessment | Renal Toxicity | Response of tumor to treatment | Effect of Genotype on Hearing Loss and Hearing Protection | Glutathione serum level
- URL:** <https://ClinicalTrials.gov/show/NCT02094625>
- 6. Title:** **Efficacy and Safety of AUT00063 Versus Placebo in Age-Related Hearing Loss**
- Conditions:** Age-Related Hearing Loss
- Interventions:** Drug: AUT00063 | Drug: Placebo
- Sponsor/Collaborators:** Autifony Therapeutics Limited
- Phases:** Phase 2
- Start Date:** January 2015 **Completion Date:** March 2016
- Last Updated:** August 17, 2015
- Outcome Measures:** Change in hearing loss after 4 weeks of treatment | Change in parameters of hearing performance from baseline to day 28 | To further investigate the safety and tolerability profile of repeat administration of AUT00063 by assessing vital signs, physical examination, laboratory exams and ECG | Pharmacokinetic of AUT00063, plasma levels
- URL:** <https://ClinicalTrials.gov/show/NCT02345031>
- 7. Title:** **Protective Effects of EPI-743 on Noise-Induced Hearing Loss**
- Conditions:** Noise-induced Hearing Loss
- Interventions:** Drug: EPI-743 | Drug: Placebo
- Sponsor/Collaborators:** Edison Pharmaceuticals Inc
- Phases:** Phase 2
- Start Date:** October 2014 **Completion Date:** September 2015
- Last Updated:** August 3, 2015
- Outcome Measures:** Pure tone audiometry | Time to recovery following acute noise exposure
- URL:** <https://ClinicalTrials.gov/show/NCT02257983>

- 8. Title:** **Phase 3 Clinical Trial: D-Methionine to Reduce Noise-Induced Hearing Loss (NIHL)**
Conditions: Noise-Induced Hearing Loss
Interventions: Drug: D-methionine, oral liquid suspension | Other: Placebo Comparator
Sponsor/Collaborators: Southern Illinois University | Department of Defense
Phases: Phase 3
Start Date: September 2013 **Completion Date:** March 2018
Last Updated: August 5, 2015
Outcome Measures: Pure tone air conduction threshold | Tinnitus scales
URL: <https://ClinicalTrials.gov/show/NCT01345474>
- 9. Title:** **AM-111 in the Treatment of Acute Inner Ear Hearing Loss**
Conditions: Hearing Loss
Interventions: Other: Placebo | Drug: AM-111 0.4 mg/ml | Drug: AM-111 0.8 mg/ml
Sponsor/Collaborators: Auris Medical AG | Auris Medical, Inc.
Phases: Phase 3
Start Date: October 2015 **Completion Date:** September 2017
Last Updated: September 24, 2015
Outcome Measures: Pure tone average (PTA; average of the hearing threshold of three contiguous most affected hearing frequencies in dB)
URL: <https://ClinicalTrials.gov/show/NCT02561091>
- 10. Title:** **AM-101 in the Treatment of Acute Tinnitus 2**
Conditions: Tinnitus
Interventions: Drug: AM-101 | Drug: Placebo
Sponsor/Collaborators: Auris Medical, Inc.
Phases: Phase 3
Start Date: February 2014 **Completion Date:** March 2016
Last Updated: August 26, 2015
Outcome Measures: Tinnitus loudness | Tinnitus questionnaire | Hearing threshold | Adverse events and serious adverse events
URL: <https://ClinicalTrials.gov/show/NCT01803646>
- 11. Title:** **AM-101 in the Treatment of Acute Tinnitus 3**
Conditions: Tinnitus
Interventions: Drug: AM-101 | Drug: Placebo
Sponsor/Collaborators: Auris Medical AG | Auris Medical, Inc.
Phases: Phase 3
Start Date: January 2014 **Completion Date:** February 2016
Last Updated: August 28, 2015

- Outcome Measures:** Tinnitus loudness | Hearing threshold | Responders | Tinnitus questionnaires | Adverse events and serious adverse events
URL: <https://ClinicalTrials.gov/show/NCT02040194>
- 12. Title:** **Cholesterol and Antioxidant Treatment in Patients With Smith-Lemli-Opitz Syndrome (SLOS)**
Conditions: Smith-Lemli-Opitz Syndrome | Cone-Rod Dystrophy | Hearing Loss
Interventions: Drug: Antioxidants | Drug: Cholesterol
Sponsor/Collaborators: University of Colorado, Denver
Start Date: December 2008 **Completion Date:** December 2018
Last Updated: July 24, 2015
Outcome Measures: Electroretinogram (ERG) testing | ABR (Auditory Brainstem response) testing
URL: <https://ClinicalTrials.gov/show/NCT01773278>
- 13. Title:** **Efficacy of Trans-tympanic Injections of a Sodium Thiosulfate Gel to Prevent Cisplatin-induced Ototoxicity**
Conditions: DDP | Head and Neck Cancer | Adverse Effect
Interventions: Drug: Trans-tympanic injection of a sodium thiosulfate gel
Sponsor/Collaborators: Centre Hospitalier Universitaire de Québec, CHU de Québec
Phases: Phase 2
Start Date: January 2015 **Completion Date:** December 2016
Last Updated: January 5, 2015
Outcome Measures: Hearing loss at high frequencies | Cochlear damage | Hearing loss at lower frequencies | Adverse effects of trans-tympanic injections
URL: <https://ClinicalTrials.gov/show/NCT02281006>
- 14. Title:** **Investigating the Neurobiology of Tinnitus**
Conditions: Tinnitus | Traumatic Brain Injury | Post Traumatic Stress Disorder
Sponsor/Collaborators: Washington University School of Medicine | Department of Defense
Start Date: March 2015 **Completion Date:** June 2018
Last Updated: December 8, 2014
Outcome Measures: Development of Tinnitus | Mild Traumatic Brain Injury | Post Traumatic Stress Disorder
URL: <https://ClinicalTrials.gov/show/NCT01294124>
- 15. Title:** **Cisplatin With or Without Sodium Thiosulfate in Treating Young Patients With Stage I, Stage II, or Stage III Childhood Liver Cancer**
Conditions: Liver Cancer | Ototoxicity

Interventions:	Drug: cisplatin Drug: sodium thiosulfate Genetic: gene rearrangement analysis Genetic: microarray analysis Genetic: proteomic profiling Other: immunohistochemistry staining method Other: laboratory biomarker analysis Procedure: adjuvant therapy Procedure: neoadjuvant therapy Procedure: therapeutic conventional surgery
Sponsor/Collaborators:	Children's Cancer and Leukaemia Group National Cancer Institute (NCI)
Phases:	Phase 3
Start Date:	December 2007
Last Updated:	August 9, 2013
Outcome Measures:	Rate of Brock grade ≥ 1 hearing loss determined after end of trial treatment or at an age of at least 3.5 years Response to preoperative chemotherapy Complete resection Complete remission Event-free survival (EFS) Overall survival (OS) Toxicity as graded by CTCAE v 3.0 Long-term renal clearance Feasibility of central audiology review
URL:	https://ClinicalTrials.gov/show/NCT00652132
16. Title:	Sudden Hearing Loss Multi-center Clinical Trial
Conditions:	Full-frequency Sudden Hearing Loss
Interventions:	Drug: Dexamethasone Phosphate Drug: Dexamethasone Phosphate Drug: Ginaton
Sponsor/Collaborators:	Peking University People's Hospital
Start Date:	January 2014
Last Updated:	December 31, 2013
Outcome Measures:	Pure tone audiometry test Tinnitus with Evaluation questionnaire Vertigo with Evaluation questionnaire
URL:	https://ClinicalTrials.gov/show/NCT02026479
17. Title:	Efficacy, Safety, and Tolerability of Ancrod in Patients With Sudden Hearing Loss
Conditions:	Hearing Loss Deafness Hearing Loss, Sensorineural Hearing Disorders Ear Diseases
Interventions:	Drug: Ancrod Drug: Saline solution
Sponsor/Collaborators:	Nordmark Arzneimittel GmbH & Co. KG ClinSupport GmbH MWI Medizinisches Wirtschaftsinstitut GmbH ProjectPharm s.r.o. LCR Leading Clinical Research s.r.o.
Phases:	Phase 1 Phase 2
Start Date:	May 2013
Completion Date:	October 2015

Last Updated:	July 9, 2015
Outcome Measures:	Change in PTA (pure tone audiogram) in the affected ear Change in speech recognition in the affected ear
URL:	https://ClinicalTrials.gov/show/NCT01621256
18. Title:	Commercial Lidocaine Patch as a Treatment for Ear-ringing
Conditions:	Tinnitus
Interventions:	Drug: Transdermal Lidocaine
Sponsor/Collaborators:	University of California, Davis
Phases:	Phase 0
Start Date:	March 2014
Completion Date:	Null
Last Updated:	March 28, 2014
Outcome Measures:	Tinnitus Functional Index (TFI)
URL:	https://ClinicalTrials.gov/show/NCT02088866
19. Title:	Fludrocortisone for Sudden Hearing Loss
Conditions:	Hearing Loss, Sensorineural
Interventions:	Drug: Fludrocortisone
Sponsor/Collaborators:	Oregon Health and Science University
Start Date:	August 2012
Completion Date:	August 2016
Last Updated:	April 21, 2015
Outcome Measures:	Hearing
URL:	https://ClinicalTrials.gov/show/NCT01186185
20. Title:	Dexamethasone in Preventing Hearing Loss in Patient Receiving Cisplatin
Conditions:	Malignant Neoplasm Ototoxicity
Interventions:	Drug: Dexamethasone Other: Placebo Drug: Cisplatin
Sponsor/Collaborators:	Aaron Moberly Ohio State University Comprehensive Cancer Center
Start Date:	August 2014
Completion Date:	Null
Last Updated:	October 15, 2015
Outcome Measures:	Change in score of pure tone audiometry of conventional and high-frequency ranges (hearing level decibels [dB] hearing level) Change in score of distortion product otoacoustic emissions of conventional and high-frequency ranges (amplitude dB sound pressure level) Presence of ototoxicity as defined by the American Speech-Language Hearing Association (ASHA)
URL:	https://ClinicalTrials.gov/show/NCT02382068
21. Title:	Preventing Nephrotoxicity and Ototoxicity From Osteosarcoma Therapy

Conditions: Osteosarcoma | Nephrotoxicity | Ototoxicity
Interventions: Drug: Pantoprazole | Drug: High-dose methotrexate infusion duration
Sponsor/Collaborators: Children's Hospital of Philadelphia | Gateway for Cancer Research
Phases: Phase 2
Start Date: April 2013 **Completion Date:** November 2017
Last Updated: June 11, 2015
Outcome Measures: Change of urinary biomarker concentration from pre treatment and 24 hours after cisplatin or High-dose Methotrexate | Change of urinary biomarker concentration from pre treatment and 7 days after cisplatin or High-dose Methotrexate | Toxicity | Response to neoadjuvant therapy | Validating urinary biomarkers | Tissue microarray | Bone specific alkaline phosphatase (BSAP) | Nutritional status | Patient reported measure of symptoms | Ototoxicity
URL: <https://ClinicalTrials.gov/show/NCT01848457>

22. Title: **Effectiveness of Cannabis in the Treatment of Tinnitus Patients**
Conditions: Tinnitus
Interventions: Drug: Cannabis | Drug: Placebo
Sponsor/Collaborators: Wolfson Medical Center
Phases: Phase 1
Start Date: December 2013 **Completion Date:** Null
Last Updated: January 16, 2015
Outcome Measures: Tinnitus handicap inventory score
URL: <https://ClinicalTrials.gov/show/NCT01969474>

23. Title: **Zinc to Treat Tinnitus**
Conditions: Tinnitus
Interventions: Dietary Supplement: Zinc sulfate
Sponsor/Collaborators: University of Iowa | Tinnitus Research Initiative
Phases: Phase 2
Start Date: January 2008 **Completion Date:** December 2009
Last Updated: February 13, 2009
Outcome Measures: Tinnitus loudness and annoyance | Tinnitus handicap
URL: <https://ClinicalTrials.gov/show/NCT00683644>

24. Title: **Prevention of Noise-induced Damage by Use of Antioxidants**
Conditions: Noise-induced Tinnitus | Noise-induced Hearing Loss
Interventions: Drug: Antioxidantia
Sponsor/Collaborators: University Hospital, Antwerp

Start Date:	November 2012	Completion Date:	Null
Last Updated:	November 5, 2013		
Outcome Measures:	Protection against noise-induced tinnitus due to antioxidants Change of tinnitus duration		
URL:	https://ClinicalTrials.gov/show/NCT01727492		
25. Title:	Efficacy of Internet and Smartphone Application-delivered Tinnitus Retraining Therapy		
Conditions:	Tinnitus		
Interventions:	Drug: Ginkgo biloba Behavioral: modified tinnitus retraining therapy (TRT)		
Sponsor/Collaborators:	Seoul National University Hospital Soonchunhyang University Hospital		
Study Types:	Interventional		
Start Date:	September 2014	Completion Date:	December 2014
Last Updated:	May 13, 2014		
Outcome Measures:	Tinnitus Handicap Inventory (THI)		
URL:	https://ClinicalTrials.gov/show/NCT01663467		
26. Title:	AM-101 in the Treatment of Post-Acute Tinnitus 2		
Conditions:	Tinnitus		
Interventions:	Drug: AM-101		
Sponsor/Collaborators:	Auris Medical AG Auris Medical, Inc.		
Phases:	Phase 3		
Funded By:	Industry		
Start Date:	June 2014	Completion Date:	October 2016
Last Updated:	August 25, 2015		
Outcome Measures:	Hearing threshold Adverse events and serious adverse events		
URL:	https://ClinicalTrials.gov/show/NCT02040207		
27. Title:	AM-101 in the Treatment of Post-Acute Tinnitus 1		
Conditions:	Tinnitus		
Interventions:	Drug: AM-101		
Sponsor/Collaborators:	Auris Medical, Inc.		
Phases:	Phase 3		
Funded By:	Industry		
Study Designs:	Endpoint Classification: Safety Study Intervention Model: Single Group Assignment Primary Purpose: Treatment Masking: Open Label		
Start Date:	June 2014	Completion Date:	November 2016
Last Updated:	August 25, 2015		

Outcome Measures: Hearing threshold | Adverse events and serious adverse events

URL: <https://ClinicalTrials.gov/show/NCT01934010>

28.

Ear Toxicity Associated With Systemic Treatment With Cisplatin.

Conditions: Cisplatin | Ototoxicity | Intratympanic Steroids

Interventions: Drug: Intra-tympanic Cisplatin

Sponsor/Collaborators: Ziv Hospital

Start Date: January 2011

Completion Date: January 2012

Last Updated: January 27, 2011

Outcome Measures: Post-Treatment change in hearing | Tinnitus

URL: <https://ClinicalTrials.gov/show/NCT01285674>

FUNDING OPPORTUNITIES

Refer to the HCE website (<http://hearing.health.mil/Research/FundingInformation.aspx>) for up-to-date hearing-related research funding opportunities.



<http://hearing.health.mil/EducationAdvocacy/Newsletters.aspx>

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