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Fact Sheet for the Honorable
Daniel P. Moynihan, U.S. Senate

March 1988

TINNITUS

Federal Agencies' Research and Treatment Activities

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GAO

United States
General Accounting Office
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Human Resources Division

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March 3, 1988

The Honorable Daniel P. Moynihan
United States Senate

Dear Senator Moynihan:

In your August 5, 1987, letter you requested information about federal agencies' activities concerning tinnitus, "ringing in the ears," research and treatment. You were concerned about these activities, given the large number of people who may have tinnitus.

Tinnitus is a symptom, often accompanied by other symptoms, experienced by those with hearing disorders. The severity of tinnitus varies, and the underlying cause may be difficult to identify. For some of these people, tinnitus is a nuisance; for others, it becomes a serious problem. According to a 1983 National Institutes of Health study, as many as 5.4 million persons in the nation suffer so intensely from tinnitus that treatment is necessary.

As agreed with your office, our review focused on obtaining available information on the extent to which federal agencies

-- sponsor research to investigate tinnitus and

-- provide treatment to people with tinnitus.

To obtain information on these issues, we spoke with federal agencies that do general hearing disorder research and treatment. We found that a significant amount of data was available concerning hearing in general, but a limited amount was available on tinnitus.

We focused our review on three agencies that maintain specific data on tinnitus--the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), the National Institutes of Health; the Department of Education (DOE); and the Veterans Administration (VA). At these agencies, we interviewed key officials and reviewed reports on tinnitus and its treatment as well as research grant files; we also obtained various related documents concerning this problem.

RESEARCH EFFORTS IN FEDERAL AGENCIES

Since fiscal year 1981, NINCDS has funded the following: (1) six grants--three, totaling $1,438,032, have been completed; three, totaling $794,882, were still active as of September 1987; and (2) one contract for $404,000. No new grants were funded in fiscal year 1987. According to the deputy director, Division of Communicative Disorders, NINCDS, tinnitus is not considered a high priority relative to other hearing disorders and diseases.

Since fiscal year 1981, VA has funded eight projects for tinnitus research. Two of these projects were recently initiated, with the first progress reports submitted in fiscal year 1987. According to VA, funding for two of the projects was $440,592, as of September 30, 1987. VA did not have funding data in its central office for the remaining six projects, but VA said that funding at local VA medical centers was provided.

In addition, at the Congress's direction in 1986, DOE's Rehabilitation Services Administration funded a $4,785,000 grant to the Oregon Health Sciences University; much of the planned study during the 5-year grant is devoted to tinnitus. DOE also sponsors the Subcommittee on Hearing Impaired Persons, Interagency Committee on Handicapped Research. This subcommittee serves as a mechanism for identifying federal agencies conducting or sponsoring research relating to hearing disorders and diseases, including tinnitus symptoms.

VA PROVIDED MEDICAL TREATMENT AND DISABILITY BENEFITS

Although the Army, Navy, and Air Force treat personnel with tinnitus, they do not maintain data on the number treated. VA was the only federal agency to do so. Its data showed that during fiscal year 1986, 38 veterans with tinnitus as the principal medical problem were discharged from VA medical centers; 653 with tinnitus as a secondary medical problem were discharged. In comparison, in 1982, 61 were discharged with tinnitus as the principal medical problem; 413 were discharged with tinnitus as a secondary medical problem. VA did not, however, compile data to show the cost of providing medical care to these veterans.

VA also furnished data showing that in fiscal year 1986, about 42,000 veterans with tinnitus were given benefits through VA's pension benefit and compensation programs. For these veterans, however, tinnitus was not necessarily the only or

primary disability for which they received benefits. Moreover, VA could not provide specifics about benefit amounts given to veterans with tinnitus.

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This fact sheet includes further details on the research and treatment data provided by NINCDS, DOE, and VA. Appendices I, II, and III summarize the purposes of the NINCDS, DOE, and VA tinnitus research projects funded since 1981. We discussed the contents of this fact sheet with the officials at NINCDS, DOE, and VA responsible for tinnitus research and treatment, and we considered their comments.

Unless you publicly announce its contents earlier, we plan no further distribution of this fact sheet until 15 days from its issue date. At that time, we will provide copies to the federal agencies discussed in this fact sheet. In addition, we will make copies available to others on request.

Please call me on 275-5451 if you have any questions related to this fact sheet.

Sincerely yours,

Janet L. Shikles

Janet L. Shikles
Associate Director

Contents

ABBREVIATIONS

DOE	Department of Education
NINCDS	National Institute of Neurological and Communicative Disorders and Stroke
RSA	Rehabilitation Services Administration
TENS	transcutaneous electrical nerve stimulation
VA	Veterans Administration

TINNITUS: FEDERAL AGENCIES' RESEARCH AND TREATMENT ACTIVITIES

INTRODUCTION

In an August 5, 1987, letter, Senator Daniel P. Moynihan asked us to obtain information on the extent to which federal government agencies sponsor tinnitus, "ringing in the ears," research and treatment. The Senator requested the review because of concerns expressed by constituents.

Tinnitus is a symptom, often accompanied by other symptoms, experienced by those with hearing disorders. The severity of tinnitus varies, and the underlying cause may be difficult to identify. Tinnitus is not, therefore, easily or consistently diagnosed. According to a study sponsored by the National Research Council,[1] it is widely believed that mild, occasional tinnitus is experienced by nearly everyone at some time. The majority of tinnitus cases are probably never reported as medical or auditory problems, but are simply accepted as normal phenomena or an occasional minor irritant.

Tinnitus can, however, become as totally debilitating as any serious disorder or disease. Attempts to estimate the prevalence of tinnitus have not effectively discriminated between the most serious forms of tinnitus and the less severe or passing ones. Therefore, estimates of its prevalence vary. A 1983 study sponsored by the National Institutes of Health (NIH) estimated that 5.4 million persons suffered so intensely from the disease that treatment was necessary. The study was based on household interviews of the civilian noninstitutionalized population.

The possible causes of, as well as physical conditions associated with, tinnitus are many: (1) overdoses of various drugs and general anesthetics used during surgery; (2) partial or total immobilization of the middle-ear structures, such as that produced by osteosclerosis; (3) nerve tumors that begin inside the internal auditory canal; (4) anemia, hypertension, hypothyroidism, migraine, and multiple sclerosis; and (5) middle ear disease and ear wax. The onset of tinnitus sometimes coincides with pregnancy. Ménière's disease, a disorder of the inner ear, is characterized by tinnitus. In addition, hearing loss, such as that induced by chronic or acute exposure to intense noise, is frequently accompanied by tinnitus.

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[1]The National Research Council was established by the National Academy of Sciences in order to further the knowledge of science and technology and advise the federal government.

Drugs that help in the treatment of tinnitus have been identified, but they all have drawbacks that prevent their immediate widespread use; related drugs are being developed and studied. In the mid-1970s, a group of hearing specialists developed a device for generating a masking sound that could be mounted in a standard hearing aid. This device, called a masker, is prescribed by physicians to alleviate tinnitus.[2] It is used by a person with the problem.

OBJECTIVES, SCOPE, AND METHODOLOGY

As agreed with the requester's office, the objective of our inquiry was to obtain available information on the extent to which federal agencies

-- sponsor research to investigate tinnitus and

-- provide treatment to people with the problem.

The scope of our review included determining whether the following federal agencies spent funds on tinnitus research or treatment or both during fiscal years 1981 to 1987:

-- the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), NIH;

-- the Veterans Administration (VA);

-- the Food and Drug Administration;

-- the Rehabilitative Services Administration (RSA), Department of Education (DOE);

-- the Occupational Safety and Health Administration, Department of Labor;

-- the National Institute for Occupational Safety and Health;

-- the Indian Health Service;

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[2]The Food and Drug Administration is responsible for regulating medical devices of all kinds, including the tinnitus masker. In 1984, it placed the masker device in the lowest classification as little was known about the disease and the effects of the maskers on users. (The lowest classification allows marketing of the device where insufficient information is available for review of its ability to heal or aid in healing, or both, physical ailments.) No deadline has been established for companies to meet a higher classification.

-- the National Science Foundation;

-- the Environmental Protection Agency; and

-- the Department of Defense, including the Departments of the Army, Navy, and Air Force.

During our review, we also spoke with the National Research Council and the American Tinnitus Association (in Portland, Oregon), a private association.

We found that NINCDS, DOE, and VA had data on expenditures and activities related to tinnitus research. In addition, other federal agencies we spoke with were doing research on treatment of people with hearing impairments, disorders, or diseases. Officials of the Food and Drug Administration, DOE, and the Army, Navy, and Air Force noted that tinnitus research data may have been collected; such data were not, however, available, and it was not possible to gather or reconstruct the data. According to representatives from the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, the National Science Foundation, the Indian Health Service, and the Environmental Protection Agency, no tinnitus-related research activities were funded by their organizations between fiscal years 1981 and 1987. VA was the only federal agency that had collected data on treating people with tinnitus.

Our methodology was to gather and analyze data on the disease, including NINCDS's grant and contract files; DOE's grant data and related legislation; VA reports on tinnitus projects, medical services, and benefits; and other agencies' information and documents concerning tinnitus research and treatment. We also interviewed agency officials responsible for administering tinnitus research and treatment programs.

FEDERAL AGENCIES' RESEARCH ACTIVITIES

NINCDS has been a focal point for federal agencies' research activities relating to tinnitus. This institute, in addition to funding tinnitus research, shares research information among federal agencies. Since 1981, NINCDS, has funded six tinnitus research grants, totaling more than $2.2 million, and one contract, for $404,000.

In 1986, at the direction of the Congress, the Office of Special Education and RSA awarded a 5-year $4,785,000 grant to Oregon Health Sciences University in Portland, Oregon, for research on hearing disorders and disease, including research on tinnitus. In addition, since 1981 VA has supported eight tinnitus research projects. The cumulative reported funding for

two of the projects has been $440,592. The other six have received funding at local VA medical centers.

NINCDS Research

There are two ways by which NINCDS funds research: intramurally (research projects done by NIH scientists) and extramurally (research projects done by investigators primarily in medical schools and universities, funded by NIH grants and contracts). In fiscal year 1987, NINCDS had a total extramural research budget of $418 million, of which about $80 million was used to sponsor research activities related to communicative disorders, such as various hearing disorders, problems, and diseases, including tinnitus.

In September 1981, NINCDS issued an announcement inviting grant applications supporting research to increase the knowledge and understanding of tinnitus; no applications, however, were submitted in response to the announcement. The deputy director, Division of Communicative Disorders, believes this was the only announcement during the 1980s specifically aimed at soliciting grant proposals relating to tinnitus. According to him, one reason for the lack of additional grant solicitations is that tinnitus, in relation to other hearing disorders, is not a high priority warranting large research efforts and funding.

Between 1981 and 1987, no intramural research projects on tinnitus were funded. During this period, however, six grants directly relating to tinnitus were funded under the NINCDS extramural program; three have been completed and three were ongoing as of December 1987. According to the deputy director, other funded grants dealing with hearing may relate indirectly to tinnitus, but these would not be easily identified because the term "tinnitus" was not mentioned in the grant title.

As shown in table 1, the three completed tinnitus projects that were supported through the NINCDS extramural program were multiyear projects, funded for a total of $1,438,032.

Table 1: NINCDS Completed Grant Projects on Tinnitus (as of Sept. 30, 1987)

Grantee institution	Total funding	Grant approval date	Grant period	Project title
Oregon Health Sciences University	$932,638	4/01/81	4 years	The Study of Tinnitus
University of Illinois	267,247	8/01/81	5 years and 7 months	Psychoacoustic Studies of Subjective Tinnitus
New York University	238,147	6/01/83	3 years	Neuromagnetic and Psychophysical Study of Tinnitus

The three active tinnitus grants, funded through the NINCDS extramural program, were also multiyear projects. Collectively, as of September 30, 1987, these three grants had received $794,882 since they were initially awarded (see table 2).

Table 2: NINCDS Active Grant Projects on Tinnitus (as of Sept. 30, 1987)

Grantee institution	Cumulative funding	Grant approval date	Grant period	Project title
University of Maryland	$227,180	4/01/81	9 years	Tinnitus in Patients with Sensorineural Hearing Loss
University of Washington[a]	402,993	1/01/83	6 years	Measurements of Subjective and Objective Tinnitus
Yale University	164,709	4/01/85	3 years	Mechanism of Tinnitus

[a]This grant was first awarded to Purdue University. When the primary researcher transferred to the University of Washington, the grant was also transferred. Included in the $402,993 is $95,836, first awarded to Purdue.

Appendix I includes more information on the objectives or results or both of these NINCDS research projects.

Since fiscal year 1981, only one contract dealing specifically with tinnitus has been awarded. This 27-month contract, awarded in September 1985 to the Tulane University School of Medicine for $404,000, was for a tinnitus study for a possible orphan drug, amino-oxyacetic acid (a drug with limited potential for development by drug companies because of expected low demand). Carried out in two phases, this study attempted to determine the appropriate drug doses to be administered and conducted pilot clinical trials using the drug and a placebo. Under the contract, the drug was tested on people with tinnitus, as well as other hearing disorders, including sudden hearing loss, noise-induced hearing loss, drug-induced deafness, and traumatic deafness.

DOE's Office of Special Education and Rehabilitative Services Within RSA

The Office of Special Education and Rehabilitative Services within RSA is responsible for administering programs that promote the education of handicapped people. This includes research programs in which causes of a handicap can be found and people can be helped.

In 1986, at the direction of the Congress (Public Law 99-178), RSA awarded a 5-year $4,785,000 grant to the Oregon Health Sciences University, Oregon Hearing Research Center, for the establishment of a research center for the hearing impaired. According to DOE grant documents, a major emphasis of this grant is to be devoted to tinnitus research. The following tinnitus projects are being carried out by the university under this research grant:

-- Computerized Tinnitus Data Registry,

-- Tinnitus and Auditory Evoked Potentials,

-- Neural Mechanisms Underlying Tinnitus,

-- Parameters of Masking of Tinnitus,

-- Effects of Long-term Masking of Tinnitus Upon Hearing Sensitivity,

-- The Evaluation of a Tinnitus Simulator,

-- Parameters of Residual Inhibition,

-- Spectra of Tinnitus Maskers,

-- Use of Electrical Stimulations to Suppress Tinnitus,

-- The Use of Drug Therapy for the Treatment of Tinnitus, and

-- The Treatment of Hyperacusis by Desensitizing.

The funding amounts and time periods for these projects were not available. Appendix II, however, includes more information on the objectives of these projects. DOE also sponsors the Subcommittee on Hearing Impaired Persons, Interagency Committee on Handicapped Research. The subcommittee identifies federal agencies conducting or sponsoring research on hearing disorders and diseases. Tinnitus is one of the problems broadly included in the subcommittee's oversight responsibilities.

VA Research Activities

The VA Medical and Prosthetic Research Program focuses its research on (1) medical, dental, and psychiatric problems that are specific to the veteran population and (2) general health problems that are prevalent among veterans. Rehabilitation research and health services research are also funded. In fiscal year 1987, VA supported 6,585 investigators under this program, with funding amounting to about $192.8 million. Over two-thirds of the investigators received limited VA support--such as use of offices at VA medical centers or administrative support. Generally, a research program--that is, a battery of research projects dealing with a general research topic--for an individual medical center is approved at VA's central office, but limited data on the individual projects are available.

According to VA central office data, since fiscal year 1981, eight projects supported by VA involved tinnitus research. As of September 30, 1987, all eight were active. Funding data were available for only two of these projects. These two have received $440,592; the other six have received funding from local VA medical centers, and funding data were not available at the central office. Of the eight, two projects were recently initiated, with the first progress reports submitted in fiscal year 1987.

The data at the VA central office on these projects are summarized in table 3.

Table 3: VA Active Projects on Tinnitus (as of Sept. 30, 1987)

VA medical centers	Cumulative funding	Initial progress report[a]	Project title
Decatur, Ga.	$200,979	10/80	Three Basic Experiments in the Study of Tinnitus
Los Angeles, Calif.	239,613	06/86	Tinnitus Management with TENS Therapy[c]
Martinez, Calif.	[b]	02/84	A Pilot Investigation of Acoustic Emissions in Patients with Sensorineural Hearing Loss
New Orleans, La.	[b]	10/70	Auditory Pharmacology--Cochlear Neurohumoral Transmission and Ototoxicity
Cleveland, Ohio	[b]	09/83	Electrical Treatment of Tinnitus and Hearing Loss
Iowa City, Iowa	[b]	05/87	Validation of a Tinnitus Handicap Questionnaire
Iowa City, Iowa	[b]	03/87	Guidelines for the Quantification of Tinnitus
Biloxi, Miss.	[b]	09/85	Amino-Oxyacetic Acid in the Treatment of Tinnitus

[a]VA central office did not have information available to show the initial funding dates. VA officials noted that researchers are required to submit annual progress reports on their projects.

[b]Research project supported at VA medical center through locally directed funding; therefore, funding data were not available.

[c]TENS is an abbreviation that stands for transcutaneous (through the skin) electrical nerve stimulation (that is, the electricity passes through the skin).

Appendix III includes more information on the objectives and purposes of these VA research projects.

FEDERAL AGENCIES' TREATMENT ACTIVITIES

Although the Army, Navy, and Air Force treat service personnel with tinnitus, VA was the only federal agency that maintained data on its treatment of people with the problem. VA's programs include (1) activities at VA medical centers to provide medical services to tinnitus sufferers (691 veterans in fiscal year 1986) and (2) benefits to disabled veterans (about 42,000 veterans with tinnitus received benefits in fiscal year 1986); most of these qualified with other disabilities also.

Treatment

Veterans with hearing problems, including those with tinnitus symptoms, may be treated at the 140 audiology and speech pathology programs at VA medical centers and outpatient clinics nationwide. VA data showed that during fiscal year 1986, 38 veterans with tinnitus as their principal problem were discharged from VA medical centers and 653 with tinnitus as a secondary problem (cases where tinnitus is not the primary complaint) were discharged. In comparison, 61 with tinnitus as the principal problem and 413 with tinnitus as a secondary problem were discharged in 1982. VA did not compile cost data associated with providing medical care to these veterans.

According to the director of VA's national program of audiology and speech pathology, no major programs at VA's medical centers are specifically geared to the treatment of tinnitus. In 1980, however, VA had initiated a nationwide program at 13 clinics across the nation to provide maskers, described earlier, to veterans with the problem; it was believed maskers would be an effective solution for many afflicted with tinnitus. Few eligible veterans, however, were interested in using maskers, and the program was discontinued.

Currently, according to VA's director of audiology and speech pathology program, if there is a change in hearing loss, veterans can seek treatment, including counseling and the use of hearing aids. These treatments are available after a medical workup has been conducted to determine the causes of the problem.

Compensation

VA provides benefits to disabled veterans through its pension benefit and compensation programs. Veterans are eligible to receive benefits when they are (1) disabled by injury or disease and (2) discharged or separated under other than dishonorable conditions. About 42,000 veterans with tinnitus received benefits in fiscal year 1986, although tinnitus was not necessarily the only or primary disability for which these veterans received benefits. VA data did not disclose, however,

the amounts of benefits received for the tinnitus disability alone.

Revised regulations establishing the degree of hearing loss (including tinnitus) necessary to qualify for benefits were published on November 18, 1987, in the Federal Register. Among other things, these regulations will implement new methods for evaluating the degree of disability attributable to hearing loss. VA officials believe these methods will result in a more accurate measurement of hearing impairment and, therefore, a more equitable basis for providing benefits.

NINCDS GRANT DATA FOR FISCAL YEARS 1981-87

The Study of Tinnitus

Grantee institution	Grant funding	Initial grant approval	Grant period
Oregon Health Sciences University	$932,638	4/01/81	4 years

This project aims to obtain further data on tinnitus, as well as medical understanding of its causes, underlying mechanisms, and treatment; these data include the determination of the incidence of tinnitus, analysis of drug-induced tinnitus, development of techniques to aid in the diagnosis and evaluation of tinnitus, and evaluation of the safety and efficacy of masking and drug treatment. The grantee is relying on the patient pool at the university to integrate a variety of investigative techniques for evaluating and quantifying tinnitus cases.

Psychoacoustic Studies of Subjective Tinnitus

Grantee institution	Grant funding	Initial grant approval	Grant period
University of Illinois	$267,247	8/01/81	5 years and 7 months

This project includes a series of experiments dealing with the hearing adaptation in tinnitus. Adaptation is to be studied across the range of noise for human hearing in order to provide an objective (measurable) description of loudness in various cases of tinnitus. According to NINCDS, an objective description of the degree of noise in a given case of tinnitus would provide benchmarks for studying sound masking.

Neuromagnetic and Psychophysical Study of Tinnitus

Grantee institution	Grant funding	Initial grant approval	Grant period
New York University	$238,147	6/01/83	3 years

In this project, the grantee employed several methods to identify the site(s) of lesions underlying subjective tinnitus (no measurable causes related to the symptoms in the ear canal). Psychophysical methods were employed to identify the physical parameters of stimuli that mimic tinnitus as it was actually experienced by patients. Another purpose of the grant was to devise procedures to measure tinnitus quickly and reliably.

Tinnitus in Patients With Sensorineural Hearing Losses

Grantee institution	Grant funding	Initial grant approval	Grant period
University of Maryland	$227,180	4/01/81	9 years

The project is aimed at gathering more data to arrive at a better understanding of tinnitus in patients with hearing loss caused by noise, trauma, or exposure. In this project, an attempt is made to use perceptual and psychophysical data to specify the likely site of the generation of tinnitus (despite variation in intensity) and focus on its causes. Another objective of the project is to establish a test for tinnitus.

Measurements of Subjective and Objective Tinnitus

Grantee institution	Grant funding	Initial grant approval	Grant period
Purdue University	$ 95,836	1/01/83	6 years
University of Washington[a]	307,157		

[a]Researcher later transferred to University of Washington.

This project compares the symptoms of subjective tinnitus with various procedures that approximate the estimated frequency and intensity of subjective tinnitus. Another aspect of the study involves objective tinnitus (tinnitus for which an apparent cause can be found in the ear canal), which focuses on discovering possible causes and changes in the disorder.

APPENDIX I

Mechanism of Tinnitus

Grantee institution	Grant funding	Initial grant approval	Grant period
Yale University	$164,709	4/01/85	3 years

This project investigates a hypothesis that some forms of tinnitus may result from a decrease of calcium, which causes alteration of hair cell nerve endings that receive sounds in the inner ear. The hypothesis was to be investigated from three different perspectives, and it was hoped that the data obtained from the study would provide a better understanding of the origin of tinnitus, thus aiding in developing an animal model for tinnitus research.

DOE GRANT DATA: 1986 AWARD TO OREGON HEALTH SCIENCES UNIVERSITY

COMPUTERIZED TINNITUS DATA REGISTRY

The Oregon Health Sciences University (Oregon Hearing Research Center) had previously developed a computerized data base for medical histories, hearing data, and other data obtained from a large number of tinnitus patients. The aim of the data registry is to (1) make accessible a variety of types of sophisticated data analyses and (2) provide new insights into the possible causes, underlying mechanisms, and available treatments for tinnitus.

The objective of the project under this grant is to continue the expansion of the data registry, with changes in the computer facilities used to store and manage the data. Over the 5-year grant period, the center plans to (1) investigate the diagnostic significance of certain tinnitus symptoms or clusters of symptoms; (2) determine the difference in one agent as compared with another, for example, noise damage, middle ear disease, and other entities; (3) investigate tinnitus associated with treatable conditions of the ear, nose, or throat; (4) investigate tinnitus associated with ototoxic drugs (drugs producing adverse effects on organs or nerves involved in hearing) in hospital use; and (5) develop new methods for evaluating and quantifying the loudness of tinnitus.

TINNITUS AND AUDITORY EVOKED POTENTIALS

Four experiments are initially proposed to develop an objective electrophysiological measure of tinnitus. Subjective tinnitus, as mentioned earlier, is a tinnitus for which no causes can be measured in the ear canal; it is the sensation of sound, in the absence of an external stimulus, experienced only by the person who suffers from it. There are no outward signs, swelling, redness, or observable symptoms; there are also no direct measures other than the person's report. There are indirect measurements that, with proper care in execution, can provide additional information. An objective measure of tinnitus would be of value for research and therapy evaluation, as well as cases of litigation.

NEURAL MECHANISMS UNDERLYING TINNITUS

The purpose of this research is to gain insight into the physiological mechanisms underlying tinnitus. The effects of

known tinnitus-inducing agents on the auditory system are to be studied, using a variety of electrophysiological measures.

PARAMETERS OF MASKING OF TINNITUS

Investigators will study two types of tinnitus patients: those for whom current masking sounds can only be heard at high intensities and those for whom masking sounds will be tested. The overall significance of the project is the development of a body of data relating to the ease of masking, which could ultimately guide manufacturers in the commercial production of such equipment.

EFFECTS OF LONG-TERM MASKING OF TINNITUS UPON HEARING SENSITIVITY

The specific aim of this study is to determine the effect on hearing sensitivity resulting from the long-term use of tinnitus maskers or tinnitus instruments. Since the beginning of the masking program in 1976, there has been an effort to offer relief from tinnitus; several thousand patients have been fitted with either tinnitus maskers or tinnitus instruments.

THE EVALUATION OF A TINNITUS SIMULATOR

Efforts are being made to design and develop a prototype tinnitus simulator that will provide information similar to that provided by masking devices. The device will allow flexibility for the clinician as an evaluative tool; with the data obtained, the clinician can adjust the wearable unit to simulate the variables found to effectively mask the tinnitus.

PARAMETERS OF RESIDUAL INHIBITION

Residual inhibition is the elimination of tinnitus following the use of masking sounds. The study is designed to determine the extent to which residual inhibition can be influenced by a great variety of masking sounds. Eight different masking sounds are to be tested with the expectation that clues as to how to extend residual inhibition will be forthcoming.

SPECTRA OF TINNITUS MASKERS

Providing successful masking therapy is the general aim of this study. A major difficulty with masking is providing an acceptable sound spectrum in a small wearable device (that is, a masker). The spectrum needed to mask a person's tinnitus and

also provide relief is often highly individual. Thus, providing an individual with the sound spectrum needed can be problematic.

USE OF ELECTRICAL STIMULATIONS TO SUPPRESS TINNITUS

The specific aim of this study is to evaluate those conditions necessary for the application of electrical stimuli to the skin, much like the stimuli used for the modern-day control of pain. There are two major variables that require investigation: the wave shapes and the location of the stimuli.

THE USE OF DRUG THERAPY FOR THE TREATMENT OF TINNITUS

The hypothesis for this study is that there will be a significant reduction in the intensity of the tinnitus in patients receiving Xanax for a specified length of time. There are a number of methods reported in the literature for treating tinnitus. The results for the treatment of tinnitus by drugs, however, have been largely disappointing. The specific aim of this study is to systematically investigate the use of Xanax as a relief procedure for the treatment of tinnitus.

THE TREATMENT OF HYPERACUSIS BY DESENSITIZING

About 4,000 patients have been seen in the clinic at Oregon Health Sciences University. Of this number, less than a dozen patients have complained about an elevated sensitivity to sound. The study proposes to attempt to desensitize patients with hyperacusis (abnormal acuteness of hearing), using a masking approach. The ears are to be subjected to continual masking sounds, starting at very low intensities and gradually increasing over a time period of 6 to 8 months; at the end of treatment, any abrupt sound should bother patients less.

VA PROJECT DATA FOR FISCAL YEARS 1981-87

Three Basic Experiments in the Study of Tinnitus

VA medical center	Grant funding	Initial project date
Decatur, Ga.	$200,979	10/80[a]

This project consists of several parts, including measurement of tinnitus loudness using a comparison method, determining the effect of noise level on tinnitus loudness, and explaining why treatment is often unsuccessful.

Tinnitus Management With TENS Therapy

VA medical center	Grant funding	Initial project date
Los Angeles, Calif.	$239,613	6/86[a]

TENS (transcutaneous electrical nerve stimulation) means that the electricity passes through the skin. TENS devices have been used safely for many years to treat pain in various parts of the body, including the head. Their use in the treatment of tinnitus is a new application explored in this research project.

A Pilot Investigation of Acoustic Emissions in Patients With Sensorineural Hearing Loss

VA medical center	Grant funding	Initial project date
Martinez, Calif.	[b]	2/84[a]

Sounds made by clicks and brief tone bursts were measured in normal hearing subjects and patients with hearing loss. The sounds were recorded using an electric microphone assembly inserted in the ear canal. Analysis of the clicks showed discontinuities similar to those observed in spontaneous emission recording. In addition, the comparison of emission and audiometric data measuring the results for those with hearing loss will be reported.

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(Continued)

Electrical Treatment of Tinnitus and Hearing Loss

VA medical center	Grant funding	Initial project date
Cleveland, Ohio	b	9/83[a]

The use of electrical stimulation for the treatment of tinnitus was evaluated in a two-experiment study. Experiment 1, with seven men and three women, resulted in a defined improvement; either a complete remission of the tinnitus or a decrease in its frequency was reported. Experiment 2, with a single blind protocol, used 20 subjects, the majority of whom had tinnitus in both ears. Eighty-two percent improved, with the improvement ranging from 20 minutes to at least 6 months. The adverse effects from the stimulation were minimal. However, the results of the study have not been duplicated.

Validation of a Tinnitus Handicap Questionnaire

VA medical center	Grant funding	Initial project date
Iowa City, Iowa	b	5/87[a]

The objectives of the research are to develop and analyze a questionnaire in order to assess the impact of tinnitus on a person's well-being. The questionnaire is potentially useful as (1) a screening device to pinpoint specific handicap areas for patient referral and (2) a diagnostic tool to determine the severity of disability for each item in the questionnaire. The questionnaire includes 87 items concerning changes in a person's hearing, emotional health, and life-style because of tinnitus.

Guidelines for the Quantification of Tinnitus

VA medical center	Grant funding	Initial project date
Iowa City, Iowa	b	3/87[a]

The objectives of this research are to develop a questionnaire to estimate the impact of tinnitus on a person's life-style, assemble and evaluate a battery of psychophysical

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tests for measuring tinnitus, and determine the reliability and validity of these measures. The ultimate goals of this research are to develop measures that (1) enable an examiner to differentiate between people with legitimate tinnitus and those who may be feigning the disorder and (2) present guidelines for a schedule that relates the disability caused by tinnitus to a particular profile (derived from responses to the questionnaire or a psychophysical test battery or both).

Amino-Oxyacetic Acid in the Treatment of Tinnitus

VA medical center	Grant funding	Initial project date
Biloxi, Miss.	b	9/85[a]

This study includes patients with different types of tinnitus in order to determine whether amino-oxyacetic acid is useful in the treatment of tinnitus. After being placed on amino-oxyacetic acid or a placebo, patients are to be tested by audiometric methods at regular intervals and their tinnitus determined on a subjective rating.

Auditory Pharmacology-Cochlear Neurohumoral Transmission and Ototoxicity

VA medical center	Grant funding	Initial project date
New Orleans, La.	b	10/70[a]

This study involves primary efferent auditory transmitter activity in guinea pigs. The guinea pigs have been subjected to sound that shows an effect in a pig's inner ear. In addition, a pilot study using amino-oxyacetic acid in 10 patients with tinnitus is to be conducted.

[a]Grant period starts on date of first annual progress report because information on initial approval date was not available; grant still in effect.

[b]According to VA officials, research project supported at VA medical center through locally directed funding.

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