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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Treatment of Tinnitus

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of cochlear implants, sound masking devices, hearing aids, and transcranial magnetic stimulation medical devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of Evaluation and Treatment of Tinnitus, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

Online submissions:

<http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/>. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

E-mail submissions: [ehcsrc@ohsu.edu](mailto:ehcsrc@ohsu.edu) (please do not send zipped files - they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-494-0147 or Email: [ehcsrc@ohsu.edu](mailto:ehcsrc@ohsu.edu).

SUPPLEMENTARY INFORMATION:

In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for evaluation and treatment of tinnitus.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the Federal Register and direct postal and/or online solicitations. We are looking for studies that report on treatment of tinnitus, including those that describe adverse events, as specified in the

key questions detailed below. The entire research protocol, including the key questions, is also available online at:

<http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=811#4755>

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

Key Question (KQ) 1 and PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

In patients with symptoms of tinnitus (e.g., ringing in the ears, whooshing sounds, etc.) what is the comparative effectiveness of methods used to identify patients for further evaluation or treatment?

Population(s)

Adult patients presenting with symptoms of tinnitus (e.g., ringing in the ears, whooshing sounds, etc.)

Note: "Adults" for all KQs will include individuals 18 years of age and older.

Interventions

Direct observation or observation of sound with stethoscope; referral to a health professional with expertise on managing tinnitus (i.e., otolaryngologist, audiologist, neurologist, mental health professional; administration of scales/questionnaires to assess severity [e.g., Tinnitus Handicap Inventory, Tinnitus Reaction Questionnaire, Tinnitus Functional Index, Visual Analog Scale, and Tinnitus Severity Index, etc.]

Comparators

Different clinical evaluation methods used to characterize a diagnosis and measure severity of subjective idiopathic tinnitus

Outcomes

Final outcome: No treatment; need for specialized treatment (e.g., audiology, otolaryngology, neurology, mental health care); extent of intervention

Timing or followup

No restrictions

Setting

Primary care; specialty care (audiology, otolaryngology, neurology, mental health care)

Key Question 2 and PICOTS

In adults with subjective idiopathic (non-pulsatile) tinnitus, what is the comparative effectiveness (and/or potential harms) of medical/surgical, sound treatment/technological, or psychological/behavioral intervention (including combinations of interventions)?

## Population(s)

Adult patients with a diagnosis of subjective idiopathic (non-pulsatile) tinnitus (who are sufficiently bothered by tinnitus that they seek a treatment intervention)

Note: For KQs 2 and 3, adults diagnosed with unilateral and/or pulsatile tinnitus need to be evaluated for other medical conditions (such as acoustic neuromas). Our review will include only those cases in which a medically serious underlying pathology as the source of the tinnitus has already been ruled out.

## Interventions

Any treatment/therapy used to reduce/help cope with tinnitus including but not limited to:

- Medical/Surgical
  - Pharmacological treatments
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, and trimipramine)
    - Selective serotonin-reuptake inhibitors: fluoxetine and paroxetine
    - Other: trazodone; anxiolytics (e.g., alprazolam); vasodilators and vasoactive substances (e.g., prostaglandin E1); intravenous lidocaine; gabapentin; Botox (botulinum toxin type A); and pramipexole)
  - Laser treatments
  - TMJ treatment: dental orthotics and self-care; surgery
  - Transcranial magnetic stimulation
  - Complementary and alternative medicine therapies: G. biloba extracts; acupuncture; hyperbaric oxygen therapy; and diet, lifestyle, and sleep modifications (caffeine avoidance, exercise)
- Sound Treatments/Technologies
  - Hearing aids
  - Cochlear implants
  - Sound generators/maskers (both wearable and stationary)
  - Neuromonics
  - Tinnitus Retraining Therapy
- Psychological/Behavioral
  - Cognitive behavioral therapy

- Biofeedback
- Education
- Relaxation therapies
- Progressive Tinnitus Management
- Combination therapies
  - Any combination of tinnitus interventions (e.g., pharmacological treatment with cognitive behavioral therapy)

#### Comparators

Placebo; no treatment; wait list; treatment as usual; other intervention/treatment

#### Outcomes

- Final outcomes:
  1. Sleep disturbance
  2. Discomfort
  3. Anxiety
  4. Depression
  5. Self-reported loudness
  6. Quality of life
- Adverse effects
  1. Worsening of tinnitus
  2. Sedation
  3. Surgical complications

Timing or followup

No restrictions

#### Setting

Primary care; specialty care (audiology, otolaryngology, neurology, and mental health care)

### Key Question 3 and PICOTS

For adults with subjective idiopathic tinnitus, what prognostic factors, patient characteristics, and/or symptom characteristics affect final treatment outcomes?

#### Population(s)

Adults with a diagnosis of subjective idiopathic tinnitus (sufficiently bothered by tinnitus that they are seeking a treatment intervention)

#### Interventions

Any treatment/therapy used to reduce/help cope with tinnitus including but not limited to those described in KQ 2.

#### Comparators

- Prognostic factors: length of time to treatment after onset, audiological factors (degree and type of hearing loss, hyperacusis, loudness tolerance, masking criteria, etc.), head injury, anxiety, mental health disorders, and duration of tinnitus
- Patient characteristics: age, gender, race, medical or mental health comorbidities, socioeconomic factors, noise exposure (environmental, recreational and work-related [including active and past military duty, and occupational hazards), involvement in litigation, third-party coverage
- Symptom characteristics: origin/presumed etiology of tinnitus, ototoxicity, tinnitus duration since onset, subcategory of tinnitus, severity of tinnitus

#### Outcomes

- Final outcomes:
  1. Time until improvement
  2. Sleep disturbance
  3. Discomfort
  4. Anxiety
  5. Depression
  6. Self-reported loudness
  7. Quality of life
  8. Return to "normal" work

- Adverse effects
  1. Worsening of tinnitus
  2. Sedation
  3. Surgical complications

Timing or followup

No restrictions

Setting

Primary care; specialty care (audiology, otolaryngology, neurology, mental health)

Dated: April 4, 2012

Carolyn M. Clancy,  
AHRQ, Director

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