Commenting on Common Formats
Hospital 1.2

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the NQF, a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF then convenes an expert panel to review the comments received and provide feedback. The NQF began this process with feedback on AHRQ’s 0.1 Beta release of the Common Formats in 2008. Based upon the expert panel’s feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the new Common Formats—Hospital Version 1.2 to guide the improvement of the formats. Information on how to comment and provide feedback on the Common Formats—Hospital Version 1.2, is available at the NQF Web site for Common Formats: http://www.quality.forum.org/projects/commonformats.aspx.

The process for updating and refining the formats will continue to be an iterative one. Future versions of the Common Formats will be developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. More information on the Common Formats can be obtained through AHRQ’s PSO Web site: http://www.PSO.AHRQ.gov/index.html.

Dated: April 5, 2012.
Carolyn M. Clancy,
Director.

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) seeks 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 Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review.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 May 14, 2012.

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.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or Email: 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=8114755.

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 Web site 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 email 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 El); 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)
- Neuronomics
- 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, otoxicity, 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,
Director, AHRQ.

[FR Doc. 2012–8886 Filed 4–12–12; 8:45 am]
BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Extension of the World Trade Center Health Registry (U50) Request for Applications (RFA), OH12–001, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the aforementioned meeting:

Time and Date: 1 p.m.–2 p.m., May 16, 2012 (Closed).

Place: National Institute of Occupational Safety and Health (NIOSH), 2400 Century Parkway, NE., Atlanta, Georgia 30345, Telephone: (866) 916–5441.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Extension of the World Trade Center Health Registry (U50) RFA OH12–001”

Contact Person for More Information:
George Bockosh, M.S., Scientific Review Officer, CDC/NIOSH, 626 Cochran's Mill Road, Maitland P–05, Pittsburgh, Pennsylvania 15236, Telephone: (412) 386–6465 AND Joan Karr, Ph.D., Scientific Review Officer, CDC/NIOSH 1600 Clifton Road, NE., Maitland E–74, Atlanta, Georgia 30333, Telephone: (404) 498–2506.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 5, 2012.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–8886 Filed 4–12–12; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics, (BSC, NCHS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee:

Times and Dates: 11 a.m.–5:30 p.m., May 17, 2012, 8:30 a.m.–1 p.m., May 18, 2012.
Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.
Status: This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-US citizens, pre-approval is required (please contact Gwen Mustaf, (301) 458–4500, glm4@cdc.gov or Virginia Cain, vcain@cdc.gov at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101–20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters To Be Discussed: The agenda will include welcome remarks by the Director, NCHS; the initiation of the review of the Office of Research and Methodology: a discussion of vital statistics and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter. Written comments should not exceed five single-spaced typed pages in length and must be received by April 30, 2012.

The agenda items are subject to change as priorities dictate.

Contact Person for More Information:
Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, telephone: (301) 458–4500, fax (301) 458–4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 5, 2012.
Elaine L. Baker,
Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–8887 Filed 4–12–12; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974, as Amended by Public Law 100–503; Notice of a Computer Matching Program

AGENCY: Office of Financial Services (OFS), Office of Administration (OA), ACF, HHS.

ACTION: Request for public comment on the Public Assistance Reporting Information System (PARIS) notice of a computer matching program between the Department of Veterans Affairs and