Tinnitus: Clinical Research and Evidence-Based Practice
By James A. Henry

The purpose of this article is to briefly review research evidence that can be used to guide clinical procedures for the management of tinnitus. Because terminology in the tinnitus literature is often confusing, contradictory, and inconsistent, we will start with operational definitions.

Operational Definitions
Most generally, “tinnitus” refers to the perception of sound for which no acoustic source exists outside of the head. Note that this definition pertains only to the perception of tinnitus, and not to negative reactions that might be caused by the perception. If a person has tinnitus with no reactions, it is referred to as “non-bothersome” tinnitus. Tinnitus that causes negative reactions is “bothersome,” ranging from mildly, to moderately, to severely bothersome. The origin of the tinnitus perception can be either neurophysiologic or somatic. Neurophysiologic (“sensorineural” or “primary”) tinnitus is what most patients experience and the type for which audiologists can provide appropriate services. Somatic (“objective” or “secondary”) tinnitus, which is relatively uncommon, is real sound with an acoustic source in the region of the head or neck (and requires an examination by an otolaryngologist). Tinnitus is chronic (or “persistent”) if present for at least six months.

AAO-HNSF Clinical Practice Guideline
Clinical management of tinnitus should follow evidence-based guidelines. The highest standard for providing such evidence comes from randomized-controlled trials (RCTs) that are properly conducted and reported (Keech et al, 2007). Evidence-based guidelines for the clinical management of tinnitus did not exist until recently. In October of 2014, the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) published its clinical practice guideline (CPG) for clinical management of primary (neurophysiologic/sensorineural) tinnitus (Tunkel et al, 2014). Developing the CPG involved an exhaustive search of the peer-reviewed literature to identify appropriate RCTs for making evidence-based recommendations for clinical practice. A 23-member committee was assembled to hold meetings and to draft the guidelines, which underwent external peer review prior to publication. The CPG specifies the following as management options:

- A targeted history and physical exam to identify conditions that might be remediated.
- A comprehensive audiological exam for patients with tinnitus that is unilateral, chronic, or associated with hearing difficulties.

- Distinguish patients with chronic tinnitus from those with bothersome tinnitus of recent onset (to prioritize clinical services).
- Educate patients with chronic, bothersome tinnitus about intervention options.
- Recommend a hearing aid evaluation for patients with chronic, bothersome tinnitus and hearing loss.
- Recommend cognitive-behavioral therapy (CBT) for patients with chronic, bothersome tinnitus.

The CPG recommends against the following treatments:

- Pharmaceutical medications,
- Dietary supplements, and
- Transcranial magnetic stimulation.

Some of these recommendations might give pause to audiologists who provide tinnitus services. Other than the recommendation to provide hearing aids as needed, the only intervention recommended is CBT, which is in the domain of mental-health providers. Sound therapy,
which is practically exclusive to audiologists, is only mentioned as an “option.” Further, no particular type of sound therapy is recommended. Full disclosure to patients would therefore require telling them there is no scientific basis to claim any one type of sound therapy is more effective than any other. To adhere to the CPG recommendations, audiologists should refer patients with chronic, bothersome tinnitus to a mental-health provider who is skilled in CBT.

Cochrane Reviews
The Cochrane Collaboration is an independent, world-wide network of health-care researchers and professionals, and health-care advocates that has produced more than 5,000 “Cochrane Reviews” of primary research in health care. These rigorous, systematic reviews consider RCTs to be the standard that should inform evidence-based care for medical conditions, and their reviews are conducted accordingly.

Cochrane Reviews have addressed methods of tinnitus intervention, with one review concluding that CBT can improve quality-of-life and depression scores (Martinez-Devesa et al, 2010). Another review concluded that sound therapy can be beneficial when combined with counseling, but sound therapy on its own has not been shown to provide significant benefit (Hobson et al, 2010). The review focusing on the use of hearing aids for patients with bothersome tinnitus and hearing loss concluded, (p. 2) “there is currently no evidence to support or refute their use as a more routine intervention for tinnitus” (Hoare et al, 2014).

Agency for Healthcare Research and Quality
The Agency for Healthcare Research and Quality (AHRQ) focuses on research evidence to improve the quality of health-care services. The AHRQ completed a comparative effectiveness review for tinnitus, concluding that none of the methods reviewed had significant strength of evidence (Pichora-Fuller et al, 2013). The agency further concluded there was insufficient information to determine the strength of evidence for sound therapies, and there was low-quality evidence that CBT has a beneficial effect on quality of life. The review pointed out that CBT is commonly combined with other behavioral interventions, and that “progressive or staged treatments” are a promising area of interest for providing tinnitus clinical services.

Progressive Tinnitus Management
Tinnitus research has been conducted at the VA National Center for Rehabilitative Auditory Research (NCRAR) continuously since the facility’s inception in 1997. The NCRAR is located at the VA Portland Health Care System (VAPORHCS); tinnitus research actually started at the VAPORHCS in 1995. A total of 18 funded tinnitus projects have been completed and six are currently underway. All of these studies focus on some aspect of tinnitus clinical management. This work has provided efficacy data and identified procedures that are effective and efficient for clinical application, and has culminated in the development and evaluation of Progressive Tinnitus Management (PTM).

Evidence for PTM is based on

- 20 years of clinical research involving 24 funded studies;
- clinical implementation at audiology clinics—PTM is being used by more than 100 clinics; and

At the NCRAR, we recently completed a multi-site RCT of PTM with 300 subjects. Results of that study, which will be reported soon, were not available when the AAO-HNSF CPG was developed. We are also completing a second RCT of PTM implemented as a tele-health program. Both of these studies are validating the effectiveness of PTM and should be considered for the practice of evidence-based tinnitus management. PTM is mostly consistent with the AAO-HNSF CPG, and provides a structured and defined framework for implementing both assessment and intervention services for patients who report tinnitus.

PTM involves a series of progressive steps for patients complaining of tinnitus. These steps involve either assessment or intervention. Different levels of assessment determine patients’ need for intervention or referral to another specialty. For PTM, “intervention” is defined as clinical services delivered to address patients’ needs with respect to hearing loss, tinnitus, and/or hyperacusis. Patients progress only as far as necessary to meet their individual needs.

Beyond the initial referral level (Level 1—referral), the first PTM step is the hearing evaluation and brief assessment of tinnitus impact (Level 2—audilogic evaluation). This combined hearing/tinnitus assessment is the only service received by patients who do not need intervention. Some patients receive hearing aids or combination instruments, which addresses their hearing loss and often reduces effects of tinnitus (Shekhawat et al, 2013).

Following Level 2 services, patients are assessed to determine if
tinnitus-specific intervention is needed. If so, they are advised to attend Level 3—skills education, which combines elements of sound therapy and CBT into five weekly sessions (group or individual). These sessions are educational in nature and teach patients skills to self-manage their tinnitus (Henry et al, 2009). The education is not “treatment,” and patients are not expected to improve just by virtue of attending the sessions. Any outcomes assessment should focus on assessing patients’ confidence that they know how to self-manage their tinnitus in situations when tinnitus is problematic. Note that Level 3 sessions are provided by both an audiologist and a mental-health provider who is skilled in CBT.

If tinnitus is still problematic following Level 3 (less than five percent of patients, according to our research), the next step is Level 4—interdisciplinary evaluation. This in-depth assessment of their tinnitus needs by both an audiologist and a psychologist determines if Level 5—individualized support—should be offered. Level 5 involves individual sessions with an audiologist and/or a psychologist. As at Level 3, the Level 5 sessions provide education designed to facilitate self-management of tinnitus (with CBT being the primary intervention option). Outcomes of Level 5 should be evaluated as for outcomes of Level 3.

PTM does not necessitate a medical exam for every patient, which is determined at Levels 1 and 2 (Henry et al, 2010). If a mental-health condition is suspected at any point, the patient should be referred for mental-health screening. We do not normally advocate the use of medications, although they are certainly appropriate for patients with certain mental-health conditions. Details of PTM are available on the NCRAR Web site (www.ncrar.research.va.gov/education/documents/tinnitusdocuments/index.asp).

Conclusion
Audiologists should follow the AAO-HNSF CPG to provide evidence-based tinnitus clinical services. PTM offers a structured protocol to provide services that are mostly consistent with the CPG. At the very least, audiologists can assist patients who complain of tinnitus by evaluating their hearing, providing hearing aids, or combination instruments as needed, determining if they need tinnitus-specific intervention, and, if so, providing self-help education. Patients should be made aware of the pertinent research and the CPG, which empowers them to make informed decisions.

James A. Henry, PhD, is a research career scientist at the VA RR&D National Center for Rehabilitative Auditory Research, VA Portland Health Care System, Portland, OR.

References


