PHARMACEUTICAL INTERVENTIONS FOR HEARING LOSS (PIHL)

Reference the following open access material as:

Henry, James. Pharmaceutical Interventions for Hearing Loss. (Oct 2014). Measurement of Tinnitus [Guidelines]. Available from http://hearing.health.mil/EducationAdvocacy/Newsletters.aspx

Measurement of Tinnitus

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Tinnitus researchers and clinical audiologists routinely obtain measures of tinnitus perception (Cope, Baguley,& Moore, 2011; Davis, Paki, & Hanley, 2007; Henry, & Meikle, 2000; Henry, 2004; Hiller, & Goebel, 2007; Jastreboff, Hazell, & Graham, 1994; Johnson, Brummett, & Schleuning, 1993). Over 30 years ago formal efforts were undertaken by the CIBA Foundation in London to promote international cooperation in tinnitus research (Evered, & Lawrenson, 1981; McFadden,1982). A central concept in the CIBA Symposium was that standardization of tinnitus measures would advance international understanding and facilitate work on tinnitus. As a result of these efforts a clinical assessment battery was recommended to include pitch match, loudness match, maskability, and residual inhibition. Vernon and Meikle (1981) published procedural details for these tests (requiring special equipment that was available at the time). Currently, most audiologists who perform tinnitus evaluations use their clinical audiometer in some manner to obtain the measures. Although the clinical value of these measures is questioned, they currently are used most commonly to enhance counseling.

To date there is no known method for reducing the perception of tinnitus, which would normally be experienced as a reduction in tinnitus loudness. The problem with using psychoacoustic measures to assess outcomes of treatment for tinnitus is thus twofold: (1) the measures have not been shown to correlate with changes in functional effects of tinnitus; and (2) methods do not exist to suppress or eliminate (i.e., cure) tinnitus. For these reasons, outcomes assessment in tinnitus research relies mainly on participants' subjective ratings of functional effects of tinnitus. Numerous questionnaires have been developed for this purpose, all of which were statistically validated for intake

assessment. None, however, was specifically designed and tested to maximize responsiveness to intervention-related change. Further, no single questionnaire covered all dimensions of tinnitus functional impact, and all differed with respect to format, scaling, and wording of items. Consequently, it was difficult to compare intervention effects obtained in different clinics and in clinical trials. This has resulted in a lack of available systematic reviews, which are important for determining the clinical effectiveness of the various treatment options (Kamalski, Hoekstra et al. 2010).

A new self-report questionnaire, the Tinnitus Functional Index (TFI) has become available (Meikle et al., 2012). The TFI has documented validity both for scaling the negative impact of tinnitus for use in intake assessment and for measuring intervention-related changes ("responsiveness") in the functional effects of tinnitus. Because of its responsiveness to treatment-related change, as well as its other psychometric properties and comprehensive coverage of the domains of tinnitus impact, the TFI can be used as a standard instrument for both clinical and research settings. For evaluating tinnitus impact at intake, TFI mean scores can be stratified into five levels:

1. Not a problem: M = 14 (range: 0-17)
2. Small problem: M = 21 (range: 18-31)
3. Moderate problem: M = 42 (range: 32-53)
4. Big problem: M = 65 (range: 54-72)
5. Very big problem: M = 78 (range: 73-100)

As another way to interpret TFI scores, preliminary data support the following:

- <25 = relatively mild tinnitus (little or no need for intervention)
- 25-50 = significant problems with tinnitus (possible need for intervention)
- >50 = tinnitus severe enough to qualify for more aggressive intervention

The topic of minimum clinically important change in questionnaire index scores has generated substantial debate among measurement experts. A major issue is the considerable individual differences between patients in regard to what they consider a "meaningful change." Also, statistical demonstrations of differences between treatment groups are not necessarily indicative of changes that patients consider important or meaningful. What change in the TFI index score might our subjects consider meaningful? Using the criterion groups approach (described above), mean change scores exhibit an orderly progression from Much or Moderately improved through Unchanged to Moderately or Much worse. We interpret these data as suggesting a reduction in TFI scores of ~13 points should be meaningful to patients (there are considerable individual differences between patients in regard to what they consider a "meaningful change").

In addition to the TFI, a Visual Numeric (loudness rating) Scale (VNS) should be administered to research participants/patients at each visit (Folmer, et al., 2001). Participants should complete the scale at each appointment prior to any audiometric or psychoacoustic testing to ensure that the rating of tinnitus loudness is not affected by auditory stimulation. Careful instructions are given to participants to ensure that only a

vertical line is drawn on the scale (as compared to a circle or shaded area). They are instructed: "On the scale below, please draw a vertical line to indicate the loudness of your tinnitus at this moment."

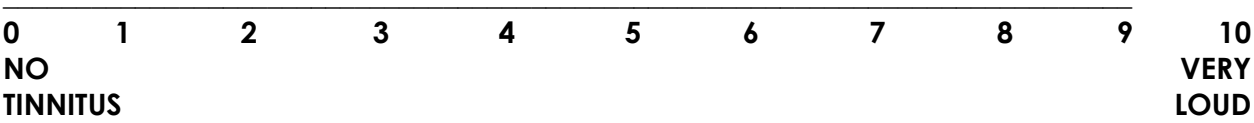

Figure 1. Visual Numeric (loudness rating) Scale (VNS) for self-rated tinnitus loudness. Participants will be instructed: "On the scale below, please draw a vertical line to indicate the loudness of your tinnitus at this moment." The VNS should be completed in a quiet exam room (not a sound booth) prior to any testing with auditory stimuli.

The Tinnitus Ototoxicity Monitoring Interview (TOMI) was developed as a clinical tool to detect tinnitus onset or changes in the tinnitus percept during treatment with potentially ototoxic drugs. Portions of the TOMI were adapted from the TRT Initial Interview (Henry et al., 2003). The TOMI is a one-page instrument that can be completed normally within about 5 minutes. Ideally, the TOMI should be administered by an audiologist or ENT physician. Because it is fully scripted, the TOMI can also be administered by a nurse or other health care professional who may not be familiar with clinical tinnitus issues, in which case the patient's responses should be reviewed by an audiologist or ENT physician.

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Acknowledgements: The TOMI was developed by Tara Zaugg, MA, Christine Kaelin, MBA, and James Henry, Ph.D.

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