

The Tinnitus Functional Index (TFI) is the first tinnitus questionnaire documented for responsiveness, and has the potential to become the new standard for evaluating the effects of intervention for tinnitus, with clinical patients and in research studies.

TINNITUS FUNCTIONAL INDEX

Development and Clinical Application

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Introduction

Epidemiology studies estimate that 10 to 15 percent of the adult population experiences chronic tinnitus (Hoffman and Reed 2004). The condition is the most prevalent service-connected disability for United States military veterans, affecting more than 1.1 million veterans in fiscal year 2013. For many of these individuals, tinnitus is “clinically significant,” causing sleep disturbance, difficulty concentrating, and emotional reactions such as frustration, anxiety, and depression.

There is no cure or drug for tinnitus, and no proven means of permanently reducing its loudness. Patients with clinically significant tinnitus must learn to manage its negative effects, and numerous behavioral methods have been developed to facilitate these efforts. Research is ongoing to evaluate existing methods and to develop new behavioral methods designed to provide tinnitus relief. In addition, research is being conducted to evaluate “treatments” for tinnitus, including drugs, acoustic protocols, and various alternative methods, such as electrical and magnetic stimulation. These treatments are intended primarily to reduce the loudness, or magnitude, of tinnitus.

Effective interventions for tinnitus are urgently needed, but the evaluation of interventions has been hindered due to the lack of a standardized measure validated for both intake and outcome assessment. In 2003, the Tinnitus Research Consortium (TRC) issued a request for proposals to conduct a study to develop a new self-report questionnaire, the Tinnitus Functional Index (TFI). The TRC Advisory Board and Chairman Dr. James Snow stipulated numerous conditions for how the TFI should

be constructed, and that the TFI would have documented validity 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.

Dr. Mary Meikle from the Oregon Hearing Research Center at Oregon Health and Science University (OHSU) submitted an application to develop the TFI. Her application was approved, and the study was funded in 2004. Dr. James Henry from the VA National Center for Rehabilitative Auditory Research (NCRAR) was co-principal investigator. The study was conducted at numerous sites, including the Cleveland Clinic in Cleveland, Ohio; Bay Pines VA Medical Center in Bay Pines, Florida; James A. Haley Veterans’ Hospital in Tampa, Florida; Oregon Health and Science University (OHSU) Tinnitus Clinic in Portland, Oregon; and the Hearing and Speech Institute in Portland, Oregon. The primary collaborators were Drs. Harvey Abrams, Eric Frederick, William Martin, Rachel McArdle, Paula Myers, Craig Newman, Sharon Sandridge, Barbara Stewart, and Susan Griest, MPH.

The OHSU Tinnitus Clinic and Cleveland Clinic had patients with more severe reactions to tinnitus. To evaluate the ability of the TFI to scale tinnitus over the widest possible range, three sites were included that had patients with milder tinnitus conditions: Bay Pines VA Medical Center, James A. Haley Veterans’ Hospital, and the Hearing and Speech Institute. The trade-off was that most of the patients at these latter three sites were males.

At the time of funding, there was a substantial amount of literature concerning self-assessment questionnaires for scaling the negative impact of tinnitus. There were

at least nine well-known English-language questionnaires. These questionnaires 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 resulted in a lack of available systematic reviews, which are important for determining the clinical effectiveness of various treatment options (Kamalski et al, 2010).

A logical question might be “why weren’t any of these previous questionnaires validated for responsiveness?” The importance of responsiveness was just being recognized by measurement experts in the 1980s, thus, until the 1990s and later, it was an unfamiliar concept to tinnitus researchers developing these questionnaires. Currently, there is extensive research literature on responsiveness and measurement sensitivity for intervention studies.

Since its original publication, the TFI has garnered considerable interest. The index is already being used in numerous clinical trials evaluating methods of tinnitus intervention, and is being translated into at least 13 languages. The purpose of the present article is to meet the needs of the audiology community by providing a succinct summary describing development of the TFI, and to provide guidelines for its use in the clinic and in clinical research.

Development of the TFI

There were five stages of TFI development: (1) construct TFI Prototype 1 (item selection and design); (2) test Prototype 1 (43 items); (3) derive TFI Prototype 2 (30 items); (4) test Prototype 2; and (5) derive final 25-item TFI. This work required four years of effort, and the primary TFI report appeared in *Ear and Hearing* in 2012 (Meikle et al, 2012). Details of this project are described in that publication. The following is a condensed description of the five stages of work.

Stage 1: Construct TFI Prototype 1

Design considerations for constructing Prototype 1 encompassed (1) responsiveness (include only those items that are demonstrated to have moderate to high sensitivity to treatment-related changes in tinnitus); (2) high construct validity for scaling tinnitus impact (each item should contribute to overall effectiveness of the questionnaire in detecting individual differences in tinnitus

impact); (3) comprehensive coverage (to strengthen content validity, items, when taken together, should address all domains of tinnitus distress that have been represented in the majority of preexisting tinnitus questionnaires); (4) brevity (limit questionnaire to 25 or fewer items if possible, but must be consistent with comprehensiveness requirement); (5) quantitative scaling (Likert-type scales preferred for all items; response options should provide high resolution without being conceptually complex); (6) ease of use for patient (wording of items should minimize reading difficulty and avoid ambiguity); (7) ease of use for examiner (scoring of items and of overall questionnaire should be simple, avoiding scale reversals and complex numerical calculations); and (8) avoidance of overly negative ideation (avoid suggesting overly negative thoughts in questionnaire items, such as suicidal thoughts, feeling victimized, feeling hopeless, feelings of despair, dread, suffering). Note that the last criterion was established by the Tinnitus Research Consortium.

The steps to constructing TFI Prototype 1 were to (1) consult with measurement experts; (2) select items; and (3) create Prototype 1. It was important not to “reinvent the wheel,” therefore the project started with existing questionnaires. The nine extant tinnitus questionnaires provided a valuable pool of questions (items). A total of 175 items were identified as important topics by the developers. There was, of course, considerable overlap among items. The selection of items followed published recommendations: use multiple judges of content validity and quantify judgments using formalized scaling procedures.

Seventeen tinnitus experts agreed to assist with the task of ensuring comprehensiveness. Eight previously had developed tinnitus questionnaires or outcome measures. The task of the Item Selection Panel was to review all 175 items from the nine tinnitus questionnaires and provide judgments about each item. The experts were asked to (1) select the dimension(s) represented by each item; and (2) rate the relevance of each item (low, moderate, high) for responsiveness or sensitivity to intervention-related change.

To rate each of the 175 items, panel experts used a Web site that provided an individual rating page for each item. The pages could be viewed in any order, and review and correction of previous responses was permitted.

For domain identification, the experts were asked to select one or more of 10 dimensions (recommended by the TRC) for which the item in question was considered relevant. If the item addressed a dimension that was not listed, that dimension could be added. For each item, “votes” for each dimension were added across reviewers.

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There were, therefore, a total of 17 possible votes for each question. Results provided 13 dimensions of tinnitus negative impact: (1) intrusiveness/unpleasantness; (2) persistence; (3) emotional distress; (4) social distress; (5) work interference; (6) leisure interference; (7) disturbance of sleep and rest; (8) disturbance of relaxation; (9) auditory perceptual problems attributed to tinnitus; (10) somatic or physical complaints attributed to tinnitus; (11) cognitive interference; (12) reduced sense of control; and (13) impaired quality of life.

Responses to the rating pages were analyzed, and 70 (of 175) items were judged by the panel to be responsive to treatment effects while addressing all major components or “dimensions” of tinnitus impact. These 70 items were reduced to 35 by eliminating questions that were redundant, referred exclusively to hearing loss, or referred to multiple subtopics within a domain. This item elimination process also used information on item effect sizes obtained during a clinical trial employing four of the nine preexisting questionnaires. A minimum of three to four items for each domain was recommended by the measurement experts. Eight items were added to meet this criterion, thus the 35 items were increased to 43 items.

The 43 initial items were formatted as questions, using a Likert-type response scale (0- to 10-point numeric rating scale). This type of scale provides good resolution for responsiveness, is familiar to many people, and is preferred over other response formats. The scale also used item-specific anchors at the two extremes. A zero to 10 response scale was recommended by the measurement experts, based on the rationale that a rapid increase in reliability is observed going from two to three response choices, three to four, etc. This increase in reliability “tends to level off at about seven, and after about 11 steps there is little gain in reliability from increasing the number of steps” (Nunnally, 1978).

Each block of three to six items used the lead-in phrase “Over the past week...” The choice of a recall interval is an important issue (U.S. Department of Health and Human Services, 2006). A brief recall interval can minimize recall errors. For respondents whose tinnitus varies over time, a brief recall interval helps to minimize response variability.

Overall Stage 1 results indicated that TFI Prototype 1 included 13 content domains, and 43 items were judged most relevant in addressing their domains and most likely to be responsive to intervention-related change. The prototype was tested with 10 patients, and no problems were reported.

Stage 2: Test TFI Prototype 1

For Stage 2, the goal was to quantitatively evaluate Prototype 1 with “tinnitus patients” for responsiveness, underlying domains (internal structure), and ability to scale tinnitus impact. The best Prototype 1 items would be retained for Prototype 2.

For Stage 2, three classes of data were acquired: (1) Initial (to assess TFI comprehensiveness and validity for scaling tinnitus impact); (2) Retest (to assess TFI test-retest reliability); and (3) Follow-up (to assess TFI responsiveness). Subjects were enrolled from patient populations at the five study sites. For the initial data, questionnaires were mailed to patients prior to their clinic visit, including a brief tinnitus history questionnaire, TFI Prototype 1, the Tinnitus Handicap Inventory (THI), and the Beck Depression Inventory-Primary Care. Patients complaining of tinnitus were asked to complete the forms at home and bring them to the clinic visit. At the visit, they had the option of participating in the study. If they declined, their questionnaires were not used. To obtain retest data, a subset of subjects completed the TFI a second time at the clinic if they had completed the initial TFI at home within the specified retest interval of 7–30 days before their clinic visit.

The follow-up data were collected at three, six, and nine months. However, at nine months there were only 25 cases for Prototype 1 and 27 for Prototype 2, which was not enough for a valid analysis of responsiveness. Therefore, nine-month data were excluded from the analysis. Patients completed the follow-up TFI and also responded to questions about tinnitus interventions received and their perceived effectiveness.

Tinnitus interventions varied widely between study sites. “More intensive” intervention included counseling, ear-level “maskers” and combination instruments, tabletop sound generators, and medications for associated sleep disturbance, anxiety, and depression. “Less intensive” intervention included hearing aids, written 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 could be used as a standard instrument for both clinical and research settings.

information, and brief counseling. There also were many combinations of interventions.

All told, 327 subjects were enrolled in Stage 2 (82 percent male, 18 percent female). Of these, 326 completed the initial questionnaires, 65 completed three-month follow-up questionnaires, and 43 completed six-month questionnaires. (There were too few follow-ups at six months for adequate statistical evaluation—the return rate for Prototype 2 was improved by increasing subject payment from \$10 to \$20 per follow-up.)

Data analysis for Prototype 1 was conducted as follows. First, data were inspected to look for items with floor and ceiling effects, and items often left unanswered (i.e., ambiguous). Next, effect sizes, commonly computed using the Cohen's *d* statistic, were calculated for the TFI index score, subscales, and for individual items. (The Cohen's *d* "effect size" is a standardized, scale-free measure of the relative size of the effect of an intervention in standard deviation units.) Data collected for Prototype 1 were observational (not experimental), thus effect sizes could not be computed to compare treatment and control groups. Instead, effect sizes were computed for "criterion groups" that were expected to differ from one another to the extent that a treatment and control group would differ.

Criterion groups were derived from subjects' responses at three and six months to the "Global Perception of Change" item, which asked patients: "Since the last time you filled out our questionnaire, how would you describe your overall tinnitus status?" Response choices ranged from 1 (very much improved) to 5 (no change) to 9 (very much worse). Because of the small follow-up sample, response categories were collapsed to create three criterion groups: (1) Improved (response choices 1–4), (2) Unchanged (response choice 5), and (3) Worse (response choices 6–9). This allowed minimally adequate sample sizes for estimating effect sizes ($n=11$ for "Improved"; $n=45$ for "Unchanged"; and $n=9$ for "Worse"). For each of the criterion groups, TFI effect sizes were calculated using the following formula: Initial mean score minus follow-up mean score, divided by the pooled standard deviation for the two scores. Effect sizes (Cohen's *d*) were considered "small" (>0.2), "medium" (>0.5), and "large" (>0.8) (Cohen, 1988).

The effect size for the improved subjects was 0.79, compared to near-zero effect sizes for unchanged and worse. Effect sizes for each of the 43 items were as follows: 14 items had "large" effect sizes (≥ 0.80); 20 items had "moderate" effect sizes (0.5–0.79), and seven had "small" effect sizes (<0.30). The two remaining items had negative effect sizes as the effects of tinnitus were worse at three months than at initial intake.

Statistical analysis of Prototype 1 provided the following results:

- Test-retest reliability: $r=0.92$, $p<.005$
- Internal consistency reliability: coefficient $\alpha=0.99$
- Item-total correlations ranged 0.56–0.91 with 37 correlations ≥ 0.70
- Criterion-related validity: High correlation ($r=0.91$) with THI; substantial correlation ($r=0.73$) with Visual Analog Scale (severity of tinnitus) included in Tinnitus Status Questionnaire

An extensive factor analysis was conducted to identify dimensions of tinnitus impact, which included Principal Components Analysis and Principal Axis Factoring. Both models were explored with and without rotation (both orthogonal and oblique). The clearest factor solutions omitted subjects responding "Not a problem" to the question "How much of a problem is your tinnitus?"—leaving 284 subjects who described their tinnitus problem as Small, Moderate, Big, or Very Big. Eight factors accounted for 80 percent of the variance: (1) intrusiveness of tinnitus; (2) emotional effects; (3) interference with thinking; (4) interference with hearing; (5) sleep disturbance; (6) interference with relaxing; (7) reduced sense of control; and (8) reduced quality of life.

Overall Stage 2 results of TFI Prototype 1 were: (1) high test-retest and internal consistency reliability; (2) good criterion-related validity; (3) clear factorial structure in agreement with expert clinical judgment, accounting for more than 80 percent of variance among 43 items; (4)

high responsiveness to treatment-related changes in tinnitus impact (0.79 effect size for overall TFI score). It was concluded that Prototype 1 provided the necessary data to develop a shorter version of the TFI (i.e., Prototype 2).

Stage 3: Derive TFI Prototype 2

The number of domains was reduced from 13 to eight as a result of two criteria: (1) Factor analysis—identified groups of questions that correlated, each group measuring different aspects of one general domain; (2) Effect sizes—items were retained that contributed to the main factors identified but they also had to have good effect sizes to be retained. For TFI Prototype 2, 30 items were selected that together encompassed all eight tinnitus dimensions and had maximal effect sizes.

Stage 4: Test TFI Prototype 2

Stage 4 involved (1) a new sample of 347 patients at the same participating sites; (2) the same procedures; (3) similar use of factor analytic techniques to check whether the eight-factor structure was confirmed; and (4) similar calculation of effect sizes to evaluate sensitivity of items and subscales (factors). The goal was to use a new sample to evaluate the 30-item Prototype 2 in terms of responsiveness, key domains (internal structure), and scaling of tinnitus impact. The best Prototype 2 items would be retained for the final TFI.

In general, Stage 4 methods and data analysis were the same as for Stage 2. Differences for Stage 4 included: (1) the Hearing and Speech Institute (Portland) discontinued participation; (2) retest data were collected only at OHSU; (3) payment to retest and follow-up subjects was raised to \$20 to increase responses; and (4) subjects with more problematic tinnitus were recruited (they were more compliant with the protocol).

For Stage 4, 347 subjects were enrolled (82 percent male; average age=60 years). Retest data were provided by 37 subjects. Follow-up data were provided by 155 subjects at three months and 85 subjects at six months. Tinnitus severity levels were higher for the Prototype 2 sample than for the Prototype 1 sample.

Despite reduction of the TFI from 43 to 30 items, Prototype 2 performed well by revealing consistent factor structure, high internal consistency reliability, good test-retest reliability, and strong construct validity for scaling tinnitus impact. Moderately high responsiveness was observed at three months, with high responsiveness at six months. We were therefore encouraged to proceed with reducing the TFI length while retaining at least three items per subscale.



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Stage 5: Derive Final 25-item TFI

For the final version of the TFI, the best-functioning items were selected, resulting in the removal of five items: (1) discomfort caused by tinnitus; (2) interference of tinnitus with participation in social events; (3) interference of tinnitus with leisure activities; (4) fatigue caused by tinnitus; and (5) amount of time that overall quality of life was reduced by tinnitus. The final TFI included eight subscales: Intrusive, Sense of Control, Cognitive, Sleep, Auditory, Relaxation, Quality of Life, and Emotional. Four items were included in the Quality of Life subscale, and there were three items each for the remaining seven subscales. All analyses used for evaluating Prototype 2 were repeated for the 25-item final TFI, using data obtained with the Prototype 2 sample.

Use of TFI in the Clinic and Clinical Research

The following is a general guide that can facilitate the interpretation of TFI scores. These beginning estimates were derived from the data collected during development of the TFI. For evaluating tinnitus impact at intake, TFI mean scores can be stratified into five levels:

- Not a problem: M=14 (range: zero–17)
- Small problem: M=21 (range: 18–31)
- Moderate problem: M=42 (range: 32–53)
- Big problem: M=65 (range: 54–72)
- 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 among patients in regard to what they consider a “meaningful change.”

REMEMBERING MARY MEIKLE

By James Henry

Mary B. Meikle, PhD, (pronounced *meekle*) lost her battle with amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig’s disease) on February 5, 2011. In 1969, Mary began working for the Kresge Hearing Research Laboratory (renamed the Oregon Hearing Research Center in 1985) at Oregon Health and Science University (OHSU), and made important contributions to the field of tinnitus research.

Mary left behind two grown children, Rick Meikle and Susan Mandell, who were by her side during her final days. Her husband of 35 years, Dr. Jack Vernon, passed away in November 2010. Dr. Vernon was the founder and director of the Oregon Hearing Research Center until he retired in 1995. Both Jack and Mary were well known for their tinnitus research and for their Tinnitus Clinic at OHSU.

Although Mary retired from OHSU in 2000, she remained very active as a researcher. Most notably, she was funded in 2004 with a grant from the Tinnitus Research Consortium (supported by private philanthropy) to develop a new tinnitus self-report questionnaire. This project was her primary research focus through the final days of her life. The project involved 20 investigators around the country who contributed in various ways. Data were collected at five clinical sites from almost 700 patients with tinnitus. This work resulted in the Tinnitus Functional Index (TFI) with documented validity for measuring treatment-related changes in tinnitus (responsiveness) and scaling the severity and negative impact of tinnitus for use in intake assessment. The TFI is the first tinnitus questionnaire that is documented for responsiveness, and has the potential to become the new standard for evaluating effects of tinnitus, with clinical patients and in research studies.

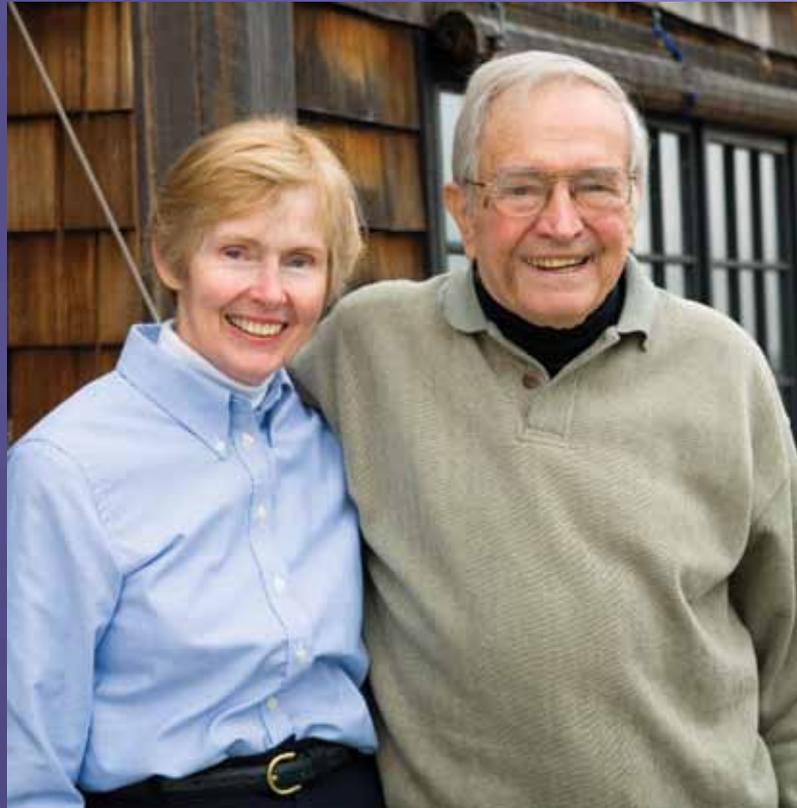
Mary’s journey conducting her TFI research took some noteworthy twists and turns. Anyone who knew Mary knows how meticulous she was in attending to every detail. When she wrote the TFI

proposal, she wasn't quite satisfied and missed the deadline to deliver the proposal to the FedEx office. For anyone else, that would have been the end of the story, but Mary pressed on—she decided to deliver it herself. She purchased a plane ticket and flew all night, arriving in Maryland the next day. Since she had worked on the proposal on the plane, and needed to print the final documents, she went to a Kinko's to print and assemble the proposal. Then—in a blinding snowstorm—she drove across the Chesapeake Bay Bridge to the home of Dr. James Snow, the Convener of the Tinnitus Research Consortium, where she knocked on his door and handed the proposal to him in person—and on time!

The twists and turns of the TFI project continued. Mary was funded in 2004 for three years to conduct the project (a one-year no-cost extension was granted to complete the work). The Consortium hoped that the project would be published in a prestigious medical journal. Mary wrote the manuscript and submitted it to *JAMA*, which rejected it because the focused topic was considered too specialized for the journal's readers. The manuscript was then sent to the *New England Journal of Medicine*, where it was rejected for a similar reason. A decision was then made to submit the report to *Ear and Hearing*. Mary completed the manuscript and submitted it to *Ear and Hearing* on February 4, 2010. The article was reviewed by four experts, and returned to Mary with 75 comments that all required a response. Needless to say, this was a daunting task, especially since Mary was exhibiting symptoms of ALS, which was formally diagnosed later in April.

Mary worked on the TFI manuscript to the point where her deteriorating health required her colleagues (including myself) to assume primary responsibility. Multiple extensions were granted by *Ear and Hearing*, and the final deadline was February 4, 2011—exactly one year after the initial submission. We completed the manuscript, and Mary contributed up until a few days before the deadline. During the last weeks, Mary's daughter, Susan, was by her side, reading our messages to her, and relaying messages back to us.

On February 4, 2011, we began uploading the revised documents on the *Ear and Hearing* Web site. This process went on until 1:00 the following morning—February 5. I immediately sent an e-mail message informing Mary that the job was finished, which was



Mary B. Meikle, PhD, and Jack A. Vernon, PhD, at their Portland, Oregon, houseboat.

later read to Mary by Susan. At 3:15 in the afternoon, Mary breathed her last breath.

This story highlights several of Mary's unique characteristics—her extreme attention to detail, her tireless dedication to completing projects, her commitment to conducting research to help people with tinnitus, and an attitude that remained consistently positive to the end. At no point did Mary complain about her failing health.

The TFI article received the 2012 *Ear and Hearing* Editor's Award for Outstanding Research in Audiology and Hearing Science. I traveled to Scottsdale, Arizona, to receive the award along with co-author Dr. Harvey Abrams at the Annual Convention of the American Auditory Society.

Mary's contributions will continue to affect clinicians and researchers in the field of tinnitus, as well as the many patients who suffer from tinnitus. She is sorely missed.

Also, statistical demonstrations of differences among 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 among patients in regard to what they consider a “meaningful change”).

The final 25-item TFI has been formally evaluated recently in the United Kingdom (Fackrell et al, 2013) and in New Zealand (Chandra, 2013). These studies suggest high convergent and discriminant validity (Chandra, 2013; Fackrell et al, 2013); and good test-retest reliability with the same factor structure (Chandra, 2013). Although translations of the TFI have yet to be formally evaluated in non-English speaking countries, the results from the United Kingdom and New Zealand suggest that the TFI can be successfully employed in different countries. Efforts are underway to translate the TFI into at least 13 languages.

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 could be used as a standard instrument for both clinical and research settings. The final 25-item TFI is available online, together with scoring instructions, all of which can be downloaded and printed (permission to use the copyrighted TFI is required from OHSU—there is no cost in most cases) at www.formstack.com/forms/?1265642-Ir7f92V4rb. 

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Singapore, and maintains an appointment at Oregon Health and Science University as professor of otolaryngology–head and neck surgery, and public health and preventive medicine. Paula Myers is chief of the Audiology Section at the James A. Haley VA Hospital, with expertise in adult development and learning, and blast injury and auditory dysfunction; her research focuses on mild TBI and auditory rehabilitation, and tinnitus self-management. Grant Searchfield, PhD, is a senior lecturer at the University of Auckland, New Zealand, and director of the university’s Hearing and Tinnitus clinic.

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