1. What are the most significant scientific discoveries in hearing and balance, taste and smell, and voice, speech, and language that have occurred in the past five years? (Please provide references to scientific journal articles, if applicable.)

Background

Subjective tinnitus is an unbearable condition resulting from the perception of sound when no external noise is present. The sound may be constant or intermittent and described as tonal, hissing, chirping or buzzing. Tinnitus is not a disease in and of itself but is regarded as a symptom associated with an array of other health conditions, the most common being hearing loss.

Demographics

The prevalence of tinnitus is staggering. Previous estimates from the United States Center for Disease Control report that 15% of Americans, over 50 million people, currently experience some form of the incurable condition. According to information, derived from the 2011-2012 National Health and Nutrition Survey and found on the American Tinnitus Association website, roughly 20 million Americans struggle with chronic burdensome tinnitus, while 2 million have extreme, debilitating cases.

In practice, the severity of the affliction varies on a case-by-case basis. The Tinnitus Practitioners Association claims that of the 50 million people with tinnitus only 15 million actively seek care, leaving some 35 of the 50 million to habituate without any care. This also suggests there are many missed opportunities for education about tinnitus including the prevention of further hearing loss.

Active military personnel and veterans, senior citizens, musicians and music lovers, motorsports and hunting enthusiasts and persons employed in loud work environments are among the groups most at risk for developing hearing loss and tinnitus. Comorbidities such as hypertension, diabetes and smoking status also put an individual at higher risk.

Etiology and Severity

The etiology of tinnitus is heterogenous. Not everyone with hearing loss develops tinnitus and not everyone who experiences tinnitus has significant hearing loss or hearing loss measured by the audiometric testing currently used in most practices. It is thought that hidden hearing loss, caused by synaptopathy, may be present in these individuals.

Those of us with tinnitus view it as occurring on a spectrum of severity. Individuals with less severe symptoms may not be bothered by tinnitus and may live near normal lives. However, as severity increases, tinnitus can become bothersome, more intrusive and even reach a debilitating point.

Impact

Tinnitus has social impacts and it adversely affects an individual’s quality of life. Painful hyperacusis that accompanies tinnitus for some, adds to the burden of tinnitus. Having tinnitus can lead to loss of relationships and livelihood resulting in isolation and loneliness. Depression and anxiety often accompany tinnitus and suicidal thoughts are significantly more common among people with tinnitus than among the general population (Szibor et al., Tinnitus and suicide: An unresolved relation. Audiol Res. 2019 May 6; 9(1): 222).

Tinnitus has a financial impact on the severely affected individual who can no longer work, but it also impacts society as well. In 2012, the Veterans Administration reportedly spent $1.2 billion on tinnitus related compensation and this was expected to exceed $3 billion by 2017 (American Tinnitus Association, Treating and Curing Tinnitus is Part of Our National Commitment to Veterans. May 22, 2014).
Treatment

Currently, there is no medical treatment or cure for tinnitus but it is a big problem and merits more attention and time.

Tinnitus Hub/Tinnitus Talk

In 2015, Tinnitus Hub was formed by Markku Vesala as a non-profit with a charitable mission. In 2017, Hazel Goedhart joined as Director and Chief Strategist. Together with these individuals, we are a patient group in the true sense of the word.

As an all-volunteer organization run for and by people with tinnitus, we strive to contribute to significant improvements in the lives of tinnitus patients. We do this by providing an online forum, known as “Tinnitus Talk”, where people with tinnitus can come together to support one another. There are more than 27,000 registered members on TinnitusTalk.com, 50-60% of whom are Americans. In 2018, there were more than 5,000,000 unique visitors to the site.

The Tinnitus Talk Podcast series with over 50,000 listeners and our Video series with over 1,000,000 views serve to educate patients and practitioners. We put patients in contact with researchers and are currently developing new initiatives that will enable us to interact with researchers during the early phases of their projects. We also work together with other tinnitus organizations and charities to promote public awareness and further research into a cure for tinnitus.

Significant Scientific Discoveries in the Field of Tinnitus Research

The earliest recorded reports of tinnitus date back to the time of the Egyptians. Although advances have been made towards understanding chronic subjective tinnitus, there have been no significant discoveries or breakthroughs that have led to an effective treatment or a cure.

Pathophysiology

The recognition that chronic tinnitus may reside in the brain was only realized in the 1990s when severing the cochlear branch of the vestibulocochlear nerve caused deafness for some but failed to silence their tinnitus. Up to that point in time, tinnitus was thought to reside exclusively in the ear. There are theories and models of tinnitus too numerous to mention here, but the actual pathophysiology, including the mechanisms that trigger and those that make it chronic, largely remain unknown and unexplained.

Habituation Therapies

Leading therapies available to tinnitus patients include sound therapies (e.g. masking, TRT), psychological therapies (e.g. CBT, PTM, mindfulness exercises), and sound amplification devices (e.g. hearing aids). Only the lattermost therapy attempts to address one common health condition associated with tinnitus by restoring some level of auditory function. The primary aims of masking and TRT are to reduce tinnitus-associated distress by layering a support sound along with the tinnitus in an attempt to acclimate the mind to its new reality (habituation). Some patients do not respond to such strategies, because the frequency, intensity and/or volume of their tinnitus is simply too intrusive to effectively reframe their noises as “the new normal.” CBT, PTM and mindfulness exercises also aim to reduce tinnitus distress, but have no effect on the actual tinnitus precept. Other therapies available to tinnitus patients involve highly experimental, variable and invasive techniques such as transcranial magnetic stimulation, vagus nerve stimulation and deep-brain stimulation. None of these approaches have provided consistent evidence for their effective treatment of tinnitus.
Neuromodulation

The lack of efficacy concerning the above-mentioned therapies have led researchers down different paths, some of which are based on the science of neuromodulation (e.g. bimodal stimulation). Bimodal stimulation is an emerging approach for driving neuroplasticity and altering neurons within the auditory system. This technique uses acoustic stimulation delivered to the ear, as in sound therapy, combined with somatosensory input to the brain thru electrical stimulation of some fibers of the Vagus or Trigeminal nerves. Experiments in rodent models have shown that the combination of sound and electrical stimulation can drive changes across the auditory system up to the midbrain and cortex that could potentially treat tinnitus (Marks KL, Martel DT, Wu C. Auditory-somatosensory bimodal stimulation desynchronizes brain circuitry to reduce tinnitus in guinea pigs and humans Sci Transl Med 2018 Jan 3;10(422).

A marketed device that delivers this bimodal form of treatment, Lenire™, is available in Ireland from the medical device company, Neuromod. This device is intended for a subset of those with tinnitus since a patient’s hearing loss can preclude successful delivery of the auditory component of the therapy. Other exclusions apply as well. Clinical trials of the device have been completed however, the results of the pivotal study have not yet been made public. In addition, Tinnitus Hub with validation from academic researchers, has undertaken a user group study, the results of which will be available in April 2020.

Dr. Susan Shore of the University of Michigan has been working on a bi-modal stimulation device for the specific treatment of tinnitus for the better part of two decades. Results from the phase one trial were promising and the project moved into Phase 2 testing which is expected to finish in summer 2020. (Marks, K.L., Martel, D.T., Wu, C., Basura, G.J., Roberts, L.E., Schwartz-Leyzac, K.C., Shore, S.E. (2018). Auditory-somatosensory bimodal stimulation desynchronizes brain circuitry to reduce tinnitus in guinea pigs and humans. Science Translational Medicine, 10(422). Retrieved from https://stm.sciencemag.org/content/10/422/eaal3175 )

Regenerative Medicine

While hearing loss has never been shown to be the direct trigger or cause of tinnitus, there is a strong association between hearing loss and tinnitus. To the extent that hearing loss causes tinnitus, it is hoped that restoring hearing through hair cell regeneration, repair of synapses or treating cochlear synaptopathy responsible for hidden hearing loss, will also work to improve or quiet tinnitus altogether.

The US FDA has granted FX-322 (Frequency Therapeutics) fast track status for the treatment of sensorineural hearing loss. Even more encouraging for the tinnitus community is that Frequency Therapeutics has added a tinnitus experimental arm to their Phase 2 study with results expected late Q3, 2020.

Hough Ear Institute has found a commercial partner for its free radical scavenger HPN-07. This drug helps to repair nerve synapses and has been shown to be safe in Phase 1 testing.

Two drugs are in test for the treatment of cochlear synaptopathy. The first is OTO-413 (Otonomy, Inc) and the second is PIPE-505 (Pipeline Therapeutics). Both of these drugs are in Phase 1/2 clinical trials with results expected in late 2020.

A Drug to Treat Tinnitus

In 2018, Professor Thanos Tzounopoulos at the University of Pittsburgh received a $2 million grant from the US Department of Defense to develop the drug RL-81. The structure of this drug is based on a molecular redesign of the epilepsy drug, retigabine/ezogabine. Retagabine is a neuronal potassium channel opener that activates a certain family of voltage-gated potassium channels in the brain. There had been anecdotal reports that using retigabine provides relief from tinnitus however, retigabine was withdrawn from the market because of a host of problematic side effects.
Knopp Biosciences is also developing a drug, KB-3061, for epilepsy. KB-3061 modulates the same receptors as retigabine and RL-81. Knopp has listed tinnitus as a potentially applicable condition for treatment with KB-3061.

In Conclusion

Members of Tinnitus Talk closely follow the activity of these companies and academics. Considering there is no medical treatment, we are eager to know if restoring hearing loss will silence tinnitus and if the drugs and other devices will provide any relief.

Unfortunately, because so little is known about the mechanisms create tinnitus, it is difficult to predict the technical or clinical success of treatments with any level of certainty. This is a situation we would like to see changed by having more government funded research allocated to understanding the pathophysiology of tinnitus.

2. What are the unmet needs in current research and training that may impact hearing and balance, taste and smell, and voice, speech and language?

Hearing Loss and Tinnitus

Hearing loss is one of the most common forms of sensory deficits in people, affecting about 37 million Americans, according to federal statistics. Hearing regeneration, whether it be the regeneration of hair cells or in the auditory nerve itself, is an active area of medical research that is moving forward at a steady pace.

Some believe tinnitus of cochlear origin may represent the majority of cases of tinnitus. Although there is a strong relationship between hearing loss and tinnitus, it has never been proven to be causal. Nonetheless, given the strong relationship, the question of whether hearing restoration will silence tinnitus a logical one.

Not all people with hearing loss develop tinnitus and not everyone with tinnitus has significant hearing loss that can be measured within the range of common audiometric equipment used in practice. In addition, tinnitus is thought to occur, in part, as a result of neuroplastic adaptations in the brain and it is unknown whether these are reversible changes. So, it remains to be seen if regenerative medicine is the answer for people with tinnitus.

Clinicians and researchers also theorize that damage occurring in the periphery (cochlea) or anywhere along the central auditory pathway can cause tinnitus. Portions of the brain outside the central auditory pathway may also be involved.

The pathophysiology of tinnitus is extremely complex in nature, and to date we have very few scholarly studies, imaging studies, and biomarkers by which we can appropriately capture an objective picture of tinnitus. This is one of the greatest unmet needs in tinnitus research.

Management Strategies and Need for a Cure

As tinnitus patients, we have a very strong desire for a cure. This is because therapies that have been made available thus far really fall into the category of management strategies intended to help us cope and habituate to the condition. Unfortunately, these do nothing to mitigate, heal or repair the damage responsible for triggering and maintaining chronic tinnitus. There is little to no change in the tinnitus precept resulting from management therapies so, the problem remains along with the anxiety provoking potential that tinnitus may worsen.

Tinnitus is a common medical condition, yet many aspects of it remain medically unaddressed. Tinnitus patients are burdened, struggling, distressed and even devastated by it. We have already talked about its major impacts in Question 1.
Scams

Tinnitus sufferers are desperate for relief. Companies and individuals are profiting from this desperation with products that promise relief or even a cure. These products, based on pseudoscience and quackery, are able to remain on the market because of the state of FDA regulation of dietary supplements. Despite education efforts and warning from their fellow suffers, people seeking relief from tinnitus, are lured into purchasing these products only to find they are ineffective.

Does Tinnitus Get Better?

Tinnitus associations have been known to promote the message that tinnitus gets. Presumably they intend this to mean that people with tinnitus eventually learn to cope and habituate. However, Tinnitus Talk members (Dave’s Tinnitus Story found at youtube.com/watch?v=skn3Cqn3k3g) and people with tinnitus whose personal stories are published (Anthony Mennella, Tinnitus Today 44(3):26 Winter 2019), say that with time, tinnitus worsens.

AAO Clinical Practice Guidelines

There is a disconnect between what clinicians and patients consider a treatment success. While clinicians see less distress as a successful outcome of therapy, patients are dissatisfied and desire complete eradication of the noise. (McFerran DJ, Stockdale D, Holme R. et al. Why is There No Cure For Tinnitus Front. Neurosci 06 Aug 2019)

Tinnitus patients bothered by tinnitus seek out medical treatment only to be offered little to no meaningful help by their physician. Clinical guidelines provide recommendations for and against various treatment options, including education and counseling, sound therapy, cognitive behavioral therapy, medications, dietary supplementation and acupuncture.

But a careful read of the AAO guidelines suggests almost nothing, except CBT, sound therapy and a hearing assessment, can be recommended for chronic tinnitus patients. (Patients who are depressed or suicidal are referred immediately for treatment of those conditions.) This is due to lack of supportive evidence for the use of the treatments considered. Ironically, tinnitus is not a psychological condition yet, psychological therapy is the one most frequently used to lessen tinnitus distress. (www.tinnitus.org.uk/is-tinnitus-a-psychological-condition Author: Dr William Sedley, Academic Clinical Lecturer in Neurology, Newcastle University, Published: 27 September 2019)

One of the first questions tinnitus patients often ask their physician is “will this get worse?” Tinnitus patients do not receive a prognosis because there are no studies and little information about the natural history or pathophysiology of the condition that can be shared.

Not all physicians and medical personnel even follow the 2014 American Academy of Otolaryngology-Head and Neck Surgery Foundation clinical practice guidelines for tinnitus, so many patients are not offered the basics like sound therapy or CBT and are not referred for a hearing test (Bhatt JM, Lin HW, Bhattacharyya N, JAMA Otolaryngol Head Neck Surg 2016:142(10):959-965).

There have been reports within tinnitus communities that some physicians have suggested branded supplements for relief from tinnitus. Could it be that even physicians are becoming frustrated with the lack of medical treatment they can offer to their tinnitus patients?

Many of us have experienced clinicians who fail to recognize tinnitus as a consequence of sudden sensorineural hearing loss—a medical emergency that must be swiftly treated with steroids, whether they be intratympanic (e.g. dexamethasone) or systemic (e.g. prednisone) in nature. Clinicians who advise the sufferer to simply “learn to live with it,” or that tinnitus is “just a harmless noise,” often contend that it is instead the patients’ reaction to the noise that is the foremost problem. This perpetuates the ignorance of the need for appropriate medical intervention and complacency towards curative research. Instead of receiving support from the medical community, the tinnitus sufferer is often made to feel at fault for not being able to habituate.
As discussed previously, millions of sufferers remain underserved by the traditional approaches afforded by the medical community to cope with their condition. In fact, many of whom could deem themselves successfully “habituated” still contend that they would sacrifice much for significant diminishing or complete abolition of their condition. This is one example of why an effective treatment for the precept or cures would greatly improve the quality of life of everyone with tinnitus and be of great benefit to society.

The Need for Coordination, Oversight and Research Funding

In our answer to question 1 we stated that there have been no real breakthroughs or discoveries in tinnitus research. Why? As tinnitus patients we feel frustration and impatience; why isn’t there a cure, why don’t we understand more, why are we not hearing of breakthroughs and feeling hope, where is the funding?

Funding is needed and there is a need for coordination and oversight of research. As patients and members of Tinnitus Hub/Talk we have the impression that tinnitus research has been inconsistent. (“Hold Out Hope” Dr. Tanisha Hammill Talks to Prof Deb Hall, BTA Website). In addition, tinnitus is perceived as being an unimportant condition and when interdisciplinary research proposals don’t fit into just one particular institute at the NIH, they go unfunded. (Tinnitus Talk Podcast Episode 1 “In Search of a Tinnitus Cure” Prof Josef Rauschecker, January 25, 2019). Researchers themselves recognize that treatments are tried before being grounded in science. One researcher described it as “a fishing expedition”. This same researcher acknowledged the need for researchers from related fields to come together and share perspectives on the science. (Dr. Susan Shore, youtube.com/watch?v=dWtcmVgGc)

We believe these perceptions have resulted, in part, from federal agencies, both the NIH and the DoD, underfunding tinnitus research such that researchers and university funders now neglect it as well. Take for example the number of papers published on tinnitus compared to depression. A PubMed search of the term ‘Depression’, which often coexists with tinnitus, was made on February 23, 2020, and returned a listing of 432,104 entries in the database. By comparison, a search of the term ‘Tinnitus’ on the same day, returned a list of only 13,131 entries in the database.

NIH is not the only agency that needs to increase funding for tinnitus research. Veterans are a group at high risk for developing hearing loss and tinnitus. In 2012, the Veterans Administration paid out $1.2 billion in tinnitus related compensation and this was expected to exceed $3 billion by 2017. In 2018 defense spending amounted to approximately $700 billion. Yet in 2018, only one of 73 hearing research programs was provided grant money by the Department of Defense. And we are aware of only one tinnitus research center that is was funded by the Department of Defense beginning in 2019. By comparison the amount of the grants for hearing and tinnitus research amounted to $4 million, not even a drop in the bucket.

Tinnitus organizations cannot fund all levels of research. The American Tinnitus Association has a very small research budget that is used to support seed grants and student research. Money for this research comes to the ATA directly or indirectly from the tinnitus community and private citizens through membership dues and donations.

According to information found on its website, since 1980 the ATA allocated over $6 million to advance tinnitus research. This translates to $150,000 per year, which is nothing in comparison to what the government can and should spend to support tinnitus research.

The Need for Patient Involvement in Research

To date, most tinnitus research has not been explicitly driven by the needs of tinnitus patients. There is a clear disconnect between what patients expect from research and what researchers are focusing on. This can be remedied by involving patients directly in research, through so-called Citizen Science. Patients should be called on to help define research priorities, research questions, design studies, and analyze data.

In Conclusion

People with tinnitus have a strong desire for a cure and there are strong reasons for that being the case.

However, the causes of tinnitus are heterogeneous, everyone’s tinnitus is different. There are likely to be tinnitus subtypes and a universal cure is not likely to be found.
Tinnitus associations are small organizations which cannot provide the large sums needed for tinnitus research.

Given the high incidence of tinnitus among the active and veteran military populations and the large amounts the VA pays for tinnitus related compensation, the Department of Defense needs to consider increasing its contribution to funding as well.

NIDCD and NIH should understand that there is a dire need for effective tinnitus treatments and ultimately cures both from a patient perspective and a healthcare professional perspective. Tinnitus has been largely ignored and that has to come to an end.

Lastly, history would suggest that the tinnitus research needs to be coordinated and progress monitored. Collaboration between researchers, and with patients, must be emphasized and researchers should be held accountable for deliverables.

3. Describe the opportunities in hearing and balance, taste and smell, and voice, speech, and language that may be realized in the next five years.

Tinnitus is heterogeneous in its etiology. And since it is an invisible condition and heard only by the afflicted person, one individual’s experience may be different than the next. The sense, among researchers, the American and British Tinnitus Associations and the patient community, is that tinnitus subtypes exist and personalized treatments and more than a single cure will be needed.

How do we make progress and how do we get there?

Improve Transparency, Determine Where Progress is Being Made, Commit to a Timeframe

As patients we are shown pictures on Facebook and we hear of research activity such as attendance at scientific meetings, networking events, round table discussions, reports in tinnitus magazines. In many, but not all, instances it’s not obvious or clear that the activity or the researchers are aligned with a common goal of finding a cure. And, as of now, no one is willing to commit to any sort of timeframe. (Video, Impressions of Tinnitus Research found at youtube.com/watch?v=ywDVcg54Dr0)

Identify Who Is Responsible For Putting A Plan In Place

Tinnitus is a complex neurological condition that requires interdisciplinary research. Although research organizations exist, we know of no organizational structure with steering committees and subcommittees responsible for creating and driving a research agenda or for driving needed change in the way tinnitus research is structured.

Understand the Pathophysiology of Tinnitus

There are no plans, that we are aware of, to focus attention on achieving a basic understanding of the pathophysiology of tinnitus. If these mechanisms were better understood, therapeutic targets could be identified which would lead to development of pharmacologic or other therapeutic approaches to address the condition. Having a few young, eager and motivated students is a good start (Onozuka J, Tinnitus Today. 44(3):19 Winter 2019), but it’s not enough. The field needs more researchers, including senior and experienced ones, willing to work in the area of tinnitus research.

It’s not clear that there are enough researchers with the proper backgrounds and training for multidisciplinary tinnitus research, nor is it clear that there is enough government funding to attract senior talent or to train young investigators in the United States to carry on this important work.
Unite Globally

Tinnitus and suffering occur worldwide. For the sake of efficiency, tinnitus researchers need to be united globally around a common plan based on a clear research agenda. Knowledge gaps need to be identified and plans made to fill them.

Research Opportunities

There are many, many opportunities in tinnitus research. In addition to the need for more funding and a clear plan, an objective measure of tinnitus is needed to move research forward.

Other opportunities include updating information on tinnitus prevalence and impact in the United States and globally, subtyping tinnitus, biomarkers of tinnitus, consensus on appropriate animal models and, importantly, studies designed to give integrated insight into the neurological pathophysiology of tinnitus on the system, tissue, cellular and molecular levels. At some point during the research, therapeutic targets will be identified and understood at the molecular level so that treatments can be made specific and with minimal side effects.

Any of the challenges and obstacles to progress we discuss in Question 4, can become an opportunity in the field of tinnitus research.

Watch the Regenerative Medicine Space

Research to restore hearing loss seems to be an exception to the current state of tinnitus research. Regenerative medicine is a very active field of research and is advancing rapidly. There are drugs slated for testing in clinical trials: FX-322 from Frequency Therapeutics intended to regenerate hair cells in the cochlea, HPN-07 from Hough Ear Institute, a free radical scavenger intended to repair lost synapses, OTO-413 from Otonomy, Inc., intended to repair ribbon synapses, PIPE-505 from Pipeline Therapeutics intended to regenerate cochlear synapses and KB-3061 from Knopp Biosciences that is aimed to modulate KV7 potassium channels.

Researchers working in the field of regenerative medicine for hearing loss speculate that restoration and repair of damaged hair cells and synapses associated with sensorineural and hidden hearing loss will help alleviate tinnitus. To the extent that an individual’s tinnitus is caused by cochlear damage, this may be true. It seems very possible that this question will be answered within the next five years.

4. What are the greatest challenges or barriers to progress in hearing and balance, taste and smell, or voice, speech, and language?

A recent scientific publication entitled “Why Is There No Cure for Tinnitus?” addresses this question in detail. The article is available open-access and can be found at frontiersin.org/articles/10.3389/fnms.2019.00802/full. We will attempt to summarize the key issues, but strongly encourage the reader to spend some time understanding the full publication and the points it conveys.

In the article, the CEO and one board member of the British Tinnitus Association along with others from industry and academia discuss the reasons that explain why there is no cure for tinnitus. Before beginning the discussion, the authors establish that there are patient and economic pressures to find a cure. However, interest in tinnitus and the output of tinnitus research pale in comparison to other conditions such as chronic pain, depression, anxiety and hearing loss.

The authors then go onto discuss the obstacles to a cure seen as a series of impediments that include:

- NIH funding allocated to tinnitus and hearing loss is nearly non-existent compared to funding for research into other conditions with a similar socio-economic burden; diabetes is given as an example.
And, despite hearing loss being identified as the 4th leading cause of years lived with a disability NIH funding still remains low.

- Tinnitus research is by nature multidisciplinary, yet there are very few research centers where cross-specialty expertise is available.
- Unclear tinnitus prevalence. Differences in study population and study design have yielded a range of tinnitus prevalence, making it difficult for pharmaceutical companies to estimate need.
- Ambiguous tinnitus definitions and subtyping;
- Homogeneous vs heterogeneous clinical trial populations and trial design;
- Lack of objective tinnitus measures and biomarkers;
- Multiple proposed theories of tinnitus pathophysiology;
- Animal models of tinnitus. Treatments that have been tested successfully in animals, fail in humans;
- Timing. There may be differences in therapeutic targets, depending on the acute versus chronic stage of tinnitus;
- Lack of agreement on outcome measures or measures of success for new treatments, e.g. reduction in distress versus reduction of tinnitus volume;
- Regulatory pathway and hurdles are not established.

To patients, such a list indicates that researchers have been somewhat undisciplined in their approach to tinnitus research. They have not been researching for a cure, but researching for the sake of doing interesting research. Take, for example, the fact that there is no objective measure of tinnitus or biomarkers and this has now become an impediment to finding a cure. The need for and the advantages of objective measures and biomarkers has long been known in any field of research, so why has the tinnitus research community not recognized and addressed this need long ago???

The paper goes onto mention the need for step change to deliver progress towards truly effective treatments. The authors call for building blocks to be put in place that include biomarkers, robust outcome measures, and meaningful subtyping of clinical phenotypes. They point out that this work will need to be interdisciplinary and an international effort and there will be a need to engage researchers and clinicians along the whole of the translational research path.

Step change is not easy and it’s not clear from the paper how or when this will come to pass only that is clearly needed. The patient community agree and need NIDCD and NIH to not only becoming large funders of tinnitus research, but also to be patient advocates as well by insuring the goal is a cure, a plan is identified, the right talent is in place, researchers are aligned with the plan and held accountable to the plan and its deliverables.

Many tinnitus patients have little-to-no identifiable hearing loss by current audiometrical standards (250hz-8khz). As many tinnitus and hearing loss sufferers know, the human ear is capable of hearing up to 20khz. Because of archaic audiometric standards, ultra-high frequencies where meaningful speech information may be derived often go unmeasured--and as such, potential hearing loss goes undetected. We contend that routine use of extended audiometry should be made the national standard. Further, we stress that hearing symmetry--that is, the difference of hearing sensitivity between ears, should be considered of medical importance.

Because tinnitus patients’ mild or “non-existent” hearing loss do not make them candidates for hearing aids (which only amplify sound within 8khz), they are often not considered candidates for medical trials. Of the 27,000+ members of Tinnitus Talk, seldom are any members admitted to clinical trials of potential vital importance. We advocate for better representation of tinnitus sufferers in clinical trials.

There has long been a disparity between how clinicians and patients measure “success.” Clinicians often consider the patients’ return-to-work and modest improvements in well-being as their form of success. As sufferers, we know that this definition of success is entirely a function of current leading researchers’
conclusions that tinnitus *distress* is the problem, and not the presence of the tinnitus itself. Now that we are in what seems to be a new era of medicine, this line of thinking will be rightfully outmoded along with psychological therapies that solely address issues proven secondary to the presence of tinnitus.

5. **What is the greatest public health need of individuals with disorders of hearing and balance, taste and smell, or voice, speech, and language that may be helped with additional research?**

Apart from the need for a cure (as discussed at length in previous answers), the need to raise awareness to tinnitus is often discussed among members of the tinnitus community. In fact, there is an entire section of the Tinnitus Talk forum devoted to the topic and it is also discussed among members of tinnitus support groups on Facebook. Many members say they were never told about tinnitus and really only learned about it when they developed it.

Raising public awareness to tinnitus is important. It is an invisible condition which makes its potential severity difficult to understand. People with tinnitus have long held the belief that someone without tinnitus can never really understand what it’s like to have the condition.

Members of our tinnitus community consider tinnitus to occur on a spectrum of severity. There are some who are not so severely affected and they can get on with their lives. These are often the tinnitus patients we see portrayed in awareness videos. It raises the impression among some in the tinnitus community that the condition is being downplayed. The devastation that can be tinnitus is never spoken of, which gives false hope and the impression that it’s OK to skip hearing protection not really necessary to take preventative measures to avoid hearing loss since everyone in the videos lives happily ever after.

Can tinnitus be prevented? Although cause and effect has not been proven, given the strong association between hearing loss and tinnitus, prevention of hearing loss seems to be the best way preventing tinnitus. From a public health perspective hearing protection gets very little attention. Our schools could do a better job of teaching it and enforcing it. Our communities could do a better job of identifying problem areas such as loud restaurants, concerts, firework displays and festivals and recommending lower noise levels and hearing protection.

Our primary care physicians could do a better job advising patients of the possible ototoxic side effects of some medications as well as recommending a periodic hearing assessment. Audiologists could do a better job setting the interval between hearing assessment and promoting the steps needed to prevent hearing loss *and* tinnitus within their local communities.

The other public health issue that is frequently discussed by people with tinnitus are safe noise levels for people with tinnitus. Given the link between noise exposure related hearing loss and tinnitus, and noise exposure with no hearing loss and tinnitus (presumed to be hidden hearing loss), it is widely recognized that there is a strong correlation between noise exposure and the onset or worsening of tinnitus. Nonetheless, there are many unanswered questions relating to the mechanism of tinnitus, hence it is our understanding that there is no clear consensus as to what is a safe level of noise exposure and for what duration for a person with tinnitus.

How would any healthcare professional be able to offer patients advice on noise safety levels in the absence of specific guidelines for tinnitus patients?
The perception amongst many of our members, for example, is that there should be lower noise safety levels recommendations for the tinnitus population and, in the absence of clear guidance on the matter, we find that many of our members tend to avoid noisy situations, which can result in the following:

- Isolation and withdrawal from social situations, which are perceived to be loud but that would not fall under the category of concerts, nightclubs and bars (such as cinemas, pubs, restaurants, churches playgrounds).
- Difficulty in implementing CBT and audiologist counselling techniques aiming to restore normal day to day living and to encourage the patient to fully engage in life.
- Possible development of sound intolerance - hyperacusis.

Additionally, there is a perception that sudden loud noises, such as sirens or even balloons popping can cause an increase in tinnitus intrusiveness due to acoustic shock, which leads many to wear hearing protection for a lot of the time, against healthcare professionals’ advice.