CLINICAL INVESTIGATION

Identifying and prioritizing unmet research questions for people with tinnitus: the James Lind Alliance Tinnitus Priority Setting Partnership

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Tinnitus represents a major burden of disability, yet there is scant evidence for effective management strategies and a lack of clinical trials to formally test even some of the most commonly used drugs and medical devices. The James Lind Alliance gives a voice to patients and clinicians to identify and prioritize important clinical research questions concerning treatment uncertainties. This article describes the initiative conducted by the Tinnitus Priority Setting Partnership; how it was set up, what the consultation process was, and how the top ten research priorities were identified. For each priority, we recommend a research strategy; either calling for a systematic review or appropriate clinical study. We promote these as topics for commissioned research and as priority areas to encourage researcher-led funding applications.

Keywords: assessment • clinical trials • diagnosis • James Lind Alliance • research • tinnitus • treatment

Tinnitus describes a ringing or hissing sound that is perceived in the ears or head, without an identifiable physical noise source. It remains one of the most common chronic hearing-related conditions in the western world with a prevalence of 10.2% in the total adult population, rising to 14.2% in those aged over 50 years of age [1]. There are no effective cures for the condition, with current treatments targeting the symptoms of tinnitus (either the effects of the condition on emotions and mood or associated hearing loss), or seeking to reduce the persons' awareness of the tinnitus sound. A majority of treatments have little or no evidence for their efficacy [2,101]. The heterogeneity of tinnitus with respect to its etiology, pathophysiology and clinical characteristics most likely exacerbates the variable individual response to tinnitus management [2–4].

Clinical research is traditionally led by scientists, clinical professionals or commercial interest and the government and charity research agendas are somewhat biased towards underpinning research and etiology (69% of total spend), with only 8% spent on evaluating treatments and therapeutic interventions [102]. To make best use of the government increase in support for clinical research, Chalmers and Glasziou, among others, have argued strongly for a more efficient research culture in which scientists study health conditions that are not only the greatest burden on the population, but also address questions about interventions and outcomes that patients and clinicians consider to be the most important [5]. This argument is highly relevant to the field of tinnitus research, which is rather patchy in terms of which key questions are driving current research programs, with considerable focus on animal models and underpinning neurophysiological mechanisms.

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Patient and public involvement has become an important theme in health and social care research. In particular, a recent UK Clinical Research Collaboration report identifies evidence for a role in making research more relevant and appropriate for users [6]. The James Lind Alliance (JLA) supports the growing role for patients, the public and clinicians in research activity in the form of Priority Setting Partnerships (PSPs) (Table 1) [103]. The purpose of this article is to describe the Tinnitus PSP in providing a platform for patients and clinicians to collaborate to identify and prioritize uncertainties or 'unanswered questions' that they agree are the most important supporting clinical research.

The JLA

The JLA was established in 2004 in the UK. It is an independent, not-for-profit initiative that is principally funded by the National Institute for Health Research (NIHR). The JLA aims to raise awareness among those who fund health research about what matters to both patients and clinicians, so that clinical research is relevant and beneficial to end users. The process starts off by defining unanswered questions about the effects of treatment - questions that cannot be adequately answered by existing research evidence, such as a reliable, up-to-date systematic reviews - and then prioritzes them according to which are the most important. The JLA provides independent facilitation and guidance to the process of identification and prioritization. This input significantly increases the effectiveness of the PSP and the Steering Group in ensuring credible and useful outcomes.

The partnership between the British Thoracic Society and Asthma UK was the first formal PSP to complete the JLA process [7]. There have since been eight further completed PSPs, with the Ear, Nose and Throat specialty contributing two completed partnerships (balance and tinnitus).

Establishing a working partnership

The JLA Tinnitus partnership began in October 2011. Its founders were the British Tinnitus Association (BTA) - the only UK-based charity dedicated to supporting people with tinnitus and funding research in this field - the NIHR Nottingham Hearing Biomedical Research Unit and the Judi Meadows Memorial Fund. The Steering Group was key to the success of the project. Its role was to oversee and drive the progress of categorizing and prioritizing identified tinnitus uncertainties. Membership of the Steering Group provided a broad representation of people from the field of tinnitus in the UK, including professional bodies, charities and advocators for people with tinnitus. The wider working partnership included 56 major UK stakeholders including individual advocators for people with tinnitus, support groups, hospital centers and commercial organizations.

Gathering suggestions for research on the assessment, diagnosis & treatment of tinnitus

A questionnaire was used to gather suggestions for clinical research from as many representatives of people with tinnitus, clinicians and scientists as possible. The survey was publicized at the London (UK) launch meeting in December 2011 and widely disseminated through our working partnership and on the BTA [104] and JLA [105] websites. The BTA played a major role in dissemination by posting the questionnaire in their members' magazine (*Quiet*, Winter 2011) with a circulation of 4500. Over a 2.5-month period, an incredible 2483 responses were submitted by 835 people (Figure 1).

Checking & categorizing submitted uncertainties

The purpose of collation was to reduce the initial list to a shorter one that would go forward to the prioritization

Table 1. Steering Group of the James Lind Alliance Tinnitus Priority Setting Partnership.					
Steering Group members	Role				
Lester Firkins	Independent chairperson, representing James Lind Alliance				
David Stockdale and Emily Broomhead	Representing British Tinnitus Association				
Deborah Hall and Najibah Mohamad	Representing NIHR Nottingham Hearing Biomedical Research Unit				
Tim Husband	Clinician representing British Society of Audiology				
Don McFerran	Clinician representing ENT UK				
Christopher Dowrick	Clinician and person with tinnitus representing general practitioners				
Emma Harrison	Person with tinnitus and representative for Action on Hearing Loss				
Philip Nash	Person with tinnitus				
Mark Fenton	Representing UK Database of Uncertainties about the Effects of Treatments, NICE				
ENT UK: Ear, Nose and Throat UK; NIHR: National Institute for Health Research.					

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Public consultation and data analysis Steering group contributions 2483 suggestions for research received Design and dissemination Consultation Respondents: 638 tinnitus sufferers; of the questionnaire to harvest 741 responses removed that 159 clinicians; 28 unknown uncertainties about tinnitus were 'void' (n = 28) or outside Mode of response: 131 postal; assessment, diagnosis and treatment 697 website; seven e-mail the scope (n = 713)Reach consensus on which responses were outside the scope of the survey Multiple uncertainties within one 1760 suggestions for research response were split into separate Responses were structured into questions (58 respondents) Uncertainties duplicated by the same 46 themes using thematic analysis Thematic analysis led by Hall and individual were minimized Mohamad with colleagues from NIHR (29 respondents) Nottingham Hearing BRU 397 edited uncertainties following Approve the thematic structure pooling responses relating to the same uncertainty Information gathered about how Approve the pooling process and many people contributed to each item ensure edited uncertainties were Collation written in 'PICO' format and lay terms, Seven 'uncertainties' were removed due to sufficient reliable evidence to seeking external opinion from answer them audiologist 390 'true' uncertainties 220 uncertainties were set aside due 170 uncertainties in 36 themes, Design and dissemination of the to ≤ two individuals submitting them each submitted by > two people questionnaire for ranking Weighting process led by Stockdale, Ranking of personal 'top tens' with colleagues from British Tinnitus Respondents: 550 tinnitus sufferers; Association, and approved by Steering nine patient representatives; 71 clinicians Group Mode of response: postal 153; e-mail 477 Scores weighted so that both groups Reviewed the list of ranks and agreed a consensus on 25 to go forward to contributed equal weighting to scores the priority setting workshop 40 uncertainties selected 130 uncertainties set aside due Prioritization to lower ranking Ten uncertainties about assessment, diagnosis and treatment chosen during the priority setting workshop. Attendees: Nine patient representatives, nine clinicians, three facilitators, five observers

Figure 1. The key steps within the stages of consultation, collation and prioritization, with contributions from the Steering Group. The final uncertainties edited into appropriate 'PICO' format. PICO describes the core elements of a well-formed clinical question: Patient, Intervention, Comparison and Outcome.

BRU: Biomedical research unit; NIHR: National Institute for Health Research; PICO: Patient, Intervention, Comparator and Outcome.

stage. Details of the process are given in Figure 1. Almost a third were removed either because there was no specific suggestion for research (classified as 'void', e.g., 'Can I have any information about your tinnitus survey?') or it was unrelated to the assessment, diagnosis and treatment of tinnitus. Qualitative research methods were used to identify, analyze and report themes within the remaining data [8]. The unprecedented number of submitted responses meant that this was one of the most time-consuming steps in the project. For each uncertainty, we required a consensus in thematic categorization across three independent raters, sought iterative input from the Steering Group and verified each uncertainty against published evidence such as the Cochrane Database of Systematic Reviews [106] and the Database of Abstracts of Reviews of Effects [107]. At the end of this process, in May 2012, we had generated a second questionnaire listing 170 distinct questions for tinnitus research spanning 36 themes.

Prioritizing the uncertainties

This questionnaire asked people to select and then rank their top ten personal 'most important uncertainties'. Again, the working partnership played a major role in distributing the questionnaire, with a hard copy being posted out with the Spring 2012 issue of the BTA's Quiet magazine. Over a 6-week period, 630 responses were received. Quantitative research methods were used to produce a final weighted rank for each uncertainty that gave equal significance to votes from members of the public and healthcare professionals. Considering this list of weighted ranks, the Steering Group agreed on a final set of 26 important uncertainties to be considered at the final prioritizing meeting. Although this final step was primarily an objective, quantitative process, the Steering Group promoted several questions on 'Cinderella' topics that members considered to be particularly under-represented in the tinnitus research field.

Developing consensus

The London priority setting workshop in July 2012 was the most exciting part of the project and the culmination of months of hard work. Its purpose was to agree on a 'top-ten' list of tinnitus uncertainties through facilitated discussion between equal numbers of patient representatives and clinicians. Extensive debates within two parallel groups containing a mixture of patients and clinicians generated independent ranked lists that were then pooled together to produce a combined version. This version initiated a second conversation amongst the whole group. Lively debate focused around a small number of questions that were particularly challenging for the group to reach a consensus.

Top ten clinical research questions

The final top ten demonstrate the breadth of research required to identify mechanisms and models of tinnitus, the need for a cure and the requirement to better understand and demonstrate the efficacy of existing treatments (Table 2, column 1). It is particularly reassuring to see questions focusing on minority issues such as pediatric tinnitus and Deaf people with tinnitus. Some of the underpinning evidence supporting each uncertainty is given in column 2, with particular emphasis on those studies outside of the Cochrane Collaboration.

Recommendations for future research strategy

In consultation with the Professional Advisors' Committee of the BTA, the Steering Group formulated ideas for future research strategies to address each uncertainty (Table 2, column 3). For so many questions there is a paucity of evidence and several of the questions in the top ten immediately lend themselves to systematic review, preferably within the Cochrane Collaboration since these are internationally recognized as the highest standard in evidence-based healthcare. The Steering Group strongly supports general improvements in methodology and reporting in clinical trials for tinnitus. These have historically been rather low in quality [2,3] and several authors have already called for methodological standards in tinnitus trials, such as developing standards for tinnitus and tinnitus-related quality of life outcome measures in clinical studies that appropriately separate the effects on tinnitus from other treatment-related improvements (generalized anxiety, depression, hearing loss and so forth) [2,4,9]. International guidelines for good clinical practice and reporting should also be used. For example, the CONSORT statement provides guidance for randomized controlled trials [108], but has rarely been adopted in tinnitus research.

Notable strengths & weaknesses

The high response rate from members of the public has enabled a voice that is rarely given an opportunity to input into tinnitus research. Anecdotal comments from a small number of basic scientists indicate some unease in this process, implying that 'patients might not sufficiently understand the condition to identify important and valid research questions'. Certainly the concept of a tinnitus uncertainty was challenging for some, with many responses being written as personal stories rather than specific questions for research. We would argue that those experiences are nevertheless extremely valuable and informative. The data management group, comprising members of the Steering Group, the JLA and the UK Database of Uncertainties about the Effects of Treatments (DUETs), used Patient, Intervention, Comparator and Outcome to identify active treatment components of the submission from the narrative text.

The implementation of the JLA Tinnitus PSP explored a novel cost-effective model involving minimal face-to-face contact with the JLA facilitator (at the launch and the priority setting workshop only) and a greater reliance on e-mail communication and teleconferencing between members of the Steering Group (five teleconferences, mostly at the collation and prioritization stages). The project was completed with a contribution of GB£6900 from the Judi Meadows Memorial Fund, with in-kind donations of staff time from the BTA and the NIHR Nottingham Hearing Biomedical Research Unit. Timescales for the project were negotiated within the partnership and carefully planned to minimize the overall duration of the project - just 11 months for the five stages of initiation, consultation, collation, prioritization and reporting. The collation stage was the most time-consuming and resource intensive because there was no way to have predicted the sheer volume of individual submissions. The Steering Group was also somewhat ill-prepared for submitting the uncertainties to the

Table 2. Top ten research suggestions identi	ified by the James Lind Allian	e Tinnitus Priority Setting Partnership.
Uncertainty in the diagnosis and assessment of treatment of tinnitus	Underpinning evidence	Suggested research strategy
What management strategies are more effective than a usual model of audiological care in improving outcomes for people with tinnitus?	Cochrane Database of Systematic Reviews [106]	Step 1 – Studies comparing effects of different management strategies in reducing the functional impact of subjective idiopathic tinnitus and improving quality of life Proceeding to Step 2 – timely systematic review of the evidence from clinical trials
Is CBT/psychological therapy, delivered by audiology professionals, effective for people with tinnitus? Here comparisons might be with usual audiological care or CBT delivered by a psychologist	Cochrane Database of Systematic Reviews [106] Hesser <i>et al.</i> [11] Cima <i>et al.</i> [11]	Step 1 – Studies evaluating CBT and/or other psychological counselling approaches delivered by appropriately trained audiology professionals
What management strategies are more effective for improving tinnitus-related insomnia than a usual model of care?	Cochrane Database of Systematic Reviews [106] McKenna and Daniel [12] Edinger <i>et al.</i> [13]	Step 1 – A study comparing the effects of different management strategies specifically aimed at improving sleep for patients with tinnitus and insomnia, including CBT as one arm of the research design
Do any of the various available complementary therapies provide improved outcome for people with tinnitus compared with a usual model of care?	Cochrane Database of Systematic Reviews [106] Park <i>et al.</i> [14] Meehan <i>et al.</i> [15]	Step 1 – Studies comparing different complementary therapies for improving functional outcomes for people with subjective idiopathic tinnitus and compared with the usual model of care. Studies should consider those complementary therapies that have been shown to be beneficial in treating other chronic health conditions Proceeding to Step 2 – Timely systematic review of the evidence from clinical trials
What type of digital hearing aid or amplification strategy provides the most effective tinnitus relief?	None found	Step 1 – Studies to determine whether digital hearing aids are effective in reducing the functional impact of subjective idiopathic tinnitus. Proceeding if necessary to Step 2 – Parallel activities comprising: i) Studies evaluating the effects of different amplification strategies for people with subjective idiopathic tinnitus ii) Studies evaluating the effects of different hearing-aid devices, including digital combination devices (hearing aid and sound masker) as one arm of the trial ii) Timely systematic review of the evidence from clinical trials
What is the optimal set of guidelines for assessing children with tinnitus?	Shetye and Kennedy [16] Savastano [17,18]	Step 1 – Parallel activities comprising: i) A systematic approach to gain consensus among a multidisciplinary panel of experts about the most appropriate assessment methods and diagnostic criteria for children with tinnitus ii) Development of an evidence-based algorithm/pathway to aid clinical diagnosis based on existing research iii) Development of a systematic form of national data collection from existing services to provide an evidence base that would inform development of guidelines
CBT: Cognitive Behavior Therapy.		

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e Tinnitus Priority Setting Partnership (cont.).	Suggested research strategy	Step 1 – Parallel activities comprising: Studies to evaluate the effects of non-audiological tinnitus interventions in reducing tinnitus symptoms for people with profound hearing loss and tinnitus A systematic review of the effects of multichannel intra-cochlear cochlear implants to suppress tinnitus Proceeding if necessary to Step 2 – Development of new treatment approaches for people with profound hearing loss or deafness and tinnitus	Step 1 – Identification of (i) meaningful criteria for tinnitus subtyping; (ii) the underpinnings of the different tinnitus subtypes in humans in terms of inner ear pathology and neurobiology and; (iii) their relevance for response to various treatments Proceeding if necessary to Step 2 – Development of an evidence-based algorithm/ pathway to guide patient assessment, diagnosis and management	Step 1 – A systematic review of the association between tinnitus and hyperacusis, including epidemiological data. Proceeding if necessary to Step 2 – Understanding of the underpinnings of tinnitus and hyperacusis in terms of inner ear pathology and neurobiology	Step 1 – Systematic reviews of the other classes of drugs that are prescribed to alleviate tinnitus and/or associated symptoms. Proceeding if necessary to Step 2 – Studies of drug treatments for reducing tinnitus symptoms, including reduced perception of the tinnitus sound	
ied by the James Lind Alliar	Underpinning evidence	Vone found	Vone found	Velson and Chen [19]	Cochrane Database of Systematic Reviews [106] Schilter <i>et al.</i> [20]	
Table 2. Top ten research suggestions identif	Uncertainty in the diagnosis amd assessment of treatment of tinnitus	How can tinnitus be effectively managed in people who are deaf or have profound hearing loss?	Are there different types of tinnitus and can they be explained by different mechanisms in the ear or brain?	What is the link between tinnitus and hyperacusis (over-sensitivity to sounds)?	Which medications have proven to be effective in tinnitus management compared with placebo?	CBT: Cognitive Behavior Therapy.

UK DUETs [109] in the reporting stage since we had not been gathering all of the necessary information along the way. We recommend other PSPs understand the reporting format of DUETs at least as early as the collation stage.

Communicating the outcome

The main legacy of the project has been its contribution to the UK DUETs. This webbased public information repository sits within NHS Evidence and is managed by the NICE. Its purpose is to make uncertainties explicit primarily to help those prioritizing research in the UK to take into account the information needs of patients, carers and clinicians. Each record within DUETs contains information about the source of the uncertainty, evidence for why it is an uncertainty, references to any reliable upto-date systematic reviews, information on any reviews that need updating or extending and any in preparation, what is needed from new research, and details of any ongoing controlled trials [109]. The intention is to publish all 390 'true' uncertainties, although this will need to be implemented gradually, due again to resource limitations. At present, the 26 prioritized uncertainties are publicly available in this database.

To raise awareness amongst key stakeholders, the top ten uncertainties have been widely disseminated to the public and hearing healthcare professionals in various membership magazines and annual meetings.

Future perspective

The JLA Tinnitus PSP most successfully engaged the public and healthcare professionals in raising profile of the unmet patient needs. In identifying what the most important questions for research are that will make a difference to people's well being, it is our sincere hope that a greater proportion of tinnitus research undertaken will be directly relevant to patient and clinician priorities. The NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) manage evaluation research programs and activities for the NIHR and it is interesting to note that from 1 April 2013, NIHR Evaluation Trials and Studies Coordinating Centre will be coordinating the work of the JLA. This organizational restructuring brings exciting opportunities to enhance funding opportunities

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for patient-centered tinnitus research either as commissioned research or as priority areas to encourage researcher-led funding applications.

Through inclusion in the DUETs database, major government funders now have easy access to a reliable knowledge base upon which to commission specific pieces of research. There is now greater potential opportunity to stimulate new research addressing those areas of acute patient need where very little research has been conducted so far, especially in children and people who are deaf. There has never been a more exciting time for tinnitus research.

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Executive summary

The James Lind Alliance (JLA) gives a voice to patients and clinicians to help shape future research agendas.

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- Over a period of 11 months, the JLA Tinnitus Priority Setting Partnership has engaged patients and clinicians to identify and prioritize uncertainties in the assessment, diagnosis and treatment of tinnitus.
- The JLA Tinnitus Priority Setting Partnership was a successful 'test case' for implementing the process in a cost-effective way over a reasonably short timescale, although success was in part due to considerable internal effort and application by key members of the Steering Group.
- The 'top ten' list represents a set of general tinnitus questions that address a broad range of important aspects of patient need and gives priority to areas previously overlooked.
- A key objective is to increase the number of clinical trials that address the needs of people with tinnitus and the hearing healthcare professionals who work with them.

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- Records the 26 priority tinnitus uncertainties with information about the source of the uncertainty, evidence for why it is an uncertainty, references to any reliable up-to-date systematic reviews, information on any reviews that need updating or extending and any in preparation, what is needed from new research, and details of any ongoing controlled trials.