ACCEPT Audit - Audit of Current Care Pathways for Tinnitus in the United Kingdom

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Executive Oversight	
Steering Committee (alphabetical)	- James Arwyn-Jones - Johan Bastianpillai - Laura Jean - Ying Ki Lee - Sirat Lodhi - Alexander North - Joseph Salem - Andrew Williamson
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Version History

Protocol Version	Date	Comment
1.0	30/11/2023	First draft of study protocol for review by the INTEGRATE Otology Subcommittee.
1.1	23/01/2024	Updated protocol draft

Definitions & Acronyms

Definitions

Local Management Team	Nominated representatives for each individual centre responsible for data collection and management
Steering Committee	INTEGRATE Otology Subcommittee

Acronyms

Acronym	**Definition**
ACCEPT	Audit of Current Care Pathways for Tinnitus
ENT	Ear, nose and throat
DHSC	Department of Health and Social Care
NICE	National Institute for Clinical Excellence

Summary

Full study title:	ACCEPT Audit - National Audit of Current Care Pathways in Tinnitus	
Short title:	ACCEPT National Audit	
Funding:	None	
Steering Committee	INTEGRATE Otology Subcommittee	
Support	TInnitus UK, British Society of Otology, British Society of Audiology, British Academy of Audiology.	
Study Design:	Multicentre Retrospective Observational Study	
Population	Adult patients with tinnitus being managed in a secondary care setting.	
Study Duration	**Anticipated start date:**	**Anticipated end date:**
	18/03/2024	**01/07/2024**
Aims	To better understand the presentation, investigation, management and natural history of patients with constant tinnitus, requiring treatment. Patients will be identified via audiology, audiovestibular medicine and ear nose and throat services across the United Kingdom.	
Methods	A multicentre, retrospective, observational study collecting objective data relating to patients presenting with tinnitus.	

Background

Tinnitus is defined as the perception of sound in the absence of external auditory stimuli (1). It has a prevalence of approximately 14% (2), and yet helping patients manage this condition remains difficult due to the fact that our understanding of its causes, risks factors, and optimal management strategies remains poor.

This issue was highlighted by the Department of Health & Social Care (DHSC) at a round table event in which a wide range of stakeholders and partners were brought together to discuss issues relating to research on adult hearing loss and tinnitus (3). A number of key challenges were identified including a scarcity of commissioned research related to hearing loss and tinnitus, and a lack of standardisation of clinical records and information that can be applied to research in this area. It was also noted that there is a need for cross-specialty research collaboration between the clinicians caring for these patients. A five year action plan for 2023-2028 from the working group was developed that aims to establish a research culture and foster high quality research in the field of hearing loss and tinnitus.

Tinnitus is often perceived as a ringing, buzzing, hissing or rushing sound, although its definition remains inconsistent and its subjective perception can vary. It may present secondary to hearing loss or other otological disease (secondary tinnitus), but can also present in isolation (primary tinnitus) (1),(4). While the exact physiological mechanisms underlying this disorder remain unclear, it has been associated with potential dysfunction in any part of the auditory pathway (5–7).

Subjective tinnitus is the most common form of tinnitus, where the sound is only heard by the patient. Objective tinnitus refers to sound which is audible to both the individual and the clinician performing clinical examination. Tinnitus can be unilateral or bilateral, constant or intermittent, and pulsatile or non-pulsatile (1). For many patients, this condition has an adverse impact on their quality of life; the prevalence of anxiety and depression in the tinnitus population is high, and may be associated with suicidal ideation (6). It also negatively impacts concentration (8), and up to 80% of sufferers are thought to experience disturbed sleep (9).

Standardised national guidance on assessment and management of tinnitus is suboptimal. Whilst guidelines do exist, there is acknowledgement of little high level evidence supporting them, leaving clinicians little to base their clinical decision making on. Clinicians are guided by general principles for the assessment and management of tinnitus, and specific tests and management strategies remain at their discretion. As no objective tests are currently recommended to determine the severity of tinnitus (several exist but few are used in practice and none are recommended in national guidance), clinicians are reliant on detailed history and subjective patient-reported measures to assess impact. National guidance recommends that impact on function, quality of life, and sleep should be assessed using the Tinnitus Functional Index questionnaire, discussion with the patient, and screening using questionnaires (e.g. Insomnia Severity Index) (10).

Several management strategies for tinnitus exist, though not all are recommended by national guidance in the UK (10), and variable outcomes have been reported (11–13). Generally, for primary tinnitus, clinical management strategies include education or counselling, relaxation therapy, tinnitus retraining therapy, cognitive behavioural therapy and sound enrichment (i.e. using hearing aids, masking devices or sound generators) (12). In addition, neuromodulation, drug therapies, and comorbid symptom (e.g. depression) management have been explored as options for patients with this condition (1).

In order to receive specialist assessment and management, patients require input from secondary care clinicians. According to Tinnitus UK, recent research findings suggest that only 50% of patients with tinnitus are referred into secondary care, although it has been demonstrated that referral to a specialist can reduce stress and anxiety, and timeliness of specialist review is highly valued by patients (14).

After tinnitus management as described above, most patients are discharged from secondary care. Concerningly, two fifths of these patients return to their primary clinicians within one year, a third of whom get re-referred to secondary care (15). This highlights the difficulty in adequately managing this condition for these patients and the suboptimal outcomes achieved from the patient perspective. There is indeed evidence of general patient dissatisfaction with tinnitus pathways (15,16). Those that have the greatest satisfaction appear to be the patients that are managed in specialist tinnitus clinics, relative to non-specific clinics in primary and secondary care.

Previous reviews of tinnitus pathways in the UK have provided insights into the departmental variation in caring for patients with this disorder (14,15,17). These studies used questionnaire-based methods to review tinnitus diagnosis and management from the perspective of healthcare providers and patients themselves. Findings suggested that local departments tended to have their own methods of diagnosis, severity assessment, and management for tinnitus, with variation of practice between and within departments. A strength of the INTEGRATE network is that we are able to utilise more granular data obtained directly from patient records, which can provide valuable and objective insights into what the patient journey is like in UK tinnitus pathways.

To improve the understanding of the presentation, investigation, and management of patients with constant tinnitus, requiring treatment, we aim to conduct a multicentre retrospective national audit on the management of patients with tinnitus presenting to an ear, nose and throat service in the United Kingdom. Patients will be identified via audiology, audiovestibular medicine, and ear nose and throat services. Secondary aims include auditing compliance of tinnitus assessment and management compared with national guidance, and assessing involvement of audiology and mental health / counselling services in current practice. Furthermore, we aim to analyse patient outcomes to identify improvements that can be made to current management pathways, and assess whether those presenting with pulsatile tinnitus can be diagnostically stratified based on clinical features and investigations.

Aims

Primary Aims:

To better understand the presentation, investigation, management and natural history of patients with constant tinnitus, requiring treatment. Patients will be identified via ear nose and throat, audiology or audiovestibular medicine and services across the United Kingdom (please see Patient Identification Process section below).

Secondary Aims:

1. To audit the compliance of tinnitus assessment and management compared with NICE clinical guidelines and BSA practice guidance.
2. To investigate the involvement of audiology services in the assessment and management of patients with tinnitus.
3. To report the outcome measures used by tinnitus services for patients with tinnitus and consider where improvements can be made along the tinnitus management pathway.
4. To investigate the involvement of mental health and/or counselling services in the assessment and management of patients with tinnitus.
5. To subanalyse patients presenting with pulsatile tinnitus to assess whether this subgroup can be diagnostically stratified based on clinical features and investigations.

Study Design and Methodology

Overall Design

We plan to conduct a multicentre, retrospective, observational study collecting objective data relating to patients presenting with tinnitus.

Setting

Secondary or tertiary care level audiology, audiovestibular medicine, or ear nose and throat services across the United Kingdom.

Timeline

Audit start date: 18/03/2024

Audit end date: 01/07/2024

Data Collection Window

Data collection will be done for new patients presenting with tinnitus as per the inclusion criteria below, to relevant clinics (Otology, general ENT, Audiology, Audiovestibular Medicine, or specialist tinnitus clinic - please see Patient Identification Process section below) within the following time period:

Start Date: 01/08/2022

End Date: 31/10/2022

Registration

This project will be registered with local audit/clinical governance departments according to their individual policies prior to the initiation of any data collection.

Study Population

Inclusion Criteria

- Aged 18 years or older
- Under the care of a secondary/tertiary care ENT, audiology or audiovestibular medicine service
- Constant tinnitus (unilateral or bilateral) requiring treatment as part of initial presentation
- At least 3 months of symptoms

Exclusion Criteria

- <3 months of tinnitus
- Presentation with and treatment for tinnitus started or completed prior to the data collection window

Patient Identification Process

Local management teams will identify new patients presenting to relevant secondary care clinics within their departments during the data collection window (01/08/2022 - 31/10/2022). Clinics included will be otology clinics, general ENT clinics, specialist tinnitus clinics, audiology clinics, and audiovestibular medicine clinics.

If you are an ENT clinician, you will not be expected to audit audiology or audiovestibular medicine clinics. If you are an audiologist, you will only be expected to audit audiology clinics, and if you are an audiovestibular clinician, you will only be expected to audit audiovestibular medicine clinics. It is encouraged, however, to collaborate with colleagues across these departments within your hospital where possible to allow for maximal data collection. Collaborators across departments will be recognised fully with collaborative co-authorship in future publications.

The total number of patients newly presenting to these clinics will be noted, and then local teams will review the patient notes for each patient to identify those with tinnitus, ensuring they are eligible for inclusion based on the study's inclusion and exclusion criteria.

Patients with tinnitus requiring treatment as part of their initial presentation and meeting other inclusion criteria will be included in the study and have completion of data collection using the data collection tool.

Anonymisation of Patient Identifiable Information & Informed Consent

This is a retrospective observational study collecting objective data relating to each patient's reason for attendance, medical history, investigation, management and outcome. All collected data will be anonymised and no identifiable data will be collected by the steering committee. Therefore, there will be no impact on the management for individual patients and they will not be identifiable. As such, obtaining consent is not required.

Data Collection and Management

Dataset

The final sample size will depend on the number of sites taking part and submitting data for this study. There is no *a priori* estimation, but it is anticipated that at least 50 centres will submit data, based on previous INTEGRATE audit participation numbers.

Data Collection Tools

Anonymised data will be locally entered into data extraction forms on Microsoft excel (Redmond, WA, USA). The quality of the data entered will be controlled by limited data entry, drop-down options and predefined data formats. Range checks for chosen fields will automatically appear where data points are outside of a pre-specified range.

Data Handling & Record Keeping

Anonymised data will be submitted via an NHS email account to the Project Management Team. No patient identifiable information will be sent or stored by the Project Management Team. The Project Management Team will not request or be provided with the names, addresses, NHS numbers, medical record numbers (MRN) or identifiable dates for any patients.

Reporting and analysis will not identify individual cases in any subsequent reports, presentations or publications. Data flow will be one way, from the Data Discloser to the Data Receiver (i.e. Project Management Team). There will be no traceability from the data receiver database to local records. If any identifiable data is received, the files will be deleted and the site will be informed.

Anonymised data may be made available to applicants who submit a project proposal to the Project Management Team, and which receives approval from the Project Management Team, expert advisory group and INTEGRATE main committee.

Local data forms should be kept according to local data governance for 12 months following submission to allow appropriate local analysis and scrutiny from the Project Management Team. At the end of this period, local data forms should be destroyed/deleted in line with local data governance policy.

The anonymised collated data will be held by the Project Management Team for at least 5 years on an NHS server to allow for appropriate scrutiny and reanalysis.

Missing Data

The Project Management Team will check submitted data for completeness and integrity. Where necessary, the PMT will contact local leads to encourage the completion of data where fields are deemed inadequate. If data is not available, the data point will be treated as null, and that record will be excluded from any relevant analysis.

Anticipated Numbers

All new patients attending relevant clinics stipulated in the Patient Identification Process section above over a three-month period (01/08/2022 - 31/10/2022) should be assessed for whether they meet the inclusion criteria in this study. The total number of patients screened should be noted, and only patients with tinnitus meeting the inclusion criteria included for further analysis. We anticipate that at least 200 newly presenting patients will be screened over the three month period, with only a minority having tinnitus meeting the inclusion criteria. As such, 200 new patients is the minimum screening requirement for taking part in submitting data for this study. Only a minority of these patients will have tinnitus and be included for further data collection and analysis, we anticipate this to be at least 5 patients, and this is the minimum inclusion number for submission.

Data Analysis and Statistics

Final statistical analysis will depend on the volume and quality of data received from participating centres. Statistical analysis will be conducted in RStudio (R foundation, Vienna, Austria).

Demographics and tumour characteristics will be summarised using mean and SD for continuous variables and counts and proportions for categorical variables. Analysis of categorical variables will be performed using the Chi-square or Fishers exact test to detect differences between two or more groups. Quantitative continuous variables will be analysed using descriptive statistics such as mean, median, quartiles, and range. Tests for homogeneity will be employed, with Student's test being used when homogeneity is confirmed, or the Mann-Whitney U, Kruskal-Wallis, Wilcoxon or Friedman tests used as appropriate when it is not confirmed.

Ethical Considerations

This project has been determined to be an audit using the HRA decision tool available at http://www.hra-decisiontools.org.uk/research/. The output from this process is available in Appendix 4.

This project will report on the outcomes of investigative management that have already occurred. As there will be no deviation from the usual standard of care, formal ethical approval is not required. Data will be anonymised by the local site lead prior to submission. Due to this, no formal informed consent is required. The study will need the approval of the local Research and Development department at each site before data collection can begin.

Authorship Policy

Criteria for inclusion as a PubMed citable collaborator

Authorship will be in line with INTEGRATE policy on multi-centre collaborative projects. Each Centre will have a named Consultant Lead, Trainee Lead, and a Local Collaborator; who will be eligible for collaborative co-authorship of publications that result from the project. Additional team members across ENT / Audiology / Audiovestibular Medicine departments within the same hospital can be added in discussion with the INTEGRATE Project Management Team and will also be included as citable collaborators. Authorship will be subject to meeting the minimum screening and inclusion numbers as outlined in the Anticipated Number section above, with at least 200 newly presenting patients screened, and at least 5 patients included.

Acknowledgements

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