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Original Article

Development of a National Ménière's Disease Registry: A Feasibility Study

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BACKGROUND: Ménière's disease is a disabling condition causing vertigo and hearing loss yet remains incompletely understood. Registry studies have the potential to answer important questions about phenotypes and natural history of clinical conditions. The aim of this study was to explore the feasibility of a patient-centered national Ménière's disease registry.

METHODS: This was an observational study carried out at 4 state-funded hospitals and 4 independent clinics, within 3 distinct urban and rural regions within the UK. Adults with Ménière's disease were eligible to participate. A range of patient reported data, questionnaire data and clinical data (audiometric, radiological, and specialist balance testing data) was inputted into a bespoke database.

RESULTS: The study recruited 411 participants. The majority of participants chose online recruitment (73%) and 27% chose via paper-based methods for participation. A small majority (57%) of participants were female. 96% of participants were of white ethnicity. Data completeness from online or postal data collection was similar. Around 20% of participants had audiological evidence of bilateral Ménière's disease.

CONCLUSION: This feasibility study has successfully piloted methods for recruitment of hundreds of participants diagnosed with Ménière's disease. Participants actively contributed their data to a robust and extensive data collection platform. The positive outcomes from this initial feasibility study are anticipated to serve as a foundation for the future expansion of the registry. This expansion holds the potential to address a broad spectrum of request, encompassing all aspects of the nature of Ménière's disease.

KEYWORDS: Ménière's disease, registries, vertigo

INTRODUCTION

Ménière's disease is characterized by recurring episodes of spontaneous vertigo, fluctuating hearing loss, tinnitus, and often a sense of ear fullness, stemming from an inner ear disorder. The disease is estimated to affect around 0.25% of the population (approximately 162 000 individuals in the UK),[1] leading to notable physical, psychological, and socioeconomic challenges. Despite the significant impact of the condition, the precise cause remains elusive.[2,3] Substantial gaps in knowledge surround various facets of Ménière's disease, encompassing its epidemiology, underlying causes, progression, clinical trajectory, and treatment effectiveness. This condition holds significant importance, evident in the fact that the James Lind Alliance recognizes Ménière's disease as the focal point for 4 of their highest-priority areas aimed at addressing uncertainties within the realm of balance disorders.[4]

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Ménière's disease is a challenging condition for patients, clinicians, and researchers. For patients, the condition has the potential to result in disabling symptoms affecting fundamental aspects of life, including communication, mobility, social, work, and leisure functions. For clinicians, the diagnosis is a challenge due to the lack of a single clear biomarker.[5] For researchers, the uncertain natural history and the relapsing–remitting nature of the condition add to the challenge, as large numbers are required to achieve adequate statistical power for clinical trials.

Some patients have a more benign course with spontaneous remission of all symptoms, whereas others progress to bilateral involvement, which, in extreme cases, can require cochlear implantation to alleviate deafness, and also experience permanent imbalance with an associated risk of falls.[6] Prognostic factors that predict the risk of a poorer outcome have yet to be established. Previous work has suggested that some test findings, such as vestibular evoked myogenic potentials, can be early indicators of bilaterality.[7] Furthermore, some treatments currently offered for Ménière's involve ablation or destruction of vestibular and cochlear organ function. In cases of unilateral disease, the vestibular effects can to an extent be mitigated by compensation, but where patients then develop contralateral disease, additional hearing, and balance disability may be accrued from this treatment choice.[8] Practical hair cell regeneration treatments for sudden sensorineural hearing loss are on the current research horizon, and therefore, natural history is so important, as well as non-ablative treatments to allow patients to benefit from these likely future developments.

Previous work has used cross-sectional retrospective data collection to putatively identify clinical subgroups of patients with Ménière's disease based on family history and additional clinical features such as migraines or autoimmune conditions.[9,10]

In many areas of clinical research, the implementation of bespoke data collection platforms and national registries has been demonstrated to be both effective and efficient in answering diverse and complex questions related to the condition(s) being studied.[11] In the case of Ménière's disease, this approach has the potential to address some of the research challenges outlined above, contributing valuable information on natural history and prognosis, as well as a structure to guide the planning of clinical trials. This article outlines a feasibility study that has taken place to assess the practicality and pilot a national Ménière's disease registry by recruiting participants from 3 distinct urban and rural regions within the UK. It is hoped that this initial piece of work will inform future endeavors to establish a nationwide Ménière's disease registry to facilitate meaningful health care research in this condition.

MAIN POINTS

- This feasibility study confirms the viability of a national Ménière's disease registry in the United Kingdom.
- It is possible to remotely acquire a rich range of patient reported, and clinician reported, data.
- Large numbers of patients can be recruited swiftly, and efficiently, using online, and postal questionnaires.

MATERIAL AND METHODS

In 2020, institutional ethics approval was granted to invite patients diagnosed with Ménière's disease to have their clinical data entered into a bespoke study data collection platform. This study was approved by the North West - Liverpool Central Research Ethics Committee, United Kingdom (Approval Number: IRAS ID:275749; Date: January 20, 2020) Patients with Ménière's disease were identified from 8 sites; 4 of these were NHS Trusts, and 4 of these were independent hospitals or clinics. Table 1 lists the sites from which patients were identified.

Potential participants were identified at ENT or audiovestibular medicine secondary/tertiary care and specialist private clinics. All potential participants had a diagnosis of probable or definite unilateral or bilateral Ménière's disease as defined by the 2015 edition of the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) criteria[12] at an appointment within the previous 10 years with experienced specialists in Otology or Audiovestibular Medicine. A full list of inclusion and exclusion criteria for participant recruitment is provided in Table 2.

Potential participants were sent a letter of invitation with the option of engaging with the recruitment process either online or via post. Participants who opted to be recruited online gave informed consent via an online system that provided them with all the necessary study materials and information. Participants opting for a paper-based process were sent consent forms, patient information sheets, and all other study materials via post. The data collected

Table 1. Hospital Recruitment Sites

NHS Centers	
A	Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich
B	Leicester Royal Infirmary, University Hospitals of Leicester, Leicester
C	Leicester Royal Infirmary, University Hospitals of Leicester, Leicester
D	Guy's Hospital and St Thomas' Hospital, London
Private Centers	
E	Spire Norwich Hospital, Norwich
F	The London Road Clinic, Leicester
G	London Hearing and Balance Centre, London
H	The London Clinic, London

Table 2. Eligibility Criteria

Inclusion Criteria
Individuals aged 18 years or over
Definite or probable diagnosis of unilateral or bilateral Ménière's disease as defined by the 2015 edition of the AAO-HNS[12]
Potential participants must have received a diagnosis of Ménière's disease within the previous 10 years or have received a new diagnosis during the recruitment window of the study.
Willingness to provide consent for data from health records to be used for research purposes.
Exclusion Criteria
Unable to provide consent
Unable/unwilling to complete questionnaires.

from participants was identical regardless of their chosen method of engagement.

Participant data were entered into the database both by patients and specialists, according to the type of data collected. Firstly, patients were asked to enter or provide demographic variables along with disease-specific and general health questionnaires related to their Ménière's disease, together with a number of validated health questionnaires on symptoms and quality of life measures. Participants were advised that this process would take between 20 and 40 minutes. Secondly, once participants had consented, the local clinical teams retrieved and uploaded clinical data related to technical medical and audiovestibular assessments. Table 3 lists the data collected directly from each study participant. Table 3 lists the data collected by the clinician team at the participants' hospital site.

Data for the study were managed through REDCap electronic data capture tools, hosted at (Location Y). REDCap stands as a secure and web-based software platform with the primary purpose of facilitating data collection for research.[13] It offers several key features, including: (1) an easily navigable interface for capturing validated data, (2) audit trails that enable the monitoring of data manipulation and export processes, (3) automated procedures for the smooth transfer of data to widely used statistical software packages, and (4) mechanisms for harmonizing data from various sources and fostering interoperability with external datasets.

Each participant was provided with a unique trial Participant Identification Number (PID). There was a clear logical separation of participant identifiable data from the study data. All data was handled in accordance with the Data Protection Act 1998 and the General Data Protection Regulation (GDPR). Access to the information was limited to the study staff and investigators, and relevant regulatory authorities. Data held on computers, including the study database, were held securely and password protected. All data were stored on a secure dedicated web server. Access was restricted by user identifiers and passwords (encrypted using a one-way encryption method). Electronic data were backed up every 24 hours to both local and remote media in an encrypted format.

The number of participants with unilateral or bilateral disease was confirmed against existing audiograms using the Barany Society audiometric definitions.[14] According to this definition, low-frequency sensorineural hearing loss is identified as*:* "An increase in pure tone thresholds that is higher (i.e., worse) in the affected ear than the contralateral ear by at least 30 dB HL at each of two contiguous frequencies below 2000 Hz. In cases of bilateral low-frequency SNHL, the absolute thresholds must be 35 dB HL or higher at each of two contiguous frequencies below 2000 Hz. If multiple audiograms are available, demonstration of recovery of low-frequency sensorineural hearing loss at some point in time further supports the diagnosis of Ménière's disease." We also allowed a diagnosis of bilateral disease if the unilateral criteria were met in both ears at different time points, even if the bilateral criteria were not met on any single audiogram.

Table 3. Datasets Provided by Participants and the Clinical Team

Self-Reported, Study-specific Data Themes (Participant Entered)
Demographics (including ethnicity and occupation)
COVID diagnosis and implications for symptoms
Disease characteristics including triggers, vertigo, and tinnitus experiences
Past medical history
Family history
Treatment of Ménière's disease (including an indication of efficacy)
Self-Reported Existing Validated Questionnaires (Participant Entered)
Disability Rating Scale (DRS)[15]
Generalized Anxiety Disorder Assessment (GAD-7)[16]
Patient Health Questionnaire (PHQ-9)[17]
Tinnitus Handicap Index (THI)[18]
Dizziness Handicap Inventory (DHI)[19]
Migraine Disability Assessment Test (MIDAS)[20]
The Social Life and Work Impact of Dizziness (SWID)[21]
Situational Vertigo Questionnaire (SVQ)[22]
Self-Administered Comorbidity Questionnaire (SCQ)[23]
Audiometric Data (Clinic Entered)
Pure tone audiometry (air conduction thresholds at the following frequencies: 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz)
Tympanometry
Vestibular Testing Data (Clinic Entered)
Caloric testing
vHIT (video head thrust test)
cVEMP (cervical Vestibular Evoked Myogenic Potentials)
Posturography
Radiology (Clinic Entered)
Radiological examinations of the internal auditory meati (IAMs) using magnetic resonance imaging (MRI) or computed tomography (CT) scans. Outcome of specialist scans performed for the purpose of identifying endolymphatic hydrops.

Table 4. Summary of Recruitment by Hospital Site

Center		By Post (N = 111)	Online (N = 300)
NHS centers		83 (74.8%)	180 (60.0%)
A	Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich	45	47
B	Leicester Royal Infirmary, University Hospitals of Leicester, Leicester	14	25
C	Charing Cross Hospital, London	5	31
D	Guy's Hospital and St Thomas' Hospital, London	19	77
Private centers		28 (25.2%)	120 (40.0%)
E	Spire Norwich Hospital, Norwich	11	31
F	The London Road Clinic, Leicester	17	78
G	London Hearing and Balance Centre, London	0	5
H	The London Clinic, London	0	6

RESULTS

Recruitment for this study began in November 2020 and ended in September 2021. In total, 723 potential participants were identified from ENT or audiovestibular medicine secondary/tertiary care and specialist private clinics, and 468 potential participants were sent a study pack. Over this ten-month recruitment period, 411 participants were recruited into this study from 8 different sites (Table 4), 263 from NHS Trusts and 148 from independent hospitals or clinics. Online recruitment was used for 300 (73%) participants, and 111 (27%) were recruited via paper. Data collection used the same format as recruitment. Those recruited via paper were, on average, older (mean age 64.4 years versus 57.0 years, $P < .001$, 2-sample t-test) and males were more likely to use the online platform (80.2% of males versus 67.1% of females, $P = .003$, chi-squared test).

Table 5 provides details regarding the demographics and disease duration of the individuals participating in this study. The participant-provided dataset produced around 150 individual data fields from each participant regarding their Ménière's disease, in addition to extensive data from their completed validated health questionnaires.

Table 5. Participant Demographics

Characteristic		Participants (N = 411)
Age at consent (years)*		Mean = 60.1, SD = 14.2 Range: 19 to 92
Age at onset (years)		Mean = 45.6, SD = 14.4 Range: 14 to 86
Disease duration (years)		Mean = 14.5, SD = 11.4 Range: 0.25 to 57
Gender	Male	172 (42.7%)
	Female	231 (57.3%)
	Missing	8
Ethnicity	White	378 (95.9%)
	Indian	8 (2.0%)
	Black	3 (0.8%)
	Mixed race	2 (0.5%)
	Other	3 (0.8%)
	Missing	17
Employment status	Employed	278 (79.9%)
	Unemployed	5 (1.4%)
	Retired	65 (18.7%)
	Missing	63

*Missing for 7 participants.

Table 6a. Completeness of Data—Participant Reported Information

Information	All Participant (N = 411)	By Post (N = 111)	Online (N = 300)
Study-specific Data			
Complete	375 (91.2%)	105 (94.6%)	270 (90.0%)
Incomplete	36 (8.8%)	6 (5.4%)	30 (10.0%)
Existing Questionnaire Data			
Complete	331 (80.5%)	85 (76.6%)	246 (82.0%)
Incomplete	80 (19.5%)	26 (23.4%)	54 (18.0%)

Table 6b. Completeness of Data—Clinical Information

Information	All Participant (N = 411)
Audiometry	
Available	387 (94.2%)
Unavailable	24 (5.8%)
Tympanometry	
Available	286 (69.6%)
Unavailable	125 (30.4%)
Caloric testing	
Available	163 (39.7%)
Unavailable	248 (60.3%)
Video head impulse test	
Available	58 (14.1%)
Unavailable	353 (85.9%)
Cervical vestibular evoked myogenic potentials	
Available	8 (1.9%)
Unavailable	403 (98.1%)
Radiology	
Available	334 (81.3%)
Unavailable	77 (18.7%)
Posturography	
Available	75 (18.2%)
Unavailable	336 (81.8%)

Table 6a provides details regarding the completeness of the participant-reported data: either study-specific or existing validated health questionnaires. There was no clear advantage to data completeness from either online or postal data collection. Table 6b provides data on the completeness of clinical data, which varied substantially according to type.

The laterality of the disease was based upon audiometry and self-reported symptoms, either as unilateral or bilateral. Self-report was unavailable in 32 participants; of those with information, unilateral disease was self-reported in 308 (81.3%) and bilateral in 71 (18.7%). The number of participants without audiometrically confirmed disease was 97; however, audiograms were available for analysis in 387 (94.2%) of participants. Bilateral disease was diagnosed in 69 (22.2%) and unilateral disease in 245 (78.0%) based on audiometric criteria: 125 in the left ear only and 120 in the right ear only. Table 6c provides a

Table 6c. Completeness of Laterality Defined by Self-report and Audiometry

	Audiometry	Undefined or Missing	Unilateral	Bilateral	Total
Self-report	Missing	9	16	7	32
	Unilateral	72	213	23	308
	Bilateral	16	16	39	71
	Total	97	245	69	411

summary of the completeness of the 2 approaches, which concurred in 250 individuals of the 288 with complete data (86.8%). While we allowed a diagnosis of bilateral disease if the unilateral criteria were met in both ears at different time points, even if the bilateral criteria were not met on any single audiogram, none of our participants with bilateral disease fulfilled this condition.

DISCUSSION

Utilizing national registries offers several advantages over more traditional data collection techniques. When executed effectively, these registries enable the examination of a sample that more accurately represents the intended population. Moreover, adopting a national perspective enhances the potential for greater patient participation within the demographic that the initiative aims to support and opens avenues for increased public engagement, thus facilitating the dissemination of information.

Patients enter their own data, so they remain in control of the process. Clinician burden is minimized to the need to confirm diagnosis and enter technical medical data. This pilot project successfully mapped out a pathway through which participants could be approached, recruited, provide consent, and enter data without any additional attendances at the hospital. This makes the process highly efficient and potentially widens access in a condition where additional visits to the hospital can be impossible due to the disabilities caused by the condition (e.g., episodic vertigo, imbalance). Furthermore, in the challenges of the recent COVID-19 pandemic and climate crisis age, minimizing travel and visits to the hospital has additional benefits.

We found that data completion rates were similar whether participants completed by paper or online routes. Those who chose paper data collection were significantly more likely to be older, and there was a significantly higher proportion of females than those who chose to enter data online. This observation illustrates that data registries need to offer diverse routes to participation in order to maximize access and inclusivity for different demographic groups. Access to this database was restricted to those able to enter data in English, which will have limited access for those with non-English-speaking backgrounds. Despite recruiting participants from regions that include a diverse range of ethnicities, over 95% of participants were white. However, this value is consistent with other epidemiological studies conducted in the UK.[2] In the UK, health care is provided free (via taxation) through the NHS, or patients can seek medical care privately, in the independent sector, paid for via self-funding or medical insurance. A greater proportion of postal respondents originated from NHS centers than private clinics; this could support the idea that under-represented groups are more likely to be identified from an NHS setting.

Whilst nearly 95% of participants had audiometry available, the availability of radiology results was only 80%. Both of these tests are essential for the diagnosis of Meniere's disease. Since this study was conducted in specialist centers, it is more likely that many of the participants were referred from elsewhere and had these essential tests performed prior to referral. This might also explain the discrepancy between self-reported and audiometrically confirmed unilateral and bilateral disease.

Registries present additional advantages to patients, caregivers and families, researchers, clinicians, and all stakeholders engaged in providing services for individuals impacted by the relevant condition under investigation. Both individual hospitals and the broader healthcare system can exploit registry data to enhance the quality of services they deliver. Likewise, individual patients and caregivers may benefit from registries as resources for acquiring deeper insights into their condition, fostering a heightened comprehension of the impact on people's lives.

There are limitations to the use of registries. Participation is necessarily through consent, and so total coverage cannot be obtained. Likewise, in order to be sure of the diagnosis, participation is restricted only to those recruited from highly specialized centers that are unlikely to be representative of the wider population. Data was entered retrospectively and subjected to challenges of potentially incomplete records. To minimize clinical workload and maximize suitability for further rollout, there was a component of patient-entered data that was subject to the constraints of subjective recall of participants in relation to patient-reported measures.

To our knowledge, this cohort of individuals with Ménière's disease provides the largest representative collection of clinically verified patient data from the UK. Over a relatively short period of time, it was possible to obtain important patient- and clinician-provided data to gain a deep understanding of the circumstances of this condition for participants. As such, it is anticipated that data from the registry will provide useful and novel insights into the nature of Ménière's disease.

This feasibility study has demonstrated that hundreds of participants with Ménière's disease can be successfully recruited to enter data into a large data collection platform. This study was able to draw on a diverse range of representative participants, from publicly funded and independent hospitals, and from 3 distinct urban and rural regions within the UK (A, B, and C). Around 20% of participants had audiological evidence of bilateral Ménière's disease. It is hoped that this initial feasibility study will pave the way for the expansion of the registry to answer fundamental and complex questions alike, regarding the nature of Ménière's disease and improve our understanding of cochleovestibular disease as a whole. The data set already obtained in this study will be further analyzed to provide insights into multiple aspects of Ménière's disease, which will form the basis of future work.

Ethics Committee Approval: This study was approved by the North West - Liverpool Central Research Ethics Committee, United Kingdom - (approval numberIRAS ID:275749; date: January 20, 2020).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer Review: Externally peer reviewed.

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