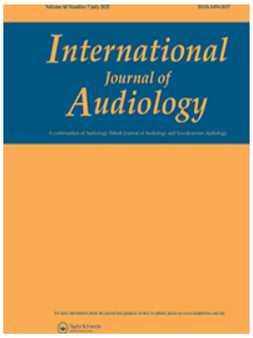

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Psychosocial outcome measures for conductive and mixed hearing loss treatment: An overview of the relevant literature

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ABSTRACT

Objective: To identify the psychosocial assessments utilized with individuals with conductive and/or mixed hearing loss as part of a broader effort by the Auditory Rehabilitation Outcomes Network (AURONET) group to develop a core set of patient-centred outcome measures.

Design: A review of articles published between 2006 and 2016 was completed. Included studies had more than three adult participants, were available in English, and reported a psychosocial outcome from any treatment of mixed and/or conductive hearing loss.

Study sample: Sixty-six articles from seven databases.

Results: Sixty-six articles met our inclusion/exclusion criteria. Within this set, 15 unique psychosocial or patient-reported outcome measures (PROs) were identified, with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Glasgow Benefit Inventory (GBI) being the most frequently dispensed. Five of the fifteen were only administered in one study. In-house questionnaires (IHQs) were reported in 19 articles.

Conclusions: Only 66 (22%) of the 300 articles with outcomes contained a PRO. Some of the mostly frequently employed PROs (e.g., APHAB) were judged to include only social items and no psychological items. Lack of PRO standardization and the use of IHQs make psychosocial comparisons across treatments in this population difficult for patients, clinicians and stakeholders.

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Introduction

The consequences of untreated hearing loss are well-documented in the literature. Many of these consequences are related to psychosocial well-being including isolation, frustration, higher listening effort, aversiveness to sounds, and hearing in social gatherings (Johnson et al. 2016; Li et al. 2014; Manrique-Huarte et al. 2016; Monzani et al. 2008; Taljaard et al. 2016). However, many of these articles focus on sensorineural hearing, including age-related losses (i.e., presbycusis). Fewer articles address conductive and/or mixed hearing losses, which occur across the lifespan. This lack of reference material is frustrating for clinicians and patients as conductive and/or mixed hearing losses frequently allow for a choice of treatment options (e.g., air conduction hearing aids, bone conducting devices, middle ear surgeries, etc.). It is also difficult to compare and contrast treatments as different studies are reporting different outcome measures.

This challenge is not unique to this population. The Outcome Measures in Rheumatology (OMERACT) group was created over 20 years ago to foster consensus in outcome measurements related to musculoskeletal and autoimmune diseases (The OMERACT Process 2018; Tugwell et al. 2007). Inconsistent conclusions were resulting from the large array of measures rheumatologists were using to make judgements about treatment efficiencies (OMERACT 2018a). The OMERACT group recognised that, in order to improve treatment efficiencies, recommendations and decisions need to be based on uniform evidence-based treatment outcomes that address the concerns and needs of the relevant stakeholders (i.e., patients, clinicians, payers, etc.). Another important development in this area was the Core Outcome Measures in Effective Trials (COMET) initiative launched in 2010. COMET maintains an up-to-date online core outcome set (COS) database that covers over 30 disease categories (The COMET Initiative 2020).

Inspired by these key initiatives, the OMERACT framework (The OMERACT Process 2018) was utilised to help establish the Auditory Rehabilitation Outcomes Network (AURONET) group. The AURONET group is an international network created to develop a core set of patient-centred outcome measures for all

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Supplemental data for this article can be accessed here.

This article has been republished with minor changes. These changes do not impact the academic content of the article.

types of hearing loss and/or interventions (Tysome et al. 2015). Other groups have also successfully utilised the OMERACT framework after identifying the need for outcome measurement consensus in their respective areas (e.g. gastroenterology (Cooney et al. 2007), chronic pain (Taylor et al. 2016), prosthodontics (Bassi et al. 2013), etc). Following the OMERACT structure, Tysome et al. (2015) detail how the AURONET group generated and prioritised four core domains: economic, hearing, physical and psychosocial. These domains represent the essential areas that should be measured in every treatment study which includes hearing loss. Working with this foundation of what core areas to measure, this project begins the investigation of how to measure these domains (OMERACT 2018b) with the ultimate goal of defining a core outcome set (COS) in a future publication. A COS are the minimum measures to be collected in any study to ensure standardisation (OMERACT 2018a).

To identify and quantify the outcome measures currently employed in these domains, an overview of the literature was undertaken. Here the AURONET group examined outcome measures applied to adults with conductive and/or mixed hearing losses following any treatment to improve their hearing. Separate publications will examine each core area (i.e. hearing, physical, economic, and psychosocial) (Hill-Feltham et al. 2019; Johansson et al. 2018). This paper will explore psychosocial measurement outcomes.

Psychosocial outcomes were identified as those outcomes relating to education, perception of self, quality of life, impact on family and ability to work (Tysome et al. 2015). They are primarily determined using instruments that utilise patient-reported outcomes measures (PROS) (e.g. questionnaires) "that come directly from the patient (i.e. study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response". (US Food & Drug Administration 2017).

This paper aims to quantify all the measures utilised in the psychosocial domain in adults with conductive and/or mixed hearing losses following any treatment to improve their hearing. With over 135 adult hearing-related questionnaires identified in the literature (Akeroyd et al. 2015), this report and its counterparts may be of interest to clinicians and researchers wanting to strengthen and standardise their COS.

Materials and methods

This project was supported by a grant from the William Demant Foundation (previously Oticon Foundation).

This review was registered prospectively in the PROSPERO International prospective register of systematic reviews (CRD42016039703) (Tysome et al. 2016) as a systematic review was initially intended. However, as the methodology did not strictly adhere to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines (Moher et al. 2015), it was recategorized as an overview (Grant & Booth 2009). An overview of surveys describes the literature but does not necessarily evaluate its quality.

Ethical considerations

This article represents a review of previously published articles. No identifiable patient details are included.

Information sources and search strategy

A search of articles published over a 10-year period (2006–2016) was conducted. Seven databases were explored: Ovid MEDLINE, Cochrane Library, Embase, CINAHL, PsycINFO, ScienceDirect and ISI Web of Science. Grey literature (i.e. information from less formal publication sources) was not sought or included. The terms and syntax of the initial literature search were developed with the assistance of health sciences librarian Laureen P. Cantwell, MSLIS, to target Ovid MEDLINE (detailed in Supplementary Appendix A). This strategy was then modified, as needed, to search the remaining databases.

Study selection process

To obtain a comprehensive result, minimal filters were applied. The initial scope were articles (1) published between 2006 and 2016 that (2) reported an outcome(s) from a treatment(s) of mixed and/or conductive hearing loss. This initial search yielded 1434 articles.

After the removal of duplicates (58), 1376 articles remained for review. These articles were split into smaller groups and then manually screened by the authors grouped in pairs. Each individual in the pair reviewed their group of articles independently, documenting their decision and reason for inclusion or exclusion. Any disparities not resolved between pairs were brought to the larger authorship group to reach an agreement to minimise the risk of bias. This pair review excluded 886 articles, leaving 485 full-text articles to assess for psychosocial outcomes. An exhaustive list of outcome measures was created from the 485 articles (Supplementary Figure 1). Each identified outcome measure was then assigned a domain (i.e. hearing, physical, economic, and psychosocial) during a consensus meeting of the authors in Nijmegen, 2017. Articles for this report were excluded if (1) they did not report a psychosocial outcome measure, (2) their full-text was not available in English, (3) it identified as a review article, (4) they reported less than four participants, or (5) included strictly paediatric participants (i.e. <16 years of age). Articles with adults and paediatric populations were included if the adult treatment outcomes were reported separately. Studies with less than four participants were excluded as a systematic review with a parallel meta-analysis was initially planned and very small studies were thought to be of a high risk of selection bias.

Data items

Sixty-six articles met our inclusion and exclusion criteria (Figure 1, Supplementary Appendix B). Data extracted from the full-text of these articles were input into a custom database designed using FileMaker (15 ProAdvanced, version 15.0.04.400, FileMaker, Inc, Santa Clara, USA) by the first author. The fields included: Title; author(s); year of publication; publication (i.e. journal); location; number of participants; type of hearing loss (e.g. acquired, conductive, unilateral); diagnosis (e.g. atresia); intervention (e.g. ossiculoplasty); study type (e.g. chart review) and outcome measure (e.g. pure-tone average). The quality of the study was not examined.

Data analysis and synthesis

The first author was responsible for separating, analysing and summarising the data items related to psychosocial outcome measures and writing portions of the manuscript content

related to this topic. The other authors catalogued and classified outcome measures, examined data, wrote and edited portions of this manuscript and contributed their expertise to the design of the review. It was decided that the data would be presented as frequency counts with in-depth descriptions as psychosocial measures require more subjective judgements than the other domains.

Results

The 66 articles originated from 20 different countries (Supplementary Table 1) primarily located in Europe, including Germany (9), England (8), the Netherlands (7), Italy (6), and Switzerland (6). The number of participants ranged from 4 to 894 ($Mdn = 19$) (Supplementary Table 1). Only 10 of the articles reported ear surgery outcomes (e.g. canalplasty, stapedotomy, tympanoplasty, etc.), while the remaining 56 reported treatment outcomes from bone conduction or middle ear technologies. 28 of the 55 articles focussed on percutaneous bone conduction solutions from Cochlear (Gothenburg, Sweden) and/or Oticon Medical (Askim, Sweden) and twelve on a specific middle ear implant (Vibrant® Soundbridge™, Med-El, Innsbruck, Austria).

The study type or design (Supplementary Table 1), if not reported in the paper, was inferred by the AURONET group (denoted * in Supplementary Table 1). Thirteen of the studies were prospective, interventional where subjects were evaluated before and after treatment. Four of these thirteen were multicentre studies.

Another 13 were identified as retrospective projects. Five of these thirteen evaluated an intervention, one using a multicentre design. Four retrospective projects also included a cross-sectional survey and five compared two different treatments, one using a multicentre setting.

Twelve of the sixty-six were classified as comparative as two different technologies or surgical techniques were being evaluated prospectively. Two prospective evaluations completed measures only postoperatively.

Seven were classified at chart reviews. Another six were chart reviews with an accompanying survey and four were postal or telephone surveys. Two studies were identified as observational projects, one prospective and one retrospective, and six were described as a single-subject repeated measures design with greater than four participants.

The number of unique psychosocial or PROs catalogued across the 66 articles was 16 (Supplementary Table 2). Forty-four studies administered one questionnaire, fourteen articles administered two questionnaires, seven articles administered three questionnaires and one study administered four questionnaires. This totalled 96 occurrences. The two most popular measures were the Abbreviated Profile of Hearing Aid Benefit (APHAB; 22 articles) and Glasgow Benefit Inventory (GBI; 20 articles). All questionnaires are described in detail below.

Psychosocial items were broken into two categories: psychological items and social items (Supplementary Table 2). This was done as social items may not directly address psychosocial well-being (e.g. from the APHAB, "When I am having a quiet conversation with a friend, I have difficulty understanding".), but much can be inferred from these questions. Whereas psychological items (e.g. from the HHI, "Does your hearing problem cause you to feel depressed?") addressed this measure more directly.

Abbreviated Profile of Hearing Aid Benefit (APHAB)

The Profile for Hearing Aid Benefit was shortened by Cox and Alexander (1995) to create the Abbreviated Profile of Hearing Aid Benefit (APHAB). This validated questionnaire contains 24 items with 3 additional checkbox questions about previous experience (e.g. none), usage (e.g. less than one-hour per day) and degree of hearing difficulty without wearing hearing aids (e.g. moderate). The 24 remaining items are separated into four subsets: ease of communication, reverberation, background noise and aversiveness of sound scored on a Likert scale from A to G. The number of psychosocial items the APHAB contains was scored to be 12 social items and zero psychological items (Supplementary Table 2).

It was the only PRO administered in 11 of the 66 papers. In the remaining 11 occurrences (22 articles in total), the APHAB was mainly paired with either the GBI (5 articles) or SSQ (3 articles). Only one of the 22 articles reported a PRO after ear surgery (i.e. stapedotomy). The most common study type was a prospective interventional and/or comparative design (13 articles).

Baha Aesthetic, Hygiene and Use (BAHU)

The Baha Aesthetic, Hygiene and Use (BAHU) questionnaire was administered in one study, combined with the APHAB and GBI. BAHU is a newly developed, unvalidated measure to evaluate a transcutaneous bone conduction device (Cochlear™ Baha® Attract system, Cochlear) using Likert scales from one to five to ask recipients to score the system's aesthetics, hygiene, ease of placement and stability of attraction (Gawęcki et al. 2016). The number of psychosocial items the BAHU contains was scored to be zero (Supplementary Table 2).

Binaural Hearing Aid Questionnaire (BHAQ)

The Binaural Hearing Aid Questionnaire (BHAQ), developed and evaluated by Chung and Stephens (1986), consists of four sections. Section A (13 items) asks about use and handling; Section B (11 items) examines listening ease in different environments; Section C (8 items) probes localisation abilities; and Section D is an open-ended response. The questionnaire aims to measure differences between conditions (i.e. two hearing aids as opposed to one). It was utilised in one project, along with the SSQ, to evaluate subjects with congenital unilateral conductive loss obtaining a percutaneous Baha. It was judged to have one psychological item (i.e. one question asks if the respondent's life has become more or less normal with two aids) and eleven social items.

Client Orientated Scale of Improvement (COSI)

The Client Orientated Scale of Improvement (COSI) is a unique PRO where patients define up to five listening situations in which they struggle (Dillon, James, and Ginis 1997). It is a validated measure that is widely used in clinical settings. And while extensively popular with clinicians, it appeared in only three studies combined with other PROs (e.g. GBI (2 articles), IHQ (2 articles)). It was found to have five social items as subjects are asked to describe listening situations. It is probable that many of these situations are social environments (e.g. communication with family, co-workers, etc.).

Entific Medical Systems Questionnaire (EMSQ)

The Entific Medical System Questionnaire (EMSQ) is a 15-item PRO administered in three studies all investigating percutaneous Cochlear Baha interventions. It was the sole questionnaire collected from two of the studies and combined with the COSI, GBI and HHI in the third. The questions explore use and handling (3 items), sound quality (3 items) and satisfaction (2 items) (Dutt et al. 2002). For research purposes, the questionnaire is frequently modified as several items ask patients to comment on the quality of clinical services and particular hearing aid features (e.g. telecoil). The EMSQ was judged to have one psychological item (i.e. "Which word or phrase best describes your present feelings about your hearing aid and its use?") with multiple answers (e.g. reduces stress) possible. Another question asks the subject to rate their satisfaction in seven different listening environments (e.g. "How would you rate your hearing aid being with family or friends at home?"); consequently, the number of social items was documented as eight.

Glasgow Benefit Inventory (GBI)

The Glasgow Benefit Inventory (GBI) is a validated 18-item post-intervention questionnaire scored on a five-point Likert scale to assess outcomes for a range of otorhinolaryngological interventions (Robinson, Gatehouse, and Browning 1996). It was judged to have four social items (e.g. "Have you been able to participate in more or fewer social activities?") and eleven psychological items (e.g. "Do you feel better or worse about yourself?").

It was utilised in 19 studies of varying designs of which only two were ear surgeries. It was the sole PRO reported in eleven of the articles and combined with the APHAB in five others.

Glasgow Hearing Aid Benefit Profile (GHABP) and Glasgow Hearing Aid Difference Profile (GHADP)

The Glasgow Hearing Aid Benefit Profile (GHABP) was administered in three articles, overlapping with the Glasgow Hearing Aid Difference Profile (GHADP) in one article. All investigated bone or middle ear technologies (i.e. percutaneous and transcutaneous bone conduction devices and middle ear implants) The GHABP is designed for new hearing aid recipients, while the GHADP is meant to evaluate a new technology dispensed to an existing user. The questions, format and scoring are the same for both.

The GHABP and GHADP ask respondents to reflect on four speech hearing situations (e.g. "Having a conversation with one other person when there is no background noise".) and to answer six questions about each situation. Each question is scored on a five-point Likert scale to assess their use, satisfaction, initial disability, initial handicap, aided benefit and aided handicap (Gatehouse 1999; Whitmer, Howell, and Akeroyd 2014). Their initial disability and aided benefit were scored to be social questions (i.e. 8 items), while their initial handicap (i.e. "How much does this situation worry, annoy or upset you?) and aided handicap were judged to be psychological questions (i.e. 8 items). The GHABP and GHADP also allow the patient to define additional situations to assess like the COSI.

Health Utilities Index (HUI)

The Health Utilities Index (HUI®) is a proprietary health-status classification system developed from research originating at McMaster University, Hamilton, Ontario, Canada (Horsman et al. 2003). It was administered in two studies in this review: once with the GHABP to evaluate a middle ear implant (Vibrant Soundbridge, Med-El) using a multicentre single-subject repeated measures design, and once with the APHAB to evaluate the Codacs™ Investigational Device (Cochlear) with stapes prosthesis using a multicenter prospective interventional design. Both studies utilised the HUI Mark 2 (HUI2) and Mark 3 (HUI3) self-administered 15-item questionnaire format.

The HUI2 and HUI3 are separate but complementary tools used to describe an individual's comprehensive health status. The HUI2 classification system has six attributes (i.e. sensation, mobility, emotion, cognition, self-care and pain). Each attribute has multiple levels (e.g. emotion has five levels, Level 1 is described as "Generally happy and free from worry".). The HUI3 classification system has eight attributes (i.e. vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain) with multiple levels. Here we judged HUI2 and HUI3 to each has one social and one psychological item. However, as the scoring system uses a complex, proprietary algorithm to calculate a health-related quality of life (HRQL) score for both the HUI2 and HUI3, it is difficult to establish the weight of each attribute in the final scoring. In the other PROs, all questions are typically of equal weight.

Hearing Device Satisfaction Scale (HDSS)

The Hearing Device Satisfaction Scale (HDSS) was developed by Symphonix (Symphonix was acquired by Med-El) to evaluate pre-operative hearing aid use and post-operative fitting of the Vibrant Soundbridge (Luetje et al. 2002). It consists of 21 items scored on a five-point Likert scale from very dissatisfied to very satisfied. Many topics are covered (e.g. cosmetics, sound quality, reliability, etc.,); however, only two questions were scored social items (i.e. speech in background noise and telephone use) and one as a psychological item (i.e. respondents are asked to rate the improvement in their quality of life). It was administered in four different studies, three with Vibrant Soundbridge (Med-El) as the intervention and one with Bonebridge (Med-El). It was the sole PRO in two articles and grouped with the APHAB and GBI in the other two.

Hearing Handicap Inventory (HHI)

The Hearing Handicap Inventory (HHI) for Adults was created and validated by Newman et al. (1990) by modifying the HHI for the Elderly. It consists of 25-items on two subscales, emotional and social/situational, scored using a three-point Likert scale (i.e. yes, sometimes, no) (Newman et al. 1991). It was judged to have 13 psychological items (e.g. "Does your hearing problem make you irritable?") and 12 social items (e.g. "Does your hearing problem cause you difficulty when attending a party?").

It was administered in two studies (with the SSQ (1 article) and with the COSI, EMSQ and GBI (1 article)) to collect cross-sectional data while retrospectively investigating treatment outcomes for percutaneous bone conducting devices.

Hearing Implant Sound Quality Index (HISQUI)

The Hearing Implant Sound Quality Index (HISQUI) is a 29-item questionnaire available from Med-El. It is designed to be administered with many of their products (e.g. cochlear implant, bone conduction implant, auditory brainstem implant, etc.). However, literature regarding its validation could only be located for cochlear implant users (Amann and Anderson 2014). Using a seven-point Likert scale, respondents score their effort and auditory abilities from never to always (e.g. "Can you effortlessly distinguish single instruments in a familiar piece of music?").

It was scored to have ten social items (e.g. "When background noise is present, can you effortlessly participate in a conversation with friends or family members?") and zero psychological items. It was administered once with the GBI and NCIQ in a retrospective investigation of a middle ear implant (Vibrant Soundbridge, Med-El).

In-house Questionnaires (IHQs)

In-house Questionnaires (IHQs) were reported in 19 articles (Supplementary Table 3). The number of items they included ranged from 1 to 18 ($Mdn = 3$). The total number of psychological items across all questionnaires was five (in 5 articles). All five questions asked about the respondent's quality of life. Social items were judged to be present in seven IHQs; all asked about speech hearing abilities in different listening situations. An IHQ was the only reported PRO in ten articles. Five of the 19 articles reported on-ear surgeries with the remaining 14 investigating treatment from bone-conducting or middle ear technologies (i.e. 12 percutaneous bone conducting devices, one transcutaneous bone-conducting system and one middle ear implant). Two of the IHQs (Huber, Schrepfer, and Eiber 2012; Karkas et al. 2009) were designed to collect feedback from surgeons and did not include any PRO items.

International Outcome Inventory for Hearing Aids (IOI-HA)

The International Outcome Inventory for Hearing Aids (IOI-HA) is a 7-item questionnaire developed and validated to self-assess hearing aid fitting outcomes (Cox & Alexander 2002; Cox et al. 2000). Each question, measured on a five-point Likert scale, aims to measure a different outcome: use, benefit, residual activity limitations, satisfaction, residual participation activities, impact on others and quality of life (Cox and Alexander 2002). Three of these questions (i.e. benefit, residual activity limitations and residual participation activities) were scored as social items and two (i.e. impact on others and quality of life) were scored as psychological items.

It was administered in four studies, three times as the sole PRO and once with an IHQ. All four studies investigated implantable technologies (i.e. percutaneous bone conducting device (2 articles); middle ear implant (2 articles)); however, no two study designs were alike.

Nijmegen Cochlear Implant Questionnaire (NCIQ)

The Nijmegen Cochlear Implant Questionnaire (NCIQ) is a lengthy 60-item PRO with three domains: physical (30 items), psychological (10 items) and social (20 items). It is marked on a five-point Likert scale from never to always. It was administered once with the GBI and HISQUI in a retrospective investigation of a middle ear implant (Vibrant Soundbridge, Med-El).

It was scored to have twenty social items (e.g. "Does your hearing impairment present a serious problem when you are with friends?") and ten psychological items (e.g. "Does your hearing impairment undermine your self-confidence?"). However, it is designed for, and has only been validated with, cochlear implant users (Hinderink, Krabbe, and Van Den Broek 2000). Some of the questions are less applicable to individuals with mixed and/or conductive hearing losses (e.g. "Are you able to shout if you need to?").

Speech, Spatial and Qualities of Hearing Scale (SSQ)

The Speech, Spatial and Qualities of Hearing Scale (SSQ) is a validated 49-item PRO scored using a visual analog scale (VAS) from zero to ten (Gatehouse & Noble 2004). It contains three subscales: speech hearing (14 items), spatial hearing (17 items) and qualities of hearing (18 items). It was judged to have 20 social items (e.g. "Do you have to put in a lot of effort to hear what is being said in conversation with others?") and zero psychological items.

The SSQ was administered in ten studies: in five articles it was the sole PRO, in two studies it was combined with the APHAB and an IHQ, and in the remaining three it was combined with either the APHAB, BHAQ or HHI. Only one of the studies reported on an ear surgery (i.e. canalplasty), while the remaining investigated bone conduction or middle ear technologies (e.g. percutaneous bone conducting devices (6 articles)). The most common study type was a chart review (3 articles), with two of the three administering the SSQ to obtain cross-sectional data.

Tinnitus Handicap Inventory (THI)

The Tinnitus Handicap Inventory (THI) is a 25-item PRO created and validated by Newman, Jacobson, and Spitzer (1996). Questions are separated into three subscales: functional (12 items), emotional (8 items) and catastrophic (5 items), and scored using a three-point Likert scale. It was judged to have 13 psychological items (e.g. "Because of your tinnitus, do you feel frustrated?") and 12 social items (e.g. "Does the loudness of your tinnitus make it difficult for you to hear people?").

It was the sole PRO administered in one study (Freni et al. 2014) retrospectively comparing stapedotomy techniques.

Discussion

The value of patient-reported outcome measures in the evaluation process of hearing loss interventions has been promoted since the mid-1980s (Hampson 2012). PROs are an important component of health-related study designs as they document unobservable symptoms, concepts and experiences only known by the respondent. Audiometric measures, determined to be in the hearing domain by the AURONET group, alone are insufficient to assess the hearing-related quality of life. This paper considered all administered questionnaires to separate, evaluate and document any psychosocial measures. Most of the research originated from European centres; however, as we only included articles with English full-text, this observation has limited generality.

Only 66 (22%) of the 300 articles (Supplementary Figure 1) that met our inclusion/exclusion criteria contained at least one PRO, demonstrating underuse of PROs in adults treated for

conductive and/or mixed hearing losses. It is promising that only 15 unique PROs (removing IHQs) were catalogued across the 66 articles. This small number should indicate that the same PROS are being administered across studies, which should allow for meaningful comparisons. However, five of the questionnaires (i.e. BAHU, BHAQ, HISQUI, NCIQ, THI) were only reported in one article, making comparisons impossible. In addition, the HISQUI and NCIQ have only been validated, to our knowledge, with cochlear implant (CI) users.

All PROs, except for the BAHU (Supplementary Table 2), evaluated psychosocial well-being through the inclusion of social items (i.e. asking how the respondent understands speech in different listening environments). And although these responses relate to psychosocial health, they also contribute valuable information to the hearing domain. These complex interactions between domains are unavoidable. However, the AURONET group aims to be mindful of these relationships when developing a core set of patient-centred outcome measures to create a comprehensive balanced assessment battery that minimises redundancies.

No psychological items were deemed to be present in five of the PROs (Supplementary Table 2): APHAB, BAHU, COSI, HISQUI and SSQ. This observation is important as the APHAB and SSQ were two of the most frequently administered questions, with 22 and 10 occurrences respectively. Consequently, dispensing these questionnaires as the sole PRO may limit the ability of the examiner to accurately evaluate the respondent's psychosocial health.

It should be noted that BAHU, EMSQ, HDSS and HISQUI are manufacturer-developed (i.e. Cochlear and Med-El) PROs tailored to evaluate their respective products. The number of questions ranged from 4 to 29 with all but the BAHU asking respondents to evaluate their hearing abilities in different social situations (Supplementary Table 2). And although valuable information can be extracted to assess benefit, their narrow purpose makes comparisons across treatments challenging. In addition, researchers and clinicians are unlikely to utilise these assessments outside of their intended scope, even with modifications, as more suitable options are available. However, it should be mentioned that the EMSQ contained one unique psychological item that asked subjects to describe their feelings about their device and its use, with closed set and open response options.

Ten PROs remain after eliminating the manufacturer-developed and CI user validated assessments: APHAB, BHAQ, COSI, GBI, GHABP/GHADP, HUI, HHI, IOI-HA, SSQ and THI. All except the HUI would be considered by most to be disease-specific questionnaires. They are designed to assess or detect changes in a specific population (i.e. hearing loss). The HUI, a valuable generic measure administered in two studies that contain two social and two psychological items, is only available to those who purchase the patented software. This could be a limitation for some investigators.

Only ten (15%) of the 66 articles reported outcomes related to ear surgery (e.g. stapedotomy). Each of these studies only administered one PRO: APHAB (1), GBI (2), IHQ (5), SSQ (1), THI (1). As previously stated, the APHAB and the SSQ do not contain any psychological items. Two of the five IHQs (Huber, Schrepfer, and Eiber 2012; Karkas et al. 2009) were dispensed to surgeons. The remaining three each included only two questions that assessed either tinnitus severity, surgical satisfaction, global satisfaction, phone usage or hearing impairment.

The creation of new PROs, whether by the manufacturer or the investigator using study-specific IHQs, most likely originates from a lack of awareness and/or need. Existing validated questionnaires may not evaluate a specific feature (e.g. magnet strength in a transcutaneous bone conduction system) of interest to the examiner. However, this should be avoided whenever possible (Velentgas, Dreyer, and Wu 2013). Unique PROs limit the abilities of stakeholders to make comparisons across treatments and populations. Without a lengthy testing period, a new PRO may also fail to measure what was intended. A study that administers a unique PRO should also administer a questionnaire with established reliability and validity (Velentgas, Dreyer, and Wu 2013).

Of the 19 IHQs catalogued in this review (Supplementary Table 3), 8 contained no psychosocial items. The remaining contained no more than one psychological question and 0–7 ($Mdn = 0$) social items. One of the most common IHQ items was about device usage, the specific amount of time worn. Investigators are likely inferring a strong positive correlation with benefit from this item.

This desire by investigators to document device usage time using PROs is one of many issues to be addressed by the AURONET group in the next step. Each of the items and/or measures identified in this review will now undergo an assessment using the OMERACT three-part filter of truth, discrimination and feasibility (The OMERACT Process 2018). It is critical that each measure is stable, sensitive, practical to administer and valid (i.e. measures what it claims to measure).

Conclusion

The information contained in this overview is an important first step to successfully finalise a core outcome set for this population. Researchers and clinicians may be stationary in their methods and opposed to change. However, this review clearly establishes a lack of standardisation in the psychosocial domain and the need for consistent, and possibly new or different, methods. This is important to communicate to stakeholders (i.e. patients, clinicians, investigators, manufacturers, etc.) so that current and future treatment alternatives can be uniformly and objectively evaluated.

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