Patient-reported outcome measures for hearing aid benefit and satisfaction: Content validity and readability

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ABSTRACT

Purpose: Numerous patient-reported outcome measures (PROMs) are available to measure hearing aid benefit and satisfaction. It is unclear to what extent currently available PROMs on hearing aid outcomes, often developed decades ago, meet current guidelines for good content validity and readability. This study evaluated the content validity and readability of PROMs that focus on perceived hearing aid benefit and/or satisfaction.

Method: A literature review was conducted to identify eligible instruments. Content validity evaluation included mapping extracted questionnaire items to the World Health Organization's International Classification of Functioning, Disability, and Health (WHO-ICF) framework. In addition, study design in content validity methodology was evaluated using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) study design checklist for PROM instruments. Readability was estimated using the Simple Measure of Gobbledygook (SMOG) measure.

Results: Thirteen questionnaires were identified and evaluated. Item content focused primarily on the components of environmental factors as well as activity limitations and participation restrictions with less emphasis on body functions and personal factors. The content validity methodology analysis revealed an under use or lack of reporting of a qualitative methodology in assessing patient and professional perspectives. All the included questionnaires exceeded the recommended sixth-grade reading level.

Conclusions: The categories covered by hearing aid PROMs vary considerably, with no single instrument comprehensively covering all the key ICF components. Future development of hearing aid outcome measures should consider a mixed methodology approach for improved content validity and ensure an appropriate reading level.

KEYWORDS

Hearing aids, Questionnaires, Outcome measures, Patient-reported outcome measures, International Classification of Functioning, Disability, and Health (ICF), Content validity, Readability

INTRODUCTION

Hearing aids are the most common sensory management rehabilitation option for individuals with hearing loss (Boothroyd, 2007; Ferguson et al., 2019; Kochkin, 2009). Hearing aid use (e.g., hours of usage per day), benefit, and satisfaction are typical constructs considered as hearing aid outcomes. Hearing aid benefit is defined as improvements in hearing function and communication abilities resulting from hearing aid usage and measured with dimensions such as improvement in hearing, communication, daily life activities, participation, and overall quality of life (Humes, 1999; Humes, 2003; Wong et al., 2003). Hearing aid satisfaction can be described as a "pleasurable emotional experience as an outcome of an evaluation of performance" and is often measured along dimensions of acoustic benefit, comfort, appearance, cost, and service delivery (Wong et al., 2003, p 117). Indeed, Gatehouse (2001) described hearing aid satisfaction as a complex component or outcome with many elements. Hearing aid satisfaction is generally related to experience, expectation, personality and attitude, usage, the type of hearing aid(s), sound quality, different listening situations, and difficulties in hearing aid use (Wong et al., 2003). These hearing aid outcomes can be measured utilizing two methodological approaches: (1) an objective approach of measuring hearing aid performance in a clinical setting, including real-ear measurements, as well as assessing speech recognition (e.g., unaided versus aided; in quiet versus in noise) (Humes, 1999; Humes, 2003); (2) a subjective approach or self-reported measure of hearing aid outcomes (Humes, 2003). The latter is also known as a patient-reported outcome measure

(PROM), assessing various constructs such as perceived hearing aid benefit or satisfaction using self-reported questionnaires.

A combination of objective and subjective measures is often used in clinical and research settings to measure and demonstrate the success of hearing aid outcomes. Hearing care professionals measure hearing aid outcomes to develop realistic, individualized goals and expectations, along with proper guidance on hearing aid fitting and management over time (Bray & Nilsson, 2002). Documenting hearing aid outcomes helps establish the cost-effectiveness of hearing aids to funding agencies such as insurance companies and veteran administrations to improve access to hearing aids (Gatehouse, 2001). Recent evidence indicates that hearing rehabilitation by means of hearing aids can improve socio-emotional, cognitive, and physical dimensions of well-being (for an overview, see Vercammen et al., 2020). Therefore, measuring hearing aid outcomes that include aspects of well-being is important for patients and other healthcare professionals to realize and understand the direct positive impact that improved hearing can have on a person's quality of life (Saunders et al., 2021). These factors emphasize the importance of valid and reliable hearing aid outcome measures and the careful selection of the outcomes for clinical and research purposes.

Numerous PROM tools are available for audiologists to measure hearing aid benefit and satisfaction, such as the International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002) or the Profile of Hearing Aid Performance (PHAP; Cox & Gilmore, 1990). However, the various hearing aid outcome measures focus on different outcome constructs. For example, the Satisfaction with Amplification in Daily Life questionnaire (SADL; Cox & Alexander, 1999) measures satisfaction with hearing aids, while hearing aid benefit is the focus of questionnaires such as the Abbreviated Profile of Hearing Aid Benefit (APHAB;

Cox & Alexander, 1995). The extent of prior consultation with relevant stakeholders (i.e., clinicians, patients) for the items included in these available PROMs was often not fully reported. Furthermore, a lack of consensus on a comprehensive set of hearing aid outcome domains to be included during assessment and a lack of knowledge of measurement properties of the outcome measures lead to difficulties in the questionnaire selection process (Allen et al., 2022). According to COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN; Mokkink et al., 2016; Mokkink et al., 2010), four measurement properties should be considered when evaluating or selecting outcome measures, namely (a) validity (i.e., content, construct, and criterion), (b) reliability (i.e., reliability, measurement error, and internal consistency), (c) responsiveness, and (d) interpretability. Content validity is often considered the most critical measurement property of a PROM, and it refers to the degree to which the content of the outcome measure instrument (i.e., the questions and response options) is an adequate reflection of the construct aimed to be measured (Mokkink et al., 2010; Terwee et al., 2018). When content validity of an outcome measure is concerned, best practice is to measure and report the relevance of test items to the construct to be measured, the target population, the context of use, and patients' and professionals' experience of the condition (Gagnier et al., 2021; Prinsen et al., 2016; Terwee et al., 2018). It is also essential to examine if all key concepts are included in the tool and if all items, response options, and instructions are comprehensible to intended users (Gagnier et al., 2021). The published reports of hearing aid outcome measures often exclude one or many crucial factors related to content validity (Saunders et al., 2005). Many shortened versions of questionnaires lack validation information, and psychometric properties are often only available for the full versions of the questionnaires (Whitmer et al., 2016). As a result, it is uncertain to what extent current PROMs on hearing aid outcomes have good content validity.

In addition to content validity, feasibility is another essential factor to consider when selecting an outcomes measure instrument (Prinsen et al., 2016; Terwee et al., 2018). Feasibility aspects that should be considered include the patient's and clinician's readability, ease of administration, interpretability of the scores, instrument length, and completion time (Prinsen et al., 2016). In addition, the PROM should be inclusive, equitable, and accessible to all patients from different demographics, socioeconomic, educational, and health statuses, including previous under-served groups (e.g., minority ethnic groups, participants from low-middle-income-countries) to avoid health disparities (Calvert et al., 2022). To improve inclusivity, Calvert and colleagues (2022) described various actions, e.g., representative patient input in the identification of key concepts to be measured, promoting digital inclusion by providing alternative modes of delivery of the PROM, development of culturally relevant translations etc. Assessing the readability of PROMs is essential because reading levels that are too high for the reader can result in non-completion by some users, reading and comprehension difficulties, partial or missing information while completing the outcome measure instrument, and/or providing unrelated answers (Atcherson et al., 2011). Consequently, the treatment, planning, and outcomes based on responses obtained from these questionnaires may not be valid and reliable (Zraick et al., 2012). A limited number of studies have evaluated the readability of hearing health-related PROMs (e.g., Douglas & Kelly-Campbell, 2018; Manchaiah et al., 2019). Findings indicate that most of the existing PROMs designed to determine hearing disability (see Manchaiah et al., 2019) or to be used within the field of adult audiological rehabilitation (see Douglas & Kelly-Campbell, 2018) have reading grade levels higher than the recommended fifth or sixth reading grade level for health-related materials (Douglas & Kelly-Campbell, 2018; Manchaiah et al., 2019; Wang et al., 2013; Weis, 2003). There is a need therefore to evaluate the readability of PROMs on hearing aid outcomes of benefit and satisfaction.

This study aimed to evaluate the content validity and the readability of hearing aid PROMs developed to quantify hearing aid satisfaction and/or benefit. Content validity was assessed by linking the questionnaire items to the World Health Organization's International Classification of Functioning, Disability, and Health framework (WHO-ICF; World Health Organization, 2001). The ICF is both a conceptual model and a classification system. The conceptual model is based on a multidimensional model that integrates medical and social models of health. It conceptualizes functioning and disability as a complex interaction between personal, environmental, and health condition-related factors. Given the complex nature of hearing disability, assessment and management of hearing loss should be based on a multidimensional, biopsychosocial model, considering aspects such as body structure and functions, individual experiences, and the individual's social and environmental context (Granberg, Möller, et al., 2014; Granberg, Swanepoel, et al., 2014). The ICF classification has four components grouped under two parts. The components of body functions and structures as well as the activity and participation component are grouped under the functioning and disability part (World Health Organization, 2001). The components of environmental and personal factors are grouped under the contextual factors part. Difficulties concerning body function and structures are expressed as impairments while the corresponding terminology regarding activity and participation are activity limitation and participation restriction. Each component contains multi-level numerical coded categories and subcategories with definitions and inclusion and exclusion criteria to guide the linking process (e.g., d3503 – Conversing with one person; d3504 – Conversing with many people).

The objective of hearing aid fitting is to reduce activity limitations and participation restrictions experienced due to hearing loss and improve health-related quality of life

(Gatehouse, 2001). Self-report measures are ideally situated to capture the lived experience of activity limitations and participation restrictions due to hearing loss and hence the effect of the intervention (Gatehouse, 2001). When a self-report measure is used to assess the rehabilitative outcomes of individuals with hearing loss, Cox and colleagues (2000) indicated that an optimal measure should consider benefit in terms of both activity limitation and participation restriction reduction and should include a satisfaction assessment. As previously stated, satisfaction can be assessed along various dimensions, e.g., sound quality, listening situations or contexts, etc. Based on these recommendations, the key components of the ICF seem to align well with the hearing aid outcome constructs of benefit and satisfaction. The key components include body function (e.g., hearing function, emotional function, relating to benefit), activity limitations and participation restrictions (e.g., speech understanding, which can relate to benefit on a personal level of function in everyday activities; ability to participate in group conversations, which can relate to benefit in terms of psychosocial functioning), environmental factors (e.g., the impact of hearing aids on speech understanding), and personal factors (e.g., the influence of age on hearing aid use and perceived benefit and satisfaction). These key components can also align with health-related quality of life and satisfaction. Therefore, it would be expected that a comprehensive hearing aid PROM should consider the key components of the ICF relevant to hearing health and functioning when using hearing aids. However, it should be noted that most of the current hearing aid PROMs were developed prior to the more recent guidelines of the ICF as well as before the establishment of the COSMIN principles (Mokkink et al., 2016).

In addition to the ICF mapping, content validity was evaluated by assessing the study design of the included PROMs. The study design was evaluated to determine the appropriateness of the content validity methodology used during the development of the outcome measures.

Combined, these aspects relate to the content validity and feasibility of the questionnaire instruments (Terwee et al., 2018).

METHOD

Search Strategy and Inclusion Criteria

Questionnaires focusing on hearing aid benefit and/or satisfaction were identified using a two-step process. In the initial stage, seven review articles (Bennett et al., 2015; Gatehouse, 2001; Humes, 1999; Mendel, 2009; Saunders et al., 2005; Taylor, 2007; Weinstein, 1997) and three book chapters (Bentler et al., 2016; Bray & Nilsson, 2002; Whitmer et al., 2016) published between 1997 to 2015 were reviewed. In the second stage, a PubMed (MEDLINE) search was conducted independently by two researchers (NS and LK) in December 2021 to identify published articles related to hearing aid PROMs. Keyword phrases used in the search were: ("hearing aid" AND "benefit" AND "questionnaire"); ("hearing aid" AND "outcome" AND "questionnaire"); ("hearing aid" AND "satisfaction" AND "questionnaire").

The hearing aid benefit and/or satisfaction PROMs were included based on the following criteria: (a) assessed hearing aid benefit and/or satisfaction for adult hearing aid owners with items that met the definition of hearing aid satisfaction/benefit, as defined by Wong et al. (2003) and (b) published in the English language. Questionnaires with a confined focus on specific aspects of amplification, such as binaural amplification benefit, aided loudness, amplification device handling skills, adverse reaction to amplification, or hearing handicap, were excluded from the study. Also, PROM instruments developed specifically to assess amplification benefit from implanted devices (e.g., cochlear implants), those that targeted the pediatric population, and those not developed for clinical use were excluded from this study.

All the included questionnaires were evaluated for 1) content validity (including ICF mapping and assessing study design in terms of content validity methodology) and 2) readability.

Content Validity Evaluation

ICF Mapping (Linking)

The content of the questionnaire items was mapped (linked) using The World Health Organization's International Classification of Functioning, Disability, and Health framework (WHO-ICF; World Health Organization, 2001). Linking is a scientific process where established linking rules are used. When linking, the entire ICF creates the foundation for the linking process. In the current study, each item of the questionnaires were linked to specific ICF categories using established linking rules developed specifically for outcome measures (Cieza et al., 2019; Cieza et al., 2005). Because the included questionnaires consisted of hearing and hearing aid-related statements or questions to be evaluated by respondents, these questions and statements required interpretation of the underlying meaning for linking them to the ICF codes. Personal factors were not classified in detail under the ICF. Therefore, a separate personal factors coding system recommended by audiologists and sociologists with expertise in hearing disability was used for analysis and classification (Stephens, 2002; Stephens & Danermark, 2005). Using this classification system, personal factors were categorized as follows: (a) gender, race, age; (b) other health conditions; (c) fitness; (d) lifestyle; (e) habits; (f) upbringing; (g) coping styles; (h) social background; (i) education; (j) profession; (k) past and current experience; (l) overall behavior pattern and character style; and (m) individual psychological assets. The items not covered in the ICF were coded as *not coded (nc)*. It should be noted that the generic linking rules in the standardized classification were supplemented using specific rules developed for the field of audiology to improve the

reliability and transparency of the linking process of audiological research data (Granberg, Möller, et al., 2014). Examples of the linking process is provided in Table 1.

The items of the questionnaires were reviewed and linked independently by two researchers (SG and EK). For a few items, disagreements in the linking were noted and resolved by discussion between the two researchers. Six already linked questionnaires (APHAB, GHABP, HAPI, IOI-HA, PHAB, SADL) were obtained from another study (Granberg, Möller, et al., 2014), and the linking of these questionnaires were also used in the previous study.

Study Design Assessment: Content Validity Methodology

The study design of all the selected articles was examined to evaluate the content validity assessments during the development of hearing aid benefit/satisfaction questionnaires. The analysis was done using the COSMIN Study Design checklist for PROMs (Mokkink et al., 2019). The study design checklist for content validity assessment rates the study design on a five-point rating scale (i.e., very good, adequate, doubtful, inadequate, not applicable) based on nine factors. The nine factors considered were (1) perspective of the patients, (2) perspective of the professionals, (3) include professionals from all relevant disciplines, (4) appropriate sample size (i.e., evaluate each item in an appropriate number of patients or professionals; 30-49 participants or four to six participants is considered as an adequate sample size for quantitative and qualitative studies, respectively; $\geq$ 50 participants or $\geq$ seven participants is considered as very good for quantitative and qualitative studies, respectively; Mokkink et al., 2019), (5) use of skilled group moderators or interviewers, (6) meetings and interviews based on appropriate topic or interview guidelines, (7) record and transcribe verbatim meeting or interview data, (8) appropriate approach to analyze data (i.e., a widely

recognized or well-justified approach should be used; Mokkink et al., 2019), (9) involve at least two researchers in analysis.

Readability Evaluation

The readability of a PROM is an important aspect of feasibility to consider. In recent studies, four readability measures were selected to analyze the readability of audiological PROMs (e.g., Atcherson et al., 2013; Atcherson et al., 2011; Douglas & Kelly-Campbell, 2018; Kelly-Campbell et al., 2012; Manchaiah et al., 2019), namely: (i) Flesch Reading Ease (FRE; Flesch, 1948); (ii) Flesch-Kincaid Grade Level Formula (F-KGL; Kincaid et al., 1975); (iii) Simple Measure of Gobbledygook (SMOG; Mc Laughlin, 1969); and (iv) FORd CAylor STicht (FORCAST; Caylor et al., 1973). However, there is no standard for choosing readability formulas (Breese & Burman, 2005). Since the SMOG formula is based on an assumption of 100% comprehension and is recommended for use with health information (Wang et al., 2013) it was used to conduct a quantitative readability estimate on each included questionnaire. Questionnaire items are often written in sentences. The SMOG formula also considers the number of sentences in addition to syllable count to calculate reading grade level (RGL) (McLaughlin, 1969). RGL is used to present the results of SMOG analyses. RGL uses the US school grade level as a reference and indicates that the average student in that grade level can read the text. For example, a score of 9.4 implies that an average ninth-grade student understands the text. The Readability Studio Standard Edition 2012 (http://www.oleandersolutions.com/) software was used to compute the readability estimates in all the included hearing aid PROMs. The software randomly selects 100 words for analysis. To ensure accuracy, this readability analysis was repeated three times, and the results were averaged for each questionnaire. Only the individual questionnaire items were included in the analysis, excluding the response options and instructions.

RESULTS

Identified Questionnaire Instruments

From the initial search of seven review articles and three book chapters, we identified 49 hearing aid PROMs. The database search with keywords yielded no extra questionnaires. Each of these 49 questionnaires was evaluated for eligibility based on the inclusion criteria, and 36 questionnaires were excluded (see the list in Appendix 1) for the following reasons:

(i) Fourteen questionnaires were excluded as these questionnaires did not meet the hearing aid benefit and/or satisfaction definition by Wong et al. (2003).

(ii) Seven questionnaires were excluded since they had a confined focus and assessed a single dimension of outcome or targeted a specific group of adults, namely: Profile of Aided Loudness (PAL; Palmer et al., 1999), Performance Inventory for Profound and Severe Loss (PIPSL; Owens & Raggio, 1988), Practical Hearing Aid Skill Test (PHAST; Desjardins & Doherty, 2009), Style Preference Survey (SPS; Smith et al., 2013), Binaural Hearing Aid Questionnaire (BHAQ; Chung & Stephens, 1986), Intelligibility Rating Improvement Scale (IRIS; Cox et al., 1991), Negative Reactions to Hearing Aids (NRHA; Surr & Hawkins, 1988), and Psychosocial Impact of Assistive Device Scale (PIADS; Jutai & Day, 2002).

(iii) Six questionnaires were excluded during screening as they did not focus on hearing aid outcomes but on hearing disability. The hearing aid PROMs included questions mainly focused on perceived hearing aid experiences. For example, the first question of the IOI-HA (Cox & Alexander, 2002) questionnaire reads “Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?” In contrast, the questions included in hearing disability PROMs focused more on perceived hearing difficulty(ies) and the consequent effect(s) on different dimensions of a

person's life. For example, the Hearing Handicap Inventory for the Elderly (HHIE; Ventry & Weinstein, 1982) has a situational question (S-1) that reads "Does a hearing problem cause you to use the phone less often than you would like?". It should be noted that some PROMs with a hearing disability focus have been used as a measure of hearing aid benefit by comparing pre- and post-fitting differences (e.g., Newman & Weinstein, 1988). However, as this study focused on hearing aid PROMs, general hearing difficulty questionnaires were not included.

(iv) Four generic tools were excluded as they are not as sensitive to the improvements produced by hearing aids as hearing aid-specific questionnaires (Whitmer et al., 2016).

(v) Two questionnaires were excluded as they were not developed for clinical use.

(vi) The Client Oriented Scale of Improvement (COSI; Dillon et al., 1997) was not included since the user-defined listening situations, identified during the initial phase of the COSI administration, are open-ended in nature. Furthermore, the COSI does not have specific items with content that can be evaluated using the ICF.

(vii) MarkeTrak Hearing Aid Satisfaction Survey (Kochkin, 1990) and Dynamic Assessment of Hearing Aid (DAHA; Cienkowski et al., 2006) were excluded as the full length questionnaire could not be obtained.

After exclusion, ten full and three shortened questionnaires (see Table 2) were subjected to further evaluation. All the questionnaires included in the study assessed hearing aid outcomes in adults and/or older adults. The Hearing Aid User's Questionnaire (HAUQ; Dillon et al., 1999) has some items relating to hearing aid use, yet it was still included as the majority of the items focused on benefit and/or satisfaction. The PHAP and the Profile of Hearing Aid

Benefit (PHAB; Cox et al., 1991) have the same questionnaire items; therefore, only the PHAP was included. Table 2 displays the list of included questionnaires with the response options, population, and the person to administer the questionnaire (i.e., patient-administered vs. clinician-administered) as reported by the developers.

Content Validity Evaluation

ICF Mapping

Table 3 displays the frequency count of the total ICF categories and the linking of each hearing aid PROM item to the specific ICF component. The questionnaires focused mostly on environmental factors and activity limitations and participation restrictions. All the included questionnaires had at least one item linked to the environmental component. The activity limitations and participation restrictions component was linked to ~69% of items in 12 of the 13 included questionnaires. The component of body function was less represented as only ten hearing aid PROMs had ~2-38% of items linked to this component. The questionnaires focused the least on the component of personal concerns. More than half of the questionnaires (i.e., seven out of 13 questionnaires) had no items referring to personal factors. In addition, some variation in the main ICF components covered in each questionnaire is seen. For example, the focus of hearing aid PROMs on activity limitations and participation restrictions varied from approximately 12% to 69%. Yet, one questionnaire (i.e., HAUQ) had no item linked to this component. Similarly, most questionnaires had at least eight items linked to environmental factors, but one questionnaire (i.e., HSS-HA) only had one item covering this component.

The frequency of occurrence of categories and subcategories in each ICF component (i.e., body function, activity limitations and participation restrictions, environmental factors, and

personal factors) for all the hearing aid PROMs are shown in Tables 4 – 7. Some of the questionnaire items' content could not be linked to any of the categories in the ICF, for example: "first time", "how many times", or "most frequently". This resulted in 160 items in a *nc* (i.e., not coded) category.

From Table 4, it is clear that the most frequently occurring category in the body function component was hearing function (b230). The categories of emotional function (b152), perceptual function (b156), as well as auditory perception (b1560) were also often linked to questionnaire items. Although temperament and personality functions (b126), attention (b140), and memory (b144) are included in the ICF, none of the questionnaires covered these categories.

The most frequently occurring categories in the component of activity limitations and participation restrictions were: listening (d115), communicating with-receiving-spoken messages (d310), conversation (d350), conversing with one person (d3503), family and intimate relationships (d760 and d770, respectively) (see Table 5). Categories such as handling stress and other psychological demands (d240) and using communication devices and techniques (d360), and using transportation (d471) under activity limitations and participation restrictions were not included in any of the questionnaires considered in the study. Activity limitations and participation restrictions related to the categories of daily routine (d230), discussion (d355), education (d810-839), religion and spirituality (d930) were seldom included.

The hearing aid PROMs extensively covered the ICF component of environmental factors. The categories that occurred most frequently include assistive products and technology for

communication (e1251), design, construction, and building products and technology of buildings for public use (e150), and categories of sound (e250) (Table 6). Category items of immediate family (e310), individual attitudes of immediate family members (e410), and societal attitudes (e460), these items were not linked to any of the items in the hearing aid PROMs included in this study.

Personal factors were the least represented in the items in the hearing aid outcome questionnaires. Overall behavior pattern and character style, lifestyle, and individual psychological assets were the most frequently assessed personal factors, with the item of habits being less often linked to questionnaire items (see Table 7).

Study Design Assessment: Content Validity Methodology

A total of twelve out of thirteen questionnaires were assessed for their development methodology (Table 8). The Hearing Aid Users Questionnaire (HAUQ; Dillon et al., 1999) was not included as the information on the questionnaire's development was unavailable. The COSMIN checklist recommends using both qualitative and quantitative approaches to check the item relevance, comprehensiveness, and comprehensibility from the patient's perspective and relevance and comprehensiveness from the professional's perspective. Ten out of twelve questionnaires used adequate quantitative methodological approaches to assess patients' perspectives. The Hearing Aid Performance Questionnaire (HAPQ; Gatehouse et al., 2006) used quantitative methods (inadequate) but did not include adequate details regarding the approach used to evaluate the patients' perspectives. The Device-Orientated Subjective Outcome Scale (DOSO; Cox et al., 2014) and the Hearing Satisfaction Scale for Hearing Aids (HSS-HA; Stewart, 2001) used qualitative and quantitative approaches to study patient perspectives. However, they lacked information regarding what dimensions of patient

perspectives were assessed. Only the Satisfaction with Amplification in Daily Life (SADL; Cox et al., 1999) questionnaire used quantitative and qualitative approaches and evaluated all three dimensions of patient perspectives.

Considering professional perspectives, only four questionnaires (DOSO, HSS-HA, SHAPIE, and IOI-HA) explicitly used adequate procedures. HSS-HA is the only questionnaire developed with inputs from audiologists and otolaryngologists. All questionnaires except the IOI-HA and the HAPQ used a sample size ≥50 (very good) for quantitative methods. Among questionnaires with qualitative methodologies (DOSO, IOI-HA, HSS-HA, SHAPIE, and SADL), the DOSO and SADL used an appropriate number of patients (≥7: very good) to obtain patient perspectives. The IOI-HA and SHAPIE questionnaires used an adequate number of professionals (4-6) to gather professional perspectives; however, these PROMs did not assess patients' perspective. In the DOSO questionnaire, the professional sample size was not reported. In the HSS-HA questionnaire both patient and professional sample sizes were not disclosed. The COSMIN checklist recommends using skilled moderators and interviewers and appropriate topic and interview guides during qualitative research methods. Also, it recommends transcribing interview responses verbatim for further analysis. Only for the SADL questionnaire were these recommendations followed, while these details were missing from DOSO, HSS-HA, and IOI-HA questionnaires. When the number of researchers involved in the analysis was considered, all the questionnaires met the COSMIN recommendation of involving a minimum of two researchers (adequate) in the process.

Readability Evaluation

The results of the readability assessment are displayed in Table 9. All of the included hearing aid PROMs had a RGL of the eighth-grade reading level or higher. Thus, all the PROMs

studied here exceeded the sixth reading grade level recommended by health literacy experts (Doak et al., 1996; Donald & Kelly-Campbell, 2016; Yin et al., 2007).

DISCUSSION

The identified hearing aid PROMs were evaluated according to the ICF components, content validity methodology, and readability. The ICF categories measured by the hearing aid PROMs varied considerably, indicating that benefit and satisfaction are broad, complex constructs related to various factors.

The included questionnaires focus mainly on the ICF component of environmental factors as well as the component of activity limitations and participation restrictions. The high representation of environmental factors in the included instruments is also noteworthy. The ICF highlights that contextual factors (i.e., environmental and personal factors) can influence the degree to which disability or residual disability (i.e., residual hearing difficulties experienced with the use of hearing aids) is noticed by an individual. The finding that most hearing aid PROMs also have a considerable focus on the activity limitations and participation restriction component can be viewed as a strength. Activity limitations and participation restrictions constitute a core element of the ICF and thus cover multiple factors that may affect outcomes of hearing aid use in daily life (Danermark et al., 2010; Danermark et al., 2013). It is important to consider these two key ICF components (i.e., activity limitations and participation restrictions, and environmental factors) when determining hearing aid outcomes (i.e., benefit and satisfaction). However, this should be approached from the perspective of how the intervention (i.e., hearing aids) alleviates the multidimensional difficulties associated with the disability (i.e., hearing difficulty) in daily living. Furthermore, various factors, included under activity limitations and participation

restrictions, can align with the perceived benefits of hearing aid use on the socio-emotional well-being of the hearing aid user. For instance, these factors may include increased engagement in daily life activities, enhanced social interactions, and improved psychosocial functioning, as highlighted in studies conducted by Ferguson et al. (2017) and Oosthuizen et al. (2022).

The ICF also defines body function as a core element. It is not surprising that the hearing aid PROMs do not have this component well presented due to its focus on different body functions in addition to hearing functions. Nonetheless, including questionnaire items related to the impact of hearing aid use on body functions are imperative, as these can align with factors affecting physical well-being. For example, how hearing aid use affects the wearer's sense of environmental awareness (i.e., detecting subtle sounds, such as footsteps of someone approaching the hearing aid wearer, sound localization) as this may affect feelings of safety and security and motivate hearing aid wearers to maintain an active lifestyle (Vercammen et al., 2020). From extant literature, it is known that older adults with hearing loss are significantly more at risk of falling compared to their peers with normal hearing (Jiam et al., 2016). Therefore, considering the perceived impact of hearing aid benefits on vestibular function in hearing aid PROMs can also link with physical well-being, especially for older adults.

A biopsychosocial perspective should form the basis of an outcomes measure instrument to be comprehensive and capture the various factors affecting outcomes and performance. The recent call to action to redefine the outcomes of audiological intervention (Saunders et al., 2021) highlighted that these outcomes extend beyond mere improvement in hearing and communication. Well-being and quality of life must also be considered in the assessment and

outcomes of hearing rehabilitation (Humes, 2021; Saunders et al., 2021). Therefore, a hearing aid PROM that includes multidimensional aspects will align with a holistic well-being approach. Moreover, with an aging world population, the importance of supporting healthy aging (United Nations, 2020) and, thus, well-being should be emphasized and included in outcome measures, especially for older adult patients.

Certain factors from the ICF components were not included or included to a lesser extent in the hearing aid PROMs. Factors such as immediate family, individual attitudes of immediate family members, and societal attitudes in the component of environmental factors were not covered by items in the evaluated instruments. Determining attitudes of family members or significant others toward hearing aids and the extent of benefit that the hearing aid user obtains from it could be a valuable aspect to include in a hearing aid outcome measure. The attitudes of significant others can have a positive or negative impact on hearing aid use and thus the outcomes (Chundu et al., 2021; Laplante-Lévesque et al., 2012; Linssen et al., 2013). In addition, the body function component includes cognitive factors such as attention and memory, which were not included in the evaluated questionnaires. To date, there is limited empirical evidence on the possible effect of amplification on long-term cognitive outcomes in older adults (Dawes, 2019; Kalluri & Humes, 2012). However, a recent study indicated that hearing aid use may hold cognitive benefits for adult users compared to non-users (Dillard et al., 2022). In addition, more immediate perceived effects of hearing aid use on cognitive well-being could be considered in hearing aid PROMs, such as the impact on listening effort or listening-related fatigue. Results from studies examining the effect of amplification on listening effort suggest that improving audibility by wearing hearing aids can reduce cognitive load during listening (Hornsby, 2013; Picou et al., 2013). When listening effort is reduced, it may also reduce feelings of fatigue (Holman et al., 2019). Also, the factor of

temperament and personality functions was not linked to any questionnaire items. Including this factor in a hearing aid outcomes measure could be valuable as a negative attitude of the hearing aid owner could have an adverse effect on hearing aid outcomes (Chundu et al., 2021; Gallagher & Woodside, 2018; Laplante-Lévesque et al., 2012; Linssen et al., 2013).

Various items were included to a lesser extent in the hearing aid PROMs, including use of transportation, acquisition of goods and services, informal social relationships, recreation and leisure, education, and activities and participation related to religion and spirituality. These factors relate to various aspects that can be part of hearing aid users' daily living and socio-emotional and physical well-being. When hearing aid owners perceive their hearing aid(s) to be integrated into their daily living and facilitate meaningful participation in activities of their everyday life, improved benefit and satisfaction are often reported (Lockey et al., 2010).

The content validity analysis revealed an under use or lack of reporting of qualitative methods in assessing the patient and professional perspectives. The results indicated that only five of the questionnaires studied here reported the use of qualitative methods in their development: the DOSO, IOI-HA, SADL, SHAPIE, and HSS-HA. Even among these five questionnaires, only two questionnaires used an appropriate patient sample size (DOSO and SADL), and two questionnaires used an appropriate professional sample size (IOI-HA and SHAPIE). In addition, only one questionnaire (SADL) included details regarding the use of skilled moderators and interviewers, interview guidelines, and the use of an appropriate recording of interview responses. Other questionnaires used either less than recommended sample size or did not report on sample size and essential methodological details. The under usage of qualitative methodology emphasizes the need to employ a mixed methodology approach in developing hearing aid benefit and satisfaction measures as it provides the

opportunity to assess patient and professional perspectives systematically. In contrast, all questionnaires, except the IOI-HA, used quantitative methods with appropriate sample size and analysis methods to evaluate content validity.

The majority of the questionnaires evaluated in this study require completion by the hearing aid user. The results from the SMOG measure indicate that all the hearing aid PROMs included in this study exceeded the recommended health literacy level of fifth to sixth RGL (Douglas & Kelly-Campbell, 2018; Manchaiah et al., 2019; Wang et al., 2013; Weis, 2003). Ensuring appropriate readability of audiological PROMs is important to achieving patient/family-centered care. Therefore, developers of future PROMs should strongly consider conducting readability assessments of PROMs (Douglas & Kelly-Campbell, 2018).

Clinical Implications

The linking of questionnaire items to the ICF clearly shows that no single hearing aid PROM comprehensively covers all the ICF categories. Similarly, the content validity assessment of hearing disability questionnaires by Manchaiah and colleagues (2019) also revealed that no hearing disability PROM included all the ICF categories. Some similarities and differences are evident regarding the most prominent ICF components among these different PROMs. Body function and activity limitations were the focus of most hearing disability questionnaire items, with much less emphasis on environmental factors (Manchaiah et al., 2019). In contrast, we found that hearing aid PROMs mainly included items related to environmental factors, activity limitations and participation restrictions, with less emphasis on body function. This also corresponds with what Whitmer et al. (2016) reported in their thorough review of hearing aid validation questionnaires, namely that the domains covered by these PROMs have remained relatively fixed since the 1980s, focusing on psychosocial or speech

understanding benefits and/or satisfaction. The component of personal factors was the least covered by both hearing disability (Manchaiah et al., 2019) and hearing aid PROMs. The latter highlights a potentially significant gap in the current hearing aid PROMs. Results from a recent data-driven synthesis of research (Vas et al., 2017) and from a systematic review of qualitative studies of hearing aid experiences in adults (Oosthuizen et al., 2022) highlight that personal factors (e.g., emotions, identity, stigma, attitude of the person towards hearing aids, self-perceived need for hearing aids) might affect the experiences, outcomes and possibly the success of hearing aid intervention. Clinically, this would imply that audiologists should keep in mind to enquire about these factors by use of open-ended questions during initial and follow-up consultations.

It is important to take into consideration that most of the included PROMs were developed before the creation of the ICF (9/13: APHAB, GHABP, HAPI, HAQU, HDABI, PHAP, SADL, SHAPI, SHAPIE), and therefore it can be assumed that the development of these questionnaires did not consider the guidelines provided by the ICF. However, this manuscript presents a theoretical study to improve researchers' and clinicians' understanding of the components measured with existing hearing aid PROMs. We acknowledge that hearing aid benefit and satisfaction are broad constructs and including all key concepts in a single PROM will be impractical. However, two of the hearing aid outcome questionnaires studied here, the APHAB and SADL, include items mapped to each of the four overarching components of the ICF, namely body functions, activity and participation, environmental and personal factors. Thus, the APHAB and SADL questionnaires appear to have relevant questionnaire content. Using those questionnaires can be recommended as it may result in a more comprehensive assessment of hearing aid outcomes.

The finding that all hearing aid PROMs required higher reading levels to comprehend questionnaire items suggests that those with lower education levels may not easily understand these PROMs. Older adults are expected to be the primary consumers of hearing aids as the global prevalence of hearing loss (moderate or higher grade severity) increases exponentially with age (World Health Organization, 2021). Older adults often have cognitive, visual, and health literacy deficits that may impact their reading and comprehension abilities (Krauss Whitbourne, 2005; Kutner et al., 2006). Hence, ensuring that PROMs have an appropriate reading level for this population group is essential. The recommended reading grade level of health-related information for elderly patients is at the mid-primary school level (Caposecco et al., 2014). Hence, it can be recommended that clinicians administer hearing aid PROMs in an interview format to elderly patients or those with lower literacy levels to provide explanations as necessary.

Limitations and Future Directions

Although this study is the first to evaluate the content validity of hearing aid related PROMs, with the ICF as the benchmark, and the readability of these PROMs, several limitations should be noted. Firstly, the search strategy employed has inherent limitations, which may have resulted in the omission of less commonly reported PROMs. Additionally, the inclusion of only English language questionnaire instruments may introduce potential selection bias. The analysis included multiple questionnaires from the same source (e.g., APHAB is a truncation of PHAP, SHAPIE is a truncation of SHAPI), but did not incorporate shortened versions of the original questionnaires when quantifying ICF components.

We acknowledge that most of the hearing aid PROMS studied here were developed before the ICF in 2001 and the subsequent more detailed hearing core sets in 2014 (Granberg, Dahlström, et al., 2014; Granberg, Möller, et al., 2014; Granberg, Swanepoel, et al., 2014). Similarly, the COSMIN guidelines were also developed after the questionnaires included in this study. However, the COSMIN checklist is considered a current standard of health status measurement (Whitmer et al., 2016). Furthermore, it is important to acknowledge that readability assessments have limitations and do not provide a complete prediction of comprehensibility (Atcherson et al., 2011). Within the confines of the present study and in relation to content validity, it is important to note that the term "readability" should not be conflated with the concept of comprehensibility. Factors such as familiarity with the content, motivation, interest, layout, format, and font size of the document can also impact readability (Doak et al., 1996; Meade & Smith, 1991).

For future questionnaire development, consideration of specific measurement properties recommended by the COSMIN guidelines and incorporating both patient and professional opinions regarding relevancy, construct, population, context, response options, comprehensiveness, and comprehensibility is recommended (Gagnier et al., 2021). However, it is worth noting that only about 45% of the included PROMs explicitly used expert consensus and patient trials during questionnaire development, highlighting the need for future developers to consider these aspects.

While this study focused primarily on content validity and readability, it is important to recognize the significance of other factors such as criterion validity and reliability, which were not addressed here. Additionally, the classical psychometric approaches employed to assess the validity and reliability of the existing PROMs have generated discussions

regarding their suitability for surveys with categorical (ordinal) responses (e.g., Cassarly et al., 2020; Heffernan et al., 2019; Leijon et al., 2021; Liddell & Kruschke, 2018). Moreover, the limited sample diversity obtained primarily from community clinics may restrict the generalization of findings. Therefore, the conclusions drawn regarding content validity and readability should not be the sole guidelines for selecting questionnaires for clinical or research purposes.

Furthermore, the exclusion of open-ended questionnaires in this study (e.g., COSI), due to their inability to be coded using the ICF, should not disregard the potential benefits of using open-ended questions in clinical intake interviews and follow-up appointments. Open-ended questions allow for user-defined specific listening situations and the exploration of lived experiences, facilitating a patient-centred approach. Considering personal aspects, such as user expectations, in future PROM development is crucial, as expectations can influence perceived benefits, satisfaction, and overall hearing aid outcomes (Whitmer et al., 2016).

CONCLUSIONS

The hearing aid PROMs included in this study focussed primarily on the ICF components of environmental factors as well as activity limitations and participation restrictions, with less emphasis on body function and personal factors. The questionnaires also varied in terms of the extent to which each of the different ICF components was represented in the instrument. The lack of explicit use of modern qualitative methods in developing many hearing aid PROMs does not allow a complete assessment of their content validity. Readability of the PROMs of hearing aid benefit and/or satisfaction is questionable as all questionnaires' reading levels exceeded the sixth-grade reading level. Results of this study may point to

important aspects to consider along existing guidelines for validity and readability in future research on hearing aid outcome measures.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding author.

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