

Title

Validation of Teleaudiology Hearing Aid Rehabilitation Services for Adults: A Systematic Review of Outcome Measurement Tools

Running head

Validation of teleaudiology hearing aid services

Article category

Systematic review

Authors

Karina FM Tao,^{a,b,c,d,i} Christopher G Brennan-Jones,^{a,b,c,e,i} Dona MP Jayakody,^{a,b,i} De Wet Swanepoel,^{a,b,f} Gaetano Fava,^{g,h} Sandra R Bellekom,^{a,b} Robert H Eikelboom^{a,b,f}

Affiliations

^a Ear Sciences Centre, Medical School, The University of Western Australia, Perth, Australia.

^b Ear Science Institute Australia, Perth, Australia.

^c Telethon Kids Institute Australia, The University of Western Australia, Perth, Australia

^d CAPES Foundation, Ministry of Education of Brazil, Brasilia, Brazil

^e Department of Audiology, Perth Children's Hospital, Perth, Australia

^f Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa.

^g Comunicare Centre, LLC, New York, NY, USA

^h HiTalk Comunicação & Consultoria Ltda, Sao Paulo, Brazil

ⁱ Faculty of Health and Medical Sciences, The University of Western Australia, Perth, Australia

Correspondence

Karina F.M. Tao, Ear Health Team, Telethon Kids Institute Australia, 15 Hospital Ave, 6009, Nedlands, Perth, Australia. E-mail: karina.tao@telethonkids.org.au

ORCID ID 0000-0001-7666-4899

Abstract

Purpose: To investigate outcome measurement tools for the validation of teleaudiology hearing aid rehabilitation services for adults.

Methods: A search strategy was developed to identify tools used to evaluate standard and teleaudiology hearing aid rehabilitation services for adults. A seven-domain hearing-health-care service model for validation was defined and used to analyse the applicability and suitability of patient- and service-centred tools. This model and the applicability and suitability criteria were based on the literature, the International Classification of Functioning (ICF) framework, and gold standard professional practice guidelines, which together formed the validation framework used in this study.

Results: Eighteen tools were identified and assessed against the validation framework. These tools were found to primarily assess aspects in the patient communication domain and rarely in the domain of service provision. All the included tools had some applicable items for teleaudiology hearing aid services; three tools were judged as suitable and four partially suitable for validating these services.

Conclusion: Although there is a set of suitable tools available to validate teleaudiology hearing aid rehabilitation services, none of them cover all the seven domains of the validation model used by this review and few are focussed on a specific domain. Further improvement and/or development of new tools to comprehensively validate these services is still necessary. At this stage, this still limits clinical audiology practice research, especially in teleaudiology.

Keywords

Audiology, Hearing aids, Telemedicine, Treatment outcome, Outcome assessment, Professional practice

Introduction

Hearing loss (HL) is the third most common impairment and the fourth highest cause of years lived with disability worldwide, currently affecting 6.1% of the world's population and predicted to affect one in four people by 2030 [1-5]. There is a global demand for teleaudiology hearing aid (HA) services (delivery of HA fitting and follow-up consultations) with a shortage of audiologists to provide services to the hearing-impaired population [3-9]. Alongside the global shortage of audiologists, there is an uneven global geographical distribution of audiologists; there is a strong correlation between the populations with the highest prevalence of hearing loss and countries with the greatest shortages of hearing professionals [4,10]. Teleaudiology offers potential solutions to improve access to hearing rehabilitation services to the underserved populations and has shown to improve it in situations where face-to-face services are restricted such as during the COVID-19 crisis [11-13]. However, there is still limited published evidence to support the implementation of teleaudiology services [14-17]. This limitation may be due to the lack of consensus on how to assess and validate standard and teleaudiology rehabilitation services.

A review of teleaudiology studies has shown that there is little consistency in methodology, with a range of used outcome measurement tools [14]. This may be related to the lack of agreement in the literature regarding what outcomes to measure and which tools to use to measure these outcomes, especially in relation to HA rehabilitation services [18,19]. This in turn can influence the quality and comparability of the evidence that is generated [14,18-21], and therefore the reliability of findings.

Although teleaudiology is a different mode of service-delivery to standard clinical practice, the clinical scope of practice remains the same. Hence, to allow the stakeholders and policy makers to make informed decisions about the validity of teleaudiology clinical services, it is important to compare the outcomes of teleaudiology services to those of standard face-to-face services (as a gold standard). Outcome measurement tools that assess domains that are common to both modes of service provision are therefore

required. In order to validate a service, it is vital to determine what domains should be measured, whether the items of available tools target these domains, and the outcomes of interest.

Validation can be defined as the result of systematically testing and establishing if a product, service or system meets the customers' and stakeholders' needs in regard to acceptance and suitability [22]. This definition indicates that services should be validated using patient- and service-centred tools that are individualised to the user's (e.g. patient) and provider's situations (clinical staff, e.g. clinician and facilitator). In the case of the provision of HA services, these tools should measure the outcomes of the individual's hearing-specific issues, needs or goals and their experience with services received (aspects and/or procedures) common to both teleaudiology and standard face-to-face modes. These outcomes usually relate to:

- (i) the effectiveness of the service (e.g. benefit);
- (ii) the quality of service rendered by the provider and received by the patient (customer satisfaction, e.g. satisfaction with continuity of care, cost, service/product use and delivery);
- (iii) the efficiency of the service, particularly regarding its delivery to the patient (e.g. travel and consultation time and associated and non-associated costs (the latter being with equipment and resources allocated by the clinic for the intervention); and
- (iv) the barriers to service-delivery, benefit and satisfaction [14].

To determine the effectiveness, efficiency and quality of services, patient- and service-centred tools should ideally present items individualised to the specific needs and experience of the patient, rather than generalised to the target population [23]. In the case of HA services, customised treatment is required. This individualised approach in patient-centred health care has been advocated as best practice for the health management of adults and important to improve health and these service outcomes [24-29]. These patient- and service-centred tools would thus capture and consequently reflect individual patient real outcomes in HA rehabilitation services; and besides, improve reliability and usefulness of findings [30,31]. In addition, the use of an individualised and consistent methodological approach could provide high-quality data across research studies [14,32,33].

While professional bodies have published guidelines for the standardization of clinical practice and have begun to include recommendations for teleaudiology, gaps remain in the validation process. To the best of the authors' knowledge, there are no published systematic reviews of outcome measurement tools to validate HA teleaudiology or traditional services and guide clinical and research practice. There is also no systematic method for the identification of suitable outcome measurement tools to validate teleaudiology HA rehabilitation services, or even standard face-to-face services; confident referencing of suitable tools is necessary [18]. Such a systematic method would help to close important gaps in knowledge of what to measure, and how to measure outcomes. It would also help identify domains that should be measured, and criteria for the identification of suitable tools, reflecting the construct to be measured. Furthermore, identifying tools suitable to validate both teleaudiology and standard clinical audiology practices would help standardize assessment, evaluation and validation of clinical and research practices, thereby, improving clinical and research outcomes.

This review was guided by a validation framework consistent with two complementary facets:

- (i) A hearing health-care-service model of validation, as a reference of measures (domains) to be assessed in these HA services.
- (ii) Criteria for the applicability and suitability of the evaluation of outcome measurement tools within the context of HA service-delivery settings.

The aims of this review were therefore twofold: (1) to systematically identify and analyse the suitability of tools to validate teleaudiology HA rehabilitation services; (2) to provide guidance on the usefulness of these tools within the HA services context and according to the proposed validation framework for measuring outcomes. The research questions of this review included:

- (i) Are there any published, validated or non-validated patient- and/or service-centred tools developed specifically for evaluating teleaudiology HA services for adults that are applicable for the validation of these services?

- (ii) Are there any published, validated patient- and/or service-centred tools developed for the evaluation of standard face-to-face HA services for adults that are applicable for the validation of teleaudiology services?
- (iii) Is there a set of tools suitable for the validation of teleaudiology services for adults?

Methods

This study was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines [34]. The review was conducted in two parts:

- Part 1: tools developed or modified existing tools for evaluating teleaudiology HA services; and
- Part 2: tools developed for evaluating standard face-to-face HA services.

Part 1 addressed the first research question, and Part 2 addressed the second research question; both parts examined the applicability of the tools for the validation of teleaudiology services. Both parts also addressed the third research question on the suitability and referencing of the tools for the validation of teleaudiology services.

Inclusion and exclusion criteria

All articles related to HA rehabilitation services for adults, focussing on teleaudiology, and published in English between 1 January 1990 and 1 September 2019, were considered for Part 1. Publications between 1 January 2000 and 1 September 2019 related to standard face-to-face HA rehabilitation services (HA fitting and follow-up consultations) for adults were considered for Part 2; this would capture most tools used in clinical research for the assessment of these hearing services. Only empirical research and literature review studies were eligible for inclusion.

Only tools with less than 30 items were considered for the analysis, as shorter and non-time-consuming tools would be more readily adopted into routine practice [24], in relation to the appropriateness and

usability of the tools for clinical and research practice (see Suitability criteria below). Furthermore, it was the intention to identify appropriate tools useful for both clinical and research practice (not exclusive), as this would best ensure that real-world clinical practice outcomes are examined in the research context.

Tools that appeared to be patient- and service-centred in relation to audiology rehabilitation services for fitting HAs were included in the scope of this review:

- Patient-centred tools, i.e. focussed on individual patients needs/issues/goals and/or experiences resulting from the service (treatment) provided.
- Service-centred tools, i.e. focussed on the service-delivery aspects individually experienced by the patients and/or clinical staff (e.g. clinician, facilitator).

This review considered the inclusion of the following types of tools:

- Device-centred tools (i.e. tools focussed on the device, usually performance and features). This could be the case if individual patient's issues or experiences related to a device (i.e. HA) were somehow the centre of the assessment.
- Generic tools (i.e. designed to measure a broad range of health care aspects or medical conditions, usually suitable for the general population). This would be the case if the tools were changed or modified specifically for the evaluation of teleaudiology, or validated for the assessment of standard face-to-face audiology rehabilitation services for HA fitting.

Thereby, this review focussed on disease/condition-specific, patient- and service-centred tools for assessing real-world outcomes related to HA services.

The following were not considered to be within the scope of this review:

- Tools focussed on evaluating non-clinical auditory factors (i.e. expectations, attitude and motivation, other health/mental/physical impairment, and psychological disorders such as stress, anxiety and depression);

- Tools focussed on assessing speech perception, recognition or understanding in an aided condition (i.e. speech tests); applying tests in an uncontrolled environment (e.g. home) is currently a technical challenge regarding calibration;
- Tools focussed on patients wearing other hearing devices other than a traditional HA (e.g. bone anchored HA, cochlear or middle ear implants, tinnitus maskers or assistive listening devices);
- Studies on HAs other than on intervention with HAs (e.g. algorithms, HA amplification gain or features, speech processors, remote controls or HA mobile apps); and
- Tools for screening, diagnosis or prevention of hearing loss.

Information sources and search strategy

The search was conducted using electronic databases that include journals most likely to index reports on rehabilitative audiology: PubMed, CINAHL Plus (EBSCOhost), Scopus, MEDLINE (Ovid), EMBASE (Ovid) [35,36].

Keywords and Medical Subject Headings (MeSH) (Table 1) for Part 1 were on the domains of telehealth AND hearing aid AND service AND validation AND tools AND NOT (paediatric or child or children or infant or teenagers or adolescents or implant(s) or implantation or tinnitus). Part 2 used the same search strategy but without the terms in the telehealth domain. Searches were conducted in the title and abstract fields.

Study and tool selection

Titles and abstracts were analysed against the eligibility criteria after the removal of duplicates. Studies that did not provide an abstract, or abstracts with insufficient information were kept for full-text analysis. Teleaudiology HA rehabilitation studies included in review articles on teleaudiology HA services that

Table 1 Search strategy domains, respective key words, and MeSH terms used in this review.

Domain	Key words	MeSH Terms
Telehealth	telemedicine OR ehealth OR "e_health" OR "e-health" OR telehealth OR "tele-health" OR teleaudiology OR "tele-audiology" OR teleconsultation OR "tele-consultation" OR telefitting OR "tele-fitting" OR remote OR telerehabilitation OR "tele-rehabilitation" OR telepractice OR "tele-practice" OR "telehearing" OR "tele-hearing" OR teleintervention OR tele-intervention OR mhealth OR "m-health" OR "m_health" OR "mobile health"	telemedicine OR telerehabilitation OR teleconsultation
Hearing aids	"hearing aid" OR "hearing-aid" OR "hearing aids" OR "hearing-aids" OR "hearing device" OR "hearing instrument"	hearing aids
Service	clinic OR service(s) OR intervention(s) OR rehabilitation OR clinical OR consultation(s) OR procedures	health Services OR auditory rehabilitation OR patient care OR outcome assessment OR health care quality OR health care delivery
Validation	valid OR validation OR validity OR validate OR validated OR application OR evaluation OR assessment	evaluation studies as topic
Tools	outcome OR survey OR questionnaire OR tool OR instrument OR measure OR test	surveys and questionnaires

were not retrieved through the search strategy were also retrieved and judged against Part 1's eligibility criteria.

Articles describing the validation of each tool identified, that were not retrieved through the search, were purposefully sourced from databases or via Google Scholar. These were screened to determine their eligibility for Part 2. However, any other tools used in these additional articles and published before 2000 were not included in this review. Relevant information from these additional articles was extracted and presented as supplementary material. Articles and the respective tools were then analysed against the eligibility criteria for inclusion in the analysis.

Covidence (Veritas Health Innovation, Melbourne, 2015) (www.covidence.org), and EndNote (www.endnote.com) were used to manage the articles.

Data extraction and analysis

A list of tools described in the included studies was generated. The following information was extracted: (i) study authors; (ii) year of publication; (iii) tools used that met the eligibility criteria of this review; (iv) references to articles on the validation or development of each tool; (v) aims/purpose of the tools as stated by the tools' original authors; (vi) main outcome measures assessed by the tools; (vii) administrative details (e.g. units of measure, condition of application (aided/unaided; pre-/post-intervention), mode of administration, administrator, estimated time required for application, example of an item); (viii) number of items that were service- and/or patient-centred and related to the seven domains of the HA rehabilitation services; (ix) characteristics of the population used in the validation. For the purposes of this study, tools were considered as 'validated' for audiology services, if they were reported as validated by their original authors. This review proposed and utilised a validation framework for the systematic analysis and the identification of the applicability and suitability of the outcome measurement tools for the validation of HA services.

Validation model (hearing-health-care service model of validation)

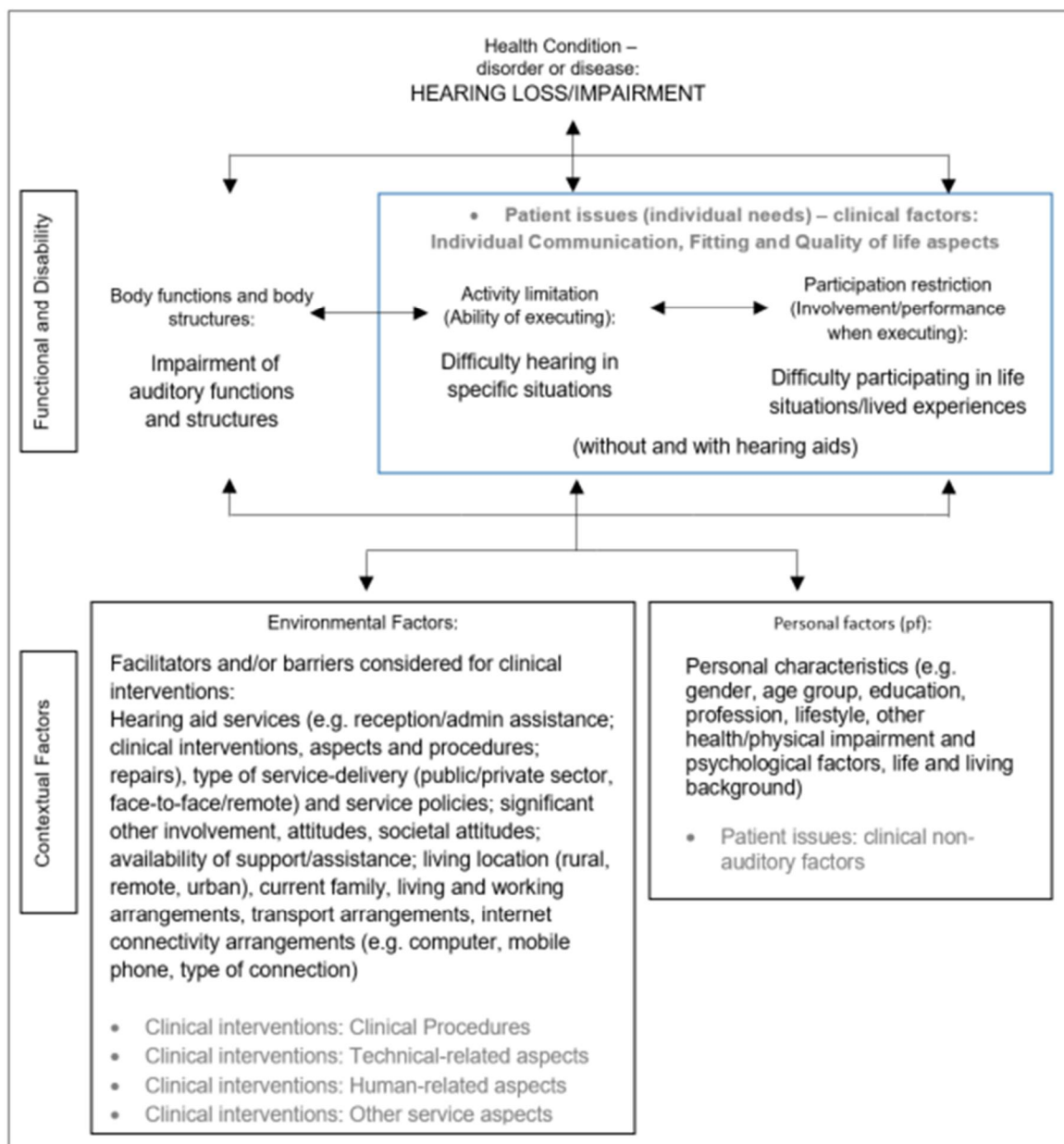
The validation model used in this review was based on the Professional bodies' guidelines as gold-standard practice (e.g. American Speech-Language-Hearing Association (ASHA), American Academy of Audiology (AAA) and Audiology Society of Australia (ASA, British Society of Audiology (BSA)) [37-41]) and on the World Health Organization's International Classification of Functioning, Disability and Health ICF framework (Appendix A) [42,43] alongside the literature supporting the rationale for the HA rehabilitation services (further elaborated in Tao, 2020). This ICF theoretical framework provides an understanding of the levels of functioning and disability of an individual within the context of environmental and personal factors. All the HA rehabilitation service practices identified by these sources were categorised into seven domains: patient communication, HA fitting and quality of life aspects (patient outcomes) and consultation procedures, technical- and human-related clinical aspects, and other service aspects (service outcomes). All of the seven domains identified are common to both standard and teleaudiology services. The service domains also consider aspects specific to teleaudiology service-delivery, e.g. connectivity issues. Thus, these seven domains determine a hearing-health-care service model by which HA rehabilitation service can be validated (Table 2) (see how this model fits into the ICF framework in Figure 1). This model is reported by this review as the 'validation model', because it presents the measures that should be investigated when there is an intention to validate the HA rehabilitation services.

Applicability and suitability criteria for the validation of HA services

Applicability criteria

Table 2 Descriptors for the patient and service domains of the hearing aid rehabilitation services as a validation model.

Hearing-health-care service model for the validation of teleaudiology and standard hearing aid rehabilitation services (descriptors) for clinical and research practice	
Patient domain	Service domain
Patient hearing needs, goals or issues	Clinical service needs, goals, or issues
<p>Clinical factors:</p> <p>1. Patient's Communication: <i>Factors that should be identified and/or measured prior to interventions, monitored and/or measured during interventions, and measured after interventions.</i></p> <ul style="list-style-type: none"> a) <i>Listening situation:</i> involves the ability to listening or hearing something or someone without the exchange of information (e.g. hear the TV or movie at the cinema) b) <i>Social hearing-related situation:</i> involves interaction, understanding the conversation with others (two-way – with the exchange of information) and socializing with others' or other's needs (e.g. hear the TV at a comfortable level for others, have a conversation with less repeats) c) <i>Emotional hearing-related situation:</i> involves feelings/emotions regarding the hearing difficulty (e.g. feeling frustrated when trying to have a conversation with a friend or when watching TV) <p>2. Patient's Fitting (patient's preference or performance with the device)</p> <ul style="list-style-type: none"> a) <i>Sound parameters</i> (i.e. loudness and quality of the sound) b) <i>Physical comfort</i> (e.g. losing ear piece, sore ear) c) <i>Ease of management</i> (i.e. insertion/removal, on/off, identifying left/right aid, and how and when changing battery, cleaning and care, using the controls on the device/remote/app when enable for volume or manual programs, using the accessories, troubleshooting device malfunctioning) <p>3. Quality of Life (hearing-specific health-related aspects of life) (self-perceived biopsychosocial functioning of impaired body in life):</p> <ul style="list-style-type: none"> a) <i>Specific aspects:</i> Ability/Disability Performance/Handicap Social/Emotional impact on others, on relationships/interactions and on mental health Self-consciousness b) <i>Global aspects:</i> Well-being (self-perceived life balance and satisfaction with life) 	<p>Clinical intervention procedures:</p> <p>4. Consultation procedures: <i>Individual procedures delivered in the HA fitting and/or follow-up consultations.</i></p> <ul style="list-style-type: none"> a) <i>Physical management</i> (i.e. fitting and comfort with ear moulds, domes, tubes and device); b) <i>Sensory management</i> (i.e. fitting, programming, fine-adjustments and verification of the device with real ear measurements); c) <i>Instructions</i> (i.e. training and demonstration of device use, device management and troubleshooting); d) <i>Counselling</i> (i.e. informational and emotional in which also include communication strategies, expectations, attitude or motivation and hearing aid use) e) <i>Validation</i> (Validated and reliable speech tests and questionnaires applied in aided condition). <p>NB: When validating teleaudiology services, clinicians/stakeholders should be attentive to further investigations on speech tests validation for application in aided condition (e.g. without headphones and in a free field) to the intended measure (e.g. screening/assessment, peripheral/central auditory processes), and to whether or not the test is representative of real world condition.</p> <p>Clinical service aspects (involved in the communication between patient and clinician / facilitator):</p> <p>5. Technical-related: aspects related to those that clinical matter depends on (e.g. equipment functioning, internet connection, etc.)</p> <p>6. Human-related: social and emotional service-related aspects usually involving patient or clinician/facilitator perceptions (e.g. interpersonal interaction, communication, competency or skills, trust, etc.)</p> <p>7. Other service aspects (related to overall outcome/aspect of the service/product):</p> <p>Overall hearing aid/service/consultation benefit, satisfaction, use, cost, maintenance, time, type of service-delivery, adherence, continuity of care, service-delivery performed taking non-clinical factors into consideration for treatment, etc.</p>



Note: The word “hearing” used for activity limitations and participation restrictions means ‘listening and comprehending’ auditory information (Granberg et al. 2014).

Figure 1. The integrative model of Functioning and Disability (WHO, 2001) for the hearing rehabilitation through teleaudiology and standard hearing aid services.

The applicability of the tools to validate teleaudiology HA rehabilitation services was assessed and analysed in two stages. First, according to the descriptors for each aspect involved in the patient and service domains of the validation model (Table 2), and second, according to the nature of the tools (whether individualised to the patient, generalised to the population, or a mix of these two; the authors were in agreement on categorisations and classifications applied in this study).

A tool item (usually an open or closed question or statement) was considered as ‘individualised’ if its content (pre-established topic/context/situation) is customisable to the individual real-life experience or style, rather than beliefs.

A tool item was considered as ‘generalised’ if its content is related to any specific situation that may not be part of a person’s real life experience or style, especially if a “not applicable” response option is not available (e.g. hearing the TV, or having dinner with family, visiting a neighbour, managing HA controls, etc.).

A tool with ‘mixed’ nature was considered as ‘partially applicable’ to validate teleaudiology HA rehabilitation services. A tool containing all the items as individualised and targeting patient and/or service domains of the validation model was considered as ‘fully applicable’ to validate teleaudiology HA rehabilitation services.

The degree of individualisation of the tools was expressed as a percentage, for both patient- and service-centeredness for each of the domains and overall tool (the number of individualised items over the total number of items). The tabulated information was used to identify patterns, and to develop an understanding of the applicability of the tools for assessing HA rehabilitation services. The applicability and suitability of the tools for the validation of HA rehabilitation services in routine clinical practice was also judged.

Suitability criteria

The suitability of the tools to validate teleaudiology HA services was assessed and analysed against the suitability criteria used in this review as per aims of this review, and not necessarily according to the aims of the included tools.

The tools were judged suitable according to the following criteria:

- (i) Tools that are fully applicable to validate HA services and with more reliable composite measures of the domains (greater focus on one domain) than other tools that assess the same domain(s) and investigate the same measures of outcome(s) (measures of service evaluation e.g. benefit, satisfaction, product or service use; and measures of service validation e.g. effectiveness, quality, efficiency, barriers or limitations).
- (ii) Tools that were reported or calculated to take 10 or fewer minutes to administer. For tools that did not report the time predicted for its completion, each item with open answers was attributed one minute, and each item with closed-set answers was attributed 30 seconds. This criterion was necessary because it is assumed that more than one tool will be needed to evaluate all the seven domains.
- (iii) Tools that can be easily incorporated into clinical practice with minimal disruption to the service-delivery, viz:
 - (a) tools with items that can be utilised during the consultations as part of clinical routine practice, and/or
 - (b) tool that can be completed before and/or after the consultation without assistance (e.g. through electronic means) at or outside of the clinic.

Furthermore, partially applicable tools were also analysed against the suitability criteria if they assessed aspects/domains not assessed by the suitable tools, or assessed different outcomes of the same domains assessed by the suitable tools. In that case, (i) above should be worded and read as ‘partially applicable’ rather than ‘fully applicable’.

The validation model in combination with the applicability and suitability criteria determined the ‘validation framework’ used in this review. This systematic method designed for this review assists with psychometric data for subsequent validity of these tools (i.e. that they properly measure the matter of interest [44]). Validity of an outcome measurement tool is not measured or determined by one event, but rather through an incremental and unending complex process, as its facets (psychometric properties) depend on the application of the tool across studies (Hyde, 2000; Bennett et al. 2015). A systematic method of identifying the tools suitable for a specific intended purpose in a specific context (i.e. measuring outcomes for the validation of HA rehabilitation services) is essential prior focussing on assessing the validity of these tools, as it streamlines and improves the process of validation of these tools. Thus, assessment of the validity of the tools is not one of the aims of this review but, this review provides grounds for their continue validation and guides future studies.

Although it was not the intention of this study to assess any psychometric properties of the included tools, the framework evaluates whether the tool measures what it is intended to measure (face validity), and the extent the tool’s items represents the domain(s) of interest (content validity) [45]. This framework thereby, can help to construct the validity of a tool [44,45], and represents an understanding of what aspects one should be measuring for patient-centred hearing care services.

Data synthesis

The data was assessed and tabulated to determine the applicability, suitability and usefulness of the tools for the validation of teleaudiology HA services.

Results

Part 1: Tools specifically developed or modified for evaluating teleaudiology HA services

The database search yielded 20 articles related to evaluating teleaudiology HA services (Figure 2). Of the 20 articles screened, six articles were examined for eligibility; two experimental studies and four systematic reviews. Three of these systematic reviews [14,18,46] provided five additional articles to consider after duplicates were removed, and with three tools. These five articles were not retrieved in the initial search because their identifiers did not match with those used in this review. A total of five tools were identified from these articles, but only one tool was specifically designed for teleaudiology purposes [47]. This tool is a modified version of a generic tool, the Patient Experience Questionnaire (PEQ), originally described and developed for measuring patient experiences immediately after a health service [48] (see supplementary material S.1).

Applicability

Based on the applicability criteria, analysis of the modified PEQ tool showed that all the items are individualised for the patient. These items measure outcomes in three of the service domains responsible for contextual factors (intervention procedures, human-related aspects and other service aspects) (Table 3 and Supplementary material S.2). This tool was thus, assessed as being fully applicable for the validation of teleaudiology HA services.

Suitability

The modified PEQ was assessed as suitable for validating teleaudiology HA services. This tool consists entirely of items with individualised nature that assess three out of the four service domains, and provides four measures of service validation (barriers, time-efficiency, quality and effectiveness) (Table 3). In addition, this tool is quick to administer, and can be easily applied via electronic means (Table 4).

The modified PEQ tool measures:

- (i) service effectiveness through items in the section “outcomes from this specific visit”,

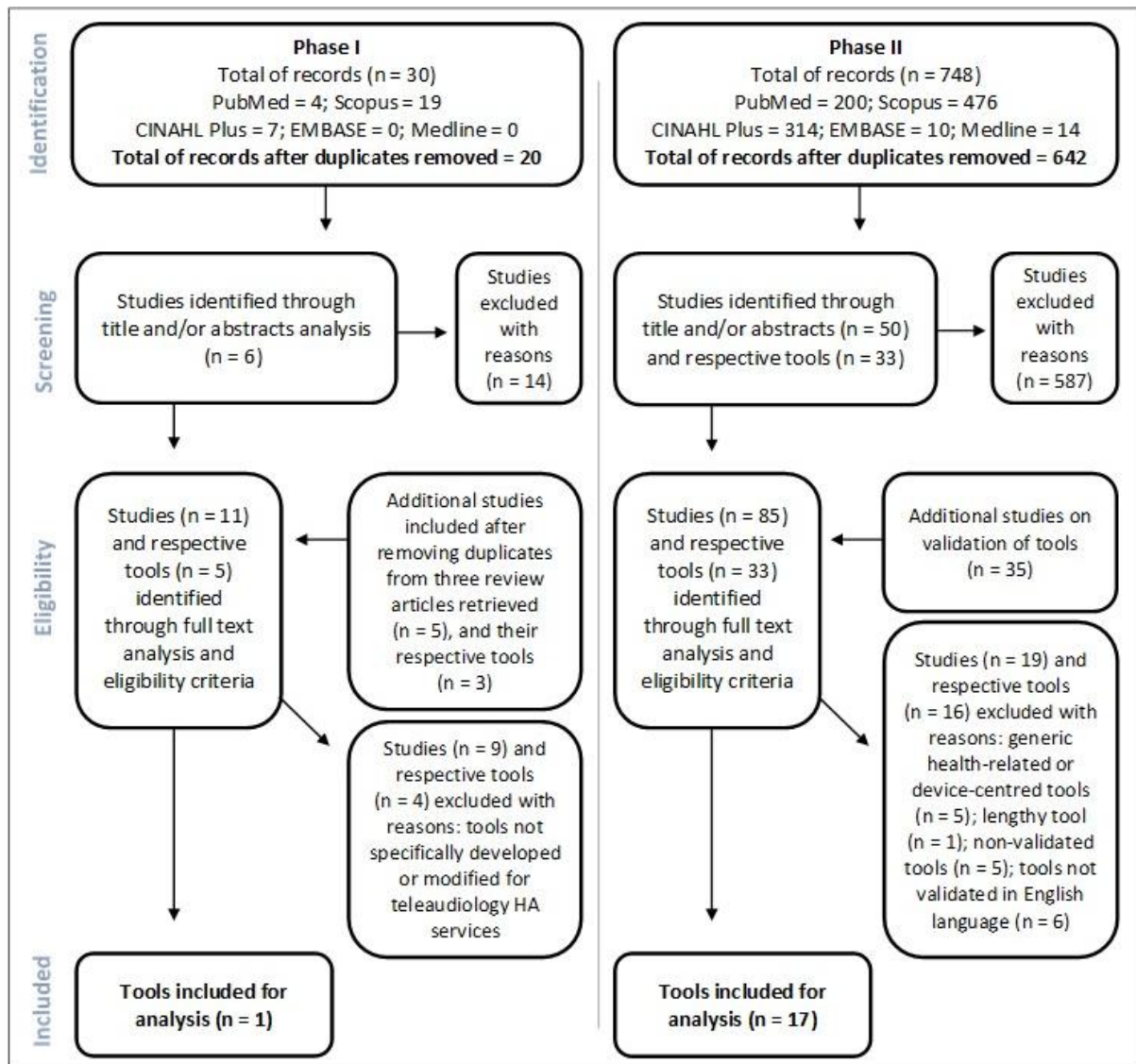


Figure 2. Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) flow chart of this systematic review. Left: Part 1 – tools for evaluating teleaudiology services for hearing aid rehabilitation; Right: tools for evaluating standard services for hearing aid rehabilitation.

Table 3 Applicability and suitability of tools in percentage of individualised items for each tool assessed in this review.

	Tool	PEQ (modified version)	APHAB	STHP	MARS- HA	SADL	DAHA	IOH-HA	COSI	HHIE	HHIE-S	HHIA	HHIA-S	HAUQ	PHAST-R	HASK	EAR	SHAPIE	GHABP
Applicability	100% of items	✓						✓	✓										
	> 50% of items			✓	✓	✓	✓							✓	✓	✓	✓		✓
	< 50% of items		✓							✓	✓	✓	✓					✓	
Patient domain	Communication (% of items)		(4.1) same item measures Fitting	(55.0)	(16)	(20)	(12.5)	(28.6)	(100.0)	(48.0) some items also measure Fitting and QoL	(40.0) some items also measure Fitting and QoL	(40.0) some items also measure QoL	(30.0) some items also measure QoL	(4.7)			(61.1) some items also measure Fitting and QoL	(8.0)	Subject-specified (16.6) Prespecified (17.8)
	Fitting (% of items)		(4.1)		(58.3)	(13)	(43.7)			(4.0)	(10.0)			(23.8)	(75.0)	(75.0)	(27.7)		
	Quality of life (% of items)					(27)	(25.0)	(57.1)		(12)	(30.0)	(12.0)	(20.0)				(38.8)		
Service domain	Intervention Procedures	(20.0)																	
	Intervention Technical-related aspects																		
	Intervention Human-related aspects	(60.0)				(6.6)													
	Other service aspects	(20.0)				(26.7)	(6.2)	(42.8)						(43.8)			(11.1)		Subject-specified (50.0) Prespecified (10.7)

Note: Percentages in bold indicate the tools that were judged mostly suitable (more comprehensive or better complementing other tool for assessing the respective domain (for more information see Table 4 and 5).

Legend: Patient Experience Questionnaire (PEQ) [47,48]; The Abbreviated Profile of Hearing Aid Benefit (APHAB) [49]; The International Outcome Inventory for Hearing Aids (IOI-HA) [49-51]; The Screening Test for Hearing Problems (STHP) [50]; The Measure of Audiological Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA) [52]; Satisfaction with Amplification in Daily Life (SADL) [53,54]; Dynamic Assessment of Hearing Aids (DAHA) [55]; The International Outcome Inventory for Hearing Aids (IOI-HA) [51,56,57]; Client Oriented Scale of Improvement (COSI) [58-60]; Hearing Handicap Inventory for the Elderly (HHIE) [61-63] and the Screening Version (HHIE-S) [64,65]; Hearing Handicap Inventory for Adults (HHIA) [66,67] and screening version (HHIA-S) [66]; The Hearing Aid User's Questionnaire (HAUQ) [58]; The Practical Hearing Aids Skills Test-Revised [68,69]; The Hearing Aid Skills and Knowledge (HASK) [70]; Effectiveness of Auditory Rehabilitation (EAR) [71]; The Shortened Hearing Aid Performance Inventory (SHAPIE) [72]; Glasgow Hearing Aid Benefit Profile (GHABP) [73].

- (ii) service quality through items in the section “communication experience” and “immediate emotions after consultation”,
- (iii) service time-efficiency through an item from “communication barriers” section, and
- (iv) barriers to interpersonal interaction between patient-clinician through “communication barriers” and “experience with the facilitator” items (Table 4 and 5).

Effectiveness of overall consultation is evaluated by the item assessing whether the consultation helped the patient to have fewer communication issues from “outcomes from this specific visit”. Regarding the specific clinical procedures of the service domain, this tool implicitly investigates procedures such as counselling and instructions delivered to the patient through the other items in this section.

Part 2: Validated tools developed for evaluating standard HA rehabilitation services

The database search yielded 642 studies related to evaluating standard HA rehabilitation services (Figure 2). Of the 642 records screened, 50 articles were examined for eligibility. Of these, 33 tools were identified and analysed against eligibility criteria. 17 fulfilled the criteria and were included for analyses of their applicability (Table 3 and Supplementary material S.2) and suitability to validate teleaudiology (and standard) HA services (Table 3 and 4). Descriptions of these tools can be found in the supplementary material S.1.

Applicability

All the 17 tools measured at least one aspect of the domains in the validation model. However, the level of applicability for the validation of teleaudiology services varied (Table 3 and Supplementary material S.2) [51, 55-73]. Two tools were assessed as fully applicable, as they are 100% individualised in nature and their items measure patient and/or service domains of the validation model. Nine tools have more than 50% of their items with an individualised nature measuring aspects of the patient and/or service domains of the validation model. They were judged as partially applicable. Six tools have less than 50%

of their items that are individualised in nature, and hence were considered as poorly applicable. None of these six tools presented individualised items that assessed aspects/domains or outcomes with greater focus than the other eleven tools.

Suitability

Two tools, Client Oriented Scale of Improvement (COSI) and The International Outcome Inventory for Hearing Aids (IOI-HA), were judged suitable for the validation of teleaudiology (as well as standard) HA services because they consist of purely individualised items that measure different domains more comprehensively (Supplementary material S.2); they are brief, requiring no more than 10 minutes to administer, and can easily be incorporated into routine clinical practice or applied through electronic means (Table 4). Their usefulness is reported in Table 5.

- The COSI assesses three aspects of the patient communication domain (listening situations, social, and emotional hearing-related situations) and provides measures of benefit validating the service effectiveness on improving communication. This is the only tool that can assess all three aspects of this domain. Whilst the patient and the clinician should ensure that the three aspects of this domain are explored, only the aspects considered important by the patient should be recorded for assessment. This tool measures effectiveness of the service on patient communication.
- The IOI-HA assesses four of the five aspects (not self-consciousness) of the patient quality of life domain, as well as some aspects of the other services domain (i.e. HA benefit, satisfaction and use). The outcomes of this tool provide measures of HA usage, benefit to patients' quality of life and satisfaction with the product (implicitly measuring the whole service behind it) validating the effectiveness and quality of the service in changing patients' quality of life. Among included tools, this tool is the one that most comprehensively assesses aspects of the quality of life domain.

Table 4 Set of suitable tools for the validation of teleaudiology hearing aid rehabilitation services (evaluated through the validation framework of the study), and information on their usefulness.

<i>Suitability criteria</i>	Fully applicable (100% individualised items assessing domains of the hearing-health-care model)	Measures of service assessment within the patient and service domains of the hearing-health-care model, best complementing each other	Measures of service evaluation of the described domains	Measures of service validation of the evaluated domains	Brief (not time-consuming) - applicable items	Easily incorporated into clinical practice:		Set of tools suitable for the validation of teleaudiology hearing aid services # tool partially suitable
<i>Disease-specific tool</i>						(a) items can be investigated during consultation as part of clinical routine practice	(b) self-report that can be completed through electronic means	
PEQ (modified version)	✓	✓Service Intervention procedures such as counselling and instructions. ✓Service Human-related social and emotional aspects. ✓Other service aspects related to the overall consultation and type of service-delivery.	Benefit Time-efficiency Service use and delivery	Effectiveness Quality Efficiency (time) Barriers	✓	NA	✓	✓
IOH-HA	✓	✓Patient QoL (residual disability, handicap, social/emotional ImpOth/relationships, enjoyment of life aspects). ✓Other service aspects (HA benefit, satisfaction and use).	Benefit Satisfaction Product use	Effectiveness Quality	✓	✓	✓	✓
DAHA		✓Patient Communication (social hearing-related). ✓Patient Fitting (sound parameters, physical comfort, ease of management). ✓QoL (self-consciousness). ✓Other service aspects (cost and maintenance).	Satisfaction	Quality	✓	NA	✓	#
SADL		✓Service Human-related aspects (hearing professional competency/skills).	Service use	Quality	✓	NA	✓	#
HAUQ		✓Patient Fitting (sound parameters such as quality of own voice, loudness, feedback; physical comfort and ease of management as for example the need of help for adjusting the aids). ✓Other service aspects (HA and service satisfaction and need of continuity of care).	Benefit Satisfaction	Effectiveness Quality	✓	✓ (Patient Fitting) NA (Service)	✓	#
COSI	✓	✓Patient Communication (Listening, Social and Emotional hearing-related).	Benefit	Effectiveness	✓	✓	✓	✓
HASK		✓Patient Fitting (Ease of management as for example, insertion/removal, change batteries and troubleshooting).	Benefit	Effectiveness	✓ (only if investigated during consultation)	✓	✓	#

Note: NA = not applicable (items should not be evaluated by the clinician)

Table 5 Usefulness of the suitable tools for measuring domains of the validation model for HA rehabilitation services.

<i>Domain</i> <i>Validation measure</i>	Communication	Fitting	Quality of life	Clinical intervention procedures	Service technical-related aspects	Service human-related aspects	Other service aspects
Effectiveness	COSI (full) [Benefit]	HAUQ (# 4) HASK (full if add "NA" option to # 7-9) [Benefit]	IOI-HA (# 3, 5-7) [Benefit]	PEQ (# 1-3) [Benefit]			PEQ (# 4) IOI-HA (# 1, 2) [Benefit]
Quality	DAHA (all # communication dimension if add "NA" option to #radio/TV, most phones) [Satisfaction]	DAHA (all # sound quality dimension; # physical comfort, # convenience/ease to use, # hearing aid style) [Satisfaction]	DAHA (all # personal reactions dimension) [Satisfaction]			PEQ (# 5-8) SADL (# 12) [Service use]	DAHA (# cost & maintenance) IOI-HA (# 4) HAUQ (# 5-8) [Satisfaction]
Efficiency							PEQ (# 10) [Time-efficiency]
Barriers						PEQ (# 9, 11-13, 15) [Service use and delivery] * To add "NA" option to # 13-14 for face-to-face services	PEQ (# 14) [Service delivery]

Note: Name of the tool (items applicable), [measure of evaluation] per domain.

Four tools (The Hearing Aid User's Questionnaire (HAUQ), The Hearing Aid Skills and Knowledge (HASK), Dynamic Assessment of Hearing Aids (DAHA) and Satisfaction with Amplification in Daily Life (SADL)) measure some of the remaining domains and aspects of the validation model not covered by the COSI and IOI-HA. These tools were judged as being partially suitable for the validation of teleaudiology HA services, as they present some items that are generalised to the population, hence, not fully applicable. Despite this, these four tools also complement the measures of service validation, the quality and effectiveness of the services provided to patients (their usefulness is reported in Table 5):

- The HAUQ assesses the three categories of the patient fitting domain (sound parameters, physical comfort and ease of management) as well as some services aspects (i.e. HA and service satisfaction, need of continuity of care). The outcomes of these items help validate the effectiveness and quality of the service by measuring the benefit of the service provided to patients' fitting success and satisfaction with the service, respectively. Two other tools, the MARS-HA and the EAR, also measure benefits in the patient fitting domain. However, they do not assess sound parameters or the need for assistance to adjust the HA settings. Although the MARS-HA assesses the ease of management more comprehensively than the HAUQ and the EAR, it does not cover all the items covered by HASK. None of these tools present "not applicable" as a response option for the items assessing the patient fitting aspects. For this reason, these related items were considered generalised and were not suitable for the validation of teleaudiology services.
- The HASK is entirely focussed on the ease of management aspect of the patient fitting domain. This tool partially contributes to validating the effectiveness of the service by measuring the benefit of the services that is provided for a successful fitting. The HASK also complements the limited number of 'ease of management' items of the HAUQ. Items of the HASK can be easily incorporated into clinical notes and can also be investigated informally during a routine consultation.

- The DAHA assesses one aspect of the patient communication domain (social hearing-related), all three aspects of patient fitting domain and one aspect (self-consciousness) of quality of life domain. Only two items of this tool ('radio/TV' and 'most phones') were considered generalised due to lack of "not applicable" response option in them. The outcomes of items in the DAHA help validate the quality of the service by measuring patient satisfaction with their HA(s). This tool is short and is presented in an electronic format, thus suitable for use in assessing teleaudiology services.
- The SADL complements the measures from the DAHA, HAUQ, IOI-HA and PEQ by contributing one item that assesses the human-related service aspects (hearing professional competency/skills). This item contributes to validating the quality of the service through measuring service satisfaction. Of all the eighteen tools included in this review, the SADL is the only tool that assesses most of the domains of the validation model. However, this tool did not comprehensively assess each domain compared to the other tools judged suitable.

Two of the tools discussed above (SADL and HAUQ) consist of items that are suitable for validating teleaudiology services. Had the DAHA and HASK contained "not applicable" as a response option, these two tools could have been considered fully applicable and suitable to validate quality and effectiveness of teleaudiology services.

[Table 4 near here]

[Table 5 near here]

Discussion

This systematic review investigated the tools used in the literature for the evaluation of HA rehabilitation services by the use of a validation framework. The core of the three research questions were on whether there are outcome measurement tools that can evaluate and validate HA rehabilitation services or not.

The first two questions are regarding the applicability of these tools for the validation of teleaudiology HA services for adults. The third question is regarding the suitability of applicable tools for the validation of HA services for adults. Only one tool (modified version of the PEQ tool) was applicable for validating teleaudiology services, although this was not re-validated. Seventeen tools were somewhat applicable to validate teleaudiology HA services, seven of which were identified to be suitable for the validation of both teleaudiology and traditional HA patient-centred services.

Two important aspects of this study should be discussed: (i) The usefulness of the suitable tools identified in this review, and recommendations for the validation of HA rehabilitation services; (ii) The reasons for proposing and using a validation framework for guiding the validation of HA rehabilitation services.

Usefulness of suitable tools and recommendations for the validation of HA rehabilitation services

This review demonstrates that tools that were developed and intended to assess HA clinical practice outcomes usually present a varied level of applicability for assessing patient or service aspects involved in the rehabilitation. It has shown that some of them (COSI, IOI-HA and PEQ modified) are fully applicable and, thus, suitable for the purpose of validation of HA rehabilitation. Other tools were judged to be partially applicable, but improvements on some of the current tools or development of new tools would be required before they could be used to validate HA rehabilitation.

In terms of the scope of the tools that were assessed, this review showed that seven tools (COSI, IOI-HA, PEQ, DAHA, HAUQ, HASK and SADL) were suitable for evaluating a range of patient-service outcomes from patient and service domains. Although these tools can be used together to validate standard and teleaudiology HA services in a general sense, it is important to know what type of outcomes they are actually measuring on the domains they assess, and which outcomes are not assessed.

To assist with clarifying what outcomes these tools are measuring, the outcomes were each classified as a measure of evaluation or of validation. Evaluation measures include benefit, satisfaction, service use, product use, cost, time-efficiency. Validation measures are derived from evaluation measures, and include effectiveness, quality, efficiency and barriers. For example, benefit was classified as a measure of evaluation because it determined effectiveness (a measure of validation) in one of the service domains (communication). Similarly, satisfaction contributes to the level of fulfilment (a measure of evaluation), which determines the quality of the service in one or more domains. The seven tools judged as the most suitable (Table 3 and 4) are now discussed in light of each of the domains explored in this review, taking into consideration these service outcomes.

(i) *Patient Communication domain*

- *Service effectiveness on patient communication*

Results from measurements in the patient communication domain should reveal changes in the hearing ability and performance in the three communication aspects (listening, social and emotional hearing-related). Effectiveness on communication determines whether there is a residual limitation yet to be addressed. If the patient's communication needs are met, the service was effective in treating the patient's communication issues. To determine the effectiveness, tools need to be applied pre-and-post treatment.

Among all the tools that were reviewed in this manuscript, the COSI was the only tool that is 100% individualised and able to measure all the three communication aspects. The COSI provides a list of categories that can be used to classify different listening situations reported by the individuals. This tool can also be used for research purposes even though it does not measure the same situations for all the patients. Although clinicians already investigate communication needs as part of routine practice, and some might consider that this tool would not significantly benefit their clinical practice [58], this tool is well suited to registering and managing changes in patient need during treatment. The incorporation of

this tool into clinical routine practice would provide data that can be used by clinicians to help in treatment decisions, managers to inform business decisions, and researchers for research studies.

It can be understood that both scales of the COSI (improvement and final ability) measure the same outcome (benefit) at the end of the treatment. Dillon (1997) demonstrated that they are associated ($r=0.66$) and as both scales measure how rehabilitation has reduced patient's 'activity limitations' and 'participation restrictions', what suggests that they may be applied independently of each other [59]. Comparisons before-after treatment are important for informing whether changes have occurred with the service. Dillon et al. (1999) do not provide the normative data to support this comparison as they used retrospective data from COSI applications only after treatment [58]. However, a recent study [74]) showed that the COSI is sensitive to changes with interventions after at least two follow-up consultations, and provided data for clinical and research usefulness when interpreting results of the COSI scale of improvement.

It is important to note that although the HAUQ is one of the tools that is part of the set of tools judged to be the most suitable for validating HA rehabilitation services, and one item (#3) measures two of the three aspects of the patient communication domain, it evaluates pre-established communication situations (Supplementary material S.2) and showed to not capture patient real-world outcomes as COSI does for this domain [74].

- *Service quality on patient's communication*

If a patient's communication needs are met at a patient's satisfaction level satisfactorily, then it is assumed that the quality of the service delivered was 'good' with a rating dependent on the scale used for measuring the related outcomes. This outcome is usually measured at the end of the treatment. If pre-to-post treatment comparisons were investigated, the comparison would measure the 'service effect' rather than the 'quality of the service provided'.

The COSI measures how well self-reported communication issues have improved after started using the HA. As improved benefit in important situations for the patient is associated with improved satisfaction [75], the COSI may implicitly measure participant satisfaction with his/her improved communication, which would lessen the need to specifically question patients about their satisfaction with communication.

In order to measure a patient's satisfaction with their ability to communicate and performance with the device, the clinician could ask a simple question (e.g. 'Are you satisfied with your hearing ability and your performance in the daily situations important for you?'). Validation of this new item would be needed for standardized application.

Adding a scale of satisfaction to the COSI would also assess the satisfaction with the changes on communication situations, and help specifically measure the patient's satisfaction with his/her ability to communicate wearing the device. We recommend using a validated scale similar to the one used in the GHABP (item #6), 'For this situation, how satisfied are you with your HA?', but making the participant satisfaction a focal point of the measurement (wording should not direct the satisfaction to the HA, i.e. it should not be 'For this situation, how satisfied are you with your communication wearing the HA?' [sic]).

The DAHA measures HA satisfaction relative to different patient and service aspects. With regards to the communication domain, the DAHA only assesses situations related to socialisation. The two items that are generalised to the population (i.e. radio/TV and most phones) are not in a specific context. Therefore, they may be suitable for a certain population (e.g. urban) even though these items do not specifically define the communication aspect of measurement, as the patient does not report/disclose the situational context when answering the question (the question does not require it to be reported).

However, there is still a need for a suitable tool that can be easily incorporated into clinical practice routine to measure patient satisfaction with communication ability or performance in individual situations without focussing on the device.

(ii) *Patient fitting domain*

- *Service effectiveness on patient's fitting*

Measurements in the patient fitting domain should reveal changes in patient's HA fitting issues with treatment and determine whether a patient is still having problems with the fitting and which fitting aspects need to be addressed. HA fitting problems are associated with different aspects that fall into three categories:

- a) sound parameters (aspects related to the quality of sound, including feedback and loudness, that can be evaluated and interpreted from reporting of experienced situations or objectively by patients reporting what they feel about the sound, e.g. "I cannot hear my son as he talks too softly" or "sounds are quite dull"),
- b) physical comfort (aspects related to the comfort wearing the device and ear piece, e.g. bad fitting, feeling plugged-up, coming out/off, hurting) and
- c) ease of management (aspects related to the management of the device, e.g. insertion/removal, positioning in the ear, changing batteries, recharging).

If a patient's fitting needs are met, then the service was effective for treating HA fitting problems.

Measures of identification of issues and changes should be applied before and after interventions, ideally immediately at the start of each consultation in both teleaudiology and standard practices; changes should be measured after the patient has had time to experience the solution provided. This will help determine the effect of the service (benefit) on fitting aspects that are under investigation. Hence, it is important to identify specific fitting issues. However, a tool with an open-set (individualised) approach for assessing aspects in the patient fitting domain was not identified; the individualised closed questions presented by the HAUQ and the HASK cannot measure the degree of improvement in a manner that it is usually done in the routine practice. The three categories of aspects in the fitting domain are equally clinically important for promoting the use of HAs. However, no tool was found which was specifically developed

for investigating fitting issues related to sound parameters whereas aspects related to the ease of management (usually including physical comfort with fitting) are available and have received more attention in audiology research [21,76]. A more comprehensive tool assessing changes of individual fitting issues of any nature during the patient journey would be of a significant contribution.

The HAUQ measures benefit of the service related to the patient's HA fitting covering some of the main aspects of the sound parameters (e.g. quality of own voice, loudness and presence of feedback), physical comfort (e.g. with the ear piece or device) and with ease of management (e.g. positioning the HA in and removing it, need of help).

The HASK complements the HAUQ with a more comprehensive assessment of ease of management aspects. Ease of management items such as adjusting the controls (be it for volume, telephone or programs) should be assessed only if these aspects were set up for the patient to use. Including, a 'not applicable' option as a response category may be useful too.

Although these tools are intended to measure any remaining fitting issues at the end of the treatment, questions can also be incorporated into clinical notes in a checklist format, and can be investigated during consultations as part of clinical routine. This can help to improve treatment management and provide data for research and management control. Alternatively, items can be sent to patients or to the community clinic through electronic means as a self-report tool, as there is evidence that shows that patients can accurately identify and report their management difficulties [77].

- *Service quality on patient fitting*

Information on satisfaction in the patient fitting domain is important for managing a patient as it informs what aspects need attention, and which solutions can be planned or re-evaluated. Just as for patient communication, if patient's fitting needs are met (or issues are solved/improved) satisfactorily, then the

service can be considered to have delivered good quality. This outcome can be measured together with the effectiveness, immediately before each consultation for comparison of changes.

The DAHA was the only tool that measures quality of the patient fitting domain through asking about satisfaction on few specific HA fitting aspects; a more comprehensive tool is yet required for this assessment on individual needs of patients regarding the fitting aspects.

(iii) *Patient quality of life domain*

Validated measures of quality and effectiveness based on the patient's quality of life domain provide evidence of the effectiveness and quality of a HA rehabilitation service, as improvement in quality of life is the final goal from a patient-centred care service (Robinson et al., 2008). However, aspects of quality of life cannot be measured on their own as they cannot pinpoint where the problem is, especially if the outcomes are not as expected by the stakeholders or patients (including family/significant others). Each of the other six domains of the validation model contribute to changes in hearing-related quality of life. Hence, it is expected that quality of life measurements would be partially associated with each of the other domains and they altogether should be measured for the validation of these services. If the intention is to validate only clinical aspects of patient functioning then all the aspects in the patient domain should be measured.

- *Service effectiveness on patient's quality of life*

Information on the changes in patients' quality of life determines the effectiveness of the service and may be likely to influence the patient's decision on whether or not to continue treatment with the health provider and recommend the service to the others. Furthermore, it will provide information for making decisions on the patient's treatment management as well as on the direction of clinical practice, and may influence changes in business practices.

The IOI-HA questionnaire [51] was the only tool that focussed on measuring aspects of patient quality of life domain through individualised items. However, the findings of this study show that there was no tool to evaluate the self-perceived impact of patient's final hearing on his/her social and emotional relationships and mental health in daily activities and well-being (e.g. whether treatment reduced arguments in his/her relationships, improved clarity of thoughts, thinking process, attention, concentration, makes feel more comfortable and relaxed). These patient quality of life aspects are still to be explored by quality of life disease-specific outcome measurement tools for HA rehabilitation.

- *Service quality on patient's quality of life*

Measuring satisfaction in association with an improvement in hearing related-quality of life can also help to understand a patient's decision to continue (or not to continue) their relationship with the provider. If positive changes in the quality of life reach a satisfactory level, then it can be assumed that the service quality is good. This satisfaction can be measured by simply asking the patient their satisfaction with changes in aspects of their life, or a scale with different levels of satisfaction can be used to investigate this, if this is of interest of stakeholders or researchers.

The SADL [54] and the DAHA [55] both measure aspects of self-consciousness. However, the DAHA was judged to be more objective and easier to apply through validated electronic means. There is still a need for a suitable tool to measure satisfaction on the other aspects of life in this domain.

(iv) *Service domain: Clinical Intervention procedures*

Measurements of benefit and satisfaction with each clinical procedure of the validation model that are involved in the rehabilitation process are crucial for the identification of which procedures deserve attention and improvement. This domain was not measured by any tool included in Part 2. For this domain, outcomes should be measured immediately after a consultation and at the end of the treatment programme to assess the overall service.

- *Effectiveness of the clinical intervention procedures*

Items measuring benefit should assess the degree of help achieved from the procedure performed by the clinician on improving patient hearing or hearing-related issues in treatment. A validated tool that measured these aspects was not identified. The modified PEQ measures service use to determine the effectiveness of clinical intervention procedures that are not clearly identified in the items of the “outcome of this specific visit” dimension. Therefore, suitable tools that explore the effectiveness of individual procedures are still to be developed.

- *Quality of the clinical intervention procedures*

Items measuring this outcome should ask about the degree of satisfaction with the procedure performed by the clinician on improving patient hearing issues or hearing-related issues in treatment. The HAUQ is the only tool that measures the continuity of care and overall service satisfaction related to the treatment and repair through a single item for each aspect. However, a slight change in wording of the questions related to service satisfaction is deemed necessary, as the original tool refers to a specific chain of clinics. There is still a need for a more comprehensive tool measuring aspects of the clinical intervention procedures domain from an individualised patient experience.

(v) *Service domain: Clinical technical-related aspects*

Clinical technical-related aspects are those that are decisive for the delivery of the service especially when delivering remote services; for example, functioning equipment (including the HA), stable internet connection, good quality audio and video transmission. Outcomes of technical aspects are important contributors for the retention of the patient with the same provider [78]. Assessment of technical aspects will determine whether there is a need for the provisioning of technical training or solutions. Measures of outcome can take place immediately after the consultation. There was no tool available allowing identification of technical issues and assessment of whether any technical issues affected the satisfaction

with service from the audiologist's and patient's perspective or not. As no tools were found to be suitable to assess these aspects, it can be assumed that these aspects have not been investigated in audiology research to the date of this review.

(vi) *Service domain: Clinical human-related aspects*

Clinical human-related aspects assess interpersonal communication and interaction between the clinician/staff and the patient. This interaction plays an important role in both standard and teleconsultation. Positive interpersonal relationships allow both parties to exchange information and carry out effective treatment-related discussions [78,79]. Measuring clinical human-related aspects will help determine whether further training on social-emotional-personal skills is needed for clinicians/staff (e.g. facilitator/audiologist assistant) involved in the treatment, and whether human-related aspects affect patient benefit or satisfaction with the service delivered. Items that measure effectiveness should be investigated through patient or clinician/facilitator feedback after the provision of the service. This involves the assessment of experiences with service use/delivery including aspects that will be important for building patient trust and adherence.

- *Quality of clinical human-related aspects of the service*

Items that measure the quality of the clinical human-related aspects of the service should measure the degree of satisfaction. Measurements should be made immediately after the consultation to avoid difficulty with recall and unreliable answers. The PEQ (modified version) assessed aspects related to clinician-patient interaction and communication, and patient emotions related to this interaction. The SADL contributed with one item that complements the PEQ with a question about perception of clinician's competency. A 'not applicable' response for PEQ items #13 and #14 would enable this tool be applicable for standard face-to-face consultations too. Alternatively, a slight change to wording of the section related to these items (i.e. 'facilitator' could be 'facilitator/anyone, but the audiologist, in the consult room who is not familiar to the patient') would also make these questions applicable in

conventional practice. The HASS-P and HASS-A mentioned above may also identify whether there were any human-related issues and if it affected satisfaction with the service.

- *Barriers to clinical human-related aspects of the service*

Barriers to the delivery of the service are measured by assessing service or product use. Items that measure barriers in the clinical human-related aspects are important to identify patient's or clinician's impressions about the service provided. Not paying attention to consumer or provider feedback could compromise the delivery of the treatment and the quality of the service. The PEQ measures barriers to patient-clinician interaction from the patient's perspective. However, clinical human-related aspects as barriers (e.g. professional competency or confidence) to service delivery are not investigated by any of the tools included in this review. Although the HASS-P and HASS-A were not retrieved as part of this systematic review, they can also potentially fill this gap as they investigate whether any human-related aspects interfered in the patient's and audiologist's satisfaction with overall and specific aspects of the consultations. It also proves an opportunity for the respondent to describe these aspects.

(vii) *Service domains: other aspects*

There are other service aspects that are related to the overall perspective of an outcome or aspect of the service or product. Tools should measure the service and product use at the end or after completion of the rehabilitation process.

- *Effectiveness of other service aspects*

Overall benefit with the service/product of interest is measured by asking questions about the extent of help received or change perceived. However, these questions alone may not provide sufficient information on which aspect of the service delivery made the person respond to the question, but will provide an overall judgment of the patient/family/significant other. Where conflicting results have been received by the provider, tools that measure effectiveness of other patient or service domains can be used

to obtain the missing information. Alternatively, an open-ended question asking a patient to provide additional information could also be used for qualitative analysis.

The PEQ could measure the effect of the overall consultation on reducing patient communication problems. The IOI-HA and HAUQ present similar questions that measure overall HA benefit and use (daily hours of usage). Although benefit can be reported when using a HA for, say, a few hours each day, there may be other problems (e.g. difficulty related to management, sound, comfort or a self-perceived limited need for a HA in daily life) that could prevent patients from wearing their aids for longer periods [20]. Therefore, HA use may not be a good test of service effectiveness. Other specific aspects (e.g. fitting, communication needs) should also be investigated.

- *Quality of other service aspects*

Overall satisfaction with the service/product of interest is measured by asking the patient to what extent he/she liked the service/product. Quality measurement informs to what extent the service has achieved patient expectations; this outcome can influence a patient's decision as to whether or not to continue their care in the clinic, recommend the service or product to others and use the service more often. Hence, measurement of quality is important for understanding patient opinion about the service aspects, as it can influence changes in the provision of the services to improve service quality and, thereby, meet patient expectations with their continuity of care.

The IOI-HA measures HA satisfaction through the item that investigates the level of worthiness of the acquired device ("Do you think your HA is worth the trouble?"). The DAHA measures satisfaction with the cost of the HA and maintenance while the HAUQ measures satisfaction with the device, overall service, personal treatment and the need for continuity of care. This domain was quite comprehensively measured by these suitable tools, but improvements can be made by including new aspects that the clinician or researcher may be interested in measuring (e.g. satisfaction with the home visit by the

facilitator for the teleconsultation, and with the booking service for consultations that may be online or by phone).

- *Efficiency of other service aspects*

Items that measure efficiency in the ‘other services’ domain would be related to achieving patient hearing goals related to time, effort and resources. The efficiency is assessed through aspects related to, for example, the (i) time spent on consultations (productivity) or in clinical/technical/human procedures involved in the consultations, or (ii) number of consultations or visits to the clinic. These contribute to an understanding whether the time or number of consultations (e.g. follow-up appointments) committed to the patients were sufficient to address patient problems satisfactorily. The PEQ provides a single item measure of time-efficiency related to productivity; the item is ‘During consultation, much time was spent on “small talk”’. There is still a need for suitable tools to measure other aspects of efficiency.

Other considerations

Constant market and consumer pressure to improve hearing health care services requires the service providers to prove that they can make a difference in their patients’ and their families’ lives. Nevertheless, the success of a service to a patient’s daily-life does not depend only on the delivery of a good quality service. There are a number of important factors such as ageing (e.g. physical or central processing problems), co-morbidities (e.g. cognitive decline, chronic ear disease, etc.), aided audibility (residual hearing loss), and supra threshold distortion (e.g. difficulties to recognise timbre, intonation) that may confound the findings [80]. In situations where the expected outcomes were not met, these confounding factors should be explored in order to identify the cause of the problem. This can be done through assessment of clinical non-auditory factors such as other health impairments (e.g. cognitive decline, comorbidities) and psychological factors (expectations, attitude, motivation, depression and anxiety).

Methodology of this review

The validation framework: the need for a specific hearing-health-care service model for treating hearing impaired adults

The World Health Organization provides a broad classification of categories linked to the ICF framework for hearing loss (ICF core sets) [43,81]. However, the ICF core sets were not used as a baseline, but rather this study proposed and utilised another validation model for the following reasons.

These ICF classifications were based on a generic health-related quality of life approach and developed based on feedback received from patients, researchers and multidisciplinary professionals who work with hearing impaired people (e.g. audiologists, social workers, psychologists) [82]. Granberg et al. (2014) reported that linking categories of the ICF core sets to the tools was a challenging task [83]. The authors concluded that this was due to the audiological research tools not focussing on hearing impairments [83]. However, these linking difficulties may have been due to the broad nature of these categories, in that these cannot reflect a specific treatment such as the rehabilitation with HAs fitting. Generic health-related quality of life tools are not sensitive enough to assess hearing rehabilitation outcomes [84]. When the methodology for this review was designed, we posited that the lack of a set of core measures representing specific aspects of the HA rehabilitation services commonly delivered by teleaudiology and standard practice would be a solution for the development of more adequate tools and/or future specific ICF categories for hearing loss rehabilitated with HAs. Therefore, this alternative core set of measures (Table 2) that complies with the ICF framework (Figure 1, Appendix A) [43] could potentially be the solution for eliminating variables and appropriately assessing the focus of the tools used in audiology research.

Of note is the finding of this systematic review that the included tools all focus on hearing impairment of the patient although they rarely consider the individual variability between people. This shows that a specific health care service model that provides a specific approach to the health condition, e.g. HA

rehabilitation for hearing impairment, as proposed and used in this review for hearing, can determine the consistency between and within assessment tools and can more adequately measure hearing impairments than a broad approach as provided by the ICF core sets. Further studies on the linking of the ICF core sets to the validation model used in this review may be useful to understand to what extent one reflects the other. Further information regarding the link between the dimensions of the ICF framework and the domains of the hearing-health-care model of this review can be found in Tao, 2020.

Regarding overcoming the barrier to reliable clinical and research outcomes, findings from this review revealed that this validation framework can standardize the validation of clinical and research practices; substantially improve reliability and quality of evidence; and facilitate consistency across studies and consequently meta-analysis studies. Its use in clinical practice and in future clinical research and ICF studies on HA rehabilitation is encouraged by this review.

Furthermore, this review's validation framework helps to evaluate the construct validity of the tools for the validation of patient-centred health-related quality of life services such as the HA rehabilitation services [45]. The tools' sensitivity in detecting changes or confirming/rejecting hypotheses is tested when they are applied into practice; in this way the construct validity of these tools is confirmed [45].

Conclusion

This study contributes to improving the current body of knowledge on the assessment of service provision. It provides guidance for the validation of teleaudiology services as well as for standard HA services for clinical and research purposes. It also informs what to measure and which tools may be most appropriate for the validation of both teleaudiology and standard HA rehabilitation services.

Whilst all of the tools presented items that are applicable for validating HA clinical practice services, only three are fully applicable for both tele-audiology and standard HA rehabilitation services: the COSI

assessing communication domain, the IOI-HA assessing quality of life domain, and the PEQ assessing service domain. However, none of the assessed tools comprehensively evaluates outcomes of all the four service validation measures (i.e. effectiveness, quality, efficiency and barriers) of a single domain of the validation model. It was unlikely that this review would have identified one tool that measure all the seven domains involved in the HA rehabilitation service-delivery for all four service validation outcomes due to the complexity of this type of service. All these outcomes were measured only for the domain of ‘other service aspects’ but only by when utilising some items from four different tools. The four partially applicable tools identified by this review for the validation of HA clinical practice services presented items measuring different domains of these services as best complementing the measures of the fully applicable tools. Of note, the DAHA and HASK can be fully applied if a “not applicable” response category be added to their generalised items. In addition, some of the gaps identified in the HAUQ and SADL can be filled by the fully applicable tools (e.g. the IOI-HA and COSI).

This set of seven tools referenced as suitable for use in both teleaudiology and standard HA rehabilitation services mostly cover effectiveness and quality of the services, whereas efficiency and barriers remain underexplored. There is a need for improvement and development of new tools to address these gaps.

Three recently published tools, Hearing aid Improvement Instrument (HAI), HA Satisfaction with Service-Patient/Participant and Audiologist (HASS-P and HASS-A) [74,85] were developed specifically for teleaudiology, and appear to fill in some of the gaps identified in this review.

Therefore, this review shows that whilst there are limitations in the currently available tools, especially related to the technical aspects in teleaudiology services, investigations of the outcomes of HA real-world clinical practices remain similarly limited.

In addition, this review provided a validation framework that could measure the face and content as part of construct validity of assessment tools for the validation of HA rehabilitation services. Other psychometric properties (e.g. reliability, responsiveness) were not judged by this review, as it relied on the information provided by the original authors even though this assessment is dependent on the

methodology applied for its validation that is ongoing with every new study methodology. Revalidation of modified tools and new tools would be needed. The validation framework (validation model, applicability and suitability criteria) proposed by this review is recommended for developing or assessing tools for the validation of teleaudiology and standard HA rehabilitation patient-centred services.

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Appendix

Appendix A. The integrative model of functioning and disability (WHO, 2001).

