

**Development and implementation of an
ICF-based e-intake tool in clinical otology and audiology practice
viewing the patient from a biopsychosocial perspective**

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The studies presented in this thesis were conducted within the Amsterdam UMC, Vrije Universiteit Amsterdam, Otolaryngology – Head and Neck Surgery, Ear & Hearing, Amsterdam Public Health research institute, De Boelelaan 1117, Amsterdam, Netherlands.

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VRIJE UNIVERSITEIT

**Development and implementation of an
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Chapter 1:

General introduction and outline of this thesis

Ear and hearing problems have a profound impact on one's functioning in daily life. This thesis' focus is on improving the intake process of these patients in the clinical practice, by creating an integral view of the patient's functioning. And thereby, aiming for enhanced diagnostics and treatment. In the following case example, it is illustrated how a typical patient with a health condition of the ear, taking hearing impairment as an example, may experience (hearing) problems, and how he may enter the clinical care system:

Hans is 65 years old and suffers from a hearing impairment since a few years. Hans has trouble understanding speech over the phone and he has difficulties following group conversations, both in informal settings and at work, and especially in noisy backgrounds. Hans works as an accountant for a large company, and his work tasks include many telephone calls and face-to-face group meetings. His work is at a fast and demanding level, and the hearing impairment and associated communication problems restrict him in doing his work tasks well. Furthermore, the hearing impairment has resulted in him withdrawing from social activities with friends and family more and more. Following these limitations and restrictions, he frequently feels depressed and stressed about his problems, and his self-confidence is negatively affected. He feels ashamed of his hearing impairment and tries to hide it as he does not want colleagues, his employer, or friends to know about it. Hans is married, has three adult children, one of them who still lives with him, and his wife. In addition to his hearing problems, Hans has type 1 diabetes. His partner and children are losing patience with his lack of taking action on his problems and urge him to see a doctor.

Via the general practitioner, Hans is referred to the ENT outpatient clinic. It is his first time at the ENT department, and he is quite nervous about the intake appointment: his biggest concern is whether he is ever going to be able to hear properly again? Can he continue to work on the same level as he currently does? He is not ready for early retirement. Is a hearing aid the only option? His appearance is important to him, so he does not want a hearing aid that is visible to everyone. As part of the intake, the audiology assistant first administers tone and speech audiometry. The ENT surgeon reviews the test results before seeing Hans, and she concludes that he has a sensorineural hearing loss. Based on the audiograms alone, hearing aids seem the straightforward intervention.

This case example demonstrates that hearing impairment has a multidimensional character, i.e., problems go beyond being able to hear, and impact on and interact with various domains of someone's functioning in daily life¹. For a complete and efficient diagnosis and treatment of an individual with hearing impairment, it is necessary that all relevant aspects of functioning are evaluated and not just basic auditory functions such as perception of pure-tones and speech. A broad approach is particularly essential during the early stages of assessment and diagnosis, as then, this information can be used to initiate a personalized treatment². The challenge is to obtain this functioning profile, covering all relevant aspects, in an integral and comprehensive way¹.

To address this challenge, the work presented in this thesis specifically focuses on the development and implementation of an intake tool that can facilitate a comprehensive and efficient assessment of adult patients' functioning, and can be used in the clinical otology practice.

In this Introduction, an overview is presented on: the nature and impact of hearing impairment and ear disorders, the conceptual framework that is used as a basis for the development of the intake tool, and the theoretical and methodological assumptions that are used. Furthermore, the motivation, the aims, and designs of the studies that constitute this thesis are introduced. The chapter ends with the outline of this thesis.

Hearing impairment and ear disorders

Various definitions regarding the degree of hearing impairment exist, but the World Health Organization (WHO)'s grading is often used to classify hearing impairment. It defines hearing impairment in the better ear as mild (20-34 dB), moderate (35-49 dB), moderately severe (50-64 dB), severe (65-79 dB) or profound (80-94 dB) (WHO HI grade³). A moderate-to-profound hearing impairment is regarded as disabling hearing impairment in most WHO reports³⁻⁵. It should be mentioned that also mild levels of hearing impairment have been shown to be disabling and thus deserve attention (e.g.,^{3,5}). The WHO estimated that there are 360 million persons in the world currently living with a disabling hearing impairment, of whom 91% are adults⁶. Due to the aging of the population and to policies to increase the retirement age, more economic pressure on the healthcare systems is expected in the future⁷.

The term "hearing impairment" is generally used by professionals when describing different types of hearing loss. Hearing impairment can broadly be classified in three main groups: conductive, sensorineural, and mixed hearing loss. Conductive hearing loss is caused by disorders that affect the outer or middle ear, impairing the transfer of the incoming sound wave to the cochlea⁸. Examples of common outer ear disorders and problems are otitis externa, presence of a foreign body, and cerumen impaction. Examples of common middle ear disorders are otitis media, cholesteatoma, otosclerosis, and perforation of the tympanic membrane⁹. An impairment in these areas primarily results in reduced sensitivity to sounds that are normally heard⁸. Conductive hearing loss can usually be treated medically, e.g., with antibiotics or surgery or sometimes hearing aids¹⁰. Sensorineural hearing loss is caused by disorders that affect the inner ear and central auditory neural pathways⁸. The main function of the inner ear is to transform the incoming sound wave into electrical impulses and transmit these via the cochlear nerve to the temporal lobes in the brain for interpretation and possible action⁸. A sensorineural hearing loss results in reduced sensitivity and inadequate sound transmission to the brain, causing sounds being perceived as blurred, weak or constrainedly loud. Examples of causes of sensorineural hearing loss include hereditary conditions, presbycusis (i.e., hearing loss due to ageing), and noise exposure¹¹.

More than 90% of all adults with hearing impairment suffer from this type of loss¹⁰. Unlike many conductive losses, there is no medical treatment for sensorineural hearing loss⁸. They are usually treated by providing hearing aids; however given the inadequate transmission of sound, the effect of this treatment is mostly only partial. Mixed hearing loss is a combination of conductive and sensorineural hearing loss, and may be caused by the presence of two separate ear disorders in the same ear (e.g., noise exposure and otitis media), or by a single ear disorder that affects the conductive and sensorineural systems (e.g., advanced otosclerosis)⁸.

Hearing impairment not only originates from ear problems or disorders that cause disruption of structures in the ear. For instance, there are various higher mental functions that can influence whether or not sound (including speech) is perceived and understood effectively^{12, 13}. Depending on the listening task and how adverse the listening conditions are (e.g., noisy, reverberant), cognitive abilities (top-down processes) interact with auditory factors (bottom-up processes) at different levels in the auditory system, as such influencing the perception of speech¹⁴.

Furthermore, hearing impairment may be associated with various other symptoms and health conditions. Individuals can suffer from other ear-related problems, like tinnitus or vestibular symptoms, that may interact with hearing impairment¹⁵⁻¹⁷. Additionally, in most cases, people with an ear disorder (such as cholesteatoma) also have a hearing impairment¹⁸. Also non-auditory age-related health conditions may influence hearing impairment¹⁹⁻²¹. For example, cross-sectional and longitudinal studies indicate (causal) relationships between hearing impairment and diabetes²²⁻²⁴, cardiovascular conditions²⁵, and hypertension²⁶. Recent cross-sectional and longitudinal evidence also indicates causal associations between hearing impairment and cognitive decline^{27, 28}, with dementia occurring earlier and more often in hearing impaired individuals^{29, 30}.

Psychosocial impact of hearing impairment and ear disorders in adults

As illustrated in the case example, the impact of hearing impairment on everyday functioning can be extensive, in particular in case of sensorineural hearing loss. At the activity and participation level, hearing impairment may negatively impact everyday spoken communication, such as in group situations and over the telephone, in work activities, in informal interactions with family and friends, and in social activities³¹⁻³⁵. As a result, hearing impairment may have a significant effect on an individual's psychosocial well-being, as well as on that of their family^{36, 37}. Adverse effects of hearing impairment on psychological outcomes such as depressive and anxiety symptoms, and feelings of loneliness are well-established³⁸⁻⁴¹. Other common psychological consequences include embarrassment and stigmatization^{42, 43}.

At the contextual level, various environmental and personal factors can act as facilitators or as barriers to the functioning of an individual with hearing impairment. For example, characteristics of the acoustical environment (e.g., level of noise and reverberation) may help or strongly hinder a person's ability to understand speech during work or informal conversations⁴⁴. In addition, such as in the case example, the degree of perceived social support or attitude from family and colleagues, or society at large, may be important social environmental facilitators or barriers to the individual's experienced levels of activity limitations and participation restrictions⁴⁵. Personal factors can influence someone's experience of disability and include factors like gender, age, educational level, and intrinsic behavioural factors^{19,20,29}. To illustrate the latter, the coping behaviour of a hearing-impaired individual can be a relevant mediating factor of psychosocial problems⁴⁶.

In contrast to hearing impairment, the impact that ear disorders can have on individuals is far less well-described in the literature. If described, results mostly relate to the impact of the hearing impairment resulting from the ear disorder. Studies for instance showed the psychosocial consequences of chronic otitis media on early childhood developmental activities, on educational attainment, and on vocational and employment outcomes^{6, 47, 48}. The impact of ear-related symptoms like dizziness and imbalance have also been examined. These symptoms seem to substantially impact independence, physical, cognitive, and emotional functions, as well as activities and participation in everyday life⁴⁹⁻⁵¹.

Ear and hearing health care

In the Netherlands, adults seeking help for their ear or hearing problems can enter the health care system via the general practitioner or the hearing aid dispenser (primary care). If indicated, an individual can be referred to an ear nose and throat (ENT) department or to an audiology clinic (AC) for secondary or tertiary care. This thesis focusses on this type of health care (further referred to as clinical oto-audiology care).

Before any intervention can be started, patients are usually invited for an intake appointment or admission interview. Generally, a patient's basic (hearing) health, need for care, and expectations are assessed and discussed. Traditionally, assessment and decision making are largely driven by clinical assessment of auditory structures and functions (e.g., site of lesion, type and magnitude of hearing loss) as measured via audiometry (e.g., pure-tone-audiometry) and medical examinations (e.g., otoscopy). A consequence of this approach to care is that interventions focus on the improvement of auditory function, with the most common treatment options being fitting of hearing aids, cochlear implants or surgery (in ENT).

In light of what is known about the multidimensionality of hearing impairment, it is often argued that the decision to undertake treatment or intervention should be based on perceived needs rather than on objectively measured impairment in body functions and

structures alone. In addition, the WHO states that one of the important shortcomings of current health care systems is fragmentation of care, which prevents an integral approach to the needs of the patient^{52, 53}. Taking an individual's total functioning instead of only the impairment into account may help to overcome fragmentation and to improve inter-professional collaboration across disciplines⁵³. Currently, the care that someone with ear or hearing problems receives often depends on the specific expertise and discipline of the professional who is encountered first in the care pathway. These differences underline the need for an approach to care in which the ear and hearing(-related) problems and the needs of the patient are in the centre, and that are assessed and recorded in a uniform and integral way.

Paradigm shift

Changing the focus from impairment in structures and functions to functioning viewed from a broader perspective of health implies a paradigm shift. A gradual change in perceptions of how health care should be viewed and practiced is ongoing. This change goes from understanding health conditions from a biomedical perspective focusing on the individual's physical aspects only, to a more biopsychosocial perspective that recognizes the relationship between the individual and other related context⁵⁴, just as described above. The biopsychosocial model posits that biological, psychological, and environmental or social factors all influence an individual's functioning and health outcomes⁵⁵. Moreover, individual differences are critical when it comes to patients' experience of impairment and its associated limitations and restrictions^{55, 56}. The individual variability in difficulties experienced secondary to hearing impairment is well documented (e.g., ⁵⁷).

Led by these insights and by the research into the psychosocial factors influencing rehabilitation and patient outcomes (e.g., ^{58, 59}), the need for this paradigm shift and change in focus has been mentioned repeatedly in audiology (e.g., ^{56, 60, 61}). To enhance treatment efficacy and patient outcomes, it is argued that service delivery models that centre on the person, rather than on the disease or impairment should be utilized⁵⁶. This shift towards a biopsychosocial model mirrors widespread recommendations and changes occurring throughout the health care system as a whole. The Institute Of Medicine (IOM) identifies quality health care as care which is safe, effective, patient-centred, timely, efficient, and equitable⁶². Specifically, the IOM (2001) defines patient-centred care as "respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions"^{62(p. 6)}.

Patient-centred care refers to patient-health care professional interaction, and emphasizes the importance of relationship building, sharing of input and control in information exchange and decision making⁶³. Thereby, patient-centred care also advocates a more biopsychosocial and mutualistic approach to health care delivery^{64, 65}. In the context of audiology, Grennes and colleagues defined patient-centred care from the perspectives of older adults that were

experienced with hearing rehabilitation⁶⁶. Three key elements of individualized care were identified: 1) an individualized therapeutic relationship, 2) individual characteristics of audiologist and patients should be displayed, and 3) the individual should be informed and involved in the clinical processes.

Although the biopsychosocial, patient-centred approach is advocated by health care professionals and policy makers, its actual implementation in clinical practice is still a hurdle to take in many fields, including that of ear and hearing care. This is due to variability in the definitions of functioning, the perceived barriers to valid and reliable measurements of functioning, and the inherent difficulty with shifting traditional clinical behavioural patterns¹⁻⁶⁷. A common framework to guide implementation of this new policy is advocated⁶⁸. In addition, it is recommended that clinical practice expands its methodologies and tools for synthesizing all relevant patient information. Such a framework and tools could potentially guide health care professionals in considering all relevant domains of the person's health and functioning, facilitating individualized and meaningful goal setting, subsequently indicating appropriate intervention strategies and choosing appropriate outcome measures to monitor functioning.

The International Classification of Functioning, Disability and Health

In 2001, the World Health Assembly endorsed the International Classification of Functioning, Disability and Health (ICF), for providing a standardized and uniform reference for describing functioning and disability from a biopsychosocial perspective, and that could be applied for all kinds of health conditions. A person's functioning is conceptualized as the dynamic interaction between health conditions and contextual factors (environmental and personal factors)⁶⁹, as depicted in Figure 1.

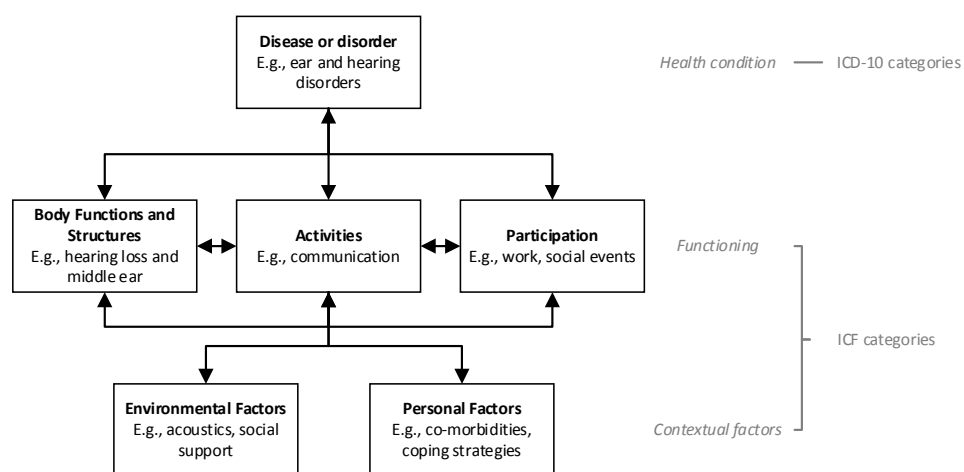


FIGURE 1. WHO's conceptual model of health, illustrated using ear-related categories

The figure further illustrates that the ICF model incorporates two main parts. Part 1 deals with functioning and part 2 covers contextual factors. Functioning includes the components Body Functions (physiological functions of body systems (including psychological functions)), Body Structures (anatomical parts of the body), Activities (execution of tasks and demands of life) and Participation (engagement in life situations). Functioning is an umbrella term encompassing all body functions, activities and participation, and disability serves as an umbrella term for all impairments, limitations, and restrictions herein⁶⁹. Contextual Factors interact with these constructs and include Environmental Factors (factors that make up the physical, social, and attitudinal environmental in which people live and conduct their lives) and Personal Factors (e.g., gender, age, habits, lifestyle, coping styles). Each ICF component consists of multiple domains, and each domain consist of categories that are the units of the classification⁷⁰. Health conditions (diseases or disorders) are a component of the integrative model, and can be classified using the International Classification of Diseases (ICD-10)⁷¹.

In addition to the model shown in Figure 1, the ICF applies a comprehensive categorization and coding system. Categories are hierarchically organized in a stem-branch-leaf scheme using inter-linked levels. Part 1 (Functioning) is divided into the components Body Functions, Body Structures and Activities and Participation. Part 2 (Contextual Factors) is divided into the components Environmental Factors and Personal Factors. Personal Factors are not yet classified in the ICF, although some examples are provided.

The classification comes with a standardized language. The prefix to an ICF code is a single letter, representing the components (b: Body Functions, s: Body Structures, d: Activities and Participation; and e: Environmental Factors). This letter is followed by 1 digit indicating the chapter, which is the first level, followed by the code for the second level categories (2 digits), and the third and fourth level categories (1 digit each). Categories at higher levels are more detailed. Therefore, a lower-level category shares the attributes of the higher-level categories of which it is a member. The hierarchical structure and standardized language of the ICF is illustrated for ear-related categories in Figure 2.

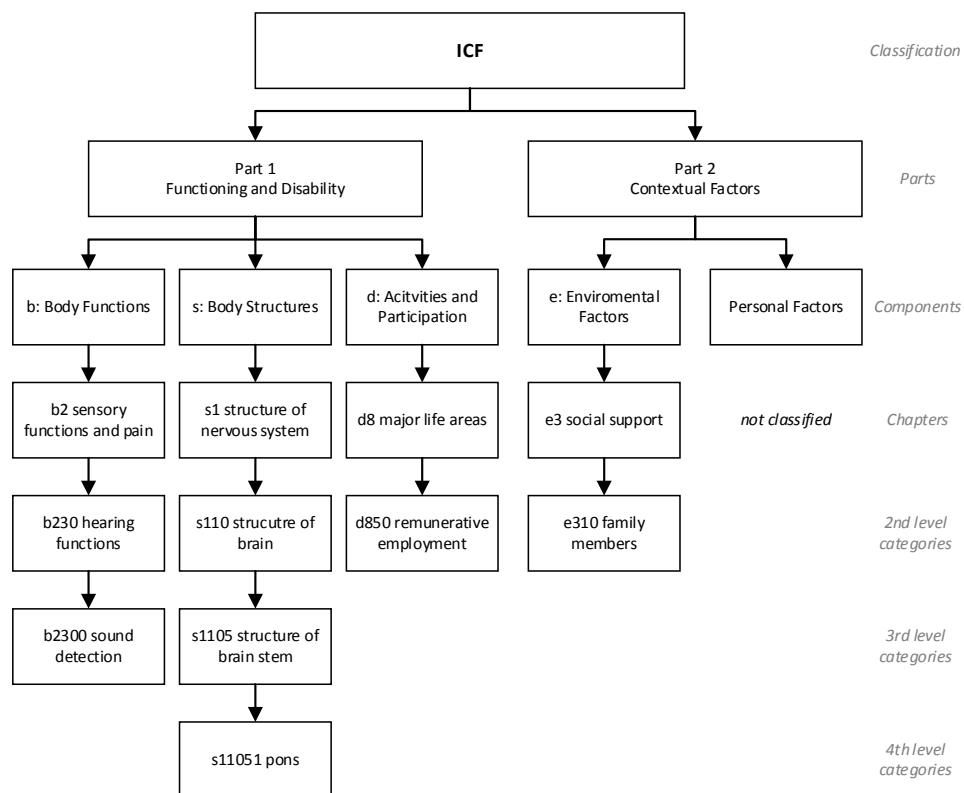


FIGURE 2. The hierarchical structure and standard terminology of the ICF, adopted to ear-related categories

Clinical use of the ICF in clinical oto-audiology intake practice

Within the ICF framework, audiometry may be seen as the method for the assessment of impairment to the body functions and structures associated with hearing. However, it is for instance not reflective of the associated psychosocial impact of the hearing problems on a person. The information provided in the case description of Hans at the beginning of this chapter has been linked to the appropriate ICF components (see Table 1). By summarizing the information about Hans’ functioning in this way, it becomes apparent that the framework and coding of the ICF can potentially make a significant contribution to the range and depth of information about a patient’s functioning that can be mapped. This could add to a better understanding of a patient’s problems, and help facilitate patient-centred care in the sense that the individual needs of the patient may be evoked and focussed on.

TABLE 1. Summary of Hans's information linked to the ICF

Component	Specification	ICF Code
Body impairment	- Sensorineural hearing loss as measured via tone and speech audiometry (audiograms)	b230, s250
	- Feels depressed, stressed, and embarrassed	b152
Activity limitations and participation restrictions	- Problems in group conversations with family and friends, especially in noisy backgrounds	d3504, e2501
	- Problems in conversations over the phone	d360
	- Experiences restrictions at work, especially during telephone calls and face-to-face group meetings	d3504, d760, d850, d360, d3503, e1250
	- Reduction in attendance at social events	d9205
Environmental support	- Immediate family losing patience with Hans's lack of taking action	e410
Personal factors	- Gender: Male	NA
	- Age: 55 years old	NA
	- Comorbidity: type 1 diabetes	NA
	- History: ear infections	NA
	- Marital status: Married	NA
	- Living situation: living with partner and three adult children, 1 still living at home.	NA
	- Appearance is important; visible hearing aids are a problem	NA
	- Has thus far not acted on his hearing problems	NA
- Self-confidence is negatively affected by the hearing impairment	NA	

NA = not applicable (the component Personal Factors is not yet classified in the ICF)

By shifting and broadening the focus from a health condition to impact, the ICF places all health conditions on an equal footing allowing them to be compared using a common metric⁷². Thereby the ICF facilitates the identification of the breath of health and health-related complaints across health domains, and is not only relevant in clinical oto-audiology care. The specific deployment of the ICF, and the categories that are most relevant for describing the functioning of an individual with a particular health condition, depends on the specific setting (e.g., health domain and purpose)^{69, 73}. With regard to the work in this thesis, in addition to the clinical oto-audiology practice, the ICF was also used to identify rehabilitation needs in low vision rehabilitation (Chapter 4, further introduced later in this introduction).

Moreover, comprising over 1400 categories, the ICF's applicability in everyday clinical practice is unworkable. The utility of the ICF as a practicing standard therefore needs to be enhanced by adapting the ICF to the perspectives and needs of different users and clinical settings. As an important step in this process, the WHO started the development of ICF Core Sets. A Core Set is a shortlist of ICF categories that are most relevant to be assessed and reported in the context of a particular health condition or setting⁷³.

ICF Core Sets for Hearing Loss

Supported by the WHO, Danermark and colleagues initiated the development of the ICF Core Sets for Hearing Loss (CSHL) in 2010¹. The main aim was to identify ICF categories of particular relevance for adults with hearing loss for use in clinical encounters and research¹. The development of the CSHL carefully followed the WHO guidelines. The developmental process consisted of two phases⁷³. The Preparatory Phase and Phase I. These have been completed. The Preparatory Phase covered four studies: 1) an international expert survey to identify relevant aspects of functioning, disability and contextual factors from hearing health professional perspective⁷⁴, 2) a systematic review on outcome measures used in audiological research⁷⁵, 3) a linking study of the identified outcome measures to the ICF classification⁷⁶, and, 4) patient interviews to determine the patient perspective on relevant areas of functioning, disability, and contextual factors in adults with hearing loss⁷⁷. During the international conference in 2013 (Phase I), hearing health professionals reached consensus on the ICF categories that should be included in the CSHL⁷⁸.

Completion of Phase I resulted in the first versions of two related Core Sets: a Comprehensive and a Brief one. The Comprehensive CSHL comprises 117 ICF categories. The Brief CSHL includes 27 of these, and serves as the minimal set of categories for the assessment and reporting of functioning and health in adults with hearing loss⁷⁸. The Comprehensive CSHL serves as a guide for multiprofessional, comprehensive assessment. In this thesis, the Brief CSHL was chosen as a starting point for the development of the intake tool. The ICF categories included in the Brief CSHL are presented in Appendix 1.

Validation and implementation of the Brief Core Set for Hearing Loss

Following the Preparatory Phase and Phase I, the WHO development process guidelines prescribe the execution of Phase II. In this phase, the Core Sets need to be validated and implemented in clinical practice⁷³. The studies described in this thesis relate to this Phase II (see Figure 3).

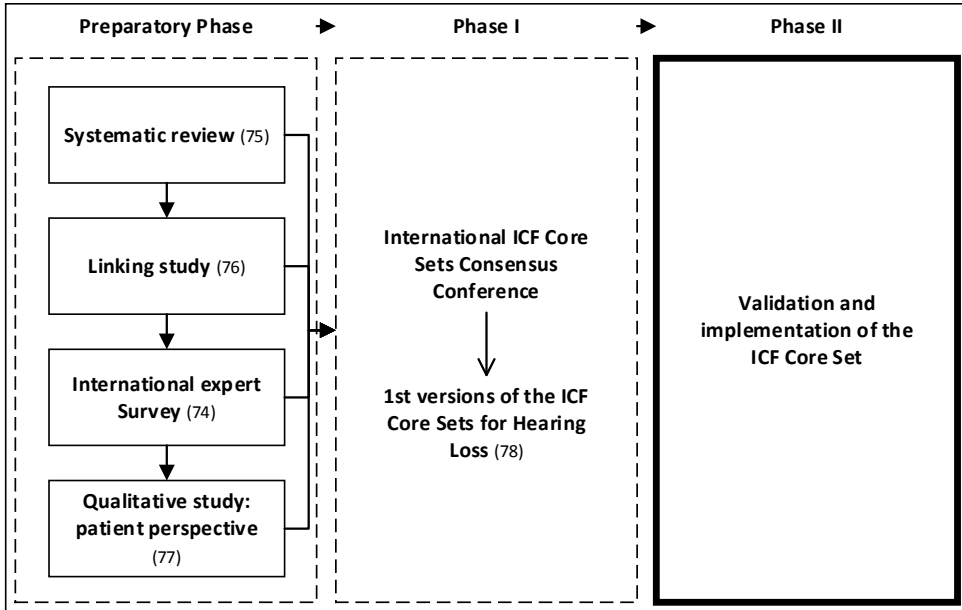


FIGURE 3. Procedure of the ICF Core Sets project development. Phase II as applied to the intake process within the clinical oto-audiology practice is the focus of this thesis

Since its conception, various researchers across the world have undertaken attempts to test and validate the Brief CSHL. In the United States, Alfakir and colleagues examined the validity of the Brief CSHL as an outcome measure within audiology rehabilitation (AR) programs⁷⁹⁻⁸¹. In Australia, the relevance of the Brief CSHL for providing patient- and family-centred audiology care has been outlined⁸²⁻⁸⁴. In Sweden, the School of Medical Sciences at Örebro University recently started to validate and operationalize the Brief CSHL into a self-assessment instrument⁸⁵. In addition, the concept of participation of the ICF is being operationalized in the UK by Heffernan and colleagues, through the development and validation of the Social Participation Restrictions Questionnaire^{86, 87}.

In line with our goal to improve the intake process of adults with ear and hearing problems, we specifically focused on the validation and implementation of the CSHL with respect to the intake of patients that enrol for ear and hearing care at Dutch ENT departments and in audiology clinics. The content validity of the Core Sets was evaluated in this context. The content of the intake documentation in Dutch secondary and tertiary care settings was compared with the content of the Comprehensive CSHL and Brief CSHL (Chapter 2).

The overarching aim of the ICF Core Sets for Hearing Loss project is providing an international standard for describing functioning of a person with hearing loss, and to promote the use of the ICF in the audiology community^{1, 78}. Using the CSHL as a common reference tool allows for the comparison of information on both a national and international level, across practices

and institutions and even across health conditions (see paragraph below). International collaboration, alignment and exchanging experiences in applying the CSHL in practices across the world is therefore important⁸⁸. Over the course of this PhD project, a collaboration was established with dr. Alfakir and dr. Zapala who are based at Mayo Clinic, Florida, United States of America. In the Mayo Clinic, the concept of integrated care is supported through a common medical documentation system that is accessible and shared by all healthcare providers within the clinic. The system captures patient information recorded by all healthcare providers (referred to as 'multidisciplinary intake documentation'). We benchmarked the extent to which discipline-specific intake documentation used by audiologists and otorhinolaryngologists and Mayo Clinic's multidisciplinary intake documentation, covered ICF categories from the Comprehensive CSHL and Brief CSHL (Chapter 3). The data collected in these parallel studies (one in the Netherlands and the other in the USA) will disclose any differences between the Dutch and US setting.

ICF in low vision rehabilitation

In a separate study, performed at the dept. of Ophthalmology, it was examined which dimensions of the ICF were represented in the intake documents used in low vision rehabilitation^{89,90}. The study was initiated in Dutch low vision Multidisciplinary Rehabilitation Centres (MRC) in response to a reported need for examination of the full range of possible rehabilitation needs of patients with visual impairments. It was also indicated that instruments should be specific for different groups of patients with visual impairment. As a first step, a synthesis of rehabilitation needs reported in intake assessments by 18-25 year young adults with visual impairment were linked to the structure of the ICF (Chapter 4).

The linking of the ICF to intake documents in different clinical care contexts in this thesis allows us to verify the model's universal applicability. More specifically, it could be demonstrated if and if so, to what extent, it can be used to assist health care professionals in different disciplines and care settings to acquire and map existing knowledge, in creating new knowledge, and applying it for specific purposes.

An ICF-based e-intake tool

One drawback of the ICF (and thus also of the CSHL) is that it defines which aspects of functioning need to be considered, but it does not define *how* this should be done. Additional steps are therefore required to enable the use of the CSHL in clinical practice. These include: A. the operationalization of the CSHL-ICF-categories into a practical intake tool, and B. the implementation of this instrument in clinical practice.

A. Operationalization

In **this** thesis, an attempt to operationalize the categories of the Brief CSHL into a Patient Reported Outcome Measure (PROM) is described. This PROM is further referred to as the “**ICF-based e-intake tool**” or “intake tool”. The use of PROMs are recommended in value-based health care⁹¹. PROMs refer to reports coming directly from patients about how they function or feel in relation to a health condition and its therapy, without interpretation of the patient’s responses by a health care professional or anyone else⁹². PROMs usually take the form of a standardized questionnaire. In clinical practice, PROMs can be used to promote patient-centred care, guide clinical decision making, and facilitate communication between the patient and health care professionals⁹³. The possible application purposes of PROMs in clinical practice are various, and include: diagnostic screening, monitoring health, aiding in health care decision (decision aids), and monitoring quality of patient care⁹⁴.

The aim of the intake tool is to support the identification of problems and contextual factors relevant to patients’ functioning with their ear or hearing problem. It thus serves as a diagnostic screening tool. It is aimed at helping to provide tailored care, specific to patients’ problems and needs (Chapter 5).

The most important measurement property of a PROM is content validity⁹⁵. According to the COSMIN-guideline, content validation is the degree to which the content of an instrument is an adequate reflection of the construct to be measured⁹⁶. It refers to the relevance, comprehensiveness, and comprehensibility of the PROM for the construct, target population, and context of use of interest⁹⁵. Following its initial development within the project team, assessment of the content validity of the intake tool is also described in Chapter 5 of this thesis.

B. Implementation

Although positive effects of using PROMs in clinical practice have been shown, getting them effectively implemented in clinical practice remains a challenge, like with any modifications to existing clinical practice. The introduction of PROMs in clinical routine can therefore be viewed as a complex health care innovation requiring careful planning, design, and implementation⁹⁷. Known factors that influence successful implementation include factors that relate to the patient and the health care professional, technology (e-health), and the underlying health care system⁹⁸. The potential effect of the use of PROMs on health outcomes is crucially mediated by the modification of the behaviour of both patients and health care professionals^{99, 100}. For example, implementing evidence into practice requires intervention at the provider level to support health care professionals to modify established patterns of care¹⁰¹. Changing their behaviour requires an understanding of the influences on behaviour in the context in which they occur. Hence, their views can give important insights in how the intake tool could be promoted and harmonised. Commonly reported provider barriers in PROM implementation include time constraints, lack of training, and doubt about

the added value of PROMs. Key facilitating factors of integrating PROMs in clinical practice are guidelines, automatic flagging of important patient scores, appointing a team coordinator, and providing sufficient training of the staff^{102, 103}. So far, no studies have been conducted on the barriers to and enablers of the implementation of PROMs in clinical otolaryngology practice. A better understanding of the perceived enablers of and barriers to the use of the ICF-based e-intake tool, and subsequent targeting of these enablers and barriers, are a first step to successful implementation and routine use of the intake tool in clinical practice.

Expertise from the field of implementation science and theories of behaviour change are recommended to help successful implementation of interventions (e.g., the ICF-based e-intake tool) into clinical practice¹⁰⁴⁻¹⁰⁶. In this thesis we adopted Michie's Capability Opportunity Motivation-Behaviour (COM-B) model and Behavioural Change Wheel (BCW) framework to guide the development of a behaviour change intervention to facilitate the implementation of the intake tool¹⁰⁷. The COM-B model and BCW are further described and explained in detail in Chapters 6 and 7. Three main stages can be identified in the design process (see Figure 5).

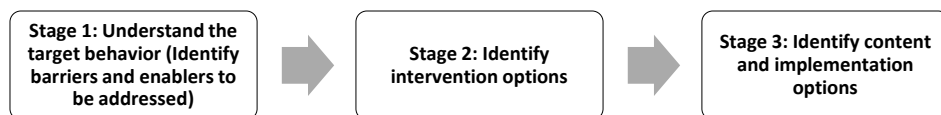


FIGURE 5. Three main stages of a behaviour change intervention design process¹⁰⁸

In this thesis, barriers to and enablers of the implementation of the intake tool as perceived by hearing health professionals and patients (stage 1) are described and categorized (Chapter 6). In addition, the results of stage 1 are used to perform the remaining stages (i.e., stages 2 and 3) and an intervention for the implementation of the intake tool is developed (Chapter 7).

Aim and outline of this thesis

The overall aim of the work in this thesis is to apply the biopsychosocial perspective of the ICF in the intake in clinical oto-audiology practice, by developing and implementing an intake tool based on the Brief Core Set for Hearing Loss. The first part of this thesis focuses on obtaining knowledge on current practices across different contexts and settings, by linking intake documentation to the categories of the ICF. This part covers Chapters 2, 3, and 4:

In **Chapter 2**, the content of the intake documentation currently used in secondary and tertiary ear and hearing care settings in the Netherlands was linked to the content of the ICF Core Sets for Hearing Loss. Specifically, the extent to which the intake documentation represented the categories of the Core Sets and whether there were any extra (ICF-) categories that were expressed in intake documentation and are not part of the Core Sets, were assessed.

In **Chapter 3**, the content of the multidisciplinary and discipline-specific intake documentation of the Mayo Clinic, Florida, USA, was linked to the content of the ICF Core Sets for Hearing Loss. A similar method as in Chapter 2 was applied.

In **Chapter 4**, the rehabilitation needs of visual impaired young adults in the intake documentation of Dutch low vision multidisciplinary rehabilitation centres were linked to the total ICF classification.

The second part of this thesis focuses on the operationalization and implementation of the Brief ICF Core Set for Hearing Loss in clinical oto-audiology practice using a PROM-based e-intake tool. This part covers Chapters 5, 6, and 7:

In **Chapter 5**, the development process of the ICF-based e-intake tool is described. The process comprised a mixed methodology study including the selection of a pool of items of existing validated PROMs, a formal decision-making process, and qualitative content assessments. In addition, the integration of the ICF-based e-intake tool in a computer-based system is described.

In **Chapter 6**, the identification and categorization of barriers to and enablers of the implementation of the ICF-based e-intake tool in clinical oto-audiology practice is described. The COM-B model was used as a framework to categorize the data into capability, opportunity and motivation-related barriers and enablers.

In **Chapter 7**, the development process of an intervention for the implementation of the ICF-based e-intake tool is described. The Behavioural Change Wheel method was used to guide the process of developing this intervention.

Finally, **Chapter 8** summarizes and discusses the main findings of the individual chapters. In addition, implications for clinical practice and recommendations for further research are provided.

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APPENDIX 1. Categories included in the Brief Core Set for Hearing Loss⁷⁸

Body Functions		
b126	Temperament and personality functions	General mental functions of constitutional disposition of the individual to react in a particular way to situations, including the set of mental characteristics that makes the individual distinct from others.
b140	Attention functions	Specific mental functions of focusing on an external stimulus or internal experience for the required period of time.
b144	Memory functions	Specific mental functions of registering and storing information and retrieving it as needed.
b152	Emotional functions	Specific mental functions related to the feeling and affective components of the processes of the mind.
b210	Seeing functions	Sensory functions relating to sensing the presence of light and sensing the form, size, shape and colour of the visual stimuli.
b230	Hearing functions	Sensory functions relating to sensing the presence of sounds and discriminating the location, pitch, loudness and quality of sound.
b240	Sensations associated with hearing and vestibular functions	Sensations of dizziness, falling, tinnitus and vertigo.
Body Structures		
s110	Structure of brain	
s240	Structure of external ear	
s250	Structure of middle ear	
s260	Structure of inner ear	
Activities and Participation		
d115	Listening	Using the sense of hearing intentionally to experience auditory stimuli, such as listening to a radio, music or a lecture.
d240	Handling stress and other psychological demands	Carrying out simple or complex and coordinated actions to manage and control the psychological demands required to carry out tasks demanding significant responsibilities and involving stress, distraction, or crises, such as driving a vehicle during heavy traffic or taking care of many children
d310	Communicating with - receiving - spoken messages	Comprehending literal and implied meanings of messages in spoken language, such as understanding that a statement asserts a fact or is an idiomatic expression.
d350	Conversation	Starting, sustaining and ending an interchange of thoughts and ideas, carried out by means of spoken, written, sign or other forms of language, with one or more people one knows or who are strangers, in formal or casual settings.
d360	Using communication devices and techniques	Using devices, techniques and other means for the purposes of communicating, such as calling a friend on the telephone.
d760	Family relationships	Creating and maintaining kinship relationships, such as with members of the nuclear family, extended family, foster and adopted family and step-relationships, more distant relationships such as second cousins, or legal guardians.

<i>Activities and Participation (continued)</i>		
d820	School education	Gaining admission to school, engaging in all school-related responsibilities and privileges, and learning the course material, subjects and other curriculum requirements in a primary or secondary education programme, including attending school regularly, working cooperatively with other students, taking direction from teachers, organizing, studying and completing assigned tasks and projects, and advancing to other stages of education.
d850	Remunerative employment	Engaging in all aspects of work, as an occupation, trade, profession or other form of employment, for payment, as an employee, full or part time, or self-employed, such as seeking employment and getting a job, doing the required tasks of the job, attending work on time as required, supervising other workers or being supervised, and performing required tasks alone or in groups.
d910	Community life	Engaging in all aspects of community social life, such as engaging in charitable organizations, service clubs or professional social organizations.
Environmental Factors		
e125	Products and technology for communication	Equipment, products and technologies used by people in activities of sending and receiving information, including those adapted or specially designed, located in, on or near the person using them.
e250	Sound	A phenomenon that is or may be heard, such as banging, ringing, thumping, singing, whistling, yelling or buzzing, in any volume, timbre or tone, and that may provide useful or distracting information about the world.
e310	Immediate family	Individuals related by birth, marriage or other relationship recognized by the culture as immediate family, such as spouses, partners, parents, siblings, children, foster parents, adoptive parents and grandparents.
e355	Health professionals	All service providers working within the context of the health system, such as doctors, nurses, physiotherapists, occupational therapists, speech therapists, audiologists, orthotist-prosthetists, medical social workers.
e410	Individual attitudes of immediate family members	General or specific opinions and beliefs of immediate family members about the person or about other matters (e.g., social, political and economic issues), that influence individual behaviour and actions.
e460	Societal attitudes	General or specific opinions and beliefs generally held by people of a culture, society, subcultural or other social group about other individuals or about other social, political and economic issues, that influence group or individual behaviour and actions.
e580	Health services, systems and policies	Services, systems and policies for preventing and treating health problems, providing medical rehabilitation and promoting a healthy lifestyle.

Chapter 2:

Overlap and non-overlap between the ICF Core Sets for Hearing Loss and otology and audiology intake documentation

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ABSTRACT

Objectives: The International Classification of Functioning Disability and Health (ICF) Core Sets for Hearing Loss (CSHL) were developed to serve as a standard for the assessment and reporting of the functioning and health of patients with HL. The aim of the present study was to compare the content of the intake documentation currently used in secondary and tertiary hearing care settings in the Netherlands with the content of the CSHL. Research questions were: (1) To what extent are the CSHL represented in the Dutch Otology and Audiology intake documentation? (2) Are there any extra ICF categories expressed in the intake documentation that are currently not part of the CSHL, or constructs expressed that are not part of the ICF?

Design: Multicentre patient record study including 176 adult patients from two secondary, and two tertiary hearing care settings. The intake documentation was selected from anonymized patient records. The content was linked to the appropriate ICF category from the whole ICF classification using established linking rules. The extent to which the CSHL were represented in the intake documentation was determined by assessing the overlap between the ICF categories in the CSHL and the list of unique ICF categories extracted from the intake documentation. Any extra constructs that were expressed in the intake documentation but are not part of the CSHL were described as well, differentiating between ICF categories that are not part of the CSHL and constructs that are not part of the ICF classification.

Results: In total, otology and audiology intake documentation represented 24 of the 27 Brief CSHL categories (i.e., 89%), and 60 of the 117 Comprehensive CSHL categories (i.e., 51%). Various CSHL categories were not represented, including higher mental functions (Body Functions), civic life aspects (Activities and Participation), and support and attitudes of family (Environmental Factors). One extra ICF category emerged from the intake documentation that is currently not included in the CSHL: sleep functions. Various Personal Factors emerged from the intake documentation that are currently not defined in the ICF classification.

Conclusions: The results showed substantial overlap between the CSHL and the intake documentation of otology and audiology, but also revealed areas of non-overlap. These findings contribute to the evaluation of the content validity of the CSHL. The overlap can be viewed as supportive of the CSHLs' content validity. The non-overlap in CSHL categories indicates that current Dutch intake procedures may not cover all aspects relevant to patients with ear/hearing problems. The identification of extra constructs suggests that the CSHL may not include all areas of functioning that are relevant to Dutch Otology and Audiology patients. Consideration of incorporating both aspects into future intake practice deserves attention. Operationalization of the CSHL categories, including the extra constructs identified in this study, into a practical and integral intake instrument seems an important next step.

INTRODUCTION

Hearing problems may lead to limitations in daily activities and restrictions in societal participation. This in turn may affect an individual's health-related quality of life and cognitive and emotional functioning¹⁻⁴. External factors, like the acoustical environment, and personal factors like coping strategies have been shown to influence a person's functioning⁵. Treating patients with hearing loss (HL) therefore requires the assessment and documentation of functioning from the body, person, and societal perspective. Incomplete coverage of relevant aspects of the condition pre, during, and post treatment may lead to unaddressed health care needs and missed treatment-effects. In line with this, a multidimensional and integrated approach to assessing functioning and health of adults with hearing impairment was advocated⁶.

In the Netherlands, persons seeking help for their hearing problem can enter the health care system via primary care (general practitioner or the hearing aid dispenser). If necessary, an individual can be referred to secondary (district hospital) or tertiary care (academic hospital) subsequently. Typically, multiple disciplines can be involved in the secondary and tertiary hearing care including ear nose and throat (ENT) specialists, or – in case of an audiology clinic (AC) – audiologists, psychologists, speech language pathologists, and social workers. Individuals admitted for care at the department of Otology (as part of ENT), or at an AC, are invited for an intake visit before the treatment or intervention. During this visit, a patient's basic (hearing) health, need for care, and expectations are assessed and discussed. Information about a person's functioning that is documented accordingly should facilitate a proficient and interconnected collaboration between the team members and the patient during the care process. However, it is challenging to define functioning and need for care in a shared methodology that is usable for all healthcare professionals involved. A shared framework is fundamental in achieving inter-professional collaboration⁷. In The Netherlands, there is however no uniform practice or standard protocol for hearing care professionals to conceptualize and operationalize a person's functioning in an integrated and comprehensive way; for each discipline different frames of reference are used to guide and document the intake. This hampers efficient interdisciplinary communication. Moreover, with the increased recognition of the importance of patient-centred care⁸ growing medical costs, and the increasing demands for quality, the urge for efficient and evidence-based care is rising. This underlines the need for a common language and a reference system that functions across professional boundaries in hearing care, and enables a comprehensive and integrated assessment of patient's functioning in a standardized way.

The World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) was established for that purpose. It aims to provide a unified reference framework for the description and classification of health conditions, using standard concepts and terminology⁹. The classification system is structured hierarchically,

distinguishing two main parts. The first part concerns functioning and disability, and is divided into the components Body Functions (BF; emotional, cognitive, and physical), Body Structure (BS; anatomy), Activities (tasks and demands of life), and Participation (engagement in life situations). The second part, contextual factors, is divided into the components Environmental Factors (EF; physical, social, and attitudinal world) and Personal Factors (PF; gender, age, habits, lifestyle, coping styles). Each of these components (except Personal Factors, which is not coded in the ICF because of the wide international variability) consists of various domains and within each domain there are categories that serve as the units of the ICF classification. Previous scientific and clinical audiological work supports the ICF's value as a reference system^{3, 10}. However, comprising over 1400 categories, the ICF's applicability in everyday clinical practice is unworkable, and first needs to be adapted to the perspectives and needs of different users and clinical settings. For that purpose, the WHO started the development of ICF Core Sets. A core set comprises a selection of essential categories out of the full set of ICF categories that are relevant for a specific health condition. In 2010, the development of the ICF Core Sets for HL (CSHL) was initiated, aiming to identifying ICF categories of particular relevance for adults with HL for use in clinical encounters and research¹¹. The development of ICF CSHL follows the WHO guidelines and consists of three phases: a preparatory phase, a consensus phase (phase I), and a validation phase (phase II)¹². The preparatory phase covered four studies: an international expert survey¹³, systematic reviews^{14, 15}, and patient interviews¹⁶. During an international conference in 2013 (phase I), hearing professionals reached consensus on which ICF categories to include in the CSHL. There is a Comprehensive Core Set and a Brief one. The Comprehensive CSHL (117 ICF categories) serves as a guide for multi-professional comprehensive assessment. The Brief CSHL (with 27 ICF categories) serves as minimal standard for the assessment and reporting of functioning and health in clinical studies¹⁷.

The present study is part of phase II and concerns the validation of the CSHL. We examined the empirical validity of the CSHL by implementing and testing them in clinical practice. Implementation of core sets can be carried out in different ways depending on their specific purposes¹². A core set can be applied as a clinical tool to support clinicians in areas, such as needs assessment, rehabilitation, and measuring outcomes^{3, 10, 18}. In two recently conducted studies, Alfakir et al.^{19, 20} examined the validity of the Brief CSHL as an outcome measure within audiologic rehabilitation (AR) programs. In their first study, they explored the dimensions of hearing performance measures that were used in a standard care university clinic, and examined if those dimensions supported the structure of the Brief CSHL. Eighteen of 27 items from the Brief CSHL were linked to ICF categories. Subsequent factor analysis confirmed the original structure of the ICF framework. In their second study, the Brief CSHL was operationalized to define successful aging post cochlear implantation. Twenty of 27 items from the Brief CSHL were linked. In both studies, it was concluded that applying the WHO-ICF framework could maximize clinical outcomes of AR programs. In the present study, we specifically focus on the content validation of the CSHL with respect to the intake of

patients applying for hearing care at otology departments and in audiology clinics. The objective of the present study was to compare the content of the intake documentation currently used in secondary and tertiary hearing care settings in the Netherlands with the content of the CSHL. Specifically, the research questions were:

- To what extent are the CSHL represented in Dutch otology and audiology intake documentation?
- Are there any extra ICF categories expressed in Dutch otology and audiology intake documentation that are currently not part of the CSHL, or are there extra constructs expressed in the intake documentation that are not part of the ICF? If so, what are these constructs?

MATERIALS AND METHODS

Study design and setting

A multicentre patient record study was carried out. Patient records from patients of both tertiary and secondary settings were included to pursue a sample representative of patients in the Dutch clinical hearing health care settings. These settings included:

- I. Section of Otology of the ENT department of VU University Medical Center in Amsterdam (tertiary setting);
- II. Section of Otology of the ENT department of the Westfriesgasthuis in Hoorn (secondary setting);
- III. Audiology Clinic of the ENT department of VU University Medical Center in Amsterdam (tertiary setting);
- IV. The Audiology Clinic Holland Noord (ACHN) in Alkmaar (secondary setting).

All patient records were anonymized before data extraction. This study was approved by the Medical Ethics Committee of the VU University Medical Centre, Amsterdam, The Netherlands (reference number 2013-067).

Selection of patient records

Intake documentation forms were selected from patient records of adults who applied for care at the ENT departments or the ACs in 2013. A patient record was eligible if it was of a patient who was at least 18 years of age and if the record included documentation of the first intake appointment. No exclusion criteria were applied. To ensure a representative sample of patient records, the procedure of patient record selection was as follows: first, relevant patient groups were identified based on their diseases/ complaints. For the otology setting, groups of patients were categorized according to the International Classification of Diseases version 2010 (ICD-10). The diagnostic groups were divided into the four domains of the ICD-10, Chap. VIII, "Diseases of the ear and mastoid process": diseases of the external ear; diseases of the middle ear; diseases of the inner ear; and other diseases. For the AC setting, patient groups were identified and categorized based on diagnostics and type of rehabilitation.

Second, per group, the patient records were stratified into age bands (i.e., 18 to 25, 26 to 67, >67). Per age band, the first two patient records were included for the analyses.

Data extraction and linking to the ICF

Once all patient records were collected, we first identified the intake documentation forms. Upon reviewing the documentation forms, we identified different methods used for the intake or admission of patients. In the otology settings, the main element of the standard intake procedure is an admission interview carried out by the ENT physician. It is a semi-structured interview for which a standard intake form is used to document the information discussed during the consultation. It aims at distinguishing “reasons for attendance,” and includes the “anamnesis” (covering medical history and complaints, allergies, current medication, and family history). All otology patients were assessed using this general format, but the precise structure was different for tertiary and secondary otology settings (see Appendix 1). In the AC departments, several structured questionnaires are part of the standard intake procedure, including both patient-administered and interview-administered measures (see Appendix 2). The administration of these instruments differed for different patient groups, but was consistent within the respective patient group. For example, the Amsterdam Inventory for Auditory Disability and Handicap is part of the intake for patients visiting the AC for a vocational rehabilitation program, and the International Outcome Inventory for Hearing Aids is part of the standard intake procedure for patients visiting the AC for a hearing aid assessment. In addition, unstructured free text forms were included in the intake documentation. Here, notes could be made by the professional to summarize what was discussed during the appointment, including patient complaints not assessed in structured questionnaires. No uniform practice was identified in documenting information on this form. This form was part of the intake documentation for all audiology patients. Both the questionnaires and the notes were included for data extraction, linking, and analyses. Second, relevant content was extracted from the intake documentation forms and was linked to the most precisely corresponding ICF category. The ICF categories are hierarchically organized in a stem-branch-leaf scheme using interlinked levels, and are denoted by unique alphanumeric code. The letters refer to the components (b: BF, s: BS, d: Activities and Participation; and e: EF). This letter is followed by one digit indicating the chapter, which is the first level, followed by the code for the second-level categories (two digits), and the third and fourth level categories (one digit each). Categories at higher levels are more detailed. Therefore, a lower-level category shares the attributes of the higher-level categories of which it is a member.

The linking was performed according to the “seven-step linking procedure” as established by Granberg et al. (2014)¹⁵. This procedure combines the linking rules already established by the WHO²¹ and additional rules developed especially for the audiological field [see Appendix 1 in Supplementary Digital Content of Granberg et al. (2014)¹⁵]. The exact linking method is fully explained in Granberg et al. (2014)¹⁵. The linking was conducted by LvL. An example of the linking process is provided in Table 1.

TABLE 1. Example of the procedure used to link the content of the intake documentation to the ICF following the seven-step linking procedure

1: Meaning unit	2: Meaningful concept	3: Interpretation of the underlying meaning	4: Linking unit	5: ICF category	6: Linking rule
“Patient <u>experiences limited hearing since winter 2011</u> . Since then the patient’s <u>hearing loss limited the patient’s social life</u> . Especially <u>speech comprehension in noisy environments</u> is difficult.”	Experiencing limited hearing	Hearing functions	Limited hearing	b230	Granberg et al. ¹⁵ , rule 6
	Since winter 2011	Time interval	-	nc	Cieza et al. ²¹ , Tab I, rule c
	Hearing loss	Stated as a health condition	Hearing loss	HC	Cieza et al. ²¹ , Tab II, rule 8
	Limited social life	Social life limited and restricted	Social life	d9205*	
	Speech comprehension	Intended listening	Speech comprehension	d310	Granberg et al. ¹⁵ , rule 6
	in noisy environment is hard	Environmental noise	Noisy environment	e250, e150	Granberg et al. ¹⁵ , rule 7

HC=health condition, nc=not covered

*Because d9205 is not part of the CSHL, but d920 is, the meaningful concept was also linked to d920.

If a specific category was identified of which its higher level category was in the CSHL, the meaning unit was also linked to the higher level ICF category. For example, if the meaning unit was “ringing in ears”, this was linked to the category b2400 ‘ringing in ears or tinnitus’. This higher category is not part of the CSHL, and therefore was also linked to b240 ‘sensations associated with hearing and vestibular functions’ which is part of the CSHL.

Data analysis

Descriptive statistics (frequencies, means, and SDs) were calculated for patients’ sociodemographic and condition-related characteristics. The extent to which the CSHL were represented in the intake documentation was determined by assessing the overlap between the ICF categories in the CSHL and the list of unique ICF categories extracted from the intake documentation. Overlap was expressed as percentage of CSHL represented. We also determined the extent to which there was non-overlap. This was the proportion of the CSHL categories not represented in the intake documentation. Non-overlap also covered the extra (non) ICF categories that were expressed in the intake documentation but are not part of the CSHL. We differentiated between non-CSHL categories and constructs currently not part of the ICF. Figure 1 provides a graphical illustration of the non-overlap between the CSHL, the

ICF classification (total) and the intake documentation. To ensure reliability of the ICF-linking procedure, eight randomly selected patient records (two records per hearing care setting) were independently analysed by another researcher (MP). The linking results of MP were compared with that of LvL. The degree of agreement between the results was determined at the component level, chapter level, and second- and third-level categories by calculating percent agreement (i.e., the proportion of the number of meaning units on which the researchers' categorizations fully matched).

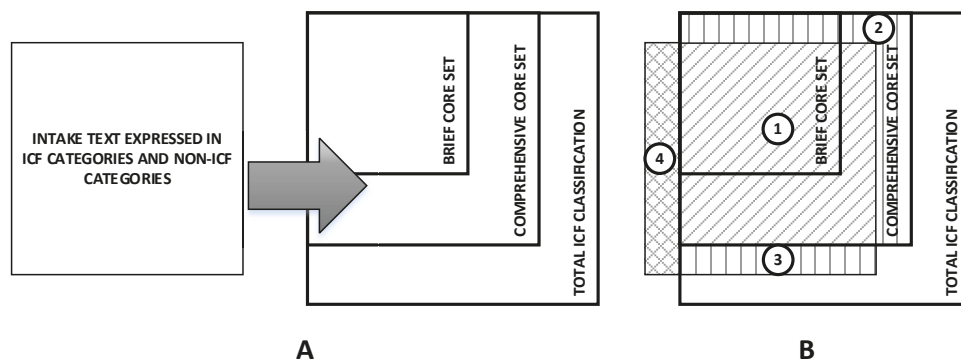


FIGURE 1. Graphical illustration of the (non) overlap between the CSHL, the ICF classification (total) and the intake documentation

A, Intake text was linked to the ICF classification, and resulted in a list of unique ICF categories and constructs not part of the ICF. The overlap and non-overlap between the list of unique ICF categories extracted from the intake documentation and the ICF categories that are part of the CSHL was determined.

B, The (non) overlap of the unique ICF categories extracted from the intake documentation and the ICF categories that are included in the CSHL. 1 = CSHL categories represented in intake documentation; 2 = CSHL categories not represented in intake documentation; 3 = Identified ICF categories in intake documentation that were not part of the CSHL; 4 = Identified constructs in intake documentation that were not part of the ICF classification. HL indicates hearing loss; ICF, International Classification of Functioning Disability and Health.

RESULTS

Descriptives

In total, 176 patient records were included. The upper panel of Table 2 shows the sociodemographic and condition-related characteristics of the included patients. The content of 176 patient records was linked, yielding a total of 141 unique ICF categories. In the lower part of Table 2, the overlap between this unique list and the CSHL categories are reported. Percent agreement between the two raters varied between 90 (comparison of linkage to second-level categories) and 100% (comparison of linkage at the categories' component level, chapter level and fourth level).

TABLE 2. Sociodemographic- and condition-related data of the total sample (upper panel) and (sub)total representation of the CSHL within intake documentation, given in percentage of CSHL categories presented (lower panel)

Variable	Total	Otology		Audiology	
		I.	II.	III.	VI.
Centre:					
Setting:		Tertiary	Secondary	Tertiary	Secondary
Number of participants	167	80	53	27	16
Mean age ± SD	52 ± 21	51 ± 22	55 ± 20	44 ± 17	57 ± 24
(range)	(18-92)	(18-92)	(18-85)	(18-71)	(18-92)
Female sex, %	42.8	48.8	54.7	30.0	37.5
Otology diagnosis, %					
Diseases of external ear (H60-H62)	-	18.8%	20.8%	NA	NA
Diseases of middle ear and mastoid (H65-H75)	-	38.7%	37.7%	NA	NA
Diseases of inner ear (H80-H83)	-	10%	17%	NA	NA
Other diseases of the ear (H90-H95)	-	27.5%	24.5%	NA	NA
Audiology-group, %					
Diagnostics	-	NA	NA	18.5	37.5
Rehabilitation	-	NA	NA	63	25*
Tinnitus	-	NA	NA	18.5	37.5
Represented categories, N; %					
Brief CSHL (27=100%)	24; 89	17; 63	14; 52	22; 81%	19; 70
BF (7=100%)	6; 86	5; 71	4; 57	6; 86%	4; 57
BS (4=100%)	4; 100	4; 100	4; 100	2; 50%	2; 50
A&P (9=100%)	9; 100	5; 56	3; 33	9; 100%	9; 100
EF (7=100%)	5; 57	3; 43	3; 43	5; 57%	4; 57
Comprehensive CSHL (117=100%)	60; 51	31; 26	16; 14	58; 50%	43; 37
BF (22=100%)	17; 77	11; 50	4; 18	17; 77%	9; 41
BS (5=100%)	4; 80	4; 80	4; 80	2; 40%	2; 40
A&P (42=100%)	26; 62	9; 21	5; 12	26; 62%	23; 55
EF (48=100%)	13; 27	7; 15	3; 6	13; 27%	9; 19

All data is shown separately for the different otology and audiology settings. I = Section of Otology of the ENT department of VU University Medical Center in Amsterdam; II = Section of Otology of the ENT department of the Westfriesgasthuis in Hoorn; III = Audiology Clinic of the ENT department of VU University Medical Center in Amsterdam; IV = The Audiology Clinic Holland Noord (ACHN) in Alkmaar. *No patient records available for age band 18-25. A&P, Activities and Participation; BF, Body Functions; BS, Body Structures; EF, Environmental Factors; ENT, ear nose and throat; ICF, International Classification; NA, not applicable.

CSHL categories represented in otology and audiology intake documentation

The total percentage of the CSHL categories identified in the intake documentation was 89% for the Brief and 51% for the Comprehensive CSHL. The ICF categories encountered in the intake documents are shown in Tables 3–6. Each table shows the results for each of the ICF components separately: BF (Table 3), BS (Table 4), Activities and Participation (A&P; Table 5), and EF (Table 6). The results are reported per discipline (otology and audiology).

Body Functions

Regarding the BF component, 71% of the ICF categories in the Brief CSHL and 50% of the ICF categories of the Comprehensive CSHL were represented in the otology intake documentation. The second-level category b230 “hearing functions” was documented and most of its third-level categories (b2300 to b2304). This typically concerned a report of a general complaint of HL, for example, “patient suffers from impaired hearing” or concerned specific information on type of HL, for example, “patient experiences difficulties in speech discrimination” (i.e., b2303). Voice functions (b130) were reported in the context of communication abilities as well. Intake text on b240 “sensations associated with hearing and vestibular functions” mainly concerned short statements indicating specific complaints such as “suffers from aural pressure” or more simply “dizziness+”. Specific complaints about hearing also included the presence or absence of pain (b280). The CSHL categories on global mental functions (intellectual functions; driving functions; motivation; personality), specific mental functions (memory functions; perceptual functions: auditory and visual perception; higher-level cognitive functions; mental functions of language) were not represented in the otology intake documentation. In the audiology setting, larger overlap with the CSHL categories was found in the intake documentation (Table 2). Because the Amsterdam Hearing Inventory for Auditory Disability and Handicap was administered in the tertiary AC setting, all specific hearing functions (i.e., b2301 to b2304) could be linked, for example “Can you hear cars that are passing or approaching?”. Linking to category b240 “sensations associated with hearing and vestibular functions” occurred mostly for tinnitus (i.e., b2400), and concerned for example the question of whether the patient suffered from tinnitus (if so, what kind of tone(s)/sound or frequency). This and other standard questions were identified in the tinnitus-specific questionnaires that are used in the intakes. In accordance with the non-overlap observed for otology, various categories of mental functioning (e.g., intellectual functions; motivation) were not covered in the audiology intake documentation.

Body Structures

Most of the identified BS categories in the otology intake documentation (s110, s240, s250, s260, see Table 4) were found in the reports on the medical history. This included reports of results of earlier tests such CT/MR-scans to exclude cholesteatoma of middle ear, or statements related to other past events (“patient has a retracted tympanic membrane”). As shown in Table 2, a lower percentage of BS categories was identified in the audiological intake documentation compared with the otology intake documentation. The extra components in

the otology intake documentation concerned structures of the brain and inner ear. Reports of structures of head and neck regions did not emerge in otology or audiology intake documentation.

Activities and Participation

The percentage of overlap between the CSHL and the otology intake documentation of the A&P component was 56% of the Brief and 21% of the Comprehensive CSHL categories. Various CSHL A&P categories [e.g., psychosocial stress (d2), communication (d3), study and employment (d8), and recreation and leisure activities (d9)] were represented in the otology intake documentation. Examples of intake content belonging to communication (d3) included “the direct communication with a person is mediocre”; and “patient experiences difficulties in following a conversation.” Intake content linked to study and employment (d8) concerned information on the study currently followed by the patient, or his/her current profession, or indications of problems in this regard: “the patient has problems at school”; and “patient’s HL interferes with occupational functioning.” Intake content linked to recreation and leisure (d9) concerned sports or hobbies in which the patient indicated to experience the ear and hearing problem, or it was reported that these problems had a negative impact on socializing in general. CSHL categories related to learning and applying knowledge (e.g., watching, listening), domestic life (e.g., acquisition of goods and services), interpersonal relationships (e.g., formal and informal relationships), economic life, and civic life (e.g., religion and spirituality) were not found in the intake documentation. The high level of non-overlap that was found in the otology intake documentation contrasts the relatively high proportion of A&P categories found in the audiology intake documentation. For the A&P component, the largest overlap between the CSHL and the intake documentation was found for the categories d3 (communication) and d7 (interpersonal relationships). All categories in d3 (d310 to d360) were represented and often included questions about the use of (formal) sign language, telecommunication, and carrying out or following conversations with one or more persons. Five out of seven categories belonging to interpersonal relationships (d7) of the Comprehensive CSHL emerged in the intake documentation (e.g., “Does your hearing impairment entail significant problems in your contact with friends/your partner?”). CSHL categories related to economic, civil, and political life were not found in the audiology or otology intake documentation.

Environmental Factors

Otology intake documentation on products for communication (e1251) included information about (use of) hearing aids (e.g., “patient uses hearing aids”). Environmental sound (e250) was usually reported as barrier (e.g., “environmental noise hinders the patient”), and support from a health professional (e355) included information on (previous) hearing health care the patient had received. In the intake files, no information on attitudes (e4) or services, systems, and policies (e5) was documented. For the EF categories, there was more overlap between the CSHL and the intake documentation in the audiology setting than in the otology setting.

EF categories that were found in the audiology intake documentations, but not in the otology intake documentation were “support and relationship from colleagues and employers” (e325, e330), individual attitudes of health professionals (e440) and labour services (e590). Categories referring to other types of support or attitudes (e.g., e320 “friends,” e480 “societal attitudes”) and categories referring to systems and services (e.g., e580 “health services, systems, and policies”) were not expressed in either the audiology or otology intake documentation.

TABLE 3. Body Functions component – The set of unique BF-categories that the content of the intake documentation of patient records at the otology and audiology setting was linked to. Overlap and non-overlap with the categories the CSHL is indicated

ICF category	ICF category description	Otology	Audiology	C	B
b1100	State of consciousness	■			
b117	Intellectual functions			●	
b126	Temperament and personality functions		■	●	●
b1266	Confidence		■		
b130	Energy and drive functions				
b1300	Energy level	■	■	●	
b1301	Motivation			●	
b134	Sleep functions	■	■		
b1340	Amount of sleep		■		
b1341	Onset of sleep	■			
b1344	Functions involving the sleep cycle				
b140	Attention functions	■	■	●	●
b1401	Shifting attention		■		
b144	Memory functions			●	●
b152	Emotional Functions	■	■	●	●
b1522	Range of emotion		■		
b1560	Auditory perception		■	●	
b1561	Visual perception			●	
b164	Higher-level cognitive functions			●	
b167	Mental functions of language		■	●	
b210	Seeing functions	■	■	●	●
b230	Hearing functions	■	■		●
b2300	Sound detections		■	●	
b2301	Sound discrimination	■	■	●	
b2302	Localization of sound source		■	●	
b2303	Lateralization of sound		■		
b2304	Speech discrimination	■	■	●	
b235	Vestibular functions	■		●	
b2351	Vestibular function of balance	■	■		
b240	Sensations associated with hearing and vestibular functions	■	■	●	●
b2400	Ringling in ears or tinnitus	■	■		
b2401	Dizziness	■	■		
b2402	Sensation of falling	■			

TABLE 3. *continued*

ICF category	ICF category description	Otology	Audiology	C	B		
b2403	Nausea associated with dizziness or vertigo	■	■				
b2404	Irritation in the ear						
b2405	Aural pressure						
b250	Taste function						
b255	Smell function						
b265	Touch function						
b2702	Sensitivity to pressure						
b280	Sensation of pain			■	■	●	
b2801	Pain in body part			■	■		
b28010	Pain in head and neck						
b310	Voice functions	■	■	●			
b3100	Production of voice	■	■				
b3101	Quality of voice						
b320	Articulation functions		■	●			
b330	Fluency and rhythm of speech functions		■	●			
b3303	Melody of speech		■				
b3400	Production of notes		■				
b410	Heart functions	■					
b430	Haematological system functions						
b440	Respiration						
b4400	Respiration rate						
b4552	Fatigability						
b1502	Chewing						
b5105	Swallowing						
b530	Weight maintenance functions associated with the digestive system						
b5401	Carbohydrate metabolism						
b5500	Body temperature						
b770	Gait pattern functions						
b7801	Sensation of muscle spasm						
b840	Sensations related to the skin						
	CSHL categories not represented in intake documentation						
	CSHL categories represented in intake documentation						
	Extra non-CSHL categories identified in intake documentation						

C= Comprehensive CSHL; B= Brief CSHL; nd = not defined

TABLE 4. Body Structures component – The set of unique BS-categories that the content of the intake documentation of patient records at the otology and audiology setting was linked to. Overlap and non-overlap with the categories the CSHL is indicated

ICF category	ICF category description	Otology	Audiology	C	B
s110	Structure of brain	■		•	•
s220	Structure of eye ball	■			
s230	Structures around the eye	■			
s240-s260	Structure of ear	■	■		
s240	Structure of external ear	■	■	•	•
s250	Structure of middle ear	■	■	•	•
s2500	Tympanic membrane	■	■		
s260	Structure of inner ear	■		•	•
s310	Structure of nose	■			
s330	Structure of pharynx	■			
s710	Structure of head and neck region			•	
s810	Structure of areas of skin	■			
■	CSHL categories not represented in intake documentation				
■	CSHL categories represented in intake documentation				
■	Extra non-CSHL categories identified in intake documentation				

C= Comprehensive CSHL; B= Brief CSHL

TABLE 5. Activities and Participation component – The set of unique A&P-categories that the content of the intake documentation of patient records at the otology and audiology setting was linked to. Overlap and non-overlap with the categories the CSHL is indicated

ICF category	ICF category description	Otology	Audiology	C	B
A&P-nd		■	■		
d110	Watching		■	•	
d115	Listening		■	•	•
d140	Learning to read			•	
d155	Acquiring skills			•	
d160	Focusing attention		■	•	
d166	Reading		■		
d170	Writing		■		
d175	Solving problems			•	
d220	Undertaking multiple tasks			•	
d240	Handling stress and other psychological demands	■	■	•	•
d2401	Handling stress	■	■		
d310	Communicating with – receiving – spoken messages	■	■	•	•
d315	Communicating with – receiving – nonverbal messages	■	■	•	
d330	Speaking	■	■	•	
d3350	Producing body language		■		
d3351	Producing signs and signals		■		
d340	Producing messages in formal sign language		■		
d350	Conversation	■	■		•
d3500	Starting a conversation		■		

TABLE 5. *continued*

ICF category	ICF category description	Otology	Audiology	C	B
d3503	Conversing with one person		■	•	
d3504	Conversing with many people		■	•	
d355	Discussion	■	■	•	
d3550	Discussion with one person		■		
d3551	Discussion with many people	■	■		
d360	Using communication devices and techniques		■	•	•
d3600	Using telecommunication devices		■		
d3602	Using communication techniques		■		
d3-nd					
d410	Changing basic body position	■			
d415	Maintaining a body position				
d420	Transferring oneself	■			
d440	Fine hand use		■	•	
d450	Walking	■			
d470	Using transportation		■	•	
d4702	Using public motorized transportation		■		
d475	Driving		■	•	
d4750	Driving human-powered vehicles		■		
d4751	Driving motorized vehicles		■		
d4-nd		■	■		
d550	Eating				
d560	Drinking				
d610	Acquiring a place to live	■			
d620	Acquisition of goods and services		■	•	
d6200	Shopping		■		
d6201	Gathering daily necessities		■		
d630-d649	Household tasks		■		
d640	Doing housework		■		
d660	Assisting others			•	
d710	Basic interpersonal interactions			•	
d720	Complex interpersonal interactions			•	
d730	Relating with strangers		■	•	
d740	Formal relationships		■	•	
d7401	Relating with subordinates		■		
d7402	Relating with equals		■		
d750	Informal social relationships		■	•	
d7500	Informal relationships with friends		■		
d7501	Informal relationships with neighbours		■		
d7502	Informal relationships with acquaintances		■		
d7503	Informal relationships with co-inhabitants		■		
d760	Family relationships		■	•	•
d770	Intimate relationships		■	•	
d7700	Romantic relationships		■		
d810	Informal training			•	
d815	Preschool information		■		
d820	School education	■	■	•	•
d825	Vocational training			•	
d830	Higher education	■	■	•	

TABLE 5. *continued*

ICF category	ICF category description	Otology	Audiology	C	B
d840	Apprenticeship (work preparation)			•	
d845	Acquiring, keeping and terminating a job			•	
d850	Remunerative employment			•	•
d855	Non-remunerative employment			•	
d860	Basic economic transactions			•	
d870	Economic self-sufficiency			•	
d910	Community life			•	•
d9100	Informal associations				
d920	Recreation and leisure			•	
d9201	Sports				
d9203	Crafts				
d9204	Hobbies				
d9205	Socializing				
d930	Religion and spirituality			•	
d940	Human rights			•	
d950	Political life and citizenship			•	

	CSHL categories not represented in intake documentation
	CSHL categories represented in intake documentation
	Extra non-CSHL categories identified in intake documentation

C= Comprehensive CSHL; B= Brief CSHL; nd = not defined

TABLE 6. Environmental Factors component – The set of unique EF-categories that the content of the intake documentation of patient records at the otology and audiology setting was linked to. Overlap and non-overlap with the categories the CSHL is indicated

ICF category	ICF category description	Otology	Audiology	C	B
e115	Products and technology for personal use and daily living			•	
e120	Products and technology for personal indoor and outdoor mobility and transportation			•	
e1200	General products and technology for personal indoor and outdoor mobility and transportation				
e125	Products and technology for communication			•	•
e1250	General products and technology for communication				
e1251	Assistive products and technology for communication				
e130	Products and technology for education			•	
e135	Products and technology for employment			•	
e140	Products and technology for culture, recreation and sport			•	
e145	Products and technology for the practice of religion and spirituality			•	
e150	Design, construction and building products and technology of buildings for public use			•	
e155	Design, construction and building products and technology of buildings for private use			•	
e1-nd					
e225	Climate			•	
e240	Light			•	

TABLE 6. *continued*

ICF category	ICF category description	Otology	Audiology	C	B
e250	Sound				•
e2500	Sound intensity			•	
e2501	Sound quality			•	
e310	Immediate family				•
e315	Extended family			•	
e320	Friends			•	
e325	Acquaintances, peers, colleagues, neighbours and community members			•	
e330	People in position of authority			•	
e335	People in subordinate positions			•	
e340	Personal care providers and personal assistants			•	
e345	Strangers			•	
e350	Domesticated animals			•	
e355	Health professionals			•	•
e360	Other professionals			•	
e3-nd					
e410	Individual attitudes of immediate family members			•	•
e415	Individual attitudes of extended family members			•	
e420	Individual attitude of friends			•	
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members			•	
e430	Individual attitudes of people in position of authority			•	
e440	Individual attitudes of personal care providers and personal assistants			•	
e445	Individual attitudes of strangers			•	
e450	Individual attitudes of health professionals			•	
e455	Individual attitude of other professionals			•	
e460	Societal attitudes			•	•
e465	Social norms, practices and ideologies			•	
e4-nd					
e515	Architecture and construction services, systems and policies			•	
e525	Housing services, systems and policies			•	
e535	Communication services, systems and policies			•	
e540	Transportation services, systems and policies			•	
e545	Civil protection services, systems and policies			•	
e550	Legal services, systems and policies			•	
e555	Associations and organizational services, systems and policies			•	
e560	Media services, systems and policies			•	
e575	General social support services, systems and policies			•	
e580	Health services, systems and policies			•	•
e585	Education and training services, systems and policies			•	
e590	Labour and employment services, systems and policies			•	
e5-nd					

	CSHL categories not represented in intake documentation
	CSHL categories represented in intake documentation
	Extra non-CSHL categories identified in intake documentation

C= Comprehensive CSHL; B= Brief CSHL; nd = not defined

Extra ICF categories not part of the CSHL, and extra constructs that are not part of or are not specified by the ICF that were extracted from otology and audiology intake documentation ICF categories not part of the CSHL

Tables 3, 4, 5, and 6 show the extra ICF categories that were found in the intake documentation but that are currently not part of the CSHL (shown in grey). Of these categories, 46% concerned a third-level category of a second-level category that is included in the CSHL. For example, the second-level category b240 “sensations associated with hearing and vestibular functions” from the CSHL was in fact documented in more detail by the underlying third-level categories b2400 to b2405. Also “not defined” was linked (also shown in the tables), and concerned units that were too generic to be linked to a specific category. Examples are “tinnitus has great influence on daily life” (A&P-nd), “problems with communication” (d3-nd) and “mobility in traffic” (d4-nd). Within the otology intake documentation, extra ICF categories mostly emerged in the BF component, of which most of these categories were logical additions in the context of otology. These are part of the general anamnesis, for example, checking whether a patient has a fever in case of an ear infection (b5500 body temperature), or they fit in the broader setting of ENT, for example, taste-, smell-, swallowing-, and respiratory functions. Within the audiology intake documentation most extra categories belonged to the A&P component, and were lower-level categories of the 2nd level categories of the CSHL. Especially content regarding communication and interpersonal relationships was documented in detail (i.e., d7 and d3 categories). Noteworthy is that in both otology and audiology settings, the ICF category “sleep functions” (b134) was extracted from the intake documentation, which is currently not part of the CSHL.

Extra constructs not part of or not specified in the ICF

We identified various constructs that could not be linked to the ICF classification, such as the ICD-10 health conditions and (medical) treatment (e.g., myringoplasty surgery). In addition, we identified a range of Personal Factors that are not specified in the ICF yet. These factors included patient’s “demographic” characteristics (e.g., age, sex), family situation (e.g., “patient has daughter of 3 years old”), personal attitudes of patients (e.g., “patient has a temperate attitude”), other (hearing-related) health conditions and medical history (e.g., “high blood pressure,” or “had many ear infection in her youth”), and coping styles (e.g., “patient has difficulties in coping with HL”). Furthermore, there were some factors labelled with “not covered.” These generally related to information about disease or treatment aspects that are not part of the ICF classification (e.g., side effects), or were qualifiers, for instance indicating duration and severity of complaints.

Comparison of the percentages of CSHL represented in secondary and tertiary care settings

For all components, the secondary care settings had lower percentages of CSHL categories represented in the intake documentation in comparison with the tertiary care settings of the corresponding discipline. Moreover, in the secondary care settings, no new 2nd level categories of the CSHL were identified other than those identified in the intake documentation of the tertiary settings. When comparing the tertiary and secondary otology settings, overlap with the Brief CSHL was slightly lower in the secondary setting than in the tertiary setting. This difference was more pronounced for the categories of the Comprehensive CSHL. Comparison of the tertiary AC and the secondary AC showed a similar trend: the intake documentation of the secondary AC showed a smaller overlap with the Comprehensive CSHL than the tertiary AC. This was mostly the case for the BF and EF components.

DISCUSSION

In the present study, we aimed to examine the extent to which the Brief and Comprehensive CSHL are represented in the current intake documentation in the Dutch Otology and Audiology practice. The findings contribute to the evaluation of the content validity of the CSHL. Considerable overlap between ICF categories in the CSHL and in the intake documentation emerged. In total, 24 items of the 27 Brief CSHL categories (89%) were represented in the otology and audiology intake documentation. The categories of the components BF, BS, and A&P were fully represented, except for 1 category in BF (memory functions). The CSHL categories of the EF component were less well represented (57%). For the Comprehensive CSHL, smaller overlap with the intake documentation was found across all components. In total, the intake documentation covered 60 categories out of the in total 117 CSHL categories (51%). One could argue that the non-overlap with the CSHL categories (Fig. 1, non-overlap nos. 1 and 2) indicates lack of validity of the Core Sets, and that the CSHL categories that had not emerged from the intake documentation may be questioned. However, one could also argue that the otology and audiology intake procedures should be improved such that the intake fully matches the CSHL. The identification of the extra (ICF) categories in the intake documentation (Fig. 1, nos. 3 and 4) indicates that expansion of the CSHL may be suggested when used in the context of an intake procedure. This is a valid option, as the CSHL are intended to serve as the minimum dataset that needs to be reported. It may be expanded for any purpose stated²². In the paragraphs below, findings of overlap and non-overlap are discussed per ICF component, followed by a discussion on the relevance of the extra identified ICF categories and non-ICF constructs. Finally, study limitations and future directions are addressed.

CSHL categories: overlap and non-overlap

Body Structures and Body Functions

Traditionally, care for ear and hearing tends to focus on the physical aspects and treatment of disease. Therefore, it is not surprising that there was a large overlap for the CSHL categories that belong to the components of BS and BF. However CSHL categories on sensory perception (i.e., “mental functions involved in discriminating sounds, tones, pitches, and other acoustic stimuli”) and (higher) mental functions were not found in the intake documentation, despite the fact that the relationship between hearing and cognitive functions seems well established. For instance, (working) memory, information processing speed, and attention have been found to be essential for speech comprehension and auditory functioning²³⁻²⁷. Pichora-Fuller (2015)²⁸ underlines that incorporating cognitive factors into audiologic practice would contribute to better hearing and communication and to healthy aging. The current findings demonstrate that the results of this large body of research have not found their way to clinical practice yet.

Activities and Participation

The high percentage of represented A&P CSHL categories in the otology and audiology intake documentation (i.e., 62%) is mainly due to the large percentage of A&P categories reflected in the audiology intake documentation. AC care aims at enhancing the A&P of an individual with hearing difficulties, and hence there is particular focus on psychosocial aspects of HL, additional to the functional aspects. Our results suggest that the patient perspective is well taken into account in an AC. As reported by Granberg et al. (2014)¹⁶, patients with HL attach great value to seeing their A&P problems addressed in AR. There were a number of CSHL categories from the A&P domain that did not emerge in the intake documentation. These concerned aspects related to economic and civic life. These issues do seem relevant to consider in AR, given that poor hearing ability is associated with relatively lower income, and lower probability of having paid work²⁹. Although “work” is addressed in the intake of the AC (by using the Amsterdam Checklist for Hearing and Work), economic self-sufficiency is not yet part of it. The present study suggests that it may be important to include it in standard audiologic care. Religion and spirituality are civic life aspects that were also not represented in the intake documentation. If attending religious services/being active in a spiritual community is an important part of an individual’s life, limitations in this respect may negatively impact a person’s health and wellbeing. Religious attendance is a major source of social engagement and an important aspect of the social networks for many older individuals^{30, 31}. Moreover, these enhanced supportive networks in religious attendance have shown to be protective against loneliness³². Hearing problems may reduce the enjoyment of these kind of activities or cause a person to avoid them³³. Religious attendance as a potential indicator of social isolation on hearing disability in the elderly is also recognized by the well-validated and widely used Hearing Handicap Inventory for the Elderly³⁴. Being sensitive to the religious and spiritual needs seems important and may therefore be part of assessing the person as a whole.

Environmental Factors

The smallest percentage of overlap was found for the EF CSHL categories. This was the case for both the otology and the audiology setting. Especially the percentage of EF Comprehensive CSHL categories covered by the intake documentation was low (i.e., 15 and 27% for the otology and audiology intake documentation, respectively). Not surprisingly, categories related to assistive products such as hearing aids, and the acoustical environment were found in the intake documentation. However, categories referring to support from and attitudes of members in the patient's direct social network (e.g., family and friends) were not encountered in the intake documentation. Various studies have shown that social support, in particular from family, may influence help seeking for hearing difficulties, and uptake of and compliance with rehabilitative interventions³⁵⁻³⁸. Moreover, hearing impairment not only affect the person with the hearing impairment, but also the patient's family can experience so-called third-party disability^{3, 39}. It is therefore encouraging to note that there is growing recognition among audiologists of the importance of promoting partnership with family members during the hearing rehabilitation process⁴⁰. The current findings confirm that such partnership is not yet part of standard clinical care. Also CSHL categories reflecting services, systems, and policies were barely represented in the intake documentation, while it is known that individuals with communication difficulties experience social disadvantage in accessibility and usability of sectors where effective communications is critical. This includes health and social care services, education, local government, and justice services⁴¹. In addition, social inclusion of persons with hearing impairment in community services has been recognized as an area of concern. This was for instance supported by The Royal National Institute for Deaf People of the United Kingdom that concluded that British people with HL face barriers to social inclusion in health and social care services, education, employment, transport, media, and commercial services⁴².

Extra categories

ICF categories not part of the CSHL

The 2nd level ICF category b134 "sleep functions" emerged in both the otology and audiology intake documentation, but is currently not part of the CSHL. Including sleep functions in the intake process seems warranted, as good quality of sleep is important for healthy functioning both physically and mentally⁴³ and various studies have shown that sleeping disorders are associated with hearing problems, including HL and tinnitus⁴⁴⁻⁴⁷. The extra third-level ICF categories that were identified mostly concerned the more detailed categories of second-level categories that are included in the CSHL. This finding indicates that some (sub) topics may require more detailed attention than currently spelled out in the CSHL. Examples of these categories are b240 "sensations associated with hearing and vestibular functions," and d750 "informal relationships."

Constructs not part of the ICF

The Personal Factors (PF) component was occasionally addressed in the intake documentation. PFs are not classified in the ICF, but the WHO describes them as “the particular background of an individual’s life and living. It comprises features of the individual that are not part of a health condition or health states”⁹. PFs include, but are not limited to, demographics, other health conditions, coping styles, social background, education and profession, past life events, overall behaviour patterns, and other factors playing a role in disability. PFs such as personality and coping are known to affect hearing aid uptake and communication strategies (e.g., ⁴⁸). Moreover, in the CSHL study on the patient perspective¹⁶, it was found that patients reported extensively on a wide range of PFs in the context of HL, thereby indirectly indicating their importance for their functioning and disability. In our study, also medical history and other health conditions were linked as PFs. Information on PFs is needed to get a complete picture of the patient’s profile that may help to optimize patient care⁴⁹. As the PF component in the ICF is currently limited to a simple enumeration of possible categories or domains, a validated categorization of the PF component should be developed first, before it can be included in the CSHL. Some constructs that are important for evaluating hearing disability could not be linked to the ICF classification, including the course and duration of complaints, and specific treatment details. However, one could argue that these factors are important for a deeper understanding of a patient’s (evaluation of) functioning that it is therefore worthwhile to consider to add them to the CSHL. The aim of the ICF, however, is not to replace profession-specific models. Rather, the profession-specific assessments, methods, and knowledge in which the abovementioned constructs would be covered can be used effectively complementary to the ICF⁴⁹.

Study limitations and future directions

This study is unique in its approach of linking current Dutch otology and audiology clinical intake documentation to the ICF framework. However, the study has some limitations. The content evaluation fully relied on information entered in the patient records. This might have led to missing data on topics that were actually addressed during the intake conversation between the professional and the patient, but which were not written down in the patient record. However, the patient record is the main means of communication between professionals, and comprehensive documentation of significant topics is especially important in interdisciplinary settings, and therefore, should be complete. Furthermore, we identified different intake documentation methods, causing variability across the intake in subjects that were included in this study. In addition, no information was gathered on how the information was queried due the retrospective nature of the present study. This might have biased our results. However, because our aim was to review the current intake documentation of all kinds of patient groups visiting ENT departments or ACs, therewith including all methods of the intake documentation, this is a necessary weakness in the iterative validation process of the CSHL. Originally the CSHL were developed for the patients functioning with HL¹³. We however used the CSHL to additionally assess the intake documentation of otology patients,

thereby also assuming their applicability to patients with specific ear problems (e.g., aural pressure, cholesteatoma). In the Netherlands, particularly in tertiary care, otology and audiology collaborate and pursue an integral approach for providing health care. We therefore validated the CSHL considering the intakes of both settings. Some limitations of our study may restrict the generalizability of the results. Many people with HL in The Netherlands only visit a hearing aid dispenser when seeking care for their hearing problems. Not all of them are further referred to an AC and an ENT professional. This study does not reveal to what extent the intake process carried out in a dispenser setting addresses the categories of the CSHL. This was beyond the scope of the present study. Overlap between content of the intake documentation in a hearing aid dispensers setting and the CSHL should be investigated in future research. Finally, it must be mentioned that the Dutch hearing health care system may differ from that of other countries, compromising the generalizability of our findings to other countries. Additional validation studies with patient records from other countries and cultures should be carried out to examine this.

Toward an integrated tool

Otology and audiology care in the Netherlands currently lacks standardized documentation of relevant categories that need to be addressed in the intake phase before treatment or rehabilitation. This was shown in the present study. We observed differences in the intake documentation between and within care settings. A tool like the CSHL will assist professionals to implement an integral perspective in hearing health care⁶. The CSHL defines, in theory, all categories that are relevant to the functioning of patients with HL and consequently what to address and assess among patients with HL. It provides a comprehensive, multidimensional perspective. Application of the CSHL can ensure consistency in terminology across disciplines, improve inter- and intra-professional communication, and facilitate multidisciplinary responsibility. Subsequently, the CSHL categories can be regarded as the common standard from which different professionals start their assessments and interventions. The functioning profile that can be created can be used as a reference for monitoring the patient and for follow-up visits. The intake phase is considered particularly important for setting up patient-centred consultation⁵⁰. Patient-centred care and the systematic monitoring of that care are facilitated by such a reference system.

CONCLUSIONS

This study showed substantial overlap between the CSHL and the intake documentation of otology and audiology settings in the Netherlands, but also areas of non-overlap were identified. The substantial overlap supports the Core Sets' content validity. The non-overlap between the CSHL and the intake documentation uncovered the areas that are currently not addressed in clinical audiology and otology practice, but that should be taken into consideration according to the CSHL. The results of this study thus suggest that the current intake procedures may not cover all aspects that are relevant to patients with HL. It is therefore recommended to adapt these current standards and complete them with the missing categories. However, the ICF Core Sets do define "what to measure", but they do not indicate "how to measure". Therefore, operationalization of the categories into a practical and integral intake instrument would be the next step that needs to be taken. This requires further research, and would also require the consideration of including the extra ICF categories and constructs (i.e., sleep functions and personal factors) that were identified in the present study.

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APPENDIX 1. Content of anamnesis forms Otolaryngology settings

Standard anamnesis components VU University Medical Center:

- Reason for visit
- Anamnesis
 - o Medical history
 - o Allergies
 - o Intoxication
 - o Medication
 - o (Social (i.e., work))
 - o Family anamnesis

Standard anamnesis components Westfriesgasthuis:

- Referral
- Reason for referral
- Additional information from GP (patient history)
- ENT-relevant history
- Specific anamnesis
- General health
- Medication
- Allergies
- Intoxication
- Other anamnesis
- Work

APPENDIX 2. Anamnesis questionnaires and forms in Audiology Clinics

Questionnaire	Reference / Developers*	AC VUmc	ACHN
Amsterdam Checklist for Hearing and Work	Kramer SE, Kapteyn TS, Houtgast T (2006). Occupational performance: comparing normally-hearing and hearing-impaired employees using the Amsterdam Checklist for Hearing and Work. <i>Int J Audiol</i> , 45, 503-12.	X	X
Amsterdam Inventory for Auditory Disability and Handicap	Kramer SE, Kateyn TS, Festen JM (1998). The self-reported handicapping effect of hearing disabilities. <i>Audiology</i> , 37, 203-12.	X	X
Cochlear Implantation form – intake and anamnesis audiologist and social worker	AC VUmc*	X	
Cochlear Implantation questionnaire	AC VUmc*	X	
Form for fitting hearing aid – first fitting	AC VUmc*	X	
International Outcome Inventory for Hearing Aids (IOI-HA)	Cox RM and Alexander GC (2002). The International Outcome Inventory for Hearing Aids (IOI-HA): psychometric properties of the English version. <i>Int J Audiol</i> , 41, 30-5.	X	
Nijmegen Cochlear Implant Questionnaire (NCIQ)	Hinderink JB, Krabbe PF, van den Broek P (2000). Development and application of a health-related quality-of-life instrument for adults with cochlear implants: the Nijmegen cochlear implant questionnaire. <i>Otolaryngol Head Neck Surg</i> , 123, 756-65.	X	
Standard anamnesis form	ACHN*		X
Tinnitus anamnesis form	AC VUmc*	X	
Tinnitus Handicap Inventory (THI)	Newman CW, Jacobson GP, Spitzer JB (1996). Development of the Tinnitus Handicap Inventory. <i>Arch Otolaryngol Head Neck Surg</i> , 122, 143-8.	X	X
Tinnitus evaluation questionnaire	AC VUmc	X	
Tinnitus questionnaire	AC VUmc	X	

AC VUmc = Audiology Clinic of the ENT department of VU University Medical Center; ACHN = Audiology Clinic Holland Noord

*Internally developed

Chapter 3:

Comparing the International Classification of Functioning, Disability and Health Core Sets for Hearing Loss and otorhinolaryngology/ audiology intake documentation at Mayo Clinic

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ABSTRACT

Objectives: The International Classification of Functioning, Disability, and Health (ICF) Core Sets for Hearing Loss (CSHL) consists of short lists of categories from the entire ICF classification that are thought to be the most relevant for describing the functioning of persons with hearing loss. A comprehensive intake that covers all factors included in the CSHL holds the promise of developing a tailored treatment plan that fully complements the patient's needs. The Comprehensive CSHL contains 117 categories and serves as a guide for multi-professional, comprehensive assessment. The Brief CSHL includes 27 of the 117 categories and represents the minimal spectrum of functioning of persons with HL for single-discipline encounters or clinical trials. The authors first sought to benchmark the extent to which audiologist (AUD) and otorhinolaryngologist (ORL) discipline-specific intake documentation, as well as Mayo Clinic's multidisciplinary intake documentation, captures CSHL categories.

Design: A retrospective study design including 168 patient records from the Department of Otorhinolaryngology/Audiology of Mayo Clinic in Jacksonville, Florida. Anonymized intake documentation forms and reports were selected from patient records filed between January 2016 and May 2017. Data were extracted from the intake documentation forms and reports and linked to ICF categories using pre-established linking rules. "Overlap", defined as the percentage of CSHL categories represented in the intake documentation, was calculated across document types. In addition, extra non-CSHL categories (ICF categories that are not part of the CSHL) and extra constructs (constructs that are not part of the ICF classification) found in the patient records were described.

Results: The total overlap of multidisciplinary intake documentation with CSHL categories was 100% for the Brief CSHL and 50% for the Comprehensive CSHL. Brief CSHL overlap for discipline-specific documentation fell short at 70% for both AUD and ORL. Important extra non-CSHL categories were identified and included "sleep function" and "motor-related functions and activities", which mostly were reported in relation to tinnitus and vestibular disorders.

Conclusion: The multidisciplinary intake documentation of Mayo Clinic showed 100% overlap with the Brief CSHL, while important areas of non-overlap were identified in AUD- and ORL-specific reports. The CSHL provides a framework for describing each hearing-impaired individual's unique capabilities and needs in ways currently not documented by audiological and otological evaluations, potentially setting the stage for more effective individualized patient care. Efforts to further validate the CSHL may require the involvement of multidisciplinary institutions with commonly shared electronic health records to adequately capture the breath of the CSHL.

INTRODUCTION

Capturing what matters to people living with hearing problems (i.e., the patient perspective) is essential in hearing health care^{1,2}. This critical need was recently highlighted in the National Academies of Sciences, Engineering, and Medicine (NAEM) report entitled: *Hearing Healthcare for Adults: Priorities for Improving Accessibility and Affordability*³. The report states that efficient and effective hearing health care services should address hearing-related problems from both a disease- and functioning perspective (i.e., a biopsychosocial perspective) (see chapter 3).

The need for this biopsychosocial perspective of hearing problems has been recognized for a number of years^{4,5}, as has the need for an adequate diagnostic taxonomy or descriptive reference system to accommodate this. The World Health Organization's International Classification of Functioning, Disability, and Health (ICF) is often suggested as such a reference system^{6,7}. Endorsed by previous work, the ICF perspective posits that a full understanding of a person's hearing problem can be obtained if assessment goes beyond the biomedical approach, which focuses on impairments of auditory structures and functions, to additionally include assessment of a person's complementary systems (e.g., visual, mental, cognitive, physical), ability to complete activities and participate in community life (e.g., communication, work), personal attributes (e.g., coping styles, comorbidities), physical setting (e.g., noise, light), and social environment (e.g., familial support)^{1,2,6,8-15}. In other words, the ICF can potentially help professionals to balance their attention between the disease-focused biomedical perspective and a biopsychosocial perspective of the lived health of a patient, thereby acknowledging that inter-individual differences can drive patients with the same degree of impairment to require and prefer different types of services or modes of service delivery.

The ICF complements the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) (International Statistical Classification of Diseases and Related Health Problems 10th Revision [ICD-10]-WHO, 2016)¹⁶. From an audiological perspective, this means that practitioners can use the ICD-10 to classify a person's health conditions (HCs), and the ICF can be used to classify categories that may influence a person's functioning- and disability levels (for examples see: ^{14,17-20}). The overarching purpose of the ICF is to provide a unified reference framework and language related to functioning, to improve assessment, management, and communication, between professionals and between professionals and patients²¹. In the ICF, functioning refers to all body functions (BFs), activities, and participation of an individual; disability refers to all impairments, limitations, and restrictions herein, respectively²². In addition, the ICF lists contextual factors (environmental factors [EFs] and personal factors [PFs]) that interact with these components. All components of functioning and EFs are listed in the standard terminology of the ICF and are subdivided into many chapters and categories.

The ICF categories are further organized in a stem-branch-leaf scheme using interlinked levels and are denoted by unique alphanumeric codes. The letters refer to the components (b: BFs; s: body structures [BSs]; d: activities and participation [A&P]; and e: EFs), followed by 1 digit indicating the chapter (first level), followed by the code for second-level categories (two digits), and the third-level categories (one digit each). An example is provided in Figure 1.

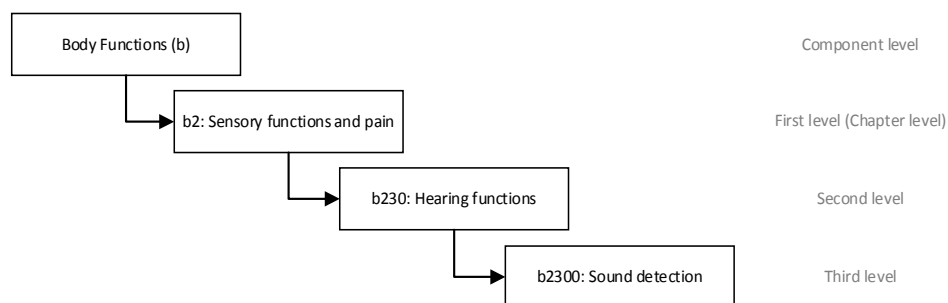


FIGURE 1. Hierarchical structure of the ICF with examples from the component of BF

The ICF is a generic framework for describing health and disability in all kinds of diseases or HCs. As a result, it can be too complex for use in daily practice. ICF “Core Sets” are subsets of the entire ICF that create manageable reference systems for specific clinical practice and research applications. They are comprised of ICF categories that are considered most relevant for describing the functioning of a person with a specific HC²³; and have been developed for many different HCs including the ICF Core Set for Hearing Loss (CSHL)²⁴. The development of the CSHL follows WHO guidelines and consists of a three-phase, multi-method scientific process²³. The preparatory phase and a consensus phase (phase I) have been completed^{2, 9-12}. Completion of phase I resulted in the development of two related Core Sets. The Comprehensive CSHL contains 117 categories and serves as a guide for multi-professional comprehensive assessment. A shorter, “Brief ” CSHL was also developed as a subset of the Comprehensive CSHL. The Brief CSHL includes 27 of the 117 Comprehensive CSHL categories and represents the minimal spectrum of functioning of persons with HL for single-discipline encounters or clinical trials. Phase II is currently ongoing and covers the validation of the CSHL to test how they can be efficiently used in clinical practice. The CSHL is intended to assist clinicians in identifying factors that are likely to be relevant to the functioning of an individual with HL, and that ultimately are necessary to address if optimum hearing care is to be delivered. Because the intake assessment is the basis for assessing the needs of the individual with HL and should drive the development of a personalized treatment plan, incorporating the CSHL into the intake procedure of new patients would seem to be a necessary precondition for evaluating its usefulness in clinical practice.

The Mayo Clinic is a large healthcare institution that is organized around the principle of integrated care. Integrated care refers to a collaborative, multidisciplinary approach to patient care and requires a common medical documentation system (an electronic health

record) that is accessible and shared by all providers. In addition to the audiology (AUD) and otorhinolaryngology (ORL) discipline-specific intake documentation, the Mayo Clinic's common medical documentation system's multidisciplinary intake documentation captures patient information recorded by all healthcare providers. We sought to assess how well current multidisciplinary and discipline-specific intake documentation generated by AUD and ORL providers captures CSHL-related information in patients with ear and hearing problems. Our overarching goal is to enhance patient-centred hearing healthcare by identifying factors beyond the standard audiological evaluation (in this case, the CSHL), that are relevant to achieving optimal functioning and lived experience in individuals with hearing difficulties.

The objective of the present study was to benchmark the extent to which the CSHL categories are captured in hearing healthcare provider records, as this is a necessary precondition for studying the clinical effectiveness of the CSHL. As such, this study is a preliminary step in Phase II of the CSHL.

MATERIALS AND METHODS

Study design and setting

A retrospective study design was carried out. Patient records from the Department of Otorhinolaryngology/Audiology of Mayo Clinic in Jacksonville, Florida, were included. This study was approved by the institutional review board of the Mayo Clinic Foundation (IRB 17-004102).

Selection of patient records

At Mayo Clinic, persons seeking help for ear and hearing problems can receive care at the Department of Otorhinolaryngology/ Audiology via self-referral, external referral, or internal referral. Subsequently, patients can be referred to ORLs or AUDs or both. Typically, both AUDs and ORLs are involved in an individual's hearing care when patients have or are at risk for ear diseases. The intake documentation forms from patients visiting an AUD were selected as a starting point, and the patients' ORL intake reports were additionally included when they were available. Intake documentation forms were selected from patient records filed between January 2016 and May 2017. To select eligible patient records, a database was created consisting of new patients (i.e., not previously seen by Mayo Clinic AUDs) seen between January 2016 and May 2017. To ensure the random selection of a representative sample of patient records, the database was structured following three categorization schemes: (1) ICD-10 diagnosis, (2) year (2016 or 2017), and (3) age band (i.e., 18–25, 26–67, > 67). For 2016, the first two patient records of each age band per ICD-10 code were included in the analyses (when available). In response to the attention that was rendered by the CSHL project, in early 2017, the intake documentation forms used by AUDs at Mayo Clinic were modified in an attempt to focus more on the functioning aspects of HL^{13, 14}. For 2017, only one patient record per age band per ICD-10 code was included. The goal of incorporating this

smaller cohort was to assess whether the modification of the standardized intake documentation forms had changed actual intake documentation reports.

Intake data sources

Different methods for intake and admission of patients are applied at Mayo Clinic. The four associated formats included in the analyses are described below.

Structured intake forms

Structured intake forms are self-administered by AUD patients before their intake consultation and are filled out in the waiting room. The structured intake forms used in 2016 included categories such as the reason for visit, experienced ear problems, health history, and also the Handicap Hearing Inventory for Adults (HHI-A)²⁵. In 2017, the structured intake forms included six items of the Speech, Spatial, and Qualities of Hearing Scale (SSQ6)²⁶ instead of the HHI-A.

Additional questionnaires

Additional questionnaires are the Dizziness Handicap Inventory (DHI)²⁷ and the Tinnitus Handicap Inventory (THI)²⁸. These are also self-administered by AUD patients with vestibular- and tinnitus problems, respectively, in the waiting room before intake consultation.

Semi-structured intake reports

Semi-structured intake reports are written by the clinician (i.e., AUDs or ORLs) during and after the intake consultation. The following information is recorded: chief complaint/reason for attendance, background and related information (e.g., clinical history), evaluation summary results (i.e., AUD and ORL tests), other test results (e.g., HHI-A, SSQ6 scores), impressions (i.e., conclusions based on AUD and ORL tests and other tests), and management plan.

Mayo Clinic standard intake forms

Standard practice at Mayo Clinic requires health care professionals to review the most recent patient provided information (PPI) and history and physical (H&P) forms before the consultation. In these forms, the clinician provides a summary of the patient's general and condition-related health status, past evaluations, and findings (see Appendix 1).

Linking of patient record content to the ICF

All information documented in the intake was extracted from the intake data sources mentioned earlier and linked to the most precisely corresponding ICF category. The linking was performed following the seven-step linking procedure as established by Granberg et al. (2014)¹⁰. This procedure combines the linking rules already established by the WHO²⁹, and the additional rules that were developed especially for the AUD field.

The exact linking method is fully explained by Granberg et al. (2014)¹⁰. The linking was conducted by the first two authors (R. A. and L. v. L.).

Data analysis

Descriptive statistics were calculated for patient sociodemographic and condition-related characteristics. Sociodemographic characteristics included age and sex. Condition-related characteristics included the four domains of the ICD-10, chapter VIII, “Diseases of the ear and mastoid process”: diseases of the external ear; diseases of the middle ear; diseases of the inner ear; and other diseases of the ear. To determine the extent to which the CSHL were represented in the intake documentation, the overlap between ICF categories in the CSHL and the list of unique ICF categories extracted from the intake data sources was assessed. The same method as used by van Leeuwen et al. (2017)³⁰ was applied and is briefly described as follows:

- Overlap was expressed as percentage of CSHL categories that were represented in intake documentation.
- Non-overlap was defined as the percentage of the CSHL categories that were not represented in the intake documentation.
- Extra ICF categories were constructs expressed in the intake documentation but are not part of the CSHL, or constructs currently not part of the ICF.

Please note that PFs are not yet classified within the ICF but the following list of examples that is provided in the ICF’s description: demographics, other HCs, coping styles, social background, education and profession, past life events, overall behaviour patterns, and other factors playing a role in disability²². All constructs that were linked to this example were considered.

Overlap and non-overlap were assessed separately for the Brief CSHL and the Comprehensive CSHL. Figure 2 provides a schematic illustration of the overlap and non-overlap between the CSHLs, total ICF classification, and intake documentation.

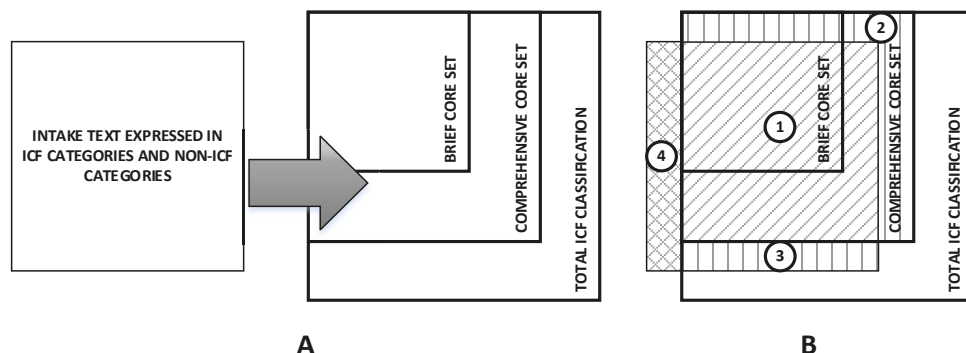


FIGURE 2. Graphical illustration of the (non-)overlap between the CSHL, the ICF classification (total) and the intake documentation

A, Intake text was linked to the ICF classification, and resulted in a list of unique ICF categories and constructs not part of the ICF. The overlap and non-overlap between the list of unique ICF categories extracted from the intake documentation and the ICF categories that are part of the CSHL was determined.

B, The (non) overlap of the unique ICF categories extracted from the intake documentation and the ICF categories that are included in the CSHL. 1 = CSHL categories represented in intake documentation; 2 = CSHL categories not represented in intake documentation; 3 = Identified ICF categories in intake documentation that were not part of the CSHL; 4 = Identified constructs in intake documentation that were not part of the ICF classification. HL indicates hearing loss; ICF, International Classification of Functioning Disability and Health.

To ensure reliability of the ICF-linking procedure, all intake documentation was linked by two authors (R. A. and L. v. L.). The degree of agreement in the linking of the two raters was determined at the component level, chapter level, and second and third-level categories. The percentage of agreement varied between 80% (comparison of linkage to second-level categories) and 100% (comparison of linkage to the component level, chapter level, and third-level categories).

RESULTS

Descriptives

In total, 123 patient records were included for 2016, and 45 patient records were included for 2017. The upper panel of Table 1 shows the sociodemographic and condition-related characteristics of the included patients. Of the 123 records from 2016, 56 (46%) included an ORL intake report in addition to the AUD intake report.

TABLE 1. Sociodemographic and condition-related characteristics of the two cohorts (upper panel) and sub-total and total representation of the CSHL within intake documentation, provided as the percentage of CSHL categories per method of intake documentation (lower panel)

Variables	2016 Cohort			2017 Cohort	
Number of patient records	123			45	
Mean age ± SD	52.6 ± 20.8			54.5 ± 20.1	
Female sex (%)	53.7			53.3	
ICD-10 diagnosis (%)					
Diseases of external ear (H60–H62)	6.5%			2.2%	
Diseases of middle ear and mastoid (H65–H75)	15.4%			15.6%	
Diseases of inner ear (H80–H83)	20.3%			20.0%	
Other diseases of the ear (H90–H95)	44.7%			37.8%	
Other specified*	13.0%			24.4%	

CSHL-represented categories, N; (%)	Total	2016 Cohort			2017 Cohort	
		AUD intake reports	AUD intake forms	ORL intake reports	AUD intake reports	AUD intake forms
Brief CSHL (27 = 100%)	27; 100	19; 70	14; 52	19; 70	18; 67	14; 52
BS (4 = 100%)	4; 100	4; 100	0; 0	4; 100	4; 100	1; 25
BF (7 = 100%)	7; 100	4; 57	4; 57	6; 86	4; 57	6; 86
A&P (9 = 100%)	9; 100	6; 67	8; 89	4; 44	7; 78	5; 56
EF (7 = 100%)	7; 100	5; 71	2; 29	5; 71	3; 43	2; 29
Comprehensive CSHL (117 = 100%)	58; 50	36; 31	22; 19	31; 26	25; 21	24; 21
BS (5 = 100%)	5; 100	5; 100	0; 0	5; 100	4; 80	1; 20
BF (22 = 100%)	20; 91	12; 55	7; 32	10; 45	10; 45	10; 45
A&P (42 = 100%)	19; 45	11; 26	12; 29	6; 14	8; 19	9; 21
EF (48 = 100%)	14; 29	8; 17	3; 6	10; 21	3; 6	4; 8

A&P, activities and participation; AUD, audiology; BF, body functions; BS, body structures; CSHL, Core Set for Hearing Loss; EF, environmental factors; ICD-10, International Statistical Classification of Diseases and Related Health Problems, 10th revision; ICF, International Classification of Functioning, Disability, and Health; ORL, otorhinolaryngology. *Other specified diagnoses included: dizziness and giddiness (R42), other abnormalities of gait and mobility (R26.89), and encounters for general adult examination (Z00), or encounter for examination of ears and hearing (Z01).

Overlap and non-overlap between intake documentation and CSHL

When all the different methods for intake and admission of patients from 2016 were taken together, the total overlap between the CSHL categories and the categories identified in the intake documentation was 100% for the Brief CSHL and 50% for the Comprehensive CSHL. More details of the overlap and non-overlap results for the different ICF domains are presented in Tables 2, 3, 4, and 5. The results are reported per type of intake documentation method that was encountered in the patient records.

Results of the 2016 cohort are discussed below for AUDs and ORLs, respectively. Lastly, a comparison is made between the 2016 and 2017 cohorts.

Body Structures

All BS categories of the Brief and the Comprehensive CSHL were identified in AUD and ORL intake documentation (Table 2). Most of these categories were found in the patient history or the assessment section of the intake reports (e.g., conductive HL may indicate impairments in the middle ear [s250], and sensorineural loss indicates impairments in the inner ear [s260]). Examples of patient history statements included: “Patient was told he had some holes in his ears” (s250), “indication of perforations in tympanic membrane” (s2501), or “ear mass in right ear canal” (s240).

Body Functions

The categories of the BF component identified in patient records showed 57%, and 86% overlap with the Brief CSHL for AUD intake documentation and ORL intake documentation, respectively (Table 3). For the Comprehensive CSHL, these percentages were 55% and 45%. For AUD intake documentation, the second-level ICF category “hearing functions” (b230) and its second-level categories (b2300-b2304) were all represented in intake reports and structured intake forms. Also, the second-level category “sensations associated with hearing and vestibular functions” (b240) was often linked together with the more detailed third-level categories b2400-b2405 (e.g., “irritation in the ear” [b2404]). Information on b240 was either reported as a reason for referral (e.g., tinnitus) or found in a list of ear-related complaints that the AUD could use to check for its presence (e.g., “History was positive for tinnitus”; “Patient does not report dizziness/balance problems, aural pressure/fullness”). “Vestibular functions” (b235) were extensively reported on in the records as well, either in the list of ear- and hearing-related complaints or more comprehensively in the vestibular report. Regarding ORL reports, information on b230 and b240 was less extensively reported on as compared with AUD reports. Information on higher mental functions (i.e., energy, motivation, and attention functions) was never represented in the reports. Both AUDs and ORLs reported on “pain” (b280), mostly related to “pain in the ears” (i.e., coded as b28010). No documentation on “voice functions” (b310) and “speech functions” (b330) was identified in any of the AUD or ORL intake documentation.

Activities and Participation

The percentage of overlap between the CSHL and the intake documentation of the A&P component was 67% and 44% of the Brief CSHL and 26% and 14% of the Comprehensive CSHL for AUD and ORL reports, respectively (Table 4). The following categories were represented in AUD reports but not in the ORL reports: “learning and knowledge” (d1), including “watching” (d110), “listening” (d115), “focusing attention” (d160), and “handling stress” (d240). The latter was mostly reported in relation to tinnitus. Categories on “communication” (d3) were well represented in AUD reports.

Here is an example of a AUD report fragment: “Overall, the patient reports having modest problems understanding speech on a daily basis (d310). The patient reports difficulties understanding speech spoken in background noise (d310, e250) or in group conversation situations (d3504), over distances (e2-nd) and over electronic media (d360).” In addition, because the HHI-A was administered as part of the structured intake forms, the category “formal and informal interpersonal relationship” (d740, d750) was linked. An example item included: “Does a hearing problem cause you difficulty hearing/understanding co-workers, clients, or customers?.” No information was reported in the intake documentation on “basic and complex interpersonal interactions” (d710, d720), such as tolerance in relationships or maintaining and managing interactions with other people. The only communication category of the CSHL that the ORL intake reports covered was the category “receiving spoken messages” (d310). The category “interpersonal interactions and relationships” (d7) was not represented in any of the intake documentation. Furthermore, AUDs and ORLs included little to no documentation on “mobility” (d4), “domestic life” (d6), and “education, apprenticeship and economic” (d8) categories. In contrast, information on “remunerative employment” (d850) and “recreation and leisure” (d9) was reported both in the AUD and ORL reports, mostly in the context of noise exposure (e.g., “noise exposure [occupational, military]”, “noise exposure [recreational, fire arm use]”) or as a brief statement in the patient history (e.g., profession: “The patient is working in a lab at University”).

Environmental Factors

AUD and ORL reports showed similar levels of overlap for categories in the EF component: 71% and 71% overlap with the Brief CSHL and 17% and 21% with the Comprehensive CSHL, respectively (Table 5). When documentation was linked to “products and technology for communication” (i.e., e125, and more specifically, e1251), this mostly related to hearing aids ownership, hearing aid use, and hearing aid prescription/recommendation by the AUD or ORL. Following one of the linking rules of Granberg et al. (2014b), both “sound” (e250) and “design” (e150) were linked when there were reports on public arena settings such as restaurants (e.g., “When the patient is in loud restaurants, the tinnitus worsens”). When the intake documentation reported: “The patient is accompanied by wife/friend/daughter/mother,” this was linked to “support from family” (e310). Referral information was linked to “support from health professionals” (e355). Reports on previous treatments or diagnostics by other health care providers as part of the patient’s history was linked to “Information on health services” (e580).

76 TABLE 2. Overlap and non-overlap in CSHL categories of the Body Structure component between intake documentation and CSHL

CSHL category	Description	AUD													
		2016					2017								
		Intake reports	Intake forms	Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI	Structured questionnaires	ORL intake report	PPI/H&P			
s110*	Structure of brain	X		X											X
s240*	Structure of external ear	X													X
s250*	Structure of middle ear	X		X											X
s2500	<i>Tympanic membrane</i>	X													X
s2501	<i>Eustachian canal</i>	X													X
s260*	Structure of inner ear	X		X											X
s2600	<i>Cochlea</i>	X													X
s2601	<i>Vestibular labyrinth</i>	X													X
s2602	<i>Semicircular canals</i>	X		X											X
s2603	<i>Internal auditory meatus</i>	X													X
s710	Structure of head and neck region	X													X

X, overlap; empty cells indicate non-overlap. AUD, audiology; CSHL, Core Set for Hearing Loss; DHI, Dizziness Handicap Inventory; H&P, history and physical; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; PPI, patient provided information; THI, Tinnitus Handicap Inventory.

* CSHL categories that are part of the Brief Core Set categories; CSHL categories without an * are part of the Comprehensive Core Set categories; CSHL categories in italics include the identified third-level CSHL categories of the second-level categories that are included in the Core Sets in the intake documentation.

TABLE 3. Overlap and non-overlap in CSHL categories of the Body Function component between intake documentation and CSHL

CSHL category	Description	AUD																			
		2016					2017														
		Intake reports	Intake forms	Intake reports	Intake forms	Intake forms	Structured questionnaires	THI	DHI	ORL intake report	PPI/H&P										
b117	Intellectual functions																			X	
b126*	Temperament and personality functions		X				X			X											X
b1260	<i>Extraversion</i>		X																		
b1263	<i>Psychic stability</i>		X																		
b1300	Energy level					X				X											
b1301	Motivation																				
b140*	Attention functions	X								X											X
b1401	<i>Sustaining attention</i>	X																			
b144*	Memory functions																				
b152*	Emotional functions	X								X											X
b156	<i>Perceptual functions</i>	X								X											X
b1560	Auditory perception	X																			
b1561	Visual perception																				
b164	Higher-level cognitive functions									X											
b167	Mental functions of language																				
b210*	Seeing functions	X								X											X
b2100	<i>Visual acuity functions</i>	X								X											X
b21020	<i>Light sensitivity</i>	X																			
b230*	Hearing functions	X								X											X
b2300	Sound detection	X								X											X
b2301	Sound discrimination	X								X											
b2302	Localization of sound source	X								X											
b2303	<i>Lateralization of sound</i>									X											X
b2304	Speech discrimination	X								X											X

TABLE 3. continued

CSHL category	Description	AUD												
		2016					2017							
		Intake reports	Intake forms	Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI	ORL intake report	PPI/H&P			
b235	Vestibular functions	X	X	X	X									X
b2350	Vestibular function of position			X										
b2351	Vestibular function of balance	X	X										X	
b240*	Sensations associated with hearing and vestibular functions	X	X	X	X									X
b2400	Ringling in ears or tinnitus	X	X	X	X								X	
b2401	Dizziness	X	X	X	X								X	
b2402	Sensation of falling	X	X	X	X								X	
b2403	Nausea associated with dizziness or vertigo	X												
b2404	Irritation in the ear													X
b2405	Aural pressure	X		X										X
b280	Sensation of pain	X		X										X
b28010	Pain in head and neck	X		X										X
b28013	Pain in back			X										X
b28015	Pain in lower limb			X										X
b28018	Pain in body part, other specified	X												
b310	Voice functions													
b320	Articulation functions													X
b330	Fluency and rhythm of speech functions			X										

X, overlap; empty cells indicate non-overlap. AUD, audiology; CSHL, Core Set for Hearing Loss; DHI, Dizziness Handicap Inventory; H&P, history and physical; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; PPI, patient provided information; THI, Tinnitus Handicap Inventory.

* CSHL categories that are part of the Brief Core Set categories; CSHL categories without an * are part of the Comprehensive Core Set categories; CSHL categories in italics include the identified third-level CSHL categories of the second-level categories that are included in the Core Sets in the intake documentation.

TABLE 4. Overlap and non-overlap in CSHL categories of the Activities and Participation component between intake documentation and CSHL

CSHL category	Description	AUD																				
		2016					2017															
		Intake reports	Intake forms	Intake reports	Intake forms	Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI											
d110	Watching	X					X															
d115*	Listening																					
d140	Learning to read		X				X														X	
d155	Acquiring skills																					
d160	Focusing attention																					
d175	Solving problems			X																	X	
d220	Undertaking multiple tasks																					
d240*	Handling stress and other psychological demands			X																	X	
d2401	Handling stress			X																	X	
d310*	Communicating with – receiving – spoken messages			X																		X
d315	Communicating with – receiving – nonverbal messages								X													
d329	Communicating – receiving, other specified and unspecified																					
d330	Speaking								X													X
d350*	Conversation			X					X													X
d3503	Conversing with 1 person			X					X													X
d3504	Conversing with many people								X													X
d355	Discussion																					
d360*	Using communication devices and techniques																					X

80 TABLE 4. continued

CSHL category	Description	AUD						ORL intake report	PPI/H&P
		2016		2017		Structured questionnaires			
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI		
d3600	<i>Using telecommunication devices</i>	X	X	X					
d399	<i>Communication, unspecified</i>	X		X					
d440	<i>Fine hand use</i>				X				
d470	<i>Using transportation</i>						X		
d475	<i>Driving</i>								
d620	<i>Acquisition of goods and services</i>		X						
d6200	<i>Shopping</i>		X						
d660	<i>Assisting others</i>								
d710	<i>Basic interpersonal interactions</i>								
d720	<i>Complex interpersonal interactions</i>								
d730	<i>Relating with strangers</i>		X						
d740	<i>Formal relationships</i>		X					X	
d750	<i>Informal social relationships</i>		X		X				
d7500	<i>Informal relationships with friends</i>		X		X	X			
d7501	<i>Informal relationships with neighbors</i>		X						
d7502	<i>Informal relationships with acquaintances</i>		X						
d760*	<i>Family relationships</i>		X						
d770	<i>Intimate relationships</i>				X	X			
d810	<i>Informal training</i>								
d820*	<i>School education</i>	X						X	
d825	<i>Vocational training</i>								
d830	<i>Higher education</i>								
d839	<i>Education, other specified and unspecified</i>							X	
d840	<i>Apprenticeship (work preparation)</i>	X							

TABLE 4. continued

CSHL category	Description	AUD						ORL intake report	PPI/H&P
		2016		2017		Structured questionnaires			
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI		
d845	Acquiring, keeping, and terminating a job								
d850*	Remunerative employment	X		X		X		X	X
d855	Nonremunerative employment								
d860	Basic economic transactions								
d870	Economic self-sufficiency								
d910*	Community life		X	X	X				
d9100	<i>Informal associations</i>		X						
d920	Recreation and leisure	X	X	X				X	
d9200	<i>Play</i>								
d9201	<i>Sports</i>			X				X	
d9202	<i>Arts and culture</i>		X					X	
d9205	<i>Socializing</i>		X					X	
d930	Religion and spirituality								
d940	Human rights								
d950	Political life and citizenship					X			

X, overlap; empty cells indicate non-overlap. AUD, audiology; CSHL, Core Set for Hearing Loss; DHI, Dizziness Handicap Inventory; H&P, history and physical; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; PPI, patient provided information; THI, Tinnitus Handicap Inventory.

* CSHL categories that are part of the Brief Core Set categories; CSHL categories without an * are part of the Comprehensive Core Set categories; CSHL categories in italics include the identified third-level CSHL categories of the second-level categories that are included in the Core Sets in the intake documentation.

TABLE 5. continued

CSHL category	Description	AUD						ORL intake report	PPI/H&P
		2016		2017		Structured questionnaires			
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI		
e240	Light						X		
e2400	<i>Light intensity</i>						X		
e250*	Sound		X					X	
e2500	Sound intensity	X		X				X	
e2501	Sound quality	X		X				X	
e310*	Immediate family	X	X					X	
e315	Extended family	X	X						
e320	Friends							X	
e325	Acquaintances, peers, colleagues, neighbours, and community members								
e330	People in position of authority								
e335	People in subordinate positions								
e340	Personal care providers and personal assistants								
e345	Strangers								
e350	Domesticated animals								
e355*	Health professionals								
e360	Other professionals	X						X	
e410*	Individual attitudes of immediate family members								
e415	Individual attitudes of extended family members								
e420	Individual attitude of friends								
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours, and community members								

84 TABLE 5. continued

CSHL category	Description	AUD				ORL intake report	PPI/H&P
		2016		2017			
		Intake reports	Intake forms	Intake reports	Intake forms		
e430	Individual attitudes of people in position of authority						
e440	Individual attitudes of personal care providers and personal assistants						
e445	Individual attitudes of strangers						
e450	Individual attitudes of health professionals						X
e455	Individual attitude of other professionals						
e460*	Societal attitudes						X
e465	Social norms, practices, and ideologies						
e515	Architecture and construction services, systems, and policies						
e525	Housing services, systems, and policies						
e535	Communication services, systems, and policies						
e540	Transportation services, systems, and policies						
e545	Civil protection services, systems, and policies						
e550	Legal services, systems, and policies						
e555	Associations and organizational services, systems, and policies						

TABLE 5. continued

CSHL category	Description	AUD										
		2016			2017			Structured questionnaires				
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI					
e560	Media services, systems, and policies											
e575	General social support services, systems, and policies											
e580*	Health services, systems, and policies	X		X								X
e5800	<i>Health services</i>	X		X								X
e585	Education and training services, systems, and policies											
e590	Labour and employment services, systems, and policies											

X, overlap; empty cells indicate non-overlap. AUD, audiology; CSHL, Core Set for Hearing Loss; DHI, Dizziness Handicap Inventory; H&P, history and physical; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; PPI, patient provided information; THI, Tinnitus Handicap Inventory.

* CSHL categories that are part of the Brief Core Set categories; CSHL categories without an * are part of the Comprehensive Core Set categories; CSHL categories in italics include the identified third-level CSHL categories of the second-level categories that are included in the Core Sets in the intake documentation.

88 TABLE 6. Extra ICF categories identified in the intake documentation

ICF category	Description	AUD					
		2016		2017		Structured questionnaires	
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI
BS							
s310	Structure of nose						X
s320	Structure of mouth						X
s330	Structure of pharynx						X
s340	Structure of larynx						X
s430	Structure of respiratory system						X
s750	Structure of lower extremity	X					
s8100	Skin of head and neck region	X					X
BF							
b110	Consciousness functions			X			X
b114	Orientation functions			X			
b134	Sleep functions			X		X	
b1341	Onset of sleep	X					
b1342	Maintenance of sleep	X					
b215	Functions and structures adjoining the eye			X			X
b420	Blood pressure functions			X			
b452	Fatigability			X			
b730	Muscle tone functions			X			
b750	Motor reflex functions			X			
b7602	Coordination of voluntary movements			X			
b7653	Stereotypies and motor perseveration			X			X

TABLE 6. continued

ICF category	Description	AUD						ORL intake report
		2016		2017		Structured questionnaires		
		Intake reports	Intake forms	Intake reports	Intake forms	THI	DHI	
A&P								
d166	Reading					X	X	
d410	Changing basic body position	X		X			X	
d4104	Standing	X						
d420	Transferring oneself	X						
d445	Hand and arm use			X				
d450	Walking	X					X	X
d460	Moving around in different locations						X	
d4600	Moving around within the home						X	
d4603	Moving around outside the home and other buildings						X	
d610	Acquiring a place to live							X
d630-d649	Household tasks					X	X	
d6409	Doing household, unspecified							
d6506	Taking care of animals						X	
d510	Washing oneself							
d570	Looking after one's health	X						X
d5701	Managing diet and fitness	X						

X, identified extra ICF categories. A&P, activities and participation; AUD, audiology; BF, body functions; BS, body structures; DHI, Dizziness Handicap Inventory; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; THI, Tinnitus Handicap Inventory.

88 TABLE 7. Extra non-ICF constructs identified in the intake documentation

Construct	Description	AUD					
		2016		2017		ORL intake report	PPI/H&P
		Intake reports	Intake forms	Intake reports	Intake forms		
Health conditions	Ear-related	X		X		X	
Personal factors	General						X
	Age	X		X		X	
	Sex	X		X		X	
	Medical history	X		X		X	
	Family history	X		X		X	
	Social history						X
	Marital status					X	X
	Living area (geographic)					X	
	Living situation						X
	Medication	X		X		X	
	Allergies						X
	Review of systems						X
	Treatments	X		X		X	
	Harmful exposures						X
	Noise exposure	X		X			
Qualifier	Ototoxic medication exposure						
	Course of complaint	X	X	X	X	X	X
	Severity of complaint	X	X	X	X	X	X
Time	Onset complaint	X		X		X	
	Duration complaint	X		X		X	
	Stopping complaint	X		X		X	

X, identified extra non-ICF constructs. AUD, audiology; CSHL, Core Set for Hearing Loss; H&P, history and physical; ICF, *International Classification of Functioning, Disability, and Health*; ORL, otorhinolaryngology; PPI, patient provided information.

Extra ICF categories

Extra BS categories mostly originated from the ORL intake documentation (Table 6). For example, all ORL records included a standard summary of the diagnostic review of the patient's nose, mouth, pharynx, and larynx structures. Most of the extra BS categories are related to tinnitus and vestibular/balance problems. For example, information on "sleep functions" (b134) was often identified in tinnitus patients' records, and "motor functions" (b7) and "mobility" (d4) for patients with vestibular/balance problems.

Extra non-ICF constructs

Most of the extra non-ICF constructs that were identified in the AUD and ORL intake documentation were either ICD-10 diagnostic codes or PFs (Table 7). The following PFs were identified: age, sex, other HCs/comorbidities, medication/ototoxic medication, past exposure to significant noise, and previous ear/head traumas and ear surgeries. In addition, most ORL intake reports described the specific circumstances under which the patient experienced the complaint onset (e.g., during the take-off of an aircraft) and the referral pathway to Mayo Clinic.

Intake reports from 2016 versus 2017

The number of CSHL categories that were identified in the intake reports of 2016 did not differ from the number that were identified in 2017 (Table 1, lower panel). Regarding the 2017 intake forms, less A&P categories were covered, and there was more focus on the categories in the BF component in 2017 as compared with 2016.

Additional information via Mayo Clinic standard intake forms

The information extracted from the PPI and H&P forms mostly added information on PFs and included information on social history (e.g., social and psychosocial habits) and general health information. Also, information relating to intellect, memory, and cognitive functions were identified in some of the H&P forms.

DISCUSSION

The aim of the present study was to assess the extent to which AUD and ORL discipline—specific intake documentation as well as Mayo Clinic's multidisciplinary intake documentation captured the aspects of the CSHL. One hundred percent overlap was found for the Brief CSHL, and 50% overlap was found for the Comprehensive CSHL. These findings are comparable to the results of van Leeuwen et al. (2017)³⁰, who found an overlap of 89% and 51% for the Brief and Comprehensive CSHL, respectively. Regarding the Comprehensive CSHL, intake documentation covered all categories from the BS component, and a large overlap was identified for the BF component. Large non-overlap was found for the A&P and EF components, which is also in line with what van Leeuwen et al. (2017)³⁰ found. Examples of absent CSHL A&P categories include precise description of difficulties related to "learning

and applying knowledge” (d1), “mobility” (d4), and “interpersonal interactions” (d7). Regarding the EF component, little coverage in the intake documentation was found for “support” (e3), “attitudes” (e4), and “support services other than health services” (e5). All these categories have been found to be potentially important for an individual’s well-being and accessibility to support services¹¹. These findings on A&P and EF components confirm that the current AUD and ORL practice is predominated by the clinical perspective of ear disease (BS and BF components). ORLs reported especially poorly on the CSHL categories in A&P and EF components, suggesting that ORLs are even more led by a clinical perspective of ear disease than the AUDs. This could also result partly from the fact that – in contrast with the AUDs – no structured intake forms were used by ORLs. Alternatively, because AUD evaluations are routinely performed before ORL evaluations, and both disciplines share a common electronic health record, efforts to capture aspects of the clinical picture in the ORL evaluation that had already been identified in the AUD record would be duplicative and would remove one of the principal efficiencies of a single shared electronic health record—removing the need for redundant evaluation. The relevance and importance of many of the missed categories of the CSHL have been addressed in previous studies and is therefore not the focus of this discussion^{6, 8, 13-15, 17-19}.

As mentioned in the Methods section, AUD intake documentation forms were adjusted early in 2017 in an attempt to – In line with the CSHL – collect more functioning-focused information. The intent was to assess constructs such as participation, PFs and to some extent EFs on a global (chapter) level. The change of the structured intake forms in 2017 did not substantially increase the number of CSHL categories that were reported. Regarding the Comprehensive CSHL, larger non-overlap with A&P categories in the intake forms was identified, which also seems to have led to less A&P documentation in the intake reports written by AUDs. Further, although new categories were identified in the 2017 version, other categories previously captured in the intake documentation of 2016 were not covered in the 2017 version. During the intake documentation change in 2017, a trade-off was made between a more detailed description of some aspects of day to day life and the identification of difficulties and challenges in the broad sense. We could not evaluate whether this strategy was more or less sensitive in identifying hearing-related problems. Ultimately, future validation processes will provide evidence for how best to standardize an inventory of all relevant categories.

Extra ICF categories

Extra ICF categories were identified in the BS, BF, and A&P components. The extra ICF categories in the BS component were mostly identified in the ORL intake documentation reports and are logical additions in the context of otology as part of ORL. Regarding BF and A&P, most of the extra ICF categories were documented in the records of patients with tinnitus or vestibular evaluations. For example, the extra ICF categories linked in vestibular evaluations included “motor functions” and “mobility” (i.e., “gait pattern functions” [b770],

“changing basic body position” [d410], “maintaining a body position” [d415], “walking” [d450], and “moving around” [d460]). This is not surprising, as vestibular and balance disorders are commonly associated with mobility problems. Vestibular and balance disorders can have a major impact on functioning in daily life^{31,32}, and taking into account all relevant aspects of the HC, functioning- and disability- related factors to these disorders are therefore essential. The extra ICF categories that were linked to the intake documentation forms and reports are all included in the Brief Core Set for Vertigo³³. We suggest that the ICF Core Set for Vertigo could be combined or integrated with the CSHL when patients present with HL and vestibular deficits. Further, both in the AUD and ORL intake documentation the ICF category “sleep functions” (b134) was reported. This category seems important for individuals with HL and tinnitus or vestibular problems^{27,28}. This finding is consistent with the study of van Leeuwen et al. (2017)³⁰ and provides additional support for the inclusion of this category into the CSHL.

Non-ICF constructs

The non-ICF constructs identified in the intake documentation mostly concerned PFs. Note that, at the time of this writing, the list of categories to be included in the PF component is tentative and incomplete and does not concern any classification. The PF component is currently brief and described in the ICF as “internal factors, which may include gender, age, coping styles, social background, education, profession, past and current experience, overall behaviour pattern, character and other factors that influence how disability is experienced by the individual”^{22, p8}. However, not developing categories for PFs in the ICF was a well-thought out decision at that time. The reasons were: (1) there is too much cultural variation to define an exclusive set of relevant PFs, and (2) there is no consensus-based robust conceptualization or definition of what PFs are yet²². Additional difficulties with the conceptualization and categorization of PFs have been identified^{34, 35}. One is that the tentative list of factors potentially overlaps with other components of the ICF model. For example, age and gender have biological roots (and so would be captured by BF and BS) but are also socially constructed (e.g., being a woman is not merely a biological distinction but also a social one and so would be captured by PF). Also, many of the psychological assets in the ICF tentative list (e.g., cognitive psychological factors and emotional reactions) overlap with the categories of mental functions of the BF component. It could, therefore, be argued that our linking of such factors should have been to existing ICF components instead of labelling them as PFs and thus “non-ICF constructs.” Another difficulty is that the position of PFs in the ICF model is similar to that of EFs (they act as a facilitator or a barrier to an individual’s functioning), but they are often not interpreted in this way³⁴. Despite the fact that currently there is no clear definition and categorization for PFs, we – In line with Granberg et al. (2014)¹¹ and Alfakir et al. (2015)¹⁴ – argue that consideration of PFs would add to gaining a comprehensive perspective about a person’s functioning. For example, a person’s general or situation-specific coping style can be an important factor that can directly

affect a person's A&P (both as a facilitator and a barrier)^{14, 36-40}. Although challenging, some standardization of the PF component would facilitate this.

Intake reports versus structured intake forms and questionnaires

Information provided by the structured AUD intake forms and questionnaires accounted for a large part of the overlap that was found (Tables 2, 3, 4, 5). This suggests that standardized self-reported measurement instruments, such as health status questionnaires, may contribute to a better understanding of a patient's functioning and disability (i.e., explain their concerns regarding hearing complaints). Moreover, using such instruments aligns with patient-centred care by explicitly assessing the patient perspective⁴¹. In particular, structured intake forms and questionnaires may help direct the conversation between the clinician and the patient to systematically explore and understand the full extent and context of the problems experienced by the patient. Information not directly related to the audiological impairment is considered particularly important for setting up patient-centred consultation for rehabilitation¹⁷⁻¹⁹. It is important to note that, patient-centred care has been found to be associated with improved patient outcomes including higher levels of satisfaction with care and better treatment adherence in the primary care setting⁴²⁻⁴⁴. However, in the present study, there was little indication that the detailed information captured in intake questionnaires were considered in the AUDs' assessment and management documentation. In the intake reports, AUDs seemed to heuristically make statements about the presence and degree of hearing or communication "impairment" based on clinical measurements: hearing loss magnitude, speech recognition test results, and questionnaire scores. The specific problems experienced by the patient were seldom explicitly described. Moreover, factors beyond these clinical measures that can influence performance of routine auditory activities or affect the patient's overall ability to participate in society (such as chronic pain, depression, cognitive challenges, problematic social interactions, etc.) were not explicitly identified or addressed, even when these problems appeared strongly related to the participation needs that drove the patient to seek audiological services in the first place. Failing to consider all aspects relevant to hearing yields an incomplete understanding of an individual's functioning and personal situation¹¹, thereby possibly limiting patient-centred care.

Various barriers may limit implementation of patient-reported information beyond the standard evaluation in clinical practice. For example, AUDs may not wish to identify or take ownership of problems beyond those anticipated by the degree of HL, even though they may influence the person's ability to use hearing on a day-to-day basis, particularly if AUDs are not in a position to effectively organize treatments for those problems. Scope of practice limitations, reimbursement challenges, or limited access to other healthcare providers may be at play. However, when hearing healthcare services are limited to the provision of hearing aid devices or corrective surgeries, "hearing evaluations" can devolve into a screening exercise to identify candidates for those treatments, rather than careful exploration into the nature and context of a person's unique hearing difficulties and needs.

Failure to offer an array of hearing health care intervention options targeted to patients' needs has been reported to be a major factor contributing to low hearing aid or communication program utilization rates⁴⁵. Use of the CSHL may help structure a more explicit understanding of the various needs of the person with hearing difficulties by placing identified deficits/impairments into a more relevant individualized context. The goal is to facilitate better patient-centred care and ultimately improve patient outcomes^{3, 46}.

It is important to recognize that the CSHL was envisioned to contain categories that are likely to be relevant to an individual patient's functioning. However, operationalizing the CSHL as a way to describe and predict auditory functioning in clinical practice is still developing. The hope is that the CSHL will identify factors that are amenable to available rehabilitation, and make a difference in clinical outcomes (see for instance Alfakir and Holmes (2017)²⁰). Validation studies focusing on how to implement the CSHL in aural rehabilitation practice are needed.

Mayo Clinic's multidisciplinary intake documentation

As mentioned in the Methods, standard practice at Mayo Clinic requires AUDs and ORLs to review PPI forms and clinical H&P forms before the intake consultation. In the present study, important CSHL categories were identified in these forms that were not captured by the AUD or ORL documentation. For example, information about a patient's complementary systems (e.g., visual, mental), was captured within the context of the multidisciplinary intake documentation that was not identified in the AUD or ORL specific intake documentation. This "additional" information adds to the construction of a more comprehensive picture of the patient⁴⁷⁻⁵¹, and potentially could contribute to more successful treatment outcomes in patients with HL. One of the advantages of shared intake documentation forms is that information across disciplines can be quickly reviewed without the burden of each practitioner collecting all data from every patient themselves. However, as with the structured intake forms and questionnaires, it was not always clear if and how this additional information influenced the patient's management plan.

The AUD and ORL discipline-specific documentation in the present study had similar amounts of overlap with the CSHL as those identified in the study by van Leeuwen et al. (2017)³⁰. In that study, overlap was assessed in AUD and ORL clinics without a shared multidisciplinary electronic health record. This may indicate a bias for each discipline to frame the patient's hearing problems from a restricted, discipline-specific viewpoint. Developing a systematic standard for collecting and reporting CSHL information might promote a more holistic clinical conception of the patient's presenting hearing problem by AUDs and ORLs.

Toward ICF implementation in hearing healthcare

The overall scope of the CSHL can seem overwhelmingly broad in the setting of a single discipline clinic. At least initially, its implementation may be more easily achieved in multidisciplinary group practice settings that use a shared electronic health record. The Mayo Clinic has the integrated electronic health system already in place, but to be useful, more efficient and validated ways of collecting and presenting CSHL data from individual patients will need to be developed. An alternative to relying on a shared multidisciplinary electronic health record to capture all CSHL categories, and that also aligns with patient-centred care, is the operationalization of the CSHL into an electronic patient-reported outcome measure (e-PROM). e-PROMs can contribute to the electronic health record by facilitating better integration of patient needs, preferences and valued outcomes into all treatment and rehabilitation decisions⁵². Moreover, e-PROMs can provide information from the patient perspective on functioning and may provide an effective way of monitoring patient-valued outcomes.

Study limitations

The aim of our study was to identify all the different CSHL categories that were reported in the intake documentation, independent of how often a category was reported. As a consequence, this study does not reveal how often certain categories were documented, nor if lack of documentation occurred simply because patients in our sample did not have a relevant CSHL-related problem. Also, our study relied on information entered in the patient records. We cannot assess whether identified CSHL data were relevant to the care of an individual patient. Nor can we determine if CSHL data were considered when a plan of care was developed. These concerns will be the focus of future validation studies. Another limitation of our study that might limit the generalizability is that we linked the CSHL categories to the intake documentation in a largely diagnostic clinical setting.

Our study does not reveal how the CSHL would be represented in a purely audiology rehabilitation setting. Our patient population did include audiology rehabilitation patients, such as patients with hearing aids or cochlear implants. By design, the Mayo Clinic evaluation process is structured first to identify and treat ear disease. Aural rehabilitation assessment and planning occurs after the medical (bio-physical) focused evaluation is completed. As a result, the current clinical intake process is dominated by the clinical perspective of ear disease. In rehabilitation settings, the goal is to improve an individual's functioning in daily life. Documentation overlap with the psychosocial CSHL categories might be higher than in Mayo Clinic's clinical setting. This should be investigated in future research.

The international perspective

The aim to implement the CSHL into Mayo Clinic's system alongside similar initiatives in the Netherlands³⁰, align with the objectives of the World Health Organization's Global Disability Action Plan 2014–2021, Better Health for All People With Disability⁵³. These include: "(1) to remove barriers and improve access to health services and programs, (2) strengthen and extend rehabilitation, assistive devices and support services, and community-based rehabilitation, and (3) enhance collection of relevant and internationally comparable data on disability, and research on disability and related services." The ultimate aim is to "enable people with disabilities to fulfil their aspirations in all aspects of life." This study is an important first step toward the overarching goal to improve the functioning and lived experience of persons with hearing problems.

CONCLUSIONS

The multidisciplinary intake documentation of Mayo Clinic showed 100% overlap with the Brief CSHL, while important areas of non-overlap were identified in AUD- and ORL discipline-specific reports. This highlights the breadth of health factors that can potentially impact the functioning of individuals with ear and hearing problems and are not commonly included in the discipline-specific intake evaluations. With this in mind, efforts to further validate the CSHL may require the involvement of multidisciplinary institutions with commonly shared electronic health records. Taking into account all relevant aspects of a patient's functioning would seem to be essential to development and evaluation of new, patient-tailored treatments. A combined multidisciplinary documentation document or a more efficient means of collecting CSHL information (possibly via e-PROMs) will be required to capture CSHL-related information in discipline-specific clinics.

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APPENDIX 1. Mayo Clinic standard intake forms

Structured PPI form:

Heading	Sub-heading (1)	Sub-heading (2)
Referring Provider Information		
Past Medical	Past medical history	
	Surgical history	
Patient Family History	Family history	
Current Visit Information	Demographic Information	
	Local MD	
	Medications	
	Allergies	
	Review of systems	Constitutional
		Skin
		Eyes
		Ear-Nose-Throat (ENT)
		Respiratory (Resp)
		Cardiovascular (CV)
		Gastrointestinal (GI)
		Musculoskeletal
		Neurological (Neur)
		Gynecological (Gyn)
		Genitourinary (GU)
		Endo
		Communicable disease
		Other symptoms
		Allergies/ immunizations
	Preventive screening	
	Social history	Relationships status
		Level of education
		Employment status
		Fear [<i>e.g., afraid in own home</i>]
		Fearful for own safety [<i>yes/no</i>]
	Habits	Tobacco
		Alcohol
		Drugs
	Self-care/ home environment	Climb two flights of stairs [<i>yes/no</i>]
		Dependence on devices
	Immunizations	

Example of semi-structured H&P form from General Internal Medicine (GIM):

Heading	Sub-heading (1)	Sub-heading (2)
Visit information	Visit type Accompanied by Source of history Referral source	
Chief complaint		
History of present illness		
Histories	Family history	Social and psychosocial habits
Health status	Social history Allergies Medications	Current medications Documented medications
Health maintenance	Problem list	
Review of systems		
Physical examination	Height Weight Body Mass Index Temperature value Heart rate Non-invasive Systolic Blood Pressure (SBP) Non-invasive Diastolic Blood Pressure (DBP) General	(i.e., alertness, orientation, distress)
	Head Ear Nose-Throat (HENT) Eye Neck Respiratory Cardiovascular Gastrointestinal Lymphatics Musculoskeletal Integumentary (rash) Neurologic Psychiatric	
Review/management		
Impression/ plan		
Professional services		

Chapter 4:

Investigating rehabilitation needs of visually impaired young adults according to the International Classification of Functioning, Disability and Health

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ABSTRACT

Purpose: To gain qualitative insight into the rehabilitation needs of visually impaired young adults (18–25 years) and how these needs relate to the International Classification of Functioning, Disability and Health (ICF) and patient characteristics.

Methods: Rehabilitation needs and patient characteristics of young adults (N=392) who applied for multidisciplinary services in 2012 and 2013 were obtained from structured and semi-structured intake records. Linking rules were used to assess how the needs related to Environmental Factors, Body Functions, Body Structures, and Activity and Participation (A&P) ICF components. The relationship between the type of rehabilitation goal and patient characteristics was assessed using multivariate logistic regression analyses.

Results: Most rehabilitation needs (67.6%; N = 510) were found on the A&P component of the ICF. Most prevalent needs were related to ‘major life areas’ (e.g., finding internship or job), followed by the chapters: ‘mobility’ (e.g., self-reliance in travelling), ‘communication’ (e.g., using communication devices and techniques), ‘general tasks and demands’ (e.g., psychological aspects of vision loss) and ‘domestic life’ (e.g., household tasks). Patients in one of the multidisciplinary rehabilitation centres (odds ratio (OR) = 7.07; 95% confidence interval (CI) [2.97–16.83]) and patients with comorbidity (OR = 3.82; 95% CI [1.62–9.02]) were more likely to report rehabilitation needs related to chapter E3 ‘support and relationships’.

Conclusion: ‘Major life areas’ prevail in the content of rehabilitation needs, but tend to overshadow topics regarding peer interaction and social, community and civic life. A suitable survey method for young adults with visual impairments is required that contains rehabilitation domains and goals relevant to their lives and development.

INTRODUCTION

Having a visual impairment significantly affects an individual's daily functioning and quality of life¹⁻⁴. Research on the transition to adulthood for young adults with disabilities indicates that the process can be highly challenging⁵. Having to deal with a disability is likely to interfere with changes in the important life transitions, possibly resulting in psychological distress⁶ and disruption in the individual's pursuit of developmental tasks⁷. Consequently, the transition to adulthood may be less successful which, in turn, may compromise a young adult's physical, social and psychological potential, and opportunities for full participation in adult life⁸. In making the transition from childhood to adult life, young adults who are blind or visually impaired may need information and advice specific to their needs. Rehabilitation services can play a role in helping young people recognize where the difficulties are and what can be done to overcome or to minimize them.

The transition comprises a series of developmental tasks and pursuits of life goals, for example completing school, gaining employment, independent living and selecting a partner⁹⁻¹³, and is characterized by a longing for independence and autonomy. However, most reports on young adults with a visual disability only focus on the transition to and from educational services and on career planning (e.g., ^{14, 15}). Although dropout rates and graduation rates are normal among youths with a visual impairment¹⁴, there is a gap in employment rates compared with youths without visual disabilities¹⁵. The study by Rainey et al. (2014)¹⁶ on the rehabilitation needs of children and adolescents with visual impairments indicates that the transition process into adulthood already starts in the age group of 12- to 18-year-olds (i.e., adolescents). Rehabilitation needs of children aged < 12 years mainly focused on the life domains (according to the International Classification of Functioning, Disability and Health; ICF) regarding 'learning and applying knowledge' and 'mobility'. The focus in adolescents was much more related to independence issues such as self-care, running household tasks and finding appropriate secondary education. Adolescents with visual impairments also show increased interests in social relationships, including relationships with friends and intimate and romantic relationships^{10, 17}. However, several studies found that adolescents with visual impairments experienced difficulties in this regard, threatening psychosocial development and the quality and maintenance of such relationships^{9-12, 18, 19}.

Although some elements essential to transition have been proposed, a synthesis of this information in relation to rehabilitation needs in young adults with visual impairments is lacking. Insight into topics that are affected by the disability during the transition period can be helpful to better understand adaptation to the visual impairment and may provide indications as to which additional support is needed. The ICF is generally accepted as a reference framework in rehabilitation²⁰ and especially the Activity and Participation (A&P) component of the ICF provides a common language for professionals when identifying

rehabilitation needs. Applying the ICF framework facilitates the identification and understanding of rehabilitation needs, as well as formulation of responses to the disability and health-related needs^{21, 22}. To our knowledge, no study has comprehensively described and appraised the content of rehabilitation needs in young adults with a visual impairment. Therefore, this study investigates whether the shift in rehabilitation needs by different age bands found in the study of Rainey et al. (2014)¹⁶ continues in the rehabilitation needs of young adults and how these needs fit the structure of the ICF. Also, the relationship between rehabilitation needs and various patient characteristics was investigated.

METHOD

Study design and setting

This study was a patient record study involving two multidisciplinary rehabilitation centres (MRCs): Royal Dutch Visio and Bartiméus, both located in the Netherlands. Patient records were anonymized. The study was approved as an amendment to a study protocol aimed at the development of intake modules for visually impaired children (0–18 years) by the Medical Ethical Committee of the VU University Medical Center, Amsterdam, the Netherlands.

Participants

All patient records of young adults who applied for multidisciplinary services between 2012 and 2013 were eligible for inclusion. Inclusion requirements involved the following: (1) young adults aged 18–25 years, (2) the record containing a signed rehabilitation plan with at least one rehabilitation goal and (3) the young adult was eligible for care at Royal Dutch Visio or Bartiméus. Eligibility requirements for care at Royal Dutch Visio or Bartiméus include criteria according to the World Health Organisation (WHO), where low vision is defined as a visual acuity < 0.3 but ≥ 0.05 (Snellen notation) and/or a visual field of $< 20^\circ$ around the central fixation point, or other severe visual field defects (i.e., hemianopia or cortical visual impairment). In addition, blindness is defined as < 0.05 and/or a visual field of $< 10^\circ$ around the central fixation point²³. Furthermore, an individual is considered eligible for care at a MRC if the visual impairment causes limitations in activities of daily living (ADL) that cannot be solved by regular healthcare services²⁴.

Measurement outcome

The main outcome measure was the type of rehabilitation needs. Within the Dutch MRCs, rehabilitation needs are set during an intake procedure and documented in signed rehabilitation plans. Upon examination of the rehabilitation plans, two different intake methods were identified: a semi-structured approach and a structured approach.

Rehabilitation needs obtained from the semi-structured approach

A (scheduled) semi-structured intake procedure usually starts with a concise telephone conversation between the patient and a professional intaker from the MRC, to clarify the

rehabilitation needs. Rehabilitation needs are formulated into goals and documented by the intake professional in a predefined format, which follows the ICF structure. In this study, rehabilitation needs were obtained from these formats, and linking rules²⁵ were used to assess how these needs related to the structure of the Environmental Factors, Body Functions, Body Structures and A&P components of the ICF. This procedure was performed by one researcher (LvL). Patients' rehabilitation needs were translated into categories of the ICF to make the data accessible for evaluation.

The linking rule procedure comprises two steps. First, meaningful concepts were identified within the written rehabilitation goal. Second, all meaningful concepts were linked to the most precise ICF component (1st level), chapter (2nd level) and (sub) category (3rd and 4th levels). To enhance comparisons of frequencies within the study population, each meaningful concept that was linked to the 2nd, 3rd or 4th level was also given the ICF code on the corresponding higher ICF levels (e.g., meaningful concepts linked to the 3rd-level d830 were also linked to the 2nd-level d8 and the 1st-level A&P). If the concept could not be linked to the ICF classification, it was assigned the code 'not definable'. If the concept was not recorded in the ICF classification, it was assigned the code 'not covered'. An example of the linking procedure is presented in Table 1. A second researcher (i.e., LR) was consulted in case of uncertainty regarding the allocation of rehabilitation needs to the different ICF categories. The second researcher independently linked the need to the ICF. Discrepancies were resolved by a discussion between the two researchers in which a final allocation was chosen jointly.

TABLE 1. Example of the linking process of rehabilitation needs to corresponding ICF codes

1. Rehabilitation goal				
"Wants to know about her opportunities for higher education and work. Wants another cane. Wants another Daisy Player. Requires some mental support for the loss of vision."				
2. Meaningful concepts	3. ICF linking			
	1st level	2nd level	3rd level	4th level
Higher education	A&P	D8: major life areas	d830: higher education	NC
Work	A&P	D8: major life areas	d840-d859: work and employment	NC
Cane	Environment	E1: products and technology	e120: Products and technology for personal indoor and outdoor mobility and transportation	e201: Assistive products and technology for personal indoor and outdoor mobility and transportation
Daisy Player	Environment	E1: products and technology	e125: Products and technology for communication	NC
Mental support	A&P	D2: general tasks and demands	d240: Handling stress and other psychological demands	NC

NC = not covered

Rehabilitation needs obtained by the structured approach

Rehabilitation needs from structured intake records were obtained with the Participation and Activity Inventory (PAI) (formerly known as the Dutch ICF Activity Inventory, which is the adapted Dutch version of Massof's Activity Inventory²⁶). Based on legal and organizational divisions, in the Netherlands young adults are part of the department of rehabilitation for adults and, consequently, the adult PAI version was applied to them. The PAI is administered by telephone. However, the questionnaire is not always applied to young adults. It is unknown why professionals choose to administer or not to administer the PAI. The PAI is structured on the basis of the A&P component of the ICF. The A&P component assesses nine separate ICF chapters: 'learning and applying knowledge', 'general tasks and demands', 'communication', 'mobility', 'self-care', 'domestic life', 'interpersonal interactions and relationships', 'major life areas', and 'community, social and civic life'. It was developed for adults with a visual impairment and was adopted by the two largest Dutch rehabilitation organizations for the visually impaired²⁷⁻³⁰. An activity is defined as 'the execution of a task', and participation has been defined as 'involvement in life situations'²¹. The PAI consists of specific activities, referred to as 'tasks', which are generally difficult for individuals with a visual impairment²⁹. The rehabilitation needs that were identified with the PAI were collected at the goal level (e.g., mobility outside) and at the task level (e.g., cycling). The central question addresses how difficult it is for the client to carry out a purpose or task (e.g., How difficult is it for you to move around in your home, without someone else's assistance?). Response categories are as follows: not difficult (0), slightly difficult (1), difficult (2), very difficult (3) and not possible (4). In the patient records, tasks with a score of ≥ 1 were regarded as a rehabilitation need.

Statistical analyses

Descriptive statistics [frequencies, means and standard deviations (SDs)] were assessed for the different codes of the ICF that were used for linking and for the number of rehabilitation needs. To examine the relationship between type of rehabilitation needs and the various patient characteristics, that is gender, number of ocular diagnoses, visual acuity of the best eye, comorbidity (cognitive, hearing and neurological impairment) and type of MRC (Royal Dutch Visio and Bartiméus), multivariate logistic regression analyses were performed. Due to differences in documentation of rehabilitation needs between the two intake methods, the relationships between patient characteristics and ICF categories/PAI domains were analysed separately. To enable meaningful statistical analyses, visual acuity scores were transformed into logMAR scores, comorbidity was dichotomized into no comorbidity and ≥ 1 comorbidity, and the categorical variable type of MRC Royal Dutch Visio (versus Bartiméus) was used as reference group. To determine which variable could be included in the multivariable model, univariate regression analyses were conducted first, after which a forward stepwise routine was followed. An independent variable was considered (potentially) explanatory in the multivariate models if the p-value was < 0.1 . To investigate whether patient characteristics cause rehabilitation needs in specific ICF categories/ PAI domains, the number of

rehabilitation needs in a particular ICF chapter were dichotomized into ≥ 1 versus no (0) rehabilitation goal in this chapter. All statistical analyses were performed using Excel 2010 and the Statistical Package for Social Science (SPSS) (version 20.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Patient characteristics

Data extraction was carried out in 2014. Figure 1 shows the selection of patient records, the distribution of these records among the two assessment sites (i.e., Royal Dutch Visio and Bartiméus), and which type of intake method was used at these MRCs. The excluded patient records often included only registration for visual function testing (80%). Patient characteristics of the young adults of the studied patient records are presented in Table 2. No significant differences were found between the patient characteristics of both groups. Information on diagnosis was available in 315 records (98.7%). The most common diagnosis reported was nystagmus (16.8%), followed by optic atrophy (7.6%), conerod dystrophy (6.7%) and retinitis pigmentosa (6.0%).

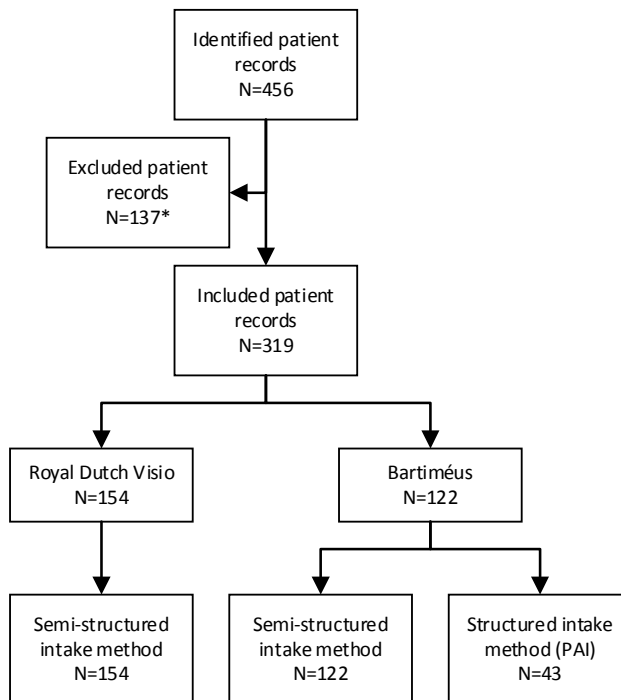


FIGURE 1. Flowchart of selection of patient records, the distribution of patient records among the MRCs, and type of intake method. *No signed rehabilitation plan available

TABLE 2. Patient characteristics (N=319)

	Semi-structured intake (N=276)	Structured intake (N=43)
Age (years), mean \pm SD (range)	21.3 \pm 2.0 (18-25)	21.8 \pm 2.3 (18-25)
Gender, % female	54.0%	65.1%
Visual acuity, logMAR (SD) ¹	0.66 (0.50)	0.65 (0.46)
Low vision, N (%) ²	84 (30.4)	15 (34.9)
Blind, N (%) ²	22 (8.0)	5 (11.6)
Comorbidity, N (%) ³		
- Cognitive impairment	36 (13.0)	2 (4.7)
- Hearing impairment	4 (1.4)	2 (4.7)
- Neurological impairment	18 (6.5)	2 (4.7)

SD = standard deviation; logMAR = logarithm of the minimal angle of resolution

¹Semi-structured intake: N=172; 104 patient records did not include information on visual acuity; Structured intake: N=30 13 patient records did not include information on visual acuity.

² Semi-structured intake: 66 patients with information on visual acuity did not met criteria for low vision/blindness; Structured intake: 10 patients with information on visual acuity did not met criteria for low vision/blindness;

³N one of the patients was diagnosed with more than one co-morbidity simultaneously.

Rehabilitation needs based on semi-structured intake method

A total of 755 meaningful concepts were identified in 276 rehabilitation plan documents obtained from patient records which were based on the semi-structured intake method (mean 2.6, SD 2.1). Figure 2 presents the distribution of needs linked to the specific 3rd-level items in the chapters of 'Body functions' and 'Environmental factors'. Rehabilitation needs linked to 'Body functions' (7.7%, N = 58) were mainly about information on visual ability (i.e., B2 sensory functions) and pain, specifically b210 'seeing functions'). A significant amount of rehabilitation needs were linked to 'Environmental factors' (21.2%, N = 160). Rehabilitation needs within this component most often concerned products for communication (55.0%), especially for everyday use or for education/employment. For example, young adults asked for assistance with reimbursement applications to health insurance companies, about purchasing a computer. The chapter E3 'support and relationships' was also frequently linked (28.1%), mainly concerning support for professionals (i.e., e355 'health professionals'). An example of such a rehabilitation goal was 'support, advice and guidance for the health professional to learn how to deal with the visual impairment of the young adult'.

Most rehabilitation needs (67.6%) could be linked to the A&P component of the ICF. The A&P chapter 'major life areas' (D8) was most frequently linked (24.5%), followed by the chapters 'mobility' (D4), 'communication' (D3) and 'general tasks and demands' (D2) (20.2%, 16.7% and 11.8%, respectively). The chapter 'domestic life' (D6) was also regularly linked to the rehabilitation needs (10.2%). Figure 3 shows the distribution of the specific 3rd-level items in the different chapters of the A&P component. Rehabilitation needs in the chapter 'major life areas' prioritized around higher education (d830) and options for work (d840–d859). Rehabilitation needs were formulated mainly as 'I need help to optimally structure my education' or 'I need help in finding a suitable internship or job', as well as the broad

question 'What are my (higher) education and job opportunities?'. In the 'mobility' chapter, concepts of independence and freedom in mobility prevailed. Rehabilitation needs were often linked to d460 'moving around in different locations' and d470 'using transportation'; examples of rehabilitation needs included similarities of the phrases 'learning new routes' and 'travel using public transportation'. Needs linked to the chapter 'communication' almost always related to improving computer skills, reflected by the high frequency of d360 'using communication devices and techniques'. Most of the rehabilitation needs linked to the chapter 'general tasks and demands' concerned needs related to category d240 'handling stress and other psychological demands', referring to the request for psychological support in dealing with the (progressive course of the) impairment. With regard to the chapter 'domestic life', rehabilitation needs focussed on 'living independently' (i.e., d610 'acquiring a place to live') and self-reliance in 'carrying out household tasks' (i.e., d630–d649 'doing housework'). Very few rehabilitation needs regarding 'interpersonal interactions and relationships' (D7) and 'community, social and civic life' (D9) were raised (3.5%).

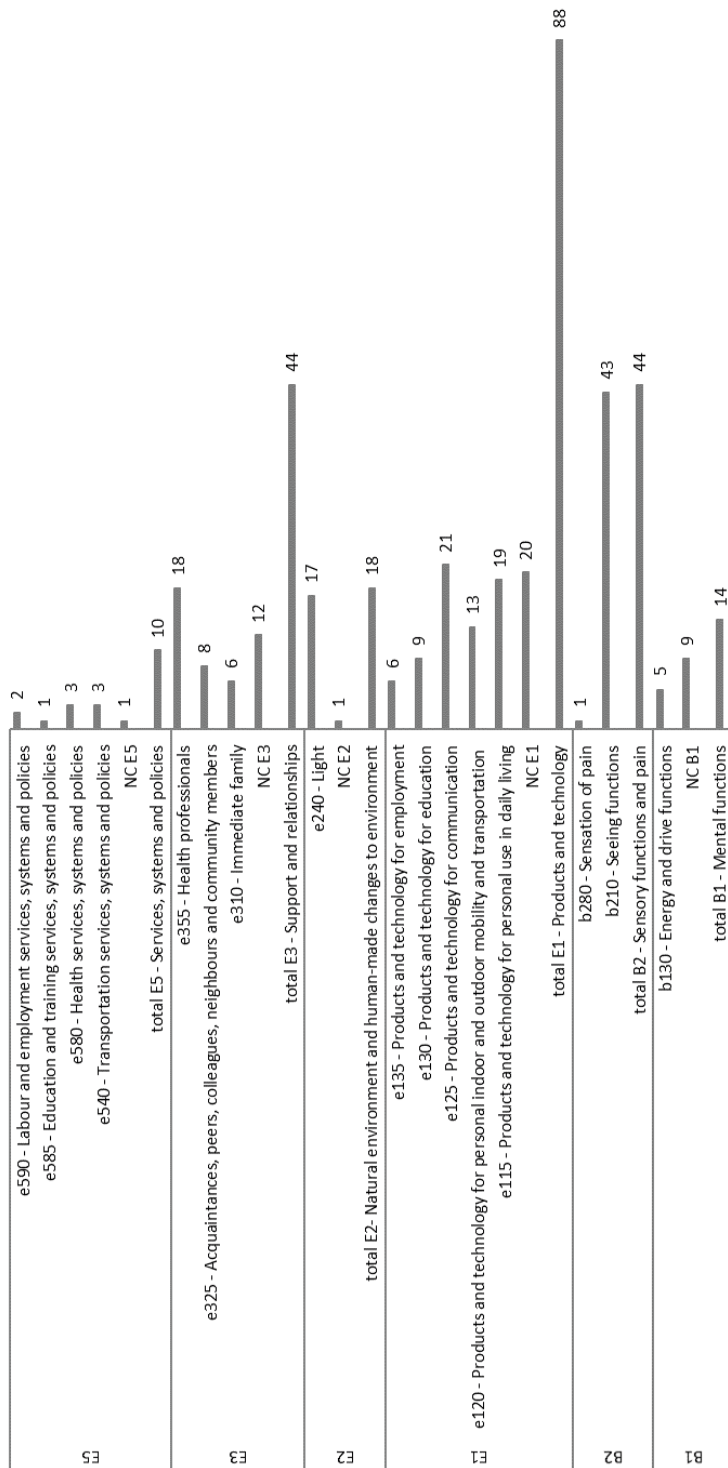


FIGURE 2. Frequency of ICF codes in the ICF component Body Functions and Environmental Factors, abstracted from the rehabilitation needs from the semi-structured intake method (N=286) of young adults with visual impairment. *NC = not covered*

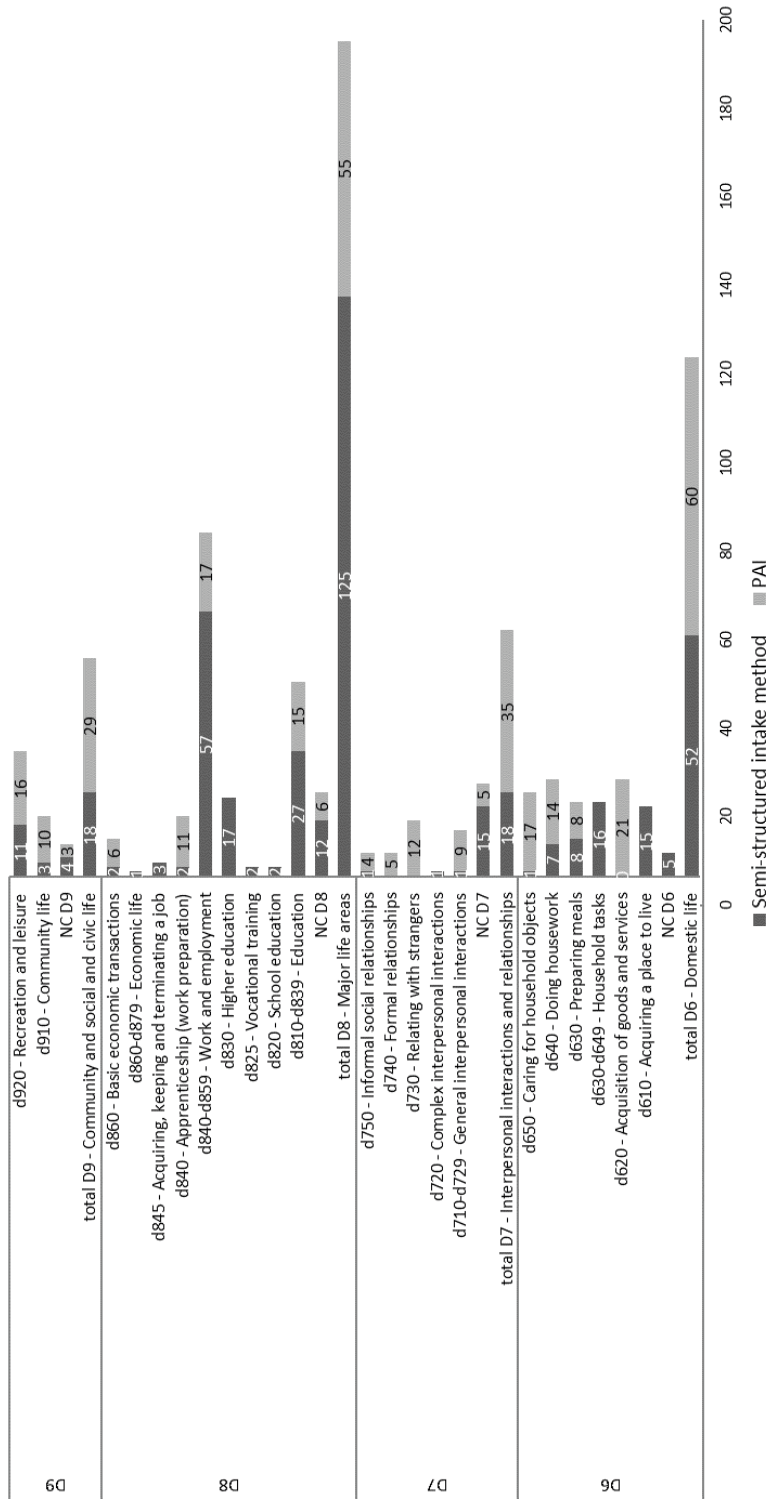


FIGURE 3. Frequency of ICF codes in the ICF component Activities and Participation, abstracted from the rehabilitation needs from the semi-structured intake method (N=286) and structured intake method (N=43) of young adults with visual impairment. *NC = not covered*

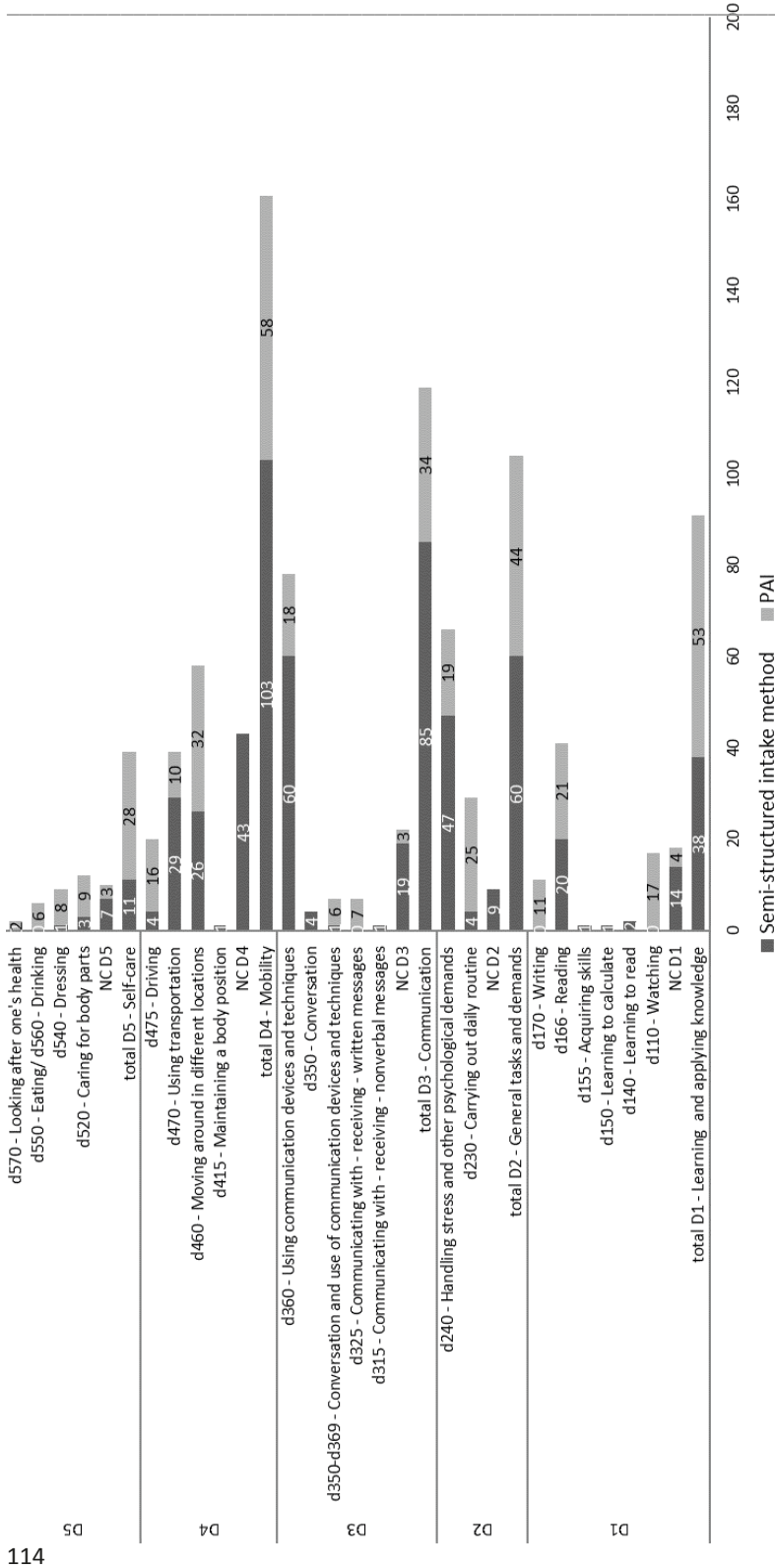


FIGURE 3. Continued

Rehabilitation needs based on structured intake (PAI)

In total, 43 patient records (13.5%) included scoring results on the PAI. The mean number of rehabilitation needs identified using the PAI was 10.6 ± 9.1 . Topics that were reported in the PAI priority lists, that is the list of topics patients indicated they wish to receive rehabilitation, are also shown in Fig. 3. The scoring of the PAI shows a tendency similar to the results of the ICF linking mentioned above: topics regarding education and job application, mobility in different locations, computer skills, emotional aspects, and a variety of household tasks most frequently required priority. However, chapter D1 'learning and applying knowledge' received more emphasis, in which especially the task 'reading' was often mentioned.

Relationship between patient characteristics and ICF domains

Logistic regression analyses were conducted to assess associations between type of rehabilitation goal and an individual patient's characteristics. Univariate regression analyses showed that type of MRC was significantly associated with D1 'learning and applying knowledge' (OR = 0.15; 95% CI [0.05–0.45]), D2 'general tasks and demands' (OR = 3.82; 95% CI [1.62–9.02]) and D4 'mobility' (OR = 0.63; 95% CI [0.21–0.62]), indicating that for one MRC, it was more likely rehabilitation needs were extracted regarding general tasks and demands and less likely for learning and applying knowledge and mobility. Furthermore, patients with comorbidity (i.e. cognitive, hearing or neurological impairment) were more likely to report rehabilitation needs related to chapter B2 'sensory functions and pain' (OR = 2.48; 95% CI [1.22–5.05]) and less likely to chapter D8 'major life areas' (OR = 0.43; 95% CI [0.21–0.88]). LogMAR visual acuity was related to having rehabilitation needs in E1 'products and technology' (OR = 3.92; 95% CI [1.89–8.15]) and not to having rehabilitation needs in D1 'learning and applying knowledge' (OR = 0.20; 95% CI [0.07–0.63]). With respect to chapter E3 'support and relationships', a multivariate regression model was found: patients of one type of MRC (OR = 7.07; 95% CI [2.97–16.83]) and patients with comorbidity (OR = 3.82; 95% CI [1.62–9.02]) were more likely to report rehabilitation needs related to this chapter. No significant associations were found between patient characteristics and rehabilitation needs in ICF domains assessed with the PAI.

DISCUSSION

The present study provides insight into the content of rehabilitation needs as formulated in patient records of visually impaired young adults (aged 18–25 years) visiting Dutch MRCs. It was examined whether the shift in rehabilitation needs by different age bands found in the study of Rainey et al. (2013) continued in young adults. Furthermore, the relationship between type of rehabilitation needs and patient characteristics, and the intake method were evaluated. Linking rules and ICF classification allowed for a structured method to define the contents of rehabilitation goals.

Rehabilitation needs

Regarding the rehabilitation needs identified in this study, the focus seems to be on the A&P component of the ICF (i.e., linking frequency 67.6%), emphasizing that rehabilitation services of MRCs have their main focus on needs related to the execution of tasks and involvement in life situations. Items within the chapters ‘domestic life’ (i.e., living independently and household tasks) and ‘major life areas’ (i.e., education and work life) were among the highest percentages of topics identified in the rehabilitation needs, supporting the existing evidence that these are major themes in the transition to adult life^{31, 32}. In particular, needs regarding education and work life prevailed in frequency. This is probably the most important life event in young adults’ transition into adulthood, induced by expectations of society and their own ambitions. Attending postsecondary education and being competitively employed are considered normative social roles of young adulthood³³. Having a job is the most direct means of achieving economic and residential independence³⁴. Being a student in postsecondary education is regarded as an investment towards future employment and improving earned income^{35, 36}. Achievement of these life goals has been linked to various positive outcomes among people with visual impairment (e.g., greater perceived self-efficacy and satisfaction with social contacts).

Another chapter of the A&P component that was frequently linked was ‘mobility’. The identified rehabilitation needs in this chapter generally related to items regarding self-reliance, both in travelling (e.g., driving or using public transportation) and moving around in different places (e.g., finding the way to and in school/college). This finding is consistent with the increasing desire for independence and autonomy, which are fundamental concepts in the transition period. This tendency is also reflected in findings on the chapter ‘domestic life’, as the items that were linked were mainly focused on running a household independently. The frequent linking to the ICF chapter ‘communication’ (especially to codes related to using computer technologies) fits the picture of automation and constantly advancing technologies in this field. Nowadays, skills in this area are indispensable in the private, school and work environment. Although chapters and categories in the A&P component of the ICF are predominant in the rehabilitation needs, the component Environmental Factors should not be overlooked, as items under this component cover 21.2% of the identified rehabilitation

needs. The frequent linking to ‘products and technology’ and, more specifically, ‘products for communication’, correspond to the frequent linking in the ‘communication’ chapter of the A&P component. The finding that these items are often addressed as rehabilitation needs stresses the importance of including topics regarding the ICF component Environmental Factors in the intake procedure for young adults with a visual impairment.

The findings of the ICF linking in the A&P component complement the results of the patient record study in visually impaired children (0–18) by Rainey et al. (2014)¹⁶. Their results on the proportion of needs found per A&P chapter of the ICF included trends for age on the chapters ‘mobility’ and ‘major life areas’, meaning that, with increasing age, these domains were more often reported in the patient records. These are precisely the domains that were the most prevalent rehabilitation needs in the young adults’ patient records. Furthermore, rehabilitation needs relating to the chapter ‘domestic life’ increased in frequency within adolescents; this rising rate appears to continue in the present study among young adults. In the present study, needs relating to the chapter ‘interpersonal interactions and relationships’ seem to require little consideration in young adults’ lives. Although, overall, this domain is increasing in the study by Rainey et al. (2014)¹⁶, the propensity weakened in adolescents. In addition, the chapter ‘community, social and civic life’ also received little attention in the formulation of rehabilitation needs by both adolescents and young adults. The low representation of these chapters in the rehabilitation needs of the present study is noteworthy, as they are inconsistent with the literature reporting that adolescents and young adults with visual impairments encounter challenges when it comes to social participation and inclusion in their communities of peers, relationships and leisure activities¹⁰. Social relationships play an important role in coping with visual impairment and – in adolescence and young adulthood, peer support in particular – which is reflected by the need for independence and the desire to want to fit in¹⁰. Moreover, social support might be especially important in the period of transition to adult life because of the many changes that take place. Although it is possible our studied population did not experience needs in this area, based on the literature^{10, 12, 17-19}, this seems unlikely. A possible explanation for the low percentage of rehabilitation needs in these chapters is that young adults may not feel comfortable sharing issues about relationships in their encounter with the intaker. Alternatively, the topic may have been overlooked by the professionals; a study by Boerner and Cimarolli (2005)³⁷ found that functional needs compared to relationship needs were more commonly addressed by vision rehabilitation services.

Rehabilitation needs and patient characteristics

Only a few significant associations were found between patient characteristics (gender, comorbidity, number of ocular diagnoses and logMAR visual acuity) and the type of rehabilitation needs (ICF chapters). Obviously, there were more needs reported with regard to visual ability for patients with more severely impaired vision, implying a greater need for optical aids or other assistive devices and questions on how they can improve reading ability.

Rehabilitation needs set for patients with a comorbidity almost always came from the supervisors (e.g., counsellors in a residential centre) of the young adult, explaining the finding that comorbidity creates questions regarding the visual ability of the young adult (e.g., ‘What does the client actually see?’) and the need for support for the supervisor (e.g., ‘supervisor wants tips on how to properly handle the visual impairment of the client’). Most patients with comorbidity had a cognitive impairment. The fact that having comorbidity resulted in fewer questions on ‘major life areas’ is therefore not surprising, as the items under this chapter do not properly fit the life situations of most persons with cognitive impairments (e.g., daytime activity programme versus studying and working). These findings suggest that patients with coexisting impairments have (to some extent) different rehabilitation needs. Also, associations between the type of MRC and different types of rehabilitation needs (i.e., ‘sensory functions and pain’ and ‘major life areas’) indicate that either the MRCs serve different subgroups of young adults, which is unlikely, or that they differ in their intake methods. Differences might be overcome with a sector-wide structured approach to goal setting.

Rehabilitation needs and method of intake

The intake process within the MRCs evaluated in the present study did not appear to be consistent. The evaluated rehabilitation needs were obtained from either a semi-structured intake method or a structured intake method via the PAI. With regard to the rehabilitation needs set with the PAI, the same categories compared with the needs set by the semi-structured method were considered most frequently: mobility, household, and study and work. However, the systematic intake with the PAI resulted in more rehabilitation needs (mean number 11 versus 3) and also a better representation of needs on important domains found in the literature, that is domains regarding relationships and recreation and leisure are better represented as compared with the representation of these domains in the semi-structured intake approach. Significantly, more rehabilitation needs were identified in the chapter interpersonal interaction and relationships, and different social occasions in the leisure domain were scored a number of times as well. Apparently, inventorying these domains indicates rehabilitation needs on maintaining contacts and social activities, of which very few were identified using the semi-structured method. During the semi-structured intake, it seems more likely that the rehabilitation needs in areas that are more straightforward (i.e., economic and residential independence) overshadow rehabilitation needs in other domains (i.e., (romantic) relationships).

Unlike a former study in which semi-structured and structured methods (PAI) were compared²⁷, a direct comparison between these intake methods could not be performed in this study. Therefore, it cannot be concluded that the observed differences between the two methods are true. Bruijning et al. (2012)²⁷ found that only 22% of the rehabilitation needs identified by the PAI were present in the ‘usual’ semi-structured intake records. The systematic character of the PAI seemed to prevent important topics being overlooked.

Therefore, systematically identifying rehabilitation needs seems the preferred method. However, the current PAI approach is probably not optimal for young adults because the content of the items in the domains of the questionnaire was designed in a broader more general scope of 'adults', that is individuals already in adulthood versus individuals transitioning into adulthood. Moreover, no young adults were involved in the development of the PAI (i.e., mean age: 65, SD 16.5, range [38–90] years)²⁸. Thus, the content of the PAI may not be fully consistent with the needs of young adults who experience many life situations for the first time in their lives. Furthermore, the PAI was only based on the A&P component of the ICF, whereas the rehabilitation needs identified in the semi-structured method suggest that other components of the ICF are also relevant (e.g., Environmental Factors).

Limitations

Several limitations need to be acknowledged. Because the rehabilitation needs studied were drawn from young adults who have pursued rehabilitation services (i.e., at Royal Dutch Visio or Bartiméus), this limits the generalizability of the results to these young adults with visual impairments as compared to those who do not seek such services. Furthermore, analyses in the present study relied on information entered in the patient record; this led to missing values on patient characteristics and, possibly, to missing rehabilitation needs that were addressed in the intake but were not documented in the record. The PAI was only administered to 43 young adults of whom no semi-structured goal-setting plan was available. These factors limited thorough comparison of semi-structured intake versus structured intake via the PAI. Moreover, no data were available on the reasons why the PAI was not administered in the other cases and, therefore, no valid explanation can be given for this event. It might indicate that the intaker judged that there was inadequate connection between the PAI and the target group. To be eligible for rehabilitation services at one of the MRCs, an individual has to meet the criteria for blindness or low vision of the WHO. Remarkably, information on visual acuity was poorly documented (missing rate 36.7%) and, of the patients for whom visual acuity was reported, 37.6% did not meet the WHO criteria. This finding may be explained by the fact that, although not reported, the criteria for visual field loss were met, or perhaps because (besides the WHO criteria) the Dutch guidelines for referral to MRCs state that services should also be provided to individuals who experience vision-related difficulties in activities of daily living that cannot be solved by regular healthcare services²⁴.

CONCLUSION AND PRACTICAL IMPLICATION

In conclusion, the focus of rehabilitation needs of young adults (18–25 years) assessed by intake professionals seems to lie in specific topics of the ICF, specifically in the categories education and work. This major focus tends to overshadow topics regarding peer interaction and community, social and civic life. Based on the results of the present study, the quality of rehabilitation for young adults with visual impairment in the Netherlands can be improved. Young adults with disabilities, including young adults with visual impairment, are susceptible for having unsuccessful transitions. Therefore, it is essential that rehabilitation services consider young adults in transition to adulthood as a separate group that needs specialized care. Moreover, an integrated and structured approach facilitates ‘patient-centred care’, which is considered an important marker in health care. Therefore, although comprehensive administration of important life areas is supported using a structured approach, the PAI approach for adults is not optimal for use among young adults. The results of the present study can be used to modify or adapt the current intake and treatment of young adults with visual impairments.

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Chapter 5:

Operationalization of the Brief ICF Core Set for Hearing Loss. An ICF-based e-intake tool in clinical otology and audiology practice

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Operationalization of the Brief ICF Core Set for Hearing Loss. An ICF-based e-Intake Tool in
Clinical Otology and Audiology Practice.

ABSTRACT

Objectives: According to the ICF, functioning reflects the interplay between an individual's body structures and functions, activities, participation, environmental and personal factors. To be useful in clinical practice, these concepts need to be operationalized into a practical and integral instrument. The Brief international Classification of Functioning, Disability and Health Core Set for Hearing Loss (CSHL) provides a minimal standard for the assessment of functioning in adults with hearing loss. The objective of the present study was to operationalize the Brief CSHL into a digital intake tool that could be used in adult patients with ear and hearing problems as part of their intake in otology-audiology care.

Design: A three-step-approach was followed: 1) Selecting and formulating questionnaire-items and scoring methods, using the 27 categories of the Brief CSHL as a basis. Additional categories were selected based on relevant literature and clinical expertise. Items were selected from existing, commonly used disease-specific questionnaires, generic questionnaires, or the WHO's official descriptions of ICF categories. Method of scoring was based on the existing item's response categories, or on the ICF qualifiers. 2) Carrying out an expert survey and a pilot-study (using the three-step test interview (TSTI)). Relevant stakeholders and patients were asked about the relevance, comprehensiveness, and comprehensibility of the items. Results were discussed in the project group and items were modified based on consensus. 3) Integration of the intake tool into a computer-based system for use in clinical routine.

Results: The newly developed intake tool consists of 62 items, clustered into 6 domains: (1) general information, including reason for visit, socio-demographic and medical background; (2) general body functions; (3) ear and hearing structures and functions; (4) activities and participation; (5) environmental factors; and (6) personal factors (mastery and coping). Based on stakeholders' responses, the instructions of the items on activities and participation, and environmental factors were adapted. The TSTI showed that the tool had sufficient content validity but that some items on environmental factors were redundant. Overall, the stakeholders and patients indicated that the intake tool was relevant and had a logical and clear structure. The tool was integrated in an online portal.

Conclusions: In the current study, an ICF-based e-intake tool was developed that aims to assess self-reported functioning problems in adults with an ear/hearing problem. The relevance, comprehensiveness, and comprehensibility of the originally proposed item list was supported, although the stakeholder and patient feedback resulted into some changes of the tool on item-level. At the time of writing, a large-scale field-test study is carried out to optimize the content of the intake tool and to assess its feasibility. Ultimately, the functioning information gained with the tool could promote individualized ear and hearing care from a biopsychosocial perspective.

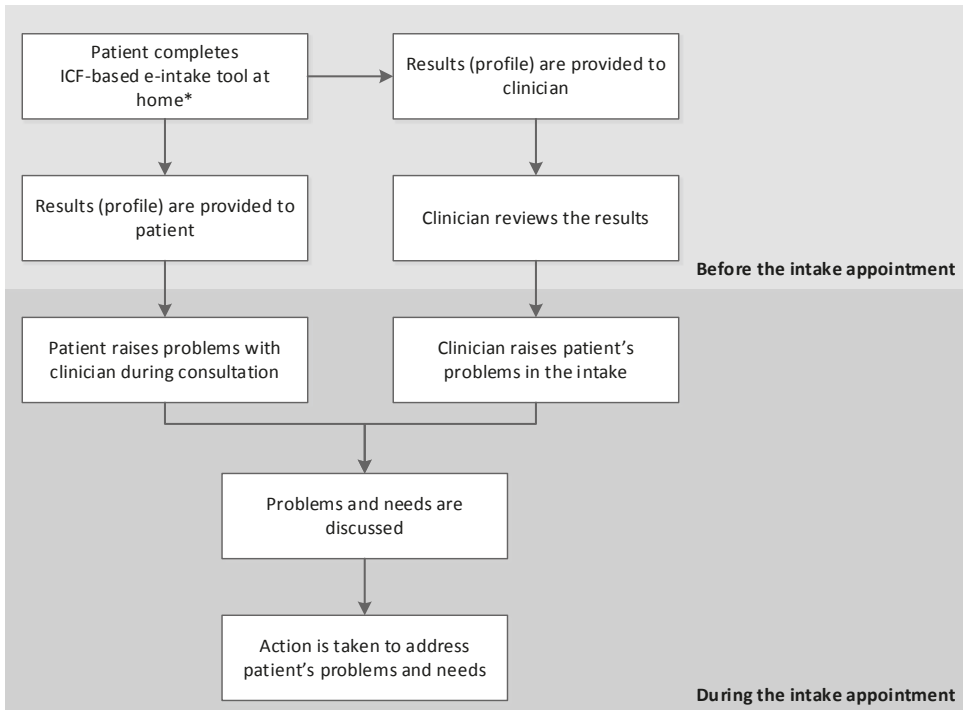
INTRODUCTION

The consequences of ear and hearing problems are multifaceted and often go beyond the level of ear and auditory impairments in structures and functions: various aspects of functioning in daily life, an general health can be negatively affected (e.g., restrictions in social relationships, inability to perform work, depressed mood)¹⁻⁵. Promoting, maintaining, and improving overall functioning from a holistic perspective, instead of applying a mere focus on impaired body structures and functions is increasingly recognized as the primary target and point of departure in clinical audiology routine and research^{1, 6-10}. To successfully assess the level of functioning of an individual with hearing problems, it is necessary to capture the whole spectrum of a person's impairments, activity limitations, participation restrictions, and relevant contextual factors from a bio-psychosocial perspective of health¹¹. According to Hopfe et al. (2018)¹², such functioning information would form a good basis for identifying all relevant aspects that should be addressed in their care. More specifically, identified problems can then be translated into needs for health, rehabilitation, and possible other services, thereby informing and supporting the care of individual patients^{12, 13}. However, a challenging issue in oto-audiology clinical practice was the lack of a universal definition and an instrument describing functioning in a standardized way^{7, 11, 14-17}.

The International Classification of Functioning, Disability and Health (ICF) of the World Health Organization provides a comprehensive framework to describe functioning, and is based on a bio-psychosocial model of health¹⁸. According to the ICF, an individual's level of functioning is the outcome of a complex interaction between a health condition, body function and structures (emotional, cognitive, and physical functions and anatomy), activities (tasks and demands of life), participation (engagement in life situations), and contextual factors. Contextual factors are distinguished into environmental factors (i.e., elements within the physical, social and attitudinal world of an individual that can act as a barrier to or facilitator of functioning), and personal factors that influence how disability is experienced by the individual (e.g., gender, age, habits, lifestyle, coping styles)¹⁸. To make the ICF specific for adults with hearing loss, the ICF Core Sets for Hearing Loss (CSHL) were developed^{7, 15}. These CSHL are shortlists of ICF categories that are considered most relevant for describing relevant functioning domains (body functions, body structures, activities, and participation) and environmental factors in adults with hearing loss. The Brief ICF CSHL provides a minimal standard for identifying these issues associated with hearing problems, whereas the Comprehensive ICF CSHL is meant for multi-professional comprehensive assessment^{7, 15}. The Core Sets are developed through a WHO-defined process, including three phases: Preparatory Phase, Phase I, and Phase II. The Preparatory Phase consisted of four scientific studies, addressing the selection of relevant ICF categories from different perspectives: (1) a systematic literature review of outcome measures used in research on adults with hearing loss and (2) linking these to the ICF classification (researcher perspective), (3) an internet-based international expert survey with hearing health professionals (expert perspective), and

(4) qualitative focus group interviews with Dutch and South-African adult patients (patient perspective). The information collected during the Preparatory Phase was presented at a consensus meeting (Phase I), at which consensus was reached on the final set of ICF categories to be included in the CSHL¹⁹⁻²². Phase II is currently ongoing, aiming to validate and implement the Core Sets in practice²³. Note that the Core Sets provide a minimal standard to describe the typical spectrum of problems in functioning. This standard may be extended for any purpose stated, such as according to the needs of the specific setting²⁴. In our previous two studies, we evaluated whether the content of the Core Sets were represented in the intake documents of oto-audiology practices in the Netherlands and USA. We examined the ‘overlap’ (i.e., the percentage of CSHL categories included in the intake documentation). Both studies showed substantial overlap (50 to 100%), supporting the CSHL’s content validity^{16, 17}. However, there was also partial ‘non-overlap’, especially in psychosocial topics, indicating that current intake procedures may not cover all aspects relevant to patients with ear and/or hearing problems (as indicated by the CSHL). In addition, the ICF’s category sleep function and various personal factors (currently not included in the CSHL), emerged from the intake documents as potentially relevant for functioning, and thus suggested that the CSHL may need to be expanded.

Whereas the CSHL covers a list of aspects that would need to be considered to describe functioning, it is not known *how* this should be done. In other words, operationalization of the CSHL can take different forms. The aim of the current study was to operationalize the Brief CSHL into a tool to be used as an intake (admission) instrument for patients visiting the oto-audiology department for the first time. This tool is further referred to as “ICF-based e-intake tool”. Given that an individual’s functioning is best assessed from the patient’s perspective²⁵, we chose to operationalize the Brief CSHL into a Patient Reported Outcome Measure (PROM). PROMs can serve different purposes in clinical practice. They can serve as diagnostic screening tools, tools to monitor health (e.g., during and after rehabilitation), decision aids, and as a means to monitor quality of patient care²⁶. The goal of our tool is to *screen* adults with ear and/or hearing problems (for simplicity, these are further indicated as: ‘ear and hearing problems’) to be able to *identify* the problems and environmental and personal factors that are relevant to their functioning. This screening is done prior to their treatment, and is meant to support the intake procedure and subsequent treatment or intervention. By 1) providing an overview of the patient’s responses (i.e., his/her ‘functioning profile’) both to the clinician *and* the patient before the intake appointment; 2) by discussing the profile during the intake appointment, and 3) by providing tailored follow-up actions or treatment opportunities within the tool, we aim to support patient-centred care and shared decision-making. The pathways through which we expect the intake tool may support such personalized care planning of individuals with ear and hearing problems is summarized in Figure 1²⁷.



*Preferably the patient completes the intake tool at home, at a time and moment of their own choosing. When this is not possible, the intake tool can be completed in the waiting room.

FIGURE 1. Logic model of the intake tool's feedback mechanisms, in which an integral assessment of the patient is obtained. *Modified from Greenhalgh et al. (2017)²⁷*

It is important to recognize that the intake tool in itself will not assure patient-centred care²⁸. Rather, the functioning profile may act as a potential facilitator of patient-centred care. It is envisaged as a starting point of the intake process, enhancing communication between the clinician and the patient about the experienced challenges in functioning, clarifying priorities for care, and fostering equal partnership in determining treatment.

The objective of this paper is to describe the process of developing the self-reported part of the intake tool. The other part of the tool (i.e., providing treatment options tailored to the results of a particular patient) still is a future step at the moment of writing, and will be described in a future study. The development of a measurement instrument usually comprises the following six steps: 1) definition and elaboration of the construct intended to be measured, 2) choice of measurement method, 3) selecting and formulating items, 4) choice of scoring method, 5) content evaluation, 6) field-testing²⁹. Steps 1-2 were previously determined for the intake tool, and have been explained above. This study focuses on steps 3-5. These were carried out using a mixed method design, and included: the selection of appropriate items from a pool of items of existing, commonly used PROMs, a formal decision-

making process, and qualitative content assessments. In addition, the integration of the ICF-based e-intake tool in a computer-based system is described.

MATERIALS AND METHODS

Selecting and formulating items and choice of scoring method

A). Selection of categories to be represented in the ICF-based e-intake tool

Additional categories to the Brief CSHL were selected based on our previous study¹⁷ and on the basis of expertise of clinicians (i.e., experienced audiologist, ENT surgeon, and psychologist).

B). Formulating items for the selected ICF categories

The method used to formulate items for the Core Set categories involved a formal decision-making and consensus process in the multidisciplinary project team consisting of an ENT surgeon, audiologist, psychologist and researchers.

First, a pool of items was developed by linking the items from existing questionnaires to the ICF categories of the Brief CSHL and the selected additional categories. This item pool was used to determine which specific items were found to be appropriate to measure the corresponding category. The linking study by Granberg and colleagues²⁰ in which outcome measures were linked to the ICF was used as a reference. Each member of the project team evaluated and rated the relevance of each item (Phase A). The items were selected from (1) existing ear and hearing questionnaires that are relevant for the field as shown by the review study by Granberg et al.¹⁹, that were available in the Dutch language, (2) additional questionnaires routinely used in Dutch clinical oto-audiology practice at the time of the study, and (3) general functioning questionnaires based on the concepts of the ICF (e.g., WHO Disability Assessment Schedule 2.0 (WHODAS 2.0)³⁰; World Health Survey (WHS)³¹). This item pool was used to select specific items that were considered appropriate to screen the ICF categories. Each member of the project team evaluated and indicated the relevance (yes, no) of each item and provided additional comments to motivate their choice (Phase A).

Second, the results of Phase A were discussed in various meetings until consensus was reached about operationalization of each ICF category. New items were created in cases where existing items could not be linked to the particular category, or where they were considered unsuitable. For the formulations of particular constructs of these items, we used the official descriptions of the ICF categories as formulated by the WHO (e.g., e3 support and relationships: “people or animals that provide practical physical or emotional support, nurturing, protection, assistance and relationships to other persons, in their home, place of work, school or at play or in other aspects of their daily activities”). For all items, rules were drawn up to secure uniform formulations (e.g., regarding the recall period, and the experienced degree of difficulty).

C). Determining scoring method

For existing items that were adopted verbatim, scoring was based on the original answer categories. For the items formulated by the project group, the ICF qualifiers were used to describe the extent of a problem in a particular domain (i.e., no problem (0); mild problem (1); moderate problem (2); severe problem (3); complete problem (4))¹³.

Phases A-C resulted in a preliminary item list agreed upon within the project team.

Content evaluation

The aim of this part was to test whether the item list was judged relevant (all items should be relevant for the construct of interest within a specific population and context of use), comprehensive (no key aspects of the construct should be missing) and comprehensible (the items should be understood by patients as intended)³². The preliminary item list was therefore administered to a panel of relevant stakeholder representatives. After that, it was piloted in a group of patients.

D). Expert survey

An expert survey was conducted among Dutch representatives of all relevant stakeholders i.e., patients, audiologists, ENT surgeons, a general practitioner, and a clinimetrician/methodologist. The selection of experts was based on a convenience sampling method and recruitment took place through the contacts of the project team members via email. When an expert indicated to be willing to participate, L.v.L. explained the study in more detail via email or telephone and sent the expert survey via email. Consent was implicit by agreeing to participate in the expert survey via email, after which the survey was sent. The representatives were asked to score each item on its relevance and comprehensibility. In addition, the item list was rated on comprehensiveness and the order in which the domains and associated items were queried. At the end of the survey, respondents were able to provide additional comments. See Appendix 1 for the survey questions. In addition to the expert survey, the main developer of the ICF CSHL (dr. Granberg) was consulted for feedback on the item list. This was done by using survey questions via email. Specific attention was asked for the operationalization of the hearing related categories. This was done because the description of ICF categories relating to hearing, listening, and communication are unclear and overlapping (as previously pointed out by the developers²⁰).

E). Patient pilot-study

The modified item list was tested in a small sample of patients who were randomly selected from the VUmc patient pool of new patients that were scheduled for their first appointment. Patients were recruited at Amsterdam UMC, location VUmc in Amsterdam, the Netherlands. Patients were included who: visited the outpatient clinic of the VUmc for an ear and/or hearing problem for the first time, were 18 years or older, and who spoke Dutch. A maximum variation strategy³³ was applied to select participants, with regard to patients' ear/hearing

problem(s), gender, and age. This way, we aimed for a heterogeneous group of patients, covering the full spectrum of oto-audiology characteristics, with an equal gender distribution, and a wide age range. Recruitment of patients took place via the secretary of the department, who sent an information letter two weeks prior to the scheduled intake visit per email. When a patient indicated to be willing to participate, L.v.L. explained the study in more detail and scheduled the study interview. Recruitment of new patients ceased when variation was achieved. Patients were interviewed directly prior to their appointment with the audiologist or ENT surgeon. They were therefore asked to arrive half an hour earlier.

All patients were interviewed at the outpatient clinic of VUmc. Prior to the interview, written informed consent was obtained. The intake tool was administered in a digital format. Interviews were held in Dutch. The aim of the pilot study was to study the relevance, comprehensibility and comprehensiveness of the intake tool. This was done based on the "three-step test" interview (TSTI)³⁴. The TSTI combines observational and interviewing techniques to identify how items are interpreted and whether problems occur during completion of the item list. The TSTI comprises three consecutive steps: concurrent thinking aloud, retrospective interview, and a semi-structured interview using an interview guide.

- During the first step, the interviewer observed the patients as they were completing the item list. Patients were asked and encouraged to verbalize their thoughts while doing so. The interviewer used prompts to encourage the patient to verbalize his/her thoughts. The patient's comments and interviewer's observations were written down by the interviewer. The time needed to complete the item list was also noted by the interviewer.
- During the second step, patients were interviewed regarding their response behaviour and comments made during the first step.
- During the third step, a brief structured interview was conducted about the comprehensibility and comprehensiveness of the item list, the format of the intake tool and how the patient preferred to view the results of the completed item list. In addition, patients were invited to share any additional comments about the intake tool. See Appendix 2 for the interviewer prompts and interview guide.

To minimize patient burden, a time slot of 30 minutes was reserved for the interview. The digital item list was pre-tested by colleagues, and it was judged this time slot should be feasible to complete the item list in about 15 minutes (first step) and complete the interview in the other 15 minutes (i.e., second and third step). In one case, the intake consult was postponed somewhat (with the consent of the patient and the clinician) so that sufficient time would be available for the interview. No repeat interviews were carried out.

Data analysis:

For the data collected in the expert survey, results and comments were summarized by L.v.L. and discussed within the project group. Items were modified based on consensus in the project group.

All patients were interviewed by a researcher who was trained and experienced in qualitative research methods (L.v.L.). Please see Appendix 3 for the researcher's characteristics, which have been reported according to the COREQ criteria³⁵. All patient interviews were audio-recorded and transcribed verbatim. Qualitative content analysis was used to analyse the data³³. Coding was on item level (except for comments made in step 3 which concerned the item list as a whole and lay out of the intake tool), across the 3 steps of the interview. Comments and problems were labelled based on content and subsequently grouped into categories. Transcription and coding were performed by L.v.L., under supervision of M.P. and S.K.. Transcripts were not returned to participants for comment or correction. Results were discussed and items were modified based on consensus in the project group.

This study was approved by the Medical Ethics Committee of the VU University Medical Centre, Amsterdam, The Netherlands (reference number 2013-067).

Digital format

For mode of administration we explored various options to integrate the intake tool in a digital format. This was done to allow for a rapid provision of the patient's 'functioning profile' to the patient and clinician to be used in the intake.

RESULTS**Selecting and formulating items and choice of scoring method***A). Identification of categories to be represented in the ICF-based e-intake tool*

a total of 39 categories were chosen to be covered in the intake tool, including 27 categories from the original Brief CSHL and 12 additional categories.

Additional categories were added based on our previous research. These categories were:

- Sleep functions (i.e., b134) and Personal Factors. Our previous study showed that sleep functions and personal factors are important for the patients with ear and hearing problems, and these categories are not part of the Core Set¹⁷. Literature substantiates the relevance of these categories for this patient group^{21, 36-40}, and therefore the project team decided to include them in the intake tool.

Additional categories that were added based on clinical expertise within the team were:

- The subcategories of the ICF categories (i.e., third-level) b230 'hearing function' and b240 'sensations associated with hearing and vestibular functions' (i.e., b2301-

- b2304 and b2400-b2405). The project team decided to include these specified categories as the Brief CSHL includes only second-level categories⁷. Hearing impairment and ear complaints are the ‘core business’ of ear and hearing care, and therefore more detailed information on hearing functions and ear functions was preferred;
- The ICF categories b250 ‘taste function’ and b255 ‘smell function’. These were included because in the field of otology these are considered important indicators for nerve damage to the auditory organ.

Please note that Personal Factors are not yet classified within the ICF. However, a list of examples is available from the ICF and these include: demographics, other health conditions (HCs), coping styles, social background, education and profession, past life events, overall behaviour patterns, and other factors playing a role in disability¹⁸. In addition to demographics, other HCs, social background, education and profession, the constructs chosen to operationalize personal factors were mastery and coping behaviours in communication situations. These constructs were selected, because with our intake tool we aimed for 1) a global view of personal factors that indicate how people deal with setbacks such as diseases (including hearing impairment/ ear problems) (i.e., mastery), and 2) a specific view of personal factors that indicate how the patient deals with his/her ear and hearing problems at the moment (i.e., coping behaviours in communication). Mastery is the extent to which a person perceives one’s life as being under one’s own control in contrast to being fatalistically ruled⁴¹. It is considered as a relevant psychosocial resource when coping with stressful life events. For example, a higher sense of mastery is associated with better psychosocial adjustment to the hearing impairment in older adults⁴². Regarding coping behaviours, evidence shows that applying maladaptive (as compared to adaptive) coping behaviours can lead to higher levels of hearing disability, and subsequent psychosocial problems in people with hearing impairment (e.g., ⁴³).

B-C). Operationalization and scoring

The ICF categories were divided into the following domains: (1) general information, including reason for visit, sociodemographic and medical background related items; (2) general body functions; (3) ear and hearing structures and functions; (4) activities and participation; (5) environmental factors; and (6) mastery and coping. Below, per domain is described how the categories were operationalized.

General information (Personal Factors)

In a previous qualitative study patients indicated that they would like to start the intake tool with reporting the reason for their visit to the outpatient clinic. This way, the focus of the visit would be clear to the professional⁴⁴. Therefore, the category “reason for visit” was included as the first item.

For the operationalization of demographics, other HCs, social background, education and profession-related factors, items were based on similar items used in large national studies (i.e., LASA⁴⁵; and NL-SH⁴⁶).

General Body Functions

For the operationalization of body functions, items were based on the content and wording of the items in the Speech Spatial and Qualities Questionnaire (SSQ)⁴⁷, items used in a large national cohort study (LASA)⁴⁵, WHODAS 2.0, WHS and WHO's official descriptions of ICF categories. Items were formulated as "How much difficulty do you have ... [with sleeping]". Scoring was based on the ICF qualifier to specify the degree of difficulty.

For the operationalization of body functions category 'temperament and personality functions', the construct self-esteem was selected. This was done on the one hand because it is known that a poor hearing status can negatively affect self-esteem (e.g., ^{42, 48}). And on the other hand, the level of confidence/self-esteem can influence the management of hearing loss, for instance through applying certain coping strategies^{49, 50}. Moreover, it is known that involvement from the social environment can positively address incurred hearing losses and lead to important benefits including higher self-esteem⁵¹. Lastly, hearing loss management through taking up hearing aids negatively influences one's confidence levels (stigma) while it could also improve self-esteem (because communication improved). 'Emotional functions' was operationalized through the constructs feelings of loneliness, depressive complaints, and anxiety complaints. These constructs are known to be commonly affected by ear and hearing problems (e.g., ^{42, 52-54}).

Ear and hearing Structures and Functions

For the operationalization of the ICF categories on ear structures, a figure was made in which the patient could indicate where he/she thinks his/her ear and hearing problem is located. Also the response option 'I don't know' was added. It was decided that it would be relevant to know how well the patient would be able to indicate the location of the hearing or ear problem, to discuss this during the intake and to be able to nuance or correct perceptions.

For the operationalization of the hearing, listening, and communication ICF categories (i.e., b230, d115, d310, d350 and d360), the project group agreed to use the validated, 28-item version of the Amsterdam Inventory for Auditory Disability and Handicap (AIADH)^{55, 56}. The AIADH is being used widely in Dutch clinical practice for hearing aid rehabilitation. The AIADH assesses self-reported disabilities and handicap in everyday hearing. The AIADH items cover five hearing domains via five subscales: auditory localization, intelligibility in noise, intelligibility in quiet, detection of sounds, distinction of sounds. For each of the five factors, we selected the most discriminating item based on Item Response Theory⁵⁶. For instance, for the factor 'auditory localization', the item "Can you hear from what corner of a lecture room someone is asking a question during a meeting?" was chosen, because this item had the

highest discriminative ability to indicate auditory disability. In addition to selecting the items with the highest discriminatory power, the additional items on ‘conversations over the telephone’ and ‘conversations in quiet’ were chosen so that all ICF categories were represented. Scoring was based on the original 4-point response scale, “never, sometimes, often, always”.

For the operationalization of ear problems, wording was based on clinical expertise, and the operationalization ran parallel to, and was influenced by, the development of the Otology QUestionnaire Amsterdam (OQUA)⁵⁷. Scoring was based on the ICF qualifier system, by which the severity of the complaint can be graded.

Activities & Participation and Environmental Factors

For the operationalization of ICF categories in the A&P and EF domains, formulation was based on the wording of WHODAS 2.0 and WHS items and WHO’s official descriptions of ICF categories. Items in the A&P domain were formulated as “How much difficulty do you have in ... [participating in community activities]”. Items in the EF domain were formulated as “To what extent do you feel supported/ hindered in you daily functioning by ... [your healthcare providers]”. Scoring was again based on ICF qualifier system, to specify the degree of difficulty (A&P) and degree of perceived support and degree of impediment (EF).

Mastery and coping behaviour (Personal Factors)

The construct of mastery was operationalized using an abbreviated 5-item version of the Pearling Mastery Scale⁴¹. The scale measures the extent to which an individual regards their life chances as being under their personal control rather than being fatalistically ruled. Scoring was based on the original 5-point Likert scale, ranging from “strongly disagree” to “strongly agree”.

For the operationalization of copying behaviour relating to hearing impairment, items of the subscales ‘communication strategies’ and ‘personal adjustment’ (including embarrassment and acceptance of the ear and hearing problem) of the Communication Profile for the Hearing Impaired (CPHI) were chosen. Similar to the items of AIADH, CPHI-items with the highest discriminating power were included as reported in⁵⁸. Scoring was based on the original 5-point Likert scale, ranging from “strongly disagree” to “strongly agree”. In addition, the response option ‘not applicable’ was included to give patients the possibility to indicate that the situation did not apply to their personal situation.

Content evaluation

D). Expert survey

All invited experts responded positively to the invitation and expert survey. In total, the preliminary item list was assessed by 10 stakeholders: 4 patient representatives from Dutch patient organizations, 2 audiologists (1 from an secondary centre and 1 from an academic centre), 2 (resident) ENT surgeons (1 from an secondary hospital and 1 from an academic hospital), a general practitioner, and a clinimetrician/ methodologist.

With regard to the relevance of the items, most experts rated the items as relevant, but an important comment was made by the clinicians. Initially, patients had to answer the item in relation to its influence on functioning in daily life in general. However, clinicians indicated that these questions would be more relevant when they would be explicitly related to the patient's ear and/or hearing problems.

With regard to the comprehensibility of the items, items were generally well understood but some suggestions for clarification of the particular items' formulation or response categories were made.

With regard to the comprehensiveness of the total item list, no important domains were considered to be missing. One of the patient representatives indicated the need for the opportunity to further explain his/her given pre-defined answers on the items. The order of the item list was found adequate.

E). Patient pilot study

Forty-seven patients were invited, and eleven patients participated in the TSTI (response rate 23%). Table 1 shows their characteristics. The categorization according to the International Classification of Diseases version 2010 (ICD-10) - chapter VIII, "Diseases of the ear and mastoid process": diseases of the external ear; diseases of the middle ear; diseases of the inner ear; and other diseases – shows that the patients represented the broad range of ear and hearing problems that can be expected in oto-audiology care.

TABLE 1. Characteristics of participants involved in pilot testing (N=11)

Variable	Total	Otology patients	Audiology patients
Number of participants	11	6	5
Gender male/female	5/6	2/4	3/2
Age in years mean (range)	59.8 (44-75)	60 (45-75)	59.5 (44-68)
Diagnosis, N			
<i>Diseases of external ear (H60-H62)</i>	1	1	
<i>Diseases of middle ear and mastoid (H65-H75)</i>	1	1	
<i>Diseases of inner ear (H80-H83)</i>	1	1	
<i>Other diseases of the ear (H90-H95)</i>			
• <i>Hearing loss</i>	6	2	4
• <i>Tinnitus</i>	2		2
• <i>Cochlear implant</i>	1	1	
Education level, N			
<i>High</i>	5	2	3
<i>Moderate</i>	4	4	
<i>Low</i>	2		2

The mean time to fill in the item list was 16 minutes (range: 9-24 minutes).

Steps 1 and 2: Thinking aloud and retrospective interview

The data collected in steps 1 and 2 showed that every patient encountered problems with at least one of the items of the intake tool. All patients filled in every item. Three categories of comments/problems were identified: (1) problems with response options; (2) difficulty with formulations; (3) response to the item would depend on the specific situation. These categories are discussed below.

Problems with response options

One respondent mentioned she found it difficult to choose between the response categories that indicated the degree of difficulty she experienced.

“Then I think ‘maybe it is not so bad [the ear problem]’, for example compared to others. I find it very difficult to say such a thing about yourself”.

Two respondents indicated problems with the item about localization of the ear/hearing problem. They did not know how to answer this question.

Difficult formulations

Almost every patient encountered problems with answering the environmental factors items. Problems related to the fact that each category was questioned twice, i.e., first to what degree the category acted as a barrier to the person’s functioning, and then to what degree the category acted as a facilitator of the person’s functioning. Patients suggested that only one item per category should be asked, and this could be either in the formulation as a barrier

or a facilitating factor. In addition, the item about the accessibility to care was not well understood. One respondent reported to have problems with the item about which chronic diseases are experienced 'at this moment'. The respondent indicated to have had problems, but he "*did not suffer from it at this moment*", and therefore did not know how to answer this item. Another respondent thought the item on feelings of loneliness was difficultly formulated.

Response would be dependent on specific situation

Some patients indicated that the answer on items "*depended on the situation*", but could always answer the question after some consideration. For example, regarding the item about difficulties when attending education, one respondent reported that the answer on this question would depend on whether the education material was provided orally or in a written fashion. Another example was the items on coping behaviour (personal factors). It was reported that whether or not to cope well would depend on the specific (social) situation. One respondent suggested to include the option to provide comments in the items, to be able to better explain or nuance the chosen response category.

Instructions were not read

A consistent observation was that patients did not always read the instructions at the beginning of each domain or subset of items.

Step 3: Structured interview

The data collected in step 3 showed that all patients thought that the intake tool was relevant in the context of their intake. Regarding the content of the item list, patients stated that the items were relevant to them, and comprehensible for the most part (except for those on environmental factors). Regarding the comprehensiveness of the item list, some patients indicated that more detail on some specific complaints would be desirable but they did not miss any key concepts. They also agreed on the general nature of the intake tool and mentioned that further specification may not be feasible. Regarding the lay-out of the item list, it was mentioned twice that the font size should be somewhat bigger. Regarding the presentation of the (future) functioning profile, patients found this difficult to comment on because they found it hard to envisage. The option to be able to save or print the filled-out form seemed the most convenient for them. Regarding the layout of the intake tool, a simple format and a low quantity of questions per screen was preferred.

Amendments to the intake tool

Based on the responses of the experts, changes were made in the instructions of the items of the activities and participation and environmental factors domains so that they specifically address these factors in relation to the patient's ear and hearing problems. The description was adjusted into "The following questions are about the influence of your ear and hearing problem on your daily activities" (A&P) and "The following questions relate to the influence

of different environmental factors on your daily functioning. With regard to your ear and hearing problem, indicate to what extent these provide support for your daily functioning” (EF). In addition, some items were modified to improve the wording of the item.

In response to problems that patients encountered while answering the environmental factors items, the items and response categories were adapted. From the literature it is known that positive items are generally preferred. Therefore, only items about the facilitating effect of the item were retained. In addition, the item about the accessibility to care was simplified. The items that were adopted from existing questionnaires were retained despite the (few) identified problems. The instructions therefore should receive more emphasis by using a bold font style and in case of a page break within the same domain the instructions need to be repeated at the top of the new page. The table with the final item list is available in Appendix 4.

Digital format

The online portal “KLIK” was chosen to implement the intake tool. The KLIK method provides an online environment to administer PROMs digitally. The use of KLIK is as follows. Before the intake visit, patients are asked to register to the online portal (www.hetklik.nl). After completion of the questionnaire, the patient’s outcomes are digitally presented and converted into a “functioning profile”. A three-colour traffic light system was chosen to be used to indicate in which area(s) further detailed examination(s), action(s) and/or intervention(s) are needed. Figure 2 provides an example of such a functioning profile. Because the cut-off points can only be determined after sufficient data collection, the traffic light system could not be utilized for the first version of the tool. The functioning profile can be saved as PDF and/or can be printed. This way, it could be used by patients in preparing for and during the intake appointment. Moreover, the PDF-format allows it to be added to the patient’s medical file such that it is visible to clinicians.

ACTIVITIES AND PARTICIPATION	
How much difficulty do you have in dealing with stressful situations?	Severe difficulty
How much difficulty do you have in interacting with your immediate family members? (for example with you father, mother, partner, child)	No difficulty
How much difficulty do you have when attending education or courses?	Moderate difficulty
Think about your (volunteer) work for the next question. How much difficulty do you have in carrying out your important work tasks?	Moderate difficulty
How much difficulty do you have in participating in community activities (such as festivities, religious and other activities)?	Mild difficulty

FIGURE 2. Example of electronic Functioning Profile, domain Activities and Participation, using traffic lights. *Note: This figure is purely illustrative and not based on cut-offs*

DISCUSSION

This study aimed to operationalize the recently developed ICF Brief Core Sets for Hearing Loss⁷ into an intake tool for patients with ear and hearing problems visiting the audiology or ENT outpatient clinic for their problems. This study is considered to be part of Phase II of the WHO's Core Set's development process²³. The ICF-based e-intake tool assesses the functioning in patients with ear and hearing problems, and also includes the assessment of potentially influencing environmental and personal factors. The current version of the intake tool covers 39 ICF categories. It comprises 62 items and it takes approximately 16 minutes to complete.

Content validity is the most important measurement property of a PROM³². The results of the current study present preliminary evidence to support the content validity of the tool as an instrument to screen for ear and hearing problems relating to functioning, and the environmental and personal factors that may interact with these problems. Furthermore, overall, the intake tool was perceived to be relevant and to have a logical and clear structure, as indicated by the stakeholder representatives and the patients that participated in the pilot study.

The tool was integrated into a digital, web-based patient system called KLIK. The integration of the intake tool into such a system will enable its use by clinicians⁵⁹. For instance, we are able to use routing pathways that offer certain items based on a patient's response on a previous item, to integrate algorithms for data interpretation, and to present a summary of the patient's answers in a graphical functioning profile. KLIK has been adopted and implemented for PROMs in different settings and in different hospitals across the Netherlands, in both child and adult care⁶⁰. The feasibility and user-friendliness of our intake tool in oto-audiology patients will need to be further evaluated to optimize its intended use in clinical otology and audiology practice.

Clinical implications

Patient-centred care

The intake tool is developed with the ultimate aim to improve patient-centred care in oto-audiology practice. It is important to recognize that the intake tool in itself will not directly cause patient-centred care²⁸. Rather, the functioning profile of the intake tool may act as a facilitator of patient-centred care. It is considered a starting point of the intake process, enhancing communication between the clinician and the patient about the experienced challenges in functioning, clarifying priorities for care, and fostering equal partnership in determining treatment⁶¹. In addition, it is important to emphasize that the goal of the intake tool is not to replace the intake appointment, but to serve as an aid to facilitate the intake conversation.

Several studies have addressed the impact of self-reported instruments on the (intake) appointment with the clinician. Reviews provide evidence of improved patient-clinician communication, better identification of psychosocial problems, and better guidance in clinical decisions made in response to patient-reported symptoms⁶²⁻⁶⁶. However, whether the intake tool will indeed facilitate patient-centred care, will partly depend on its successful implementation. That will imply shifts in practices for both patients and clinicians in order to accommodate the collection and the feedback of the patient-reported information. Changing practices is known to be challenging⁶⁷⁻⁶⁹. In parallel studies, we identified the perceived barriers to and enablers of using the intake tool⁴⁴, and used this information for the development of an implementation intervention⁵⁹.

A tool for clinical oto-audiology practice

With our intake tool, we opted for an integrated and uniform approach to collect functioning information in the initial contact, independent of the specific oto/audiology discipline the patient encounters first. Information about a person's functioning documented during the intake should facilitate a proficient and interconnected collaboration between the team members during the care process, i.e., by using the standardized intake tool in both disciplines.

Operationalization of other ICF Core Sets

Over the past few years, operationalization of ICF Core Sets for use in clinical practice occurred in other domains. Examples are the Brief Core Set Questionnaire of Breast Cancer for Screening in cancer care (BCSQ-BC-S)⁷⁰, the Work rehabilitation Questionnaire for vocational rehabilitation (WORQ)⁷¹, a health index for patients with ankylosing spondylitis (ASAS-HI)⁷², the Neuromuscular disease impact profile for neuromuscular diseases (MDIP)⁷³, and the ICF CS based questionnaire for non-traumatic spinal cord injury⁷⁴. Contrary to our diagnostic screening tool, these PROMs were developed to measure the effect of treatments or interventions on functioning; they also not consider contextual factors. In the current project, the concept of functioning is considered very broadly, and consist of multiple domains and categories (i.e., underlying constructs). We chose for a tool that facilitates a quick, standardized screen for ear and hearing-related functioning issues to highlight aspects that need further examination and/or actions. It is known that having only one to two items to measure a construct generally yields insufficient reliability for evaluative purposes⁷⁵. Including more items per construct was discussed within the project team, but this would yield a too lengthy questionnaire and therefore would result in an unacceptable patient burden. If effect measurement of treatments would be desired in the future, a more detailed assessment of sub constructs of functioning could be obtained by combining the tool with validated symptom-specific questionnaires. For example, to measure improvement in self-perceived disability and handicap in everyday hearing, the full version of the AIADH could be incorporated. Similarly, to measure the effect of treatment or interventions on patient's coping behaviour, the full CPHI could be added. Also other PROMs not part of the intake tool

may be used. Examples are the Dizziness Handicap Inventory to measure dizziness. Such multi-item scales would then also be suitable for follow-up measurements as they have better sensitivity and responsiveness than 1 or 2-item scales. Such an approach fell outside the scope of the current project and if effect evaluation is strived for, this will need to be researched in the future.

International perspective

With regard to the international use of the CSHL, the following objectives are considered important: 1) To promote and guide further development of Core Sets for use in clinical practice, research and education in the field of Audiology, 2) To develop strategies for the implementation of the ICF Core Sets for HL in clinical practice, 3) To encourage international collaboration and alignment in these processes, 4) To promote (and support where ever possible) use of guidelines for translation and cross-cultural adaptation to enhance confidence in the functional equivalence of translated versions of the same hearing-related instrument for use in different language and cultures⁷⁶. Similar activities to operationalize the Brief Core Set through a PROM are ongoing in the US^{16, 77, 78}, and in Sweden⁷⁹. The experience gained in our study, in combination with the other initiatives, are of major importance to achieving the working group's goals.

Methodological considerations

Operationalization

We chose to operationalize the ICF-category 'emotional functions' into feelings of loneliness (item 14, Appendix 2), sorrow, sadness, depressive complaints (item 15, Appendix 2), and feelings of worry and anxiety (item 16, Appendix 2). With regard to psychological personality traits in the component personal factors, 'mastery' and 'coping behaviour' were selected. The importance of all of the selected categories is evident from the literature. Altogether we argue that these provide a representative picture of a patient's personality/intrinsic factors potentially influencing living with ear and hearing problems in daily life. Nevertheless, the choice for including only these two categories may seem arbitrary and other additional categories could have been considered. An example is frustration, which is a well-known consequence of hearing impairment^{1, 80}. Another consideration concerns existing difficulties with regard to the conceptualization and categorization of personal factors^{81, 82}. For example, the psychological assets in the personal factors component (e.g., emotional reactions) seem to overlap with the categories of mental functions of the BF component. This was also the case in the current study. We tried to adhere to the descriptions of the ICF categories, but the choice for the operationalization of embarrassment as a personal factor rather than an emotional reaction (see items 53 and 55, SCD 1), may therefore be regarded as somewhat arbitrary.

Another possible shortcoming of the operationalization process may be the consensus being based on expertise from a small group of experts from one hospital setting. Consequently, choices were made based on preferences within this setting and thus may not apply in other (hospital) settings. However, we validated our choices as much as possible by testing the draft item list in a broader expert group and in a heterogeneous sample of patients.

Different response formats were selected for the different domains in our intake tool. Previous research showed that mixed response scales may be confusing for respondents⁸³. Moreover, it is known from the literature that the patient's self-reported data should be easy to interpret by the clinician in order to facilitate its implementation⁶⁵. Mixed response scales may hamper that. However, both experts and patients included in the content assessment did not report important problems with the response scales (except for the domain of environmental factors, which was adapted accordingly). With regard to clinician burden and ease of using the intake tool, our other study in which we identified the barriers and enabler to use the intake tool, indicated that clinicians indeed preferred a simple overview of easy to interpret results⁴⁴. At this point in the development process, such an overview has not been developed and considered for review by the clinicians yet. This will be addressed during next steps of the development and testing of the tool (see further under 'Future research directions').

Content assessment

With regard to the data of the patient pilot-study, bias could have occurred because the interviewer was also part of the project team. However, the aim of the pilot study was to ensure that the questionnaire content would match the target group, so the interviewer was motivated to know all the critical points in order to be able to improve the content of the item list. Therefore, we do not expect this was a negative factor. A limiting factor was the use of closed-ended questions in the interview guide, which may have limited the respondents' answers and more detailed explanations of their experiences with the item list.

Generalizability

Another possible limitation is that the tool is developed in Dutch, and decisions were made based on the Dutch health care system. Instruments must fit into the health care system where they should be applied²⁶. The current version of the intake tool is intended for use in the Dutch otology and audiology system, which - for now - limits its use to Dutch speaking patients. Its application and generalizability to other countries and care systems would need to be addressed in future work.

It may be argued that it this study was limited in the sense that the consensus meeting on the selection and initial formulation of the items did not include patient representatives. As already mentioned in the Introduction, the development of the ICF Core Sets for Hearing Loss did include patients' participation in various stages of the Core Sets' development and

consensus process. The patient perspective on functioning with hearing loss was carefully mapped in a qualitative focus group study²¹. The current study did include the patients' voice in the pilot study and a wide range of ear/hearing problems was included. Nonetheless, this concerned only a limited absolute number of highly motivated patients who thus may not be representative of the average patient.

Future research directions

The suitability and use of the intake tool for all patient groups will need further evaluation in a large-scale field-test study. In addition, to make the clinician's and patient's use of the intake tool as efficient as possible, the ease of reviewing and interpreting the patient's scores will need to be addressed. For clinicians, a system that has been shown to be easy to use is the traffic light system. It is also easy to read (provides a graphical summary format), and can deliver concrete actions to take. Such a traffic light system was successfully applied in paediatric cancer care⁸⁴. However, applying it requires relevant cut-offs for the each item and/or underlying domains. Moreover, a follow-up decision tree is needed to guide clinicians on their actions (e.g., treatment options, referral to another health care professional)⁵⁹. A field-test study and the input of and consensus among clinicians will be needed to determine meaningful cut-offs. This is essential for clinicians' motivation to use the tool⁸⁵.

CONCLUSION

The current study describes the development of an ICF-based e-intake tool to be used by patients and clinicians to assess functioning in individual adults with ear and hearing problems. Based on stakeholders' responses, item instructions for activities and participation, and environmental factors were adapted and explicitly related to patients' ear and hearing problems. Patients' responses resulted in changes to the items of environmental factors. Overall, the intake tool was perceived to be relevant and to have a logical and clear structure. In addition, the tool showed sufficient content validity. The findings of the current study cover important developmental steps taken towards creating an intake facilitating individualized clinical otology and audiology services using a biopsychosocial perspective.

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APPENDIX 1. Instructions and questions expert survey

Instructions:

SURVEY EXPERT CONSULTATION	
Thank you for participating in this survey!	
Instructions:	
<ul style="list-style-type: none"> - Save this file with your name after the title of the document; - Check per question whether you find the question relevant and whether you find the question comprehensible. <ul style="list-style-type: none"> o Relevant: Is the question relevant to mapping the functioning (in the broad sense) of adults with hearing/ear problems? o Comprehensible: Is the question easy to understand and unambiguous for the target group (adults with hearing/ear problems)? - State per instruction whether this is comprehensible; - Under "Explanation and/ or other comments" you can indicate per question/ instruction why you do not find it relevant/ comprehensible and how the item should be adapted; - Sometimes you are asked how you judge the suitability of answer categories. Please indicate whether you think this is suitable (yes / no, if "no", please explain). 	
Other comments:	
<ul style="list-style-type: none"> - The questions are in orange coloured boxes; - Sometimes there is a question or instruction "[routing]". This indicates that this question is only asked if a specific answer has been given to a previous question. 	
Good luck!	

Question per instruction:

Is the instruction complete and comprehensibly formulated?

- yes
 no (please, explain below)

Explanation and/or other comments: _____

Question per item:

The question is:

- Relevant: yes
 no (please, explain below)

- Comprehensible: yes
 no (please, explain below)

Explanation and/or other comments: _____

Questions answer categories:

Are the answer categories of the above items ([domain]) suitable?

yes

no, modification is necessary (please, explain below)

Explanation and/or other comments: _____

Questions at the end of the survey:

Thank you very much for your time. There are two final questions that we would like to ask you about the questionnaire as a whole.

1. As mentioned before, the questionnaire aims to give a comprehensive picture of the functioning of adults with hearing/ear problems. Does this questionnaire give you a complete overview of all domains that are relevant to the functioning of adults with hearing/ear problems?

yes

no, modification is necessary (please, explain below)

2. The questionnaire consists of 7 parts. Do you think the order of the different parts is logical?

yes

no, modification is necessary (please, explain below)

Explanation and / or other comments: _____

APPENDIX 2. Interviewer prompts and interview guide

Think aloud prompts (step 1):

Encourage/ adjust:

- "keep talking"
- "say what you think out loud"
- "good, you are doing very well, keep it up"

Too many comments:

- "Please, only say out loud what you think as you read and answer the question. Please do not comment on these thoughts. Ignore me, pretend I am not here. In the next phase of this interview you have plenty time for additional comments".

Example interview questions regarding response behaviour and comments (step 2):

- "You said / did What did you think at that time?"
- "You stopped for a moment, what did you think at that time?"
- "Is it true that I heard you say ..?"

Structured interview (step 3):

1. Questions about the content of the questionnaire

Instruction: As described in the beginning of the questionnaire, the questionnaire is intended to provide an overview of your ear or hearing problems in daily life, with the aim to identify any problem areas prior to your intake appointment. Once you have completed the questionnaire, it will be sent to your ENT surgeon or audiologist. Together you will discuss the questionnaire during your appointment.

- Are there topics or questions that you have missed in the questionnaire?
- Are there topics or questions that are too much / unnecessary / redundant in your opinion?
- Are there any questions that you found unclear, or that you did not understand (and which we have not yet discussed in the previous step of the interview)?
- What did you think of the language used in the questionnaire?
- Do you find the order of the questions in the questionnaire logical?

2. Questions about the functioning profile

Instruction: We want to present the answers of the questionnaire in an overview, a so-called functioning profile, so that this can be used during the intake consultation. This functioning profile can be used by the ENT surgeon or audiologist during the consultation to discuss your functioning with you.

- Would you like to have this overview of answers presented to yourself before the consultation?
- How would you like to see this presented to you? (for example in graphs, or in scores etc.)

3. Questions about the layout of the questionnaire

- What do you think of the general appearance of the intake questionnaire?
- What would improve the appearance?
 - o font, font size, (background) color
- What do you think of the amount of questions per page?

4. Additional remarks

Do you have any other or additional remarks about the questionnaire?

156 APPENDIX 3. Consolidated criteria for reporting qualitative research (COREQ) - Domain 1: research team and reflexivity

Personal characteristics	Guide questions/ description	
1. Interviewer/ facilitator	Which author/s conducted the interview of focus group?	Lisette van Leeuwen (L.v.L.), first author
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	MSc.
3. Occupation	What was their occupation at the time of the study?	PhD candidate
4. Gender	Was the researcher male or female?	Female
5. Experience and training	What experience or training did the researcher have?	- Research master in epidemiology (2012-2013); - Course focus group studies (Evers Research, Rotterdam, the Netherlands) (2017); - Experience in various qualitative studies, e.g., Rainey et al., 2016 ⁱ ; van Leeuwen et al., 2017 ⁱⁱ ; Bruinewoud et al., 2018 ⁱⁱⁱ ; van Leeuwen et al., 2018 ^{iv} .
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Patients were recruited by the department's secretary, who sent an information letter two weeks prior to the scheduled intake visit. When a patient indicated to be willing to participate, L.v.L. explained the study in more detail and scheduled the study interview. Patients were provided with an information letter, in which it was explained that the study was part of a project in which an intake tool was developed; the goal of the intake tool was explained; the procedure and time of the expected time of the interview were explained
7. Participants knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	The researcher performing the interviews was also part of the project team who developed the intake tool. Bias could have occurred because the interviewer was also part of the project team that developed the item list. However, the aim of the pilot study is to ensure that the content of the questionnaire matches the target group as well as possible, so the researcher was motivated to know all the critical points in order to be able to improve the item list. (This 'limitation' is also included in the discussion of the manuscript).
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	

ⁱ Rainey L, Elsmann EBM, van Nispen RMA, van Leeuwen LM, van Rens GHMB. Comprehending the impact of low vision on the lives of children and adolescents: a qualitative approach. *Qual Life Res.* 2016;25(10):2633-2643. doi: 10.1007/s11136-016-1292-8.

ⁱⁱ van Leeuwen LM, Mookink LB, Kamin CP, de Groot V, van den Berg P, Ostelo RWJG, Uitdehaag BMJ. Measurement properties of the Arm Function in Multiple Sclerosis Questionnaire (AMSQ): a study based on Classical Test Theory. *Disabil Rehabil.* 2017;39(20):2097-2104. doi: 10.1080/09638288.2016.1213898.

ⁱⁱⁱ Bruinewoud EM, Kraak JT, van Leeuwen LM, Kramer SE, Merkus P. The Otology Questionnaire Amsterdam: a generic patient reported outcome measure about the severity and impact of ear complaints. A cross-sectional study on the development of this questionnaire. *Clin Otolaryngol.* 2018;43(1):240-248. doi: 10.1111/coa.12950.

^{iv} van Leeuwen LM, Pronk M, Merkus P, Govers ST, Anema JR, Kramer SE. Barriers to and enablers of the implementation of an ICF-based intake tool in clinical otology and audiology practice – a qualitative pre-implementation study. *PLoS One* 2018;13(12):e0208797. doi: 10.1371/journal.pone.0208797.

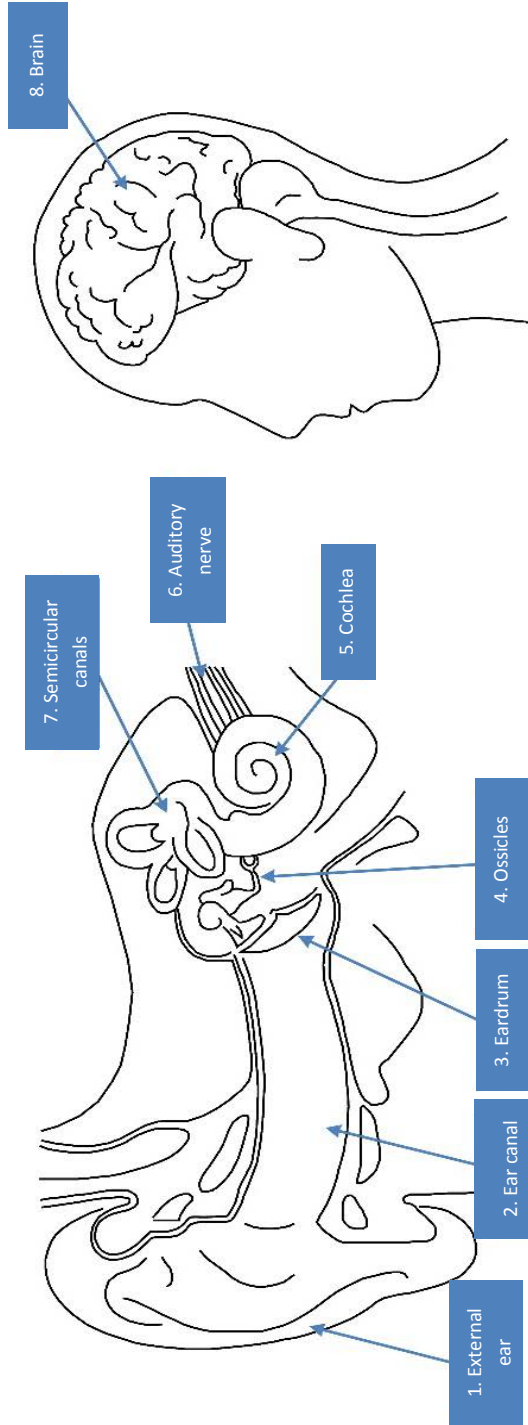
APPENDIX 4. Final item list

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
1. Reason for visit	Open	-	Previous interview study with patients'	
SOCIODEMOGRAPHIC INFORMATION				
2. Current living situation	I live with my partner (1); I live together with my partner and child/children (2); I live without a partner but together with one or more family members (e.g., parent, son/daughter) (3); I live alone in a health care institution (4); I live alone, independently; Other (open).	PF	Consensus	NL-SH
3. Current work situation*	Full-time job (1); Part-time job (2); Unemployed (3); Unfit for work (4); Retired (5); Student (6); Voluntary work (7); Receiving benefit (8); Looking for a job (9); Other (open)	PF	Consensus	LASA
3.1 Occupation	Open	PF	Consensus	NL-SH
4. School education		PF	Consensus	NL-SH
4.1 Did you go to a primary or secondary school for the Deaf/hearing impaired	Yes (1)/No (2)	PF	Consensus	N.A.

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
MEDICAL BACKGROUND				
5. Do you use hearing aids?	Yes (1); No (2); I do not know (3)	PF	Brief CSHL	NL-SH
5.1. If yes: How old were you when you received your first hearing aid?	Open	PF	Consensus	N.A.
6. Does anyone in your family (parents, brothers, sisters and/or children) also have an ear and/or hearing problem?*	Yes, my parents (1); Yes, my siblings (2); Yes my children (3); Yes, my grandparents (4); No (5); I do not know (88); Other (open)	PF	Consensus	NL-SH
6.1. If yes: Are the ear and/or hearing problems of your family member(s) hereditary?	Yes (1); No (2); I do not know (88)			N.A.
7. Do you currently have a serious or long-term condition or illness? (in addition to your ear and/or hearing problems)	Yes (1)/ No (2)	PF	Consensus	PredictEAR
7.1 If yes: Tick the box of the condition or disease you currently have or have had in the past 12 months.	Migraine or regular severe headache (1); High blood pressure (2); asthma, chronic bronchitis, pulmonary emphysema or CARA (3); Psoriasis; Chronic eczema (4); Dizziness with falling (5); Severe or persistent bowel disorders, longer than three months (6); Involuntary urine loss (incontinence)(7); Joint wear and tear (osteoarthritis, rheumatism) of hips or knees (8); chronic joint inflammation (inflammatory rheumatism, chronic rheumatism, rheumatoid arthritis) (9); Severe or persistent condition of the back (including hernia) (10); Other serious or persistent diseases of the neck or shoulders (11); Other serious or persistent disorders of elbow, wrist or hand (12); Diabetes (type 1 or 2) (13); Stroke (TIA, cerebral infarction or cerebral hemorrhage) (14); Heart attack (15); Other serious heart disease (16); Cancer (17); Other (open)	PF	Consensus	LASA

continued

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
FUNCTIONING				
Body structure				
8. Can you indicate in the figure below where you think your complaint originates from? <i>You can tick multiple structures/ parts of the ear. If you do not know, you can tick 'I do not know'.</i>	External ear (1); Ear canal (2); Eardrum (3); Ossicles (4); Cochlea (5); Auditory nerve (6); Semicircular canals (7); Brain (8); I do not know (88)	s240 – structure of external ear; s250 – structure of middle ear; s260 – structure of inner ear	Brief CS HL	N.A.



Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
General body functions				
The following questions are about physical and mental complaints. For each question, indicate to what extent you are currently experiencing this complaint in general.				
9. How much difficulty do you have with sleeping (falling asleep, waking up often during the night or waking up early in the morning)?	No difficulty (0) – Very severe difficulty (4)	b134 – sleep functions	Previous patient-record study ⁱⁱ	WHS/ definition ICF category
10. How much difficulty do you have concentrating on doing something for ten minutes?	No difficulty (0) – Very severe difficulty (4)	b140 – attention functions	Brief CSHL	WHODAS 2.0
11. How much difficulty do you have concentrating when listening to something or someone?	No difficulty (0) – Very severe difficulty (4)	b140 – attention functions	Brief CSHL	SSQ-3-14
12. How much difficulty do you have remembering things?	No difficulty (0) – Very severe difficulty (4)	b144 – memory functions	Brief CSHL	WHS/ definition ICF category
13. To what extent do you feel sad, anxious or depressed?	Not sad, anxious or depressed (0) – Completely sad, anxious or depressed (4)	b152 – emotional functions	Brief CSHL	WHS/ definition ICF category
14. If we divide people in: the not lonely, the moderately lonely, the severely lonely, and the extremely lonely, what would you consider yourself to be?	Not lonely (0) – Extremely lonely (4)	b152 – emotional functions	Brief CSHL	Expert consult
15. Can you read small to normal print in the newspaper with glasses or contact lenses if necessary?	Yes (1)/ No (2)	b210 – seeing functions	Brief CSHL	LASA
16. Can you recognize someone's face at a distance of 4 meters, with glasses or contact lenses if necessary?	Yes (1)/ No (2)	b210 – seeing functions	Brief CSHL	LASA

continued

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
Hearing related problems				
<i>The following questions are about hearing in different hearing situations. Indicate which situations currently present difficulties. The intention is that you answer your daily, usual situation when answering the questions.</i>				
17. Can you hear somebody approaching from behind?	Almost never (0) – Almost always (3)	b2300 – sound detection	Comprehensive CSHL	AIAHD
18. Can you hear cars passing by?	Almost never (0) – Almost always (3)	b2301 – sound discrimination	Comprehensive CSHL	AIAHD
19. Can you hear from what corner of a lecture room someone is asking question during a meeting?	Almost never (0) – Almost always (3)	b2302 – sound localization	Comprehensive CSHL	AIAHD
20. Can you understand the presenter of the news on TV?	Almost never (0) – Almost always (3)	d310 – communicating with – receiving – spoken messages	Comprehensive CSHL	AIAHD
21. Can you easily carry on a conversation with somebody in a bus or car?	Almost never (0) – Almost always (3)	d350 – conversation in background noise	Brief CSHL	AIAHD
22. Can you carry on a conversation between a few people during dinner?	Almost never (0) – Almost always (3)	d350 – conversation, e250 – sound	Brief CSHL	AIAHD
23. Can you carry on a telephone conversation in a quiet room?	Almost never (0) – Almost always (3)	d360 – using communication devices and techniques	Brief CSHL	AIAHD
24. Due to my ear and/or hearing problem, my self-confidence is:	Not affected (0) – Completely affected (4)	b126 – temperament and personality functions	Brief CSHL	Expert

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
Ear related problems				
<i>The following questions are about various complaints that you might experience. For each complaint, indicate to what extent you are currently suffering from it:</i>				
25. Ringing ears/ tinnitus (this is a ringing, beeping or buzzing sound that you hear in the ear or in the head)	Not suffering (0) – complete suffering (4), Not applicable (77)	b2400 – tinnitus	Comprehensive	Consensus/ OQUA
26. Dizziness	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b2401 – dizziness	Comprehensive	Consensus/ OQUA
27. Tendency to fall	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b2402 – sensation of falling	Comprehensive	Consensus/ OQUA
28. Irritation (e.g., itching) on or in the ear	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b2404 – irritation in the ear	Comprehensive	Consensus/ OQUA
29. Pus or fluid from the ear or running ear (not normal ear wax but abnormal moisture)	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b2404 – irritation in the ear	Comprehensive	Consensus/ OQUA
30. Feeling of pressure on the ear/ “popping” of the ear	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b2405 – aural pressure	Comprehensive	Consensus/ OQUA
31. Pain on/in the ear	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b280 – sensation of pain	Comprehensive	Consensus/ OQUA
32. Taste loss	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b250 – taste function	Total ICF classification, clinical expertise	Consensus/ OQUA
33. Smell loss	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b255 – smell function	Total ICF classification, clinical expertise	Consensus/ OQUA
34. Indicate to what extent you suffer from headaches	Not suffering (0) – Very severe suffering (4), Not applicable (77)	b280 – sensation of pain	Comprehensive	Consensus/ OQUA

continued

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
Activities and participation				
<i>The following questions are about the influence of your ear and/or hearing problems on your daily activities.</i>				
35. How much difficulty do you have in dealing with stressful situations?	No difficulty (0) – Very severe difficulty (4)	d240 – handling stress and other psychological demands d760 – family relationships	Brief CSHL	WHODAS 2.0/ definition ICF category
36. How much difficulty do you have in interacting with your immediate family members? (for example with your father, mother, partner, child)	No difficulty (0) – Very severe difficulty (4)	d760 – family relationships	Brief CSHL	WHODAS 2.0/ definition ICF category
37. How much difficulty do you have when attending education or courses?	No difficulty (0) – Very severe difficulty (4)	d820 – school education	Brief CSHL	WHODAS 2.0/ definition ICF category
38. Think about your (volunteer) work for the next question. How much difficulty do you have carrying out your important work tasks?	No difficulty (0) – Very severe difficulty (4)	d850 – remunerative employment	Brief CSHL	WHODAS 2.0/ definition ICF category
39. How much difficulty do you have in participating in community activities (such as festivities, religious and other activities)?	No difficulty (0) – Very severe difficulty (4)	d910 – community life	Brief CSHL	WHODAS 2.0/ definition ICF category

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
CONTEXTUAL FACTORS				
Environmental factors				
<i>The following questions relate to the influence of different environmental factors on your daily functioning.</i>				
<i>With regard to your ear and/or hearing problem, indicate to what extent these environmental factors provide support for your daily functioning</i>				
40. To what extent does your hearing aid (such as your hearing aid, Cochlear Implant, or BAHA) help you in your daily functioning?	Not (0) – Completely (4)	e125 – products and technology for communication	Brief CSHL	Definition ICF category and patients' input
41. To what extent do you feel supported in your daily functioning by your family members (e.g., your father / mother / partner / child)? <i>When answering this question, think about the person who is most influential.</i>	Not supported (0) – Completely supported (4), Not applicable (77)	e310 – immediate family	Brief CSHL	Definition ICF category and patients' input
42. To what extent do you feel supported by your healthcare provider(s) (e.g., your general practitioner, dispenser, ENT doctor, or care providers of the Audiology Clinic)? <i>When answering this question, think of the most important healthcare provider(s) you have experienced so far in the context of your ear and/or hearing problems</i>	Not supported (0) – Completely supported (4), Not applicable (77)	e355 – health professionals	Brief CSHL	Definition ICF category and patients' input
43. To what extent do you feel supported by opinions in society about ear and/or hearing problems? <i>When answering this question, think of general opinions or views of people in our society about people with ear and/or hearing problems.</i>	Not supported (0) – Completely supported (4), Not applicable (77)	e460 – societal attitudes	Brief CSHL	Definition ICF category and patients' input
44. How easily can you go to your care provider(s) with your ear and/or hearing problem?	Not easily (0); Easily (1); Very easily (2); Not applicable (77)	e580 – health services, systems and policies	Brief CSHL	Definition ICF category and patients' input
44.1. To your general practitioner				
44.2. To the dispenser				
44.3. To the ENT surgeon				
44.4. To the Audiology Centre				

continued

Item of ICF based intake tool: presented as construct or question	Response scale (scoring)	ICF category	Included how?	Worded how?
Personal factors				
This section is about your feelings, attitudes and assumptions. Below are a number of statements. Please, indicate for each statement to what extent you agree or disagree. When answering this question, think about your general daily situation.				
45. I have little control over the things that happen to me	Completely disagree (1) – Completely agree (5)	PF	Consensus	PMS
46. I cannot solve some of my problems with any possibility	Completely disagree (1) – Completely agree (5)	PF	Consensus	PMS
47. There is little that I can do to change important things in my life	Completely disagree (1) – Completely agree (5)	PF	Consensus	PMS
48. I often feel helpless when dealing with the problems of life	Completely disagree (1) – Completely agree (5)	PF	Consensus	PMS
49. Sometimes I feel that I am a plaything of life	Completely disagree (1) – Completely agree (5)	PF	Consensus	PMS
To what extent do you agree with the following statements? The statements are about your feelings and attitudes towards your ear and/or hearing problem. When answering this question, think again about your general daily situation.				
50. I avoid conversations with others because of my ear and/or hearing problem	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi
51. I avoid conversations with strangers because of my ear and/or hearing problem	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi
52. In a group I choose my place so that I can hear everything better	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi
53. I am afraid that I am stupid when I do not understand others because of my ear and/or hearing problem	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi
54. I find it difficult to accept that I have an ear and/or hearing problem	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi
55. Sometimes I am ashamed of my ear and/or hearing problem	Strongly disagree (1) – Strongly agree (5), Not applicable (77)	PF	Consensus	CPhi

* Multiple answers possible; AIAHD = Amsterdam Inventory for Auditory Disability and Handicap (see Kramer et al. 1995)ⁱⁱⁱ; CPhi = Communication Profile for the Hearing Impaired (see Mokkin et al. 2010)^{iv}; OQUA = Otology Questionnaire Amsterdam (see Bruinewoud et al. 2018)^v; LASA = Longitudinal Aging Study Amsterdam (see Hoogendijk et al., (2016)^{vi} and www.lasa.vu.nl; N.A.= not applicable; NL-SH = Netherlands Longitudinal Study on Hearing (see Stam et al. 2016)^{vii}; PF = Personal Factor; PMS = Pearlin Mastery Scale (see Pearlin and Schooler 1978)^{viii}; PredictEAR = Dutch questionnaire-study on predictors of entering a hearing aid evaluation period (see Pronk et al. 2018)^{ix}; SSQ = Speech, Spatial and Qualities of Hearing Scale (see Gatehouse and Noble 2004)^x; WHODAS 2.0 = WHO Disability Assessment Schedule 2.0 (see Üstün et al. 2010)^{xi}; WHS = World Health Survey (see WHO, 2012)^{xii}.

- ⁱ van Leeuwen LM, Pronk M, Merkus P, Goverts ST, Anema JR, Kramer SE. Barriers to and enablers of the implementation of an ICF-based intake tool in clinical otology and audiology practice – a qualitative pre-implementation study. *PLoS One*. 2018;13(12):e0208797.
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- ^{xi} Üstün TB, Kostanjsek N, Chatterji S, Rehm J. Measuring health and disability: Manual for WHO disability assessment schedule (WHODAS 2.0). Geneva: World Health Organization; 2010.
- ^{xii} World Health Organization (WHO). World Health Survey 2002; Individual Questionnaire 2012. Available from: <http://www.who.int/healthinfo/survey/whslongindividuala.pdf>, cited 23 April 2019.

Chapter 6:

Barriers to and enablers of the implementation of an ICF-based intake tool in clinical otology and audiology practice – a qualitative pre-implementation study

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Barriers to and enablers of the implementation of an ICF-based intake tool in clinical
otology and audiology practice – a qualitative pre-implementation study
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ABSTRACT

The authors are developing an intake tool based on the Brief International Classification of Functioning Disability and Health Core Set for Hearing Loss, by operationalizing its categories into a Patient Reported Outcome Measure. This study was aimed at identifying enablers and barriers to using this tool as perceived by hearing health professionals (HHPs) and patients. Focus groups and interviews were held with HHPs (ENT surgeons, N=14; audiologists, N=8) and patients (N=18). Interview questions were based on the Capability-Opportunity-Motivation-Behavior (COM-B) model. Using the COM-B model and the Theoretical Domains Framework (TDF), transcript fragments were divided into meaning units, which were then categorized into capability-, opportunity- and motivation-related barriers and enablers. These were further specified into TDF domains. HHP barriers included: lack of time to use the tool (O); and fear of being made responsible for addressing any emerging problems, which may be outside the expertise of the HHP (M). Enablers included integration of the tool in the electronic patient record (O); opportunity for the patient to be better prepared for the intake visit (M); and provision of a complete picture of the patient's functioning via the tool (M). Patient barriers included fear of losing personal contact with the HHP (M); and fear that use of the tool might negatively affect conversations with the HHP (M). Enablers included knowledge on the aim and relevance of the tool (C); expected better self-preparation (M); and a more focused intake (M). These findings suggest that an intervention is needed to enhance HHPs' knowledge, skills and motivation regarding the relevance and the clinical usefulness of the tool. Providing clear and specific information on the purpose of the tool can also enhance patient motivation. For both HHPs and patients, opportunities relating to the (digital) administration and the design of the tool provide additional targets for successful implementation.

INTRODUCTION

Adults with ear and hearing problems may experience both physical impairments and psychosocial consequences that can significantly impact their functioning in daily life¹. *Functioning* is a multidimensional construct. According to the World Health Organization (WHO) it reflects the interplay of an individual's body structures and functions, activities, participation and contextual factors. In other words, a whole-person perspective is required to assess functioning of an individual with a particular health condition (here: ear/hearing problems)². It is acknowledged that ear and hearing health care should consider a patient's total functioning to provide optimal care and obtain optimal outcomes (e.g., ³⁻⁵). However, ear and hearing problems are often understood in the context of the specific disease (medical perspective) with a focus on relieving the impairments that exist on the level of body functions and body structures. Such an approach does not include the level of participation (restrictions) and the individual's personal and environmental context, and therefore only partially describes and addresses the consequences of ear and hearing problem ^{4, 6}. Any inclusion of these aspects in current clinical practice is unlikely to be standardized.

The use of WHO's International Classification of Disability and Health (ICF)² as a frame of reference to assess an individual's total functioning may facilitate a better understanding of the (consequences of) ear or hearing problems for the individual patient and improve health care provision (e.g., ^{3, 6, 7}). However, the ICF consists of more than 1400 categories, which is not workable in clinical practice, and ICF Core Sets have therefore been developed. These are lists of selected categories that have been demonstrated to be the most relevant for describing the functioning of a person with a specific health condition. Following the need for a standard instrument to facilitate a common validated way for assessing the effect of hearing loss on the lives of adults, the ICF Core Sets for Hearing Loss (CSHL) were established according to strict procedures prescribed by the WHO⁸. The Core Sets were developed based on a series of preparatory studies which included the researcher, clinician and patient perspectives and an international consensus process⁴. The Comprehensive CSHL contains 117 categories to be taken into account in a multi-professional comprehensive assessment of a patient's functioning with hearing problems. The Brief CSHL includes 27 of the 117 categories and represents the minimal set that should be assessed in a person with HL in single discipline encounters or clinical trials.

In a prior study, we examined the content validity of the CSHL with respect to the intake procedures used for patients in Dutch oto-audiology practices⁹. Results revealed some gaps in the current intake documentation and indicated that implementation of the CSHL in the Dutch practice could complement current practice and help professionals obtain an integral perspective of the patient's functioning⁹. However, a drawback of the CSHL is that they define 'what to measure', but not 'how to measure'. Additional steps are therefore required to enable the use of the CSHL in clinical practice, i.e., i) operationalization of the CSHL into a

practical intake tool and ii) implementation of this instrument in clinical practice. In a parallel study we focus on step i) by operationalizing the Brief CSHL into a Patient Reported Outcome Measure (PROM) (results will be described elsewhere). The current study focuses on step ii). Throughout the study we used a rough conceptual description of the intake tool which was presented to the study participants. In the remainder of this paper we will refer to this conceptual description as the 'ICF-based intake tool'.

It is often argued that PROMs can facilitate patient-centred care. However, simply implementing a PROM does not imply patient-centred practice, unless it serves to strengthen the patient-clinician relationship, promotes communication about things that matter to the patient, increases patients' knowledge about their health, and facilitates their involvement in their own care¹⁰. It is therefore important to realize that the intake tool itself does not represent patient-centred care, but it may be a step towards it. The profile generated by the intake tool can be used as a starting point in the intake, to facilitate communication between patients and clinicians and foster an equal partnership in determining treatment. The degree of patient-centeredness is the result of this process. In a next step, guidelines and pointers for the clinicians on how to discuss the intake tool's outcomes and the patient's treatment options in a patient-centred way will therefore be required. However, as a first step, the context and mechanisms through which the intake tool is meant to affect change should be considered¹¹. Testing for the presence of factors that are necessary to influence and produce desired outcomes (here: using the intake tool in a way so it facilitates patient-centred care) is therefore important¹². This involves the careful examination of implementation context/processes that support or impede the utilization of the intake tool¹¹⁻¹³. This study is a critical evaluation of the implementation of the ICF-based intake tool from the perspectives of the hearing health professional (HHP) and the patient. This is important, given that if the newly developed ICF-based intake tool is poorly implemented and not routinely used as intended, the potential benefits will not be achieved.

The importance of careful implementation is reflected in the fact that although there is mounting evidence that PROMs can impact upon processes of care and clinical outcomes^{12, 14-18}, this impact may vary widely¹⁹⁻²¹. Implementation of PROMs in clinical practice implies shifts in practices for both patients and health care providers in order to accommodate the collection and the feedback of the PROM information. Changing these practices is known to be a challenging process²²⁻²⁴. Potentially impeding or enabling factors for the implementation of PROMs can be found at various levels, and include factors related to the PROM itself (e.g., simplicity and adaptability to the context), professionals and patients involved (e.g., knowledge and expectations), and the social, organizational, economic and political context (e.g., costs-effectiveness)²⁵. Trying to implement a change in clinical practice requires consideration of individual *behaviour change* of all parties involved²⁶⁻²⁸. Successful adoption of a new practice or intervention (here: use of an ICF-based intake tool) is enhanced when it is compatible with the users' values and current needs^{22, 23}. It is therefore important for the

implementation of the ICF-based intake tool in oto-audiological clinical practice to understand the specific information HHPs find useful in their setting and the obstacles they perceive to the routine assessment of PROMs as part of clinical care. Patient engagement in using PROMs is of paramount importance to limit the impact of response burden and to enhance successful PROM implementation^{13, 29}. In other fields of healthcare, reported barriers to the use of PROMs include: lack of time, preference for physiological measures (in contrast to self-report measures), perceived lack of clinical relevance, uncertainty in interpreting PROM result and patient burden³⁰. Currently no information is available about the barriers and enablers related to the implementation of PROMs in the clinical oto-audiology setting. A better understanding of the perceived enablers of- and barriers to the use of an ICF-based intake tool, and subsequent targeting of these enablers and barriers could contribute to successful implementation and routine use of the ICF based intake tool in clinical practice.

Implementation researchers strongly recommend the use of a theoretical framework to increase the likelihood of identifying and subsequently targeting the full range of enablers and barriers to implementation (e.g.,³¹). This study therefore used a theory-based approach to identify barriers to and enablers of the use of the ICF-based intake tool perceived by HHPs and patients. HHPs included ENT surgeons and post-academically skilled medical physicist audiologists (further referred to as audiologists). The careful identification and categorization of barriers and enablers, which is described in the current study, is necessary to develop an intervention for the implementation of the intake tool (e.g.,³¹), which will be determined in a future study.

MATERIALS AND METHOD

Study design

A qualitative study was performed using structured individual interviews with patients and HHPs (one audiologist), and semi-structured focus groups with HHPs (i.e., ENT surgeons and audiologists). The focus groups and individual interviews were performed to identify the possible enablers of and barriers to the use of the ICF-based intake tool, and to identify what changes implementation of the tool would require in current practice.

Description of the ICF-based intake tool

In the current study, the patients and HHPs were introduced to the ICF-based intake tool and its intended use in clinical practice. We provided the following information:

- The patient was to be asked to complete a questionnaire assessing relevant aspects of their functioning prior to his/her intake visit;
- The patient's responses were to be made available to both the patient and the HHP and thereby serve as a communication tool that could guide the intake and subsequent treatment process.

The overall aim of the overarching research project is to improve patient-centred care in otology and audiology. Hearing impairment is a condition central to each of these disciplines and multiple disciplines are often involved in the tertiary care. To enable better coordination and continuity of care we therefore opted for an integrated approach to collect functioning information in the initial contact across all patients, independent of the specific oto/audiology discipline through which the patient enters the care system. Note that the CSHL was developed for adults with hearing loss, which explains why we created an ICF-based intake tool for patients who come to an Audiology Center and/or an ENT practice for hearing loss-related complaints. ENT practices in the Netherlands serve patients with a wide range of ear complaints, of which hearing loss is the most prominent one which often coexists with ear disorders. Also, an exact diagnosis often is yet to be determined at the start of a rehabilitation trajectory. In addition, for the same hearing complaint, patients can come into the hospital via a referral to either an ENT surgeon or the audiologist. These factors underline the need for a common language and reference system that functions across professional boundaries. This should start immediately after patients are referred to our hospital. Based on these facts, and given our preference for a uniform tool, we have chosen to create this new intake tool using the CSHL as reference.

The theory-based approach

A large pool of psychological theories explaining behaviour change are available to guide implementation research. Examples are the health belief model (HBM)³², theory of planned behaviour (TPB)³³, and the transtheoretical model (TTM)³⁴. However, literature suggests that such models may fail to consistently and reliably explain variability in human behaviours (e.g.,³⁵). Moreover, many of these theories use overlapping constructs and lack guidance for selecting the best one³⁶. The Capability Opportunity Motivation-Behaviour (COM-B) model was developed by integrating concepts from 19 frameworks of behaviour change identified in a systematic review by Michie and colleagues (2011)²⁸ and has been applied successfully by others in the context of hearing health care^{37, 38}.

The model proposes that for someone to engage in a particular behaviour (B) they must be physically and psychologically able (C), have the social and physical opportunity (O) to perform the behaviour and, lastly, be motivated (M) to perform the behaviour. Motivation covers automatic processes such as emotional reactions and impulses and reflective processes such as intention and beliefs.

In addition to the COM-B model we used the Theoretical Domains Framework (TDF) for a more detailed evaluation of HHP and patient barriers and enablers. The TDF is an integrated theoretical framework synthesized from 128 theoretical constructs from 33 theories judged most relevant to implementation questions^{39, 40}. It has been linked to the COM-B model by Michie and colleagues (2014)⁴¹. Based on the TDF, the C, O, and M components of the COM-

B are further divided into 14 key theoretical domains of behaviour that an implementation intervention might focus on⁴⁰. The TDF provides a more granular understanding of psychological capability and reflective motivational processes than the COM-B alone³⁹. Moreover, the TDF was recommended in a recent paper to guide the development of behaviour change interventions for clinicians and patients aimed at addressing the barriers to and maximizing the enablers of PROM implementation²⁴. The domains of the TDF include:

- knowledge;
- cognitive and interpersonal skills;
- memory, attention and decision processes;
- behavioral regulation;
- environmental context and resources;
- social influences;
- social/ professional role and identity;
- beliefs about capabilities;
- optimism;
- intentions;
- goals;
- beliefs about consequences;
- reinforcement;
- emotions.

A specification of each COM component and its related TDF domain(s) is provided in Appendix 1.

Recruitment and sampling

HHPs

HHPs were included via convenience methods. An invitation e-mail was sent from the research team to a staff member of each setting. We then provided staff with further information and contacted them to arrange the focus groups. The focus groups were organized in or following existing (educational) meetings. Aiming at a sample representative of Dutch clinical hearing health care settings we included ENT surgeons and audiologists from the Amsterdam UMC, location VUmc, department of Otolaryngology-Head and Neck Surgery, a secondary Otolaryngology Department and a secondary Audiological Center in the study. These included:

- Ten ENT surgeons at the section of Otology of the department of Otolaryngology- Head and Neck Surgery of Amsterdam UMC, location VUmc (tertiary setting).
- Four ENT surgeons at the department of Otolaryngology of the WestFriesGasthuis (WFG) hospital in Hoorn (secondary setting).
- Seven audiologists at the University Audiology Center of the department of Otolaryngology- Head and Neck Surgery of Amsterdam UMC, location VUmc (tertiary setting);

- One audiologist at the Audiology Center Holland Noord (ACHN) in Alkmaar (secondary setting).

Table 1 shows the characteristics of the participating HHPs.

TABLE 1. Characteristics of the Hearing Health Professionals (N=20) participating in the study

Variable	ENT surgeons		Audiologists	
	1	2	3	4
Setting*				
Number of participants	8	4	7	1
- ENT residents/ audiologists in training	6	-	2	-
Gender male/female	6/2	3/1	5/2	1/0
Age mean; SD	31.6; 5.2	50; 5.7	42.3; 8.1	52
Years of work experience mean (range)	5.9 (2-15)	16.3 (11-26)	8.3 (1-20)	24

*Setting: Amsterdam UMC, location VUmc section Otolology =1, WFG = 2, Amsterdam UMC, location VUmc Audiology Center = 3, ACHN = 4
 ENT= ear nose and throat

Patients

Patients with ear and/or hearing problems were recruited at Amsterdam UMC, location VUmc in Amsterdam. Only patients meeting the following inclusion criteria were invited: visiting the outpatient clinic of the Amsterdam UMC, location VUmc for the first time, above the age of 18 years. A maximum variation strategy was applied with regard to the ear/hearing problem and age, in order to form a heterogeneous group covering the full spectrum of otology/audiology patients characteristics. Recruitment of participants took place in the waiting room via the HHPs assistants. The HHPs assistants selected eligible patients, announced the study, and asked whether patients would potentially be willing to participate. LvL then explained the study more in detail and invited the patient to participate in an interview. Patients were scheduled for an interview prior to their visit to the outpatient clinic for an intake with an audiologist or ENT surgeon. Eighteen patients were included and were asked to sign informed consent forms. Table 2 shows their sociodemographic and condition-related characteristics. All patients were interviewed by LvL at the outpatient clinic of Amsterdam UMC, location VUmc, in a separate room before their scheduled intake consult.

TABLE 2. Characteristics of the patients (N=18) participating in the study

Variable	Total	Otology patients	Audiology patients
Number of participants	18	12	6
Gender male/female	55.6	58.3	33.3
Age mean (range)	54.5 (18-84)	52.6 (18-77)	58 (20-84)
Country of birth The Netherlands/Other country	16/2	10/2	6/0
Otology diagnosis (%)			
- Diseases of external ear (ICD-10: H60-H62)	-	2	Na
- Diseases of middle ear and mastoid (ICD-10: H65-H75)	-	3	Na
- Diseases of inner ear (ICD-10: H90-H95)	-	2	Na
- Other diseases of the ear (ICD-10: H90-H95)	-	5	6
Audiology diagnosis group (%)			
- Tinnitus	-	Na	1
- Hearing loss	-	Na	3
- Cochlear Implant	-	Na	2

Na = not applicable; ICD-10 = 10th revision of International Classification of Diseases and Related Health Problems

Focus groups and interview procedures

The interview guides that were used for the structured group discussions and individual interviews are shown in Appendix 2. The topics and questions were designed to identify barriers and enablers based on the components of the COM-B model.

Focus groups with HHPs

One discipline-specific focus group meeting was conducted within each setting. One audiologist was interviewed individually. A topic list was used to facilitate group discussion. The topics related to current practice and perceptions regarding using the ICF based intake tool in routine care. HHPs were asked about their current practice and what they thought could be potential tools or methods to support their intake (Q1-Q3), and what requirements they had in mind in order for them to actually use such a tool in their clinical practice (Q4-Q6). The focus groups and individual interview with the audiologist of ACHN took about one hour.

Individual interviews with patients

A structured interview guide was used in the patient interviews. Patients were asked about their experiences with intakes, (Q1), and what they considered important in intakes (Q2-Q5). Secondly, the ICF-based intake tool was introduced and its intended use was briefly explained. Patients were asked what they thought of filling out and using such a tool for the intake (Q6). Subsequently, they were asked to indicate which conditions the ICF-based intake tool would have to meet for them to use it (Q7-Q10). Interviews took between 15-30 minutes.

LvL conducted all the interviews and moderated the focus groups. Because of the large number of HHPs participating in the two focus groups at Amsterdam UMC, location VUmc, an observant was present during these focus groups to help monitor the group process.

Analysis

All focus group meetings and interviews were audio recorded. LvL transcribed and anonymized all interviews. Data analysis (content areas; i.e., explicit areas of relevant content) was based on the qualitative data analysis method by Graneheim and Lundman, as described in Knudsen et al. (2012)⁴². Data saturation was reached for the patients when all patient groups commonly seen in oto-audiology practice were represented in the sample and the final interview yielded no new unique responses. Due to time restrictions, data collection among the HHPs was not based on data saturation and significant barriers and enablers may therefore have been missed. The interview transcript fragments that were relevant to the content areas were divided into meaning units. Subsequently, the COM-B model and the TDF were used to categorize the meaning units into capability-, opportunity- and motivation-related barriers and enablers, and further specified into TDF domains.

In order to ensure reliability of the analysis procedure⁴², one randomly selected patient interview transcript and 10% of two randomly selected focus group transcripts were independently analyzed by MP and SEK. The percent agreement between the analyses of LvL, MP, and SEK was calculated for the categorization of the meaning units into COM-B components as well as TDF domains. Any discrepancies were discussed until consensus was reached on the optimal categorization.

Ethics

The study was approved by the Medical Ethical Committee of the Amsterdam UMC, location VUmc, Amsterdam; the Netherlands. Data collection was carried out between November 2016 and February 2017.

RESULTS

The barriers and enablers found for HHPs and patients are presented in Tables 3 and 4, and Tables 5 and 6, respectively. The identified factors, together with illustrative quotes from participants, are described in more depth below and are categorized according to the COM-B components. Results are presented separately for HHPs and patients. Supplemental text is provided in brackets when further clarification was deemed necessary for the readability of quotes.

Barriers and enablers perceived by HHPs (Tables 3 and 4)

Capability

Both ENT surgeons and audiologists expressed that psychosocial factors (which would be captured by the ICF-based intake tool) can influence the daily life functioning of patients with ear and hearing problems. This was identified as a *psychosocial capability* (COM-B) by HHPs that can be further linked to the TDF category *knowledge*. HHPs knowledge on the relevance of the ICF is therefore a factor that could act as a potential enabler to implementing the intake tool.

“These are factors [the bio-psychosocial factors in the intake tool] that affect the well-being of the patient and may also direct the patient’s complaints.” (ENT surgeon)

Another *psychological capability* that was identified as an enabler, was that audiologists reported that discussing psychosocial- and contextual factors with their patients is a common part of their current intake practice. This factor was linked to the *skills* and *behavioural regulation* category of the TDF because it covers clinical experience.

“One question I ask very often is ‘in which situations do you notice your problems specifically in your daily life, in what aspects of your daily life do you encounter them?’” (audiologist)

“We ask what their personal environment looks like, what kind of people what kind of situations, and what role the problem plays here in.” (audiologist)

Another factor that was identified as an enabler linked to *skills* and *behavioural regulation* (TDF) was the audiologists’ familiarity with using structured intake-forms and questionnaires. In contrast to audiologists, the ENT surgeons reported that they are not used to assessing and discussing psychosocial and contextual factors with their patients in current practice, which was therefore identified as a barrier for this group. Also, they expressed their concerns about their current lack of *skills* to deal with patients’ psychosocial complaints. Addressing such complaints was perceived to be outside their area of expertise.

“We are not specifically trained for that [to address psychosocial factors].” (ENT surgeon)

Furthermore, some ENT surgeons indicated a lack of *knowledge* (TDF) regarding the hospital’s internal psychosocial referral pathways, and did not appear to know about the social worker as a member of the multidisciplinary audiology team in the department of Otolaryngology-Head and Neck Surgery in the Amsterdam UMC, location VUmc.

Opportunity

Identified opportunity barriers and enablers all related to the physical environment (COM-B level) and were categorized under *environmental context and resources* (TDF level). Both ENT surgeons and audiologists perceived the limited time available to use the intake tool as an important potential barrier. Specifically, reported concerns related to the short time frame per intake and the high turnover practice that was already pressuring current usual practice. Use of the tool was viewed as adding even more to their task load, as yet another extensive list of topics had to be reviewed and addressed. It was viewed as unworkable in daily practice.

“We only have ten minutes for the intake, and in those ten minutes the patient needs to come in, you need to do the intake conversation, the physical examination, and explain the treatment. Everything that makes the intake more complex or broader will be frustrating, I think”. (ENT surgeon)

Environmental context and resources (TDF) related to enablers were also raised. Both ENT surgeons and audiologists indicated that a potentially workable method is to ask the patient to complete the tool independently, before the intake, and preferably online. They expressed a preference for closed-ended rather than open-ended questions to prevent overly exhaustive descriptions of complaints by patients. This would make the complaints time-consuming to review and difficult to address. In addition, ENT surgeons indicated their preference for *“an easy overview of the results”* in which *“it is immediately clear what is filled in by the patient”*, emphasizing that this overview should be very simple and easy to use. ENT surgeons suggested that this overview should only show the problem areas of the patient’s functioning, and should not include factors the patient reported no problems with. In this way the HHP could immediately focus on the real problem areas during the intake.

ENT surgeons reported that prompts and triggers for appropriate treatment options or referral pathways to other appropriate health professionals – corresponding to the fields of functioning that would pop up as ‘problem areas’ – could work as a potential enabler of using the tool.

“It could be useful if we had referral trajectories within the hospital [...] that you get a pop-up saying ‘refer to discipline x’ and that this discipline is located in room y.” (ENT surgeon)

Another enabler mentioned by both ENT surgeons and audiologists was that the overview of the patient’s functioning should be integrated in the hospital/center’s electronic system. Moreover, HHPs reported that the intake tool must be accessible to patients, including quick and easy access to the digital intake tool before the intake visit, use of simple language (i.e., suitable for low literate patients), and flexibility with regard to administration method (e.g.,

availability via desktop, laptop, smartphone, but also on paper in case the patient does not use a personal computer).

Motivation

All identified motivational barriers and enablers were linked to the component *reflective motivation* (COM-B level). Both ENT surgeons and audiologists expressed concerns about being responsible for addressing any problems reported by the patients in the intake tool (TDF: *professional roles and responsibilities*), specifically problems that in their opinion are not directly related to the patient's ear/hearing problems and/or to their own expertise or capabilities (e.g., depressive complaints) (TDF: *beliefs about their capabilities*). They mentioned they may not want to focus on problem areas that they cannot treat. This barrier was linked to the TDF domain *goals* of the intake.

“You want to know about those factors that you can actively intervene on. So you want to ask those questions that provide information about what to do with the patient. The factors we cannot intervene, I do not want to focus on.” (audiologist)

ENT surgeons feared that including such items in the tool might lead patients to expect that they would address these problems (TDF: *beliefs about consequences*); and if this did not happen there could be a mismatch between patient expectations and the HHP's actions.

“If patients report that they are really depressed and you only address the factors relating to the ear, because that is what matters to you [as a doctor], you do not match the expectation you created by the questions you asked.” (ENT surgeon)

In the audiologists' focus group, the opposite opinion also emerged: it is their professional responsibility to address all the complaints and problems of the patient, even if they are only indirectly related to the ear or hearing problem. It was mentioned that these complaints should be addressed at least to the degree of checking whether the patient is already being seen by another health care practitioner.

Some of the ENT surgeons and audiologists questioned whether the tool was relevant for all patient groups (TDF: *beliefs about consequences*). They did not see added value of the tool for patients with what they viewed as 'well-defined ear/hearing problems', for example patients with simple ear infections or patients with typical presbycusis and, in their view, evident treatment options (e.g., medication and hearing aids, respectively). In this light, it was also questioned whether additional information on psychosocial and contextual factors would change treatment strategy.

“A large proportion of otology problems are concrete problems. For example, presbycusis and ear infections are problems I do not need all sorts of lists for in advance.” (ENT surgeon)

“If you split a patient’s complaint and needs up into all sorts of categories during your anamnesis and you end up with a hearing aid yes or no either way, the question is whether it is useful to know about all the patient’s complaints.” (audiologist)

Also, it was believed that a lot of (psycho-social) problems are already solved by the standard treatment strategy, so there is no need to address the psychosocial problem separately; TDF: *intentions* to use the intake tool.

“If a patient has a running ear, which you identify in 3 questions and by a quick look into the ear, you prescribe eardrops. And if the person has been feeling miserable and depressed because of the running ear, then it will not change the treatment strategy you have chosen.” (ENT surgeon)

Another shared concern relating to *beliefs about the negative consequences* of the intake tool (TDF) was that when you list all potential problems that patients with ear/hearing problems may have, patients will be more likely to report them and you end up with a list of problems patients might have not raised without such a list. Other *beliefs about the negative consequences* of the tool (TDF) included audiologists’ concern that a standardized tool might lead to an overly automated intake process. This could compromise open conversation with and attention to the patient and implied the risk of the intake tool replacing the patient-HHP interaction. They also were concerned that questions would be asked only because they are listed in the intake tool, and not because they are relevant for all individual patients.

“A disadvantage could be that you feel you have to ask the question, because it is on the list, while you normal would not have asked this particular patient.” (audiologist)

Similarly, an ENT surgeon expressed his fear that use of the tool would cause a *“fixed frame without room for nuance”*.

Regarding the suitability of the intake tool into clinical practice, ENT surgeons did perceive added value in its use in the Audiological Center (for audiology patients). For the ENT intake practice (otology patients) it was generally regarded as unsuitable. The ENT surgeons perceived the AC as (already) being more focused on the rehabilitation of psychosocial aspects of hearing problems. Another suitable application of the tool was seen in scientific research, as an instrument for measuring pre- and post- intervention outcomes. These perceptions were categorized as a barrier related to ENT surgeons’ *professional role and responsibility* (TDF).

An important enabler mentioned by the audiologists was that they strive for a comprehensive review of each individual patient, to improve their current practice to get the complete picture of the patient's functioning with his or her problems (TDF: *goal*).

"A fundamental issue is that if I try to get a complete picture of a patient from the referral letter, the anamnesis and the audiogram, am I overlooking anything? I may think that I can build a complete picture from those reports, but there may be another factor that is not mentioned in these documents. So if you have an instrument that can guarantee that completeness, that would be good."
(audiologist)

Some audiologists saw the added value of the intake tool in managing the patient's expectations regarding treatment (TDF: *goal*): the patients' responses can be used to indicate the areas where patients cannot expect improvement.

"That you are able [with the tool] to prepare the patient that it [the intervention or treatment] will give improvement in some areas, and not in some other areas."
(audiologist)

A motivational enabler mentioned by ENT surgeons that was categorized under positive *beliefs about the consequences* of the intake tool (TDF) was the perceived added value of the tool for the intake, including a better preparation by the patient. This added value was mainly seen for patients with complex problems, e.g., patients with tinnitus and vertigo.

Another factor that would enhance the motivation of ENT surgeons to use the intake tool is if the tool ensured increased patient satisfaction with the care provided (TDF: *goal*). However, they expressed their concern that the benefit to patient care is only theoretical, and not practical in clinical practice (TDF: *pessimism*).

"The medical problem tells you where you can help the patient, and that is quite limited. If you look at very broad domains of functioning, then it's only a small part of what we are able to treat. [...] Again, the politically correct answer would be everything to improve patient's wellbeing, but that is theory; in practice your options are limited". (ENT surgeon)

Another mentioned motivational enabler relating to the *goal* of the intake (TDF) was the tool's potential to make the intake process more time-efficient. However, because the required investment in time and effort to use the tool was viewed as greater than current practice, it was not considered a realistic option for most of their patient groups.

184 TABLE 3. Identified barriers to the use of the ICF-based intake tool as perceived by hearing health professionals

COM-component	Setting*	Theme	TDF
Psychological capability	1,2	<i>In current practice, assessing/discussing psychosocial and contextual factors are not included (or to a limited extent)</i>	Skills, Behavioural regulation
	1,2 1	<i>In current practice, HHPs lack the skills to address patients' psychosocial complaints Lack of knowledge regarding internal referral pathways for patient problems relating to psychosocial factors</i>	Skills Knowledge
Physical opportunity	1,2,3,4	<i>Reviewing a patient's responses on a long intake tool and acting on them is not perceived as feasible in daily practice</i>	Environmental context and resources
	1,3	<i>High turnover, practice limiting the time for the intake</i>	Environmental context and resources
	1,3	<i>Limited time frame per intake, restricting the number of topics to discuss</i>	Environmental context and resources
	1,2	<i>Perceived (extra) time investment to use the intake tool</i>	Environmental context and resources
	2,4	<i>Open-ended questions should be avoided, as they take too much time to review and are difficult to address</i>	Environmental context and resources
Reflective motivation	1,2,3	<i>Feeling responsible for addressing any functioning topics that arise from the intake tool</i>	Social/ professional role and identity
	1,2	<i>Perception that the intake tool is suitable in an Audiological Center or as an research tool, but is less suitable in the Otology intake practice</i>	Social/ professional role and identity
	1,2	<i>Attitude that it is sufficient to rely on own questions and own structure during the intake and consultation as compared to pre-defined and structured format</i>	Beliefs about capabilities
	1,2,3	<i>Not feeling competent in using the intake tool with regard to having to address patient problems in areas beyond the HHP's expertise or capabilities</i>	Beliefs about capabilities
	1	<i>Uncertainty about the patient's satisfaction with the provided care</i>	Optimism (pessimism)
	1	<i>Uncertainty about whether patients will perceive the intake tool as relevant or not</i>	Optimism (pessimism)
	1	<i>Perception that the benefit to patient care is only theoretical, and does not work in practice</i>	Optimism (pessimism)
	1,2,3	<i>Perception that the intake tool will not affect the choice of a treatment strategy (for most patients)</i>	Goals
	1,2	<i>Attitude that the psychosocial factors included in the intake tool do not match the expertise and interest of the HHP</i>	Goals
	1	<i>Perception that there is no need for a comprehensive list of questions, as there are only a few questions that have to be asked to the patient to know what is going on</i>	Intentions
	1,2,3	<i>Perception that the intake tool has no added value in patients with well-defined ear/hearing problems (e.g., ear infection, presbycusis), for whom the treatment options are evident in their view (e.g., medication, hearing aids)</i>	Beliefs about consequences
	1,2,3	<i>Fear that additional questions in the intake tool (as compared with current practice) will raise additional problems the HHP has to assess</i>	Beliefs about consequences

TABLE 3. continued

COM-component	Setting*	Theme	TDF
	1,2,3	Fear that patients expect that the intake tool is used and topics are discussed, while the HHPs may not consider it relevant: mismatch between expectations of the patients and the HHP's actions	Beliefs about consequences
	1,3	Fear of getting responsibility for addressing problems that would arise not be in the expertise of the HHP	Beliefs about consequences
	1,2	Concern that use of the intake tool would create more work	Beliefs about consequences
	3	Fear that questions will only be asked because these are part of the intake tool, and not because these are relevant to the patient	Beliefs about consequences
	1,3	Concern that the cause of the problems reported by patients may not always be ear/hearing-related	Beliefs about consequences
	2	Fear that format of the tool could cause a fixed frame for the intake consultation, without room for nuance	Beliefs about consequences

*Setting: 1 = Amsterdam UMC, location VUmc section Otolology, 2 = WFG, 3 = Amsterdam UMC, location VUmc Audiology Clinic, 4 = ACHN; COM-B = Capability, Opportunity, Motivation-Behaviour; TDF = Theoretical Domains Framework; HHP = hearing health professional

186 TABLE 4. Identified enablers of the use of the ICF-based intake tool as perceived by hearing health professionals

COM-component	Setting*	Theme	TDF
Psychological capability	1,2,3,4	Knowledge that psychosocial factors may affect the daily functioning of the patient and can underlie the patient's ear and hearing complaints	Knowledge
	3,4	In current practice discussing psychosocial- and contextual factors are already part of the intake practice	Skills, Behavioral regulation
Physical opportunity	3,4	In current practice various structured questionnaires/intake-forms are already part of the intake	Skills, Behavioral regulation
	1,2,3,4	Patient's responses should be presented in a simple overview that is easy to use	Environmental context and resources
	1,2,3,4	The intake tool should be provided in a digital format	Environmental context and resources
	1,2,3,4	The intake tool should be self-administered by the patient	Environmental context and resources
	1,2,3,4	The intake tool should predominantly contain closed-ended questions	Environmental context and resources
	1,2,3,4	The intake tool should be integrated into the hospital/centre's electronic system	Environmental context and resources
	1,2	The overview of patient's responses should only show the problem areas of the patient's functioning, and should not include factors the patient reports no problems with	Environmental context and resources
	2,4	Use of the intake tool should be easy regarding accessibility, language, and administration method	Environmental context and resources
	1,4	The intake tool should include prompts and triggers for treatment options or referral pathways to direct the actions of the HHP	Environmental context and resources
	3,4	The intake tool should be designed as a decision tree format	Environmental context and resources
Reflective motivation	3	Sense of professional responsibility to address all the complaints and problems of the patient (including complaints not relating to the ear and hearing domain)	Professional role and identity
	1,2,3	Perceived added value of using the intake tool in patients with complex problems (i.e., patients referred from tertiary care, and patients with tinnitus or vertigo)	Intentions
	3,4	Ambition to get the (more) complete picture of the patient's functioning	Intentions
	2	Willingness to try out the intake tool	Intentions
	3	Recognition that a complete picture of the patient cannot be guaranteed in current practice and that this may be facilitated by using the intake tool	Goals
	1	Perceived value of the intake tool, if the tool ensures increased patient satisfaction with the care provided	Goals
	1	Use of an efficient intake tool may save time	Goals
	2	Perceived value of the intake tool facilitating a better preparation by the patient	Goals
	3	Perceived value of the intake tool in managing the patient's expectations regarding treatment/intervention outcomes (e.g., to indicate the areas where the patient may or may not expect improvement)	Goals

*Setting: 1 = Amsterdam UMC, location VUmc section Otolology, 2 = WFG, 3 = Amsterdam UMC, location VUmc Audiology Clinic, 4 = ACHN
 COM-B = Capability, Opportunity, Motivation- Behaviour; TDF = Theoretical Domains Framework; HHP = hearing health professional

Barriers and enablers perceived by patients (Table 5 and 6)

Capability

Most patients expressed that they needed clear information on the aim and the relevance of the intake tool to use it. These factors were identified as domains of *knowledge* (TDF) enabling patients to use the tool. In addition, patients mentioned that it was important to have clear instructions on how to fill out the questionnaire and interpret and use the intake tool's output, in order to facilitate discussion of their responses with the HHP (linked to TDF domains *knowledge* and *skills*).

“It is important to explain why you should fill in the questions and how it can help in the conversation [with the HHP]”. (patient)

However, it was also indicated that such an explanation should be short and concise. Instructions on how to respond to particular questions were only appreciated if essential for the correct interpretation of the question. Furthermore, patients underlined that medical jargon should be avoided (TDF: *knowledge*).

Opportunity

Similar to the HHP reports, identified enablers in the *physical opportunity* component (COM-B level) mainly related to the TDF domain *environmental context and availability of resources*. A number of patients indicated their preference for a digital intake tool to be completed at home. They felt they had more time and tranquillity there to complete the questionnaire at their convenience. The reported maximum time considered adequate for completing the intake tool was about 15 minutes, although reactions ranged from *“Definitely not too long, 5 to 10 minutes”* to *“As long as necessary, maybe an hour?”*. Most patients indicated that they would like to receive their responses after completion of the questionnaire, but found it difficult to say in what format. Most patients indicated that a printed version, and the ability to save it as a PDF with all questions and answers listed would be sufficient. One patient indicated that access to the tool should be easy and straightforward. The log in process should be designed accordingly.

“If you have to login into a questionnaire, it may not always be as expected so you cannot log in. If people run into a roadblock here, including myself, I would find that very annoying. So it must be something easy, not something complicated.” (patient)

At the COM-B level *social opportunity*, support from immediate family members with filling out the intake tool was identified as a potential enabler by younger adults (ages 18 and 19) (i.e., support from parents) and older adults (i.e., support from the partner, children or a caregiver). These patients expressed that they would value the opportunity to discuss the questions and answers with their family members.

“Interviewer: Do you want or need support from others, like your partner or caregiver, to fill in the intake tool? Patient: Yes maybe some questions I would like to discuss with her [patient referring to patient’s mom].” (patient)

Motivation

All identified motivational barriers and enablers were linked to the component *reflective motivation* (COM-B level). A potential barrier related to the TDF domain *beliefs about the negative consequences* of the intake tool was the fear that the intake tool would get in the way of the (open) conversation with and personal attention from the HHP. Some patients therefore indicated that the use of the intake tool should not negatively affect or replace the conversation with the HHP. Also important was that the intake tool should not shorten or dominate the intake.

Information on the purpose of the questionnaire and what would subsequently be done with the patient’s responses were identified as important enablers for the patient’s *intention* to use the intake tool.

“It must be clear what will happen with it [the responses that the patient has provided], and what the purpose is, that must be clear too.” (patient)

Generally, patients seemed to value the idea of collecting all relevant information regarding their functioning, and that this information was shared with the HHP before the intake took place. They perceived various potential benefits (TDF: *beliefs about the positive consequences* of the intake tool), including better preparation by both the patient and the HHP. It was regarded as important that the HHP would actually use the intake tool and not duplicate questions in the face-to-face intake.

“If you let me fill in a questionnaire in advance, you [the HHP] should let me know that you have read it [...] But do not ask the questions again, or show that you [the HHP] did not read it. Because then I will feel like I am not heard.” (patient)

Regarding other *beliefs about the positive consequences* of the intake tool (TDF), patients valued the possibility of being able to prepare for the intake by filling out the questionnaire beforehand at home. Some patients indicated being quite nervous during intakes, which often made them forget to ask the questions they intended to ask.

“[...] when I am there [in the consulting room], you are often put on a very different track, so you forget your own questions [...] There’s always some nervousness that makes you forget what you intended to ask.” (patient)

Some patients mentioned that the intake tool could help them order/structure their thoughts. The overview of their responses would help them during the intake to address their concerns and questions. Some patients also valued the perceived effect of facilitating more depth and more focus on their specific complaints during the intake, because many questions have already been asked and answered.

"You may get a better conversation with the doctor because you stay away from the standardized facts that usually take up a large amount of the time of the intake conversation, and now those facts are already there. Then you can go into more depth.. yes if it [the tool] has such a function, then I am all for it." (patient)

"If you have the opportunity to fill in a questionnaire or to make comments in advance, and formulate your own ideas about what may be causing your complaints, you can be much more focused during the intake conversation with the doctor. I think that is very important, or could be anyway." (patient)

Related to this, providing information beforehand was perceived to be potentially time-efficient in the intake (TDF: *goals*). Another motivational enabler to fill in the intake tool was that it could contribute to being heard and taken seriously by the HHP (TDF: *beliefs about the positive consequences*).

"I would be motivated to use the intake tool if I think it helps to be taken seriously and therefore to receive better care." (patient)

Some patients indicated that they would be motivated to fill out the questionnaire if they could start with reporting their problem or the reason for their visit. Subsequently, the questions in the different functioning-categories could follow. In this way, their specific complaint or needs would be placed at the center of the intake. This method was categorized as a *goal* of using the intake tool (TDF). Some patients mentioned their motivation to complete the intake tool and share their results to help future patients, science, and/or society (TDF: *goals*). They mentioned hoping that the factors generated by the intake tool would provide insights for the development of new treatment options.

190 TABLE 5. Identified barriers to the use of the ICF-based intake tool as perceived by patients

COM-component	Theme	TDF
Psychological capability	<i>Information and instructions of the intake tool should not be too long or extended</i>	Skills
Physical opportunity	<i>Use of medical jargon should be avoided</i>	Skills
Motivation	<i>The time that is needed to complete the questionnaire should not be too long</i>	Environmental context and resources
	<i>The questions in the questionnaire should not be duplicated in the intake conversation, i.e., the patient's responses should be reviewed by the HHP before the intake visit</i>	Goals
	<i>The intake should not be shortened or dominated by the intake tool</i>	Goals
	<i>Providing the patient's responses to the HHP prior to the intake visit should not negatively affect or replace the (open) conversation with the HHP</i>	Beliefs about consequences
	<i>Use of the intake tool should not reduce the personal attention of the HHP for the patient and his/her problems.</i>	Beliefs about consequences

COM-B = Capability, Opportunity, Motivation- Behaviour; TDF = Theoretical Domains Framework; HHP = hearing health professional

TABLE 6. Identified enablers of the use of the ICF-based intake tool as perceived by patients

COM-component	Theme	TDF
Psychological capability	<i>Information on the aim and relevance of the intake tool are important</i>	Knowledge
	<i>Instructions on how to fill out and use the intake tool are important</i>	Knowledge/ skills
Physical opportunity	<i>Preference to complete the intake tool at home (versus in the clinic)</i>	Environmental context and resources
	<i>Opportunity to fill out the intake tool both on paper and digitally (on the computer)</i>	Environmental context and resources
Social opportunity	<i>In case of a digital intake tool: easy and straightforward accessibility is important (i.e., log-in process)</i>	Environmental context and resources
	<i>In case of a digital intake tool: a possibility to save the responses after completion of the questionnaire is important, to be able to use it in preparation for the intake with the HHP</i>	Environmental context and resources
Motivation	<i>Perceived value of social support from family members with filling out the intake tool</i>	Social influences
	<i>Motivation to use the intake tool would be strengthened when the information on the purpose of the intake tool is clear</i>	Intentions
	<i>Motivation to use the intake tool would be strengthened if patients could start with reporting their problem/ reason for visit, so that their specific complaint or need is placed at the center of the intake</i>	Goals
	<i>Perceived value of collecting all relevant information regarding one's functioning, and sharing this information with the HHP before the intake</i>	Goals
	<i>Perceived value of the intake tool facilitating better preparation of oneself for the intake visit</i>	Goals
	<i>Perceived value of the intake tool contributing to a better understanding or insight into the impact of one's own ear/hearing problem</i>	Goals
	<i>Perceived value of the intake tool contributing to better care provision</i>	Goals
	<i>Perceived value in sharing results to help future patients, science, and/or society</i>	Goals
	<i>Perceived time-efficiency in the intake</i>	Beliefs about consequences
	<i>Perceived value of the intake tool in directing the intake towards the actual complaints and needs of the patient</i>	Beliefs about consequences
	<i>Perceived value of the intake tool in facilitating the intake conversation, because both the patient and health professional are prepared better</i>	Beliefs about consequences

COM-B = Capability, Opportunity, Motivation-Behaviour; TDF = Theoretical Domains Framework; HHP = hearing health professional

Overlap in barriers and enablers perceived by HHPs and patients

There is some overlap between several barriers and enablers mentioned by HHPs and patients. Regarding capability, for example, both HHPs and patients indicated the need to enhance their knowledge on and skills for using the intake tool. Regarding the opportunity-related factors HHPs and patients indicated that the time needed to complete the questionnaire and review the results respectively, should be limited. In addition, HHPs and most patients preferred a digital tool that is easily accessible for patients. As to motivational factors, both HHPs and patients expressed their concern about the intake tool negatively affecting the intake.

Reliability of content analysis

Percent agreement between the three raters varied between 81 (comparison at the TDF level) and 100% (comparison of at the COM-B level).

DISCUSSION

This study used the COM-B model and TDF framework to guide the identification of barriers to and enablers of the use of an ICF-based intake tool in routine clinical oto-audiological practice as perceived by HHPs and patients. During focus groups and individual interviews, HHPs and patients reflected on factors related to their capabilities, their motivation and their physical and social opportunities to use the ICF-based intake tool. Barriers reported by HHPs were linked to a lack of knowledge and skills, time constraints, professional role and identity, and beliefs about the potential consequences of the ICF-based intake tool. Many identified enablers related to the environmental context. Patients were generally willing to use the ICF-based intake tool but reported some barriers with regard to beliefs about potential negative consequences of the tool (e.g., loss of personal contact with the HHP and compromised conversations with the HHP). The most relevant HHP- and patient specific barriers and enablers are discussed below.

Hearing health professionals

HHPs expressed a number of advantages of using the intake tool and preferences over current practice (i.e., motivational enablers). One advantage was the potential benefit that patients could be better prepared for the intake (e.g., patients may become better aware of and specify their actual range of complaints). Also valued was the potential benefit for the HHP that the tool could help obtain a more complete picture of the patient, and could serve to manage patient expectations about the treatment and to manage patient complaints. These expectations are in accordance with the tool's aims as described in the Introduction and these enablers should therefore be taken into account when implementing the tool.

A large number of barriers identified for the HHPs were also identified in previous studies on using PROMs in clinical practice^{19, 23, 30, 43, 44}. These include perceived lack of time to use the tool and additional burden on HHPs; scepticism regarding the usefulness of the tool and its advantage as compared to current practice; the benefit to patient care is perceived to be only theoretical; and the risk that the tool might replace the patient-doctor interaction. Concerns were also raised about the content of the ICF-based intake tool, i.e., that the items in the tool assess factors the HHP is not familiar with and/or feels incapable of handling (e.g., psychosocial aspects). Other concerns regarded the suitability of the tool for all groups of patients (in terms of diagnosis group). These concerns may lead to behaviour that can hamper the targeted behaviour change and therefore implementation. It should be noted that these concerns were strongest among the ENT surgeons and less among the audiologists. Analysis using the TDF suggested that HHPs' capabilities could benefit from enhancing their knowledge about and skills to incorporate the bio-psychosocial approach of the ICF, as well their beliefs about their capabilities, goals in their intakes, and beliefs regarding the consequences of using the tool (motivation).

As mentioned previously, our aim is to develop an intake tool that is viable in all patients who visit an AC or ENT practice with any ear complaint. For this purpose, the CSHL was used as a reference, although some additions were made to render the tool suitable for all types of patients. However, HHPs questioned whether the tool was relevant and necessary for all of their patient groups, as they felt some ear and hearing problems require very straightforward and evident treatment (e.g., eardrops for a simple ear infection). From the perspective of the CSHL this is a biomedical view, which is contrary to the comprehensive functioning view that is implementation of the CSHL into practice aims for. Moreover, the HHPs' scepticism about the redundancy of the tool for some patient groups was in strong contrast with the patient findings. All participating patients (see Table 2) saw relevance in the tool, including patients with 'well-defined' ear and hearing problems and 'evident' treatment options. It should be noted that the broad applicability of the tool still has to be demonstrated in practice. The HHPs' concern will be addressed during the field-test study of the tool and possible adjustments will be made before final implementation into routine practice.

HPPs (particularly ENT surgeons) also reported that the tool did not align fully with their professional identity and norms. Dealing with perceptions of compatibility of new tools and interventions with existing norms is known to be challenging (e.g., ^{21, 45}). An intervention is needed to motivate HHPs and reassure them that the use of PROMs is potentially beneficial and can accommodate their professional identity, which ultimately leads to improved quality of care. Hanbury (2017) recommends the use of the following strategy: emphasize the commonality between PROMs and current ways of working²¹. She suggests that promoting PROMs by drawing attention to how PROMs are just another way of gaining information to inform decision making (rather than imposing a new way of working) may facilitate implementation.

The HHPs highlighted several conditions in the environmental context that could lead to a potentially successful use of the intake tool. These enablers related to the design of the tool (including the preference for a patient-administered, digital tool), and (digital) environmental structures (i.e., integration in the Electronic Patient File (EPF)). Migration of PROM to the EPF system has been shown to be feasible in other studies but requires local engagement^{46, 47}. Software for an eHealth-PROM should ensure that the tool provides all desired functionalities and can accommodate possible future changes⁴⁸. Furthermore, HHPs reported that it is important for them to be able to interpret the scores immediately, which has been recommended by other studies as well¹³. In our study, prompts were identified as possibly important strategies to simplify the use of the intake tool in routine daily practice, including prompts for referral pathways for problems that are perceived as being outside the HHPs' expertise. Developing strategies that guide HHPs to act on patient problem areas that they deem vague or outside their area of expertise is reported in the literature¹³. The ISOQOL guideline for the implementation of PROMs in clinical practice describes three solutions for this: 1) utilization of disease management pathways (i.e., prompting a specific action for follow-up), 2) further exploration of patients' problems identified by the PROM to gain full understanding of the problem(s) and 3) utilization of multiple team members to address complex patient problems. Another enabling factor mentioned by the HHPs was that the tool should only show the responses of items that indicate a problem. However, such a method can only be applied when valid cut-off points are available. This should be taken into account in the future tool.

To enhance strategies for responding to issues identified by PROMs, Snyder et al. (2012) state that it is essential to train clinicians in how to interpret scores and how to respond to the identified patients' problems before implementing PROMs⁴⁹. Generating standard operating procedures can ensure consistency in adopting a new approach as the new norm in health care practice⁵⁰. However, the HHPs participating in the current study expressed the concern that the tool would cause an overly standardized way of performing the intake ('a fixed framework'). Our results therefore confirm the recommendations by the National Institutes of Health (NIH) that this standardization must be balanced with the need for flexibility in integrating the ICF-based intake tool in the clinical workflow, in order to limit perceived burden of the HHPs³⁰.

Lack of time was perceived as an important HHP barrier to implementation of the intake tool. Time is also a frequently mentioned obstacle to implementing PROMs³⁰, which is also consistent with previous observations that clinicians are often of the opinion that a change in clinical practice will automatically be accompanied by an increase in workload²⁵. However, research shows that this is not necessarily the case. The study by Engelen et al. (2011) showed that adding feedback of health-related quality of life via PROMs did not lengthen consultation duration⁵¹. Another study suggested that the barrier 'limited time' is raised because of the

idea that time has to be spent on tasks that are perceived as not supporting the professional's role, rather than time being regarded as a limited resource in itself⁴⁵.

Possible ways to change HHP behaviour can be found in (PROM-) implementation literature. For example, Michie and colleagues (2005)⁵² recommended using persuasive communication, providing information regarding the link between target behaviour (here: using the intake tool) and outcome (here: anticipated patient benefit, patient-centeredness, valued based health care), and targeting barriers relating to knowledge and perceptions of the consequences of adopting the new behaviour/way of working by providing feedback⁵². The latter is supported by a systematic review of facilitators and barriers to implementing PROMs in clinical palliative care practice, which demonstrates that providing feedback to clinicians can be a powerful tool to influence beliefs and attitudes towards to use of PROMs in clinical practice⁴⁴. In a next study such intervention components will be further explored and developed.

Differences between ENT surgeons and audiologists

The larger range of barriers mentioned by the ENT surgeons as compared to the audiologists, suggests that ENT surgeons were most critical about the tool. The interviewed audiologists seemed to be more willing to apply the intake tool into practice; they acknowledged its potential value to construct a complete picture of the patient, and to not overlook important patient problems. The difference in the extent to which the ICF categories of the Brief CSHL overlapped with current practices of audiology and ENT was shown in our previous study⁹. The audiology patient intake documentation covered the bio-psychosocial categories of the Brief CSHL to a much higher degree (i.e., 81%) than the intake documentation of the otology patients (i.e., 63%). It should be noted that the audiologists participating in this study were all used to working in a multidisciplinary setting and many of them were familiar with the ICF. It is therefore likely that the concepts of the ICF were already partly integrated in their way of clinical thinking and their current audiology practice. The ENT surgeons' stronger focus on biomedical aspects may also be explained by the fact that they see many patients with problems relating to the structure of the ear, for which a structural treatment is possible (e.g., ossicular chain reconstruction operations). This focus may cause less time and attention to be spent on psychosocial and contextual factors. Also, as mentioned earlier, audiologists already apply different PROMs in their current intake practice and appreciate their value in adding important information to the intake process. In current otology intake practice no PROMs are applied for clinical use. The ENT surgeon- and audiologist-specific findings have potential implications for the implementation of the intake tool: perhaps discipline-specific implementation interventions should be considered.

Patients

Patients were generally positive and willing to use the tool. Patients' motivation to use the intake tool seemed to be especially enhanced by the enablers that related to the perceived benefits of the tool's goals and patient's beliefs about the positive consequences of the tool. Perceived benefits were focused on an increased patient engagement in care, with the intake tool facilitating better preparation for the intake visit with the HHP and more focus on their specific complaints and needs. The patients' positive response to using the intake tool is consistent with the increased willingness of patients to share their data with clinicians^{53, 54}.

Despite these predominantly positive perceptions, concerns were also expressed, specifically regarding the loss of personal contact with the HHP and compromised conversations with the HHP. This is a common perceived belief, which needs to be anticipated in the text introducing the tool to patients⁴⁸. An important aim of the tool is that the provided information adds to the patient-HHP conversation and does not limit the discussion about possible causes and consequences. The intake tool's aim is to provide a complete picture of the patient's complaints and needs, facilitating personal attention of and conversation with the HHP and thereby serving as a communication tool that ultimately leads to an agreed-upon treatment approach.

The primary reported patient barrier to the use of PROMs in the literature is perceived burden. This means that the tool should not be too long, should be easy to use and should have clinical impact³⁰. In addition it is argued that if PROM-reports automatically trigger events that mitigate the problem (e.g., communication with the doctor, patient education), the perception of burden is mitigated as well, and patients are more willing to accept the time and effort required to answer questions³⁰. The recommended amount of time for any PROM is 10-15 minutes¹⁸, which was supported by our findings as well. Also, a critical driver of high patient compliance with PROMs in other studies is that patients know their questionnaire responses are reviewed by the doctor and used⁴⁷ in the clinical consultation. This emerged from our findings as well. Moreover, this is consistent with anticipated patient expectations HHPs mentioned in the focus groups. However, HHPs reported this as a barrier to using the intake tool, as they feared the responsibility of having to review and act upon all patient responses. This contradiction requires careful consideration in the implementation plan.

Some patients expressed a preference for an open question to add narrative comments about their specific complaints/reason for visit. This is similar to findings of another qualitative study of patient and clinician views on QoL assessment in oncology practice²³, which stated that such findings help to bridge the gap between standard measurement and issues that matter to patients and should therefore be considered when implementing PROMs in clinical practice. However, our results also showed that HHP perceived the use of

open questions as a barrier. Adoption of open questions should therefore be carefully considered.

Regarding the environmental opportunities and the presentation of the intake tool, the patients' preferences, such as electronic administration at home, should be addressed in the implementation plan. In addition, there should be a back-up system for administration in the clinic (e.g., distribution of iPads to collect data). Patients showed interest in the use of electronic portals; these have been suggested to benefit feelings of being (better) prepared for clinical appointments, higher satisfaction with treatment choices, and better adherence to medical advice⁴⁸. However, our findings also revealed that efforts need to be made to include patients who are less likely to engage with electronic assessments (e.g., due to unfamiliarity or no access to a personal computer). Providing feedback following completion of a questionnaire is another enabler that is reported in literature and confirmed in our data. It helps patients understand the goals and motivates them to complete questionnaires again^{12,13}. It should be noted that in our study patients had difficulty indicating in what format they would prefer this feedback. We did not provide concrete visual examples of possible output options, which may have limited the range of potential options that patients came up with.

Overlap in barriers and enablers perceived by HHPs and patients

The observed overlap in enablers and barriers perceived by HHPs and patients is an important finding, as this will facilitate the acceptance of the intake tool. Especially with regard to the administration and design of the tool patients and clinicians seemed to be in agreement. An accepted method of PROM data collection within the clinical workflow is essential for successful implementation⁵⁵. The concern raised by both the HHPs and patients that the intake tool could compromise the intake suggests that a PROM could be detrimental to the initial aim of promoting patient-centred care. This indicates that simply implementing PROMs in practice does not automatically result in patient-centred care, and emphasizes the importance of studying the intake tool's implementation context. This study is an important first step, and the processes that support or impede the utilization of the intake tool should be continuously monitored in the further implementation process.

Strengths and limitations

The strengths of the study relate to the use of the COM-B model and TDF. This approach provides an opportunity to design a theoretically informed (implementation) intervention²⁸. In qualitative research, trustworthiness is highly important and should be guaranteed⁴². Trustworthiness comprises credibility (quality of the methodology used to conduct and evaluate a study), transferability (study provides rich contextual information), and dependability (consistency in the treatment of data is obtained and kept transparent). By using a theoretical approach; data from HHPs and patients; by providing quotes; and by using structured analysis, including a reliability analysis, we feel that we have ensured the

trustworthiness of the study. In the implementation literature we find the recommendation that users of the potential intervention should be involved in all steps of the development and implementation of the intervention. This study included both user groups: HHPs and patients. Another strength is the inclusion of HHPs from both academic and secondary settings, enabling the broad examination of the perspectives and attitudes of Dutch oto-audiology care professionals.

Some limitations need to be discussed as well. Firstly, following the application of the behavioural change theory of COM-B in our study, we used a deductive analysis approach to identify and classify the barriers and enablers. One drawback of this approach is that it may have limited the scope and the depth of data interpretation. Because of practical reasons, data collection among HHPs was not based on data saturation principles. This may have limited the identification of other barriers and enablers to using the intake tool. However, there was considerable overlap in the responses in the discipline specific meetings, suggesting that the lack of data saturation may be limited. By including only the HHP- and the patient perspectives (i.e., the users of the intake tool), other barriers or enablers of importance may have been overlooked. The wider health care system include a broader range of factors that may affect the successful implementation of the intake tool. Examples concern stakeholders involved in the practical organization and ongoing support for collecting and integrating PROM data in patient records and in the clinical workflow. Moreover, the context-specific setting may limit the generalizability of our findings to some extent. The study was conducted in the Netherlands, and the transferability of the findings beyond the context of the Dutch health care system will require adaptation to the local context. Another limitation relates to the publication of the current project. This study is part of a larger overarching project that focusses on the development and implementation of the ICF-based intake tool, and publishing the studies in separate papers may reduce the clinical impact of this work⁵⁶. However, the studies will also be presented as a consolidated package as part of a PhD thesis, which will include the overall clinical implications of the work. In addition, we feel that by publishing the research articles of this project separately, another relevant purpose is served: providing a detailed example on how to carefully apply the COM-B model to design an intervention. If all studies would have been presented in one paper, many helpful details in this regard would have been lost. Note that the publication and dissemination of this work is not sufficient for clinical implementation, as recently highlighted by Boisvert et al. (2017)⁵⁷. They suggested that the current 'research-to-practice pathways', including peer-reviewed publications, may not be sufficient for an effective clinical implementation of evidence-based practice and patient-centred care in the field of audiology. Working together with the clinical work field was found to be key to ensure that clinicians and other stakeholders are integrated in the research process⁵⁷. In the current project, staff members of the audiology and otology departments are part of the project group. The current study shows that other clinicians were also included in the development

process of the tool, and the enablers and barriers they perceived will be used to develop an adequate implementation intervention.

Implications of the study for research practice and policy

Results from this study are required to inform the development of an implementation plan aimed at incorporating the ICF based intake tool in routine clinical otology and audiology practice. Regarding the development of strategies for responding to issues identified by the ICF-based intake tool in order to facilitate implementation, additional research is required into existing possible effective treatment options and referral paths that correspond with 'problem' areas of functioning. Further research will also have to show whether the ICF-based intake tool is suitable and relevant for all patients visiting the audiology clinic and ENT practice. Although the rationale for using the intake tool in both audiology and otology has been outlined in the methods, the intake tool may not be suitable for all otologic patients. The optimization of the intake tool will be an ongoing process, requiring continuous evaluations, if necessary followed by modification.

CONCLUSION

We aim to develop and implement an ICF-based intake tool for use in routine Dutch oto-audiology practice. This study identified barriers to and enablers of the use of the tool as perceived by HHPs and patients based on the COM-B and TDF. For the implementation to succeed, HHPs' knowledge, skills and motivation regarding the relevance, clinical usefulness and clinical benefit of the tool need to be enhanced. Patients motivation to use the tool can be enhanced by providing clear and specific information on its purpose and relevance. For both HHPs and patients, opportunities in the environmental context and resources provide additional targets for successful implementation. This qualitative work is a pre-implementation step. In a next step, strategies for the implementation of the ICF-based intake tool will be developed based on the barriers and enablers that were identified in the current study. In addition, evidence on interventions from other implementation studies will be used. The final implementation intervention will be determined via a consensus procedure with relevant stakeholders.

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APPENDIX 1. COM-B components and their related TDF domains, definitions and theoretical constructs*

COM-B component (definition)	TDF domain (definition, <i>theoretical constructs</i>)
Physical capability Physical skill, strength or stamina	Physical skills
Psychological capability Knowledge or psychological skills, strength or stamina to engage in necessary mental processes	<p>Knowledge An awareness of the existence of something. <i>Knowledge (including knowledge of condition/ scientific rationale); procedural knowledge; knowledge of task environment.</i></p> <p>Cognitive and interpersonal skills An ability or proficiency acquired through practice. <i>Skills; skill development; competence; ability; interpersonal skills; practice; skill assessment</i></p> <p>Memory, attention, and decision processes The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives. <i>Memory; attention; attention control; decision making; cognitive overload/ tiredness</i></p> <p>Behavioural regulation Anything aimed at managing or changing objectively observed or measured actions. <i>Self-monitoring; breaking habit; action planning</i></p>
Physical opportunity Opportunity afforded by the environment involving time, resources, locations, cues, physical ‘affordance’	Environmental context and resources Any circumstance of a person’s situation or environment that encourages the development of skills and abilities, independence, and adaptive behaviour. <i>Environmental stressors; resources/ material resources; organizational culture/ climate; salient events/ critical incidents; person x environment interaction; barriers and facilitators</i>
Social opportunity Opportunity afforded by interpersonal influences, social cues and cultural norms that influence the way that we think about things, e.g., the words and concepts that make up our language	Social influences Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours <i>Social pressure; social norms; group conformity; social comparisons; group norms; social support; power; intergroup conflict; alienation; group identity; modelling</i>
Reflective motivation Reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)	Social/professional role and identity A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting. <i>Professional identity; professional role; social identity; identity; professional boundaries; professional confidence; group identity; leadership; organizational commitment</i>

*adopted from: Michie S, Atkins L, West R. *The behavior change wheel: a guide to designing interventions*. London: Silverback Publishing; 2014.

continued

COM-B component (definition)	TDF domain (definition, <i>theoretical constructs</i>)
	<p>Beliefs about capabilities Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use. <i>Self-confidence; perceived competence; self-efficacy; perceived behavioural control; beliefs; self-esteem; empowerment; professional confidence</i></p> <p>Optimism The confidence that things will happen for the best or that desired goals will be attained. <i>Optimism; pessimism; unrealistic optimism; identity</i></p> <p>Intentions A conscious decision to perform a behaviour or a resolve to act in a certain way. <i>Stability of intentions; stages of change model; trans theoretical model and stages of change</i></p> <p>Goals Mental representations of outcomes or end states that an individual wants to achieve. <i>Goals (distal/ proximal); goal priority; goal/ target setting; goals (autonomous/ controlled); action planning; implementation intention</i></p> <p>Beliefs about consequences Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation. <i>Beliefs; outcome expectancies; characteristics of outcome expectancies; anticipated regret; consequences</i></p>
<p>Automatic motivation Automatic processes involving emotional reactions, desires (wants and needs), impulses, inhibitions, drive states and reflex responses</p>	<p>Reinforcement Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus. <i>Rewards (proximal/ distal, valued/ not valued, probable/ improbable); incentives; punishment; consequences; reinforcement; contingencies; sanctions</i></p> <p>Emotion A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event. <i>Fear; anxiety; affect; stress; depression; positive/ negative affect; burn-out</i></p>

APPENDIX 2. Interview guides used in the focus groups and individual interviews

Hearing health professionals:

Topic guide used in the focus groups and in one of the individual interviews (one audiologist)

1. Can you describe the intake process in your current practice?
2. In an ideal situation, what should the intake consultation look like in your view?
3. (How) Could a different or new method support you in this ideal situation?
4. What requirements should this method meet?
5. Suppose patients would answer questions about a number of topics that related to their functioning with their ear/hearing problems in their daily lives, and you would receive the answers to these questions in an overview. And you would review these answers some time before or during the intake appointment. What would you think of such a method?
6. What requirements should this method meet such that you would want to use the method?
 - a. What knowledge would you need to have in order to be able to use the method?
 - b. Try to think very practically: What should happen in practice for you to use the method? How should the environment be adapted for you to use the method?
 - c. What would motivate you to use the method?

Patients:

Structured interview questions used in the individual interviews

1. Try to think of an earlier intake conversation that you had. It can be with *any* health care professional. What was your experience back then? What did you like and what did you not like about this intake conversation? (possible follow-up question: What would you like to see improved in the intake conversation?)
2. What topics do you hope that a healthcare provider would ask about/ would have specific attention for?
3. In an ideal situation, what should an intake consultation look like in your view?
4. In this ideal situation, would an overview of the relevant topics that you just mentioned, which you can prepare in advance, support you in any way?
5. What requirements should this method meet?
6. Suppose we shape the method in such a way that you as a patient would complete questions about relevant topics prior to the intake consultation, and you would discuss the summary of your answers during the intake conversation with the ENT-doctor or audiologist. What do you think of such a form/method?
7. Do you think it is important to be provided with information about why it would be important for you to fill in the questionnaire?
8. What would you like to know about using the questionnaire?
 - a. Knowledge about relevance?
 - b. Knowledge about how to fill in the questionnaire? (instructions)

9. Try to think very practically. What should happen in practice for you to fill in the questionnaire?; How should the environment be adapted to fill in the questionnaire?
 - a. What is the maximum time that you would be prepared to spend on filling out the questionnaire?
 - b. Where and in what way would you like to receive the questionnaire (at home/ in the waiting room, via the internet / on paper)?
 - c. In what way would you want to obtain the (overview of your) results or answers?
 - d. Would you find it important to know whether or not other patients filled in the questionnaire as well?
 - e. Would you like to receive reminders for completing the questionnaire in time?
 - f. Would you want any support or help from others, like your partner or caregiver, to fill in the questionnaire?
10. What would motivate you to fill in the questionnaire?
 - a. Do you want to feel a sense of pleasure (fun) or satisfaction during or after completing the questionnaire?
 - b. Would you like to feel that it is relevant to fill in the questionnaire? For example, that the negative consequences outweigh the positive consequences of filling in the questionnaire?

Chapter 7:

Developing an intervention to implement an ICF-based e-intake tool in clinical otology and audiology practice

Submitted as:

van Leeuwen LM, Pronk M, Merkus P, Goverts ST, Anema JR, Kramer SE.
Developing an intervention to implement an ICF-based e-intake tool
in clinical otology and audiology practice.

ABSTRACT

Objective: To develop an intervention for the implementation of an ICF-based e-intake tool in clinical oto-audiology practice.

Design: Intervention design study using the eight-stepped Behaviour Change Wheel. Hearing health professionals' (HHPs) and patients' barriers of and enablers to the use of the tool were identified in our previous study (step 1-4). Following these steps, relevant intervention functions and policy categories were selected to address the reported barriers and enablers (steps 5-6); and behaviour change techniques and delivery modes were chosen for the selected intervention functions (steps 7-8).

Study sample: Twenty-one hearing health professionals and eighteen patients.

Results: For HHPs, the intervention functions education, training, enablement, modelling, persuasion and environmental restructuring were selected (5). Guidelines, service provision, and changes in the environment were identified as appropriate policy categories (6). These were linked to nine behaviour change techniques (e.g., information on health consequences), delivered through educational/training materials and workshops, and environmental factors (7-8). For patients, the intervention functions education and enablement were selected, supported through service provision (5-6). These were linked to three behaviour change techniques (e.g., environmental factors), delivered through their incorporation into the tool (7-8).

Conclusions: A multifaceted intervention was proposed to support the successful implementation of the intake tool.

INTRODUCTION

Over the last years, a paradigm shift has been observed towards providing more patient-centred care by treating the patient from a biopsychosocial perspective rather than from a biomedical perspective (i.e., just treating the patient's disorder or disease) has been observed. The need for such a biopsychosocial approach has also been recognized in ear and hearing health care, as has the need for a standardized reference system to facilitate this¹⁻⁴. The World Health Organization's International Classification of Functioning, Disability and Health (ICF) provides such a reference system or model⁵. The classification system can be used to describe health conditions in all their complexity in a standardized way. According to the ICF, functioning reflects the interplay between an individual's body structures and functions, activities, participation, and the contextual factors around this individual. To facilitate the application of the ICF in ear and hearing health care, ICF Core Sets for Hearing Loss (CSHL) were developed¹. These represent shortlists of ICF categories that cover the most relevant areas of functioning of adults with hearing loss¹.

Capturing functioning information is particularly essential during the early stages of assessment and diagnosis. This way, the design of a personalized treatment plan can be facilitated^{6, 7}. The Brief CSHL provides a minimal standard for organizing and documenting hearing-related functioning information and can be taken as a starting point for diagnosis, rehabilitation, and other services⁸⁻¹⁰. To allow application of the Brief CSHL in intake practice, operationalization of the ICF categories is required first, followed by the design of an intervention to actually implement the CSHL.

Patients' self-report is recommended as the most appropriate measure for capturing functioning information^{11, 12}. We have developed an intake tool through operationalizing the categories of the Brief CSHL into a digital Patient Reported Outcome Measure (PROM), which we have named the "ICF-based e-intake tool". The development process comprised a mixed methodology study including qualitative content assessments, in which all stakeholders' (i.e., patient representatives, hearing health professionals, researchers¹³) views were incorporated. The goal of the intake tool is to screen adults with ear and/or hearing problems in order to be able to identify potential functioning problems and relevant influencing contextual factors. With such information, patients' care plans can be tailored to their specific problems and needs. The intended use is that adult patients complete the questionnaire part of the intake tool prior to their intake, after which the responses become available for both the patient and the clinician. By making the intake tool an integral part of clinical care, we aim to facilitate communication between clinicians and patients and shared treatment planning¹⁴. It is envisaged that use of the tool would optimize the individual patient's care and treatment outcomes. Nevertheless, it is known that the actual integration and use of PROMs in clinical practice (i.e., implementation into routine care) often is challenging and suboptimal¹⁵⁻¹⁸.

Implementing a new tool into clinical practice involves changes in established practices. Specifically, human behaviour change is an essential element of implementation processes¹⁹. For example, the potential effect of the use of PROMs on health outcomes is crucially mediated by the modification of the behaviour of both patients and health care professionals^{20, 21}. The field of implementation science and theories of behaviour change can inform the implementation of PROMs and can ensure that potential challenges are anticipated upon and can be addressed²². In order for the implementation of the intake tool to become successful, a carefully developed theory-based (behaviour change) intervention is needed^{20, 22}. Despite this knowledge, prior studies on the implementation of PROMs often lacked a careful assessment of barriers to and enablers of change and had insufficient methodological rigor^{15, 22}.

As recommended by the Medical Research Council, behaviour change interventions should be evidence-based and draw on relevant and coherent theoretical frameworks^{23, 24}. The Behaviour Change Wheel (BCW) is such a framework, and is recommended when undertaking theoretically-informed research in the context of hearing health care²⁵. The process of intervention development using the BCW is outlined in detail¹⁹, and has been applied successfully in different contexts (e.g., implementing international sexual counselling guidelines in clinical cardiac rehabilitation²⁶; improving screening for people with mental illness²⁷). In audiology research, Barker and colleagues^{28, 29} successfully used the BCW to develop an intervention to improve hearing-aid use in adult auditory rehabilitation.

The BCW synthesizes 19 theoretical frameworks of behaviour change and is based on a model of human behaviour, the COM-B model¹⁹. The COM-B model presents human behaviour (B) as resulting from the interaction between physical and psychological capabilities (C), opportunities provided by the physical and social environment (O), and reflective and automatic motivation (M)¹⁹. In a previous study, we performed the first stage of the BCW method, which focuses on understanding the behavior that needs to change (“use of the intake tool by patients and hearing health professionals (HHPs)”). We used the COM-B model to identify and categorize barriers to and enablers of the use of the intake tool, perceived from the perspectives of patients and HHPs¹⁰. Focus groups and interviews with HHPs (N=20) and patients (N=18) were performed. Two important HHP barriers that were identified included expected lack of time to use the intake tool (O); and fear of being held responsible for addressing any emerging problems that would be outside the expertise of the HHP (M). Important enablers that were identified included: the integration of the intake tool in the electronic patient record (O); the opportunity for the patient to be better prepared for the intake visit (M); and provision of a complete picture of the patient’s functioning via the intake tool (M). Identified patients’ barriers included fear of losing personal contact with the HHP (M); and fear that use of the intake tool might negatively affect conversations with the HHP (M). Identified enablers included sufficient knowledge on the aim and relevance of the intake

tool (C); better self-preparation for the intake (M); and a more focused intake procedure (M). In both HHPs and patients, various factors relating to the design of the intake tool were reported to enable its use (O).

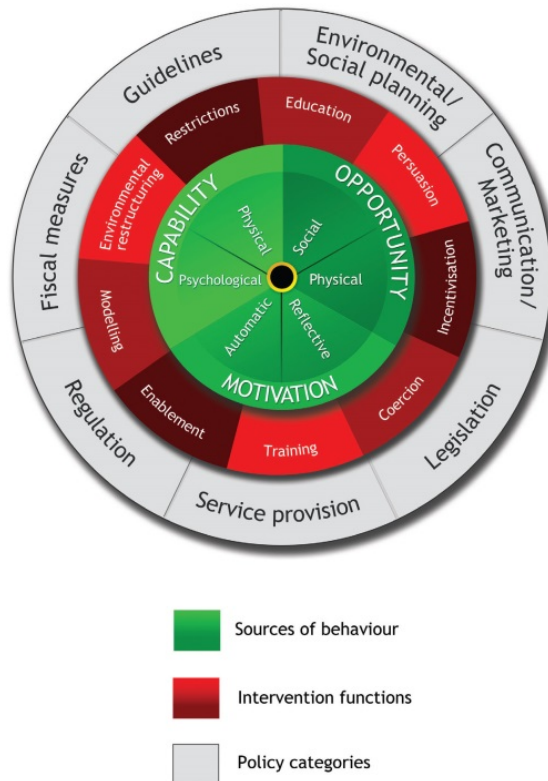


FIGURE 1. The Behaviour Change Wheel

Reprinted from *The Behaviour Change Wheel: a guide to designing interventions*. By Michie S, Atkins L, West R. London: Silverback Publishing. Copyright [2014] by Michie S Atkins L, West R. Reprinted with permission.

In the BCW, the COM-B model is surrounded by nine general intervention functions and seven policy categories (see Figure 1). The BCW provides a systematic method of identifying relevant intervention functions and policy categories based on what is understood about the target behaviour (here: information on barriers to and enablers of using the intake tool). In addition, the general intervention functions can be translated into behaviour change techniques to define the content of the intervention. The aim of the current study was to develop an intervention for the implementation of the ICF-based e-intake tool in clinical oto-audiology practice, using the BCW method.

MATERIALS AND METHODS

The BCW method provides an eight-stepped procedure for designing behaviour change interventions, covering 3 main stages: 1) understand the behaviour, 2) identify intervention options, and 3) identify content and implementation options of the intervention³⁰. Note that stage 1 has already been performed in a previous study. The current study focused on stages 2 and 3 of the BCW method. Figure 2 describes the steps of the BCW method. The steps are further explained below, and the steps of stage 1 (our previous study) are summarized here as well.

Stage 1: Understand the behaviour (step 1-4) (previous study)

Stage 1 includes four steps that are needed to lay the ground work for understanding the target behaviour³⁰. Steps 1 to 3 cover the identification, selection and specification of the behaviour(s) to target, respectively. Step 4 covers the identification of what needs to change in order to achieve the target behaviour and the specific enablers of and barriers to that behaviour. The target behaviour was defined as: “use of the intake tool by patients and HHPs”. In addition to the COM-B model, we applied the Theoretical Domains Framework (TDF) for a more detailed evaluation of HHP and patient barriers and enablers. The TDF specifies the C, O, and M components as theoretical domains of behaviour related to implementation³¹. These include for example knowledge, skills, beliefs about own capabilities, and emotion³².

Stage 2: Identify intervention options (steps 5-6)

Stage 2 covers two steps. The first is the identification of intervention functions, i.e., the general categories through which behaviour may change (i.e., from not using an intake tool into using an intake tool) (step5). The second is identification of policy categories to support the delivery of the intervention functions (step 6)³⁰.

Step 5: Identification of intervention functions

Intervention functions were identified by linking them to the COM-B components and TDF domains identified in step 4. We used the APEASE criteria to select the most context-appropriate intervention function(s) for each barrier and enabler. APEASE stands for affordability, practicability, effectiveness/cost-effectiveness, acceptability, side effects/safety and equity³⁰. Ideally, intervention function(s) are chosen which are optimal on all these criteria.

Step 6: Identification of policy categories

Policy categories were identified by linking them to the intervention functions chosen in step 5. Again, we used the APEASE criteria in the selection process.

Stage 3: Identify content and implementation options (steps 7-8)

Stage 3 covers two steps which aim to specify intervention content in terms of behaviour change techniques (BCT) (step 7) and to identify the mode of delivery for the intervention (step 8). Stage 3 took place in a consensus meeting with the research team. Each member of the research team had expertise on one or more areas of relevance: clinical ear and hearing practice, evidence-based implementation, or the ICF. In the consensus process, supporting evidence found in the literature on the BCTs and delivery modes formed the basis for the group discussion.

Step 7: Identification of BCTs

BCTs were linked to the selected intervention functions (step 5). BCTs are the smallest, active components of an implementation intervention to change behaviour³⁰. A taxonomy of 93 techniques has been developed (BCTTv1; ³³). From this taxonomy, the BCW method identifies the most frequently used BCTs for each intervention function³⁰. This list was used as a reference in the current study.

Step 8: Identification of delivery mode

The most optimal modes to deliver each of the chosen techniques (step 7) were identified (i.e., face-to face, over distance).

Intervention content

Lastly, the BCTs were translated into intervention content. To optimize the completeness of the reporting of the intervention, the TiDieR checklist was used³⁴.

Ethics

The study was approved by the Medical Ethical Committee of the Amsterdam UMC, location VU University Medical Center (VUmc), Amsterdam; the Netherlands. Data collection was carried out between November 2016 and February 2017.

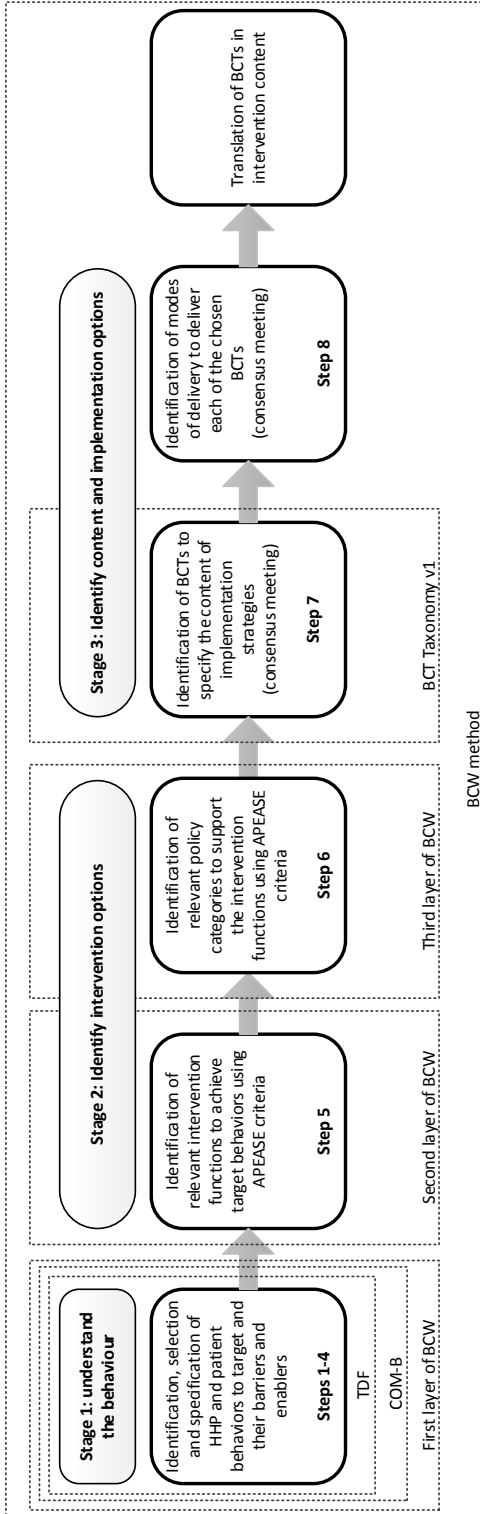


FIGURE 2. The stages and specific steps of the BCW method, related to the layers of the BCW

APEASE criteria = optimal affordability, practicability, effectiveness, acceptability, side effects and equity. TDF = Theoretical Domains Framework; COM-B = capability, opportunity, motivation-behaviour model; BCW = behaviour change wheel.

RESULTS

Stage 1 (previous study)

The specified target behaviours for both the HHP and the patients that were identified in our previous study are shown in Table 1.

All identified enablers and barriers are presented in columns 2 and 3 of Tables 2 and 3 for HHPs and patients, respectively. The tables also show the capability-, opportunity-, and motivational-components (column 1), and TDF-domains (column 4) that the barriers and enablers were linked to. The key supporting articles that were used to inform the selection of intervention functions, policy categories, and BCTs, are provided in Appendix 1.

TABLE 1. Specification of the selected target behaviours

	<i>Hearing health professionals</i>	<i>Patients</i>
Target behaviour	Use of an ICF-based e-intake tool	Use of an ICF-based e-intake tool
Who	All audiologists and ENT surgeons (otologists) of the Amsterdam UMC, location VUmc	All adult patients with ear or hearing problems visiting the outpatient clinic of the Amsterdam UMC, location VUmc for the first time
What	(1) Reviewing the patient's responses in preparation on the intake and (2) using the intake tool during the intake to discuss the patient's needs and to together specify a treatment plan that is tailored to the patient's needs	(1) Filling out the questionnaire-part of the intake tool prior to the intake
When	Before and during the intake of each new patient with ear or hearing problems visiting the outpatient clinic of the Amsterdam UMC, location VUmc for the first time	Before the intake
Where	At the outpatient clinic in their consultation room (1 and 2)	At home or in the waiting room*
How often	(1) Prior to each intake consultation of each new patient; (2) During the intake consultation and treatment of these patients	Once

*preference will be determined in this current study

Note. Table derived from the worksheet adapted from *The Behavior Change Wheel: a guide to designing interventions* (p. 56) by Michie S, Atkins L and West R, 2014, Great Britain: Silverback Publishing. Copyright Year by "Susan Michie, Lou Atkins and Robert West".

Stage 2

Step 5: Intervention functions

Education, persuasion, training, environmental restructuring, enablement and modelling were identified as the most appropriate intervention functions for HHPs (see Table 2 column 5). The use of the APEASE criteria to select the most relevant intervention functions is shown in Appendix 2. Education, such as information about the content of the intake tool and how to use it, persuasion (such as persuasive communication) and training (such as role play) were selected for overcoming the HHPs' perceived barriers relating to the negative consequences of the intake tool, their own professional identity and their self-efficacy. Modelling was selected as an option to demonstrate how to use the intake tool. Enablement was selected to, for example, help HHPs to interpret the results of the intake tool. In addition, environmental restructuring was selected to incorporate specific design features and functionalities in the intake tool that adhere to the HHPs' preferences (e.g., integration into electronic patient record and provision of summaries of the results). This with the aim to make the data of the intake tool easily accessible and actionable.

For patients, *education, persuasion, enablement* and factors relating to *environmental restructuring* were selected as the most appropriate intervention functions (see Table 3, column 5). Education was selected to facilitate knowledge about the purpose and relevance of the intake tool and to provide instructions on how to fill out the intake tool. Persuasive communication techniques were selected for reinforcing patients' motivational beliefs about the positive consequences of using the intake tool. Enablement and environmental restructuring were selected to enable the preferred administration of the intake tool, and to adapt the design and functionalities of the intake tool to the patients' preferences (e.g., ensure easy accessibility to the digital questionnaire).

Step 6: Policy categories

How the APEASE criteria were used to select the most relevant policy categories is shown in Appendix 3. For HHPs, three policy categories were selected: *guidelines, environmental/social planning* and *service provision* (see Table 2, column 6). 'Guidelines' were selected as a means to provide HHPs with educational and instructional intervention functions. The categories 'service provision' and 'environmental planning' were selected as the most appropriate for training and modelling skills that would enable the practical use of the intake tool.

For patients, only the category *service provision* was considered an appropriate policy category (see Table 3, column 6). This is because the use of the intake tool can be considered as provision of a service. It was envisaged that all identified intervention functions for patients would be incorporated into the intake tool itself and thus are presented to the patient when the intake tool is provided to them.

Stage 3

Step 7: Behaviour change techniques

The selection of BCTs is shown in Appendix 4. The linking of the selected BCTs to the reported barriers and enablers and intervention functions is shown in column 7 of Tables 2 (HHPs) and 3 (patients). To illustrate, the BCTs that were mapped to the barriers in the knowledge and skills domain of HHPs included *the provision of information on health consequences* (e.g., provide information on the relevance of the patient's view and the ICF), *modelling/demonstration of behaviour* and *behavioural rehearsal* of relevant skills (e.g., how to use the intake tool).

For patients, all barriers and enablers relating to skills, knowledge, and motivational beliefs were addressed by the BCT *information provision* (e.g., inform the patient on the relevance and purpose of the intake tool; emphasize that the intake tool could help facilitate a more targeted intake process). Barriers and enablers identified in the environmental context were linked to the BCT *adding objects to the physical environment* (e.g., providing a digital questionnaire to be filled in at home).

Step 8: Modes of delivery

For HHPs, the following modes of delivery for the BCTs were selected: face-to-face group workshops given by an opinion leader, a digital/printed manual, design features and supporting instruments incorporated in the intake tool. In recognition of the limited time that audiologists and ENT surgeons usually have, offering an one-off workshop that could be fit in their schedules was considered best.

For patients, it was decided to provide all BCTs through service delivery via the intake tool. Important aspects include clear information provision on the intake tool's purpose, and instructions on how to use the tool (inserted in written format in the introductory text sent along with the intake tool itself). Provision of a customer service phone-number in case of technical or other problems was also selected.

TABLE 2. Intervention content targeting HHPs' barriers (A) and enablers (B) towards using the intake tool

A. HHPs' barriers towards using the intake tool, COM-B components, TDF domains, selected intervention functions, selected policy categories, selected BCTs and BCT translation into intervention content							
COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
Psychological capability	1,2	<i>In current routine practice, assessing/discussing psychosocial and contextual factors are not included (or to a limited extent)</i>	Behavioural regulation/skills	Education	Guidelines	Information on health consequences	<ul style="list-style-type: none"> Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems Provide information on improved health consequences for patients when using the ICF based intake tool
				Training	Service provision	Instruction on how to perform behaviour	<ul style="list-style-type: none"> Provide instructions on how to interpret and use the information provided by the ICF based intake tool
	1,2	<i>In current practice, HHPs lack the skills to address patients' psychosocial complaints</i>	Behavioural regulation/skills	Modelling	Service provision	Demonstration of the behaviour	<ul style="list-style-type: none"> Demonstrate how to interpret and use the information provided by the intake tool Demonstrate how to raise the issues identified with the intake tool with patients
				Training	Service provision	Behavioural practice/rehearsal Feedback on behaviour	<ul style="list-style-type: none"> Role play exercises to practice using the intake tool in the consultation room Audit and feedback after training and during adoption. Notifications should be provided and visible within the EMR to the treating HHP and his/her colleagues.

TABLE 2A. continued

COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
				Enablement	Environmental planning	Adding objects to the environment	<ul style="list-style-type: none"> - Integration of supporting instruments providing information on possible treatment options/referral pathways
	1	<i>Lack of knowledge regarding internal referral pathways for patient problems relating to psychosocial factors</i>	Knowledge	Education	Guidelines	Instruction on how to perform a behaviour	<ul style="list-style-type: none"> - Inform HHPs on internal referral pathways; i.e., the social worker, and occupational health at the department of audiology/ ENT. And providing clear instructions on how to initiate a referral to these other HHPs.
					Environmental planning/service provision	Adding objects to the environment	<ul style="list-style-type: none"> - Integration of supporting instruments providing information on possible treatment options/referral pathways
Physical opportunity	1,2,3,4 1,3	<i>Reviewing a patient's responses on a long intake tool and acting on them is not perceived as feasible in daily practice High turnover practice limiting the time for the intake</i>	Environmental context and resources	Environmental restructuring/enablement	Environmental planning/Service provision	Adding objects to the environment	<ul style="list-style-type: none"> - Integrate the intake tool in the electronic patient record system to make the tool easily accessible - Develop/integrate (graphical) summaries of patient responses and a quick overview of answers (i.e., the functioning profile) - Limit the number of open questions in the ICF based intake tool

TABLE 2A. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	1,3 1,2 2,4	<i>Limited timeframe per intake, restricting the number of topics to discuss Perceived (extra) time investment to use the intake tool Open-ended questions should be avoided, as they take too much time to review and are difficult to address</i>				Prompts/cues	<ul style="list-style-type: none"> - Integration of supporting instruments that flag the items that indicate a (possible) problem - Integration of supporting instruments to prompt HHP's to use the intake tool in every new patient that comes in (e.g., by a digital stimulus in EMR).
Reflective motivation	1,2,3 1,2	<i>Feeling responsible for addressing any functioning topics that arise from the intake tool Perception that the intake tool is suitable in an Audiology Clinic or as an research tool, but is less suitable in the Otolaryngology intake practice</i>	Social/ professional role and identity	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool
	1,2	<i>Attitude that it is sufficient to rely on own questions and own structure during the intake and consultation as compared to a pre-defined and structured format</i>	Beliefs about capabilities	Persuasion Education, persuasion	Social planning Guidelines	Credible source Information on health consequences	<ul style="list-style-type: none"> - Deploy opinion leaders to deliver the workshop and offer social support during adoption - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Deploy opinion leaders to deliver the workshop and offer social support

TABLE 2A. continued

COM- component	Setting* 1,2,3	Barrier <i>Not feeling competent in using the intake tool with regard to having to address problems in areas beyond the HHP's expertise or capabilities</i>	TDF domain Beliefs about capabilities	Intervention function Education, persuasion	Policy category Guidelines	BCT Information on health consequences	Translation of BCT into intervention content - Inform that intake tool is not intended to make the HHP treat complaints beyond their expertise, but to notice these complaints and weigh them in the treatment policy. - Instructed that they can check whether important complaints are under care, or advise the patient to seek care of an appropriate health care provider.
				Modelling	Service provision	Demonstration of the behaviour	- Demonstrate how to interpret and use the information provided by the intake tool - Demonstrate how to raise the issues identified with the intake tool with patients - Feedback during, and after training and during adoption.
				Enablement	Environmental planning/ Service provision	Adding objects to the environment	- Integration of supporting instruments providing information on possible treatment options/referral pathways
	1	<i>Uncertainty about the patient's satisfaction with the provided care</i>	Optimism (pessimism)	Persuasion	Guidelines	Information on health consequences	- Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool
	1	<i>Uncertainty about whether patients will perceive the intake tool as relevant or not</i>					
	1	<i>Perception that the benefit to patient care is only</i>					

TABLE 2A. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
		<i>theoretical, and does not work in practice</i>			Social planning	Credible source	<ul style="list-style-type: none"> - Present HHPs the results of the intake tool (results patient interviews current study). - Deploy opinion leaders to deliver the workshop and offer social support
	1,2,3	<i>Perception that the intake tool will not affect the choice of a treatment strategy (for most patients)</i>	Goals	Education, enablement	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Inform that intake tool is not intended to make the HHP treat complaints beyond their expertise, but to notice these complaints and weigh them in the treatment policy. - Instructed that they can check whether important complaints are under care, or advise the patient to seek care of an appropriate health care provider.
	1,2	<i>Attitude that the psychosocial factors included in the intake tool do not match the expertise and interest of the HHP</i>	Goals	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool

TABLE 2A. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	1	<i>Perception that there is no need for a comprehensive list of questions, as there are only a few questions that have to be asked to the patient to know what is going on</i>	Intentions	Education, persuasion	Social planning Guidelines	Credible source Information on health consequences	<ul style="list-style-type: none"> - Deploy opinion leaders to deliver the workshop and offer social support - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool
	1,2,3	<i>Perception that the intake tool has no added value in patients with well-defined ear/hearing problems (e.g., ear infection, presbycusis) for whom the treatment options are evident in their view (e.g., medication, hearing aids)</i>	Beliefs about consequences	Modelling Education, persuasion	Service provision Guidelines	Demonstration of the behaviour Information about social consequences	<ul style="list-style-type: none"> - Demonstrate how to interpret and use the information provided by the intake tool - Demonstrate how to raise the issues identified with the intake tool with patients - Present HHPs the results of patient's positive perceptions on the intake tool (results patient interviews current study) and planning a feasibility-study before deciding to implement the questionnaire for all ear and hearing patients. - Field-test study in a large, heterogeneous group of patients to test feasibility in all patient

TABLE 2A. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	1,2,3	<i>Fear that additional questions in the intake tool (as compared with current practice) will raise additional problems the HHP has to assess</i>	Beliefs about consequences	Education, enablement	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Inform that intake tool is not intended to make the HHP treat complaints beyond their expertise, but to notice these complaints and weigh them in the treatment policy. - Instructed that they can check whether important complaints are under care, or advise the patient to seek care of an appropriate health care provider.
	1,3	<i>Fear that the HHPs are considered responsible for every problem that arises from the intake tool</i>	Beliefs about consequences	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Inform that intake tool is not intended to make the HHP treat complaints beyond their expertise, but to notice these complaints and weigh them in the treatment policy. - Instructed that they can check whether important complaints are under care, or advise the patient to seek care of an appropriate health care provider.
	1,2,3	<i>Fear that patients expect that the intake tool is used and topics are discussed, while the HHPs may not consider it relevant: mismatch between expectations of the patients and the HHP's actions</i>	Beliefs about consequences	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients

TABLE 2A. continued

COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
				Modelling	Service provision	Demonstration of the behaviour	<p>when using the ICF based intake tool</p> <ul style="list-style-type: none"> - Demonstrate how to interpret and use the information provided by the intake tool - Demonstrate how to raise the issues identified with the intake tool with patients
	1,2	<i>Concern that the use of the intake tool would create more work</i>	Beliefs about consequences	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool
	3	<i>Fear that questions will only be asked because these are part of the intake tool, and not because these are relevant to the patient</i>	Beliefs about consequences	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Demonstrate how to interpret and use the information provided by the intake tool - Demonstrate how to raise the issues identified with the intake tool with patients - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems

TABLE 2A. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
						Information about social consequences	<ul style="list-style-type: none"> - Provide information on improved health consequences for patients when using the ICF based intake tool - Present HHPs the results of patient's positive perceptions on the intake tool (results patient interviews current study) and planning a feasibility-study before deciding to implement the questionnaire for all ear and hearing patients.
	1,3	<i>Concern that the cause of the problems reported by may not always be ear/hearing-related</i>	Beliefs about consequences	Education, persuasion	Guidelines	Instruction on how to perform a behaviour	<ul style="list-style-type: none"> - Provide instructions on how to interpret and use the information provided by the ICF based intake tool
	2	<i>Fear that the format of the tool could cause a fixed frame for the intake consultation, without room for nuance</i>	Beliefs about consequences	Modelling	Service provision	Demonstration of the behaviour	<ul style="list-style-type: none"> - Demonstrate how to interpret and use the information provided by the intake tool - Demonstrate how to raise the issues identified with the intake tool with patients
				Education, persuasion	Guidelines	Instruction on how to perform a behaviour	<ul style="list-style-type: none"> - Inform on the liberty to employ the intake tool, i.e., inform the HHP to implement/use the intake tool in the consultations in a way that is personally convenient to them and to use the supporting instruments in the intake tool when needed.

B. HHPs' enablers towards using the intake tool, COM-B components, TDF domains, selected intervention functions, selected policy categories, selected BCTs and BCT translation within the intervention							
COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
Psychological capability	1,2,3,4	Knowledge that psychosocial factors may affect the daily functioning of the patient and can underlie the patient's ear and hearing complaints	Knowledge	-	-	-	-
	3,4	In current practice discussing psychosocial and contextual factors are already part of the intake practice	Behavioural regulation/skills	Training	Service provision	Feedback on behaviour	- Inform that the intake tool fits well within current care approach (in Audiology practice)
	3,4	In current practice various structured questionnaires/intake-forms are already part of the intake					
Physical opportunity	1,2,3,4	Patient's responses should be presented in a simple overview that is easy to use	Environmental context and resources	Environmental restructuring, enablement	Environmental/social planning, service provision	Adding objects to the environment	- Integrate the intake tool in the electronic patient file system - Develop/integrate (graphical) summaries of patient responses and a quick overview of answers (i.e., the functioning profile) - Integration of supporting instruments that flag the items that indicate a (possible) problem - Integration of supporting instruments providing information on possible treatment options/ referral pathways - Include predominantly closed-ended questions
	1,2,3,4	The intake tool should be provided in a digital format					
	1,2,3,4	The intake tool should be self-administered by the patient					
	1,2,3,4	The intake tool should predominantly contain closed-ended questions					
	1,2,3,4	The intake tool should be integrated into the hospital/centre's electronic patient file/ system					

TABLE 2B. continued

COM- component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	1,2	<i>The overview of patient's responses should show the problem areas of the patient's functioning, and should not include factors the patient reports no problems with</i> <i>The intake tool should include prompts and triggers for treatment options or referral pathways to direct the actions of the HHP</i>					
	1,4	<i>The intake tool should include prompts and triggers for treatment options or referral pathways to direct the actions of the HHP</i>					
	2,4	<i>Use of the intake tool should be easy regarding accessibility, language, and administration method</i>	Environmental context and resources	Environmental restructuring	Environmental/ social planning	Adding objects to the environment	<ul style="list-style-type: none"> - Ensure readability and interpretability of the intake tool: reading level, font size, and general appearance. - Offer the patient multiple administration methods (online and on paper)
Reflective motivation	3	<i>Sense of professional responsibility to address all the complaints and problems of the patient (including to complaints not relating to the ear and hearing domain)</i>	Social/ professional role and identity	Enablement Education, persuasion	Service provision Guidelines	Social support Information on health consequences	<ul style="list-style-type: none"> - Offer the patient assistance or help (provide helpdesk number) - Provide information on the relevance of addressing the different components and items in the ICF Core Set for Hearing Loss on the functioning of patients with ear/hearing problems - Provide information on improved health consequences for patients when using the ICF based intake tool

TABLE 2B. continued

COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
							<ul style="list-style-type: none"> - Reinforce the message that the intake tool is not intended to make the HHP treat complaints beyond their expertise, but to notice these complaints and weigh them in the treatment policy.
	1,2,3	<i>Perceived added value of using the intake tool in patients with complex problems (i.e., patients referred from tertiary care, and patients with tinnitus or vertigo)</i>	Intentions	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool addresses the gaps in the current care approach
	3,4	<i>Ambition to get the (more) complete picture of the patient's functioning</i>	Intentions	Education, persuasion	Guidelines	Information on health consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool facilitates such complete picture of the patient
	2	<i>Willingness to try out the intake tool</i>	Intentions	-	-	-	-
	1	<i>Perceived value of the intake, if the tool increased patient satisfaction with the care provided</i>	Goals	Education, persuasion	Guidelines	Information about social and environmental consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool addresses this gap in the current care approach
	3	<i>Recognition that a complete picture of the patient cannot be guaranteed in current practice and that this may be facilitated by using the intake tool</i>	Goals	Education, persuasion	Guidelines	Information about social and environmental consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool addresses this gap in the current care approach

TABLE 2B. continued

COM-component	Setting*	Barrier	TDF domain	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	1	Use of an efficient intake tool may save time	Goals	Education, persuasion	Service provision	Restructuring the physical environment	<ul style="list-style-type: none"> - Adopting the earlier mentioned opportunity enablers to make usability of tool as time-efficient as possible
	2	Perceived value of the intake tool facilitating a better preparation by the patient	Goals	Education, persuasion	Guidelines	Information about social and environmental consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool facilitates patient self-preparation and patient engagement
	3	Perceived value of the intake tool in managing the patient's expectations regarding treatment/intervention outcomes (e.g., to indicate the areas where the patient may or may not expect improvement)	Goals	Education, persuasion	Guidelines	Information about social and environmental consequences	<ul style="list-style-type: none"> - Promoting the tool: emphasize that the intake tool could be used to guide the intake consultation and manage patient's expectations

*Setting: 1 = Amsterdam UMC, location VUmc section Otolology, 2 = WFG, 3 = Amsterdam UMC, location VUmc Audiology Clinic, 4 = ACHN; COM-B = Capability, Opportunity, Motivation-Behaviour; TDF = Theoretical Domains Framework; HHP = hearing health professional

TABLE 3. Intervention content targeting HHPs' barriers (A) and enablers (B) towards using the intake tool

A. Patients' barriers towards using the intake tool, COM-B components, TDF domains, selected intervention functions, selected policy categories, selected BCTs and BCT translation within the intervention						
COM-component	Barrier	TDF	Intervention function	Policy category	BCT	Translation of BCT into intervention content
Psychological capability	<i>Information and instructions of the intake tool should not be too long or extended</i>	Skills/Memory, attention, and decision processes	Enablement	Service provision	Information	- Avoid long or too extended information and instructions
	<i>Use of medical jargon should be avoided</i>	Skills/Memory, attention, and decision processes	Enablement	Service provision	Information	- Efforts to ensure readability and interpretability by patients (avoiding medical jargon)
Physical opportunity	<i>The time that is needed to complete the questionnaire should not be too long</i>	Environmental context and resources	Enablement/ environmental restructuring	Service provision	Information	- Restrict the length of the questionnaire to approximately 15 minutes completion time
Motivation	<i>The questions in the questionnaire should not be duplicated in the intake conversation, i.e., the patient's responses should be reviewed by the HHP before the intake visit The intake should not be shortened or dominated by the intake tool</i>	Goals	Education, persuasion	Service provision	Information	- Inform the patient on the purpose of the intake tool, i.e., to avoid overlooking patient's needs and to facilitate the communication between patient and HPP
	<i>Providing the patient's responses to the HHP prior to the intake visit should not negatively affect or replace the (open) conversation with the HHP Use of the intake tool should not reduce the personal attention of the HHP for the patient and his/her problems.</i>	Beliefs about consequences	Education, persuasion	Service provision	Information	- Inform the patient on the purpose of the intake tool, i.e., to avoid overlooking patient's needs and to facilitate the communication between patient and HPP

B. Patients' enablers towards using the intake tool, COM-B components, TDF domains, selected intervention functions, selected policy categories, selected BCTs and BCT translation within the intervention						
COM-component	Barrier	TDF	Intervention function	Policy category	BCT	Translation of BCT into intervention content
Psychological capability	<p><i>Information on the aim and relevance of the intake tool are important</i></p> <p><i>Instructions on how to fill out and use the intake tool are important</i></p>	<p>Knowledge</p> <p>Knowledge/skills</p>	<p>Education</p> <p>Education, training</p>	<p>Service provision</p> <p>Service provision</p>	<p>Information about health consequences</p> <p>Instructions on how to perform the behaviour</p> <p>Social support</p>	<ul style="list-style-type: none"> - Inform patients about the purpose and relevance of the intake tool - Provide patients with clear instructions on how to fill out the questionnaire - Advise and offer the patient the opportunity for assistance or help (provide helpdesk number) when they experience difficulties
Physical opportunity	<p><i>Preference to complete the intake tool at home (versus in the clinic)</i></p> <p><i>Opportunity to fill out the intake tool both on paper and digitally (on the computer)</i></p> <p><i>In case of a digital intake tool: easy and straightforward accessibility is important (i.e., log-in process)</i></p>	<p>Environmental context and resources</p> <p>Environmental context and resources</p> <p>Environmental context and resources</p>	<p>Enablement/ environmental restructuring</p> <p>Enablement/ environmental restructuring</p> <p>Enablement/ environmental restructuring</p>	<p>Service provision</p> <p>Service provision</p> <p>Service provision</p>	<p>Adding objects to the environment</p> <p>Adding objects to the environment</p> <p>Adding objects to the environment</p> <p>Social support</p>	<ul style="list-style-type: none"> - Send the questionnaire one week prior to the intake consultation to the e-mail address or the postal address of the patient - Provide the questionnaire both on paper and digitally, depending on the preference of the patient - Offer the digital questionnaire via a simple and user friendly interface - Advise and offer the patient the opportunity for assistance or help (provide helpdesk number) when they experience difficulties in accessing the questionnaire
	<p><i>In case of a digital intake tool: a possibility to save the responses after completion of the questionnaire is important, to be able to use it in preparation for the intake consultation with the HHP</i></p>	<p>Environmental context and resources</p>	<p>Enablement/ environmental restructuring</p>	<p>Service provision</p>	<p>Adding objects to the environment</p>	<ul style="list-style-type: none"> - Integrate the possibility to save the completed questionnaire when patient is finished

TABLE 3B. *continued*

COM- component	Barrier	TDF	Intervention function	Policy category	BCT	Translation of BCT into intervention content
Social opportunity	<i>Perceived value of social support from family members with filling out the intake tool</i>	Social influences	Enablement	-	Social support	- Advise the patients to ask a family member or caretaker to help fill in the questionnaire when they are not able to complete the questionnaire by themselves
Motivation	<i>Motivation to use the intake tool would be strengthened when the information on the purpose of the intake tool is clear</i>	Intentions	Education, persuasion	Service provision	Commitment	- Inform the patient on the purpose and relevance of the intake tool
	<i>Motivation to use the intake tool would be strengthened if patients could start with reporting their problem/ reason for visit, so that their specific complaint or need is placed at the centre of the intake</i>	Goals	Enablement	Service provision	Adding objects to the environment	- Start the questionnaire with asking the patient to report her/his reason for visiting the audiologist/ENT surgeon
	<i>Perceived value of collecting all relevant information regarding one's functioning, and sharing this information with the HHP before the intake</i>	Goals	Education, persuasion	Service provision	Information on health consequences	- Emphasize that the intake tool's aim is to help to provide a complete picture of the patient's functioning in daily life, to help the HHP not overlooking patient's problems/ needs.
	<i>Perceived value of the intake tool facilitating better preparation of oneself for the intake visit</i>	Goals	Education, persuasion	Service provision	Information on health consequences	- Emphasize that the intake tool aims to help prepare the patient for the intake appointment
	<i>Perceived value of the intake tool contributing to a better understanding or insight into the impact of one's own ear/hearing problem</i>	Goals	Education, persuasion	Service provision	Information on health consequences	- Emphasize that the intake tool could help clarify specific complaints/ provide insights into the patient's problems
	<i>Perceived value of the intake tool contributing to better care provision</i>	Goals	Education, persuasion	Service provision	Information on health consequences	- Emphasize that the intake tool ultimately aims to provide better/ more patient-centred care

TABLE 3B. *continued*

COM-component	Barrier	TDF	Intervention function	Policy category	BCT	Translation of BCT into intervention content
	<i>Perceived value in sharing results to help future patients, science, and/or society</i>	Goals	Education, persuasion	Service provision	Information on health consequences	<ul style="list-style-type: none"> - Emphasize that the data gathered from all patients together could contribute to better insights in common patient problems and may lead to more tailored treatment strategies on a larger scale
	<i>Perceived time-efficiency in the intake</i>	Beliefs about consequences	Education, persuasion	Service provision	Information on health consequences	<ul style="list-style-type: none"> - Emphasize that the intake tool aims to facilitate an efficient intake consultation, that addresses problems and needs that are relevant to the patient
	<i>Perceived value of the intake tool in directing the intake towards the actual complaints and needs of the patient</i>	Beliefs about consequences	Education, persuasion	Service provision	Information on health consequences	<ul style="list-style-type: none"> - Emphasize that the intake tool could help point out specific complaints to the clinician and facilitate a more directed intake consultation
	<i>Perceived value of the intake tool in facilitating the intake conversation, because both the patient and health professional are prepared better</i>	Beliefs about consequences	Education, persuasion	Service provision	Information on health consequences	<ul style="list-style-type: none"> - Emphasize that the intake tool could aim to facilitate the communication between patient and audiologist and/or ENT surgeon
	<i>Perceived value of the intake tool contributing to a better understanding or insight into the impact of one's own ear/hearing problem</i>	Goals	Education, persuasion	Service provision	Information on health consequences	<ul style="list-style-type: none"> - Emphasize that the intake tool could help clarify specific complaints/ provide insights into the patient's problems

COM-B = Capability, Opportunity, Motivation- Behaviour; TDF = Theoretical Domains Framework

Intervention content

The chosen BCTs were translated into concrete intervention content which is listed in the last columns of Tables 2 and 3. Table 4 gives an overview of the different intervention components and their content targeted at HHPs. Table 5 gives this overview for the patients. The completed TIDierR checklist is shown in Appendix 5.

TABLE 4. Intervention content targeted at HHPs

<i>Intervention component</i>	<i>Intervention content</i>
Education and training	<p>Provision of a concise manual with educational and instructional materials:</p> <ul style="list-style-type: none"> - Educational materials presenting the key information on the evidence base, and potential benefits of using the intake tool in clinical practice; - Educational material on HHPs' role in using the intake tool; - Instructional material explaining how to use the intake tool; - Specific guidelines suggesting clinical actions and referral pathways to manage psychosocial problems and other problems that may potentially be identified based on patient's scores on the intake tool for which the HHPs currently do not have guidelines yet. These guidelines will be developed in close collaboration with the HHPs. <p>Offering a workshop divided in an educational- and a training part:</p> <ul style="list-style-type: none"> - Educational part to: (1) provide and improve knowledge and understanding about the background and use of the intake tool; (2) motivate HHPs to use the intake tool and explain to them that the use of the intake tool is potentially beneficial, in that it will presumably help improve the quality of the patient's intake process and the subsequent care pathway, and subsequently patient satisfaction; (3) explain the intake tool with respect to layout, content, interpretation and use; (4) explain the HHPs' role in the use of the intake tool and how it may fit within their clinical practice. - Training part to: develop skills/competencies to use and interpret the scores obtained with the intake tool.
Opinion leaders	Provision of audit and feedback on HHP's performance during implementation; Identification and training of opinion leaders to deliver the workshop and offer support during implementation;
Environmental factors	<p>Integration of the intake tool in the electronic patient record system;</p> <p>Provision of environmental resources, including design and functionalities of the intake tool:</p> <ul style="list-style-type: none"> - digital reminders to use the intake tool for every new patient; - clear graphical summaries of patient responses facilitating a quick overview of answers; - flagging system to flag the items of the intake tool that indicate the areas in which the patient reports problems in; - supporting instruments to link patient results with treatment options and/or referral pathways.
Field-test study of the intake tool to test feasibility in all patient groups.	

TABLE 5. Intervention content targeted at patients

<i>Intervention component</i>	<i>Intervention content</i>
Education and instructions	<p>Provision of clear and concise educational/instructional information letter, including:</p> <ul style="list-style-type: none"> - Information about the purpose and relevance of the intake tool; - Persuasive communication techniques to motivate patients to use the intake tool by creating awareness about the potential benefits of the tool and how potential barriers of using the intake tool are addressed (for example explain that the intake tool could improve patient-clinician communication be used to aid the communication with the clinician during the intake consultation, but does not replace the face-to-face conversation during the consultation); - Instructions on how to fill out the intake tool; - Instructions explaining that the intake tool can be filled in with the help of a family member or caretaker in case the patient is not able to complete the intake tool by him/herself.
Environmental factors	<p>Remote administration of the questionnaire (option to fill it in at home prior to the intake appointment);</p> <p>Availability of different modes of administration (both digital and paper and pencil versions, the latter for digitally illiterate patients);</p> <p>Provision of environmental resources, including different design features and functionalities:</p> <ul style="list-style-type: none"> - An easily accessible and simple user interface: accessibility to the digital intake tool via one click on a link; adequate readability and interpretability of the questions by patients (i.e., avoid medical jargon, reading level and font size, and general appearance); - Offering assistance or help when the patient experiences difficulties (i.e., provide helpdesk number); - Reducing the length of the intake tool to ensure completing does not take more than 15 minutes.

DISCUSSION

This paper describes the development of an intervention to facilitate the successful implementation of an ICF-based e-intake tool in clinical oto-audiology practice. Intervention content was identified using the BCW method and was based on HHP's and patient's earlier identified barriers to and enablers of using the intake tool in clinical practice¹⁰. The current study stepwise identified different intervention functions, policy categories, and BCTs, that are considered appropriate and adequate to tackle the barriers to and promote enablers of using the intake tool in the oto-audiology practice.

Below, the intervention is further explained and related to the existing literature that was used to motivate these choices made in the BCW process, followed by a discussion of the project's strengths and limitations, implications for research and practice, and possible future directions.

Intervention content targeted at HHPs

Educational material and training

Educational interventions promote ownership and correct use of PROMs by HHPs^{35, 36}. Several studies indicate that the best way to impact change, is by *demonstrating* the value of a PROM to potential users (i.e., clinicians)³⁷⁻⁴⁰. Based on these studies and on our own results, we therefore suggest that the organization of a workshop in which the use of the intake tool is demonstrated would be an appropriate intervention. In this workshop, case studies can be used to demonstrate the mapping of patient information collected through the intake tool. It is expected that discussions among the attendants (HHPs) can help them to understand how this information can aid their clinical reasoning, and can enable them to analyse and change their attitudes^{41, 42}. Specifically, the use of role play to practice skills needed to use the intake tool can be helpful. This has shown to be an effective way to use and discuss PROM scores with patients^{39, 42}. Moreover, a group workshop may increase the chances of creating a 'social norm'¹⁹. In previous studies in other health care fields, the provision of audit and feedback positively influenced users' beliefs and attitudes towards the use of the PROM, and as such adding to the effective implementation of PROMs in clinical practice^{35, 39, 43, 44}.

In the research team's discussion about the delivery mode of the workshop, it was emphasized that the workshop would need to be brief and fit into the existing clinical schedules of the HHPs. Haverman et al. (2014)⁴² found that adequate time-management determined the chances of HHPs actually attending the workshop, and thereby the successfulness of the implementation.

Local opinion leaders

To address clinicians scepticism and other negative attitudes to the intake tool, we proposed that opinion leaders in the HHPs own discipline (audiology and ENT) could give the workshop and promote the intake tool. Senior audiology or otology staff members could serve as such opinion leaders. The effectiveness of using opinion leaders is supported by a high-quality review⁴⁵. Moreover, persistence and regular encouragement by an opinion leader have been shown to be necessary to ensure that the implementation becomes successful³⁵.

Environmental factors

HHPs identified the limited time per patient as an important barrier to using the intake tool in clinical practice. Whilst this barrier may not be easily changeable, a number of other intervention options may be used to overcome this barrier. One is the provision of sufficient support and opportunities to use the intake tool. A key strategy which was reported is the use of an *ePROM*, which is preferably integrated in the existing electronic medical record (EMR) system. Patients' results would then immediately be added to a patient's record, ready for the HHP to review. To facilitate this, a comprehensive IT infrastructure would be needed, including: (1) technical devices for data collection and output, (2) appropriate software solutions and network facilities for data transmission, storage, and back-up, (3) technical support, and (4) updates⁴⁶. In addition, issues of data security and patient confidentiality should be secured. These organizational-related issues would need to be addressed during the actual implementation process.

Other important intervention options to limit HHPs' burden included easing the process of reviewing and interpreting the patient's scores. It is proposed to do this by applying "flagging" (identified problems in functioning), an easy to read (graphical) summary format, and providing HHPs with concrete actions they could take as a follow-up. These strategies would require the definition of relevant cut-off scores, and the provision of a referral decision tree that can guide HHPs with their actions. These efforts would need to be considered during the next steps of the development process of the intake tool.

As already addressed in our previous study, audiologists generally had a more positive attitude towards implementing the intake tool as compared to the ENT surgeons¹⁰. Audiologists generally seemed more willing to change their practice in order to use the intake tool. This suggests that a "lighter version" of the workshop may be considered appropriate for the audiologists, including less verbal persuasion about the potential benefit of the tool.

Intervention content targeted at patients

Education and instructions

We proposed that patients should be provided with information on the purpose of, relevance of, and privacy issues regarding the intake tool. Other studies indicated that this is an important approach (e.g., ⁴⁶). Educational and instructional material in an information letter

could be sent along with the invitation for the appointment at the outpatient clinic. This letter would contain information about the purpose and expected patient-benefits of the intake tool, the online questionnaire and a direct link to the questionnaire. The extensiveness of information and instructions provided should be balanced with the length of the questionnaire however, as a long questionnaire was reported as a barrier to use the intake tool.

Environmental factors

Most of the practical intervention components that we formulated are consistent with documented recommendations to limit patient burden^{38, 47, 48}. These include: reaching patient where it is convenient for them (at their own private area; i.e., at home) without any time constraints; providing a simple accessibility and user interface in case of administering the e-intake tool (easy log in and navigation); and restricting the number of questions (maximum of 15 minutes completion time). Most patients reported to prefer an ePROM, but availability of a paper-pencil version could serve as back-up for those patients who would otherwise decline assessment (e.g., older people without computer experience).

Strengths and limitations

The main strength of this study is that we used a systematic, theory-driven and evidence-based method to develop an intervention to facilitate the implementation and use of the intake tool into clinical oto-audiology practice. Other strengths are the inclusion of both the patients' and the HHPs' perspectives and the incorporation of barriers and enablers for the selection of intervention options and -content. Studies have shown that early engagement of stakeholders may reduce barriers and ensure commitment to implementation^{42, 49, 50}. This also holds for patient involvement⁴⁷. Moreover, it is known that more useful results are obtained if research teams develop and evaluate an intervention for implementation simultaneously at multiple levels (e.g., patient, provider, care team workflow, medical record system) rather than treat them as separate interventions^{51, 52}. Lastly, the BCW method resulted in a multifaceted intervention, the latter of which has been shown more effective than single interventions⁵³.

The current study also has some limitations that deserve discussion. One limitation relates to the current lack of exemplary studies using the BCW method in audiology to draw on. Moreover, literature on effective interventions for the implementation of PROMs and ICF-based instruments into clinical practice is scarce too. Although the BCW provides a step-by-step process and we used expertise of experienced clinicians, there was some subjective judgment in every stage. In addition, the consensus reached in the research team was driven by expert-based knowledge of a few experts only. Although we recognize that the developed intervention covers a limited number of all possible intervention- and delivery options, it is envisaged that these yield useable outcomes for the implementation of the intake tool in the hospital setting this study was conducted in. However, this may limit the generalizability of

the intervention to other rehabilitation settings. Another consideration is that this study did not explicitly focus on the wider organizational, i.e., hospital level or socio-political level. Whereas we did take into account the practical organization of collecting data in patient records (which requires technology support as part of the hospital's structure and policy⁴²), we did not focus on other potentially important factors on the socio-political level, such as reimbursement.

Implications for research and practice

Up to now, only a small number of studies utilized theoretical models or frameworks to understand and act upon the factors influencing patients' or clinicians' behaviour in using PROMs (e.g., ⁴²). We identified only one study that used a model for implementing the ICF. Appleby and Tempest ⁴¹ used change management theory to implement the ICF framework in occupational therapy service delivery, and identified similar intervention components to be successful: using opinion leaders (process helpers and solution givers) to lead the developments, and the adoption of an interactive facilitation style (group activities). To our knowledge, our study is the first to provide an example on how to apply the BCW method to develop an intervention for a new tool in clinical oto-audiology practice. Although the importance of behaviour change interventions for implementing evidence-based practice is increasingly recognized^{54, 55}, the use of a systematic approach as described in this paper has been published only by one other research group^{28, 29}. Our use of a systematic approach and description of intervention content using standard terminology contribute to the science of implementation intervention development within audiology, but possible also in other fields.

The applicability of the intake tool in its current form still has to be proven in practice, which we plan to address in a field-test study. Based on the results, possible adjustments will be made before final implementation. In addition, commitment of HHPs to use the intake tool in practice is expected to rise with proof of relevance and effectiveness.

This study focused on short-term objectives for implementation and introducing the intake tool in clinical practice. Longer term-objectives, i.e., optimizing its use in clinical practice, will likely be successful only if ongoing training and interactive sessions with HHPs are provided to cement the changes. This also would include facilitating reflections on their progress and feedback to promote further learning and development⁴¹.

Future research

The actual translation of the proposed intervention into content in the manual, workshop, and design and functionalities of the intake tool itself is currently ongoing and involves further engagement and collaboration with relevant stakeholders (e.g., feedback of patients and HHPs, and organizational support). This also includes the field-test study, which must be carried-out before actual implementation. Then, after implementation, the effectiveness of the intervention will need to be determined in future research.

CONCLUSION

A multifaceted intervention was proposed to facilitate the implementation of an ICF-based e-intake tool by HHPs and patients in clinical oto-audiology practice. For HHPs, provision of educational/training materials and -workshops delivered by opinion leaders are recommended to enhance HHPs' knowledge, awareness, skills, and self-efficacy. In addition, adjustments in the environment and design of the intake tool are needed to facilitate practical use. For patients, various design features need to be adopted to facilitate adequate use. Also a concise information letter sent along with the intake tool is recommended, to clarify the goals and relevance, and to address concerns regarding the intake tool's impact on the relationship with the HHP. The first steps towards the implementation of the intake tool have been taken, and now need to be further worked out to an integrated implementation plan. In addition, the intake tool should be finished such that it fits HHPs' and patients' preferences (including the definition of cut-offs, referral-and treatment decision trees).

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APPENDIX 1. Key supporting articles

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 - Santana MJ, Haverman L, Absolom K, Takeuchi E, Feeny D, et al. Training clinicians in how to use patient-reported outcome measures in routine clinical practice. *Qual Life Res*. 2015;24:1707-1718.
 - Snyder CF, Aaronson NK, Choucair AK, Elliott TE, Greenhalgh J, et al. Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Qual Life Res*. 2012;21:1305-1314.
 - Wintner LM, Sztankay M, Aaronson N, Bottomley A, Giesinger JM, et al. The use of EORTC measures in daily clinical practice-A synopsis of a newly developed manual. *Eur J Cancer*. 2016;68:73-81.
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APPENDIX 2. Step 5: Identification of intervention functions

Identified intervention functions for hearing health professionals:

Intervention functions Definition	Does the intervention function meet APEASE criteria?	Elaboration
<p>Education Increasing knowledge or understanding</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: It could be delivered as a part of a workshop and as part of a written manual. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: To prevent resistance by hearing health professionals to use the intake tool is to provide them with relevant solid information justifying the potential relevance in the form of education before its actual implementation. - Side-effects: Minimal. - Equity: No negative impact.
<p>Persuasion Using communication to induce positive or negative feelings or stimulate action</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Persuasive communication could be used during a workshop (verbal) and in the manual (written). Data from patients/ case-stories can be used to show potential benefits of the tool. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Hearing health professionals would welcome relevant education and training. - Side-effects: Minimal. - Equity: No negative impact.
<p>Incentivisation Creating an expectation of reward</p>	<p>NO</p>	<p>Creating an expectation of reward was not thought to be acceptable for hearing health professionals who are expected to provide care to patients in an honest and autonomous way.</p>
<p>Coercion Creating an expectation of punishment or cost</p>	<p>NO</p>	<p>Creating an expectation of punishment or cost was not thought to be acceptable for hearing health professionals who are expected to provide care to patients in a honest and autonomous way.</p>

continued

Intervention functions Definition	Does the intervention function meet APEASE criteria?	Elaboration
<p>Training Imparting skills</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: It could be delivered as a training module in a workshop. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: To prevent resistance by hearing health professionals to use the intake tool is to provide them with relevant instructions in the form of training before its actual implementation. - Side-effects: Minimal. - Equity: No negative impact.
<p>Restriction Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)</p>	<p>NO</p>	<p>It was not thought acceptable or practicable to attempt restricting hearing health professionals' behaviour who are expected to provide care to patients in a honest and autonomous way.</p>
<p>Environmental restructuring Changing the physical or social context</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Providing the intake tool via a digital application in the hearing health professionals' (digital) environment was already part of the current project plan. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Hearing health professionals indicated the need for changes in the digital environmental to enable the use of the intake tool. - Side-effects: Minimal. - Equity: No negative impact.
<p>Modelling Providing an example of people to aspire to or imitate</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within budget. - Practicability: A "local opinion leader" (staff member) could model the targeted behaviours for their colleagues. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: It is thought that the provision of models for the target behaviour of using the intake tool would be acceptable. - Side-effects: Minimal.

continued

Intervention functions Definition	Does the intervention function meet APEASE criteria?	Elaboration
<p>Enablement Increasing means/ reducing barriers to increase capability (beyond education and training) and opportunity (beyond environmental restructuring)</p>	<p>YES</p>	<ul style="list-style-type: none"> - Equity: No negative impact. - Affordability: Covered within project budget. - Practicability: Providing the intake tool via a digital application is part of the current project plan, including implementing various functionalities in the intake tool that would adhere to the hearing health professionals' preferences and needs. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Hearing health professionals indicated the need for materials/ digital environments that would enable their use of the intake tool, and reduce the barriers to use the tool. - Side-effects: Minimal. - Equity: No negative impact.

Identified intervention functions for patients:

Intervention function Definition	Does the intervention function meet APEASE criteria?	Literature
<p>Education Increasing knowledge or understanding</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Could be provided alongside the provision of the intake tool in an information letter. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Patients indicated the need for relevant information on purpose, potential relevance, and privacy of the intake tool. - Side-effects: Minimal. - Equity: No negative impact, but literacy should be taken into account and adequate readability and interpretability ensured. These aspects have been considered in the further development process of the intake tool and will be further tested in a field-test study.
<p>Persuasion Using communication to induce positive or negative feelings or stimulate action</p>	<p>YES</p>	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Persuasive communication could be used in the information letter. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Patients indicated the need for information on the potential positive benefits of the tool, and it is thought that using persuasive communication techniques could reinforce this. - Side-effects: Minimal, the choice to use the tool is up to the patient and will not have a negative impact on the treatment. This will be stated explicitly in the information letter. - Equity: No negative impact.
<p>Incentivisation Creating an expectation of reward</p>	<p>NO</p>	<p>Creating an expectation of reward was not thought to be acceptable for patients, who should receive the best possible care independently of using the intake tool.</p>
<p>Coercion Creating an expectation of punishment or cost</p>	<p>NO</p>	<p>Creating an expectation of punishment or cost was not thought to be acceptable for patients, who should receive the best possible care independently of using the intake tool.</p>
<p>Training Imparting skills</p>	<p>NO</p>	<p>It was not thought to be practicable to organize a separate training event for patients.</p>

continued

Intervention functions Definition	Does the intervention function meet APEASE criteria?	Elaboration
<p>Restriction Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)</p> <p>Environmental restructuring Changing the physical or social context</p>	NO	<p>Restriction was not thought to be acceptable for patients, who should receive the best possible care independently of using the intake tool.</p>
	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget allocations. - Practicability: Providing the intake tool via electronic administration was already part of the current project plan. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Patients indicated the preference for a digital tool to be filled out at home. Most patients have access to the internet. - Side-effects: Minimal. - Equity: No negative impact, efforts should be made to ensure an easily accessible and simple user interface. An paper-pencil version should be available for patients who would otherwise decline using the tool.
<p>Modelling Providing an example of people to aspire to or imitate</p>	NO	<p>It was not considered necessary to use modelling to motivate patients to use the intake tool, as was indicated by our previous qualitative study.</p>
<p>Enablement Increasing means/ reducing barriers to increase capability (beyond education and training) and opportunity (beyond environmental restructuring)</p>	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget allocations. - Practicability: Providing the intake tool via a digital application that is easily accessible is part of the current project plan, including implementing design features in the intake tool that would adhere to the patients' preferences and needs. - Effectiveness: Uncertain, but preliminary evidence and recommendations in various peer-reviewed research articles. - Acceptability: Patients mentioned a number of practical enablers and barriers that will be taken into account in the design and administration of the tool. - Side-effects: Minimal. - Equity: No negative impact, efforts should be made to ensure readability and interpretability by patients: reading level, font size, and general appearance.

APPENDIX 3. Step 6: Identification of policy categories

Identified policy categories for hearing health professionals:

Policy category Definition	Does the policy category meet APEASE criteria?	Elaboration
Communication/ marketing Using print, electronic, telephonic, or broadcast media	NO	Marketing was not thought to be desirable in this stage of the project.
Guidelines Creating documents that recommend or mandate practice. This includes all changes to service provision	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Creating a manual that includes educational material and guidelines that explain and recommend how to use (the results of) the intake tool. - Effectiveness: Uncertain, but preliminary evidence and recommendations are reported in various peer-reviewed scientific articles. - Acceptability: Hearing health professionals indicated the need for relevant information via guidelines for score interpretation/ referral pathways to guide their actions. - Side-effects: Minimal. - Equity: No negative impact.
Fiscal measures Using the tax system to reduce or increase the financial cost	NO	Fiscal measures were not thought to be acceptable or applicable.
Regulation Establishing rules or principles of behaviour or practice	NO	Establishing rules was not thought to be acceptable in this stage of the project.
Legislation Making or changing laws	NO	Making laws was not thought to be acceptable in this stage of the project.
Environmental/ social planning Designing and/or controlling the physical or social environment	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Integrating the intake tool in an existing electronic system. This would be considered environmental planning. - Effectiveness: Uncertain, but preliminary evidence stems from other studies in which a tool was integrated into an electronic system was effective in facilitating its use. - Acceptability: Designing/changing the digital environment in order to be able to incorporate the tool in the system was mentioned by the hearing health professionals themselves as a preferred policy. - Side-effects: Minimal.

continued

Policy category Definition	Does the policy category meet APEASE criteria?	Elaboration
Service provision Delivering a service	YES	<ul style="list-style-type: none"> - Equity: No negative impact. - Affordability: Covered within project budget. - Practicability: Establishing supportive services (within the intake tool itself and providing education/training) to enable the use of the intake tool. This would be considered provision of services. - Effectiveness: Uncertain. - Acceptability: Hearing health professionals indicated the need for various support services, to enable the successful use of the intake tool. - Side-effects: Minimal. - Equity: No negative impact.

Identified policy categories for patients:

Policy category Definition	Does the policy category meet APEASE criteria?	Support/Literature
Communication/ marketing Using print, electronic, telephonic, or broadcast media	NO	Marketing was not thought to be practicable or acceptable in this stage of the project.
Guidelines Creating documents that recommend or mandate practice. This includes all changes to service provision	NO	Guidelines were not thought to be practicable or acceptable.
Fiscal measures Using the tax system to reduce or increase the financial cost	NO	Fiscal measures were not thought to be acceptable.
Regulation Establishing rules or principles of behaviour or practice	NO	Regulation was not thought to be acceptable.
Legislation Making or changing laws	NO	Legislation was not thought to be acceptable.
Environmental/ social planning Designing and/or controlling the physical or social environment	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Integrating the intake tool in an existing electronic system (as requested by patients). This would be considered environmental planning. - Effectiveness: Uncertain, but preliminary evidence stems from other studies in which a tool was integrated into an electronic system was effective in facilitating its use. - Acceptability: A digital format was mentioned by the patients themselves as a preferred policy. - Side-effects: Minimal. - Equity: No negative impact.
Service provision Delivering a service	YES	<ul style="list-style-type: none"> - Affordability: Covered within project budget. - Practicability: Providing the intake tool using an easy administration method and the tool including design features as proposed by the patients. This would be considered provision of services. All services are delivered alongside the intake tool. - Effectiveness: Uncertain, worth evaluating. - Acceptability: Patients were positive about the use in our previous study. - Side-effects: Minimal. - Equity: No negative impact.

APPENDIX 4. Step 7: Identification of Behaviour Change Techniques

Identified Behaviour Change Techniques (BCTs) for hearing health professionals:

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
Education	Information about health consequences	5.1	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	YES	Verbal and written information could be provided by outlining: the importance of an accurate intake process; the potential benefits of that process for the further rehabilitation pathway (potentially leading to improved health outcomes); and the supportive purpose of the tool (not intended to make the professional treat complaints beyond their expertise) (providing this positive information is also related to the component 'Persuasion').
	Information about social and environmental consequences	5.3	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour	YES	
	Feedback on behaviour	2.2	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g., form, frequency, duration, intensity)	YES	Hearing health professionals could be provided with (verbal) feedback on their behaviour in using the intake tool during the training session and when implemented in clinical practice. Audit and feedback are known to be promising techniques to improve (routine) use of patient reported outcome measures.
	Self-monitoring of behaviour	2.3	Establish a method for the person to monitor and record their behaviours as part of a behaviour change strategy	NO	Not considered acceptable; not considered practicable to implement.
	Feedback on outcome(s) of the behaviour	2.7	Monitor and provide feedback on the outcome of performance of the behaviour	NO	It is beyond the scope of the current study to provide information on the outcome(s) of the behaviour (health consequences for patients).

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Prompts/cues	7.1	Introduce or define environmental or social stimulus with the purpose of promoting or cueing the behaviour	YES	Digital cues could be built in the digital system to prompt the use of the intake tool. Hearing health care professionals indicated the need for techniques (cues) to guide their actions (i.e., treatments or referral opportunities). Also in scientific literature, it has been suggested that a helpful strategy towards clinicians using patient reported outcome measures is to define clinical triggers for interventions. For example, specific items that exceed some threshold can be highlighted on the functioning profile for the hearing health professional who can then offer referrals, specific treatment, etc. There is supportive evidence for cueing results with interventions/treatments/referral pathways (also related to the component 'environmental restructuring').
Persuasion	Credible source	9.1	Present verbal or visual communication from a credible source in favour of or against the behaviour	YES	In implementation literature it has been suggested that the engagement of "local opinion leaders" may form an important technique to overcome clinician barriers relating to their motivation to adopt new forms of clinical practice.
	Information about health consequences	5.1	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	YES	See 'Education' component above.
	Information about social and environmental consequences	5.3	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour	YES	See 'Education' component above.
	Feedback on behaviour	2.2	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g., form, frequency, duration, intensity)	YES	See 'Education' component above.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Feedback on outcome(s) of the behaviour	2.7	Monitor and provide feedback on the outcome of performance of the behaviour	NO	See 'Education' component above.
Training	Instruction on how to perform the behaviour	4.1	Advise or agree on how to perform the behaviour (includes skill training)	YES	Verbal and written information could be provided to instruct the hearing health professionals on how to use the (results of) the intake tool. In addition, they could be provided with a demonstration of how to use the intake tool, and subsequently be given the opportunity to practice their skills in using the intake tool. Using local opinion leaders to demonstrate the desired behaviour (also related to the component 'environmental restructuring'; 'credible source') and role-play exercises to practice the behaviour, are recommended by various peer-reviewed scientific articles.
	Demonstration of the behaviour	6.1	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes modelling)	YES	
	Behavioural practice and rehearsal	8.1	Promote practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	YES	
	Feedback on behaviour	2.2	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g., form, frequency, duration, intensity)	YES	See 'Education' component above.
	Self-monitoring of behaviour	2.3	Establish a method for the person to monitor and record their behaviours as part of a behaviour change strategy	NO	See 'Education' component above.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Feedback on outcome(s) of behaviour	2.7	Monitor and provide feedback on the outcome of performance of the behaviour	NO	See 'Education' component above.
Environmental restructuring	Prompts/cues	7.1	Introduce or define environmental or social stimulus with the purpose of promoting or cueing the behaviour	YES	Refer to 'education' component above. These digital stimuli need to be developed and adopted in the digital system.
	Restructuring the physical environment	12.1	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour	YES	Changes to the existing digital environment (e.g., electronic patient record system) could be made to facilitate the practical use of the intake tool. In addition, in order to facilitate use of the intake tool, the design and functionalities of the intake tool need to meet the preferences and needs of the hearing health professionals as much as possible.
	Adding objects to the environment	12.5	Add objects to the environment in order to facilitate performance of the behaviour	YES	
Modelling	Demonstration of the behaviour	6.1	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes modelling)	YES	Refer to 'training' component above, which could be provided by a local opinion leader (also related to the component 'persuasion', and the technique 'credible source').

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
Enablement	Social support	3.1	Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues, or staff) or non-contingent praise or reward for performance of the behaviour	YES	By means of a local opinion leader (also related to the component 'persuasion', and the technique 'credible source'). Indirectly by means of (staff) colleagues, with which the workshop has been followed together and who can help each other during implementation.
	Social support (practical)	3.2	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, or staff) for performance of the behaviour	YES	
	Goal setting (behaviour)	1.1	Set or agree a goal defined in terms of the behaviour to be achieved	NO	Not yet, not practicable at this stage.
	Problem solving	1.2	Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators	NO	Implementation strategies are based on enablers and barriers towards the use of the intake tool, and it is agreed that monitoring this during and after implementation is needed to inform additional implementation strategies when needed.
	Goal setting (outcome)	1.3	Set or agree a goal defined in terms of a positive outcome of wanted behaviour	NO	Not yet, not practicable at this stage.
	Action planning	1.4	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity)	NO	Not considered practicable.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Review behaviour goals	1.5	Review behaviour goal(s) jointly with the person and consider modifying goals or behaviour change strategy in light of achievement	NO	Equivalent to 'feedback on behaviour'. See 'Education' component above.
	Review outcome goals	1.7	Review outcome goal(s) jointly with the person and consider modifying goals(s) in light of achievement	NO	Not yet, part of future evaluation studies.
	Self-monitoring of behaviour	2.3	Establish a method for the person to monitor and record their behaviours as part of a behaviour change strategy	NO	See 'Education' component above.
	Restructuring the physical environment	12.1	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour	YES	See 'Environmental restructuring' component above.
	Adding objects to the environment	12.5	Add objects to the environment in order to facilitate performance of the behaviour	YES	

Identified Behaviour Change Techniques (BCTs) for patients:

Selected intervention functions	Most frequently used BCT	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
Education	Information about health consequences	5.1	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	YES	Written information could be provided by outlining the potential relevance and the purpose of the intake tool. Patients indicated this was important to enable the use of the intake tool.
	Information about social and environmental consequences	5.3	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour	YES	
	Feedback on behaviour	2.2	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g., form, frequency, duration, intensity)	NO	Not practicable to deliver in this stage of the project (relevant behaviour will not be monitored).
	Self-monitoring of behaviour	2.3	Establish a method for the person to monitor and record their behaviours as part of a behaviour change strategy	NO	Not considered feasible/ practicable to implement (relevant behaviour will not be monitored).
	Feedback on outcome(s) of the behaviour	2.7	Monitor and provide feedback on the outcome of performance of the behaviour	NO	Beyond the scope of this project.
	Prompts/cues	7.1	Introduce or define environmental or social stimulus with the purpose of promoting or cueing the behaviour	NO	Not considered applicable.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
Education (training)	Instruction on how to perform the behaviour	4.1	Advise or agree on how to perform the behaviour (includes skill training)	YES	Written information could be provided with instructions on how to fill out the intake tool. Patients indicated that instructions are important to adequately fill in the intake tool.
Persuasion	Credible source	9.1	Present verbal or visual communication from a credible source in favour of or against the behaviour	NO	Not relevant in the context of this study.
	Information about health consequences	5.1	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	YES	See 'Education' component above.
	Information about social and environmental consequences	5.3	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour	YES	See 'Education' component above.
	Feedback on behaviour	2.2	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g., form, frequency, duration, intensity)	NO	See 'Education' component above.
	Feedback on outcome(s) of the behaviour	2.7	Monitor and provide feedback on the outcome of performance of the behaviour	NO	See 'Education' component above.
Environmental restructuring	Prompts/ cues	7.1	Introduce or define environmental or social stimulus with the purpose of promoting or cueing the behaviour	NO	See 'Education' component above.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Restructuring the physical environment	12.1	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour	YES	<ul style="list-style-type: none"> - The design and administration of the intake tool needs to meet the preferences and needs of the patients. - Electronic administration of the intake tool pushed out via automated (invitation) letters, with backup data collection via secretary (e.g., iPads in clinics).
	Adding objects to the environment	12.5	Add objects to the environment in order to facilitate performance of the behaviour	YES	
Enablement	Social support	3.1	Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues, or staff) or non-contingent praise or reward for performance of the behaviour	NO	Not considered practicable/ feasible.
	Social support (practical)	3.2	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, or staff) for performance of the behaviour	YES	Written advise could be provided to the patient to ask a caretaker to help fill out the intake tool when needed. Provision of a helpdesk number for assistance or help with the intake tool when needed.
	Goal setting (behaviour)	1.1	Set or agree a goal defined in terms of the behaviour to be achieved	NO	Not considered applicable.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Problem solving	1.2	Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators	NO	Implementation strategies are based on enablers and barriers towards the use of the intake tool, and it is agreed that monitoring this during and after implementation is needed to inform additional implementation strategies when needed.
	Goal setting (outcome)	1.3	Set or agree a goal defined in terms of a positive outcome of wanted behaviour	NO	Not feasible and beyond the scope of this project.
	Action planning	1.4	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity)	NO	Not feasible and beyond the scope of this project.
	Review behaviour goals	1.5	Review behaviour goal(s) jointly with the person and consider modifying goals or behaviour change strategy in light of achievement	NO	Not feasible and beyond the scope of this project.
	Review outcome goals	1.7	Review outcome goal(s) jointly with the person and consider modifying goals(s) in light of achievement	NO	Not feasible and beyond the scope of this project.
	Self-monitoring of behaviour	2.3	Establish a method for the person to monitor and record their behaviours as part of a behaviour change strategy	NO	See 'Education' component above.

continued

Selected intervention function	Most frequently used BCTs	BCT Taxonomy (v1) code	Definition	APEASE/ consensus	Elaboration
	Adding objects to the environment	12.5	Add objects to the environment in order to facilitate performance of the behaviour	YES	See 'Environmental restructuring' component above.
	Restructuring the physical environment	12.1	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour	YES	

APPENDIX 5. Completed TIDieR (Template for Intervention Description and Replication) checklist

Item no	Item	hearing health care professionals (HHPs)	patients
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Intervention to implement an ICF-based e-intake tool in clinical oto-audiology practice	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Implementation of new tools in clinical practice is challenging and requires a theory-based approach. An existing issue limiting successful implementation is failing to identify and addressing clinicians' and patients' barriers to use the tool, and acting on them. An intervention was developed using the theory-based Behaviour Change Wheel method. The aim was to develop and intervention to implement an ICF-based e-intake tool (further referred to as intake tool) to be used by hearing health care professionals (HHPs) and patients in clinical oto-audiology practice.	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	<p>(1) Workshop: education and training;</p> <p>(2) Written manual for using the tool: educational and instructional material;</p> <p>(3) Local opinion leaders leading the workshop and offering social support (instrumentally and emotionally).</p> <p>(4) Environmental resources: optimal digital design and functionalities of the intake tool (including supporting instruments to help hearing health professionals interpret the patient's functioning profile and to guide their further actions).</p> <p>Further details are provided in the manuscript.</p>	<p>(1) Informational material (including persuasive communication techniques);</p> <p>(2) Environmental resources: multiple administration methods and optimal design of the intake tool.</p> <p>Further details are provided in the manuscript.</p>

Item no	Item	hearing health care professionals (HHPs)	patients
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	<p>The intervention covers nine behaviour change techniques targeted at HHPs. The educational and instructional materials, and workshop aims to: optimize professionals' knowledge about the background on the intake tool, foster their awareness of the importance of using the intake tool, teach them skills and increase their self-efficacy, and address any negative beliefs they might have.</p> <p>The environmental resources will be addressed such that the practical use of the tool is as (time-)efficient as possible. The support of an opinion leader will enhance motivation, and will be used for feedback and social support.</p> <p>Further details are provided in the manuscript.</p>	<p>The intervention consists of 3 behaviour change techniques targeted at patients, which will be provided along with the intake tool.</p> <p>Further details are provided in the manuscript.</p>
WHO PROVIDED			
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	<ul style="list-style-type: none"> - HHPs will receive a one-time workshop divided in an educational- and a training part, and is provided by a local opinion leader (staff member). - Local opinion leaders will be selected and briefed by the research team. These opinion leaders will be provided with the manual and workshop material. Opinion leaders are deployed per department (University Audiology Center and section of Otology), and include staff members (one staff audiologists and one staff otologists). - HHPs will receive the intake tool via an online software system. 	<p>Patients will receive the intake tool via an online software system.</p>

continued

Item no	Item	hearing health care professionals (HHPs)	patients
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	<ul style="list-style-type: none"> - The workshop will be delivered in a face to face group session by the opinion leader (one for audiologists, one for otologists). - Educational and instructional material will be delivered via a written manual. - The intake tool and its desired functionalities (details are provided in the manuscript) will be provided via an online software system (preferably integrated in the patient record system). 	Delivered in/ along with the intake tool, which will be provided via an online portal (preferably integrated in the patient record system). A paper version will serve as back-up for those patients who would otherwise decline the use of the intake tool.
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	The intervention will be delivered at University Audiology Center and section of Otology of the the department of Otolaryngology-Head and Neck Surgery of the Amsterdam UMC, location VUmc, Amsterdam, The Netherlands.	N/A (incorporated into the intake tool, which will be provided to patients digitally, at their home).
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Workshop for HHPs will be delivered once, before actual implementation of the intake tool. Duration of the workshop needs to be further specified during the concrete content development of the workshop.	Patients will be asked to fill in the intake tool before their intake consultation. Both the patient and the HHP will use the intake tool during the intake appointment.
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A (intervention not yet delivered).	N/A (intervention not yet delivered).

Item no	Item	hearing health care professionals (HHPs)	patients
MODIFICATIONS			
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A (intervention not yet delivered).	N/A (intervention not yet delivered).
HOW WELL			
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Fidelity of the intervention will need to be assessed in future research.	Fidelity of the intervention will need to be assessed in future research.
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A (intake tool not yet implemented).	N/A (intake tool not yet implemented).

** **Authors** – use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported. † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see [BMJ 2014;348:g1687](https://doi.org/10.1186/s12874-014-348-g1687)) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Chapter 8:

General discussion

This thesis' focus is on improving the intake process of patients with ear and hearing problems, by developing and implementing an intake tool based on the Brief Core Set for Hearing Loss (CSHL) in clinical oto-audiology practice. We refer to this tool as the **ICF-based e-intake tool**. This chapter provides a general discussion of the results of the individual chapters. First, the main findings are presented. Second, considerations on the different aspects experienced in the presented studies are discussed. Third, the international perspective on the use of the CSHL and the implementation of other Core Sets is addressed. Finally, implications for clinical practice and recommendations for further research are provided.

MAIN FINDINGS

In what way each study contributed to the development and implementation of the ICF-based e-intake tool, is graphically represented in Figure 1 and described in the following paragraphs.

In the studies described in **Chapters 2 and 3**, the content of the Comprehensive and Brief CSHL were compared with the content of the intake documentation of patients enrolling for ear and hearing care. These studies were performed at Ear Nose Throat (ENT) departments and in audiology clinics in the Netherlands and the United States of America (USA). In both studies, a high percentage of overlap was found when all intake documentation was taken together. This large overlap supports the content validity of the CSHL. On an individual patient level, however, the degree of overlap found between the patient's record and the CSHL varied greatly. Variability was also found within disciplines, between disciplines (otology and audiology), between settings (secondary and tertiary), and between countries. Furthermore, the results highlighted an overall lower representation of the CSHL-Activities and Participation and Environmental Factors components in the intake documentation as compared to Body Functions and Structures components. This suggests that the current otology and audiology practice still is predominated by the biomedical perspective towards hearing impairment and ear disorders. The identification of extra categories in the intake documentation that are not included in the CSHL, suggests that these may need to be expanded in the context of the oto-audiology intake procedure. This is a valid option, as the CSHL are intended to serve as the minimum dataset that needs to be reported. It may be expanded for any purpose stated¹. Overall, the findings indicate that otology and audiology intake currently lack consistent, and standardized documentation of relevant categories that - following the ICF CSHL - would need to be addressed in a patient's intake procedure and subsequent treatment plan. To follow the advice of the ICF, it was therefore concluded that current standard procedures need to be adapted (including the adoption of the extra categories identified) so that the biopsychosocial perspective on the patient's functioning would be incorporated.

In the study described in **Chapter 4**, the rehabilitation needs of visually impaired young patients of Dutch Multidisciplinary Low Vision Rehabilitation Centres were linked to the ICF categories. The results illustrated the benefits of using a structured ICF intake method over non- or semi-structured intake methods without an underlying conceptual model. Use of the ICF-based structured method resulted in more frequent and better representation of relevant domains in the rehabilitation needs that were documented. The results - obtained in a clinical discipline other than otology or audiology - support the relevance and implementation of a structured and ICF-based intake tool in clinical practice in general.

In **Chapter 5**, it was described how the ICF Brief CSHL categories were operationalized into a Patient Reported Outcome Measure (PROM). The results of the pilot study that was part of this developmental process, showed sufficient content validity of the intake tool in a Dutch clinical oto-audiology care setting. In addition, the integration of the intake tool into an electronic system (KLIK) was described. It is recommended that the intake tool should be further optimized, e.g., by defining meaningful cut-off scores to enhance the ease of reviewing and interpreting patient's scores on the intake tool.

In **Chapters 6 and 7**, the implementation of the intake tool was described. Chapter 6 focused on the barriers to and enablers of the implementation from the perspectives of patients and hearing health professionals (HHPs: ENT surgeons and audiologists). Results showed that HHPs' knowledge, skills, and motivation regarding the relevance and the clinical usefulness of the intake tool would need to be enhanced to allow successful uptake in clinical practice. For patients, the provision of clear and specific information on the purpose of the intake tool would be needed to enhance their motivation for filling out the intake tool. Opportunities relating to the (digital) administration and the design of the tool provided additional targets for successful implementation. Chapter 7 focused on the development of an intervention for the implementation of the intake tool. Intervention content was based on the barriers and enablers identified in Chapter 6, and on the available evidence on interventions from other implementation studies. For HHPs, provision of educational/training materials and workshops delivered by opinion leaders, and feedback on HHP's performance during implementation, were recommended. For patients, an information letter to clarify the intake tool's goals and relevance, and to address concerns regarding the intake tool's impact on the relationship with the HHP, was recommended. In addition, it was recommended that the intake tool should be further developed such that it would fit HHPs' and patients' preferences when applied in the clinic (also including the definition of cut-off scores, referral- and treatment decision trees). The first steps towards the implementation of the intake tool have been taken, and now need to be further worked out into an integrated implementation plan.

***Field-test study**

Currently a field-test study is being carried out, in which the intake tool is provided in a large sample of patients. The aim of the field-test study is to obtain sufficient data so that the choice for the cut-off scores of the individual items (or domains) can be supported by the distributions of the answers. Another aim is to further optimize (the content of) the intake tool.

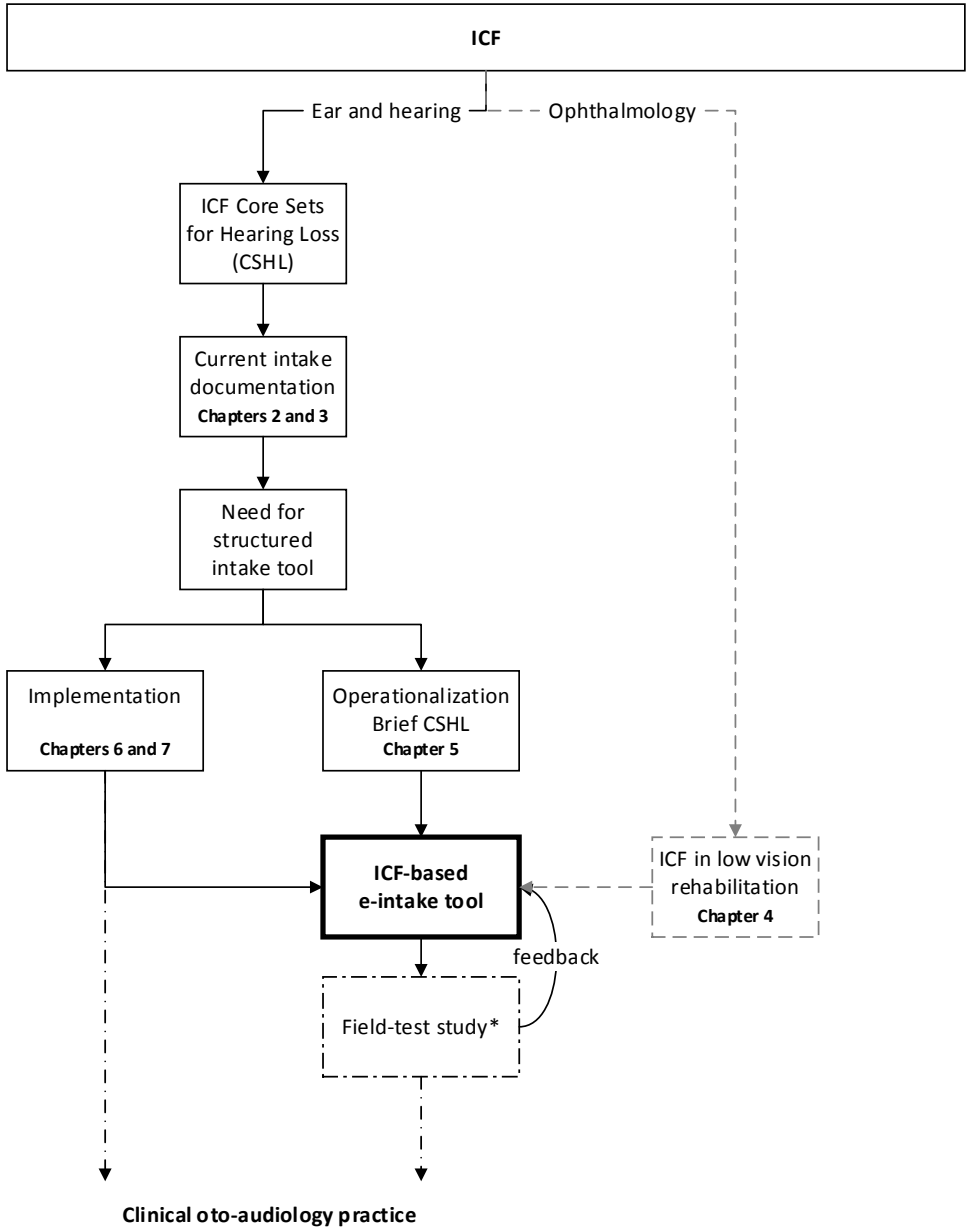


FIGURE 1. Graphical representation of the studies for the ICF-based e-intake tool

CONSIDERATIONS

In the next paragraphs it is discussed that the different aspects experienced in the presented studies have given rise to some considerations. These are identified and discussed below.

Advocating a uniform, standardized approach, and the relationship with patient-centred care

The aim of the work presented in this thesis was to improve the intake process such that it would use the biopsychosocial perspective of the ICF in a standardized way. Ultimately, the aim is to enable more individualized health care provision which is more patient-centred, and eventually improving patient outcomes. As referred to in the Introduction of this thesis, patient-centred care in clinical practice refers to the active involvement of the patient in decision making, planning, and carrying out of the health care. An interesting and fundamental point of consideration here is the apparent disconnection between patient-centred care and standardizing the intake procedure using a structured intake tool. Patient-centred care may be more in line with an open, unstructured approach to the intake to allow for individual differences. Nonetheless, a need for a structured approach to include the patient's view was recognized. An intake would ideally be open in nature, but to ensure that the patient's preferences are taken into account, a health care professional would need to be open to any information a patient is willing to share and be ready to create an atmosphere and prompt patients to share information. The variability between patients as well as health care professionals in that respect, can be very high. The patient-record studies (Chapters 2-3) showed that the range of functioning-related CSHL-factors that are assessed during the intake indeed vary greatly within and between disciplines. Moreover, it was found that - overall - many psychosocial topics were documented to a limited extent only. These findings do not seem to be limited to either the Dutch or USA context, the results were similar. Similarly, an Australian observational study of initial audiology assessment appointments showed that during the diagnostic and management planning phase of appointments, the largest part of audiologist's talk was focused on the medical condition or hearing aids, not on the patient's lifestyle or psychosocial topics^{2,3}. A focus on body function and structure alone is not considered patient-centred. There will be large variations in contextual factors (e.g., comorbidity, personality) which in turn, influence how impairments are experienced in daily life (i.e., activity limitations and participation restrictions). In order to stimulate and facilitate a move towards more patient-centred care provision, and supported by our results, implementation of a standard and *structured* intake tool covering a biopsychosocial perspective on functioning with ear and hearing problems seems an important first step.

As discussed in Chapters 5 and 6, it is important to realize that the ICF-based e-intake tool itself does not automatically assure patient-centred care. Instead, it should be viewed as an instrument that potentially facilitates a step towards such a model of care. The underlying assumption is that measurement of patient reported outcomes, along with adequate provision of the PROM-results and information on follow-up actions, will finally stimulate and incentivise HHPs to provide care that is tailored to the specific needs of their patients⁴.

Specifically, the patient's functioning profile generated by the intake tool can be used as a starting point in the intake, to facilitate communication between patients and HHPs, and to foster an equal partnership in determining treatment⁵. Whether the HHPs will actually use the intake tool with their patients in a patient-centred way was beyond the scope of the current thesis and will need to be carried out in future work.

Both HHPs and patients raised the concern that the intake tool could compromise the intake (a 'normal' conversation), i.e., that the use of the intake tool might negatively affect or replace the conversation with the HHP (Chapter 6). This underlines the importance of identifying the assumptions, expectations, and perceptions to using (the outcomes of) the intake tool, and of developing a theory of change as part of the implementation intervention development process⁶. Careful consideration of the target behaviour(s) and the implementation context^{4, 7, 8}, is necessary to ensure that the provision of the intake tool and its results to patients and HHPs can actually assist with communication, improvements in patient management, and provision of patient-centred care.

Applicability in audiology clinics and ENT departments

While hearing impairment is a condition central in both the otology (as part of ENT) and audiology discipline, there are differences in the disciplines' focus. Audiology is concerned with interdisciplinary diagnosis and rehabilitation of persons with hearing impairment. In contrast, ENT surgeons are trained in the medical and surgical treatment of hearing impairment and disorders of the ear. Given the differences in these approaches, in patient-population, and patient-problems, implementation of the intake tool in the audiology clinical practice may seem more logical at first sight. This point was also raised by the ENT surgeons participating in the implementation study (Chapter 6): they wondered whether the intake tool would be suitable in their practice and in all patients they see.

In Dutch university medical centres, audiology and otology are closely related sections within one overarching department of otolaryngology, head and neck surgery. Moreover, in the Dutch care-system, patients who are referred to clinical care with the same hearing complaints can be either referred to an ENT department or Audiology Clinic (AC). In university medical centres like the Amsterdam UMC, patients can be quickly referred by ENT surgeons to audiologists, or vice versa. In addition, often both disciplines are involved in the trajectory of care of one patient. In our philosophy, this requires an integrated approach that should start on the day the patient is referred to our hospital. This should be independent of the specific discipline that the patient is referred to. In addition, it will be possible to compare intake data across different health conditions, services, and disciplines. Besides smoother exchange of patient-data, combining and comparing data could possibly lead to new insights and improved care provision.

Also in the literature it has been emphasized that implementing the ICF solely in rehabilitation settings (like in Chapter 4) is not enough for reforming health care. Stucki (2016) for instance emphasizes that only if the ICF is universally adopted by medical colleagues, and - ideally - is integrated into the health care system at large, it can be used optimally as a general shared language for clinical practice, evidence-informed policy and research⁹. Accordingly, it seems logical that integration of the ICF needs to start with closely related disciplines, such as Dutch clinical oto-audiology care settings.

Screening versus effect measurement

We chose to operationalize the Brief CSHL into an intake tool that could facilitate standardized screening of problems and contextual factors relevant to adult's functioning. With functioning as a multidimensional construct, it is important that all aspects that need further examination or actions would be highlighted. For effect measurement however, multiple items per sub-construct are required to obtain reliable outcomes¹⁰. It was discussed within our project group that including more items per sub-construct would yield a too lengthy questionnaire and therefore would imply an unacceptable burden for the patient (Chapter 5). If effect measurement of treatments using the intake tool would be desired in the future, the intake tool would need to be adapted or complemented. In Chapter 5 we already highlighted the option to combine the intake tool with validated symptom-specific questionnaires. Such an approach would enable the measurement of treatment or intervention effect on sub-constructs. A possible disadvantage would arise in patients with multiple complaints across various sub-constructs. They would need to complete multiple questionnaires, resulting in a considerable burden. An appealing alternative would be a computer adaptive testing (CAT) version, created with Item Response Theory (IRT) to shorten the list of items required for effect measurement⁷. This way, the individual patients only complete items that are suitable to their situation. Therefore, the use of CAT may improve data quality and collection efficiency, further facilitating the use of PROMs¹¹.

Theory-based approach for implementing the intake tool

Following the recognition of the importance of patient-centred care, and capturing outcomes that matter to patients, there is a growing international momentum for standardising patient outcome assessments in clinical practice across health care fields. However, as outlined in Chapters 6 and 7, the implementation of PROMs is often suboptimal, limiting its effectiveness in clinical practice¹²⁻¹⁴. Systematic reviews on the impact of using PROMs in clinical practice (e.g., ¹⁵⁻²⁰) consistently report methodological limitations with regard to design and analysis of the studies evaluating the impact of PROMs⁷. In addition, the studies in these systematic reviews demonstrated an incomplete understanding of the mechanisms by which the PROM in clinical practice operates^{7, 16}. Assumptions that health care professionals can and will automatically implement new interventions into their daily practice is naïve. Barriers to and enablers of PROM-use in clinical practice have been highlighted in various studies, and international best practices to guide PROM collection in

clinical practice have been established. Examples are the ISOQOL User's Guide and its recently published Companion Guide on how to Implementing Patient-Reported Outcome Assessment in Clinical Practice^{21, 22}, and the Framework for implementing PROs in clinical practice⁷. It has been argued that implementation of PROMs should be founded on theory that provides a foundation for understanding, designing, and evaluating implementation processes (e.g.,⁴). Moreover, the linking of theory with intervention design is consistent with the advice given in the Medical Research Council (MRC) guidance on the development of complex interventions^{23, 24} (See Table 1, first column). The use of theory in the development and evaluation of interventions, and the importance of implementation is also advocated by one of the key Dutch research organization (ZonMw)²⁵. Despite this call for the use of theory during the development phase of intervention development, there is very limited information or advice on how to choose an appropriate theory. So, the recommendations are there, but the practical experiences with theory-based PROM implementation have only been documented to a limited extent. By way of operationalization of the development phase of the MRC framework, we used the Behaviour Change Wheel (BCW). The stages of the BCW, and their steps that are described in Chapter 7, strongly match the phases of the MRC framework, and have been linked to them by Sinnott et al. (2015)²⁶ (See Table 1, second column). Although the BCW framework that was used in our implementation studies is not new, and also has been used in audiology research before^{27, 28}, we believe that researchers and health care professionals might benefit from our applied example of an implementation intervention development process in this unique setting in this series of studies. Moreover, to our knowledge, this work is innovative because the vast majority of studies integrating PROMs in clinical practice have not used (behavioural change) theory approaches in (the development of) their implementation interventions.

TABLE 1. MRC framework phases of intervention development and linked BCW stages

MRC phases ²³	BCW stages ⁸
1. Identify the evidence base	1. Understand the behaviour
2. Identify/develop theory	2. Identify intervention options
3. Model process and outcomes	3. Identify content and implementation options

Integration of the intake tool into a digital system

A key recommendation to facilitate the implementation of PROMs in clinical practice that is often reported in the literature, is to support PROM data collection and analyses in a computer-based system^{22, 29, 30}. Practical advantages provided by computerized administration include no missing data due to otherwise skipping of questions and automated scoring, inputting, and storing. Issues with administration have been shown to be important barriers to the uptake of PROMs in clinical practice²⁹⁻³¹ and were found in the study of Chapter 6 of this thesis as well. Moreover, the digital integration of PROMs in Electronic Health Records (EHR) was an important enabler that also emerged from our study (Chapter 6). Not surprisingly, this was especially found important by the HHPs.

Unfortunately, the full integration of the intake tool into the EHR system was not possible during the timeframe of the PhD project, despite significant efforts to establish this. Therefore, we opted for the existing online portal called KLIK (www.hetklik.nl). We chose KLIK, because it is especially suitable for facilitating the use of PROMs in clinical practice, which is fully in line with our methods. Other benefits of using this system include that it has already undergone some optimization following experience in different clinical care settings, and that ongoing ICT support is in place. Shortcomings are that the format of KLIK could not be fully specified to the intake tool, in the sense that tailoring the lay out of the tool was possible only to a limited extent. For example, the log-in page is not content-specific to the (aims of) the intake tool. However, the most significant downside of a separate online system is that extra actions are required to integrate the PROM-data into the general EHR system, and thus also not allow for direct integration with other (relevant) patient data. It is desirable that the intake tool will be integrated in the EHR in the future, by linking KLIK to the EHR system or preferably by integrating the PROM in itself directly in the EHR.

Broader implementation context

In this thesis the main focus was on the perspectives and needs of the end-users of the intake tool: patients and HHPs. This is an important starting point for successful implementation of the tool. However, implementation involves a larger context⁸ that may be challenging. This was also faced when attempting to integrate the intake tool digitally in the EHR system. The challenges underline the complexity of the implementation context and emphasized the importance of the various actors playing a role, at a hospital level setting (e.g., facilitating integration of tools into the EHR), and possibly even up to the setting of professional organisations (e.g., guidelines) and government (e.g., mandating the use PROMs in clinical practice). It is important to be aware of these actors and their influencing role in the failure or success of the integration of PROMs in clinical practice.

Generalizability of our results

For a tool to be effectively implemented, the precondition is that it is tailored to the specific context and organizational structure⁸. The current version of the intake tool is intended for use in the Dutch system, and for Dutch patients. This currently limits its applicability to Dutch speaking patients only and to a clinical oto-audiology care setting. The generalizability of the intake tool's suitability to other countries with other care systems is thus unsure. The translation of the intake tool to other languages and the validation of this version to the particular cultural setting would be future steps that could be taken.

INTERNATIONAL PERSPECTIVE

International perspective on the Brief CSHL

As already mentioned in the General introduction and in Chapter 5, there are other initiatives to integrate the ICF Brief CSHL into clinical (oto-)audiology practice. In the USA, Alfakir and Holmes (2018) developed a questionnaire based on ICF category descriptions and ICF qualifiers, to measure the presence and magnitude of the constructs measured by the particular ICF categories³². It is meant as a clinical tool to capture interactions between the general domains of the ICF, and to assist health care professionals in their decision making³². Recently, an Swiss project was announced that focusses on the development and implementation of a PROM that is based on the Brief CSHL³³. No results are yet available. From the studies in this thesis it is apparent that practicable forms of the ICF CSHL should be tailored to the specific context and specific aim of the instrument. Collecting information on the same ICF-categories enhances communication and comparability of patient(s) (outcomes) that enrolled in the (oto-)audiology context internationally. The practical experience with operationalizing, implementing, and using the ICF CSHL in clinical practice in the Netherlands, could be combined with the experiences of the other initiatives. This is important to guide further development and implementation of the CSHL for use in clinical practice, research, and education, and to seek international collaboration and alignment in these processes, so that comparison can be facilitated. This is in line with objectives of the international rehabilitative audiology working group on the further development process of the Core Sets (International Collegium Rehabilitative Audiology (ICRA)³⁴). Of note, the ICF CSHL are dynamic, and it is expected that after their global application the content of the Core Sets will be revised and will evolve over time. For example, in Chapters 2-3 we proposed the inclusion of the ICF category 'sleep function' and Personal Factors. In addition, in Chapter 5, we opted for the expansion of ear and hearing categories. It is important to learn from ongoing initiatives on applying the ICF CSHL in practice. The collaboration on the patient record study in Mayo Clinic (Chapter 3) was a valuable experience in this regard, and maintenance of such collaborations and extension to other settings or countries should be considered. This with the ultimate aim of strengthening the support for the application of functioning information (by using the ICF) in ear and hearing care, and thereby patient care internationally.

Operationalisation and implementation of other ICF Core Sets

The implementation of the ICF in clinical care is worldwide, and across many health conditions, a pressing topic and an ongoing process⁹. One important implementation strategy is the development of Core Sets. Over 40 other ICF Core Sets have been developed³⁵, and also many initiatives have been taken to operationalize them into practical tools for clinical practice. Depending on the specific aims, the ICF categories of the Core Sets were operationalized into guidelines, PROMs, and toolboxes. The ICF Research Branch website forms a valuable platform where all relevant projects and publications are listed (www.icf-

research-branch.org). In Chapter 5, a few of the PROM-based instruments have been listed. Literature on the implementation of these Core Sets is limited. To our knowledge, one other project specifically focussed on the implementation of the Core Sets, namely that of rehabilitation of hand conditions. The Lighthouse Project Hand was initiated to operationalize, implement, and use the ICF Core Sets for hand conditions into a monitoring tool in the institutions of the statutory accident insurance in Germany³⁶. To facilitate its implementation, strategies include teaching materials, manuals and an e-learning tool for clinical practice and research. These seem similar to the implementation intervention components that we proposed in this thesis, but a description on how these strategies exactly were developed is lacking. Reporting the process is important to be able to learn from each other. This with the aim to improve implementation and optimize the dissemination of the ICF in specific health care systems.

Therefore, it might be beneficial to define a “Phase III” in the WHO development process of ICF Core Sets to underline the importance of and to carefully guide the implementation of the Core Sets. In the current development process model, the description of Phase II is limited to “introducing the Core Sets in practice”³⁷. The description includes the validation of the Core Sets, and the development and implementation of ICF-based instruments³⁷. A separate, well-defined implementation phase, with a theory-based approach, would increase the chances for successful implementation. It should be realized that this is a challenging assignment though, as implementation science is developing rapidly and application of the Core Sets is dependent on its specific goals in clinical practice.

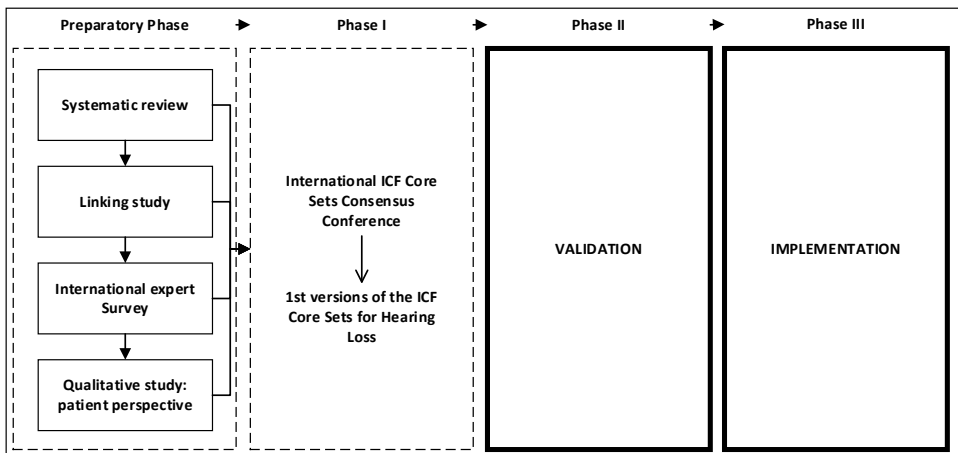


FIGURE 2. Proposal to include Phase III ‘implementation’ to the Core Set development-process

IMPLICATIONS FOR CLINICAL PRACTICE

The results of the studies presented in this thesis are relevant for current health care provision, which faces the challenge of implementing and operationalizing the biopsychosocial perspective and patient-centred care. The international ear and hearing field, as well as Dutch guidelines³⁸ promote an ICF-based approach to hearing rehabilitation. It is preferred that in this approach, attention is paid to the limitations and problems experienced by hearing impaired individuals in carrying out activities and participating in society, as well as the influence that the environment and personal factors have. The provision of value-based health care, and the focus of a patient-centred approach, including an equal partnership between the patient and health care professional, to hearing rehabilitation is also underlined in these guidelines and recommendations³⁸⁻⁴¹.

The work in this thesis showed that current oto-audiology intake standards would need to be adapted to meet the standard of the ICF Brief CSHL, and to reach to full potential of applying structured PROMs. The findings of this thesis are encouraging in that important steps have been taken towards creating a tool that facilitates individualized clinical otology and audiology services from a biopsychosocial perspective, in a potentially patient-centred way. Regarding the intake tool's implementation a multifaceted intervention is designed, and encouraging findings are that patients were generally enthusiastic about its aim, and that despite important barriers, also audiologist and ENT surgeons acknowledged its potential.

The application of the ICF in different health care settings and populations in this thesis (i.e., ophthalmology and oto-audiology setting, diagnostics and rehabilitation, and national and international setting; Chapters 2-4), provides support for the external validity of the ICF as a reference framework in the intake.

The aim of our ICF-based e-intake tool is not to replace profession-specific methods. Rather, it is an aid for the management and treatment of, and communication with, the patient besides other (clinical) tools, profession-specific assessments, methods and knowledge. Whether the intake tool will improve patient-centred care, as already mentioned, will partly depend on the success of implementation of the use of the intake tool. As shown in this thesis, implementing the intake tool in the oto-audiology setting requires a significant shift in how HHPs view their role, how outcome feedback is framed, and how data are integrated and used for intake practice improvement. These aspects require that certain measures need to be taken regarding the design and implementation of PROMs, such as our intake tool, in this setting. The studies in this thesis focused on short-term objectives regarding the implementation and regarding the introduction of the intake tool in clinical practice. Longer term-objectives would relate to optimizing the content and use of the intake tool in clinical practice, and will likely only be successful if ongoing training, interactive sessions, as well as

reflections on progress and feedback (with HHPs), are provided and shared⁴². Moreover, a sustainable approach to using the intake tool requires significant long-term commitment of budget, a coherent system, and active support from the organization^{43, 44}. The work in this thesis supports the view of Kyte and colleagues in the sense that a bottom-up approach generates PROM-related insights that are relevant to patients and health care professionals⁴⁵. However, from the work of Gibbons and Fitzpatrick (2018) it is clear that although the bottom-up approach is important for support for the introduction of a PROM, it subsequently requires a top-down approach. In other words, broader coordination ‘from above’ is crucial too⁴³. In summary, it is a two-way avenue.

RECOMMENDATIONS FOR FURTHER RESEARCH

Based on the work described in this thesis, several recommendations for further research can be formulated. Firstly, as mentioned, knowledge is needed to determine cut-off scores that can help guide the HHPs in further referral or actions for treatment or rehabilitation. Regarding the development of strategies for responding to the outcomes of the intake tool, additional work is required into existing possible effective treatment options and referral paths that correspond with ‘problem’ areas of functioning. Furthermore, research on various patient groups will provide knowledge on the specific needs patients have and, consequently, this should facilitate better tailoring of care provision. As mentioned earlier in this chapter, currently, a field-test study is ongoing in which the intake tool is administered to all new patients who apply for ear and hearing care at our department. This study is expected to provide valuable information for the definition of cut-offs and formulation of treatment strategies.

The research in this thesis covers the first stage of the UK MRC Framework for the development, evaluation and implementation of complex interventions²³ (i.e., the development stage of the complex intervention, see above). We incorporated the BCW to help us design a complex intervention to change the behaviours of patients and HHPs. With regard to the process to the actual implementation of the intake tool, future research goals can be formulated using the remaining stages of the MRC Framework: piloting the implementation intervention and testing the intervention for feasibility prior to evaluation, involving a process evaluation and economic evaluation (MRC stage 2), evaluation of the implementation intervention, including assessing its effectiveness (MRC stage 3), and, finally, the actual implementation (MRC stage 4). In addition, further research will have to show whether the ICF-based e-intake tool in its current form is suitable and relevant for all patients visiting the audiology clinic and ENT practice. Also the suitability of the tool in otology and audiology practice needs to be further investigated. For example, it should be studied whether the final implementation of the tool should be discipline-specific. The optimization of the intake tool will be an ongoing process, requiring continuous evaluations, if necessary, followed by modification.

The actual translation of the implementation intervention, and specific content in the manual, workshop, and design and functionalities of the intake tool is needed. This intervention would also need to include further engagement and collaboration with relevant stakeholders (e.g., feedback of patients and HHPs, and organizational support).

Also the (cost-)effectiveness of the intake tool needs to be researched, to be able to determine the actual gain of the implementation of the intake tool in patient outcomes. Parameters to measure the success of the intake tool may include patient-health care professional communication (e.g., topics discussed during the intake appointment), diagnosis and recognition, utilization of services and referral pathways, and patient experience (e.g., satisfaction with the intake procedure).

Finally, data collected with the intake tool may be used to differentiate between different patient groups within and between disciplines. In addition, further studies may aim to investigate the application of the intake tool in other (international) centres, with the aim to enhance comparability of data across all audiology and otology settings in the Netherlands as well as internationally.

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Summary

BACKGROUND AND AIMS

Ear and hearing problems can have a major impact on a person's functioning in daily life. Beyond being able to hear less, ear and hearing problems may lead to limitations in daily activities and restrictions in societal participation¹⁻⁵. In turn, this may affect one's psychosocial well-being, cognitive, and emotional functioning⁶⁻⁹. External factors, such as a person's capacity to cope with challenges and setbacks, influence the functioning of a person as well¹⁰⁻¹². For a complete and efficient diagnosis and treatment of persons with ear and hearing problems, it is therefore necessary that not only the auditory functions and structures are evaluated, but that also all relevant aspects of functioning are evaluated. The current approach to diagnosis and treatment of ear and hearing problems differs and depends on the focus and expertise of the care provider(s) and institution(s) involved. It is therefore essential that such a broad approach, in which all relevant aspects are listed in a standardized manner, is applied during the early stage of assessment and diagnosis. Another important reason to broaden the focus to the person's total functioning is that it can support *patient-centred care*. Here, the care is no longer organized from the perspective of care providers, but starts from the perspective of the patient. A standard and uniform reference for such an approach is offered by the International Classification of Functioning, Disability and Health (ICF) framework developed by the World Health Organization¹³. The ICF is based on the biopsychosocial model, where a person's body functions and structures, activities, participation, and contextual factors (environmental and personal factors) are recognized as important aspects of human functioning and health. Various studies have highlighted the need for such a reference framework in ear and hearing care and recommend the application of the ICF (e.g.,¹⁴⁻¹⁶). To make the ICF specific for adults with hearing loss, the ICF Core Sets for Hearing Loss (CSHL) were developed^{14, 17-21}. These are shortlists of ICF categories that are considered most relevant for describing the functioning domains and environmental factors of adults with hearing loss. The Brief CSHL provides a minimal standard for identifying the issues associated with hearing problems and potentially provides a good basis for identifying factors that are relevant in the intake procedure for adult patients with ear and hearing problems visiting an Ear Nose and Throat (ENT) department or an Audiology Clinic (AC).

The overall aim of the work in this thesis was to apply the biopsychosocial perspective of the ICF in the intake of adult patients with ear and hearing problems, by developing and implementing an intake tool based on the Brief CSHL in clinical oto-audiology practice: the '**ICF-based e-intake tool**'. To this end, the Brief CSHL was operationalized into a patient reported outcome measure (PROM). With this intake tool, adults with ear and hearing problems can be screened such that problems and contextual factors relevant to their functioning can be determined and the subsequent care can be tailored to their specific needs. In this thesis, the need for and the creation of the intake tool are described. In addition, it was investigated what is needed to successfully implement the intake tool in clinical practice.

MAIN FINDINGS

Overlap and non-overlap between the CSHL and clinical otology and audiology intake documentation (Chapters 2-3)

In the studies of Chapters 2 and 3, the content of the CSHL were compared with the content of the intake documentation of adult patients enrolling for ear and hearing care at ENT departments and ACs in the Netherlands and the USA. The overlap between the CSHL categories and otology and audiology intake documentation in the Dutch setting was 89% for the Brief CSHL, and 51% for the Comprehensive CSHL (Chapter 2). It is important to note that these percentages do not apply per individual patient record, but apply to all the records of ENT and AC examined together. Various CSHL categories were not found in the intake documentation, including higher mental functions (Body Functions), civic life aspects (Activities and Participation), and support and attitudes of family (Environmental Factors). One extra ICF category emerged from the intake documentation that currently is not part of the CSHL: “sleep functions”. Also some Personal Factors that are currently not included in the ICF classification were found in the intake documentation.

In the USA setting (Chapter 3), the intake documentation of the Mayo Clinic was examined. The Mayo Clinic uses a common medical documentation system (an electronic health record) that is accessible and shared by all providers. In addition to the discipline-specific intake documentation, the system captures patient information recorded by all healthcare providers (referred to as ‘multidisciplinary intake documentation’). The overlap between the CSHL categories and all intake documentation was 100% for the Brief CSHL and 50% for the Comprehensive CSHL. The overlap for audiology and otorhinolaryngology discipline-specific intake documentation was 70% for the Brief CSHL. A lower representation of the Activities and Participation- and Environmental Factors components as compared to Body Functions and Structures was found. Consistent with the results from the Dutch setting, the extra ICF category “sleep functions” was identified, in addition to the ICF category “motor-related functions and activities” (e.g., mobility) and various Personal Factors.

The overall overlap between the CSHL and the intake documentation showed in the two studies supported the CSHLs’ content validity. The partial non-overlap indicates that current intake procedures may not cover all aspects relevant to patients with ear and hearing problems. Furthermore, in both studies different intake documentation methods were identified. Depending on the type of patient, the care provider or department, and the centre, an intake method was applied. These different methods imply differences in the identified topics during the intake procedure. In addition, the identification of the extra categories suggested that the CSHL may need to be expanded in the context of the intake procedure. Based on the findings of these studies, it was concluded that there was a need to develop a practical, systematic intake standard for collecting CSHL information in clinical oto-audiology practice.

Applying the ICF in low vision rehabilitation (Chapter 4)

In the study of Chapter 4, the rehabilitation needs of visually impaired young adults (18–25 years of age) and how these needs relate to the ICF, was investigated. Young adults' intake documentation from two Dutch low vision Multidisciplinary Rehabilitation Centres (MRC) were linked to the categories of the ICF classification. It was found that most identified rehabilitation needs related to categories from the Activities and Participation component (i.e., linking frequency 67.6%). Most of those needs related to education and work life, running a household independently, self-reliance in mobility, using communication devices and techniques, and psychological consequences of having a visual impairment. Topics relating to interpersonal interactions and relationships and community, social and civic life received little attention in the formulation of rehabilitation needs by visually impaired young adults, although these have been shown to be important in literature. Identified rehabilitation needs in the component Environmental Factors (i.e., linking frequency 21.2%), including support from communication products, stress the importance of including topics on this component in the standard intake procedure as well.

The intake processes within the MRCs were not uniform: rehabilitation needs were obtained from either (1) a semi-structured intake method or (2) a structured intake method via the Participation Activity Inventory (PAI)²². Although similar ICF categories were identified across the methods, the systematic intake with the PAI resulted in 1) more rehabilitation needs (mean number of 11 vs 3 without the PAI) and 2) a better representation of needs on important domains reported in literature. Therefore, a systematic way of identifying rehabilitation needs seems the preferred method. In conclusion, the findings indicated that there is a need for a suitable survey method that elicits domains relevant to young adults' lives and development and can be translated into meaningful rehabilitation goals.

In addition to the differences in health domain (ophthalmology versus oto-audiology) there is an important difference between the studies in Chapters 2-3 and Chapter 4 with regard to the phase of care. The first two chapters concern patients who first report with their health care needs, while patients from Chapter 4 concern patients for whom the diagnosis of the functional problem has already been established, with a specific need in the field of rehabilitation. The lessons that can be learned on the basis of Chapter 4 for the development of the intake tool in clinical oto-audiology practice are: 1) the inclusion of aspects of functioning in an intake tool seems to be necessary to ensure relevant patient-needs are identified; 2) the categories that are relevant in the intake depends on the setting and purpose of the intake procedure; 3) the ICF model appears to be a suitable framework for systematically mapping the functioning of individuals.

Operationalisation of ICF Core Set for Hearing Loss into an ICF-based e-intake tool (Chapter 5)

Chapter 5 describes the development process of the ICF-based e-intake tool. This process comprised a mixed methodology: 1) the selection of items from a pool of items of existing validated PROMs, 2) a formal and consensus based decision-making process on the inclusion of items, and 3) qualitative content assessments using an expert survey and a pilot study in patients. The outcome was a disease-specific e-intake tool consisting of 62 items clustered into 6 domains: (1) general information, including reason for visit, socio-demographic and medical background related items; (2) general body functions; (3) ear- and hearing structure and function; (4) activities and participation; (5) environmental factors; and (6) personal factors (mastery and coping). Based on stakeholders' (i.e., audiologists, ENT surgeons, patient-representatives, and researchers) responses, the instructions of the items of Activities and Participation, and Environmental Factors were adapted such that they explicitly related to patients' ear and hearing problems. The pilot study showed that the intake tool sufficiently measured what was intended to be measured (content validity). In addition, both stakeholders and patients perceived the intake tool to be relevant and to have a logical and clear structure. Finally, the pilot study resulted in changes to the formulation of the items on environmental factors.

The existing online portal "KLIK" was chosen as the vehicle to implement the intake tool digitally. By using this portal, after completion of the questionnaire, the patient's outcomes are digitally presented and converted into a "functioning profile", which is accessible both by the patient and the treating health care professional(s). Further research is recommended to address the ease of reviewing and interpreting the patient's profile, including the definition of relevant cut-off scores for individual items or domains and the development of a referral decision tree to guide health care professionals on their actions.

Implementation of the ICF-based e-intake tool in clinical otology and audiology practice (Chapters 6-7)

Chapters 6 and 7 describe the studies which focused on the implementation process of the ICF-based e-intake tool. The Behaviour Change Wheel (BCW) framework was used for this, which helps with choosing and designing interventions for behavioural change. This can be a change for both patients (here: completing the intake tool) and for health care professionals (here: using the intake tool). By using the BCW method a theory-informed and systematic approach could be adopted to structure the intervention development process. The BCW is based on a theoretical COM-B model that proposes that for someone to engage in a particular behaviour (B) they must be physically and psychologically capable (C), have the social and physical opportunity (O) to perform the behaviour, and be motivated (M) to perform the behaviour. Using the COM-B model and the more specific Theoretical Domains Framework, firstly, barriers and enablers to using the intake tool perceived by health care professionals and patients were identified and categorized, respectively (Chapter 6).

Focus groups and interviews with health care professionals (ENT surgeons, N = 14; audiologists, N = 8) and patients (N = 18) were performed to this end. Health care professional barriers that emerged included: lack of time to use the intake tool (O) and fear of being held responsible for addressing any emerging problems, even if these would be outside the expertise of the health care professional (M). Health care professional enablers that were identified included: the integration of the intake tool in the electronic patient record (O); the opportunity for the patient to be better prepared for the intake visit (M); and provision of a complete picture of the patient's functioning via the intake tool (M). Patient barriers included the fear of losing personal contact with the health care professional (M); and the fear that use of the intake tool might negatively affect the conversation with the health care professional (M). Patient enablers included having sufficient knowledge on the aim and relevance of the intake tool (C); the expectation of a better self-preparation for the intake appointment (M); and the expectation of a more focused intake procedure (M).

Secondly, in the study of Chapter 7, an intervention for the implementation of the ICF-based e-intake tool was developed. The development of the intervention was based on the identified barriers and enablers of Chapter 6, and on the available evidence on interventions from other implementation studies. Via a consensus procedure with relevant stakeholders (i.e., health care professionals, an implementation expert, and researchers), a multifaceted intervention was proposed. For health care professionals the provision of educational/training materials and -workshops delivered by opinion leaders (i.e., audiology and ENT staff-members) were suggested. These would need to enhance health care professionals' knowledge, awareness, skills, and self-efficacy for using the intake tool. Other intervention components included adjustments in the design of the intake tool to facilitate the practical use of the intake tool. For patients, a concise information letter is needed to be sent along with the intake tool. This letter should clarify the goals and relevance of the intake tool, and should address the concerns patients might have regarding the possible negative impact that the intake tool would have on their relationship with the health care professional.

The results of Chapter 7 provide a first step towards the successful implementation of the intake tool. In the next step, this implementation intervention would need to be operationalized into an integrated implementation plan.

General discussion (Chapter 8)

Chapter 8 discusses the main findings presented in this thesis. Also, considerations that were experienced in the studies were discussed, and possible implications for clinical practice and future research were outlined. The studies in this thesis showed that current oto-audiology intake standards would need to be adapted to meet the standard of the ICF Brief CSHL. Important developmental steps have been taken towards creating an intake tool (**the ICF-based e-intake-tool**) that aims to facilitate individualized clinical oto-audiology services from a biopsychosocial perspective. With the tool, patient-centred care can be supported by the

broad view that is presented in a standardized way to health care professionals, prior to intake appointments. Future objectives include the optimization of the content and the use of the intake tool in clinical practice. This will require ongoing training, interactive sessions, as well as reflections on progress and feedback with health care professionals. Moreover, a significant long-term commitment of budget and organizational support is required to accommodate the use of the intake tool. Future research should focus on the further optimization of the intake tool and its actual implementation in clinical practice. Then, the effectiveness of the implementation intervention, and, ultimately, the effectiveness of the intake tool on (the quality of) patient care can be determined.

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Samenvatting (Dutch summary)

ACHTERGROND EN DOELSTELLING

Problemen met oor en gehoor kunnen een grote impact hebben op iemands functioneren en leven. Naast het minder goed kunnen horen, leiden (h)oorproblemen vaak tot beperkingen in het uitvoeren van allerlei dagelijkse activiteiten en daarmee in het meedoen in het maatschappelijke leven¹⁻⁵. Dit kan vervolgens iemands psychosociale welzijn, cognitieve- en emotionele functioneren beïnvloeden⁶⁻⁹. Externe factoren, zoals de fysieke en sociale omgeving en persoonlijke factoren, zoals iemands capaciteit om met uitdagingen of tegenslagen om te gaan, bepalen mede het functioneren van een persoon¹⁰⁻¹². Voor een volledige en efficiënte diagnostiek en behandeling van een persoon met (h)oorproblemen is het noodzakelijk dat niet alleen de auditieve functies en anatomische en fysiologische eigenschappen van het oor worden geëvalueerd, maar ook dat in beeld wordt gebracht wat dit voor iemands functioneren in bredere zin betekent. De benadering om tot een diagnose en behandelplan van (h)oorproblemen te komen verschilt en hangt onder andere af van de focus en expertise van de betrokken zorgverlener(s) en zorginstelling(en). Het is daarom essentieel dat een dergelijke aanpak, waarin alle relevante aspecten gestandaardiseerd worden geïnventariseerd, al wordt toegepast tijdens een vroeg stadium van beoordeling en diagnose. Een andere belangrijke reden is dat het verbreden van de focus op de totale persoon in zijn of haar context, kan helpen om de zorg *patiëntgericht* te maken. De zorg wordt zo niet langer georganiseerd vanuit het perspectief van de zorgverleners of de instelling waaraan ze gelieerd zijn, maar begint vanuit het perspectief van de patiënt.

Een methode om tot het ontwerp van een integrale en gestandaardiseerde methode voor een intake¹ te komen wordt geboden door de Internationale Classificatie van het menselijk Functioneren (Engels: International Classification of Functioning, Disability and Health, ICF). De ICF is een uitgave van de Wereldgezondheidsorganisatie (Engels: World Health Organization, WHO), en bestaat uit een raamwerk van classificaties die tezamen een internationaal overeengekomen begrippenkader vormen voor het beschrijven van het menselijk functioneren¹³. Het ICF model gaat er vanuit dat naast biologische aspecten, psychologische en sociale factoren een belangrijke rol spelen in het functioneren van een persoon (een zogenaamd 'biopsychosociaal perspectief'). De ICF maakt daarbij onderscheid tussen functies, anatomische eigenschappen, dagelijkse activiteiten, maatschappelijke participatie en contextuele factoren (externe factoren en persoonlijke factoren). Met de door de ICF geboden denkwijze en het bijbehorende begrippenkader kan het functioneren van een persoon met (h)oorproblemen systematisch beschreven worden in samenhang met alle factoren die er invloed op uitoefenen. De behoefte aan een dergelijk kader voor oor- en gehoorzorg is in verschillende (internationale) studies aangetoond en ook de toepassing van de ICF wordt aanbevolen¹⁴⁻¹⁶. Met meer dan 1400 categorieën is de totale ICF classificatie echter niet praktisch voor gebruik in de klinische praktijk. Om de implementatie ervan in

¹ Een intake of intakegesprek is het eerste gesprek wat een patiënt heeft met een zorgverlener. Tijdens dit gesprek worden onder meer gezondheidsklachten besproken.

verschillende gezondheidsdomeinen te faciliteren, zijn daarom zogenaamde 'Core Sets' ontwikkeld. Core Sets zijn verkorte lijsten van ICF-categorieën die het meest relevant worden geacht voor het beschrijven van het functioneren en de daarmee samenhangende externe factoren van volwassenen met een bepaalde aandoening, zoals slechthorendheid. Zo werden in 2011 ook de ICF Core Sets voor Slechthorendheid ontwikkeld (Engels: ICF Core Sets for Hearing Loss, CSHL)^{14, 17-21}. Er zijn twee CSHL, een uitgebreide en een korte. De uitgebreide dient voor uitgebreide beoordeling door verschillende zorgverleners. De korte CSHL biedt een minimale standaard voor het identificeren van de problemen die voorkomen bij gehoorproblemen. De korte CSHL biedt mogelijk een goede basis voor het identificeren van factoren die relevant zijn bij de intake procedure voor volwassen patiënten met (h)oorproblemen die een Keel-Neus-Oor (KNO) afdeling of een audiologisch centrum (AC) bezoeken.

Het doel van het werk dat is beschreven in dit proefschrift is om het biopsychosociale perspectief van de ICF toe te passen in de intake procedure van volwassenen met (h)oorproblemen, door de CSHL te vertalen naar een intake tool die kan worden gebruikt in de klinische oto-audiologie setting: de 'ICF-based e-intake tool'. Hiertoe is de korte CSHL geoperationaliseerd in een zogenaamde 'patiënt gerapporteerde uitkomstmaat' (Engels: patient reported outcome measure; PROM). Met de intake tool kunnen volwassenen met (h)oorproblemen worden gescreend op problemen in hun functioneren en kunnen de contextuele factoren die relevant zijn voor het functioneren in kaart worden gebracht, zodat de zorgverlener en patiënt samen de zorg kunnen afstemmen op de behoeften van de patiënt. In dit proefschrift zijn de aanleiding voor en de totstandkoming van de intake tool beschreven, en is onderzocht wat er nodig is om deze intake tool in de toekomst succesvol te implementeren in de klinische oto-audiologische setting.

BEVINDINGEN

Overlap en verschillen tussen de CSHL en de intake documentatie van klinische otologie en audiologie (Hoofdstukken 2-3)

Allereerst zijn twee studies beschreven waarin de overlap en de verschillen tussen de CSHL en de huidige KNO- en AC-intake documentatie is onderzocht, in Nederland en de Verenigde Staten. De overlap tussen de CSHL-categorieën en de documentatie van de otologie en audiologie in Nederland (Hoofdstuk 2) was 89% voor de korte CSHL en 51% voor de uitgebreide CSHL. Belangrijk is te noemen dat deze percentages niet gelden per individueel patiëntdossier, maar gelden voor alle onderzochte dossiers in een KNO praktijk en AC tezamen. Verschillende CSHL-categorieën werden niet teruggevonden in de intake-documentatie, waaronder hogere mentale functies (Functies), aspecten van het maatschappelijk leven (Activiteiten en Participatie) en ondersteuning en attitudes van het gezin (sociale Externe Factoren). In de intake documentatie werd één extra ICF-categorie geïdentificeerd die momenteel geen deel uitmaakt van de CSHL: "slaapfuncties".

Ook enkele Persoonlijke Factoren, die momenteel niet zijn gespecificeerd in de ICF-classificatie, werden geïdentificeerd in de intake documentatie.

In de Amerikaanse setting (Hoofdstuk 3) werd de intake documentatie van de Mayo Clinic onderzocht. De Mayo Clinic maakt gebruik van een gemeenschappelijk medisch documentatiesysteem (een elektronisch gezondheidsdossier) dat toegankelijk is en gedeeld wordt door alle zorgverleners van de Mayo Clinic. Naast de discipline-specifieke intake documentatie (bijvoorbeeld die van KNO en audiologie), bevat dit systeem patiëntinformatie die wordt geregistreerd door alle zorgverleners. Alle intake documentatie tezamen wordt 'multidisciplinaire intake-documentatie' genoemd. De overlap tussen de ICF-categorieën uit de CSHL en uit de multidisciplinaire intake-documentatie was 100% voor de korte CSHL en 50% voor de uitgebreide CSHL. De overlap voor de discipline-specifieke intake documentatie van KNO en audiologie was 70% voor de korte CSHL. Er werd een lager percentage overlap voor ICF-categorieën uit de componenten Activiteiten en Participatie en Externe Factoren gevonden in vergelijking met de componenten Functies en Anatomische Eigenschappen. In overeenstemming met de resultaten van de studie in de Nederlandse setting (Hoofdstuk 2), werd de ICF-categorie "slaapfuncties" in de intake documentatie als extra ICF-categorie geïdentificeerd. Daarnaast werden de extra ICF-categorieën met betrekking tot bewegingsgerelateerde functies en activiteiten (bijvoorbeeld mobiliteit) en verschillende Persoonlijke Factoren geïdentificeerd.

De algehele overlap tussen het CSHL en de intake documentatie die in beide studies (Nederlandse setting en Amerikaanse setting) werd aangetoond, ondersteunen de zogenaamde 'inhoudsvaliditeit' van de CSHL. Dit houdt in: de CSHL kwam voldoende overeen met de intake documentatie. De gedeeltelijke verschillen die werden gevonden, geven aan dat de huidige intake procedures mogelijk niet alle aspecten identificeren die relevant zijn voor patiënten met (h)oorproblemen. De verschillen kunnen ook te maken hebben met de verschillende intake documentatie-methoden die gebruikt worden, afhankelijk van het type patiënt, de zorgverlener en/of de afdeling, en het zorgcentrum. Deze verschillende methoden impliceren verschillen in de geïdentificeerde functionerings-onderwerpen tijdens de intake procedure. Anderzijds duidt de identificatie van de extra categorieën er op dat de CSHL mogelijk moet worden uitgebreid in het kader van de intake-procedure en de praktijk waar deze wordt toegepast. Op basis van de bevindingen in deze beide studies werd geconcludeerd dat er behoefte is aan de ontwikkeling van een praktische, systematische intake standaard voor het verzamelen van CSHL-informatie in de klinische oto-audiologische praktijk.

Toepassing van de ICF in revalidatie voor slechthoorden- en blindheid (Hoofdstuk 4)

In de studie in Hoofdstuk 4 werd de intake-documentatie van jongvolwassenen van twee Nederlandse multidisciplinaire revalidatiecentra voor slechthoorden in kaart gebracht, door de daarin genoemde revalidatie-behoefte te linken aan de passende ICF-categorieën uit de totale ICF-classificatie. De meeste revalidatiebehoefte die werden geïdentificeerd hadden

betrekking op ICF-categorieën uit de component Activiteiten en Participatie (frequentie 67,6% van de revalidatiebehoeften). Vaak gingen de onderwerpen over onderwijs, werk, onafhankelijk een huishouden hebben, zelfredzaamheid in mobiliteit, gebruik van communicatieapparatuur en -technieken, en de psychologische gevolgen van een visuele beperking. Onderwerpen over interpersoonlijke interacties en relaties, en gemeenschaps-, sociaal- en maatschappelijk leven werden weinig gevonden in de revalidatiebehoeften, ondanks dat deze als belangrijk zijn aangetoond in de literatuur. Revalidatiebehoeften die werden geïdentificeerd in het component Externe Factoren (frequentie 21,2% van de revalidatiebehoeften) benadrukken het belang van deze component in de standaard intake procedure.

De intake-processen binnen de revalidatie centra waren niet uniform: revalidatie behoeften werden verkregen via (1) een semigestructureerde intake methode of (2) een gestructureerde intake methode middels de 'Participation Activity Inventory' (PAI)²². Vergelijkbare ICF-categorieën werden geïdentificeerd in beide intake methoden, maar de gestructureerde intake met de PAI resulteerde in 1) meer revalidatiebehoeften (gemiddeld aantal van 11 behoeften met de PAI versus 3 behoeften zonder de PAI) en 2) een betere weergave van de behoeften die in de literatuur als belangrijk worden vermeld. Daarom lijkt een gestructureerde manier om de revalidatiebehoeften te identificeren de voorkeur te hebben. Concluderend is er behoefte aan een geschikte intake-methode met domeinen die relevant zijn voor het leven en de ontwikkeling van jongvolwassenen, zodat deze kunnen worden vertaald in zinvolle revalidatie behoeften.

Naast het verschil in domein (oogheelkunde versus oto-audiologie) is de fase van zorg een ander belangrijk verschil tussen de studies in Hoofdstukken 2-3 en Hoofdstuk 4. In de eerste twee hoofdstukken gaat het om patiënten die zich voor het eerst melden met een zorgvraag, terwijl het in Hoofdstuk 4 gaat om mensen waarbij de diagnose van een ernstig functioneel probleem reeds gesteld is met een hulpvraag op het gebied van revalidatie. De lessen die op basis van Hoofdstuk 4 kunnen worden getrokken voor de ontwikkeling van de intake tool in de klinische oto-audiologische praktijk zijn: 1) het meenemen van aspecten van het functioneren in een intake tool lijkt nodig om relevante patiënt-behoeften te identificeren; 2) welke categorieën relevant zijn in de intake is afhankelijk van de setting en het doel van de intake procedure; 3) het ICF-model lijkt een geschikt kader om het functioneren van personen op een gestructureerde manier in kaart te brengen.

Operationalisatie van ICF Core Set voor Slechthorendheid in een ICF-gebaseerde e-intake tool (Hoofdstuk 5)

Hoofdstuk 5 beschrijft het ontwikkelingsproces van de ICF-based e-intake tool. Deze ontwikkeling bestond uit verschillende onderdelen: 1) de selectie van items uit een pool van items van bestaande PROMs, 2) een formeel en op consensus gebaseerd besluitvormingsproces over inclusie van items en 3) kwalitatieve inhoudsbeoordelingen met behulp van een expertonderzoek en een pilotstudie onder patiënten.

Het resultaat was een ziekte-specifieke e-intake tool bestaande uit 62 items verdeeld in 6 domeinen: (1) algemene informatie, inclusief reden voor bezoek, sociaal- demografische items en items over medische achtergrond; (2) algemene lichaamsfuncties; (3) oor- en gehoorstructuren en -functies; (4) activiteiten en participatie; (5) omgevingsfactoren; en (6) mastery en coping. Op basis van de kwalitatieve studie met experts (audiologen, KNO artsen, patiëntvertegenwoordigers en onderzoekers) werden de instructies van de items in de domeinen activiteiten en participatie en omgevingsfactoren aangepast, zodat ze expliciet gerelateerd waren aan de (h)oorproblemen van de patiënt. De pilotstudie toonde aan dat de intake tool voldoende leek te kunnen meten wat beoogd werd te meten (er werd zogenaamde inhoudsvaliditeit aangetoond). Verder beoordeelden zowel de experts als de patiënten de intake tool in het algemeen als een in potentie relevant instrument voor de intake procedure, met een logische en duidelijke structuur. Tenslotte resulteerde de pilotstudie in wijzigingen in de formulering van de items in het domein omgevingsfactoren.

Het bestaande online portaal "KLIK" werd gekozen als het middel om de intake tool digitaal te implementeren. Door het gebruik van dit portaal worden de resultaten van de patiënt na voltooiing van de vragenlijst digitaal gepresenteerd en omgezet in een "functionerings-profiel", dat zowel door de patiënt als door de behandelend zorgverlener toegankelijk is. Verder onderzoek is nodig om het beoordelen en interpreteren van het profiel van de patiënt te vergemakkelijken voor zowel de patiënt als de zorgverlener. Hieronder valt het definiëren van relevante afkapwaarden voor individuele items of domeinen en het bepalen van hoe het functionerings-profiel kan worden vertaald in behandelopties. De ontwikkeling van een beslisboom zou een mogelijk optie hiervoor kunnen zijn. Daarnaast is belangrijk om te zien hoe de zorgverlener en patiënt gezamenlijk in het beslissingsproces deelnemen, zodat de intake tool kan bijdragen aan patiëntgerichte zorg.

Implementatie van de ICF-gebaseerde e-intake tool in de klinische otologie en audiologie praktijk (Hoofdstukken 6-7)

Hoofdstukken 6 en 7 beschrijven de studies die gericht waren op het implementatieproces van de ICF-based e-intake tool. Het 'Behaviour Change Wheel' (BCW) werd hiervoor gebruikt. Het BCW helpt bij het kiezen en ontwerpen van interventies voor gedragsverandering. Dit kan verandering zijn zowel bij patiënten (hier: het invullen van de intake tool) als bij zorgverleners (hier: het gebruiken van de intake tool). Door gebruik te maken van de BCW methode wordt de interventie op een systematische manier ontwikkeld en is de interventie gebaseerd op theorie. Het BCW gaat in de kern uit van drie grootheden: Bekwaamheid ('Capability': fysieke en mentale bekwaamheid), Gelegenheid ('Opportunity': gelegenheid verschaft door sociale en fysieke omgeving) en Motivatie ('Motivation': overwogen en automatische motivatie). Samen vormen ze het COM-B model. Met behulp van het COM-B-model en het bijbehorende meer specifieke framework (bekend als het 'Theoretical Domains Framework') werden eerst belemmerende en bevorderende factoren voor het gebruik van de intake tool vanuit de perspectieven van zorgverleners en patiënten geïdentificeerd en

gecategoriseerd (Hoofdstuk 6). Focusgroepen en interviews met zorgverleners (KNO artsen, N = 14; audiologen, N = 8) en patiënten (N = 18) werden hiervoor uitgevoerd. Bij zorgverleners waren de belemmerende factoren onder meer: gebrek aan tijd om de intake tool te gebruiken (Gelegenheid) en angst om verantwoordelijk te worden gehouden voor het behandelen van de geïdentificeerde problemen, zelfs of juist als deze buiten de waargenomen expertise van de zorgverlener zouden vallen (Motivatie). Bevorderende factoren omvatten bijvoorbeeld de integratie van de intake tool in het elektronische patiëntendossier (Gelegenheid); de mogelijkheid voor de patiënt om beter voorbereid te zijn op de intake afspraak (Motivatie); en de mogelijkheid van de intake tool in het voorzien van een compleet beeld van het functioneren van de patiënt (Motivatie). Bij patiënten waren de belemmerende factoren onder meer: de angst om het persoonlijk contact met de zorgverlener te verliezen (Motivatie); en angst dat het gebruik van de intake tool een negatief effect zou kunnen hebben op gesprekken met de zorgverlener (Motivatie). Bevorderende factoren die werden geïdentificeerd door de patiënten waren het hebben van voldoende kennis over het doel en de relevantie van de intake tool (Bekwaamheid); de verwachte betere voorbereiding voor de intake afspraak (Motivatie); en de verwachting van een meer gefocuste intake procedure (Motivatie).

In het tweede deel van het onderzoek, beschreven in Hoofdstuk 7, werd een interventie ontwikkeld voor de daadwerkelijke implementatie van de ICF-based e-intake tool. De interventie werd ontwikkeld door gebruik te maken van de geïdentificeerde belemmerende en bevorderende factoren van Hoofdstuk 6 en op de beschikbare informatie over interventies uit andere implementatiestudies. Via een consensusprocedure met relevante belanghebbenden (zorgverleners, een implementatie-expert, en onderzoekers) werden zogenaamde interventie componenten geïdentificeerd. Dit zijn onderdelen van de interventie die gericht zijn op het vergemakkelijken van het gebruik van de intake tool voor zorgverleners en patiënten. Interventiecomponenten voor zorgverleners waren het aanbieden van educatief en trainingsmateriaal en workshops door opinieleiders (in dit geval Audiologie- en KNO stafleden). Het inzetten van opinieleiders zou de kennis, het bewustzijn, de vaardigheden en het vertrouwen in het eigen kunnen van zorgverleners moeten verbeteren met betrekking tot het gebruik van de intake tool. Andere interventiecomponenten omvatten aanpassingen in het ontwerp van de intake tool om het praktische gebruik van de tool te vergemakkelijken. Voor patiënten dient een beknopte informatiebrief te worden opgesteld die samen met de intake tool wordt verzonden. In deze brief is het belangrijk dat de doelen en de relevantie van de intake tool duidelijk uitgelegd zijn en dat helder is omschreven hoe de intake tool in de gesprekken met de zorgverlener wordt gebruikt.

De resultaten van Hoofdstuk 7 vormen een eerste stap naar een succesvolle implementatie van de intake tool. De volgende stap is de vertaling van deze implementatie interventie in een geïntegreerd implementatieplan.

Algemene discussie (Hoofdstuk 8)

In Hoofdstuk 8 worden de belangrijkste bevindingen uit dit proefschrift besproken en worden mogelijke gevolgen voor de klinische praktijk en voor toekomstig onderzoek geschetst. De studies in dit proefschrift laten zien dat de huidige oto-audiologie-intakestandaarden zouden moeten worden aangepast om te voldoen aan de standaard van de ICF korte CSHL. Er zijn belangrijke stappen gezet om een intake tool te creëren (**de ICF-based e-intake tool**) die patiënten met (h)oorproblematiek op een inzichtelijke en gestandaardiseerde manier in kaart brengt vanuit een biopsychosociaal perspectief. Hiermee kan het toepassen van patiëntgerichte zorg worden ondersteund, door het brede (integrale) beeld dat op een gestandaardiseerde manier wordt gepresenteerd aan de zorgverlener vooraf aan de intake afspraak. Vervolg doelstellingen zijn de optimalisatie van de inhoud en het gebruik van de intake tool in de klinische praktijk. Dit vereist continue training, interactieve sessies, evenals beschouwingen op de voortgang met en feedback van zorgverleners en patiënten. Op de lange termijn is het beschikbaar stellen van financiële en organisatorische ondersteuning vereist om het gebruik van de intake tool in de klinische praktijk mogelijk te maken. Vervolg onderzoek is nodig voor verdere optimalisatie van de intake tool en de daadwerkelijke implementatie ervan in de klinische praktijk op grote schaal. Dan kan daarna ook de effectiviteit van de implementatie interventie, en uiteindelijk de effectiviteit van de intake tool op (de kwaliteit van) de patiëntenzorg bepaald worden.

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Addendum

List of publications

About the author

Dankwoord (acknowledgements)

LIST OF PUBLICATIONS

Included in this thesis:

van Leeuwen LM, Pronk M, Merkus P, Goverts ST, Terwee CB, Kramer SE. Operationalization of the ICF Brief Core Set for Hearing Loss. An ICF-based e-intake tool in clinical otology and audiology practice. *Revision submitted*

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Alfakir R, **van Leeuwen LM**, Pronk M, Kramer SE, Zapala DA. Comparing the International Classification of Functioning, Disability, and Health Core Sets for Hearing Loss and Otorhinolaryngology/Audiology Intake Documentation at Mayo Clinic. *Ear Hear.* 2018. [Epub ahead of print] doi: 10.1097/AUD.0000000000000662.

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ABOUT THE AUTHOR

Lisette Michelle van Leeuwen was born on September 7, 1990, in Amsterdam, the Netherlands. She grew up in Maarssen. In 2008, she started her bachelor's study Health Sciences at the VU University in Amsterdam, which she completed in 2011. In 2013, Lisette received her Master's degree 'Lifestyle and Chronic Disorders', a two-year research master at the VU University. During a one-year scientific internship, she conducted two clinimetric studies at the Department of Epidemiology and Biostatistics at the VU University medical center on the validation of patient reported outcome measures in patients with Multiple Sclerosis.

At the end of 2013, Lisette started working as a research assistant at the Department of Ophthalmology at the VU University medical center. She worked on a study that focused on the inventory of a survey method to assess the participation and rehabilitation needs of young adults with visual impairments. The overall aim of the project was to improve the intake of young adults who register at rehabilitation centres, based on the structure of the International Classification of Functioning, Disability and Health (ICF).

In 2014 Lisette started working as a PhD-student at the Department of Otolaryngology-Head and Neck Surgery, section Ear & Hearing, at the VU University medical center. Building on her experience with the ICF, she investigated the possibilities for improving the intake procedure for patients with ear and hearing problems in the clinical oto-audiology practice. As part of her PhD-track, she obtained a travel grant from the EMGO+ Research Institute in 2017 for a visit to the Mayo Clinic, Jacksonville, Florida in the United States for six weeks. During this period, she worked on a patient record study comparing the intake documentation with the ICF Core Set for Hearing Loss. In addition, she participated as a member of the PhD Education Committee APH VU/VUmc and ProVUmc during the course of her PhD-track.

Currently, Lisette continues working as a postdoctoral researcher within the section Ear & Hearing at the VU University medical center.

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