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 life. 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 treatment. The challenge is to obtain this functioning profile, covering all relevant aspects, in an integral and comprehensive way.
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 otot- audiology 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 loss\textsuperscript{10}. Unlike many conductive losses, there is no medical treatment for sensorineural hearing loss\textsuperscript{6}. 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)\textsuperscript{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\textsuperscript{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 speech\textsuperscript{14}.

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 impairment\textsuperscript{15-17}. Additionally, in most cases, people with an ear disorder (such as cholesteatoma) also have a hearing impairment\textsuperscript{18}. Also non-auditory age-related health conditions may influence hearing impairment\textsuperscript{19-21}. For example, cross-sectional and longitudinal studies indicate (causal) relationships between hearing impairment and diabetes\textsuperscript{22-24}, cardiovascular conditions\textsuperscript{25}, and hypertension\textsuperscript{26}. Recent cross-sectional and longitudinal evidence also indicates causal associations between hearing impairment and cognitive decline\textsuperscript{27, 28}, with dementia occurring earlier and more often in hearing impaired individuals\textsuperscript{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 activities\textsuperscript{31-35}. 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\textsuperscript{36, 37}. Adverse effects of hearing impairment on psychological outcomes such as depressive and anxiety symptoms, and feelings of loneliness are well-established\textsuperscript{38-41}. Other common psychological consequences include embarrassment and stigmatization\textsuperscript{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 conversations\textsuperscript{44}. 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 restrictions\textsuperscript{45}. Personal factors can influence someone’s experience of disability and include factors like gender, age, educational level, and intrinsic behavioural factors\textsuperscript{19, 20, 29}. To illustrate the latter, the coping behaviour of a hearing-impaired individual can be a relevant mediating factor of psychosocial problems\textsuperscript{46}.

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\textsuperscript{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 life\textsuperscript{49-51}.

**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\textsuperscript{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 disciplines\textsuperscript{53}. 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 context\textsuperscript{54}, just as described above. The biopsychosocial model posits that biological, psychological, and environmental or social factors all influence an individual's functioning and health outcomes\textsuperscript{55}. Moreover, individual differences are critical when it comes to patients’ experience of impairment and its associated limitations and restrictions\textsuperscript{55, 56}. The individual variability in difficulties experienced secondary to hearing impairment is well documented (e.g., \textsuperscript{57}).

Led by these insights and by the research into the psychosocial factors influencing rehabilitation and patient outcomes (e.g., \textsuperscript{58, 59}), the need for this paradigm shift and change in focus has been mentioned repeatedly in audiology (e.g., \textsuperscript{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 utilized\textsuperscript{56}. 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 equitable\textsuperscript{62}. 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”\textsuperscript{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 making\textsuperscript{63}. Thereby, patient-centred care also advocates a more biopsychosocial and mutualistic approach to health care delivery\textsuperscript{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 rehabilitation\textsuperscript{66}. 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 patterns\textsuperscript{1, 67}. A common framework to guide implementation of this new policy is advocated\textsuperscript{68}. 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)\textsuperscript{69}, as depicted in Figure 1.
Chapter 1

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 herein\(^69\). 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 classification\(^70\). 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.
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

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

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 metric\textsuperscript{72}. Thereby the ICF facilitates the identification of the breadth 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)\textsuperscript{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 setting\textsuperscript{73}.

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General introduction
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 2010. The main aim was to identify ICF categories of particular relevance for adults with hearing loss for use in clinical encounters and research. The development of the CSHL carefully followed the WHO guidelines. The developmental process consisted of two phases. 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 perspective, 2) a systematic review on outcome measures used in audiological research, 3) a linking study of the identified outcome measures to the ICF classification, and, 4) patient interviews to determine the patient perspective on relevant areas of functioning, disability, and contextual factors in adults with hearing loss. During the international conference in 2013 (Phase I), hearing health professionals reached consensus on the ICF categories that should be included in the CSHL.

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 loss. 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 practice. The studies described in this thesis relate to this Phase II (see Figure 3).
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) programs. In Australia, the relevance of the Brief CSHL for providing patient- and family-centred audiology care has been outlined. In Sweden, the School of Medical Sciences at Örebro University recently started to validate and operationalize the Brief CSHL into a self-assessment instrument. 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.

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. 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 important. 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. 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 care. 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 else. 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 professionals. 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 care.

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 validity. 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 measured. It refers to the relevance, comprehensiveness, and comprehensibility of the PROM for the construct, target population, and context of use of interest. 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 implementation. 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 system. 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. For example, implementing evidence into practice requires intervention at the provider level to support health care professionals to modify established patterns of care. 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\textsuperscript{102,103}. So far, no studies have been conducted on the barriers to and enablers of the implementation of PROMs in clinical otito-audiology 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 practice\textsuperscript{104-106}. 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 tool\textsuperscript{107}. 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 process\textsuperscript{108}](image)

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.
REFERENCES


Chapter 1


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

<table>
<thead>
<tr>
<th>Body Functions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>b126</td>
<td>Temperament and personality functions</td>
</tr>
<tr>
<td>b140</td>
<td>Attention functions</td>
</tr>
<tr>
<td>b144</td>
<td>Memory functions</td>
</tr>
<tr>
<td>b152</td>
<td>Emotional functions</td>
</tr>
<tr>
<td>b210</td>
<td>Seeing functions</td>
</tr>
<tr>
<td>b230</td>
<td>Hearing functions</td>
</tr>
<tr>
<td>b240</td>
<td>Sensations associated with hearing and vestibular functions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body Structures</th>
</tr>
</thead>
<tbody>
<tr>
<td>s110</td>
</tr>
<tr>
<td>s240</td>
</tr>
<tr>
<td>s250</td>
</tr>
<tr>
<td>s260</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activities and Participation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>d115</td>
<td>Listening</td>
</tr>
<tr>
<td>d240</td>
<td>Handling stress and other psychological demands</td>
</tr>
<tr>
<td>d310</td>
<td>Communicating with - receiving - spoken messages</td>
</tr>
<tr>
<td>d350</td>
<td>Conversation</td>
</tr>
<tr>
<td>d360</td>
<td>Using communication devices and techniques</td>
</tr>
<tr>
<td>d760</td>
<td>Family relationships</td>
</tr>
</tbody>
</table>
### Activities and Participation (continued)

<table>
<thead>
<tr>
<th>Code</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>d820</td>
<td>School education</td>
<td>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.</td>
</tr>
<tr>
<td>d850</td>
<td>Remunerative employment</td>
<td>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.</td>
</tr>
<tr>
<td>d910</td>
<td>Community life</td>
<td>Engaging in all aspects of community social life, such as engaging in charitable organizations, service clubs or professional social organizations.</td>
</tr>
</tbody>
</table>

### Environmental Factors

<table>
<thead>
<tr>
<th>Code</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>e125</td>
<td>Products and technology for communication</td>
<td>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.</td>
</tr>
<tr>
<td>e250</td>
<td>Sound</td>
<td>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.</td>
</tr>
<tr>
<td>e310</td>
<td>Immediate family</td>
<td>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.</td>
</tr>
<tr>
<td>e355</td>
<td>Health professionals</td>
<td>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.</td>
</tr>
<tr>
<td>e410</td>
<td>Individual attitudes of immediate family members</td>
<td>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.</td>
</tr>
<tr>
<td>e460</td>
<td>Societal attitudes</td>
<td>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.</td>
</tr>
<tr>
<td>e580</td>
<td>Health services, systems and policies</td>
<td>Services, systems and policies for preventing and treating health problems, providing medical rehabilitation and promoting a healthy lifestyle.</td>
</tr>
</tbody>
</table>