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ORIGINAL ARTICLE

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Validation of the Brief International Classification of Functioning, Disability and Health (ICF) core set for hearing loss: an international multicentre study

Elin Karlsson[a,b,c], Elina Mäki-Torkko[a,c,d], Stephen Widén[a,b,c], Johanna Gustafsson[a,b,c], Vinaya Manchaiah[e], Faheema Mahomed-Asmail[f], De Wet Swanepoel[f], Krishna Yerraguntla[g] and Sarah Granberg[a,b,c]

[a]Faculty of Medicine and Health, Audiological Research Centre, Örebro University, Örebro, Sweden; [b]Faculty of Medicine and Health, School of Health Sciences, Örebro University, Örebro, Sweden; [c]Swedish Institute of Disability Research (SIDR), Örebro University, Örebro, Sweden; [d]Faculty of Medicine and Health, School of Medical Sciences, Örebro University, Örebro, Sweden; [e]Department of Speech and Hearing Sciences, Lamar University, Beaumont, TX, USA; [f]Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa; [g]Department of Speech and Hearing, Manipal College of Health Professions, Manipal Academy of Higher Education, Manipal, India

ABSTRACT

Objective: Hearing loss (HL) affects the everyday functioning of millions of people worldwide. The Brief International Classification of Functioning Disability and Health (ICF) core sets for HL was developed to meet the complex health care needs of adults with HL. Because the brief core set for HL has not yet been validated internationally, this study aimed to investigate its validity from an international perspective.

Design: A cross-sectional validation study based on data from structured interviews with adults with HL.

Study sample: Participants ($n = 571$) from India, South Africa, Sweden and the US were included.

Results: A six-factor solution explained 71% of the variance, focussing on issues related to *communication, the social environment, participation in society, health care services, support, relationships and emotions* ($\alpha = 0.915$). Three ICF categories demonstrated low reliability – *temperament and personality functions, seeing functions* and *school education*.

Conclusion: The Brief ICF core set for HL is valid for adults with HL internationally. However, to further increase its international validity, we recommend adding the categories *d920 recreation and leisure* and replacing *d850 school education* with the more inclusive block, *d810-d839 education*.

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Introduction

Hearing loss (HL) affects close to half a billion adults worldwide and is an important public health issue (World health organization 2020). In addition to audiological problems, HL negatively affects social, biological and psychological functions and related aspects of health (Gates and Mills 2005). Many consequences of HL make it harder to participate in conversations and social activities and may lead to reduced social engagement, increased risk of isolation, loneliness (Pronk, Deeg, and Kramer 2013; Shukla et al. 2020) and bad health (Gates and Mills 2005). Hearing loss is also associated with a decline in cognitive functions, such as working memory, which affects speech processing (Montano 2014). Considering that HL affects several parts of everyday functioning, it is of relevance to have a multidimensional and patient-centred approach to audiological rehabilitation (Montano 2014). The term functioning is multi-layered and includes functions and structures in the body of an individual, as well as the activities and participation aspects an individual can execute and be engaged in. Functioning, according to the International Classification of Functioning, Disability and Health (ICF), is always contextual, meaning that the environment where an individual works and lives plays a significant role (World Health Organization 2001). Thus, it is relevant to focus on everyday functioning to understand the complex phenomena that HL implies.

When studying human functioning, ICF is a suitable conceptual model because it provides a framework to describe how health conditions impact functioning and disability (World Health Organization 2001; Cieza and Stucki 2008). ICF is useful regardless of the degree of the functioning or the cause and duration of the disability. The focus of ICF is not on the individual but rather on the individual in a specific context (World Health Organization 2001). ICF comprises three parts: body structures and body functions, activity and participation, and contextual factors. The structure of the ICF is hierarchical, and the categories are arranged at four different levels using numerical codes when describing different aspects of health. The codes become more specific for each level (World Health Organization 2001; Cieza and Stucki 2008). The ICF categories are the same regardless of language, making the comparison of results between international studies possible (World Health Organization 2001).

CONTACT Elin Karlsson elin.karlsson@oru.se Audiological Research centre, Örebro University hospital, 701 85 Örebro, Sweden

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ICF comprises approximately 1500 codes describing many different aspects of functioning and disability (World Health Organization 2001). This makes the ICF challenging to use clinically and in research. Thus, ICF *core sets* were developed. A core set concerns a specific health condition or circumstance (e.g. HL) and comprises relevant ICF codes. There are two corresponding types of core sets, a *Comprehensive ICF core set*, which includes all ICF categories relevant to the particular health condition and a *Brief ICF core set*, which is a condensed version of the comprehensive ICF core set. When developing core sets, there is a recommended three-step methodology to apply (Selb et al. 2015). Initially, four preparatory studies explored which ICF categories may be relevant to include in the core sets. Based on the results of these studies, experts in the field of ICF and the relevant research area decide which categories should be included in the first version of the core set. Currently, there are approximately 34 different ICF core sets in approximately 25 various areas and scientific fields (Selb et al. 2015). The final steps when developing ICF core sets are validation and implementation (Selb et al. 2015).

In 2010, a project with the objective to develop international core sets for HL was initiated (ICF Research Branch 2013; Danermark et al. 2010). The aim of the ICF core sets for HL, similar to those of all ICF core sets, is to facilitate the use of ICF in clinical practice and research. The project applied the methodology outlined by the ICF Research Branch. The first step comprised four studies to create a scientific base for the core sets, focussing on the research (Granberg, Dahlstrom, et al. 2014; Granberg, Moller, et al. 2014), professional (Granberg 2015) and patient perspectives (Granberg, Pronk, et al. 2014). In all the studies, the results were linked to ICF categories (Granberg 2015). Based on these data, a consensus conference with experts including researchers, clinicians, and patients was arranged (ICF Research Branch 2013). The experts decided which ICF categories should be included in the core sets for HL, resulting in the first version of the Comprehensive ICF core set for HL comprising 117 categories and the brief consisting of 27 categories (Danermark et al. 2013).

The guidelines for the validation of ICF core sets recommends structured patient interviews using a core set and a rating scale (also called qualifiers), (Selb et al. 2015). Various methods, analyses and perspectives have been applied in previous validation studies of core sets (Cieza and Stucki 2008; Rauch, Lückenkemper, and Cieza 2012). For example, qualitative interview studies (Kirchberger et al. 2009), quantitative methods with traditional test theory, such as factor analysis and descriptive statistics (Grill and Stucki 2011), Delphi methodology (Gebhardt et al. 2010) and modern test theory, such as Rasch analysis (Alguren et al. 2011). The methods in these studies are dependent on the target population, the specific core set and the type of validity of interest.

To our best knowledge, two validation studies of ICF Core sets for HL have been identified. One of them, a pilot study by Alfakir, Holmes, and Noreen (2015) focussing on older adults ($n = 49$) and based on data from audiological patient files and from two questionnaires, demonstrated good content and construct validity where 18 of the 27 ICF categories were represented (Alfakir, Holmes, and Noreen 2015). Furthermore, explorative factor analysis (EFA) using orthogonal rotation showed a four-factor solution explaining 59.8% of the variance. In the EFA, *s240 structures of external* and *s260 structures of the inner ear* were excluded due to the low variance of the variables (Alfakir, Holmes, and Noreen 2015). In a study by van Leeuwen et al. (2017), ICF core sets for HL were used and compared with journal documentation from adult patients ($n = 176$) in otological and audiological clinics. The content was linked to ICF categories, and 23 of 27 categories were covered. In summary, the results of the two validation studies support the validity of the Brief ICF core set for HL.

However, the content and construct validity of the first version of the ICF core sets for HL have not been investigated in adults with HL from an international perspective, as previous studies only collected data from western counties. To ensure that the core sets are internationally valid and limit and clarify the impact of cultural context, it is important to implement the validation process in an internationally representative manner, similar to the preparatory studies to establish the core sets (Granberg 2015). Experts have established the ICF core sets during a consensus conference and it is now important to investigate whether the core set is valid for adults with HL. Accordingly, the present study aimed to investigate the content and construct validity of the Brief ICF core set for HL for adults with HL in an international context.

Materials and methods

Design

The current study is a cross-sectional validation study based on international data from clinical populations and coordinated from Sweden. Ethical approval was obtained in all countries – Sweden in August 2018 (2018/252), India in November 2018 (844/2018), South Africa in September 2018 (495/2018) and the US in November 2018 (IRB-FY18-387).

Recruitment procedure and study population

The study sample comprised participants from India, South Africa, Sweden and the US. The inclusion criteria were adults (aged $\geq$18 years) with mild to profound HL (as defined by the European Expert Group HEAR (HEAR 1996)). To verify HL, the latest pure tone audiogram should be a maximum of 1-year-old at the start of the study and performed in accordance with the relevant ISO standard (ISO 8253-1). Finally, the participants should be able to participate in a structured interview. Age groups (18–40, 41–60 and 60+ years) and stratified groups concerning the degree of HL (mild, moderate, and severe/profound) were defined similarly to the methodology applied in the preparatory studies in the core set for the HL project (Granberg, Pronk, et al. 2014).

Participants were recruited in accordance with the hearing health care services organisation in a specific country. In India and South Africa, participants were recruited using a convenience sampling procedure from the hearing health care clinics. In Sweden, patients from audiological clinics were selected by stratified sampling based on the latest audiogram. In the US, consecutive sampling from a clinical population was used.

Materials

The Brief ICF core set for HL (published on the ICF Research Branch webpage (ICF Research Branch 2013)) comprises 27 2nd level categories covering the most central aspects of everyday functioning in relation to HL. Because of the cultural differences concerning the category *d910 community life*, the category *d920 recreation and leisure* was added in the current validation

process. The ICF categories from the chapter of body structures – *s110 structure of brain, s240 structure of external ear, s250 structure of middle ear* and *s260 structure of inner ear* – and the activity and participation category *d115 listening* were excluded in the validation process. These categories have characteristics that are difficult for patients to assess (e.g. it is challenging for a patient to rate the structure of his/her middle ear). Therefore, the categories are difficult to evaluate in an interview session and are unlikely to be determined based on pure tone audiometry only. To ensure the reliability of the data collection process, the research group operationalised the categories of the Brief ICF core set into specific questions with a focus on hearing in an interview guide (Supplementary Annex 1). Additionally, demographic data, including age, sex, country, hearing aid usage, and level of education, were collected.

Data collection

At all study centres, hearing health care professionals recruited participants and performed the data collection. To ensure the reliability of the interviews, all the professionals participated in a one-hour online training session created by the project group before the data collection. Structured interviews were performed and, for each question in the interview guide, the participants assessed their functioning using a five-degree Likert scale and the rating options were coded from zero (no problem/impact) to four (total problem/impact). There was also an extra option, coded as 9, indicating that the question was not considered applicable to the specific individual (World Health Organization 2001).

Analyses

The responses from all countries were merged into one dataset for the analyses. The Kruskal–Wallis test (H) was used to compare the response options among the countries for continuous variables, including the degree of HL, age group and level of education. The Mann–Whitney U test (U) was used to analyse differences in categorical variables, sex and hearing aid usage. A significant level was set to $p < 0.05$. The software *Statistical Package for the Social Sciences* (SPSS) was used for all analyses.

As recommended by Grill (Grill and Stucki 2011), the frequency distribution of the rating options was examined to establish content validity. In accordance with current recommendations (Fayers 2007), response option nine, "not applicable", was managed as "missing data". Floor and ceiling effects were analysed using descriptive statistics. The limit was set to ≥20 of the lowest response option (i.e. 0) and the highest response option (i.e. 4) (Fayers 2007).

To measure the sampling adequacy and equality of variance in the samples, the Kaiser–Meyer–Olkin measure (KMO) and Bartlett's test were used. Furthermore, to determine the construct validity, Principal Component Analysis with orthogonal rotation (Varimax) were used. Eigenvalues >1 were accepted. (Fayers 2007). Power analysis for EFA showed that 220 participants were required for the study. Finally, the internal consistency (reliability) of the instrument was analysed using Cronbach's alpha (Hair 1998).

Results

Demographics

In total, 571 patients with HL participated in the study. The demographic and audiological variables are presented by country in Table 1. A higher proportion (69.7%) of participants were from high-income countries, Sweden, and the US. The distribution of men and women was approximately 50%, and most of the participants were hearing aid users. Seventy percent were older than 60 years, and only 5.4% were younger than 40 years. Of the participants, 54.8% had moderate HL, 37.1% had mild HL and 8.1% had severe or profound HL. Most of the participants (79.2%) had completed high school or higher education.

Independent variables and ICF categories

No significant differences were found in the ratings (Kruskal–Wallis test) among the four countries for any of the ICF categories. This matter was also true concerning the variable "age". For the variable "level of education", differences were found in the category *b126 temperament and personality* functions such that people with higher education had higher ratings ($H = 13.2$; $p < 0.01$). For the variable "degree of HL", differences

Table 1. Demographics of the participants with hearing loss (HL) defined according to HEAR (1999).

Country	Sweden *n* (%)	India *n* (%)	South Africa *n* (%)	USA *n* (%)	All countries *n* (%)
Participants	219 (38.4)	94 (16.5)	79 (13.8)	179 (31.3)	571 (100.0)
Sex					
Women	110 (50.2)	55 (58.5)	42 (53.2)	85 (47.5)	280 (49.0)
Men	109 (49.5)	39 (41.5)	37 (46.8)	94 (52.5)	291(51.0)
Age groups (years)					
18–40	11 (5.0)	7 (7.4)	7 (8.9)*	6 (3.4)	31 (5.4)*
41–60	47 (21.5)	38 (40.4)	10 (12.7)*	41 (22.9)	136 (23.8)*
≥61	161 (73.5)	49 (52.1)	61 (77.2)*	132 (73.7)	403 (70.6)*
Degree of HL					
Mild	82 (37.4)	41 (43.6)	28 (35.4)	61 (34.1)	212 (37.1)
Moderate	107 (48.9)	49 (52.1)	47 (59.5)	110 (61.5)	313 (54.8)
Severe/profound	30 (13.7)	4 (4.3)	4 (5.1)	8 (4.5)	46 (8.1)
Hearing aid users	201 (91.8)	16 (17.0)	45 (57.0)	163 (91.1)	425 (74.4)
Level of education					
No education	0	1 (1.1)	2 (2.5)	0	3 (0.5)
Primary school	8 (3.7)	14 (14.9)	4 (5.1)	0	26 (4.6)
Secondary school	37 (16.9)	38 (40.4)	9 (11.4)	6 (3.4)	90 (15.8)
High school	91 (41.6)	33 (35.1)	29 (36.7)	77 (43.0)	230 (40.3)
University	83 (37.9)	8 (8.5)	35 (44.3)	96 (53.6)	222 (38.9)

*$n = 78$ in South Africa and 570 in total because of 1 missing case.

were found in the categories *b126 temperament and personality functions* ($H = 12.1$; $p < 0.01$), *d240 handling stress and other psychological demands* ($H = 8.8$; $p < 0.05$), *d910 community life* ($H = 7.0$; $p < 0.05$), *e310 immediate family* ($H = 18.9$; $p < 0.01$), *e410 individual attitudes of immediate family members* ($H = 11.7$; $p < 0.05$) and *e460 societal attitudes* ($H = 14.7$; $p < 0.01$). For category *d850 remunerative employment*, the Mann–Whitney *U* test showed significant differences for the variable "sex" ($U = -2.2$; $p < 0.05$). Finally, for the variable "hearing aid usage", significant differences were demonstrated in the categories *b126 temperament and personality functions* ($U = -2.0$; $p < 0.05$) and *b230 hearing functions* ($U = -2.1$; $p < 0.05$).

Content validity

For all categories, all the response options were used (Table 2). Seven categories revealed that many participants used the response option 9 (not applicable): *b210 seeing functions*, *b240 sensations associated with hearing and vestibular functions*, *d820 school education*, *d850 remunerative employment*, *d910 community life*, *d920 recreation and leisure* and *e125 products and technology for communication*. Some categories demonstrated that many participants used the response option 0 (no problem), mostly the categories *d760 family relationships* followed by *e460 societal attitudes*, *d240 handling stress and other psychological demands, b152 emotional functions* and *d920 recreation and leisure* (Table 2).

Floor and ceiling effects

Ceiling effects (≥20% of response option 4) were noted for the categories *e125 products and technology for communication* and *e355 health professionals*. Floor effects (≥20% of the response option 0) were identified for 14 categories – *b126 temperament and personality functions*, *b140 attention functions*, *b144 memory functions*, *b152 emotional functions*, *b210 seeing functions*, *b230 hearing functions*, *d240 handling stress and other psychological demands*, *d360 using communication devices and techniques*, *d760 family relationships*, *d910 community life*, *d920 recreation and leisure*, *e310 immediate family*, *e410 individual attitudes of immediate family members* and *e460 societal attitudes*.

Construct validity

The KMO test of sampling adequacy (0.859) and Bartlett's test of sphericity were significant ($p \leq 0.001$). EFA resulted in a six-factor solution (21 categories) including all categories except *d820 school education* (Table 3). The six factors were given the following themes: factor 1 "Communication in everyday activities" (9 categories), factor 2 "Social environment" (3 categories), factor 3 "Participation in society" (3 categories), factor 4 "Effects of health care services in everyday life" (2 categories), factor 5 "Supportive functions for communication" (3 categories) and factor 6 "Emotions and relations" (2 categories).

The frequency of participants choosing option 9 for the category *d820 school education* was too high, and this category was not included in EFA. All the factors demonstrated eigenvalues ≥1 and explained altogether 71.1 percent of the variance. There was an unequal distribution of the number of participants in each country; in some of the countries, there were too few participants per category to perform factor analysis. Therefore, EFA was calculated for all four countries together ($n = 571$).

Internal consistency

Cronbach's alpha (α) was 0.915 for the total Brief ICF core set for HL (21 ICF categories included) and was found to be satisfactory for factors 1 and 2. However, for factors 3 to 6, it was low (Table 3). The distribution of Cronbach's alpha for each country and factor is presented in Table 4.

Table 2. Frequency analysis: distribution of the response options in percent: 0 = no problem/impact, 1 = mild problem/impact, 2 = moderate problem/impact, 3 = severe problem/impact and 4 = total problem/impact, 9 = not applicable or missing data.

		Response option					
Code	ICF category	0	1	2	3	4	9
b126	Temperament and personality functions	30.4	19.4	22.2	17.1	8.4	2.4
b140	Attentions functions	24.1	28.1	25.7	16.9	4.3	0.7
b144	Memory functions	32.9	38.5	19.9	6.6	1.5	0.5
b152	Emotional functions	38.3	28.0	23.6	6.8	1.7	1.6
b210	Seeing functions	50.2	24.9	12.6	4.0	0.7	7.7
b230	Hearing functions	22.7	22.6	26.0	18.5	9.4	0.7
b240	Sensations associated with hearing and vestibular functions	9.6	22.6	21.3	8.6	3.1	34.8
d240	Handling stress and other psychological demands	38.8	25.5	25.3	7.5	1.9	0.9
d310	Communicating with – receiving – spoken messages	5.4	21.3	37.8	29.5	5.6	0.3
d350	Conversation	8.6	29.3	38.3	19.2	4.2	0.5
d360	Using communication devices and techniques	20.3	27.2	36.8	13.7	1.9	0.2
d760	Family relationships	64.9	18.5	11.4	4.4	0.7	0.2
d820	School education	2.1	0.7	0.9	0.5	0.2	95.6
d850	Remunerative employment	11.0	12.6	10.1	4.9	0.7	60.7
d910	Community life	29.9	15.4	19.6	10.7	5.2	19.2
d920	Recreation and leisure	38.3	18.2	22.7	12.2	3.0	5.6
e125	Products and technology for communication	3.8	4.9	16.7	24.3	23.1	27.1
e250	Sound	14.2	19.9	28.5	23.8	12.6	1.0
e310	Immediate family	25.0	12.2	16.6	26.0	19.6	0.5
e355	Health professionals	11.5	11.9	24.3	28.3	20.3	3.7
e410	Individual attitudes of immediate family members	37.6	15.4	17.8	18.9	8.4	1.9
e460	Societal attitudes	43.4	19.1	18.2	14.7	2.8	1.9
e580	Health services, systems and policies	15.5	21	27.6	20.5	10.8	4.5

Table 3. Results of exploratory factor analysis with orthogonal rotation (Varimax).

Code	ICF category	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Total	Item- total correlation to total correlation
d350	Conversation	0.779							0.769
b240	Sensations associated with hearing and vestibular functions	0.767							0.631
d310	Communicating with – receiving – spoken messages	0.767							0.778
e250	Sound	0.746							0.762
b230	Hearing functions	0.738							0.633
d360	Using communication devices and techniques	0.719							0.663
b126	Temperament and personality functions	0.500							0.642
d850	Remunerative employment	0.485							0.565
b140	Attentions functions	0.485							0.756
e310	Immediate family		0.818						0.279
e410	Individual attitudes of immediate family members		0.733						0.505
e460	Societal attitudes		0.581						0.584
d910	Community life			0.745					0.613
d920	Recreation and leisure			0.738					0.615
e125	Products and technology for communication			0.583					0.317
e355	Health professionals				0.796				0.229
e580	Health services, systems and policies				0.705				0.584
b210	Seeing functions					0.774			0.176
b144	Memory functions					0.675			0.586
d240	Handling stress and other psychological demands					0.458			0.720
d760	Family relationships						0.772		0.364
b152	Emotional functions						0.451		0.645
Eigenvalue		8.866	2.2020	1.440	1.242	1.044	1.022		
Explained variance %		40.299	9.182	6.547	5.644	4.747	4.646	71.065	
Kaiser–Meyer–Olkin measure of sampling adequacy								0.859	
Cronbach's alpha									
Cronbach's alpha		0.873	0.713	0.590	0.516	0.537	0.539	0.915	

The results of internal reliability are presented using Cronbach's alpha and item-total correlation.

Table 4. Cronbach's alpha (α) for all factors presented for each country.

		Country			
Factor	Total	India ($n = 94$)	South Africa ($n = 79$)	Sweden ($n = 219$)	USA ($n = 179$)
1	0.873	0.870	0.919	0.871	0.842
2	0.713	0.785	0.704	0.707	0.688
3	0.590	0.679	0.592	0.528	0.584
4	0.516	0.571	0.368	0.566	0.498
5	0.537	0.240	0.661	0.507	0.600
6	0.539	0.617	0.648	0.389	0.596

Discussion

The aim of the present study was to investigate the psychometric properties of the Brief ICF core set for HL in an international context. This is the first study to evaluate the Brief ICF core set in an international context, including a large sample of participants from both low- and high-income countries. It is also the first study to operationalise the ICF categories into questions to increase reliability. The results demonstrated that the ICF categories included in the Brief ICF core set are relevant for persons with HL regardless of the degree of HL, age, sex, and cultural context. However, although the results show an overall adequate content validity from an international perspective, three ICF categories, *b126 temperament and personality functions*, *b210 seeing*, and *d820 school education*, pose validity problems.

The variance of the independent variables, such as sex, age, and level of education, was large and representative of the population. An even distribution of the variables sex, hearing aid use, and degree of HL was observed. All three eligible age groups were represented, although most of the participants (70%) were in the oldest group. However, this group corresponds to the age distribution of adult HL internationally (World health organization 2020; Gates and Mills 2005; World Health Organization 2001).

Differences between groups in relation to ICF categories

The lack of differences in ratings among the countries indicates that it is possible to co-analyse the data obtained in various cultural settings. The same conclusion was made for the variable "age". These results indicate that the Brief ICF core set for HL is valid for adults with HL of all ages, from different cultural contexts, and in both low-, middle- and high-income countries.

The variable "degree of HL" comprised three groups, and significant differences were found among six categories. The results showed that individuals with moderate HL have higher ratings that those with mild and severe/profound HL for the categories *b126 temperament and personality functions*, *d240 handling stress and other psychological demands*, *d910 community life*, *e310 immediate family*, *e410 individual attitudes of immediate family members* and *e460 societal attitudes*. This result indicates that temperament and personality, support and attitudes from family members and society, are considered important to those with moderate HL. This group was also the largest of the HL groups, and only a few of the participants had severe or profound HL, likely affecting the result. The variable "degree of HL" was, for most of the ICF categories, not a determinant of how individuals with HL experience everyday life. The experiences of disability in everyday life are complex and depend on interactions among several aspects in an individual's life (World Health Organization 2001). This view agrees with the ICF bio-psycho-social model (World Health Organization 2001). The results also demonstrate the importance of a multidimensional and broad approach within the field of hearing rehabilitation and audiological research. The degree of HL constitutes only a small part of experienced everyday functioning for individuals with HL and has also been demonstrated in previous validation studies of the Brief ICF core set for HL (Alfakir, Holmes, and Noreen 2015).

Concerning the variable "sex", differences were only found for one category, *d850 remunerative employment*. Men reported more problems associated with working life than women. This

result could partly be because men typically work in noisier environments (Campos-Serna et al. 2013). Importantly, the difference between sexes is significant but weak and the difference could be explained by the large sample size in the current study. For all other ICF categories, no significant differences were found, indicating good content validity for both sexes overall.

For the variable "level of education", differences were found in category *b126 temperament and personality functions*. This category was difficult to understand for many participants. This result might indicate that some participants are more aware of how personality and temperament impact, for example, coping strategies and hearing rehabilitation than others. In some core sets, such as the ICF core set for stroke (Kirchberger et al. 2007), 3rd level categories (more specific categories), such as *b1266 confidence*, were used. These are concrete and may be easier to interpret in relation to everyday life. This finding is important when developing new instruments based on the core set because it will be important to specify this question to increase the relevance and understandability of the item.

For the variable "hearing aid usage", significant differences were found for *b126 temperament and personality functions*. Finally, significant differences were found for the variable "hearing aid usage" in the category *b230 hearing functions*. The results showed fewer problems with hearing functions such as sound localisation and sound discrimination when using hearing aids, a finding that agrees with a previous study finding (Williger and Lang 2015).

Content validity

In this study, the frequency distribution of the responses was investigated as recommended for the validation of the ICF core sets (Grill and Stucki 2011). All the response options (0–5) were used by the respondents, indicating a satisfying number of response options (Fayers 2007). Five of the categories (*b240, d850, d910, d920* and *e125*) revealed a higher number of the response option 9 (not applicable). The category *d910 community life* could likely be explained by cultural differences in society. In some countries, such as Sweden, the expression "community life" is less used. This finding supports the recommendation of adding the category *d920 recreation and leisure* to the Brief ICF core set for HL to obtain a more sufficient cultural validity (Beaton et al. 2000). The three categories *b240 sensations associated with hearing and vestibular functions, d850 remunerative employment*, *e125 products* and *technology for communication* also demonstrated a high frequency of the response option 9. Not everyone was employed *(d850)* because 70% of the participants were retired. Almost 35% did not have tinnitus or balance problems (*b240*), and 27.1% did not use hearing aids or other assistive devices for hearing *(e125)*. In total, 95.6% of the respondents used response option 9 regarding *d820 school education*. This category is problematic because of the definition given in the ICF: "*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…*". (World Health Organization 2001, 164). An increasing number of children in the world complete primary and secondary school (UNESCO 2020); consequently, only a few adults need to participate in primary and secondary school (UNESCO 2020). This could explain why the ICF category about adults participating in primary and secondary school was irrelevant. When the ICF core set was developed, all the categories included were 2nd-level categories as recommended, including *d820 school education* (Granberg 2015). The results from the present study lead to the recommendation to exchange the category *d820 school education* to the higher-level block *d810–d839* (*education*) in the ICF (World Health Organization 2001) to make the category more valid and relevant for adults.

In the present study, the categories from the component body structures were excluded due to the nature of the categories. These categories have been shown to be valid in the previous study by Van Leeuwen et al. using another methodology (van Leeuwen et al. 2017). In the same study, all the categories except *b144 memory functions* were valid. This result differs from that in the present study. In the current study, the operationalisation of the categories into specific questions increased the reliability and understandability of each category. For example, category *b144* focussed on working memory, a clarification that aimed to make it easier for the participants to understand the question and increase the reliability. Even with this specification, the participants considered the question broad and somewhat difficult to understand. This finding might indicate that the category has a low understandability, which could decrease the reliability when used as a question in a self-assessment instrument.

The Brief ICF core set for HL covers items on a wide range of issues and has the advantage of including categories from the environmental component to represent multidimensional aspects of HL, which seem to be missing in existing hearing disability questionnaires (Manchaiah et al. 2019).

Floor and ceiling effects

The results demonstrated ceiling and floor effects with a lack of specificity in some of the categories. For example, the floor effect of the category *b126 Temperament and personality function*, which, as already stated, many participants found it difficult to answer, indicates low reliability of the specific category. The ICF categories are expected to be broad and inclusive. The broad categories serve well when a core set is used as a checklist for discussions with patients but does not work as well when used as an assessment instrument.

Construct validity

The KMO of sampling adequacy was 0.859, which is high, indicating that the variance is caused by underlying factors. Bartlett's test was significant, indicating that the variables are unrelated. Combined, the KMO and Bartlett's tests advocated the possibility to use EFA (Hair 1998). The result of EFA revealed a six-factor solution. The category *d820 school education* was excluded due to too few cases ($n = 25$). The EFA model explained 71% of the variance, indicating adequate construct validity (Hair 1998). Considering the ICF categories, no differences were found between the countries, indicating sample homogeneity. Some of the factors were not entirely homogeneous, indicating that the validity is not ideal. On the other hand, the aim of the core set was to include as many important aspects of everyday functioning as possible; therefore, it comprises many different aspects that impact the lack of homogeneity. This finding is important to consider when using the core set as a foundation to develop new instruments.

The first factor included nine categories (Table 3). Factor 1 was interpreted as **"Communication in everyday activities"** because it focuses on how individuals with HL experience disability and performance in everyday life related to communication (World Health Organization 2001) and explains most of the

variance in the Brief ICF core set for HL. Communication in activities is an important aspect of everyday life for individuals with HL. Factor 1 contained categories from all ICF components, body functions, activity and participation and environmental factors. This result strengthens the importance of the bio-psycho-social approach to HL management (Montano 2014) to address everyday aspects of communication.

Factor 2 included categories that can be associated with **"Social environment"** and comprise the three environmental categories (Table 3) that involve human support and attitudes in the environment (World Health Organization 2001). Factor 2 was the second largest factor showing the importance of the social environment for individuals with HL. The results support WHO's motivation to add environmental factors with a focus on human attitudes at different levels of ICF (World Health Organization 2001). One consequence of HL often mentioned and highly connected to societal attitudes, is social isolation (Gates and Mills 2005). One example found within factor 2, and connected to this matter, is that positive attitudes and support from significant others can facilitate everyday activities and increase the feeling of being included in society and the social environment.

Factor 3 included the three categories (*d910 community life,* d*920 recreation and leisure and e125 products and technology for communication).* The factor can be interpreted as **"Participation in society"** and included societal activities but also how hearing aids and other assistive devices may facilitate these activities.

The categories in factor 4 were interpreted as **"Effects of health care services in everyday life"** and included two environmental categories (*e355 health professionals* and *e580 health services, systems, policies*). Both categories concern the importance of support from hearing healthcare services (World Health Organization 2001). The study by Williger et al. (Williger and Lang 2015) supports this matter with the finding that good hearing rehabilitation increases the quality of everyday life.

The three categories in factor 5 were interpreted as **"Supportive functions for communication"** – *b210 seeing function, b144 memory functions* and *d240 handling stress, and other psychological demands* – and support hearing and communication. This finding agrees with that in a previous study concluding that cognitive functions such as working memory and stress affect hearing processing (Rönnberg, Holmer, and Rudner 2019). Vision (*b210 seeing function*) is a complementary sense to hear; therefore, it is important in relation to hearing functions. All three categories were unified in that they are all human resources, which interact with the hearing functions and can facilitate or make it harder in spoken communication. Factor 5 was more heterogeneous than the first four factors.

The final factor included the categories *d760 family relations* and *b152 emotional functions*, which both concern **"Emotions and relationships"** related to HL (World Health Organization 2001). This factor included two categories highly connected to family relations and how HL impacts family relationships. Studies have shown the importance of involving family members and significant others in the hearing rehabilitation process (Manchaiah et al. 2012). This involvement improves the outcome of hearing rehabilitation regarding both – knowledge about HL and the use of communication strategies (Moser, Luxenberger, and Freidl 2017).

In the study by Alfakir et al., a four-factor solution was demonstrated. This result differs from that in the current study (Alfakir, Holmes, and Noreen 2015). The differences are primarily connected to the number of factors and content of factors 3–6. Methodological differences compared with the present study were that only 18 of the 27 categories were included in that study and the selection of participants was different (older adults and a smaller sample) (Alfakir, Holmes, and Noreen 2015). Despite the differences, similarities were found between the studies, particularly in factor 2. Factor 2 includes, in both studies, categories concerning attitudes and support from immediate family members and society. It is difficult to make conclusions by comparing studies that apply different methodologies. Overall, the results seem to support the construct validity, but more studies with a focus on construct validity are needed.

Internal consistency

Cronbach's alpha was 0.915 in the present study, demonstrating good internal consistency and homogeneity (Fayers 2007) and indicating that all categories measured the same underlying phenomena (World Health Organization 2001; Hair 1998). This result agrees with the evidence-based development process of the core set (Granberg 2015). Factors 1 and 2 showed alpha values above 0.7, demonstrating good internal consistency. Factors 3, 4, 5 and 6 had alpha values above 0.5 but less than 0.6, indicating lower reliability than the two first factors (Fayers 2007). The item-total correlation is acceptable (>0.6) for most of the categories and indicates that the categories fit in the model. For the category *b210 seeing functions*, the item-total correlation was ≤ 0.2, which is below the recommended level. The participants found some of the question less relevant and had difficulties to understand the connection to hearing. This could be an indication that the item is irrelevant and should be removed or clarified. However, the low number of participants with visual impairment, together with the participants with a visual impairment rating their corrected vision as good, influences the low internal consistency. Additionally, all the response options were used, indicating that the questions should be kept in the core set because they were found to be important by people with HL.

When analysing the internal consistency for each country, the first two factors showed sufficient reliability for all countries. Factor 3 had a lower, but still acceptable, alpha value for all countries. For factor 4, the reliability was lower for South Africa than for the other countries ($\alpha = 0.368$). This factor includes the categories concerning hearing health care. In South Africa, access to hearing health care can differ depending on whether the care is public or private. For factor 5, the reliability was lower for India than for the other countries. This factor includes the category *b210 seeing functions*, which, as discussed previously, has been somewhat problematic. The question about the vision was difficult to comprehend in a hearing context and was, therefore, rated as "no problem" or "not applicable" in many instances. For factor 6, the reliability was lower for Sweden than for the other countries. Factor 6 includes the categories of family relationships and emotional functions, and participants from Sweden generally did not report HL significantly affecting their family relationships. These differences might be connected to how people live in different countries. The low number of people in Sweden experiencing that HL affects family relationships could be due to Sweden being an individualistic and secular country (Berggren and Trägårdh 2006). Another speculation might be that, in Sweden, the social stigma attached to HL could be lower than that in many other countries, resulting in increased understanding from the human surroundings, including the family.

Strengths and limitations of the study

A limitation in the present study was the difference in sampling methods. However, the sample was large and the demographics showed an adequate variance for all the independent variables, indicating that the sample was representative of individuals with HL. The category *d920 recreation and leisure* were added to the core set as a cultural adaption for countries where *d910 community life* is a less familiar term – for example, in Sweden. The results confirm this hypothesis, and a suggestion is to add the category *d920 recreation and leisure* to the core set. To improve the reliability in this study, the categories were operationalised into questions, which might have strengthened the reliability that has been problematic in previous studies (Alguren et al. 2011). Additionally, this may make the study more difficult to replicate. Another strength supporting the reliability is that all professionals collecting data in this study participated in internal education. The choice of data collection method, using structured interviews, was challenging in terms of time required but ensured high-quality responses with almost no missing data.

Conclusions

The results of this study confirm the validity of the Brief ICF core set for HL. The content of the Brief ICF core set seems to be relevant for adults with HL internationally and supports the content validity in both low- and high-income countries. The construct of the Brief ICF core set has a six-factor structure comprising areas important for everyday life for people with HL: communication in everyday activities, social environment, participation in society, effects of health care services in everyday life, supportive functions for communication, and emotions and relationships. The results confirm that HL is complex, and a multidimensional approach to hearing rehabilitation is necessary to cover central aspects of everyday life and that the Brief ICF core set supports this approach. To improve the core set further and increase the validity internationally, our suggestion is to add the category *d920 recreation and leisure* and broaden the category *d820 school education*, as well as use the higher-level block *d810-d839 (education)*. Additionally, to increase the precision and understandability when developing new instruments based on the Brief ICF core set for HL, additional information for the categories *b210 seeing functions* and *b126 temperament and personality functions* would be useful.

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Declaration of interest

No potential conflict of interest was reported by the author(s).

ORCID

Vinaya Manchaiah http://orcid.org/0000-0002-1254-8407
De Wet Swanepoel http://orcid.org/0000-0001-8313-1636
Krishna Yerraguntla http://orcid.org/0000-0003-3185-5901

References

Alfakir, R., A. E. Holmes, and F. Noreen. 2015. "Functional Performance in Older Adults with Hearing Loss: Application of the International Classification of Functioning Brief Core Set for Hearing Loss: A Pilot Study." *International Journal of Audiology* 54 (9): 579–586. doi:10.3109/14992027.2015.1023903.

Alguren, B., C. Bostan, L. Christensson, B. Fridlund, and A. Cieza. 2011. "A Multidisciplinary Cross-Cultural Measurement of Functioning after Stroke: Rasch Analysis of the Brief ICF Core Set for Stroke." *Topics in Stroke Rehabilitation* 18 (1): 573–586. doi:10.1310/tsr18s01-573.

Beaton, D. E., C. Bombardier, F. Guillemin, and F. Bosi. 2000. "Guidelines for the Process of Cross-Cultural Adaption of Self-Report Measures." *Spine* 25 (24): 3186–3191. doi:10.1097/00007632-200012150-00014.

Berggren, H., and L. Trägårdh. 2006. "Är Svenskan Människa?" *Gemenskap Och Oberoende i Det Moderna Sverige [is the Swede Human? Solidarity and Independence in Modern Sweden]*. Stockholm, Sweden: Norstedts.

Campos-Serna, J., E. Ronda-Pérez, L. Artazcoz, E. B. Moen, and F. G. Benavides. 2013. "Gender Inequalities in Occupational Health Related to the Unequal Distribution of Working and Employment Conditions: A Systematic Review." *International Journal for Equity in Health* 12 (57): 57–18. doi:10.1186/1475-9276-12-57.

Cieza, A., and G. Stucki. 2008. "The International Classification of Functioning Disability and Health: Its Development Process and Content Validity." *European Journal of Physical and Rehabilitation Medicine* 44 (3): 303–313.

Danermark, B., A. Cieza, J.-P. Gangé, F. Gimigliano, S. Granberg, L. Hickson, S. E. Kramer, et al. 2010. "International Classification of Functioning, Disability, and Health Core Sets for Hearing Loss: A Discussion Paper and Invitation." *International Journal of Audiology* 49 (4): 256–262. doi:10.3109/14992020903410110.

Danermark, B., S. Granberg, S. E. Kramer, M. Selb, and C. Moller. 2013. "The Creation of a Comprehensive and a Brief Core Set for Hearing Loss Using the International Classification of Functioning, Disability and Health." *American Journal of Audiology* 22 (2): 323–328. doi:10.1044/1059-0889(2013/12-0052).

Fayers, P. M. M. D. 2007. *Quality of Life: The Assessment, Analysis, and Interpretation of Patient-Reported Outcomes*. 2nd ed. Chichester, UK: Wiley.

Gates, G. A., and J. H. Mills. 2005. "Presbycusis." *Lancet* 366 (9491): 1111–1120. doi:10.1016/S0140-6736(05)67423-5.

Gebhardt, C., I. Kirchberger, G. Stucki, and A. Cieza. 2010. "Validation of the Comprehensive ICF Core Set for Rheumatoid Arthritis: The Perspective of Physicians." *Journal of Rehabilitation Medicine* 42 (8): 780–788. doi:10.2340/16501977-0599.

Granberg, S. 2015. *Function and Disability in Adults with Hearing Loss: Preparatory Studies in the ICF Core Sets for Hearing Loss Project*. Örebro, Sweden: Örebro universitet.

Granberg, S., J. Dahlstrom, C. Moller, K. Kahari, and B. Danermark. 2014. "The ICF Core Sets for Hearing loss-researcher perspective. Part I: Systematic Review of Outcome Measures Identified in Audiological Research." *International Journal of Audiology* 53 (2): 65–76. doi:10.3109/14992027.2013.851799.

Granberg, S., K. Moller, A. Skagerstrand, C. Moller, and B. Danermark. 2014. "The ICF Core Sets for Hearing Loss: researcher Perspective, Part II: Linking Outcome Measures to the International Classification of Functioning, Disability and Health (ICF)." *International Journal of Audiology* 53 (2): 77–87. doi:10.3109/14992027.2013.858279.

Granberg, S., M. Pronk, D. W. Swanepoel, S. E. Kramer, H. Hagsten, J. Hjaldahl, C. Möller, et al. 2014. "The ICF Core Sets for Hearing Loss Project: functioning and Disability from the Patient Perspective." *International Journal of Audiology* 53 (11): 777–786. doi:10.3109/14992027.2014.938370.

Grill, E., and G. Stucki. 2011. "Criteria for Validating Comprehensive ICF Core Sets and Developing Brief ICF Core Set Versions." *Journal of Rehabilitation Medicine* 43 (2): 87–91. doi:10.2340/16501977-0616.

Hair, J. F. 1998. *Multivariate Data Analysis*. Englewood Cliffs, NJ: Prentice Hall.

HEAR. 1996. *Terminology, Definitions and Hearing Assessments*. European Concerted Action: PL950353. European Concerted Action Project on Genetic Hearing Impairment.

ICF Research Branch. 2013. "ICF Core Set for Hearing Loss." https://www.icf-research-branch.org/icf-core-sets-projects2/other-health-conditions/icf-core-set-for-hearing-loss

Kirchberger, I., A. Glaessel, G. Stucki, and A. Cieza. 2007. "Validation of the Comprehensive International Classification of Functioning, Disability and Health Core Set for Rheumatoid Arthritis: The Perspective of

Physical Therapists." *Physical Therapy* 87 (4): 368–384. doi:10.2522/ptj.20050237.

Kirchberger, I., M. Coenen, F. X. Hierl, C. Dieterle, J. Seissler, G. Stucki, A. Cieza, et al. 2009. "Validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for Diabetes Mellitus from the Patient Perspective Using Focus Groups." *Diabetic Medicine: A Journal of the British Diabetic Association* 26 (7): 700–707. doi:10.1111/j.1464-5491.2009.02762.x.

Manchaiah, V. K. C., D. Stephens, F. Zhao, and S. E. Kramer. 2012. "The Role of Communication Partners in the Audiological Enablement/Rehabilitation of a Person with Hearing Impairment: An Overview." *Audiological Medicine* 10 (1): 21–30. doi:10.3109/1651386X.2012.655914.

Manchaiah, V., S. Granberg, V. Grover, G. H. Saunders, and H. D. Ann. 2019. "Content Validity and Readability of Patient-Reported Questionnaire Instruments of Hearing Disability." *International Journal of Audiology* 58 (9): 565–575. doi:10.1080/14992027.2019.1602738.

Montano, J. J. 2014. "Defining Audiologic Rehabilitation." In *Adult Audiologic Rehabilitation*, edited by J. J. Montano, and J. B. Spitzer, 23–34. San Diego, CA: Plural Pub.

Moser, S., W. Luxenberger, and W. Freidl. 2017. "The Influence of Social Support and Coping on Quality of Life among Elderly with Age-Related Hearing Loss." *American Journal of Audiology* 26 (2): 170–179. doi:10.1044/2017_AJA-16-0083.

Pronk, M., D. J. Deeg, and S. E. Kramer. 2013. "Hearing Status in Older Persons: A Significant Determinant of Depression and Loneliness? Results from the Longitudinal Aging Study Amsterdam." *American Journal of Audiology* 22 (2): 316–320. doi:10.1044/1059-0889(2013/12-0069).

Rauch, A., M. Lückenkemper, and A. Cieza. 2012. "Introduction to the International Classification of Functioning, Disability and Health." In *ICF Core Sets for Clinical Practice*, edited by J. Bickenbach, A. Cieza, A. Rauch, and G. Stucki, 4–13. Nottwil, Switzerland: ICF.

Rönnberg, J., E. Holmer, and M. Rudner. 2019. "Cognitive Hearing Science and Ease of Language Understanding." *International Journal of Audiology* 58 (5): 247–261. doi:10.1080/14992027.2018.1551631.

Selb, M., R. Escorpizo, N. Kostanjsek, G. Stucki, B. Üstün, and A. Cieza. 2015. "A Guide on How to Develop an International Classification of Functioning, Disability and Health Core Set." *European Journal of Physical and Rehabilitation Medicine* 51 (1): 105–117.

Shukla, A., M. Harper, E. Pedersen, A. Goman, J. J. Suen, C. Price, J. Applebaum, et al. 2020. "Hearing Loss, Loneliness, and Social Isolation: A Systematic Review." Otolaryngology-Head and Neck Surgery 162 (5): 622–633. doi:10.1177/0194599820910377.

UNESCO. 2020. Inclusion and education. Received from: https://en.unesco.org/gem-report/report/2020/inclusion.

van Leeuwen, L. M., P. Merkus, M. Pronk, M. van der Torn, M. Maré, S. T. Goverts, S. E. Kramer, et al. 2017. "Overlap and Nonoverlap between the ICF Core Sets for Hearing Loss and Otology and Audiology Intake Documentation." *Ear and Hearing* 38 (1): 103–116. doi:10.1097/AUD.0000000000000358.

Williger, B., and F. R. Lang. 2015. "Hearing Aid Use in Everyday Life: Managing Contextual Variability." *Gerontology* 61 (2): 158–165. doi:10.1159/000366062.

World Health Organization. 2001. *International Classification of Functioning, Disability and Health (ICF)*. Geneva, Switzerland: WHO.

World health organization. 2020. "Deafness and Hearing Loss." March 1. http://www.who.int/mediacentre/factsheets/fs300/en/