

# ICF Core Set for head and neck cancer: do the categories discriminate among clinically relevant subgroups of patients?

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The multidisciplinary assessment of functioning in patients with head and neck cancer (HNC) according to the *ICF Core Set for Head and Neck Cancer* (ICF-HNC) was developed in an international and multi-disciplinary approach. The ICF-HNC is an application of the ICF that was adopted by the World Health Organization. The objective of this study was to test whether categories of the ICF-HNC can discriminate among clinically relevant differences in patients. This was a cross-sectional multicentre study in which 267 patients with HNC from 11 different countries participated. All categories were tested within a cumulative logit model to identify which ICF-categories show differences in tumour location, staging, treatment modalities and time since treatment. In the comprehensive ICF-HNC, 84 of the tested categories (76%) reflect differences in at least one of the given parameters. In the Brief ICF Core Sets for HNC (ICF-HNC), all 19 categories (100%) reflect differences. Two categories (social relationships and economic self-sufficiency) showed significant differences among all tested criteria. Most categories of the ICF-HNC are sensitive to clinically relevant differences in the study population. Especially, the ICF component 'activities and participation' holds categories with high discriminative ability for clinically relevant differences. These aspects should be carefully included into rehabilitation plans for HNC.

Die fachübergreifende Bewertung der Funktionsfähigkeit bei Patienten mit Kopf-Hals-Tumoren (HNC) laut *ICF Core Set für Kopf-Hals-Tumore* (ICF-HNC) wurde per internationalem und fachübergreifendem Ansatz entwickelt. Es handelt sich dabei um eine Anwendung der internationalen Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF), die von der WHO verabschiedet wurde. Mit der vorliegenden Studie sollte untersucht werden, ob mit den Kategorien des ICF-HNC klinisch relevante Unterschiede bei Patienten festgestellt können. Dazu wurde eine multizentrische Studie mit 267 Patienten mit HNC in 11 verschiedenen Ländern durchgeführt. Alle Kategorien wurden im Rahmen eines kumulativen Logit-Modells getestet, um zu ermitteln, welche ICF-Kategorien Unterschiede bzgl. der Position des Tumors, des Staging, der Behandlungsmodalitäten und der Zeit seit der Behandlung aufweisen. In der ausführlichen ICF-HNC-Fassung wiesen 84 der getesteten Kategorien (76%) Unterschiede bei mindestens einem der Parameter auf. In der Kurzfassung von ICF-HNC wiesen alle 19 Kategorien (100%) Unterschiede auf. Zwei Kategorien (soziale Beziehungen und wirtschaftliche Unabhängigkeit)

unterscheiden unter allen getesteten Kriterien. Die meisten ICF-HNC-Kategorien reagieren sensibel auf klinisch relevante Unterschiede in der Studienpopulation. Die ICF-Komponente 'Aktivitäten und Teilhabe' insbesondere umfasst Kategorien mit starker Differenzierungsfähigkeit für klinisch relevante Unterschiede. Diese Aspekte sollten bei den Reha-Plänen für HNC-Patienten sorgfältig einbezogen werden.

Las categorías básicas de la CIF para el cáncer de cabeza y cuello (CIF-CCC) sirven de base para la valoración multidisciplinar del funcionamiento en pacientes con cáncer de cabeza y cuello (CCC). Estas categorías de la Clasificación Internacional del Funcionamiento, la Discapacidad y la Salud (CIF), han sido aprobadas por la OMS y tienen un enfoque internacional y multidisciplinario. El objetivo de nuestro estudio fue determinar si las categorías de la CIF-CCC permiten establecer diferencias clínicas importantes entre diversos pacientes con CCC. Se trata de un estudio multicentro de 267 pacientes con CCC, realizado en 11 países de manera simultánea. Todas las categorías de la CIF-CCC fueron evaluadas mediante un modelo acumulativo de regresión logística, para identificar cuáles de ellas permiten establecer diferencias concernientes a la localización del tumor, la estadificación de éste, el tratamiento utilizado y el tiempo transcurrido desde el comienzo del tratamiento. En la versión completa de la CIF-CCC, 84 (76%) de las categorías estudiadas permitieron establecer diferencias relativas a al menos uno de los parámetros evaluados. En la versión corta de la CIF-CCC, las 19 (100%) categorías estudiadas permitieron establecer dichas diferencias. Dos categorías (las relaciones sociales y la autosuficiencia económica) permitieron establecer diferencias concernientes a todos los parámetros estudiados. La mayoría de las categorías de la ICF-HNC son sensibles a las diferencias clínicas particulares de la población estudiada. Es importante destacar que el componente 'actividades y participación' de la ICF contiene categorías muy sensibles a las diferencias clínicas específicas estudiadas. Se recomienda incluir estas categorías, siempre que sea oportuno, en los planes de rehabilitación de pacientes con CCC.

Les paramètres ICF-HNC (*ICF Core Sets for Head and Neck Cancer*) établissent une structure d'évaluation multidisciplinaire du fonctionnement chez les patients souffrant d'un cancer de la tête et du cou et ont été développés selon une approche internationale et pluridisciplinaire. Ils constituent une application de la classification ICF (International Classification of

**Functioning, Disability and Health) qui a été adoptée par l'OMS. Cette étude avait pour objet de tester si les catégories de l'ICF-HNC sont susceptibles de permettre la distinction entre les différences cliniques pertinentes chez les patients. Une étude multicentrique portant sur 267 patients souffrant d'un cancer de la tête et du cou a été organisée dans 11 pays différents. Toutes les catégories ont été testées dans un modèle-logit cumulatif pour identifier les catégories ICF qui présentent des différences au niveau de la localisation de la tumeur, de son avancement, des modalités de traitement et du temps écoulé depuis le traitement. Dans l'ICF-HNC complet, 84 des catégories testées (76%) reflètent des différences pour au moins un des paramètres donnés. Dans l'ICF-HNC abrégé, les 19 catégories (100%) reflètent des différences. Deux catégories (relations sociales et autosuffisance économique) permettent la discrimination entre tous les critères testés. La plupart des catégories de l'ICF-HNC sont sensibles aux différences cliniques pertinentes dans la population étudiée. En particulier, la composante ICF activités et participation comprend des catégories qui**

## Introduction

Head and neck cancer (HNC) is not only a life-threatening disease but can also result in burdensome disability. Although cancer follow-up aims to detect and treat tumour recurrences and targets 'survival', rehabilitation aims to decrease disability and covers a wide variety of aspects including pain management, swallowing training and speech practices as well as resuming everyday tasks in life, family relationships and the financial and working situation of the patient (Bjordal *et al.*, 1999; Weymuller *et al.*, 2000; Funk *et al.*, 2004; Vartanian *et al.*, 2004; Eades *et al.*, 2009). Some correlation has been proven between functioning and long-term survival, with functioning being predictive for both observed and disease-specific survival (Goldstein *et al.*, 2007; Grignon *et al.*, 2007). On account of this duality between fighting the tumour and achieving adequate functioning in life, setting up comprehensive care plans is especially demanding in cancer and involves extra efforts of multiprofessional cooperation. Still, HNC is known to be one of the cancers with the highest demand on multiprofessional consulting and cooperation (Licitra *et al.*, 2006; Westin and Stalfors, 2008).

To optimize interventions aimed at maintaining, functioning and minimizing disability, a proper understanding of the patients' functioning and health status is needed (Stucki *et al.*, 2002b). The World Health Organization International Classification of Functioning, Disability and Health (ICF) not only provides a useful framework to classify the components of health and consequences of disease but also provides a unified language to facilitate multiprofessional understanding and cooperation (World Health Organization, 2001). According to the ICF, human

**présentent une haute capacité discriminative entre les différences cliniques pertinentes. Ces aspects devront être soigneusement inclus dans les plans de rééducation des patients souffrant de cancer de la tête et du cou. *International Journal of Rehabilitation Research* 34:121–130 © 2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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functioning and disability concerns body functions and structures, the performance of activities and participation in life situations. All of these are also modified by individual contextual factors such as environmental and personal factors (World Health Organization, 2001).

To facilitate the implementation of the ICF into clinical practice, ICF Core Sets are developed as a disease-specific selection of ICF categories out of the entire ICF (Stucki *et al.*, 2002a). This has been carried out for 16 health conditions, so far (Ruof *et al.*, 2001; Brach *et al.*, 2004; Geyh *et al.*, 2004; Stucki *et al.*, 2004; Cieza *et al.*, 2004a, 2004b; Boldt *et al.*, 2005). The ICF Core Sets for HNC (ICF-HNC) include a Comprehensive Core Set with 112 different categories and a Brief ICF Core Set with 19 categories (Tschiesner *et al.*, 2007, 2010). The Comprehensive ICF-HNC covers the typical spectrum of problems in functioning and is needed for multiprofessional comprehensive assessment in cancer follow-up and rehabilitation. The Brief ICF-HNC is a selection out of the Comprehensive Core Set, and aims to include only the most important categories across countries and health professionals. It defines categories as minimal standards to assess and report on functioning and health in any patient with HNC.

Both the Comprehensive and the Brief ICF-HNC were developed in a formal decision-making and consensus process, integrating evidence from preparatory studies (Tschiesner *et al.*, 2009a, 2009b, 2009c). Finally, the ICF-HNC has been created by a multidisciplinary team at a consensus conference, including physicians, psychologists, physical therapists, nurses and social worker (Tschiesner *et al.*, 2010). The ICF-HNC defines which

ICF categories are needed to describe functioning from a multidisciplinary team's perspective.

However, HNC is a very inhomogeneous entity with well described differences in survival and functional outcomes according to patient-related, tumour-related and treatment-related subgroups. Different tumour locations in the upper aerodigestive tract have influence on both survival rates and functional outcome (Laenger and Laenger, 2004; Alicikus *et al.*, 2009). Larger tumour stages at the point of diagnosis are related not only to decreased survival but also worse functional outcome and specific rehabilitation needs later on (Laenger and Laenger, 2004; Borggreven *et al.*, 2007; Weymuller and Bhama, 2007; Alicikus *et al.*, 2009). Not only can a variety of treatment regimens be applied for HNC (including tumour resections and possibly reconstruction) but also different protocols of radiochemotherapy and chemotherapy. Each of these can be used alone or in combination with other treatment modalities and influences patient functioning differently (Abdel-Wahab *et al.*, 2005; El-Deiry *et al.*, 2005; Scrimger *et al.*, 2007; Infante-Cossio *et al.*, 2009; van der Molen *et al.*, 2009).

A new tool to structure functional outcome and rehabilitation needs in HNC has to prove that it is able to differentiate among the relevant clinical subgroups included in HNC. Especially those aspects of functioning that differentiate among a variety of subgroups should be identified and included into rehabilitations plans for HNC.

Therefore, the objective of this study was to explore which categories of the ICF-HNC are able to discriminate functional outcome in patients with different tumour locations, tumour staging and treatment approaches over time.

## Materials and methods

This is a cross-sectional multicentre study that includes patients with HNC. The study protocol and consent forms were approved by the Ethics Committee of the University of Munich, Germany and by the Ethics Committee of each of the study centres. The inclusion criteria for patients were:

- (1) Cancer of at least one of the following cancer locations: oral region (International Classification of Disease-10: C01–C04), salivary glands (C07–C08), pharynx (C09–C13) and larynx (C32);
- (2) Patients who completed their cancer treatment. This included that all necessary surgery was performed and/or the complete radiation dose (mostly 60–70 Gy), and/or all chemotherapy cycles were administered;
- (3) Patients who were at least 18 years old;
- (4) Patients who had signed a written informed consent.

## Measures

Health professionals completed an English case record form with all 112 ICF categories of the Comprehensive

ICF-HNC. The Brief ICF-HNC includes 19 categories. They are selected from the Comprehensive Core Set at the second, more general level of the ICF classification.

The level of impairment or restriction was assessed according to the ICF Qualifier Scale in ordinal structure: 0 = no impairment/restriction (0–4%), 1 = mild impairment/restriction (5–24%), 2 = moderate impairment/restriction (25–49%), 3 = severe impairment/restriction (50–95%), 4 = complete impairment/restriction (96–100%).

According to ICF, the qualifiers for the domain of activities and participation can be used to describe 'performance' or 'capacity'. In this study, the participants were asked to describe what the patient actually does in this environment. This means that the qualifiers assessed the performance. For the environmental factor component, each ICF-category can be either a facilitator or a barrier to the patient. A comparable 0–4 scale was applied, but to denote that an ICF-category is a facilitator, a positive sign was added (e.g. +2), and to denote the ICF category as a barrier, a negative sign was added (e.g. –2). The option 'not specified' was applied if the available information was not sufficient to quantify the severity of the problem, and the option 'not applicable' was applied if the ICF category was not applicable to the patient. For impairments not caused by HNC but by a comorbidity, the option C (comorbidity) was chosen.

## Data collection

Patient selection was made with consecutive sampling. The interviews were conducted by health professionals trained in the ICF. Training involved familiarization with the World Health Organization model of functioning and disability and with the ICF. Detailed and precise guidelines to conduct these structured interviews were provided by the coordinating centre in Munich, Germany.

## Data preparation

In the ICF Core Set-based questionnaire, the response option 'not applicable' was set to a missing value and the response option 'problem caused by a comorbidity but not by HNC' was set to zero to capture only those problems related to HNC. The response option 'not specified' was set to '1' as an approximation of existing difficulties that could not be specified further.

## Analysis

Descriptive statistics were used to characterize the study population.

A regression model was used to identify ICF categories that capture significant differences among clinically relevant subgroups. These subgroups were defined as follows:

- (1) Tumour location: the groups 'oral or pharyngeal cancer' and 'laryngeal cancer' were differentiated.
- (2) Tumour staging: carried out according to the American joint committee of cancer guidelines. For this study,

- early cancer in 'stages I and II' was combined and compared with more advanced cancer in 'stages III and IV'.
- (3) Treatment modality: referred to therapeutic treatment modalities only and did not include any solemnly diagnostic procedures. Three different approaches were differentiated: 'Operation alone', 'Radio(chemo)therapy alone' and 'Operation and Radio(chemo)therapy in combination'.
  - (4) Time since cancer treatment: the time period between the end of cancer treatment and the time of the interview. Three time periods are differentiated ' $< 1$ ', '1-5' and ' $> 5$  years'.

Within the regression model, the ICF categories were used as dependent variables, whereas the variables on tumour location, tumour staging, treatment modality and time since treatment formed the independent variables.

The variable 'time since cancer treatment' is related to the idea of 'survival'. Survival, in turn, is related to the tumour stage. To test whether 'tumour staging' and 'time since cancer treatment' are independent and, therefore, can be used separately as independent variables in the regression models, a  $\chi^2$  test was carried out. A  $\chi^2$  test is a statistical procedure to test the frequency distribution in the observed sample.

ICF categories are not measured on a metric scale but on an ordinal scale. Therefore, a cumulative logit model (Tschiesner *et al.*, 2009c; Tutz, 2000) was used. It is an extension to a logit model, allowing for more than two categories for the dependent variable and taking the ordering of the dependent variable into account. For each ICF category, the subgroups of patients who have experienced significantly higher problems were identified.

This was an exploratory data analysis and, therefore, it was not adjusted for multiple testing. A level of significance of 0.05 was applied for each test. For significant relationships among subgroups, the subgroup of patients showing more problems in the ICF category was identified based on the sign of the regression coefficient.

Each ICF category with significant differences in at least one of the four independent variables was considered to be sensitive to differences in an aspect that is relevant for HNC. Therefore, all categories with significant differences were confirmed for the ICF Core Set on the assumptions of these analyses.

All analyses were carried out using SAS 9.1 and PROC LOGISTIC (SAS Institute Inc., Cary, North Carolina, USA) with logit link function and reference coding of predictor variables.

## Results

Between February 2008 and January 2009, 267 patients were interviewed at 14 different study centres in

11 countries. The sociodemographic and tumour-specific characteristics of the study population are presented in Table 1.

The  $\chi^2$  test on independence of 'tumour staging' and 'time since cancer treatment' was carried out on 221 (of 267) cases, for which information on both variables was available. The  $\chi^2$  test was not significant ( $P = 0.67$ ). Therefore, 'tumour staging' and 'time since cancer treatment' can be used separately as independent variables in the regression models.

Eighty-four categories (76%) of the Comprehensive ICF-HNC showed differences in the study population, whereas 27 categories (24%) did not. All categories that showed differences are presented in Tables 2-5.

Two ICF categories showed significant differences in all four independent variables: informal social relationships d750 and economic self-sufficiency d870. Seven categories showed differences in three variables. Four ICF categories in 'activities and participation' (eating d550, drinking d560, acquiring, keeping and terminating a job d845 and recreation

**Table 1 Patient demographics and tumour characteristics**

	Number of patients (n)	Percent (%)
All patients	267	100
Mean age [years (range)]	59 years (21-88 years)	
Sex		
Male	214	80
Female	53	20
Tumour locations		
Oral cavity and oropharynx	138	52
Hypopharynx	20	7
Larynx	92	34
Salivary glands	12	5
Not specified	5	2
Staging (American Joint Committee of Cancer, 2002)		
Stages I and II	94	35
Stage III and IV	135	51
Not available	38	14
Cancer treatment		
Operation alone	109	41
Operation and radio(chemo)therapy	114	43
Radio(chemo)therapy alone	30	11
Not available	14	5
Time since treatment [years, (range)]	2.6 years (0.08-23.9 years)	
Up to 1 year	86	32
Between 1 and 5 years	131	49
More than 5 years	38	14
Not available	12	4
WHO World region		
Americas (Brazil, USA)	24	9
European region <sup>a</sup>	178	72
South East Asia (India, Korea)	43	16
Western Pacific (Australia)	7	3
Department, health professional background		
Head and neck surgery	97	36
Maxillofacial reconstructive	68	25
Medical oncology	33	12
Psychology, psychiatry	31	12
Speech-swallowing therapy	28	10
Physiotherapy	10	4

Classification according to United Nations: [www.un.org/depts/dhl/worldregions.htm](http://www.un.org/depts/dhl/worldregions.htm).

WHO, World Health Organization.

<sup>a</sup>Study centres in Germany, Greece, Israel, Poland, Spain, United Kingdom.

**Table 2 Results of the cumulative logit model on ICF categories in the comprehensive ICF Core Sets for HNC in body functions**

ICF-category	Title	Group of patients with more problems according to parameter estimate from the cumulative logit models			
		Location	Staging	Treatment modality	Time since treatment
b130	Energy and drive functions	Oral/oropharyngeal			
b152	Emotional functions	Oral/oropharyngeal			In the first year
b1801	Body image	Oral/oropharyngeal			
b230	Hearing functions			Radio(chemo)therapy only compared with operation only	
b255	Smell function	Laryngeal			After 5 years
b280	Sensation of pain	Oral/oropharyngeal			
b310	Voice functions	Laryngeal			
b320	Articulation functions				In the first year
b435	Immunological system functions	Oral/oropharyngeal			
b440	Respiration functions	Laryngeal			
b5100	Sucking	Oral/oropharyngeal			In the first year
b5101	Biting	Oral/oropharyngeal			
b5102	Chewing	Oral/oropharyngeal			In the first year
b5103	Manipulation of food in the mouth	Oral/oropharyngeal		Operation only compared with operation and radio(chemo)therapy	In the first year
b5104	Salivation	Oral/oropharyngeal			
b51050	Oral swallowing	Oral/oropharyngeal			In the first year
b51051	Pharyngeal swallowing			Radio(chemo)therapy only compared with operation and radio(chemo)therapy	
b51052	Oesophageal swallowing			Radio(chemo)therapy only compared with operation and radio(chemo)therapy	
b530	Weight maintenance functions	Oral/oropharyngeal		Radio(chemo)therapy only compared with operation and radio(chemo)therapy	
b535	Sensations associated with the digestive system	Oral/oropharyngeal			
b555	Endocrine gland functions	Laryngeal			
b730	Muscle power functions		Stages III and IV		
b810	Protective functions of the skin	Oral/oropharyngeal			
b820	Repair functions of the skin				In the first year

Survival: 'in first year': more problems in patients in first year compared with patients within 1–5 years and more than 5 years 'after 5 years': more problems in patients after 5 years compared with patients in the first year and within 1–5 years.

HNC, head and neck cancer; ICF, International Classification of Functioning, Disability and Health.

and leisure d920), two categories in body structures (teeth s3200 and trachea s4300) and one category in body functions (manipulating food in the mouth b5103).

All 19 categories of the Brief ICF Core set for HNC were able to detect differences in the study population. The results are presented in Table 6.

The analysis also shows information as to where the main problems are for patients with HNC. The main findings are summarized as follows.

In terms of tumour location, 39 categories show significantly higher values of impairment for patients with oral or pharyngeal cancer. According to this study, this tumour location is the single most important factor for disability in patients with HNC.

Another relevant aspect for patient disability is the time since therapy: in 25 categories, the first year after cancer treatment is related to significantly more disability and a higher need for rehabilitation than any later point of time. Only very few categories result in a higher degree of disability as time goes by and are most problematic after 5 years. They include anatomic changes of the larynx, s3400–s340, the trachea s4300 and the oesophagus

s520. These difficulties are also related to laryngeal cancer.

As expected, larger tumour stages are related to more problems in functioning than the smaller stages. In 27 categories, tumour stages American Joint Committee of Cancer III–IV were related to more problems. Most of these categories are related to the ICF component of Activities and Participation (18 of the 27 categories).

Comparison of treatment options identified many specific side effects known for each of the different treatment options. In addition to this, patients after nonoperative treatment seem to have more difficulties with informal social or intimate, intimate relationships, d750 and d770, and economic self-sufficiency d870. In the ICF component of environmental factors financial *assets* e165, communication services e535, general social support e575 and e590 labour and employment services become more relevant to patients who underwent radio(chemo)therapy.

## Discussion

One of the great challenges towards care in HNC is to establish effective cooperation among health professionals. Most of the time cancer follow-up is incumbent

**Table 3 Results of the cumulative logit model on ICF categories in the comprehensive ICF Core Sets for HNC in body structures**

ICF-category	Title	Group of patients with more problems according to parameter estimate from the cumulative logit models			
		Location	Staging	Treatment modality	Time since treatment
s3200	Teeth	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	After 5 years
s32020	Hard palate	Oral/oropharyngeal			
s32021	Soft palate	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	In the first year
s3203	Tongue	Oral/oropharyngeal			
s3204	Structure of lips	Oral/oropharyngeal			
s3208	Structure of mouth, other specified	Oral/oropharyngeal			
s3209	Structure of mouth, unspecified	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	After 5 years
s3300	Nasal pharynx				
s3301	Oral pharynx	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	After 5 years
s3308	Structure of pharynx, other specified	Laryngeal			
s3400	Vocal folds	Laryngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only; operation and radio(chemo)therapy compared with operation only	After 5 years
s3408	Structure of larynx, other than vocal fold	Laryngeal			
s3409	Structure of larynx, unspecified	Laryngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only; operation and radio(chemo)therapy compared with operation only	After 5 years
s410	Structure of cardiovascular system	Oral/oropharyngeal			
s420	Structure of immune system	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only; operation and radio(chemo)therapy compared with operation only	After 5 years
s4300	Trachea	Laryngeal			
s510	Structure of salivary glands	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only; operation and radio(chemo)therapy compared with operation only	After 5 years
s520	Structure of oesophagus	Laryngeal			
s7101	Bones of face	Laryngeal	Stages III and VI	Operation only compared with radio(chemo)therapy only	In the first year
s7104	Muscles of head and neck region				
s7105	Ligaments and fasciae of head and neck region	Laryngeal	Stages III and VI	Operation only compared with radio(chemo)therapy only	In the first year
s7108	Structure of head and neck region, other specified (e.g. supralarynx and hypolarynx)				
s7109	Structure of head and neck region, unspecified	Oral/oropharyngeal	Stages III and VI	Operation only compared with radio(chemo)therapy only	In the first year
s720	Structure of shoulder region	Oral/oropharyngeal			
s7301	Structure of forearm	Oral/oropharyngeal	Stages III and VI	Operation only compared with radio(chemo)therapy only	In the first year
s750	Structure of lower extremity	Oral/oropharyngeal			
s810	Structure of areas of skin	Oral/oropharyngeal	Stages III and VI	Operation only compared with radio(chemo)therapy only	In the first year

Survival: 'in first year': more problems in patients in first year compared with patients within 1–5 years and more than 5 years 'after 5 years': more problems in patients after 5 years compared with patients in the first year and within 1–5 years.

HNC, head and neck cancer; ICF, International Classification of Functioning, Disability and Health.

on physicians who carried out the cancer treatment, for example, cancer surgeons, radiotherapists or medical oncologists. In parallel, rehabilitation of functioning and disability is accountable to rehabilitation specialists, psychologists, physiotherapists, speech and swallowing therapists, social worker etc. A multiprofessional approach is a great blessing if it is designed in a real team (Licitra *et al.*, 2006; Westin and Stafors, 2008). However, if outer structures (e.g. greater physical separation of departments and colleagues) prevent close cooperation, there is a danger of loss of information between patient referrals and, eventually, suboptimal patient care.

The ICF has been developed to facilitate multiprofessional cooperation even if this outer structure is not perfect. Consequently, the ICF-HNC has been designed to structure the rehabilitation process in a multidisciplinary team in HNC.

Now, this study has tested the clinical applicability of the ICF-HNC with statistical methodology. Its aim was to apply relevant tumour-related and treatment-related characteristics for cancer follow-up and use them to test the ICF-HNC, a new tool to structure rehabilitation plans.

In this study, we showed that the majority of categories, that is, 84 of the 112 categories (75%) of the Comprehensive ICF-HNC and 19 of the 19 categories (100%) of the Brief ICF-HNC, proved their ability to discriminate among different subgroups of patients.

A comparison of findings from this analysis with frequent findings in present research of other study groups and with other methodologies can serve to support the conclusions on rehabilitation plans in HNC.

With regard to differences in tumour location, oral and pharyngeal cancers seem to affect different and in

**Table 4 Results of the cumulative logit model on ICF categories in the comprehensive ICF Core Sets for HNC in activities and participation**

ICF-category	Title	Group of patients with more problems according to parameter estimate from the cumulative logit models			
		Location	Staging	Treatment modality	Time since treatment
d230	Carrying out daily routine				In the first year
d240	Handling stress and other psychological demands		Stages III and VI		
d330	Speaking	Laryngeal			
d360	Using communication devices and techniques	Laryngeal	Stages III and VI		
d430	Lifting and carrying objects		Stages III and VI		
d510	Washing oneself		Stages III and VI		In the first year
d520	Caring for body parts		Stages III and VI		In the first year
d550	Eating	Oral/oropharyngeal	Stages III and VI		In the first year
d560	Drinking	Oral/oropharyngeal	Stages III and VI		In the first year
d570	Looking after one's health		Stages III and VI		In the first year
d640	Doing housework	Oral/oropharyngeal	Stages III and VI		
d710	Basic interpersonal interactions		Stages III and VI		
d720	Complex interpersonal interactions		Stages III and VI		
d750	Informal social relationships	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	In the first year
d760	Family relationships		Stages III and VI		In the first year
d770	Intimate relationships			Radio(chemo)therapy only compared with operation only	
d845	Acquiring, keeping and terminating a job	Oral/oropharyngeal	Stages III and VI		In the first year
d870	Economic self-sufficiency	Oral/oropharyngeal	Stages III and VI	Radio(chemo)therapy only compared with operation only	In the first year
d910	Community life	Oral/oropharyngeal	Stages III and VI		
d920	Recreation and leisure	Oral/oropharyngeal	Stages III and VI		In the first year
d930	Religion and spirituality	Oral/oropharyngeal	Stages III and VI		

Survival: 'in first year': more problems in patients in first year compared with patients within 1–5 years and more than 5 years.  
HNC, head and neck cancer; ICF, International Classification of Functioning, Disability and Health.

**Table 5 Results of the cumulative logit model on ICF categories in the comprehensive ICF Core Sets for HNC in environmental factors**

ICF-category	Title	Group of patients with more problems according to parameter estimate from the cumulative logit models			
		Location	Staging	Treatment modality	Time since treatment
e1100	Food	Oral/oropharyngeal			In the first year
e165	Assets			Radio(chemo)therapy only compared with operation only	In the first year
e310	Immediate family				In the first year
e340	Personal care providers and personal assistants		Stages III and VI		
e355	Health professionals	Laryngeal			
e460	Societal attitudes	Laryngeal	Stages III and VI		
e535	Communication services, systems and policies	Laryngeal		Radio(chemo)therapy only compared with operation only	
e555	Associations and organizational services, systems and policies	Laryngeal			
e575	General social support services, systems and policies			Radio(chemo)therapy only compared with operation only	
e580	Health services, systems and policies	Laryngeal			
e585	Education and training services, systems and policies		Stages III and VI		
e590	Labour and employment, services, systems and policies			Radio(chemo)therapy only compared with operation only	In the first year

Survival: 'in first year': more problems in patients in first year compared with patients within 1–5 years and more than 5 years.  
HNC, head and neck cancer; ICF, International Classification of Functioning, Disability and Health.

summary even more aspects of functioning than laryngeal cancers (Mowry *et al.*, 2006; Rogers *et al.*, 2006). Therefore, Chandu *et al.* (2006) advocate site-specific assessment of functioning HNC.

Another relevant factor for patient disability is the time after treatment. The highest need for rehabilitation is within the first year after cancer treatment (Abdel-Wahab *et al.*, 2005; Scrimger *et al.*, 2007). For cancer follow-up,

**Table 6 Results on the categories of the Brief ICF Core Set for HNC**

ICF code	Title	Confirmed based on the analyses
Body functions ( <i>n</i> =6)		
b130	Energy and drive functions	Yes
b152	Emotional functions	Yes
b280	Sensation of pain	Yes
b310	Voice functions	Yes
b440	Respiration functions	Yes
b510	Ingestion functions	Yes
Body structures ( <i>n</i> =4)		
s320	Structure of mouth	Yes
s330	Structure of pharynx	Yes
s340	Structure of larynx	Yes
s710	Structure of head and neck region	Yes
Activities and participation ( <i>n</i> =6)		
d230	Carrying out daily routine	Yes
d330	Speaking	Yes
d550	Eating	Yes
d560	Drinking	Yes
d760	Family relationships	Yes
d870	Economic self sufficiency	Yes
Environmental factors ( <i>n</i> =3)		
e110	Products or substances for personal consumption (i.e. food, drugs)	Yes for food, not for drugs
e310	Immediate family	Yes
e355	Health professionals	Yes

HNC, head and neck cancer; ICF, International Classification of Functioning, Disability and Health.

the patients are frequently seen on a 6–8 week basis within the first year (Neuchrist and Formanek, 2008). However, several aspects around destroyed structures of the larynx, the trachea and the loss of smell (which is related to laryngectomy and permanent tracheotomy) become more problematic in laryngeal cancer after 5 years. Even then, regular follow-up meetings for cancer either tend to stop or, at least, to decrease towards annual meetings after 5 years. Health professionals involved in the rehabilitation of patients with HNC need to give special attention to these rather late effects.

Differences in functioning were related to different treatment options on a very general level. Owing to inconsistent level of detail in the description of cancer treatment among study centres (e.g. extension of the operation, outcome of histological margin control, mode of operative reconstruction, application mode of radiotherapy, substance for chemotherapy), statistical analyses could only be carried out on a general level of operation(s) alone versus radio(chemo)therapy alone or compared with a combination of the two. Most differences are related to well-known side effects of treatment. Extensive resections in the mouth or neck dissections in the operative group are related to more difficulties in the manipulation of food in the mouth and ligaments and fascia in the head and neck region. This group demands special care from physiotherapists and speech-swallowing therapists. In the nonoperative group, side effects of chemotherapy relate to more problems with hearing functions and side effects of radiotherapy relate to diminished saliva production and mucositis. These frequent side effects are well described for these treatment options

and are already integrated into patient care plan. New to our knowledge is the finding that patients with radiochemotherapy alone compared with patients who underwent an operation alone show more difficulties with informal and intimate relationships, economic self sufficiency, financial assets, labour and employment services and general social support. Present research has identified increased financial difficulties and discontinuation of employment in patients with HNC in general (Chaukar *et al.*, 2009). Further analyses are needed to understand the impact of different treatment modalities on environmental factors in patients' lives (Nachreiner *et al.*, 2007; Tiedtke *et al.*, 2009). For these patients, it might be helpful to involve psychologists and social workers early.

With regard to the applied statistical analyses, it is important to mention that explorative data analyses were preferred because of the relatively small sample size and to generate hypotheses with regard to the relationships between the HNC subgroups and the ICF categories. Thus, many different statistical tests have been carried out. This procedure may have led to significant effects only by chance. Therefore, the results of this study have to be interpreted as what they are, namely, explorative and not confirmative.

When planning the statistical analyses we had to decide between *t*-tests and cumulative logit models. The cumulative logit model was eventually selected to take into account the ordinal response level of the categories ranging from 0 to 4. This study was based on separate bivariate analyses comparing ICF categories with (i) tumour location, (ii) staging, (iii) treatment options or (iv) time since treatment. Alternatively, we could have included all four variables into one multivariate model. However, we chose the bivariate analyses because they have the advantage that the results can be compared more easily with other studies that analyse different aspects. For example, in another study the same tumour locations and staging but different treatment types might be analysed. In the case of bivariate analyses, at least information on tumour locations and staging can be compared with the other study, although this would not be possible if all information had been included into one model.

The data collection process on which this analysis relies has some limitations. Altogether, 14 study centres with 267 patients were involved in the data collection process. However, 178 patients (72%) are from different study centres in what the World Health Organization calls the European region. At some study centres outside Europe, there are low numbers of patients included in the study because of procedures that sometimes take a long time for local ethics approval. Further evaluations with the ICF-HNC should, therefore, include more study centres outside Europe, and time for data collection should be extended and planned *a priori*.

This content validation of the ICF-HNC confirms categories from the perspective of specificity for HNC and its discrimination power among subgroups within the large entity of HNC. However, for thorough validation of the Core Set on other aspects of cultural differences, allocation of categories to the area of different health professionals (Becker *et al.*, 2009) and the differentiation of categories into predictive categories for overall functioning are subject to further analyses.

## Conclusion

Most categories of the ICF Core Sets for HNC have proven to be specific for functioning in patients with HNC. Although some restrictions of the current version of the ICF Core Sets have been identified in this study, the majority of categories is relevant to HNC and should be assessed for thorough patient follow-up.

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