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# Development of the International Classification of Functioning, Disability and Health as a brief head and neck cancer patient questionnaire

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*Abstract.* WHO has adopted the International Classification of Functioning, Disability and Health (ICF) to assess functioning and disability. A Brief ICF Core Set for head and neck cancer comprises 19 items. This study developed a patient self-completed questionnaire from the items of the brief core set (BCSQ-H&N), compared the BCSQ-H&N questionnaire with the University of Washington v.4 (UW-QOLv4) and compared the BCSQ-H&N results with a clinician-rated evaluation. UW-QOL v4 and BCSQ-H&N were sent to 751 disease-free head and neck cancer patients in April 2008. 376 patients responded to the questionnaire and 25 were interviewed. The percentage reporting significant problems in BCSQ-H&N items ranged between 11% and 43%. The type of problem varied with tumour site. Patients with smaller tumours and patients without radiotherapy reported better outcomes. The BCSQ-H&N correlated well with appropriate items in the UW-QOLv4 especially for functional outcome. There were systematic differences between observer-rated scores and patient self-completed questionnaire responses. Patients suggested additional items for inclusion, namely taste, jaw opening, articulation function, structure of shoulder region, loss of function at the free flap donor site, and intimate relationships. Further validation is required but BCSQ-H&N shows promise as an outcome measure for global use.

Keywords: health-related quality of life; head and neck cancer; questionnaires; function; patient reported outcomes; International Classification of Functioning Disability and Health (ICF).

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Survival, loco-regional control, function and health-related quality of life (HRQOL) are important outcome parameters following head and neck cancer[27]. Functional outcome relates to HRQOL[20] and a holistic appreciation of function can help guide treatment and rehabilitation[6]. There is tremendous variation in HRQOL and functional outcomes due to the diversity of head and neck tumour sites, treatments and individual patient characteristics[10,14]. Various scales based on clinical examination have been reported[16,17,19]. There are several head and neck cancer specific HRQOL questionnaires[16], each with their own characteristics[8,9]. There is no gold standard and no widely acceptable indicator of functional outcome that applies

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across different head and neck specialties, continents and health care systems. A unified measure would support international collaboration, facilitate pooling of outcome data for comparison and for subsite analyses[2].

The World Health Organization (WHO) adopted the International Classification of Functioning, Disability and Health (ICF), to assess functioning and disability[7,28]. The ICF stands alongside the International Classification of Disease (ICD-10). The ICD-10 classifies medical diagnoses, and the ICF classifies patient functioning. The ICF is based on a comprehensive bio-psycho-social framework, including changes in body structures and body functions, the patient's ability to participate in everyday life situations and the influence of environmental and personal factors.

From the highly comprehensive ICF classification, specific ICF Core Sets have been developed[4]. The goal of the ICF Core Sets is to select disease-specific sets of categories that can serve as minimal standards for the assessment and documentation of functioning and health in clinical studies, clinical encounters and multi-professional comprehensive assessment. ICF Core Sets have been developed for 16 health conditions including chronic ischaemic heart disease[1], obstructive pulmonary disease[30], stroke[7], diabetes mellitus[18], rheumatoid arthritis[15], depression[5], breast cancer[3] and head and neck cancer[25].

ICF Core Sets are created at two levels: a Brief ICF Core Set to define categories as minimal standards to assess and report on functioning and health in any patient with head and neck cancer (HNC) and a Comprehensive ICF Core Set applicable to multi-disciplinary assessment. While the Comprehensive ICF Core Set for HNC should include the full spectrum of problems in functioning patients, the Brief ICF Core Set aims to include only the most important categories across countries and health professions. A first version of the ICF Core Set for HNC was created using an international and multi-disciplinary consensus process[2,6,11,12,21–26,29]. The Comprehensive ICF Core Set for HNC has 112 categories and from this a much smaller subset with 19 categories was proposed: the Brief ICF Core Set (Table 1).

The ICF is a clinician-rated evaluation and this poses potential disadvantages in routine practice. Assessments have to be undertaken as face to face evaluations, requiring extra time and resources in a busy outpatient setting. Clinician-rated scores might not correspond to patient perceptions. There is potential benefit in developing the BCSQ-H&N as a patient-completed questionnaire as this would be easier to integrate into routine outcome measurement and would also capture the patients' views of their functional outcome. The aims of this study were to develop the BCSQ-H&N as a patient self-rated questionnaire and to obtain patient views on its content and design. Also to compare the BCSQ-H&N with the University of Washington Quality of Life questionnaire version.4 and to compare clinician-rated scores with patient self-completed questionnaire responses.

*Table 1.* Brief ICF Core Set for HNC, $n = 19$. ICF category.

| | Title |
|---|---|
| Body functions ($n = 6$) | |
| b510 | Ingestion functions |
| b280 | Sensation of pain |
| b310 | Voice functions |
| b152 | Emotional functions |
| b130 | Energy and drive functions |
| b440 | Respiration functions |
| Body structures ($n = 4$) | |
| s320 | Structure of mouth |
| s330 | Structure of pharynx |
| s340 | Structure of larynx |
| s710 | Structure of head and neck region |
| Activities and participation ($n = 6$) | |
| d550 | Eating |
| d560 | Drinking |
| d230 | Carrying out daily routine |
| d330 | Speaking |
| d760 | Family relationships |
| d870 | Economic self-sufficiency |
| Environmental factors ($n = 3$) | |
| e310 | Immediate family |
| e110 | Products or substances for personal consumption |
| e355 | Health professionals |

## Method

Patients treated for primary squamous cell carcinoma of the head and neck, January 2002 to December 2007, were identified from the hospital database. Patients with cutaneous and salivary gland malignancy, patients treated with palliative intent, patients with recurrence and ongoing disease were excluded. Mortality status was tracked via the Office of National Statistics (ONS). The BCSQ-H&N questionnaire was included as part of an annual postal survey in March 2008 to all patients known to be alive and disease free, with reminders 4 weeks later.

A subsequent study involved head and neck cancer patients attending routine maxillofacial outpatient clinic reviews at least 6 months after their treatment had ended. Patients were asked to complete questionnaires at home followed by an interview (with SF) and repeat questionnaires at clinic. This research was conducted from 28 May 2008 to16 July 2008. The researcher (SF) piloted both the original questionnaire and interviews with members of the Merseyside Head and Neck Patient and Carer Research Forum.

The ICF Core Set for head and neck cancer is a selection of relevant categories and not a questionnaire. The BCSQ-H&N was created using the Brief ICF Core Set for HNC, it consists of 19 questions about problems in the last 30 days. It can assess size of problem and whether a problem was caused by something other than head and neck cancer. Section 1 asks about 'body structures and body functions (a problem or impairment with a part of your body, which means you have trouble doing something which you want to do)', section 2 about 'problems with activity and participation (a problem or difficulty with activity and social participation, such as being able to speak, eat or drink in ways that are socially and culturally acceptable to you)' and section 3 about 'environmental factors (how much certain factors in your living environment have either helped or hindered your progress since your diagnosis and treatment of head and neck cancer)'. In sections 1 and 2 patients grade their problems as none, mild (at a level you can tolerate, occurs rarely), moderate (sometimes interferes with your day to day life, happens occasionally), severe (partly disrupts your day to day life, occurs frequently) or complete

(totally disrupts your life, affects you every day). In section 3 they grade on a −4 to +4 scale ranging from complete hindrance to complete help.

Version 4 of the University of Washington Quality of Life (UW-QOLv4) questionnaire covers 12 domains (pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder function, taste, saliva, mood and anxiety)[13]. Each question is scaled from 0 (worst) to 100 (best) according to the hierarchy of response offered. The UW-QOL was also analysed for this study in terms of its two subscale scores, 'physical function' and 'social-emotional function'. Physical function is the simple average of the swallowing, chewing, speech, saliva, taste and appearance domain scores while social-emotional function is the simple average of the activity, recreation, pain, mood, anxiety and shoulder domains.

### Statistical method

Ethical approval from the Sefton Research Ethics Committee was obtained. Any missing data is reflected in varying denominators. The $\chi^2$-test was used to test association of patient subgroups with 'significant' problems on ICF items, with a moderate (3), severe (4) or complete (5) score being regarded as 'significant' for sections 1 and 2 and a hindrance/neither 'hindrance or help' (−4 to 0) score being regarded as 'significant' for section 3. Spearman's coefficient measured the amount of association between UWQOL subscale/domain scores and ICF item scores. Weighted and unweighted kappa statistics were computed for agreement between patient-completed ICF and interview-ICF data and between test-retest patient-completed ICF data. Kappa values above 0.60 represent 'good' agreement,

*Table 2*. Overall results for the 364 patients completing the Brief ICF questionnaire.

| Problems with parts of your body | Problem* | | Was the problem* due entirely to something else | |
|---|---|---|---|---|
| | % | *N* | % | *N* |
| Mouth function overall? | 42 | 138/330 | 3 | 4/138 |
| Biting | 37 | 122/333 | 3 | 4/122 |
| Chewing | 40 | 131/327 | 2 | 3/131 |
| Moving food around mouth | 37 | 116/317 | 0 | 0/116 |
| Saliva | 43 | 140/328 | <1 | 1/140 |
| Swallowing | 36 | 122/337 | 2 | 2/122 |
| Sucking | 24 | 79/329 | 0 | 0/79 |
| Voice function overall? | 26 | 91/344 | 0 | 0/91 |
| Producing sound | 23 | 77/334 | 0 | 0/77 |
| Quality of sound | 27 | 89/335 | 0 | 0/89 |
| Emotional functioning? | 24 | 77/323 | 3 | 2/77 |
| Energy and drive (motivation)? | 28 | 93/327 | 5 | 5/93 |
| Breathing in or out? | 14 | 47/327 | 9 | 4/47 |
| Structure of your mouth overall? | 33 | 102/310 | 4 | 4/103 |
| Structure of teeth | 34 | 111/331 | 4 | 4/111 |
| Structure of lips | 18 | 60/334 | 2 | 1/60 |
| Structure of tongue | 31 | 108/343 | 0 | 0/108 |
| Roof of mouth | 17 | 56/336 | 0 | 0/56 |
| Structure of other parts of mouth | 21 | 70/328 | 3 | 2/70 |
| Structure of your throat? | 23 | 75/330 | 1 | 1/75 |
| Structure of your voice box? | 21 | 69/331 | 1 | 1/69 |
| Structure of other parts of your head and neck? | 24 | 79/333 | 5 | 4/79 |
| Pain | 26 | 88/339 | 14 | 12/88 |
| Problems with activity and social functioning | | | | |
| Speaking? | 25 | 90/353 | 1 | 1/90 |
| Drinking? | 19 | 65/348 | 2 | 1/65 |
| Eating? | 41 | 145/354 | 2 | 3/145 |
| Carrying out your daily routine? | 22 | 75/343 | 11 | 8/75 |
| Supporting yourself financially? | 23 | 80/343 | 5 | 4/80 |
| Family relationships? | 14 | 48/343 | 2 | 1/48 |
| Problems with your environment | Problem† | | | |
| How much has your immediate family been a help or a hindrance? | 13 | 48/360 | | na |
| How much have the health professionals involved in your care been a help or a hindrance? | 11 | 39/356 | | na |
| How much of a help or hindrance are the foods, liquids, vitamins etc that you consume? | 37 | 129/350 | | na |
| How much of a help or hindrance are your medicines (prescribed or bought over the counter)? | 39 | 135/346 | | na |

*Moderate, severe or complete.
†Hindrance/neither hindrance or help.

with values above 0.80 being 'very good'. Owing to the numerous statistical tests performed, statistical significance was regarded as $p < 0.01$.

## Results

On 7 April 2008, 751 questionnaires were sent to eligible patients. The response was 50% (376/751) and there were no notable associations of response with age, sex, specialty (ENT/MFU), tumour site/staging, radiotherapy and years from diagnosis (results not shown). Mean (SD) age was 65 (11) years and 68% (256/376) were male. 43% (160) were within 2 years of treatment, 25% (93) within 3–5 years and 33% (123) within 6–16 years. Over half (58%, 217) had oral cavity tumours, with 21% (80) pharyngeal, 18% (67) laryngeal and 3% (12) other tumours. Two-thirds (70%, 262) had early clinical T1/T2 tumours, 27% (103) were T3/T4, unknown for 3% (11). 72% (272) had nodal negative tumours, 26% (97) positive tumours, 2% (7) unknown. Radiotherapy was received by 36% (136). Two-thirds (69%, 260) were treated by the maxillofacial department and one-third (31%, 116) by ENT.

There were no notable ceiling or floor effects arising from the results of the Brief ICF questionnaire. The percentage with no problems (sections 1 and 2) or complete help (section 3) ranged from 19% and 76% between items, median 50% (Table 2) while the percentage with 'significant' problems (i.e. moderate, severe or complete for sections 1 and 2 or 'lack of help' including hindrance or neutral for section 3) ranged from 11% to 43%, median 25%. The results emphasise problems particularly in mouth function and eating, with which about 40% have 'significant' problems. A minority had 'significant' problems due to something else, most notably for pain (14%), carrying out daily routine (11%) and breathing in or out (9%).

Significant problems on many ICF items were associated at $p < 0.01$with tumour site, *T* stage, *N* stage and use of radiotherapy since diagnosis (Table 3). Pharyngeal patients had notably worse mouth function and eating difficulties while laryngeal patients had worse voice function, and worse problems with their voice box and with speaking. Oral and pharyngeal patients had more problems with the structure of their tongue than laryngeal patients. Patients with more advanced clinical staging had worse mouth function, worse structure of teeth, throat and voice box and more problems with eating, drinking and speaking. Patients receiving radiotherapy since diagnosis had worse mouth and voice function and greater problems in eating, in carrying out daily routine and in supporting themselves financially. There was no association of items at $p < 0.01$ with gender and time from diagnosis. Age was associated at $p < 0.001$ with carrying out daily routine (11%, 34%, 22%, 9% for <55 years, 55–64 years, 65–74 years, 75+ years, respectively), supporting themselves financially (23%, 35%, 20%, 5%, respectively), family relationships (9%, 21%, 16%, 2%, respectively) and was associated at $p < 0.01$ with structure of lips (10%, 18%, 28%, 9%, respectively) and structure of other parts of the head (16%, 35%, 21%, 14%, respectively). There were no associations at $p < 0.01$ of any factor with section 3 environmental items (results not shown).

Correlation between ICF items and those UWQOL domains sharing similar concepts produced expected correlations (Table 4). Sections 1 and 2 were associated with physical and social-emotional subscales of the UWQOLv4, and generally more strongly with the physical subscale apart from emotional functioning, energy and drive, pain, and the social functions of carrying out daily routine, supporting themselves financially and in family relationships. ICF environmental problems were weakly correlated with UWQOL subscales (range for Spearman *r* being from −0.08 to 0.21) and are not shown in Table 4.

Minor changes to the questionnaire layout were made subsequently to help improve the response to specific questions, particularly overall mouth and overall voice function. 75 patients were eligible for the subsequent validation study. Of these 25 (33%) attended clinic for interview and also completed the ICF questionnaire at home (median 1 day, IQR 0–4 days before clinic), while 22 (29%) also completed a repeat ICF questionnaire (median 7 days, IQR 4–13 days after the first questionnaire). Though numbers are small there was consistently good test–retest agreement in patient-completed questionnaires before and after clinic (Table 5), with median (IQR) unweighted kappa values of 0.61 (0.54–0.78) and median (IQR) weighted kappa values of 0.75 (0.68–0.86). There were considerably lower levels of agreement between pre-clinic patient questionnaires and interviewer ratings, with median (IQR) unweighted kappa values of 0.31 (0.23–0.42) and median (IQR) weighted kappa values of 0.41 (0.27–0.57). Some items display evidence of systematic disagreement between patient and interviewer, in particular voice function (for which the interviewer rated problems less strongly than did the patients) and emotional functioning (for which the interviewer rated problems more strongly than patients).

## Discussion

To the authors' knowledge, this is the first time that any ICF Core Set has been developed as a patient self-completed questionnaire. The rationale is that a simple questionnaire is easier to apply as a standardised outcome measure than a clinician-rated scale. Converting the Brief ICF for head and neck cancer into a questionnaire posed problems. Firstly the ICF is written in very specific scientific language and it was necessary to reword some domains and the scoring system into a language more easily understood. Secondly, for certain domains, it was felt that a more detailed tier/level of questioning was appropriate and would be easier for patients to understand. The second level domains of structure of mouth, ingestion functions and voice functions were expanded to the third level to ask in greater depth about problems with structure and functioning, as well as identifying these domains at the second level.

The response rate to the cross-sectional survey was only 50%. There was no obvious bias in non-response. The questionnaires were sent out with questionnaires for another research study and on reflection the questionnaire package was too onerous. The data gained from the cross-sectional survey has helped support the face and construct validity of the BCSQ-H&N. Over half the patients had oral cancers, and most had early stage disease. It will be useful to investigate responses of a larger number from other head and neck subsites, different treatments and with more advanced disease. The study is cross-sectional and lacks a longitudinal element. It would be useful in the future to look at changes in patient perception over time.

It is evident that patients had problems particularly in mouth function and eating (Table 2). Problems were generally as a consequence of the cancer treatment with only a minority reporting 'significant' problems due entirely to something else (pain, carrying out daily routine, and breathing in or out). The main clinical factors that were associated with better BCSQ-H&N outcomes were early stage disease and use of

*Table 3*. Significant problem* rates for Brief ICF items by patient characteristics.

| | Oral | | Pharyngeal | | Laryngeal | | T1-2 | | T3-4 | | N0 | | N+ | | No RT | | RT | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Problems with parts of your body | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* |
| Mouth function overall? | 38 | 73/193 | 61 | 45/74 | 28 | 15/53 | 34 | 80/233 | 59 | 51/87 | 35 | 82/234 | 58 | 52/89 | 34 | 72/210 | 55 | 66/120 |
| Biting | 38 | 73/194 | 45 | 35/77 | 23 | 12/52 | 31 | 73/232 | 51 | 46/91 | 34 | 81/238 | 44 | 39/88 | 30 | 63/210 | 48 | 59/123 |
| Chewing | 38 | 72/191 | 58 | 42/73 | 25 | 13/53 | 34 | 77/225 | 53 | 49/92 | 35 | 82/233 | 51 | 45/88 | 33 | 70/210 | 52 | 61/117 |
| Moving food around mouth | 36 | 67/185 | 52 | 38/73 | 16 | 8/49 | 35 | 79/224 | 40 | 33/83 | 31 | 69/225 | 53 | 45/85 | 28 | 56/199 | 51 | 60/118 |
| Saliva | 35 | 67/190 | 67 | 51/76 | 35 | 18/52 | 38 | 88/231 | 52 | 46/88 | 32 | 75/237 | 71 | 60/85 | 34 | 72/209 | 57 | 68/119 |
| Swallowing | 26 | 51/193 | 60 | 47/78 | 38 | 21/55 | 30 | 71/235 | 49 | 45/91 | 29 | 69/239 | 55 | 50/91 | 30 | 63/211 | 47 | 59/126 |
| Sucking | 20 | 39/192 | 45 | 34/76 | 10 | 5/51 | 21 | 48/229 | 32 | 29/90 | 18 | 42/235 | 43 | 37/87 | 16 | 34/208 | 37 | 45/121 |
| Voice function overall? | 19 | 38/198 | 34 | 26/77 | 44 | 25/57 | 23 | 54/239 | 36 | 34/94 | 21 | 51/246 | 43 | 39/91 | 20 | 43/216 | 38 | 48/128 |
| Producing sound | 16 | 31/189 | 27 | 21/77 | 42 | 24/57 | 21 | 48/234 | 31 | 28/90 | 19 | 46/237 | 33 | 30/90 | 18 | 37/209 | 32 | 40/125 |
| Quality of sound | 21 | 40/191 | 30 | 23/77 | 46 | 26/57 | 23 | 54/234 | 36 | 33/91 | 23 | 55/240 | 36 | 32/88 | 19 | 41/212 | 39 | 48/123 |
| Emotional functioning? | 22 | 41/189 | 28 | 21/74 | 27 | 14/51 | 21 | 47/226 | 32 | 28/87 | 21 | 47/229 | 33 | 29/87 | 21 | 43/205 | 29 | 34/118 |
| Energy and drive (motivation)? | 24 | 45/189 | 32 | 24/74 | 42 | 22/53 | 27 | 62/226 | 33 | 30/91 | 25 | 58/230 | 38 | 34/90 | 22 | 46/208 | 39 | 47/119 |
| Breathing in or out? | 10 | 19/189 | 13 | 10/75 | 32 | 17/53 | 13 | 29/271 | 18 | 16/90 | 13 | 29/232 | 18 | 16/88 | 11 | 22/206 | 21 | 25/121 |
| Structure of your mouth overall? | 31 | 56/179 | 42 | 29/69 | 27 | 14/52 | 30 | 66/222 | 41 | 33/80 | 28 | 63/222 | 45 | 38/84 | 27 | 52/195 | 43 | 50/115 |
| Structure of teeth | 34 | 65/191 | 36 | 27/74 | 30 | 17/56 | 30 | 68/230 | 46 | 42/92 | 31 | 74/236 | 42 | 37/89 | 28 | 58/208 | 43 | 53/123 |
| Structure of lips | 22 | 42/191 | 9 | 7/77 | 16 | 9/56 | 15 | 34/233 | 26 | 24/91 | 18 | 43/239 | 18 | 16/88 | 15 | 31/210 | 23 | 29/124 |
| Structure of tongue | 35 | 69/198 | 37 | 29/79 | 14 | 8/56 | 31 | 74/236 | 33 | 32/97 | 28 | 67/243 | 44 | 41/93 | 27 | 59/216 | 39 | 49/127 |
| Roof of mouth | 18 | 35/193 | 16 | 12/77 | 14 | 8/56 | 15 | 34/232 | 23 | 22/94 | 13 | 30/239 | 29 | 26/90 | 13 | 28/211 | 22 | 28/125 |
| Structure of other parts of mouth | 22 | 42/189 | 24 | 18/74 | 16 | 9/55 | 21 | 49/231 | 23 | 20/87 | 18 | 43/236 | 31 | 26/85 | 17 | 36/206 | 28 | 34/122 |
| Structure of your throat? | 17 | 32/188 | 30 | 23/76 | 33 | 18/55 | 18 | 42/228 | 32 | 30/93 | 18 | 42/234 | 34 | 31/90 | 18 | 38/208 | 30 | 37/122 |
| Structure of your voice box? | 15 | 29/192 | 18 | 13/74 | 49 | 27/55 | 17 | 39/230 | 31 | 28/91 | 19 | 44/237 | 26 | 23/87 | 17 | 35/208 | 28 | 34/123 |
| Structure of other parts of your head and neck? | 19 | 36/191 | 31 | 23/75 | 32 | 18/57 | 22 | 52/234 | 26 | 22/89 | 18 | 43/240 | 40 | 34/86 | 18 | 38/208 | 33 | 41/125 |
| Pain? | 22 | 43/192 | 35 | 27/78 | 28 | 16/58 | 24 | 57/236 | 29 | 27/92 | 22 | 53/242 | 36 | 32/89 | 26 | 55/212 | 26 | 33/126 |
| Problems with activity and social functioning | | | | | | | | | | | | | | | | | | |
| Speaking? | 20 | 41/203 | 30 | 24/79 | 40 | 24/60 | 21 | 51/244 | 38 | 38/99 | 21 | 53/252 | 38 | 36/94 | 21 | 47/222 | 33 | 43/131 |
| Drinking? | 17 | 34/199 | 17 | 13/77 | 26 | 16/61 | 14 | 34/243 | 32 | 30/95 | 18 | 44/251 | 22 | 20/90 | 16 | 34/218 | 24 | 31/130 |
| Eating? | 37 | 75/202 | 58 | 46/79 | 34 | 21/61 | 33 | 81/246 | 62 | 60/97 | 36 | 90/252 | 56 | 53/95 | 33 | 74/223 | 54 | 71/131 |
| Carrying out your daily routine? | 17 | 33/198 | 29 | 22/76 | 28 | 16/58 | 21 | 50/239 | 25 | 24/95 | 17 | 41/247 | 38 | 34/90 | 16 | 35/218 | 32 | 40/125 |
| Supporting yourself financially? | 19 | 38/196 | 29 | 22/77 | 29 | 17/59 | 21 | 50/239 | 30 | 28/94 | 18 | 45/244 | 38 | 35/92 | 17 | 36/218 | 35 | 44/125 |
| Family relationships? | 15 | 29/195 | 12 | 9/78 | 16 | 9/59 | 13 | 32/240 | 17 | 16/93 | 13 | 31/245 | 19 | 17/91 | 12 | 26/217 | 17 | 22/126 |

Key to $\chi^2$ (site)/Fishers exact (*T* stage, *N* stage, RT) tests: $p < 0.001$, $0.001 < p < 0.01$.

* Moderate, severe or complete.

*Table 4*. Association of brief ICF items with UWQOL subscales and with conceptually close UWQOL domains.

| ICF item | UWQOL domain | Spearman R with UWQOL domain | Spearman R with UWQOL physical subscale | Spearman R with UWQOL social-emotional subscale |
|---|---|---|---|---|
| Problems with parts of your body | | | | |
| Mouth Function overall? | | | −0.76 | −0.52 |
| Biting | Chewing | −0.69 | −0.66 | −0.40 |
| Chewing | Chewing | −0.70 | −0.69 | −0.44 |
| Moving food around mouth | Chewing | −0.58 | −0.60 | −0.39 |
| Saliva | Saliva | −0.72 | −0.69 | −0.51 |
| Swallowing | Swallowing | −0.76 | −0.73 | −0.48 |
| Sucking | | | −0.63 | −0.45 |
| Voice function overall? | Speech | −0.61 | −0.53 | −0.40 |
| Producing sound | Speech | −0.53 | −0.45 | −0.37 |
| Quality of sound | Speech | −0.63 | −0.52 | −0.37 |
| Emotional functioning? | Mood/anxiety | −0.57/−0.39 | −0.48 | −0.56 |
| Energy and drive (motivation)? | Mood/anxiety | −0.54/−0.28 | −0.50 | −0.61 |
| Breathing in or out? | | | −0.35 | −0.35 |
| Structure of your mouth overall? | | | −0.57 | −0.39 |
| Structure of teeth | | | −0.47 | −0.28 |
| Structure of lips | | | −0.35 | −0.27 |
| Structure of tongue | | | −0.43 | −0.36 |
| Roof of mouth | | | −0.45 | −0.33 |
| Structure of other parts of mouth | | | −0.50 | −0.38 |
| Structure of your throat? | Swallowing | −0.53 | −0.54 | −0.41 |
| Structure of your voice box? | Speech | −0.42 | −0.37 | −0.31 |
| Structure of other parts of your head and neck? | Appearance/Shoulder | −0.40/−0.44 | −0.48 | −0.48 |
| Pain? | Pain | −0.67 | −0.42 | −0.57 |
| Problems with activity and social functioning | | | | |
| Speaking? | Speech | −0.68 | −0.51 | −0.38 |
| Drinking? | Swallowing | −0.49 | −0.52 | −0.41 |
| Eating? | Swallowing/Chewing | −0.75/−0.69 | −0.74 | −0.51 |
| Carrying out your daily routine? | Activity | −0.52 | −0.52 | −0.60 |
| Supporting yourself financially? | | | −0.45 | −0.50 |
| Family relationships? | | | −0.36 | −0.43 |

*Note:* All spearman correlations were $p < 0.001$.

radiotherapy since diagnosis (Table 3). Outcomes varied with tumour site in accordance to expectation. A similar profile is reported in the HRQOL literature[20,27]. The BCSQ-H&N is designed to assess functional outcome so it is little surprise that there were significant correlations between its items and UWQOL domains sharing similar concepts and with the physical subscale of the UW-QOL (Table 4). The BCSQ-H&N also embraces other aspects such as the social functions of carrying out daily routine, supporting oneself financially and family relationships and these correlated better with the social-emotional subscale of the UW-QOLv4.

The key finding from the observer-rated interviews was that there were differences between the patient self-completed responses and the clinician-rated scoring. Some items displayed systematic disagreement, in particular voice function (for which the interviewer rated problems less strongly than did the patients) and emotional functioning (for which the interviewer rated problems more strongly than patients). The language of the ICF is very specific for example b310 – Voice functions (functions of the production of various sounds by the passage of air through the larynx) and this domain does not address articulation functions. It is likely that patients interpreted voice function as speech and articulation of phonemes and hence rated it differently. It is well recognised that patients and clinicians can have differing views on outcome and this would support the value of patient-derived outcomes and, where possible, using both questionnaire and objective assessment.

Patients found the BCSQ-H&N relatively quick to complete and as a short questionnaire it has advantages in terms of patient compliance[15]. The questionnaire does not address certain domains such as taste (b250), jaw opening (s7103), articulation function (b320), structure of shoulder region (s720) loss of function at the free flap donor site (s7301 structure of forearm) or intimate relationships (d770). These issues are included in the Comprehensive ICF Core Set but not in the Brief. They were considered very important by many patients and it was through discussion at interview that these were highlighted. Patients felt some items were much less useful, particularly products and substances for personal consumption (e110) and these could be removed. Several patients commented that free text space would allow them to discuss certain aspects of their condition further, akin to the UW-QOLv4.

In conclusion, although there are many head and neck cancer health-related quality of life and functional outcomes assessment instruments, none of them have been universally adopted for global use. What makes the Brief ICF Core Set different is its basis within the WHO International Classification of Functioning, Disability and Health. It has the potential for international acceptance. Considerable development is required. In spite of its simplicity the BCSQ-H&N has the potential to collect patient perceptions of outcome for international comparison.

*Table 5.* Further validation analyses that compare ICF results of patient-completed questionnaires with interviewer ratings and of pre and post clinic (test–retest) patient-completed questionnaires.

| | Pre-clinic questionnaire vs Interview ratings ($N = 25$) | | | | Test–retest questionnaires ($N = 22$) | |
|---|---|---|---|---|---|---|
| | Pre-clinic patient-completed ICF | Interview ratings | >1 category disagreement | Weighted kappa agreement statistic | >1 category disagreement | Weighted kappa agreement statistic |
| Problems with parts of your body | *N* with problem* | | | | | |
| Mouth function overall? | 12 | 13 | 3/24 | 0.43 | 0/19 | 0.76 |
| Biting | 13 | 13 | 1/25 | 0.69 | 0/20 | 0.86 |
| Chewing | 13 | 15 | 2/23 | 0.65 | 0/20 | 0.91 |
| Moving food around mouth | 11 | 8 | 4/23 | 0.49 | 0/19 | 0.88 |
| Saliva | 12 | 9 | 1/24 | 0.69 | 1/19 | 0.90 |
| Swallowing | 5 | 6 | 1/24 | 0.59 | 0/19 | 0.77 |
| Sucking | 5 | 4 | 5/23 | 0.37 | 0/19 | 0.86 |
| Voice function overall? | 6 | 2 | 5/24 | 0.23 | 0/18 | 0.85 |
| Producing sound | 5 | 0 | 3/23 | 0.31 | 0/18 | 0.72 |
| Quality of sound | 6 | 1 | 4/23 | 0.39 | 0/17 | 0.70 |
| Emotional functioning? | 2 | 9 | 1/22 | 0.56 | 1/18 | 0.74 |
| Energy and drive (motivation)? | 5 | 6 | 3/22 | 0.37 | 0/16 | 0.58 |
| Breathing in or out? | 1 | 1 | 1/23 | 0.17 | 0/18 | 0.77 |
| Structure of your mouth overall? | 8 | 12 | 1/21 | 0.34 | 1/18 | 0.58 |
| Structure of teeth | 11 | 14 | 6/23 | 0.56 | 1/16 | 0.74 |
| Structure of lips | 5 | 6 | 1/23 | 0.76 | 1/17 | 0.79 |
| Structure of tongue | 8 | 6 | 2/24 | 0.60 | 1/17 | 0.68 |
| Roof of mouth | 1 | 1 | 2/23 | 0.41 | 1/17 | 0.43 |
| Structure of other parts of mouth | 4 | 7 | 6/23 | 0.27 | 1/16 | 0.46 |
| Structure of your throat? | 4 | 2 | 3/23 | 0.45 | 0/17 | 1.00 |
| Structure of your voice box? | 4 | 0 | 3/23 | 0.15 | 0/17 | 1.00 |
| Structure of other parts of your head and neck? | 4 | 8 | 4/22 | 0.33 | 1/17 | 0.63 |
| Pain? | 6 | 10 | 1/22 | 0.51 | 0/17 | 0.86 |
| Problems with activity and social functioning | | | | | | |
| Speaking? | 4 | 3 | 4/25 | 0.24 | 0/20 | 0.71 |
| Drinking? | 1 | 2 | 1/25 | 0.57 | 0/20 | 0.92 |
| Eating? | 11 | 10 | 4/25 | 0.39 | 1/20 | 0.76 |
| Carrying out your daily routine? | 3 | 4 | 2/24 | 0.49 | 1/20 | 0.68 |
| Supporting yourself financially? | 6 | 3 | 4/21 | 0.48 | 1/19 | 0.75 |
| Family relationships? | 2 | 3 | 3/25 | 0.26 | 0/20 | 0.69 |
| Problems with your environment | *N* with problem† | | | | | |
| How much has your immediate family been a help or a hindrance? | 2 | 2 | 1/25 | 0.62 | 0/19 | 0.80 |
| How much have the health professionals involved in your care been a help or a hindrance? | 1 | 0 | 3/25 | −0.01 | 1/19 | 0.68 |
| How much of a help or hindrance are the foods, liquids, vitamins etc that you consume? | 12 | 15 | 10/24 | 0.22 | 3/20 | 0.52 |
| How much of a help or hindrance are your medicines (prescribed or bought over the counter)? | 10 | 11 | 9/25 | 0.17 | 2/20 | 0.63 |

Kappa based on the full range of scores of ICF items.
* Moderate, severe or complete.
† Hindrance/neither hindrance or help.


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None.

## Ethical approval

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