



Description of the Head and Neck 5000 Questionnaires

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INTRODUCTION

In this document we describe the questions used in the Head and Neck 5000 (H&N5000) study. Questionnaires were given out at baseline (consent) and sent out at 4 and 12 months after consent during the original study. A further questionnaire was sent out 3 – 5 years after consent in the Follow up study. We divided the content of the questionnaires into sections that are made up of one or more groups and have summarised these in the table below. For each group of questions we have included the rationale for the questions, what the questions measure, validation of the questions, when used in Head and Neck 5000, and how any derived variables were created. We have included a reference list at the end of each section.

QUESTIONS USED IN THE HEAD AND NECK 5000 STUDY

Section	Group	Question(s)	Timepoint(s)
ABOUT YOU	Date	A1	All
	Date of Birth	A2	Baseline, 4m, 12m
	Height	A3	Baseline
	Current Weight	A4	All
	Weight loss	A4a-A4b	Baseline
	Gender	A4c	Baseline
	Postcode	A4d	Baseline
	Ethnicity	A4e	Baseline
	Marital status	A5	All
	Education	A6, A7	Baseline
	Smoking	A8-A12	All
	Marijuana use	A12a-A12c	3+ years
	Alcohol use	A13-A16	All
	Working and income	A17-A23	All
	WHO / ECOG performance status	A24	All
Health status (EQ-5D-5L)	A25-A26	All	
YOUR OUTLOOK	Life orientation test revised (LOT-R)	B1-B10	All
YOUR GENERAL HEALTH	EORTC Quality of life QLQ-C30	C1-C30	All
SPECIFIC ASPECTS OF YOUR HEALTH	EORTC Head and neck specific quality of life QLQ- H&N35	D1-D35	All
	Patient reported outcome Charlson co-morbidity index (PRO-CCI)	D36-D54	3+ years
	History of cervical cancer	D55-D56	3+ years
	History of tonsillectomy	D57-D58	3+ years
	Head and neck cancer recurrence	D59-D62	3+ years
YOUR FEELINGS	Hospital anxiety and depression scale (HADS)	E1-E14	All
EATING AND YOUR DIET	Fruit, vegetable and fried food consumption	F1-F3	All
	Eating habits	F4-F10	3+ years
	Antacid use	F11-F14	3+ years
	Feeding tubes	F15-F20	3+ years
THOUGHTS AROUND CANCER RECURRENCE	Fear of recurrence	G1-G4	4m, 12m, 3+ years
YOUR PERSONAL COSTS	Cost of cancer over the last year	H1-H12	4m, 12m, 3+ years
YOUR DENTAL HEALTH	Teeth and dental care	T1-T4	3+ years
YOUR SYMPTOMS	Late radiotoxicity questionnaire	L1-L33	12m, 3+ years
SEXUAL HISTORY	Sexual history questionnaire	1 – 9	Baseline

Questionnaires given out at one site only:

Section	Group	Question(s)	Timepoint(s)
YOUR QUALITY OF LIFE	The revised University of Washington QOL questionnaire	I1 – I17	Baseline, 4m, 12m
DIFFICULTIES IN YOUR LIFE	The Social Difficulties Inventory	J1 – J21	Baseline, 4m, 12m
YOUR APPEARANCE	The Derriford Appearance Scale	K (selected numbers)	Baseline, 4m, 12m

ABOUT YOU

DEMOGRAPHICS: DATE OF BIRTH, HEIGHT, WEIGHT, GENDER, POSTCODE, ETHNICITY, MARITAL STATUS AND EDUCATION (A3-A7)

Rationale for the questions

Date of birth is used to calculate age. Height and weight are used to calculate BMI. Weight and weight loss predict outcome in people with cancer. Gender and ethnicity have been linked to incidence of cancers as well as access to cancer services. Postcode is used to calculate the index of multiple deprivation. Marital status can affect lifestyle behaviour, psychological well-being and social support. The level of education has been linked to general health and to cancer survival.

What the questions measure

Question A2 asks for date of birth, which has been used to calculate age. Question A3 measures self-reported height. Question A4 measures self-reported weight. These can be used to estimate change in weight and body mass index (BMI). Questions A4a and A4b ask about change in weight and if a person had been trying to lose weight. Question A4c asks for gender and A4d for the participants postcode. A4e asks for ethnic group using categories used in the NHS. Question A5 asks about current marital status, it can be used to describe current marital status and change in marital status since diagnosis. Question A6 asks how many years of full-time education were completed and A7 asks the highest level of education obtained.

Validation of the questions

These questions have not been formally validated.

Use in head and neck 5000

The questions on height, gender, ethnicity, postcode, education, and questions A4a and A4b on recent weight loss were only asked at baseline. The questions on current weight and current marital status were asked at baseline, 4 months, 12 months and 3+ years Follow-up. Date of birth was asked at baseline, 4 months and 12 months.

Derived variables

Self-reported weight and height are used to calculate weight change and BMI. Height and weight could be reported by participants in imperial or metric but have been converted to metric for analysis. Postcode has been used for the Index of Multiple Deprivation score.

SMOKING AND ALCOHOL USE (A8-12 AND A13-16)

Rationale for the questions

Exposure to tobacco and alcohol represent established risk factors for the development of head and neck cancer (Argiris et al., 2008; IARC, 1988; IARC, 1986; Hashibe et al., 2009). In industrialised countries such as the UK, at least 75% of all head and neck cancers can be attributed to these two modifiable risk factors (Hashibe et al., 2007). Previous research suggests that for heavy smokers below the age of 46 years, there is a 20-fold increased risk of developing oral or pharyngeal cancer, whilst for heavy drinkers there is a 5-fold increased risk. The combination of heavy smoking and drinking results in an almost 50-fold increased risk (Rodriguez et al., 2004). As well as being important in the aetiology of head and neck cancer, there is evidence to suggest that continued smoking and alcohol intake after the index diagnosis is predictive of second primary tumour development (Do et al., 2003; Mayne et al., 2009). To see if this association exists in the H&N5000 cohort, we will compare outcomes of those that have stopped or reduced their use of tobacco and alcohol with those that have not modified their behaviours. We will see if there is any difference between groups in overall survival rates and disease-free survival. We also want to determine whether there are differences in survival for those participants who continued to use tobacco and/or consume alcohol during the time that they received treatment for their head and neck cancer compared to those who quit.

What the questions measure

These questions ask about current and recent tobacco and alcohol use.

Validation of the questions

These questions were originally developed for use in the CLEAR study (Sitas et al., 2015) and The Million Women study (The Million Women Study, 1999). The CLEAR study recruited residents of New South Wales, Australia ≥ 18 years old, with a first incident cancer. The Million Women Study is a national UK study of women's health, involving more than one million UK women aged 50 and over.

Use in head and neck 5000

Many of the questions about current tobacco use were included in all questionnaires. Some new questions relating to tobacco use were also included in the 3 – 5 year follow-up. These enquired about use of tobacco during the time that people received treatment for their head and neck cancer and attempts to stop using tobacco. Questions A8, A11 and A12 were used in baseline, 4 month and 12 month questionnaires. Question A8, which enquired about current smoking status, was used in all H&N5000 questionnaires but the wording and layout was modified for clarity in the 3-5 year follow-up. The wording appears as it did in the baseline questionnaire, but the layout was changed so that each of the three possible answers appear on separate lines. In the baseline questionnaire, the first two answers were positioned on the same line. It was felt that splitting them up would make the question clearer. Question A8b is similar to question A9 of the baseline questionnaire but it is phrased differently. Question A9 in the baseline questionnaire asked: "If you are a former tobacco user, how long ago did you stop using tobacco? Respondents were asked to provide their answer in years. In the current questionnaire, question A8b asks: If you are a former user of tobacco, when did you stop using tobacco? Respondents were asked to select from three possible answers: within the last month, within the last year or over a year ago. The layout of question A11 was altered slightly from previous questionnaires: rather than being positioned to the left of the answers, the tick boxes now appear to the right in order to make it easier for participants to read across and select the appropriate box.

The alcohol-related questions appeared in all questionnaires with the exception of A14 which asks about alcohol consumption just before they fell ill, this question was only present on the baseline questionnaire.

Derived variables

The amount and frequency of consumption per week of beer, spirits or wine is combined and converted into standard UK alcohol units per week using the method described by (Zuccolo et al., 2013).

Participants' alcohol consumption has been categorised using the revised UK Department of Health guidelines (UK Chief Medical Officer 2016) and included additional higher thresholds defined by the Institute of Alcohol Studies (Institute of Alcohol Studies 2013) as well as a category for people who did not consume alcohol. This results in 4 categories of alcohol consumption: low: nondrinker, 0 units/week; moderate: > 0 and ≤14 units/week; high: women > 14 and ≤35 units/week, men > 14 and ≤50 units/week; and hazardous: women > 35 units/week, men > 50 units/week (Penfold et al., 2018).

Smoking status has been defined as “current,” “former” or “never.” Never smokers were defined as having never smoked at least one tobacco product during a whole year. Former smokers were defined as having smoked at least one tobacco product a day for a period of at least a year (Beynon et al., 2018). The questionnaire differentiates between use of cigarettes, hand-rolled cigarettes, cigars and smokeless tobacco.

A variable on pack years has been created.

MARIJUANA USE (A12A-A12C)

Rationale for the questions

Marijuana has been postulated to play a role in the development of HNC. Epidemiologic evidence for an association between marijuana use and HNC is however limited and conflicting (Aldington et al., 2008). Some studies have concluded that marijuana use increases the risk of developing HNC (Aldington et al., 2008; Zhang et al., 1999; Hashibe et al., 2002; Feng et al., 2009); others suggest that moderate marijuana use can have a protective effect (Liang et al., 2009). However, an analysis of matched case-control studies found no association between lifetime marijuana use and the development of HNC (de Carvalho et al., 2015). The authors point out however that since meta-analysis was performed with case-control studies, a small or long-term effect could not be discounted. The H&N5000 cohort provides a representative, longitudinal cohort in which to examine any potential association between marijuana use and different HNC sites and whether use predicts survival.

What the questions measure

These questions ask about previous and current marijuana use and reasons for use.

Validation of the questions

These questions have not been formally validated. The questions were developed for use in this questionnaire. The marijuana terms used in these questions were selected based on a previously published questionnaire on substance abuse, which was used as part of the European School Survey Project on Alcohol and Other Drugs (ESPAD, 2016).

Use in head and neck 5000

Participants were not asked about marijuana use in the original H&N5000 questionnaires; these questions were added for the 3 – 5 year follow-up.

Derived variables

At present there are no formal coding rules or derived variables.

WORKING AND INCOME (A17-A23)

Rationale for the questions

Cancer survival has been shown to be related to socio-economic position. There is evidence that this is also true for head and neck cancer specifically (Boyd et al., 1999; Nutting et al., 2008; Reitzel et al., 2012).

What the questions measure

The questions ask about current work, the hours worked, reasons for not working, income, benefits and concerns about living with cancer.

Validation of the questions

These questions were adapted from West of Scotland Twenty-07 cohort Study (Benzeval et al., 2009) and the Alcohol-Related Cancers And Genetic-Susceptibility (ARCAGE) European multicentre head and neck case control study (Lagiou et al., 2009).

Use in head and neck 5000

These questions were used in the original questionnaires, with the exception of A17a, A18a and A22a. The additional questions added in the 3-5 year follow-up ask about people's current occupation, their reasons for not working, and whether they received support in applying for welfare benefits. Those who state that they are not working were asked if this is because of their head and neck cancer, because of additional health concerns, or because they are retired or choose not to work.

Derived variables

Possible responses to the question relating to 'income before tax' (A21) include categories for weekly and annual income. The values for weekly income have been converted to annual income by multiplying the category values by 52 and matching these with the original categories for annual income. This gives a single categorical variable detailing participants' total annual household income before tax.

HEALTH STATUS - WHO / Eastern Cooperative Oncology Group (ECOG) performance status (A24)

Rationale for the questions

The WHO/ECOG performance status has been chosen as it is a widely used measure of performance status that is frequently used in clinical research. It is a simpler scale than the other commonly used tool, the Karnofsky status, which makes it useful as a patient reported outcome measure.

What the questions measure

The WHO/ECOG performance status describes a patient's level of functioning in terms of their ability to care for themselves, their daily activity, and physical ability (walking, working, etc) (Oken et al., 1982). This measure has repeatedly been demonstrated to be an important prognostic factor for survival in various cancer forms (Sorensen et al., 1993) and some have suggested its use in assessing quality of life (Ganz et al., 1988). The WHO/ECOG scale ranks performance status (PS) on a scale of 0 to 5. A score of 5 represents deceased so we omitted the score of 5 as participants were themselves being asked to complete the questionnaire. A PS score of 0 means normal activity, PS 1 means some symptoms, but still near fully ambulatory, PS 2 means less than 50%, PS 3 means more than 50% of daytime in bed and PS 4 means completely bedridden. In clinical studies PS 3 and above is often used as a cut-off.

Validation of the questions

The WHO/ECOG performance status has been shown to be reliable in studies which have tested its inter-observer variability. Both patient and oncologist assessed scores have been shown to reflect survival

duration as well as disease stage with oncologist assessed scores being only marginally more predictive of survival (Blagden et al., 2003).

Use in head and neck 5000

The WHO/ECOG performance status has been used in all the H&N5000 questionnaires.

Derived variables

At present there are no formal coding rules or derived variables.

HEALTH STATUS EQ-5D- 5L (A25-A26)

Rationale for the questions

The EQ-5D-5L has been chosen because it provides a self-reported measure of health status, independent of clinical measures and opinions. As such it can capture the overall burden of cancer as perceived by the individual themselves. There is a growing awareness of the importance of patient-reported health outcomes (PROs) in cancer (Lipscomb et al., 2007; Clauser et al., 2007). We will be able to compare EQ-5D-5L health states (or profiles) obtained in the 3 – 5 year follow up questionnaire with those obtained at baseline, four month and twelve months, to see how participant's perceived health has changed over time.

What the questions measure

The EQ-5D-5L is designed to measure health status. It consists of 2 parts: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system defines an individual's health across five separate dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Within each dimension they indicate whether they experience no problems, slight problems, moderate problems, severe problems or extreme problems. The EQ VAS is intended to provide a quantitative measure of their health outcome. It asks respondents to rate their perception of their overall health on a 20 cm vertical, visual analogue scale with 'the best health you can imagine' set at 100 and 'the worst health you can imagine' set at 0.

Validation of the questions

The EQ-5D-5L has been validated in diverse patient populations in at least 6 different countries, including the UK (Brooks R, 2003; Greiner et al., 2003). The Head and Neck 5000 study was used to compare health related quality of life data from the EQ-5D-5L questionnaire and data collected from the cancer-specific EORTC-QLQ-C30 questionnaire. The questionnaires were found to be comparable at baseline for people diagnosed with head and neck cancer (Davies et al., 2020).

Use in head and neck 5000

The EQ-5D has been used in all H&N5000 questionnaires, however initially the EQ-5D-3L was in use, this was changed to the EQ-5D-5L in 2013.

Derived variables

EQ-5D health states can be converted into to a single summary index by applying a formula which attaches weights to each of the levels in each dimension. Instructions on how to code the EQ-5D-5L can be found on the EuroQol website: (EuroQol, 2019).

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YOUR OUTLOOK

LIFE ORIENTATION TEST REVISED (B1-10)

Rationale for the questions

A number of studies have demonstrated a link between patients' positive expectations and cancer therapy outcomes (Carver et al., 1994; Walker et al., 1999; Schulz et al., 1996; Miller et al., 1996; De Boer et al., 1998). With respect to head and neck cancer, one study found that dispositional optimism could predict 1-year survival independent of other sociodemographic and clinical variables (Allison et al., 2000). Dispositional optimism refers to the expectation that more positive than negative things will happen in the future (Scheier and Carver, 1985). The purpose of this set of questions is to establish whether H&N5000 participants feel optimistic about their future and whether their expectations have changed since they last completed the questionnaire at 12 months. A number of studies suggest that optimism is associated with better health-related quality of life (Allison et al., 2000; de Moor et al., 2006; Carver et al., 2006; Kung et al., 2006).

What the questions measure

The Life Orientation Test-Revised (LOT-R) is a 10-item scale developed to assess differences in generalized optimism versus pessimism. This refers to an individual's tendency to view the world and the future in positive or negative ways (Scheier et al., 1994).

Validation of the questions

The LOT-R has been used extensively in research and has proven useful in predicting psychological well-being, physical health and recovery after severe illness or surgery (Glaesmer et al., 2012; Scheier et al., 1994).

Use in head and neck 5000

The LOT-R was used in all H&N5000 questionnaires. There were minor changes to the wording: "I agree a lot" has become "strongly agree"; "I disagree a lot" has become "strongly disagree"; "I neither agree nor disagree" has become "neutral". These changes were made when the questionnaire was first used in H&N5000 and have stayed the same since.

Derived variables

We created a variable following the guidance given in Scheier et al., 1994 where each item in the LOT-R is given a score from 0-4, where 0 implies the lowest level of optimism and 4 implies the greatest level of optimism. Items, 3, 7 and 9 are reverse coded prior to scoring (0=4, 1=3, 2=2, 3=1, and 4=0). To determine the total score, items 1, 3, 4, 7, 9 and 10 are summed. Items 2, 5, 6 and 8 are filter items only. The possible range of scores is 0-25. A score of 0-13 denotes low optimism, 14-18 moderate optimism and 19-25 high optimism (Scheier et al., 1994).

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YOUR GENERAL HEALTH

QUALITY OF LIFE – THE EUROPEAN ORGANISATION FOR THE RESEARCH AND TREATMENT OF CANCER (EORTC) QLQ-30 (C1-C30)

Rationale for the questions

Cancer and its treatment can have profound effects on peoples' lives. Some of the effects, such as physical disfigurement, may be clearly visible. Others, like pain and fatigue, can only be determined by the individual themselves. Biological measures or clinician-reported outcomes may present a poor reflection of how an individual is coping. Even relatives or close friends may not realise the extent to which the disease is impacting on the individual's quality of life. The purpose of this section of the questionnaire is to assess the impact that the cancer is having currently on the physical, psychological, and social functioning of the individual. The European Organisation for the Research and Treatment of Cancer (EORTC) QLQ-C30 is used as an instrument for measuring health-related quality of life (HRQoL) because it has been developed for use in cancer populations specifically. There are several reasons why it is important to measure HRQoL. First, HRQoL scores are associated with survival in a heterogeneous group of cancers including lung cancer, breast cancer, melanoma, colorectal cancer and head and neck cancer (Montazeri, 2009). Second, understanding HRQoL can improve patient care. The aim of any cancer treatment is to improve the quality of an individual's life, hopefully by curing the cancer but also by minimising its effects. Conventional parameters used to assess the efficacy of treatment, such as tumour response, disease-free survival and overall survival, may be less relevant to the person with cancer. If the side effects of therapy are too high or cause a decline in quality of life, then the individual needs to have the opportunity to make an informed choice about how they want their cancer to be managed. A clinician will make a subjective judgement about their patient's quality of life when treating them but to do so they need to understand the extent to which the cancer may impact on individuals' lives.

What the questions measure

The EORTC QLQ-C30 was originally developed to assess quality of life in cancer patients participating in clinical trials. It is a 30-item questionnaire, which incorporates nine scales: five functional scales (physical, role, cognitive, emotional and social); three symptom scales (fatigue, pain and nausea and vomiting); and a global health and quality-of-life scale. There are also a number of single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea) and perceived financial impact of the disease. The questions are designed to reflect the multi-dimensionality of the QoL construct (Aaronson et al., 1993).

Validation of the questions

The EORTC-QLQ-C30 was first validated in a cross-cultural sample of lung cancer patients, conducted across 13 countries (Aaronson *et al.*, 1993). It has since been used in a wide range of cancer clinical trials, by a large number of research groups.

Use in head and neck 5000

The EORTC-QLQ-C30 has been used in all H&N5000 questionnaires. In the 3 – 5 year follow up all questions appear as they did at baseline, 4 months and 12 months, except for questions C29 and C30: how would you rate your overall health in the past week and how would you rate your overall quality of life in the past week? In earlier questionnaires, respondents were instructed to tick a box from 1 to 7 which most applied to them, where 1 signified “very poor” and 7 signified “excellent”. In the follow-up questionnaire, respondents were asked to circle the number from 1 to 7 that best applies to them. It was felt that it was easier and less ambiguous for participants to circle the number rather than tick a box with a number to the side of it. The format used in the Follow-up Study reflects how the questions were constructed in the original EORTC-QLQ-C30.

Derived variables

Variables for functional scales, symptom scales and global health status were created following the EORTC QLQ-C30 Scoring Manual. An overall summary variable was also created. For details of the scoring procedure, please refer to Fayers et al., 2001

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SPECIFIC ASPECTS OF YOUR HEALTH

EORTC HEAD AND NECK SPECIFIC QUALITY OF LIFE QLQ- H&N35 (D1-D35)

Rationale for the questions

The EORTC-QLQ-C30, used in the previous section of the questionnaire, is used to measure HRQoL in people with cancer. Whilst anyone who has received a cancer diagnosis faces a life-threatening disease, there are features of the disease which are unique to their cancer and which might therefore impact on their quality of life differently. People who have or have had HNC not only have to deal with the cancer and its treatment, but also frequently with changes to important functions like eating, swallowing, breathing and communicating (Morris, 1994). Ways in which head and neck cancer uniquely influences quality of life will be investigated using an EORTC head and neck cancer-specific module, the EORTC-QLQ-H&N35.

What the questions measure

The EORTC-QLQ-H&N35, used in combination with the EORTC-QLQ-C30, is designed to measure symptoms and difficulties relating to head and neck cancer. It comprises seven subscales: pain, swallowing, senses, speech, social eating, social contact and sexuality. There are also 10 single items which relate to problems with teeth, dry mouth, cough, opening the mouth wide, sticky saliva, weight loss, weight gain, use of nutritional supplements, feeding tubes and painkillers. Respondents are asked to indicate the extent to

which they have experienced any of the symptoms listed during the last week. The instrument therefore measures health difficulties at that moment in time.

Validation of the questions

The EORTC QLQ-H&N35, in conjunction with the QLQ-C30, was tested and validated in a large and diverse sample (n = 622) of people from twelve different countries including the UK who had either been newly diagnosed with HNC, had recurrent HNC or who had been disease-free for 1-3 years after treatment (Bjordal et al., 1993). The instrument was found to be well accepted, had a high level of construct validity, and was responsive to differences between disease status, site and patients with different performance status.

Use in head and neck 5000

The EORTC QLQ-H&N35 was included in all H&N5000 questionnaires (baseline, 4-month, 12-months and 3 – 5 year follow-up). It has not been modified between questionnaires.

Derived variables

Variables for functional scales, symptom scales and global health status were created following the EORTC QLQ-C30 Scoring Manual. For details of the scoring procedure, please refer to Fayers et al., 2001.

A summary variable has also been created.

PATIENT REPORTED OUTCOME CHARLSON CO-MORBIDITY INDEX (PRO-CCI) (D36-54)

Rationale for the questions

People with HNC often have other illnesses or conditions, generally referred to as comorbidities, which co-exist alongside their cancer (Yung and Piccirillo, 2008). Although not a feature of the cancer itself, comorbidity has an impact on prognosis (Yung and Piccirillo, 2008; Datema et al., 2010; Sabin et al., 1999; Piccirillo and Costas, 2004; Reid et al., 2001). Some comorbid conditions for instance may affect treatment selection and subsequent outcome. Comorbidity is common in people with HNC (Paleri et al., 2010) because risk factors for the development of HNC, like tobacco use and heavy alcohol consumption, are also risk factors for cardiovascular, pulmonary and hepatic diseases (Datema et al., 2010). It is important to describe the overall burden of comorbid disease in the H&N5000 cohort and to examine the prognostic utility of comorbidity on head and neck cancer. To do this the Patient Reported Outcome Charlson Co-Morbidity Index (PRO-CCI) is included in this questionnaire. The PRO-CCI is a self-administered comorbidity index which has been adapted from the Charlson comorbidity index (CCI). Participants were asked about their medical history directly rather than relying on their medical notes because there is evidence to suggest that self-administered comorbidity assessments can provide more comprehensive information than medical chart reviews (Habbous et al., 2013). In part this is because patients generally report more comorbidities than are abstracted from medical records (Katz et al., 1996; Sangha et al., 2003; Habbous et al., 2013). One explanation is that if an individual is not admitted to hospital for their health condition, information on this condition is not recorded in their hospital records. Outpatient medical records are often less complete and oriented to the index problem (Katz et al., 1996; Habbous et al., 2013), meaning that potentially important comorbidity information could be overlooked. Many of the participants in this cohort may not be attending regular appointments at this time and therefore health-related information could be overlooked if we were to rely on the hospital records alone.

What the questions measure

The PRO-CCI used in the current questionnaire was modelled on the chart-review-based Charlson comorbidity Index but was developed specifically for use in head and neck cancer populations (Habbous et al., 2013). It was developed to measure the burden of comorbidity in this population. It asks participants to

indicate whether they have ever been diagnosed with a number of different comorbidities, including diseases associated with smoking and alcohol exposure (e.g. cardiovascular disease, diabetes, COPD, and liver disease).

Validation of the questions

The original PRO-CCI was administered to 882 people with head and neck cancer (Habbous et al., 2013). Whilst this patient-reported version correlated well with the standard (medical record-abstracted) CCI for comorbidities including diabetes and prior cancer, connective tissue disease (CTD) and chronic obstructive pulmonary disease (COPD) showed marked disagreement. Discrepancies were thought to be a result of people reporting various non-rheumatological diseases or symptoms of CTD (e.g. osteoarthritis or aches and pains in the bones and joints). As a result, a modified PRO-CCI questionnaire was developed which aimed to provide more accurate reporting for CTD. This modified version was validated in an additional cohort of people with head and neck cancer, lung or oesophageal cancer (n=102). The modified PRO-CCI demonstrated high compliance, a good level of agreement with the standard CCI and was a good predictor of survival cancer (Habbous et al., 2013).

Use in head and neck 5000

The PRO-CCI was only used in the 3 – 5 year follow up questionnaire.

Derived variables

In the PRO-CCI, comorbidity is weighted and scored using the same algorithm proposed by Charlson et al (Charlson et al., 1987). Please see Supplementary Table 1 in Habbous et al., 2013 for further information on scoring.

HISTORY OF CERVICAL CANCER (D55-D56)

Rationale for the questions

The prevalence of oropharyngeal carcinoma is increasing, largely in developed countries and in younger cohorts of men (Chaturvedi et al., 2013; Kreimer et al., 2005; Mehanna et al., 2013). The epidemiologic changes have been attributed to human papilloma viruses (HPV) (Chaturvedi et al., 2011; Gillison et al., 2000; Herrero et al., 2003; Franceschi et al., 1996), the same group of viruses that are responsible for nearly all cases of cervical cancer in women (World Health Organization, 2018). HPV infections are mainly sexually transmitted through direct skin or mucosa contact (Chaturvedi et al., 2011) and the rapid increase in HPV-related oropharyngeal carcinomas has been attributed to the sexual revolution (D'Souza et al., 2014).

What the questions measure

The questions on cervical cancer ask about history of cervical cancer in female participants and history of cervical cancer in participants' female partners.

Validation of the questions

These are new questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

HISTORY OF TONSILLECTOMY (D57-D58)

Rationale for the questions

Tonsillectomy has been associated with a 60% reduction in the risk of cancer of the tonsil (Fakhry et al., 2015). The authors hypothesised that tonsillectomy may reduce the risk of oropharyngeal carcinoma by removing the tissue susceptible to HPV infection on exposure to the HPV virus, thereby decreasing the potential for subsequent malignant transformation. If confirmed, this could have important implications for questions around rising incidence, secondary prevention and treatment of oropharyngeal cancer. Rates of tonsillectomy have declined significantly since the 1950's (Grob, 2007; Ramos et al., 2013) and whilst the authors of these papers were careful not to ascribe the rise in oropharyngeal cancer cases to declines in tonsillectomy, they did show an ecological correlation in their studies.

What the questions measure

The questions ask about removal of the tonsils and of those that have had a tonsillectomy, whether this was performed prior to any treatment for head and neck cancer.

Validation of the questions

These questions were developed for this study and have not been used elsewhere.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

HEAD AND NECK CANCER RECURRENCE (D59-D62)

Rationale for the questions

People with head and neck cancer have a high risk of cancer recurrence. Data on recurrence may not be recorded in the notes of the recruiting centre as the participant may be treated for the recurrence elsewhere.

What the questions measure

These questions ask about recurrence of disease and treatment for this recurrence.

Validation of the questions

These are new questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

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YOUR FEELINGS

HOSPITAL ANXIETY AND DEPRESSION SCALE (E1-E14)

Rationale for the questions

Previous research suggests that people with head and neck cancer suffer more often from anxiety and depressive disorders than do other people with cancer (Katz et al., 2004; Kugaya et al., 2000; Singer et al., 2012). Estimates vary, but somewhere between 20-46% of people with the disease experience anxiety and/or depression in the years succeeding treatment (Kugaya et al., 2000; Singer et al., 2012; de Leeuw et al., 2000; Duffy et al., 2007; Zabora et al., 2001; Singer et al., 2009). The high prevalence most likely reflects the fact that head and neck cancer survivors often live with permanent functional impairment and disfigurement, which are in turn associated with significant social and psychological sequelae (Allison et al., 2004). If undetected or untreated, such psychological distress has been shown by a number of studies to be associated with reduced QoL, extended hospital stays, malnutrition, increased complications and treatment non-compliance (Britton et al., 2012; de Leeuw et al., 2000; Ma et al., 2013; Barber et al., 2015). The impact that this then has on disease outcomes such as recurrence and survival are unclear. The rationale behind assessing depression and anxiety in H&N5000 participants is that changes in anxiety and depression and their association with outcome can be described in this population.

What the questions measure

The questions in this section have been taken from the Hospital Anxiety and Depression Scale (HADS). The HADS was originally developed to identify caseness (i.e. whether or not a subject has the condition of interest (Burger and Neeleman, 2007) of anxiety disorders and depression among patients in non-psychiatric hospital clinics (Bjelland et al., 2002). The depression subscale items used in this instrument concentrate on the loss of pleasure response (anhedonia), which was regarded by Zigmond & Snaith as one of the two obligatory states of "major depressive disorder" (Zigmond and Snaith, 1983).

Validation of the questions

Whilst HADS was developed as a screening instrument for use in hospital outpatient departments, it has subsequently been validated for use within primary care settings and within the general population (McDowell, 2006; Snaith, 2003). Its use has been supported in two major reviews (Herrmann, 1997; Bjelland et al., 2002). Studies have used the HADS to examine psychological distress in people with head and neck cancer, worldwide and in the UK specifically. For a comprehensive overview of these, please see Joseph et al., 2013.

Use in head and neck 5000

The HADS was used in each of the H&N5000 questionnaires. It has not been modified from the original instrument (Zigmond and Snaith, 1983).

Derived variables

The Hospital Anxiety and Depression Scale (HADS) is a fourteen-item scale. Seven of the items relate to anxiety and seven relate to depression. Each item on the questionnaire is scored from 0-3, meaning that a person can score between 0 and 21 for both anxiety and depression. Cut-off points indicate whether the individual falls "within the normal range", or "mildly", "moderately", or "severely disordered" (Snaith, 1990).

Each of the subscales, namely depression and anxiety, are intended to be considered separately and not aggregated. We have created a derived variable based on the recommendations.

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EATING & YOUR DIET

FRUIT, VEGETABLE AND FRIED FOOD CONSUMPTION (F1-F3)

Rationale for the questions

Diet is implicated in the aetiology of HNC, particularly a low consumption of fruit and vegetables (Macfarlane et al., 1995) and high consumption of fried foods (Bradshaw et al., 2012). The role that diet plays in disease recurrence, however, has not been fully explored.

What the questions measure

These questions are designed to provide relative categorical rankings of individual fruit, vegetable and fried food intake. They provide an estimate of the amounts of these foods consumed over a year. Within the FFQ, one serving was defined as one piece of fruit or a “medium serving”, which is left for the respondent to decide. One study (Lang et al., 2019) collapsed the food frequency items into three categories for fruit and vegetables and two categories for deep-fried food intake: fruit intake was defined as high (more than 1 portion per day), medium (2 portions per week to 1 portion per day) and low (less than 2 portions per week); vegetable intake was defined as high (more than 1 portion per day), medium (5 portions per week to 1 portion per day), low (less than 5 portions per week); deep-fried food intake was either high (at least one portion per week) or low (less than one portion per week).

Validation of the questions

These questions have been modified from the semi-quantitative food frequency questionnaire (FFQ). The FFQ questionnaire was validated in a large prospective study of 173 female registered nurses aged 34-59 years, residing in the Boston area from 1980 to 1981 (Willett et al., 1985). The authors concluded that the self-administered dietary questionnaire could provide useful information about individual nutrient intakes over a one-year period.

Use in head and neck 5000

These questions were included in all H&N5000 questionnaires.

Derived variables

Within the FFQ, one serving was defined as one piece of fruit or a “medium serving”, which is left for the respondent to decide. One study (Lang et al., 2019) collapsed the food frequency items into three categories for fruit and vegetables and two categories for deep-fried food intake: fruit intake was defined as high (more than 1 portion per day), medium (2 portions per week to 1 portion per day) and low (less than 2 portions per week); vegetable intake was defined as high (more than 1 portion per day), medium (5 portions per week to 1 portion per day), low (less than 5 portions per week); deep-fried food intake was either high (at least one portion per week) or low (less than one portion per week).

EATING HABITS (F4-F10)

Rationale for the questions

Eating difficulties and changes in taste and odour perception following HNC treatment are well documented in the literature, (Yamashita et al., 2006; McQuestion et al., 2011; Larsson et al., 2005; Larsson et al., 2003; Porter and Scully, 2012; Rogus-Pulia et al., 2014; Epstein and Huhmann, 2012), but the majority of studies which have considered this have focused on changes in the first 3-18 months following treatment (Larsson et al., 2003). Preliminary work with survivors of HNC, conducted by Dr. Burgess-Watson and colleagues at the University of Durham (unpublished), has suggested that one way in which people may adapt to changes

in taste and/or smell is by modifying their cooking and food preparation techniques. Changes in food preparation could include blending or pureeing foods or seasoning foods differently when cooking.

What the questions measure

Questions F4-F10 are intended to ascertain whether participants' own personal experience of food and eating may have changed since receiving treatment for head and neck cancer. Some of the questions are designed to measure perceived differences in the smell or taste of foods, whilst others address more practical issues such as food preparation and waste. The purpose of this set of questions is to ascertain the extent to which different treatment modalities and/or tumour types affect eating behaviours and the perception of foods.

Validation of the questions

These are new questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

ANTACID USE (F11-F14)

Rationale for the questions

Pathologic gastroesophageal reflux is a common complaint in people with HNC (Copper et al., 2000; Sato et al., 2009) and there is evidence that it may contribute to complications after surgery or during radiation and chemotherapy (Fennerty, 2003). Antacid medications are commonly prescribed in HNC patients as part of their cancer treatment and consist of two classes: histamine 2 receptor antagonist class (H2RA) and proton pump inhibitors class (PPI). We asked participants about their use of antacids because antacid usage has been associated with a significant survival benefit (Papagerakis et al., 2014). PPIs had the greatest effect - a 45% decreased risk of death compared to those not taking antacids. H2RAs were associated with a 33% reduced risk of death. The reported survival benefit did not hold true for all drugs. For instance, omeprazole and esomeprazole both demonstrated a survival benefit whilst Pantoprazole did not; all of these drugs belong to the class PPIs.

What the questions measure

These questions ask about antacids use, prescription and over the counter, name of antacid and frequency of use.

Validation of the questions

These are new questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

FEEDING TUBES (F15-F20)

Rationale for the questions

There is evidence to suggest that many percutaneous endoscopic gastrostomy (PEG) tubes are placed unnecessarily (Madhoun et al., 2011). One study reported that 47% of people fitted with a feeding tube before the start of treatment never actually used it or used it for less than two weeks (Madhoun et al., 2011). PEG placement can result in complications such as infection, tube blockage or in extreme cases, mortality (Madhoun et al., 2011). Therefore, whilst there is undoubtedly a need for feeding tubes in HNC care, it is important to establish which individuals benefit from tube placement, especially given that feeding tube status has been found to be a very strong and significant predictor of QoL scores in people with head and neck cancer (Terrell et al., 1997; Terrell et al., 2004).

What the questions measure

These questions ask about feeding tube placement and use.

Validation of the questions

These are new questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

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THOUGHTS AROUND CANCER RECURRENCE

FEAR OF RECURRENCE (G1-G4)

Rationale for the questions

Fear of recurrence (FoR), which can be defined as the fear or worry that the cancer will return or progress in the same organ or in another part of the body (Vickberg, 2003) is a major concern for people following HNC treatment (Rogers et al., 2009; Humphris and Ozakinci, 2006). It can cause severe psychological stress, including anxiety and depression (Humphris et al., 2003) and is associated with reduced quality of life (Scharloo et al., 2005). These fears may not be unfounded, since 5-year survival rates in this group are 60% and prognosis following recurrence is poor (Woolgar et al., 1999). In one retrospective study, which included 278 people treated for HNC, 19% developed recurrent disease during the five-year study period (Kissun et al., 2006). People who are cured for their primary HNC often develop further disease (second primaries) because of field changes in the mucosa (Sabharwal et al., 2014). Whilst FoR is recognised, evidence suggests that concerns are often not spoken about as neither the individual with cancer nor the clinician feel comfortable raising the issue (Humphris and Ozakinci, 2006). The aim of this set of questions is to quantify FoR in this cohort and to further investigate any longitudinal trends or predictors of significant FoR.

What the questions measure

These questions are designed to assess severity of FoR. They ask people to indicate how often, if at all, they think about their cancer returning. They are given five possible answers ranging from 'Not at all' to 'All the time' or 'None of the time' to 'All of the time' depending on the phrasing of the question.

Validation of the questions

The four items used are part of the seven item scale used in (Rogers et al., 2016)

Use in head and neck 5000

The FoR questions have been used in all H&N5000 questionnaires.

Derived variables

Questions are coded on a scale of 1-5 whereby 1 indicates the least FoR and 5 indicates the greatest FoR. The scores for each of the four questions are summed to give an overall measure of FoR.

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YOUR PERSONAL COSTS

COST OF CANCER OVER THE LAST YEAR (H1-H12)

Rationale for the questions

There are financial consequences of a cancer diagnosis that can place added strain on people at a time when they are already experiencing a great deal of anxiety. In a report commissioned by MacMillan, four out of five people with cancer (83%) are on average, £570 a month worse off as a result of their cancer diagnosis (Davies, 2013). There were many reasons why the cost of day-to-day living may increase; the most common cost was found to be over-the-counter prescription medicines (despite people with cancer being eligible for free prescriptions in the UK), but other costs include specialized equipment, increased heating bills and the cost of travel to and from appointments (Davies, 2013).

What the questions measure

The questions in this section are designed to measure the expenses incurred by participants in the last year as a result of disease and treatment. The cost of cancer can be considered as a combination of loss of income and the additional costs experienced as a result of a person's diagnosis; for instance, the cost of

medications, home help or traveling to medical appointments.

Validation of the questions

The study team designed the questions in this section. They have not been formally validated.

Use in head and neck 5000

These questions were included in the four; twelve month and 3-5 year follow up questionnaires. For the 3-5 year follow up the wording was not modified, but the format was adjusted slightly for ease of completion. For instance, the instructions which ask participants to tick the appropriate box now appear above the 'yes', 'no' and 'N/A' options rather than beneath them. This is intended to make it less likely that respondents ticked the wrong box by mistake.

Derived variables

There are no specific coding rules for these questions.

REFERENCES

Davies SV, Hayes DA, Collard, SB (2013) 'Cancer's hidden price tag: Revealing the costs behind the illness'. Macmillan Cancer Support.

YOUR DENTAL HEALTH

TEETH AND DENTAL CARE (T1-T4)

Rationale for the questions

Focus groups have revealed that people with head and neck cancer experience a range of dental problems after treatment and that they report difficulties in accessing dental care and restorative treatment (Taylor et al., 2014). Identifying appropriately trained and experienced dental personnel to manage dental problems after cancer treatment is recognised as a significant challenge (Epstein et al., 2014). A survey of dentists in the North West of England found that a substantial number perceive barriers to providing dental care to people who have undergone radiotherapy to the head and neck, and that over half were not at all or only a little happy about managing such patients (Husein et al., 2011).

What the questions measure

The questions in this section are designed to identify the number of natural teeth (T1); to identify various problems with teeth and gums (T2); to describe use of dental services (T3) and barriers to dental treatment (T4).

Validation of the questions

Question T1 is a revised version of the Scottish Health Survey (SHS) dental module question 1 (ScotCen Social Research et al., 2016). People are able to provide reasonably reliable self-reported data concerning the number of natural teeth present (Axelsson and Helgadottir, 1995; Heløe LA 1972). Questions T2, T3 and T4 are also amended SHS dental questions.

Use in head and neck 5000

These questions were only used in the 3 – 5 year follow up questionnaire.

Derived variables

There are no specific coding rules for these questions.

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YOUR SYMPTOMS

LATE RADIOTOXICITY QUESTIONNAIRE (L1-L27)

Rationale for the questions

Radiotherapy (RT) plays an important role in the treatment of HNC. This treatment modality is however associated with significant acute and late toxicities that can have a huge impact on the individuals QoL (Jellema et al., 2007; Kakoei et al., 2012; Jensen et al., 2007). Toxicity is classified as acute or late, based upon when it develops relative to treatment. Acute effects occur during the initial phases of radiotherapy and can persist into the immediate post-treatment phase (2–3 weeks). In contrast, late toxicity can present months to years after the treatment has finished and may persist (Cox et al., 1995; Langendijk et al., 2008). Late toxicities occur as the results of irreparable damage to the vasculature, salivary glands, mucosa, connective tissue, and bone (Dirix et al., 2006). Injury to the parotid glands (salivary glands) can lead to xerostomia, a condition in which the glands do not make enough saliva to keep the mouth moist. Reduced salivary production can cause significant oral discomfort as well as problems with mastication (chewing), digestion, swallowing, and speech (Chao et al., 2001; Eisbruch et al., 2003; Malouf et al., 2003). Because saliva is needed to kill bacteria in the mouth, xerostomia is also associated with an increased risk of dental caries and oral infections (Malouf et al., 2003). An estimated 64% of long-term HNC survivors who have undergone RT experience a moderate to severe degree of xerostomia (Wijers et al., 2002), making it a frequently encountered late toxicity in people with HNC (Dirix et al., 2006). Measuring and reporting the severity of xerostomia and other late toxicities is challenging. Conventionally, it has been assessed by clinicians using toxicity reporting systems such as the Common Terminology Criteria for Adverse Events (CTCAEs) scale and the Late Effects of Normal Tissue/Somatic Objective Management Analytic scale (Ho et al., 2009). However, there is increasing evidence to suggest that patient-reported outcomes provide

valuable information about radiotoxicity and associated symptoms (Trotti et al., 2007; Jensen et al., 2007; Ho et al., 2009).

What the questions measure

These questions are designed to provide a self-reported measure of radiation-related acute morbidity and quality of life in people who have undergone radiotherapy for HNC.

Validation of the questions

These questions have been developed as part of the RAPPER study (Radiogenomics: Assessment of Polymorphisms for Predicting the Effects of Radiotherapy). The main objective of the RAPPER study is to understand why some patients who receive radiotherapy are more likely to experience side effects than others. The study aimed to recruit >6000 people with different cancer types, including breast; prostate; gynaecological; lung; and head and neck cancers. Questionnaires were designed specifically for each cancer group. We have used the questions outlined in the RAPPER head and neck questionnaire.

Use in head and neck 5000

The questions in this section were first used in the 12-month follow-up. They appeared as a separate late-toxicity questionnaire that was only sent out to those individuals who had undergone radiotherapy. For the 3-5 year follow up we only sent out a single questionnaire and the same questions on late toxicity can be found at the back of the document. Once again, only people who have received radiotherapy as part of their treatment were asked to complete these questions.

Derived variables

No details currently available.

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SEXUAL HISTORY

SEXUAL HISTORY QUESTIONNAIRE (questions 1 – 9)

Rationale for the questions

Human papillomavirus (HPV) is associated with several types of cancer, including head-and-neck cancers; in particular oropharyngeal cancer. HPV-positive oropharyngeal cancer (OPC) has a different natural history and prognosis to HPV-negative OPC and other head and neck squamous cell cancers (Evans and Powell, 2010). The questionnaire data will explore the link between sexual behaviour and head and neck cancer.

What the questions measure

The questions ask about sexual behaviour including the number and gender of sexual partners, sexual health and oral sex.

Validation of the questions

The questions are from a questionnaire designed by Sonia Duffy at the University of Michigan.

Use in head and neck 5000

The sexual history questions were only used at baseline. The layout was improved in 2013 to give more space between questions but the questions themselves were not altered.

Derived variables

We have grouped the number of oral sex partners as follows: never performed oral sex, 1-5 partners, 6+ partners.

REFERENCES

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YOUR QUALITY OF LIFE

THE REVISED UNIVERSITY OF WASHINGTON QOL QUESTIONNAIRE (I1 – I17)

Rationale for the questions

The University of Washington QoL questionnaire is a scale measuring the health-related quality of life in patients who have received treatment for head and neck cancer.

What the questions measure

The questions ask about views on health and quality of life in head and neck cancer patients. Scoring is scaled so that a score of 0 represents the worst possible response, and a score of 100 represents the best possible response. Scoring is scaled in equal stages from 0 to 100 to reflect the number of possible responses. For example, the pain domain has 5 possible responses which are scored as 0, 25, 50, 75 & 100.

Validation of the questions

The questionnaire is widely used and has been validated in studies by Hassan and Weymuller (1993) and the revised version of the questionnaire by Rogers et al (2002).

Use in head and neck 5000

The questions were used at baseline, 4 months and 12 months but only in a subset of participants from one hospital taking part in the study.

Derived variables

Guidance on the scoring can be found at [UW-QOL-update-2018.docx \(hancsupport.com\)](#)

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DIFFICULTIES IN YOUR LIFE

THE SOCIAL DIFFICULTIES INVENTORY (J1 – J21)

Rationale for the questions

Identifying social difficulties in patients undergoing a cancer diagnosis and treatment could help prevent or reduce distress (Smith et al 2007).

What the questions measure

The questions look at everyday problems experienced by cancer patients.

Validation of the questions

The Social Difficulties Inventory is a validated questionnaire developed for assessing social difficulties in cancer patients (Wright P et al. 2005)

Use in head and neck 5000

The questions were used at baseline, 4 months and 12 months but only in a subset of participants from one hospital taking part in the study.

Derived variables

Guidance on scoring can be found at Wright P et al., 2011 and a scoring guide can be obtained at: <https://licensing.leeds.ac.uk/product/the-social-difficulties-inventory>

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YOUR APPEARANCE

THE DERRIFORD APPEARANCE SCALE (K selected numbers)

Rationale for the questions

Head and neck cancer and its treatments can have a very visible impact on appearance and therefore affect body image and self-esteem. The Derriford Appearance Scales can be used to assess the distress and difficulties that people experience when living with problems of appearance.

What the questions measure

The Derriford Appearance Scales are a measure of concern about appearance.

Validation of the questions

The DAS24 is widely applicable, psychometrically robust and discriminates well between patient groups, between clinical and non-clinical populations (Carr and Moss 2005).

Use in head and neck 5000

The questions were used at baseline, 4 months and 12 months but only in a subset of participants from one hospital taking part in the study. The full DAS 24 questionnaire was not used. When the H&N5000 questionnaire was developed sections 9 – 18 of the DAS24 questions were not included, in their place some questions from DAS59 were used.

Derived variables

The coding manual for the DAS24 is available from <http://www.derriford.info/>

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