April 2018

Personalising Head and Neck Cancer Survivorship: Intervention with the Head and Neck Cancer Patients Concerns Inventory in Routine Head and Neck Cancer Outpatient Visits

Thesis submitted in accordance with the requirements of the

University of Liverpool for the degree of Doctor in Medicine (MD)

by

Miss Naseem Ghazali, BDS (Malaya), MBBS (London), MSc (London),
DOHNS, MRCS, FDSRCS, FRCS(OMFS)

Acknowledgements

British Association of Oral & Maxillofacial Surgeons
for providing the Research Endowment funds towards this study;

Professor Terry M. Jones, PhD, FRCS(ORL)
Mr Sank Tandon, FRCS(ORL)
Professor James S. Brown, MD, FDSRCS, FRCS(OMFS)
Professor Richard J. Shaw, MD, FDSRCS, FRCS(OMFS)
Aintree University Hospital and Whiston Hospital, Merseyside, for their participation in this study and data collection;

Professor Brenda Roe, PhD, MSc, BSc(Hons), RN, RHV, FRSPH
Faculty of Health, Edge Hill University, for her assistance with developing study concepts, study design, development of the thematic coding framework, manuscript editing and review;

Professor Derek Lowe, MSc C.Stat
Faculty of Health, Edge Hill University, for his assistance with developing study concepts, study design, data analysis and interpretation; quality control of data and algorithms, statistical analysis, manuscript editing and manuscript review;

Dr Janet M. Risk, PhD
University of Liverpool, for her assistance in developing study concepts, manuscript preparation, manuscript editing and manuscript review;

Professor Simon N. Rogers, MD, FDSRCS, FRCS(OMFS)
Faculty of Health, Edge Hill University, for his assistance in developing study concepts, study design, data collection, data analysis and interpretation, quality control of data and algorithms, manuscript preparation, editing and review;

This thesis is dedicated to
My parents and family for their faithful prayers, love and support; and,
Miss Lepa Lazarova, MRCS, for her constant encouragement and understanding throughout this long journey to completion.

TABLE OF CONTENTS *PAGE*

2.0. IDENTIFYING THE CONCERNS AND NEEDS OF HEAD AND NECK CANCER SURVIVORS

ABSTRACT

Personalising Head and Neck Cancer Survivorship: Intervention with the Head and Neck Cancer Patients Concerns Inventory in Routine Head and Neck Cancer Outpatient Visits

Naseem Ghazali

The Head and Neck Patients Concerns Inventory (HN-PCI) is a self-completed holistic tool that helps patients to disclose items of concern they wish to discuss. The MD study was designed to evaluate the roll-out of HN-PCI in subjects who were unfamiliar with it. The primary aim of the study was to evaluate HN-PCI can help patients self-disclose concerns. The secondary aims were to: (1) categorise HN-PCI items into domains; (2) develop a thematic content analysis; (5) examine associations between concerns and distress; (4) examine associations between clinicopathological factors with HN-PCI consultations; (5) determine if HN-PCI intervention changes consultations and the outcomes of consultations.

Method: The MD work was divided into 3 sections and undertaken in the following order: (1) Pilot study; (2) Domain generation; and (3) Main study. Sections (1) and (2) were undertaken designed to support the Main study. In the Main study, patients were recruited prospectively to a non-randomised study design composed of 3 blocks. Block 1 constituted normal practice i.e. control group, Block 2 constituted patients exposed to HN-PCI but doctors were not i.e. control in attention, and Block 3 was the HN-PCI intervention group. The primary outcome measures were the number of concern and selected and/or discussed. The secondary outcome measures were patient satisfaction with consultation, consultation length, distress level and clinical outputs. i.e. clinical decision or action taken related to the consultation.

Result: In the Pilot study, a content thematic framework was developed. Five domains were generated: (A) Physical and functional; (B) Psychological/emotional and spiritual well-being; (C) Social care/Social well-being; (D) Treatment-related; and (E) Other.

In the Main study, 365 patients were recruited, producing a matching number of audiorecorded consultation i.e. Block 1: 136 patients; Block 2: 78 patients; and Block 3: 111 patients. Introduction of HN-PCI generated a trend towards an increased number of concerns discussed when compared with control consultations. A broader range of expressed concerns was addressed in HN-PCI intervention group. More items within the Psychological/emotional and Spiritual well-being Domain were discussed in HN-PCI intervention groups. In the HN-PCI intervention groups, doctors were fair to moderately more likely to take on the patient’s agenda for discussion by addressing the items selected. These were achieved with a trend towards longer consultations.

Consultations with HN-PCI were significantly associated with certain clinicopathological factors. The HN-PCI intervention group showed higher number of medical outputs when compared with control group, suggesting that HN-PCI may facilitate collaborative decision-making. Patients with HN-PCI intervention showed a trend towards lower levels of distress post-consultation and reported significantly higher scores of satisfaction. This study also demonstrated that the HN-PCI was able to indirectly predict patients who experienced significant distress based on the number of items selected.

Conclusions

HN-PCI was able to help patients disclose a wider range of concerns in cohorts unfamiliar with the tool. Its use is associated with changes in the content of consultations, suggesting a more patient-concern focused consultation. This is possible to create a personalised, patient-centred HNV visit using the HN-PCI. However, there remain service-based barriers to fully realizing the HN-PCI tool in personalising HNC patient’s survivorship trajectory.

List of Abbreviations

AF	Altered fractionation
BSI	Brief Symptom Inventory
CF	Conventional fractionation
CNS	Clinical nurse specialist
CRT	Chemoradiotherapy
DAHNO	National Head & Neck Cancer Audit
DC	Discharge
DOH	Department of Health
DNA	Deoxyribonucleic acid
DT	Distress thermometer
EGFR	Epithelial Growth Factor Receptor
ENT	Otorhinolaryngology
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of life questionnaire, core-30
FDA	Food and Drug Agency
FOR	Fear of recurrence
FF	Free flap
FU	Follow up
GHQ-12	General Health Questionnaire-12
GWB	General wellbeing
Gy	Gray
HADS	Hospital Anxiety Depression Scale
HNC	Head and neck cancer
HN-PCI	Head and neck Patients Concerns Inventory
HRQOL	Health-related quality of life
HPV	Human Papillomavirus
Ix	Investigations
IxRes	Investigation results
IQR	Inter-quartile range
MDT	Multidisciplinary team
NCAT	National Cancer Action Team
NCCN	National Comprehensive Cancer Network
NHS	National Health Service
NICE	National Institute of Clinical Excellence
OMF	Oral & Maxillofacial
ONS	Office for National Statistics
PCI	Patients Concerns Inventory
PEG	Percutaneous endoscopic gastrostomy
PORT	Postoperative radiotherapy
PSQ-MD	Princess Margaret Hospital Patient Satisfaction with Physician
PRO	Patient –reported outcome
PROC	Patient-reported outcomes of consultation
QOL	Quality of life

RND	Radical neck dissection
RT	Radiotherapy
SCC	Squamous cell carcinoma
SD	Standard deviation
SE	Standard error
TMJ	Temporomandibular joint
TPF	Taxanes with cisplatin and fluorouracil
TST	Touch-screen technology
Tx	Treatment
TxCompl	Treatment complications
UK	United Kingdom
US	United States of America
UWQOL	University of Washington Quality of Life, version 4
WHO	World Health Organization
WL	Waiting list

List of Figures

List of Tables

CHAPTER 1

1.0. INTRODUCTION

1. 1. Cancer survivorship

The widely held, deep-rooted perception of cancer as “a death sentence” [**Ardnt et al, 2007**] is now challenged by contemporary evidence of falling cancer-related mortality rates [**Seigel et al, 2011**]. Advances in cancer management means that cancer is no longer regarded as a terminal illness for many patients. Assimilation of novel therapeutic developments into the standard of care for many cancers has successfully cured cancer or transformed its course into a long-term or chronic condition. Where long-term survival is now expected, the accompanying downside is that many will live with a host of cancer treatment after-effects that may significantly impact upon their health status and quality of life (QOL). Thus, a cancer diagnosis is not only life changing but also marks the beginning of a challenging journey into a new normality.

The rising numbers of individuals diagnosed with cancer annually, as well as improving survival rates, have led to a sustained increase in the number of cancer survivors [**Seigel et al, 2012**]. There are several definitions of cancer survivors. In the United States of America (US), the term “cancer survivor” describes any person who has been diagnosed with cancer, from the time of diagnosis through the balance of life [**Seigel et al, 2012**]. In the United Kingdom (UK), the accepted interpretation of the “cancer survivor” includes not only those who are living with or beyond cancer, but also the carers and families of survivors [**Department of Health (DOH), 2010**]. “Cancer survivorship” is a temporal passage with at least 3 distinct phases, including the time from diagnosis to the end of initial treatment, the transition from treatment to extended survival, and long-term survival [**Mullan, 1985**], and incorporates a range of experiences from those undergoing primary treatment and post-treatment remission to those who have achieved cure, and those with advanced or active disease [**DOH, 2010**].

In the US, there were an estimated 13.7 million cancer survivors at the start of 2012 [**Seigel et al, 2012**]. The majority (64%) of these survivors were diagnosed 5 years or more, and nearly one-half (45%) were aged 70 years or older [**Seigel et al, 2012**]. In the UK, there are an estimated 2 million cancer survivors, or approximately 3.3% of the UK population [**Maddams et al, 2008**]. Indeed, 10% of those aged over 65 years in the UK currently are cancer survivors [**Maddams et al, 2008**]. The numbers of cancer survivors are expected to increase to nearly 18 million by 2022 in the US [**Seigel et al, 2012**], while in the UK, an expected rise is predicted at a rate of 3.2% annually [**Maddams et al 2008**].

The size of this fast-growing trend has unsurprisingly resulted in a paradigm shift in the national approach to cancer from "survival" towards "cancer survivorship", where the focus of cancer survivorship is centred on recovery, wellbeing and health following completion of treatment [**DOH, 2010**]. Many survivors, including those who are cancer-free, must cope with the chronic effects of treatment, as well as psychological concerns, such as, fear of recurrence [**Seigel et al, 2012**]. In addition, cancer patients and survivors face a variety of medical and social concerns dependent on their age, comorbid conditions, socioeconomic status, and family/support network. It is paramount that survivors and their caregivers have the support and access to services they need to resume as normal a lifestyle as they can, after cancer treatment. The shift towards cancer survivorship is underpinned by a change in the approach to aftercare [**Davies & Batehup, 2011**] i.e. a need to personalise treatment/care plans by relying on self-reported assessments of individual needs and concerns, is critical in empowering patients towards self-management [**DOH, 2010].** In addition, a greater emphasis is placed on the prompt recognition and planning for treatment after-effects, and also for the early identification of further disease during the post-treatment period [**DOH, 2010**].

Interesting parallels can be drawn between the approaches adopted in cancer survivorship and the management of chronic conditions. The term "chronic condition" encompasses disability and disease conditions that people may 'live with' over extended periods of time (i.e. > 6 months) [**Lawn & Schoo, 2010**]. Arguably, post-treatment cancer survivors may fall within this definition. The central themes of personalised medical care [**Abrahams & Silver, 2009**; **Morton et al, 2009**], the use of patient-reported outcomes/assessments [**Her & Kavanaugh, 2012**], empowering patients towards self-management [**Tattersall, 2002**; **Bodenheimer et al, 2002**] and supporting self-management that are used in chronic conditions resonates within cancer survivorship. This is probably because self-management of persons with chronic conditions is amenable to generic approaches based on the understanding that there are generic self-management tasks regardless of diagnosis [**Lawn & Schoo, 2010**].

Personalised medical care aims to individualise care by integrating a person's unique clinical, molecular (i.e. genetic, genomic) and environmental information [**Ginsburg & Willard, 2009**]. Clinical and biological data from individual patients are traditionally used in oncology treatment decision-making and prognosis. Advances in genomic medicine, where information from the genomes and their derivatives are used in clinical decision-making, has enabled can more precise guidance in treatment-decision making and in the prediction of outcomes [**Ginsburg & Willard, 2009**]. However, integral to personalising medical care are patient-reported outcome (PRO), an important source of health status and outcome assessments [**Acquandro et al, 2003**]. PRO is defined as '*any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else'* [**Food Drug Agency (FDA), 2009, page 2**]. PRO aids in accomplishing the task of assessing individual risks, needs and preferences based on the patient's own perspectives on these issues, which are essential building blocks to personalising care.

Among PRO measures in cancer, health-related quality of life (HRQOL) is the best characterised. HRQOL measures are distinguishable by having an evaluative feature to a patient's subjective assessment of the important aspects of their wellbeing i.e. symptom impact, functional status, and/or global wellbeing [**Lipscomb et al, 2007**]. Most HRQOL functional measures are multidimensional, designed to reflect multiple domains of impact, often including physical, psychological, and social domains [**Lipscomb et al, 2007**]. The development of HRQOL is achieved through strict methodological process to produce tools with validated psychometric properties to ensure that they are fit for research purposes, in particular, clinical trials [**FDA, 2006**]. This rigid approach means that HRQOL tools are usually applied within a narrowly defined objective.

Nevertheless, adopting HRQOL PRO as a tool for routine clinical use is prevalent due to its availability and multidimensionality. The HRQOL PROs have been applied in routine clinical settings as a way of personalising the care of chronic conditions, particularly in appraising and managing the psychosocial concomitants of illness. Psychological suffering has been described using terms such as anxiety, worry, concern, fear and distress, which are frequently used interchangeably [**Anderssen-Segesten et al, 1989**]. Among the associated terminology, distress is considered as an important vital sign in cancer survivorship, and it is often associated with unmet needs among cancer survivors [**Carlson et al, 2012**]. Unaddressed worries, needs and concerns can impact the cancer patient’s health status negatively [REF]. The main challenge with identifying unmet needs of cancer patients lies in the wide spectrum of potential worries and concerns that may be experienced, these are often individualised by the patient’s personal circumstances, which may change at different time points of their survivorship. In this situation, HRQOL-based assessments may be inadequate. Instead, holistic assessments are advocated to help screen for unmet needs of survivors and their caregivers [**Richardson et al, 2005**]. Undertaking timely holistic assessments during their survivorship journey may help understand patients’ individual needs, preferences and circumstances at particular time points of their journey. Enabling patients to disclose their unique needs and concerns using appropriate PROs can facilitate discussions that address these issues. Thus, the information gained from this PRO is the first step towards delivering personalised care.

1.2. Head and Neck Cancer

Head and neck cancer (HNC) is a complex disease characterised by clinicopathological heterogeneity arising from various anatomical sites, encompassing the oral cavity, pharynx (includes the nasopharynx, oropharynx, hypopharynx), larynx, paranasal sinuses, and the salivary glands. This disease is the sixth most common cancer worldwide, accounting for 3.2% of all malignancies [**Jemal et al, 2010**]. There is considerable geographical variance in HNC incidence worldwide where highest reported rates are in some regions of France (e.g., Bas-Rhin, male incidence: 63.58 cases per 100,000) and in India/central Asia [**Seiwert & Cohen, 2005**]. In the UK, an estimated 7354 new cases of HNC were diagnosed in England and Wales during 2010-11 [**National Head and Neck Cancer Audit (DAHNO), 2012**], which has risen from the 6,700 cases estimated in 2005-06 [**DAHNO, 2007**].

The incidence of HNC increases with age, where 98% and 50% of diagnosed patients are over 40 and 60 years of age, respectively [**Mehanna et al, 2010**]. HNC is associated with a male preponderance, where the male to female ratio reported by large epidemiological studies and national cancer registries varied from 2:1 to 15:1 depending on the primary site [**Mehanna et al, 2010**]. The UK Office for National Statistics

(ONS) report on cancer incidence and mortality during the 2008-2010 period indicates that the age-standarised incidence for cancers of the lip, mouth and pharynx was 13.6 and 6.3 per 100,000 for men and women respectively, while for laryngeal cancer, this was 5.3 and 1.0 per 100,000 for men and women respectively [**ONS, 2012**]. A recent change in HNC epidemiological trend in the UK has seen a two-fold increase in the incidence of oropharyngeal cancer in just over a decade [**Oxford Cancer Intelligence unit, 2010**]. This rise was similarly observed in US [**Shiboski et al, 2005**] and occurred predominantly among the younger age group, which may partially be attributed to infection by the Human Papillomavirus (HPV) [**Hammerstedt et al, 2006; Mourad et al, 2017**].

The main aetiological factors in HNC are lifestyle-related, which interact with genetic predisposition and other environmental factors. Tobacco (smoked and smokeless types) and alcohol usage are established HNC risk factors and are prevalent in 75% of cases [**Mehanna et al, 2010**]. They are often present together and can act more than multiplicative in increasing the risk of HNC [**Hashibe et al, 2010**]. Despite marijuana smoking containing carcinogens similar to tobacco smoke, reports from large epidemiological studies found that infrequent marijuana smoking does not confer the risk of HNC but may carry a moderately high risk among the non-smoking, teetotal subgroup of patients [**Berthiller et al, 2009].** Betel quid chewing is a major HNC risk factor in endemic areas, which is related to exposure to the carcinogenic agent in areca nut, a component frequently found in the betel quid mixture [**Chen et al, 2008**]. Poor socioeconomic circumstance is associated with an increased risk of HNC [**Conway et al, 2010a**; **2010b**]. The specific socioeconomic factors associated with an increased risk of HNC may vary with areas evaluated, indicating modulating effects of other environmental factors. For example, socioeconomic circumstances associated with higher risk of HNC in Scotland were those living in areas most deprived, the unemployed and those with lower levels of education, but multivariate analysis only found smoking to be the only significant risk factor [**Conway et al, 2010a**].

There is increasing substantiation for genetic predisposition in HNC. Large observational studies report the occurrence of familial aggregations of HNC, where the risk of HNC is estimated to be three- to eightfold in first-degree relatives of HNC patients [**Jefferies et al, 1999**]. In addition, HNC has been reported in several rare cancer types that are clearly genetically determined, e.g., Fanconi's anaemia, Xeroderma pigmentosa, Li-Fraumeni syndrome, where there is a marked increased cancer risk amongst gene carriers [**Trizna & Schantz, 1992**]. More recent molecular epidemiology studies report that normal polymorphisms in some genes that mediate DNA repair, carcinogen metabolism, and cell cycle control, could increase the risk of HNC [**Sturgis & Wei, 2002; Cadoni et al, 2012**].

Infection with tumourigenic viruses is an important risk factor for HNC. The Epstein-Barr virus is associated with nasopharyngeal carcinoma [**Chang & Adami, 2006**]. More recently, there is evidence for Human Papillomavirus carcinogenicity in HNC, particularly in oropharyngeal cancers [**Kreimer et al, 2005**]. Exposure to and transmission of virus is attributed to sexual contact, where certain sexual behavior and practices are associated with an increased risk for HNC [**Heck et al, 2010**]. Dietary intake can influence the risk of developing HNC. Large epidemiological studies have found that the HNC risk may be reduced with dietary intake rich in fresh fruits and vegetables [**Chuang et al, 2012**; **Bradshow et al, 2012**; **Freedman et al, 2008**]. The risk for HNC is higher with diets containing high-fat and processed meats [**Bradshaw et al, 2012**], and in those with red meat [**Chuang et al, 2011**]. In addition, nasopharyngeal carcinoma is related to a high consumption of salt-preserved fish, a traditional staple food with carcinogenic potential in several nasopharyngeal carcinoma-endemic areas [**Chang & Adami, 2006**]. Other environmental factors include material deprivation, which is associated with a higher incidence and poorer outcomes of HNC [**O'Hanlon et al, 1996; National Head & Neck Cancer Audit** (**DAHNO), 2006**].

Patients with HNC can present with a variety of symptoms, depending on the primary site involved and the resultant functional deficit [**Mehanna et al, 2010**]. Occasionally, some are asymptomatic or present only with cervical node disease associated with an unknown primary. Patients with advanced disease at first presentation form a significant proportion of cases, particularly in developing countries and in racial/ethnic minorities living in developed countries [**Kowalski et al, 1994**]. However, the vast majority of HNC patients present with potentially curable local or locoregional disease, as metastatic disease is uncommon [**Mehta & Harrison, 2007**].

More than 90% of all malignant tumours in the head and neck are squamous cell carcinomas (SCC) arising from the lining mucosa [**DAHNO, 2007; DAHNO, 2012**]. HNC SCC spreads preferentially via the lymphatic channels to the regional lymph nodes in the neck, where positive nodal involvement carries a poor prognosis [**Greenberg et al, 2003]**. Cervical metastasis was present in 47% of neck dissection material from a large study of newly diagnosed HNC [**Woolgar, 2007**]. The predominant pattern of cervical node spread found was the 'inverted-cone pattern' (67%) and the extent of metastasis (both by volume and distribution) was greatest in tumours of the oropharynx followed by lateral tongue, ventral tongue and floor of mouth [**Woolgar, 2007**]. Extracapsular spread was present in 29% of cases [**Woolgar, 2007**] and this is particularly significant because extracapsular spread is a reliable predictive factor of locoregional recurrence, distant metastasis, and disease-specific mortality [**Greenberg et al, 2003**]. Other pathological factors that carry prognostic significance are the primary site involved, tumour size, thickness, and pattern of invasion [**Brown et al, 2006**].

Optimal management of HNC is by a multidisciplinary approach [**National Institute of Clinical Excellence (NICE), 2004**; **Perri et al, 2013**], where treatment mainstays are surgery, radiotherapy and chemotherapy. Decisions about treatment are often complex, as this process must weigh up treatment efficacy and likelihood of survival against the potential functional and quality of life outcomes [**Mehanna et al, 2010**]. The head and neck region is critical to speech, swallowing, salivation, taste/smell, vision, and is also central to body image and personal identity. These functions are frequently impaired by disease and the sequelae of treatment. The mode of treatment largely depends on the primary site, stage of disease and the patient’s overall health status. In most early stage (I and II), single modality therapy by surgery or radiotherapy (RT) is the initial treatment of choice, where there is 60–95% chance of cure with local treatment alone [**Rogers et al, 2003**]. On the other hand, multimodality therapy is often utilised for locally advanced disease, due to the higher risk of recurrence and development of distant metastasis [**Seiwert & Cohen, 2005**]. For example, surgery combined with chemotherapy and RT can improve overall survival in patients with advanced oral cancers. Cure rates vary by site and stage, ranging from more than 90% in lip and early stage laryngeal cancers to 55% and less for advanced, non-metastatic oral cavity, oropharyngeal, hypopharyngeal and laryngeal cancers.

Curative HNC surgery involves complete resection of the primary tumour with adequate margins of normal appearing tissues (approximately 1.5 to 2cm) and elective neck dissection for locoregional control [**Sutton et al, 2003**]. Access to the primary site is usually amenable transorally, while in some cases; an additional surgical procedure to improve access is required. The surgical defect created may be primarily closed, although reconstruction of the surgical defect is often necessary to optimize healing and function following tissue loss. The goal of improvements in HNC surgery is to overcome the significant functional and cosmetic defects resulting from the traditional radical approach. Newer diagnostic techniques, e.g., sentinel node biopsy and flurodeoxyglucose-PET scans, can help avoid futile extensive surgery and are increasingly used to guide surgical planning [**de Bree & Leemans, 2010**]. Technical developments producing less invasive surgical approaches can spare important anatomical structures while maintaining efficient control of local disease. This includes the use of selective neck dissection [**Robbins et al, 2002; Robbins et al, 2008**], sentinel node biopsy [**Jackson et al, 2017**], transoral lasers surgery [**Li & Richmon, 2012**], transoral robotic surgery [**Weisnstein et al, 2012**] and intraoperative navigation technology [**Jackson et al, 2017].** In addition, innovations in microvascular tissue reconstruction have enabled the repair of complex surgical defects using free-tissue flaps with reasonably good cosmetic and functional outcomes [**Wehage & Fansa, 2011**]. Despite the obvious functional and cosmetic drawbacks of major radical surgery, 95.6% of HNC patients who were disease-free at 12 months postoperative FU would still opt for surgery due to its cure rates over other treatment option with a possibly improved quality of life but with a lower chance of cure [**Vartanian & Kowalski, 2009**].

Overall, RT is utilized in approximately 78% of HNC patients, where it may be employed as a single modality treatment, or adjuvant to surgery, and/or in combination with systemic agents [**Delaney et al, 2005**]. Megavoltage external beam RT is usually directed to the primary site and the cervical draining lymphatic system. Brachytherapy is an alternative method, where localized irradiation is administered through the implantation of radiation needles into or in close proximity to the tumour. However, this technique is seldom utilised in HNC nowadays. The therapeutic radiation dose to the primary site is usually from 50 to 70 Gy, with 40 to 50 Gy delivered to the adjacent lymph nodes. While there are many regimes, most protocols administer radiation in fractions over a designated time period. Conventional fractionation (CF) regimes typically involve single daily fractions of 1.8-2 Gy, 5 days per week for 7 weeks [**Bourhis et al, 2006]**. Non-conventional fractionation (or altered fractionation, AF) includes accelerated fractionation and hyperfractionation. The aim of altered fractionated RT is to increase the dose intensity of treatment, either by increasing the total dose (hyperfractionation) or by reduction of the overall treatment time (acceleration). The MARCH meta-analysis of 15 randomised trials comparing AF with CF in non-metastatic HNC found improved survival benefits and better locoregional control with AF, where hyperfractionation had the greatest benefit relative to accelerated fractionation [**Bourhis et al, 2006]**.

RT is frequently used adjuvant to surgery. Postoperative radiotherapy (PORT) is accepted as the standard of care in HNC patients deemed at high risk of recurrence i.e. evidence of involved margins at the primary site and the presence of extracapsular spread in regional lymph nodes [**Huang et al, 1992**; **Brown et al, 2007**]. The role of PORT is debatable in a subset of HNC patients who demonstrate other pathological characteristics that are suggestive of potential aggressive behavior i.e. showing an intermediate risk of recurrence. **Brown and coworkers [2007**] found that patients with intermediate risk of recurrence who received PORT had poorer 5-year survival rates than those receiving surgery alone (54% versus 71%, p=0.002). In addition, the salvage rates of those who received surgery alone were significantly better than those who received PORT (53% versus 13%, p=0.02). The results of this study seem controversial because it contradicts the prevailing view that PORT confers therapeutic advantage in reducing the likelihood of recurrence. However, this finding probably reflects the poor predictability of using microscopic pathological features in forecasting clinical behavior and treatment response. Molecular subtyping of HNC may provide better correlation with clinical aggressiveness and therapeutic response. This revolutionary approach has been established in breast [**Moriya et al, 2010]** and prostate cancers **[Kachroo & Gnanapragasam, 2012**].

The concept of ‘organ and function preservation’ is central to the management of locally advanced HNC. This concept involves preserving an organ so that it remains satisfactorily functional with improved quality of life while maintaining or exceeding the survival rates of non-organ preserving strategies i.e. surgery, in locally advanced disease [**Mehta & Harrison, 2007; Conley et al, 2001**]. Traditional ‘organ preservation therapeutic strategies’ for locally advanced HNC involves the combined use of RT with chemotherapy (CRT). In this scenario, chemotherapy has been used as induction treatment, concomitantly with RT, or as adjuvant treatment after radiotherapy.

Early clinical trials of induction chemotherapy using cisplatin/fluoroucil followed by RT against standard surgical treatment in locally advanced laryngeal and hypopharyngeal/pyriform cancers reported organ preservation in about two-thirds of survivors, without any significant survival difference between treatment arms [**Veterans Affair, 1991; Lefebvre et al, 1996**]. More contemporary studies of induction chemotherapy have used a combination of taxanes with cisplatin and fluorouracil (TPF) in locally advanced HNC with promising results. A recent meta-analysis of these studies found that TPF induction chemotherapy regime leads to a significant survival advantage over a 3 year period with acceptable toxicity rates for patients with locally advanced HNC compared with the cisplatin-fluoroucil regime [**Qin et al, 2012**]. However, this regime is relatively new and is not widely used.

The standard of care for locally advanced HNC SCC is concomitant CRT [**Bourhis et al, 2012**]. The MACH-NC meta-analyses of 93 randomised HNC clinical trials found that concomitant CRT was associated with an increase in survival of 6.5%, a 12–13% improvement in locoregional control, and about a 3% decrease in distant metastases in comparison to RT alone over a 5 year period [**Pignon et al, 2000**; **Pignon et al, 2009**]. Nevertheless, concomitant CRT is associated with a higher incidence of acute and late toxicities [**Denis et al, 2003**].

Advancements in organ preservation strategies aim to reduce toxicity in normal tissues. Intensity modulated radiation therapy allows specific tumour targeting whilst simultaneously eliminating or substantially reducing the radiation dose to normal tissues. This technique delivers high radiation doses directly to cancer cells in a very targeted way, much more precisely than is possible with conventional RT, thereby reducing RT exposure to non-cancer tissues [**Gutiontov et al, 2015**].

Local and regional recurrences account for up to 90% of treatment failures after surgery and RT. Most studies corroborate that the median time to recurrence is 7.5 months after treatment, and 86% of the recurrences occur within 24 months [**da Silva et al, 2012**]. When primary HNC treatment fails from refractory disease or tumour recurrence, defining the best therapeutic option is a challenge. The available treatment options include re-irradiation [**Patel & Salama, 2012**] or salvage surgery [**Brown et al, 2008**]. Chemotherapy may be the only remaining option whenever salvage surgery or re-irradiation is not feasible, but this modality lacks significant or sustained efficacy

[**Vermorken et al, 2007**]. Newer biological agents developed to specifically target known dysregulated pathways, may be beneficial in this instance. Clinically tested molecular targeted agents in HNC have largely centered on epidermal growth factor receptor (EGFR) inhibitors and anti-angiogenic therapies, which include the modulation of vascular endothelial growth factor or its receptor. Encouraging results have been reported with anti-EGFR therapy, particularly with cetuximab, but targeted therapy trials in HNC to date have largely lacked efficacy or are associated with significant toxicity [**Razak et al, 2010**]. With the development of recurrent disease, the 5-year survival rate is between 20-30%.

Survival remains the primary outcome measure for HNC treatment. Overall, treatment outcomes for HNC are encouraging. In the US, trends estimated from 1975 to 2007 suggest an improvement in the 5-year survival rates for oral cavity and pharyngeal cancers and a slight reduction for laryngeal cancers. The 5-year survival rates during the period of 1975-1977, 1987-1989 and the projected rate for 2001-2007 for oral cavity and pharynx cancer were 53%, 54% and 63%, respectively; while for laryngeal cancers, the 5-year survival rates for the corresponding time periods were 66%, 66% and 63%, respectively [**Siegel et al, 2012**]. Elsewhere, improvements in HNC survival rates have also been reported in the UK [**Rogers et al, 2003**] and in some parts of Europe [**Guizard et al, 2017**]. Improvements in cancer outcomes may be attributed to early diagnosis and improvements in HNC management.

Health-related quality of life (HRQOL) is a recognised secondary outcome measure in HNC treatment [**Verdonck-de Leeuw et al, 2012; Heutte et al, 2016**], which is determined using validated patient-reported outcome measures [**Chandu et al, 2006**]. HNC-specific validated HRQOL tools are multidimensional covering physical, functional and psychosocial domains that may be altered by the disease and treatment [**Heutte et al, 2016; Pusic et al, 2007; Ringash & Bezjak, 2001**]. The treatment modalities employed in HNC are potent but toxic. HNC treatment-related toxicities can result in varying degrees of symptom burden, functional deficit and facial deformity, which associate negatively with HRQOL status. Prospective studies of HRQOL in HNC cohorts found that HRQOL is often compromised at diagnosis (baseline), becomes worse during the first year post-treatment, and approaches or attains pretreatment levels at 12-18 months post-treatment [**Hammerlid et al, 2001**; **Oskam et al, 2013; Chandu et al, 2006**], which is stable at 5-year follow up (FU). With long-term FU, while there is reasonable HRQOL status, some of the deficits from baseline levels are reportedly due to worsening statuses in selected dimensions of general HRQOL status, and in head and neck HRQOL–specific dimensions [**Oskam et al, 2013**]. This deterioration may be attributed to continued suffering from various disease- and treatment-related impairments many years after treatment, and these contribute towards decreased life satisfaction [**Mehanna & Morton, 2006; Moore et al, 2014**]. Having attained survivorship with curative treatment, the need for supportive care is greater than ever for HNC patients as they adjust to a new normality.

1.3. Head and Neck Cancer Survivorship: Unmet Needs and Concerns

There is high prevalence of unmet need for supportive care, particularly psychosocial needs among HNC survivors [**Henry et al, 2016; Guilani et al, 2016**]. Unmet psychosocial needs can negatively impact on HRQOL, and also on many aspects of care, from compliance to successful survivorship [**Gold, 2012**]. HNC survivors and their caregivers encounter a whole range of issues, concerns and needs [**Rogers et al, 2009; Wells et al, 2015].** These needs and concerns vary between patients, and also at different time point of an individual’s journey. Hence, a personalised approach may be better suited to address this problem adequately rather than a ‘one-size-fits-all’ approach.

The primary problem with unmet need is uncovering and identifying what these concerns and needs are. This requires specifically asking patients what their needs are because studies have shown that patients are reluctant to initiate these conversations with doctors. Doctors are beginning to realize that the routine HNC FU clinics offer opportunities to identify and address the unmet need in HNC survivorship rather than the sole purpose of secondary surveillance [**Simcock & Simo, 2016**].

Undertaking holistic assessments may be a way of achieving this because this process evaluates a diverse range of issues, concerns and needs that patients may have [**O’Brien et al, 2017; Guilani et al, 2016; Balfe et al, 2016; Well et al, 2015; Rogers et al, 2009**]. This is an area of significant importance in the national cancer survivorship strategy, where holistic assessments have become a standard of care for all cancer survivors [**DOH, 2007; National Cancer Action Team (NCAT, 2011**]. It is recommended that holistic assessments are self-completed by patients while in conversations with professionals, and there are a range of tools available that can assist this process [**Richardson et al, 2007**].

There is evidence that the Head and Neck Patients Concerns Inventory (HN-PCI), a holistic PRO designed to help HNC patients disclose their concerns during routine HNC FU visits. Serving as a prompt sheet, the HNC-PCI can help highlight concerns and uncover unmet needs for discussion and may improve patient-doctor communication, and promote patient-centred care.

1.4. Significance of this Study

Creating a new way of approaching HNC survivorship that is tailored to patients individual circumstances has the potential to improve their post-treatment lives. The combination of the type of cancer, its site, the treatment received, the patient's age at diagnosis, length of FU from diagnosis, underlying genetic make-up, concomitant comorbidities, personality traits, family and social circumstances all combine to make their individual circumstances unique [**Davies & Batehup, 2011; Watson et al, 2012**].

Screening for individual needs and concerns in the post-treatment phase can play a central role in personalising the care they receive during cancer survivorship. Identifying unmet needs and patient preferences, understanding their goals and health status can help promote a collaborative approach, where patients and doctors work together in addressing their concerns. In this way, the shared discussion and decision-making becomes personalised to the patient [**Davies & Batehup, 2011]**.

Since its introduction, the evidence available relating to the HN-PCI is predominantly associated with a single practitioner in a single hospital, where identification of individual patient's unmet needs using this tool has led to discussions that address the concern in clinic or resulted in referral to specific services or other professionals [**Rogers et al, 2009; Ghazali et al, 2012**]. With HN-PCI in use, any clinical decision made is more likely to be the result of collaborative decision-making based on discussions directed by the concerns selected by patients on the HN-PCI. As such, there is merit in exploring the introduction of HN-PCI to other doctors and patients within the bigger catchment area of the regional HNC unit. This way, it would be possible to evaluate if the clinical impact obtained was due to the tool and not influenced by a single practitioner at a single site.

This MD study examines the routine use of HN-PCI by HNC surgeons of two different specialties and their patients, who are unfamiliar with the HN-PCI. This study explores the potential of this tool in personalising not only the clinic discussions, but also in the care received by post-treatment HNC patients. While this study is not designed to provide definitive answers, it is hoped that it can inform future practices in improving HNC survivorship.

1.5. An overview of MD thesis

An overview of the MD thesis is presented here. Following this brief Introduction chapter, the succeeding Chapters 2 and 3 will provide with a greater detail the background understanding in the areas pertinent to this study.

Chapter 2 discusses the subject of identifying patients' concerns and needs during survivorship. This chapter provides an overview and description of the key concepts of this thesis. The concept of patient-centred care is regarded as the basis for identifying patients' concerns and needs during survivorship. The challenges encountered in identifying patients' needs and concerns during routine outpatient cancer clinics are described. An attempt to clarify interchangeable terms i.e. "need", "concern", "problems", "issues", was undertaken. The relationship between "need" and "concern" was proposed. This chapter also explores the methods of how needs and concerns have been assessed or identified in cancer care, including holistic (needs) assessment, patient-doctor communication, and the use of prompt sheets. The concept of the 'Patient Concerns Inventory' was introduced, and this was discussed in context of patient empowerment, enablement and self-management. The Head and Neck Cancer Patient Concerns Inventory (HN-PCI) was described comprehensively, including its development and validation, usage, and the impact of the instrument on clinical outcomes. Theoretical models underlying the HN-PCI were proposed as the basis for this MD work.

Chapter 3 specifically deals with head and neck cancer survivorship. A literature review was undertaken to explore for gaps in knowledge of the subject, and the chapter summarises current understanding of the key issues that head and neck cancer patients and their carers experience during the survivorship trajectory. These issues constitute the central theme of this work, and facilitate the development of the thematic framework used in content analysis of items of concern from recorded consultations.

Chapter 4 provides an overview of the work carried out in this MD thesis, which was composed of three empirical studies i.e. Pilot study, Domain generation study and Main study. This chapter provides the rationale for the MD work, its conception, aims and summarises each empirical study to provide an understanding of how each study relates together. The patient-reported outcome measures commonly used throughout the empirical studies of the MD work are also presented here.

Chapters 5, 6 and 7 detail the three empirical studies undertaken in this thesis. Chapter 5 relates to the Pilot study. Chapter 6 relates to the Domain generation study. Chapter 7 deals with the Main study of the thesis. The individual chapters contain the specific study aims and objectives, methodology employed, the results and discussion pertaining to the three empirical studies.

Chapter 8 provides the main conclusions of the MD thesis. The bibliography and appendices sections are cited at the end.

2.0. IDENTIFYING THE CONCERNS AND NEEDS OF HEAD AND NECK CANCER SURVIVORS

2.1. Introduction

The recent decade has seen significant change to the epidemiological trends in head and neck cancer (HNC), where patients are being diagnosed at a younger age with HPV-positive disease. Longer life expectancy means that many more HNC patients are expected to journey into long-term survivorship. While undergoing active treatment, patients and their caregivers have direct access to healthcare professionals in dealing with their needs and concerns. However, once treatment is completed, access to supportive services may be less accessible.

The course of HNC survivorship is not the same for every survivor due to the combination of disease heterogeneity, multimodality treatment delivered, and unique sociobiological circumstances of the individual patient. Thus, the supportive needs of HNC patients are equally diverse, and the inability to identify these needs can result in the festering of unmet needs, which can impact on cancer survival and health-related quality of life.

Identification of HNC patients' needs and concerns is the central subject of this MD thesis. This chapter explores the key conceptual matters that form the basis of this work. The subject matter was initially considered using a broad-brush approach, where fundamental ideas were identified. These include 'patient-centred care in medicine', the concept of 'need in health care' and the concept of 'patient empowerment'. Further exploration of these fundamental concepts involved examination of specific details to clarify related terminology, and to understand how these concepts transformed into healthcare policies e.g. holistic (needs) assessment.

This chapter considers the factors that influence the quality delivery of holistic (needs) assessment, particularly the use of patient-reported outcomes (PRO) to enhance the communication that occurs during this process. A theoretical framework is presented to explain the role of PROs in the dynamic encounter. The use of PROs is compatible with concept of patient empowerment in managing long-term survivors of cancer and in those with chronic illnesses.

Finally, this chapter addresses the concept of Patient Concerns Inventory, its common approach based on patient empowerment in those with long-term chronic conditions, and its influence in the development of the Head and Neck Cancer Patients’ Concerns Inventory (HN-PCI), a PRO that helps patients disclose their concerns. A comprehensive review of all published papers relating to HN-PCI was undertaken, and provides the background and rationale for this current work.

2.2. Patient-centred care in cancer survivorship

2.2.1. The concept of patient-centred care

‘Patient-centredness’ in medicine was introduced in the mid 1950s [**Balint, 1955**]. This concept suggests that patients should be understood as a unique being, and seen in their biopsychosocial entirety [**Mead & Bower, 2000**]. Central to this approach is where the provider ‘*tries to enter the patient’s world to see illness through the patient’s eyes*’ [**McWhinney, 1989**] and the resultant care provided is ‘*closely congruent with, and responsive to patients' wants, needs and preferences*' [**Laine & Davidoff, 1996**]. A comprehensive definition for patient-centred care is proposed by the US Institute of Medicine **[Committee on Quality of Health Care in America, 2001]** as being care with the following characteristics: (a) responsive to consumer needs, values and preferences; (b) integrated and coordinated; (c) relieves physical discomfort; (d) provides emotional support; (e) allows for the involvement of family and friends; and (f) supports the provision of information, communication and education to enable patients to understand and make informed decisions about their care.

As new directions and models in health care systems evolve, patient-centred care has acquired an increasingly prominent role in achieving quality care for patients and their caregivers [**Jayadevappa & Chhatre, 2011**]. Fundamental to patient-centred care is enhanced clinician–patient communication with the primary attributes of compassion, empathy, and responsiveness to the needs, values, and expressed preferences of the individual patient [**Perrochia et al, 2011; Committee on Quality of Health Care in America, 2001**].

Research evidence relating to patient-centred care may be categorised in two ways [**Lutz & Bowers, 2000**]. The first category considers patient-centred care in re-organisation of services around patients' needs. This approach considers implementation of patient-centredness in restructuring and integration of services [**Wakefield et al, 1996**], and provides the benchmark for delivery of quality care, particularly in those with chronic conditions [**Harrison et al, 2009**]. This approach in cancer is exemplified in the incorporation of patient-centred care as a key strategy in NHS policy for cancer care services [**DOH, 2004**], the National Cancer Survivorship Initiative [**DOH, 2010**] and the most recent NHS cancer policy, the Cancer Strategy Implementation Plan [**NHS England, 2016**].

The second category defines patient-centred care as efforts towards understanding and meeting patient-perceived needs, priorities, and expectations for health care in clinical practice. This approach is influenced by the quality of the interaction between the provider and the patient. According to **Street et al** [**2009**], the principle functions of patient-centered communication are the exchange of information, supporting patients' self-management, the management of uncertainty and emotions, decision making and enhancing the physician-patient relationship.

A patient-centred approach is widely acknowledged as a core value in clinician-patient interactions in the management of chronic conditions, in primary care settings [**Hudon et al, 2012**], and in cancer care [**Zucca et al, 2014].**

2.2.2. Patient-centred care in cancer

From a practical standpoint, patient-centred care in cancer is unlikely to occur without a good understanding of patient needs and factors that influence them [**Richardson et al, 2007**]. Communication during cancer care is particularly challenging due to the involvement of multiple clinicians over an extended period of time, the emotional and psychological impact of the disease, the use of complex multimodality treatments, and the uncertainties associated with disease progression and treatment toxicities [**Mazor et al, 2013; Epstein et al, 2007**]. Patient-centred cancer care places a premium on patient-centred communication skills that facilitate patient's needs to be articulated, addressed, supported and incorporated into the delivery of care in each phase of the cancer care continuum [**Committee on Quality of Health Care in America, 2001; Baile & Aaron, 2005].**

The cancer care continuum demarcates a patient's cancer experience into six phases, namely prevention, screening, diagnosis, treatment, (post-treatment) survivorship, and end of life [**Epstein et al, 2007]**. The patient's position in the cancer care continuum is one of the most important contextual elements that determines the nature of concerns raised during clinical encounters [**Epstein et al, 2007**]. The post-treatment survivorship phase is potentially the longest phase in the continuum as it begins immediately after treatment and extends to the end of life phase. Here is where potentially the greatest gap between the biomedical perspective i.e. cure or remission, and the patient's illness experience can occur [**Epstein et al, 2007**]. Through the patient-centred approach, meeting patients needs with appropriate supportive care i.e. care that helps patients and their family cope with cancer and its treatment [**Gysele et al, 2004**], can enable patients to journey the survivorship trajectory better, as many experience high levels of unmet need, particularly unmet psychosocial need [**Sanson-Fischer et al, 2000]** and experience dissatisfaction with their care [**McDowell et al, 2010**] during this phase.

2.2.3. The oncology outpatient setting

During treatment and the immediate period after can be extremely challenging times for HNC patients and the need for supportive care is greatest [**Chen et al, 2009A; Chen et al 2009B; Chen et al, 2009C; Oskam et al, 2013**]. Post-treatment outpatient clinic follow-up (FU) appointments are opportunities for patients to gain access to their clinicians/surgeons and other members of the HNC multidisciplinary team in addressing their concerns, distress and needs for supportive care. However, the clinical encounter during these appointments can be demanding for both the patient and clinicians, making the task of identifying and addressing patient concerns difficult.

Ghazali & Rogers [2011] outline the multiple challenges faced by patients and doctors in undertaking a holistic assessments while attending a busy outpatient oncology clinic, where appointments are time-constrained. Patients who attend these clinics may be unwell. Some patients have had to travel for long distances from where they live to attend centralised cancer clinics. Many experience long waiting times before being seen [**Clayton & Dudley, 2009**]. As a result, some visits are rushed due to demands on meeting hospital transport arrangements. Patients commonly experience psychological distress, as many are anxious and fear recurrence, while other experience depression [**Rogers et al, 2009**; **Llewellyn et al, 2008**].

Patients' beliefs and social pressures can contribute to why some patients may be unwilling to disclose their distress or discuss psychological concerns [**Epstein et al, 2007]**. Some patients believe that they should be '*glad that treatment was successful*', and believe that others expect them to feel this way [**Epstein et al, 2007**]. Some patients do not want to appear weak, and the fear of being stigmatised for seeking psychological help may prevent them from seeking support [**Holland & Bultz, 2007**]. Many patients fear of being a burden on clinicians who they believe are very busy with more important things to address [**Zucca et al, 2014**]. Patients are reticent in discussing sensitive and embarrassing issues, like intimacy [**Low et al, 2009**] and sexual dysfunction [**Rogers et al, 2015A]**. Those with lowered self-esteem and who have a lack of knowledge or information about their condition can find the clinical setting intimidating. In this situation, they are unable to voice their concerns, are reluctant to complain and are conscious of taking up valuable consultant time [**Rogers et al, 1999**]. Thus, patients may take a stoical view and are unwilling to disclose their concerns, worries or complaints.

Because patients tend not to disclose these concerns spontaneously, clinicians need to enquire about their concerns [**Epstein et al, 2007**]. However, clinicians are under pressure to perform cancer surveillance tasks, examine prosthesis/wounds, and provide information, advice and reassurances during this small window of opportunity at clinic appointments. When given the opportunity, patients have indicated a wide range of items of concern they wish to discuss and may wish to do so with the multiple healthcare providers they interact with throughout the survivorship phase [**Rogers et al, 2009**]. Patients want healthcare providers to enquire about their physical and emotional needs [**Richardson et al, 2007],** and their spiritual wellbeing **[Best et al, 2014].**

One barrier in assessing patient needs and concerns has been the absence of best practices in identifying needs and concerns by healthcare providers [**Wen & Gustafson, 2004**]. Assessments can be chaotic and unsystematic, and healthcare providers infrequently capture accurately what patients are trying to tell them [**Richardson et al, 2007**]. In a survey of HNC clinical nurse specialists (CNS), over three-quarters felt strongly about their personal role in uncovering unmet needs in patients, and their preference was to rely on counselling and communication methods to identify patients' concerns rather than structured screening tools [**Rogers et al, 2011A**]. The extent to which needs and concerns are identified this way is likely to depend on the quality of that **'**one-to-one**'** contact, which may not be reliable and consistent across the board. Indeed, healthcare providers vary widely in their ability to elicit relevant information, and equally, patients vary in their ability to voice their concerns and anxieties [**Richardson et al, 2007**].

Patients with inadequately addressed concerns and/or unrecognised issues may fail to get the multidisciplinary supportive care they need. Persistent unmet needs can lead to poorer overall health, inefficient use of healthcare [**Barg et al, 2007**], dissatisfaction [**McDowell et al, 2010**] and poorer health status. In these circumstances, there is benefit in introducing a framework-based approach to ensure that the needs and concerns might be identified in a standardised and structured manner [**Richardson et al, 2010**].

2.3. Conceptual issues related to 'need' in health care

Before reviewing the methods of identifying patient concerns and needs, an overview on the conceptual issues related to patient needs in health care is presented. The aim of this section is to highlight a specific methodological problem in needs-based research in cancer i.e. the conceptual uncertainties of defining "needs" and the use of related terminology e.g. "problems", "concerns", "issues" [**Sanson-Ficher et al, 2000]**. It is also critical to differentiate between patient needs in health care and health care needs, which often refer to population-based needs for health care. Other methodological limitations in needs-based research include focusing on patients with a specific type or stage of cancer only, or those receiving a particular treatment modality; restricting work into specific domains of need rather than a holistic approach; and incomparable data obtained from a single treatment centre [**Sanson-Ficher et al, 2000**].

The term 'need' is frequently used to ascribe the requirement of something because it is essential or very important. It is also used to state the necessity or obligatory nature of something that is missing [**Oxford dictionary, 2008A**]. The term conjures a sense of urgency and a condition where support or help is required [**Oxford dictionary, 2008A**]. Need is a fundamental and powerful driving force in human existence as the individual strives toward its fulfillment. Karl Marx considers the very essence of man to be constituted of his needs [**Fetscher, 1973**]. However, the universality of human need does not automatically provide a common platform for a definition of human needs in a wider context of society. A range of definitions of need have been produced through different approaches across fields of philosophy, psychology, politics, sociology and economics, which may be applicable to their own setting. In medicine, needs are primary considerations in the provision of care, where health care professionals are accustomed to assessing an individual's need for care prior to prescribing treatment. Medical professionals are also asked to assess the health needs of the population when planning for health care services.

Need and its assessment has been described as '*a conceptually muddled and technically difficult*' subject [**Stevens & Gabbay, 1991**]. Agreement on the definition of need is lacking [**Asadi-Lori et al, 2003**] due to considerable confusion and disagreement about the concept of need and health need in the literature and in practice. The following discussion provides a broad overview on the different perspectives regarding need, and to clarify the relationship between the concepts of need, health, and outcome in health care. The areas discussed are: (a) Need as an instrumental concept; (b) Need as socially constructed; and (c) Need as an outcome.

2.3.1. Need as an instrumental concept

Need could be defined as an instrumental concept, i.e. the need *for* something [**Lightfoot, 1995**]. The concept of need as being instrumental is largely based on the philosophical approach to need. In Metaphysics, **Aristotle** remarks that '*when life or existence is impossible (or when the good cannot be attained) without certain conditions, then these conditions are "necessary"; and this cause itself is a kind of necessity'*. This is to say that all human beings have a need for all that is fundamental to the maintenance of life or for a 'good' or desirable end state (i.e. tension need). Moreover, all preconditions required or instrumental to achieve maintenance of life or the 'good' end state are considered by default as being needs (i.e. teleological need).

In adopting the instrumental concept of need in health care, **James [1999]** argues that the measurement of 'real need' becomes imperative in this model and this immediately poses the problem of what 'end state' should be achieved as the direct link between need and outcome is explicitly made here. It is important to distinguish between ‘need’ and ‘want’. It may be possible to discern the difference between ‘need’ and ‘want’ in commonplace conversation i.e. people can ‘want’ something they do not ‘need’ and ‘need’ something they do not ‘want’. **Fitzgerald** [**1985**] points out that it is possible to determine what people want by observing the action of people or asking them but this is not so with needs. Individuals are not necessarily the true arbiters of what they truly need.

Doyal and Gough (**1984**) presents a basis by which the distinction between ‘needs’ and ‘wants’ can be made in their Theory of Human Needs. Need is defined as a particular category of goals that is *universally aspired* i.e. applies to all people. These goals are those that everyone shares as a virtue of being human i.e. basic human needs [**Weatherley, 1996**]. ‘Need’ can be used to refer to the ‘strategies’ for attaining goals, which in themselves, may be regarded as needs i.e. ‘intermediate needs’. The universality of needs also rests upon the principle that these needs ‘must be met if humans are to flourish’ and if these needs are unmet, ‘serious harm’ of some objective kind, will result. In this context, ‘serious harm’ is defined as a fundamental disablement in the pursuit of one’s vision of the good. In contrast to needs, ‘wants’ lack universality and are always considered as ‘perceived goals’ or desires derived from an individual’s preference or their social/cultural environment, which are justified by reasons which have little to do with more general beliefs about the human condition [**Doyal & Gough, 1984**].

The demand for an intermediate state, e.g. a health care intervention, may reflect the desire to attain the end-state **[James, 1999]. Culyer [1976]** argues that a focus on the need for health should remain central to the definition of the desired end-state, particularly as the need for health is considered as a basic human need **[Doyal & Gough, 1984]**. However, the definition of health as a desirable end-state has difficulties. Requirement for health is a universal human goal but the nature of health has often been debated. The current, widely accepted definition of health is based on the Holistic Theory of Health, where health is a holistic state of being i.e. individuals possess mental, physical and social capacity to achieve their vital goals in life **[Nordenfelt**, **2007**]. This theory suggests that to be healthy is a universal state where the individual is able to fulfill their most important goals, but because alteration to health develops over a continuum, it is possible for health to coexist with disease [**Schramme, 2007**].

Therefore, illness and disease can exist within health. This redefinition of health is able to accommodate the rise in chronic illness states [**Huber et al, 2011**], including long-term cancer survivorship.

The World Health Organisation (WHO) adopts this holistic approach to health in its definition of health as '*a state of physical, mental and social well-being, and not merely the absence of disease or infirmity'* [**WHO, 1948, page 1**]. This definition amalgamates the traditional biomedical approach (i.e. focus on aetiologic agents, pathological processes, and biological, physiological, and clinical outcomes) with the social science paradigm, or the "quality-of-life" model (i.e. focus on dimensions of functioning and overall well-being), and is used in the UK national health policies, where a 'quality of life approach' to need for health care was proposed [**DOH, 1992**]. In their review of needs for health care, **Asadi-Lari et al [2003]** state this definition as being the requirement of individuals to enable them to achieve, maintain or restore an acceptable level of social independence or quality of life, as defined by particular care agency or authority.

The Holistic Theory of Health is not without conceptual problems [**Schramme, 2007**]. A clear conceptual distinction of disease and health remains lacking due to the sole reliance on attainment of vital goals as the discerning criteria, which can lead to a broad medicalisation of many 'illness states'. For example, an overly ambitious athlete who has not reached the targeted goals may be considered as being in ill health according to Nordenfelt's **[Noordenfelt, 2007]** definition. Furthermore, the idealised positive notion of health according to this theory may not be practically attainable by an individual or collectively by society.

2.3.2. Need as socially constructed

Based on phenomenological studies, sociologists define 'need' as being socially constructed, where it is contingent upon the variables of our social existence [**Doyal & Gough, 1984; James, 1999**]. Thus, need may be defined relative to the different groups within society depending on the cultural, social and organisational context [**James, 1999**]. In relation to health needs, **Bradshaw** [**1972**] considers 'need' in two ways based on the interaction between the two main groups within the context of health care services. Patient-assessed needs are comprised of '*Felt need'* which refers to the perception of patients when they feel ill, and ‘*Expressed needs*’ which describes the process by which felt need is translated into the demands on health services. External-assessed needs are composed of ‘*Normative need*’, which refers to the definition of need by professionals (health care and social care professionals) and ‘*Comparative need*’, which is used to compare two or more patients or populations. ‘Normative need’ has been the traditional means by which health care is accessed by patients. The role of the general practitioner [**Wright et al, 1998**] and more recently, the Clinical Commissioning Group as the gate-keeper to the National Health Service (NHS) exemplifies this. In this traditional arrangement, the patient’s needs are judged against the ‘infallible’ expert standard.

The rise of consumerism in health care, exemplified by NHS choices [**DOH, 2016**], reflects another aspect of needs as being socially constructed, where the articulated experiences of service users provide counterbalance to the views of the professionals. **James** [**1999**] points out that as service users are increasingly encouraged to define their own reality, the list of needs may potentially become endless. This is encouraged by the concept of self-improvement or ‘self-actualisation’, which is a popular idea that permeates discussions on broad social constructs, such as health, well-being and quality of life. This notion is based on a psychological approach to needs proposed by **Maslow [1943]**.

In Maslow’s Theory of Human Motivation, needs are arranged in hierarchies of pre-potency, where the appearance of one need usually rests on the prior satisfaction of another, more pre-potent need. Needs are organized into four successive categories of universal human needs i.e. physiological, safety, love/acceptance and self-esteem, which must be met in turn before the final and highest goal of self-actualisation is achieved [**Maslow**, **1943**]. Despite its popularity, there is lack of empirical or phenomenological evidence to support the existence of a hierarchical organisation of needs [**Wahba & Bridwell, 1976**]. This model is also criticized for its emphasis on the needs of the individual, which may only be relevant in societies where a high value is placed on individualism [**Cianci & Gambrel, 2003**].

2.3.3. Needs from a humanitarian approach

The 'Humanitarian approach' to need for health care is based on the premise that medical care service is required or needed to alleviate human suffering [**Donabedian, 1974**]. This approach places prime importance on the management of the sick without considering the consequences of limited resources available. Consequently, while the end state of health improvement can be achieved, a more vertical distribution of health care resources occurs, with those sickly and needy patients consuming most of the limited resources.

2.3.4. Need as a utility approach

When blurring of 'needs' and 'wants' occur, all 'needs' are potentially justifiable even though resources are limited. Concerns about this have led some to suggest that need should be defined in relation to the procedures available to meet it, to the resources that permit those procedures to be used and where benefit can be demonstrated i.e. the utility approach [**Matthew, 1971; Cochrane, 1976; Acheson, 1976**]. This approach is heavily based on an economic model.

As a publically-funded body, the supply of health care service via the NHS is free for all citizens at the point of access. Therefore, the NHS faces the problem of infinite demand meeting finite resources. The economist's view of '*anything that is free will be demanded infinitely'* has undoubtedly raised significant concerns [**Vetter, 2002, page 375**]. However, in the health care setting, health from a holistic perspective is considered the desired end-state. The need for health care i.e. the intermediate need for health as the desired end-state, represents those needs that can benefit from health care services e.g. health education, disease prevention, diagnosis, treatment, rehabilitation, terminal care [**Wright et al, 1998**]. The perception that health care professionals are able to assist individuals in bringing benefit to their health lies at the root of their demand for health care services.

A more realistic approach to healthcare need, based on an economic principle of cost-effectiveness, is required to provide a wider distribution of limited resources [**Acheson, 1978**]. The distinct entities of 'need', 'demand' and 'supply' are well founded in the economic model of healthcare provision. In this model, '*Need*' is defined as '*the capacity to benefit from health care*' [**Stevens & Gillam, 1998**; **Wright et al, 1998**]. This is to say that if the needs for healthcare are to be identified then an effective intervention should be available to meet this demand and results in improved outcomes (e.g. health gain) [**Wright et al, 1998**]. Inevitably, this definition considers needs as being present if there are existing services that can offer effective outcomes. **Asadi-Lari et al** [**2003**] argues that this definition of need places a greater focus on outcomes of medical interventions, where objective measures are the preferred method in recording progress. This can result in a narrowed scope of measuring benefit, particularly when outcomes are generally inversely related to the severity of illness. The perception of benefit may vary according to viewpoints (e.g. doctors' *versus* patients' perspectives) and may be influenced by external factors (e.g. cultural, research agenda). '*Demand'* is what patients ask for and may be thought of as 'expressed need'. '*Supply*' is what healthcare service that is provided, which can vary depending on the professional expertise available, the political agenda and exiting financial means.

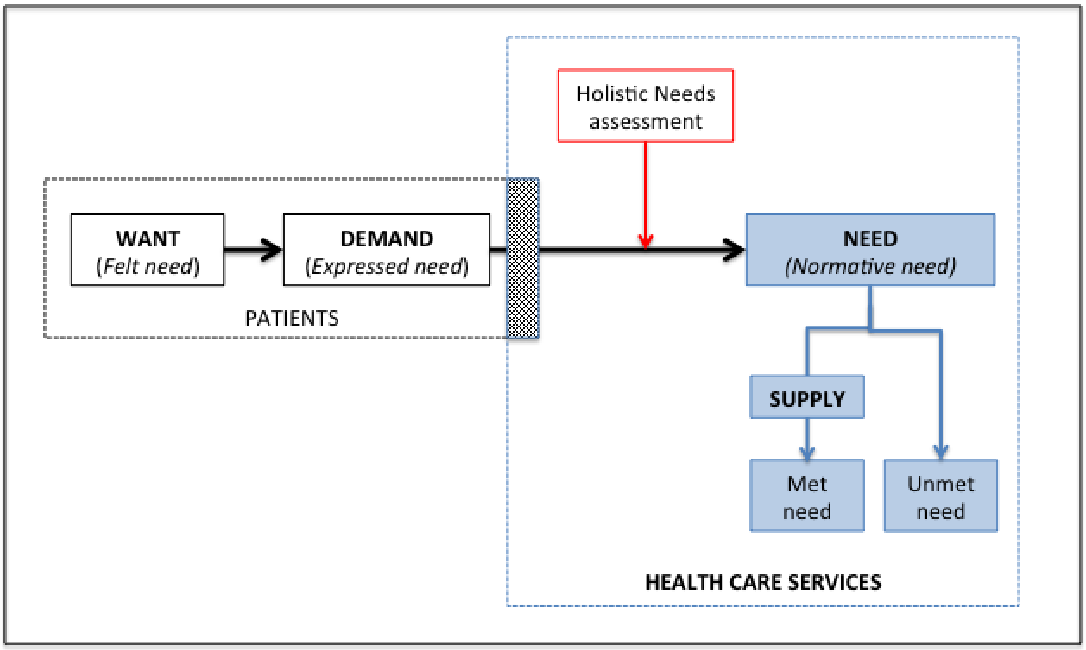
2.4. Meeting Need in Health Care

2.4.1. Defining Unmet Needs in Health Care

Figure 2.1 considers the relationship between need, demand and supply **[Wright et al, 1998]** in the common setting of a patient visit to see a clinician. This visit, i.e. shaded area of overlap between the patient and health care boxes, represents the interface by which the two main groups within the context of healthcare services interact [**Bradshaw, 1972**]. At such a visit, healthcare professionals determine the normative need i.e. capacity for patients to benefit from an existing service. When such a service is supplied and a beneficial effect is achieved, the normative need is considered met. On the other hand, when there is no service to supply and the beneficial effect is not attained, the normative need is considered unmet. From a healthcare resources perspective, patients with unmet needs are considered 'non-recipients of beneficial healthcare interventions' [**Stevens & Gillam, 1998**].

A narrowed, medical intervention-focused definition of need inevitably fails to consider the patient's perspectives. While there is a large body of work relating to unmet needs, very few studies define unmet needs specifically. Soothill et al, [2001] proposes a 'strict', patient-reported definition of unmet needs in their survey of the needs of cancer patients, whereby significant unmet needs are those needs that patients identify as being important, and were perceived to be unsatisfied. On the other hand, 'unmet needs', used interchangeably with ‘unmet supportive care needs’, was defined by **Carey et al [2011]** as those needs which lack the level of service or support an individual perceives is necessary to achieve optimal well-being. This definition provides a more balanced and practical perspective by relating the patient perspectives on the availability of services in relation to the satisfaction of their needs.

Figure 2.1. Diagram showing the relationship between needs, demand and supply. The shaded area represents the interface between patients and the healthcare professional.



It is recognised that when patients attend a clinical visit, due to barriers that may be present, their felt need may not be fully expressed into a demand for healthcare intervention or for supportive care. These undisclosed needs are hidden, and it is unlikely that healthcare professionals, unaware of its existence, are able to address these needs with the appropriate supportive care services. In various studies of cancer survivors, unmet needs are prevalent, and are associated with psychological distress and poor HRQOL status.

2.4.2. Holistic (needs) assessments

Needs assessment in health care is to gather the information required to bring about changes beneficial to the health of the population [**Stevens & Gillam, 1998**]. On an individual level, needs assessment is also defined as the process of collecting information about a patient’s needs and circumstances, making sense of that information in order to identify needs and to decide on what support or treatment can be offered, tailored to the patient [**DOH, 2003**]. In the cancer setting, patient needs assessment is an agenda driven by NICE Guidance on Improving Supportive and Palliative Care for Adults with Cancer [**NICE, 2004**], the Cancer Reform Strategy [**DOH, 2007**], National Cancer Survivorship Initiative [**DOH, 2010**] and more recently, the Macmillan Recovery Package [**Macmillan Cancer Support, 2013**], which is endorsed by NHS England Five Year Forward View [**NHS England, 2014**] and the Cancer Taskforce Strategy [**NHS England, 2017**]. The theoretical and practical guidance on the principles and practical aspects of this exercise are outlined in documents commissioned by the National Cancer Action Team (NCAT) [**Richardson et al, 2007A & 2007B; NCAT, 2011**].

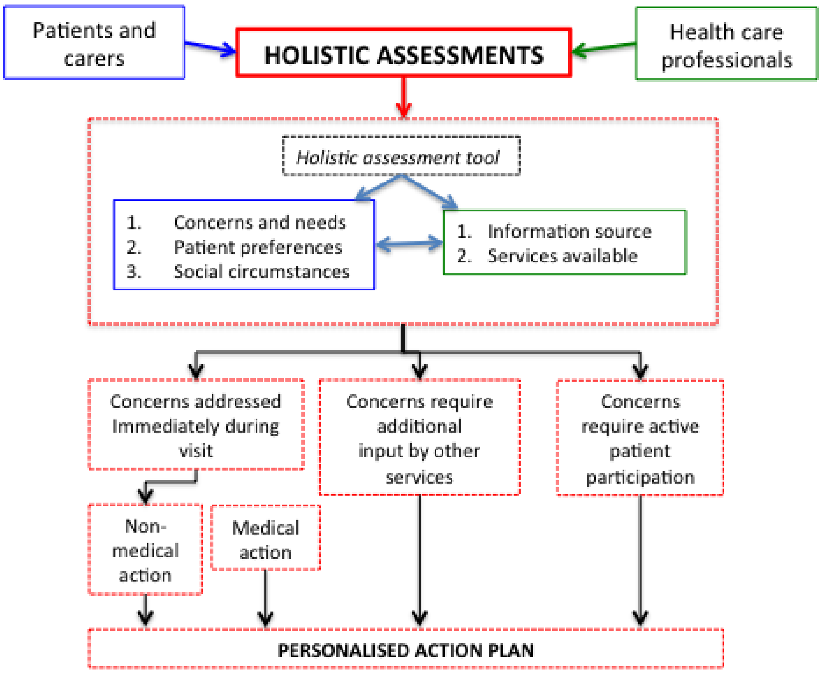
In keeping with the holistic approach to health [**WHO, 1948**], need assessment in health requires the assessment to consider the patient wholly i.e. viewing the individual as having physical, social, psychological and spiritual aspects of life, all of which are closely interconnected. Thus, holistic assessments ‘*should consider all aspects of a person’s needs and that they are seen as a whole*’ [**NCAT, 2011; page 5**]. The over-riding purpose of holistic assessments in cancer is to ensure that patients receive personalised care that reflects the patients’ health and needs.

Holistic assessment is a process that involves identifying patients concerns or problems through an assessment, and addressing these concerns by formulating an action plan [**NCAT, 2011**]. Assessment of needs, concerns or problems involves the patient using a suitable self-reported assessment tool that provides a structure for assessment conversations with healthcare professionals. This process helps patients realise that their concerns are worthy of attention and not out of the ordinary [**NCAT, 2011**]. Disclosing these concerns can create avenues for discussion, and inform them of what support service is available to them even when this is not immediately required.

During discussions, some concerns are simply dealt with immediately, for example, the visit itself provides space for patients to talk about their concerns/problems, information giving and undertaking medical actions i.e. physical examination, requests for investigations, prescription of medication [**NCAT, 2011**].

Other concerns may involve patients' active participation in resolving the concerns i.e. self-management, e.g. undertaking self-examination, participating in support groups, and adherence to physical rehabilitation programme [**NCAT, 2011**]. Some concerns would require additional input by other professionals through referrals beyond the immediate MDT, for example, psychologists, social workers, financial advisors and chaplain. Summarising the content and outcomes of the discussion into an action plan completes the holistic assessment process (Figure 2.2) [**NCAT, 2011**]. Discussions during holistic assessment can help support patients in day-to-day self-management of their condition, and preempt more serious presentation of a problem by enabling patients to seek help at an earlier stage [**NCAT, 2011**]. From the MDT's perspective, holistic assessment can help identify patients who have the greatest and/or most immediate need for supportive care, and facilitate a focused and efficient delivery of care, as resources are used more effectively [**NCAT, 2011**].

Figure 2.2. Flow chart summarising the holistic assessment process [**NCAT, 2011**]



2.4.3. Identifying needs and concerns

Best practice guidelines and government policy documents advocate screening cancer patients for supportive care needs at appropriate time points during the cancer survivorship trajectory by utilising holistic patient-reported outcome (PRO) measures [**NICE, 2004; DOH, 2010; National Comprehensive Cancer Network (NCCN), 2008; Richardson et al, 2007**]. The process of holistic assessment relies upon effective communication between the patient and their healthcare providers, using a PRO tool, which may provide the necessary structure and rigour in to the process of assessment [**NCAT, 2011**].

2.4.3.1. Communication during patient-doctor encounters

Communication is regarded an essential component in patient-centred care in cancer [**Baile & Aaron, 2005].** The basis of effective holistic assessment is good communication, which relies upon the ability of doctors/healthcare professionals to ask questions with sensitivity that enables patients to disclose their concerns, and in turn, be able to listen to, and hear out these concerns with patience and understanding while responding appropriately, with empathy and avoid blocking [**NCAT, 2011**]. Healthcare professionals should allow patients to explore their concerns, their unique situation and possible solutions. Healthcare professionals are most useful when they are able to provide information including advice on self-management, and about existing services that are available in addressing their concerns [**NCAT, 2011**].

Patients want sensitive, caring and supportive clinicians who provide information that they need, when they need it, in a way that they can understand; who listen and respond to questions and concerns, and who attempt to understand the patient’s and their family’s values, preferences and experience. The patient also plays an essential role in discussions so as to achieve a patient-centred approach [**Cegala & Post, 2009**] but patients cannot be relied solely upon to initiate discussions about their concerns because of a multitude of patient-related barriers. These barriers include poor health literacy, lack of knowledge or information to participate in shared-decision making, and having certain health beliefs *e.g. fear of distracting the doctor from treating the cancer; belief that clinicians are too busy; belief that addressing a particular need is not a core component of the clinicians role; belief that the doctor will inquire about important aspects of care; desire to be a ‘good patient’; and belief that there is nothing that can be done to help a particular symptom’* **[Zucca et al, 2014, page 2004].**

2.4.3.2. The patient-doctor encounter during routine oncology clinic

Due to the nature of the assessment, it is suggested that the holistic assessment should be undertaken in a setting that is comfortable for patients to disclose their concerns. Routine post-treatment visits in the oncology outpatient settings are occasions where oncology doctors and their patients may communicate in ways that can enhance their care. Such appointments are scheduled regularly at planned intervals over a long period of survivorship, and may be opportune moments to undertake holistic assessments so as to personalise their care.

However, the reality of routine oncology consultations is far from ideal. During routine oncology consultations, doctors spend 64-78% of their time discussing medical/technical issues [**Detmar et al, 2001**; **Fagerlind et al, 2008**]. Meanwhile, patients tend to spend equal time between medical/technical issues with HRQOL-related issues [**Detmar et al, 2001**]. It is estimated that patient-centred issues are only discussed between 16-48% in these clinics [**Detmar et al, 2001**; **Fagerlind et al, 2008]**. This occurs despite the overwhelming majority of cancer patients, their family and friends preferring a patient-centred approach during consultation [**Dowsett et al, 2000**]. Many patients (60%) have expressed their preference and willingness to discuss psychosocial issues with their cancer doctors [**Mackenzie et al, 2015**]. There is an expectation that patients are best positioned to initiate discussions surrounding their concerns, and some do [**Detmar et al, 2001]**, particularly when dealing with emotional and social concerns [**Taylor et al, 2011**], and psychological and spiritual/existential concerns [**Rodriguez et al, 2010**]. However, not all patients were willing to discuss psychosocial issues with their cancer doctor without the doctor initiating the discussion (25%) [**Detmar et al, 2000; Zucca et al, 2014**]. A smaller proportion of patients (9%) express a preference for not discussing psychosocial concerns at all during clinic appointments [**Taylor et al, 2011**].

Understanding the views and preferences of cancer doctors relating to consultations are also important, especially if doctors are expected to initiate discussions relating to psychosocial concerns. Overall, cancer doctors are interested in acquiring information about their patients' general well-being and in non-medical areas of their lives, but the natural focus is primarily the complex medical issues during visits [**Baile et al, 2011; Velikova et al, 2007**]. Lack of time during appointments and unsuitable environment are often cited as a practical reason why holistic assessments are not undertaken. There is fear of ‘opening Pandora’s box’ of problems [**Baile et al, 2011**]. Some cancer doctors express their discomfort in dealing with emotional distress [**Fagerlind et al, 2008**], and feel out of depth from a perception of being inadequately trained to handle psychosocial and/or spirituality-related consultations [**Baile et al, 2011; Best et al, 2014**]. Furthermore, some describe embarrassment when having to deal with concerns about intimacy and sexuality [**Low et al; Rogers et al, 2015].**

Doctors in oncology clinics sometimes avoid discussions of psychosocial nature. Some defer the initiation of discussions on psychosocial issues to patients [**Detmar et al, 2000; Taylor et al, 2011**]. **Taylor et al [2011]** reported that discussions relating to emotional issues in oncology clinics were only undertaken when initiated by patients despite 75% doctors expressing willingness to discuss these issues in clinic. Doctors found initiating social concerns more comfortable than emotional concerns, because many social activities were related to physical functioning [**Taylor et al, 2011**]. Considering these issues, the introduction of a PRO that can help initiate discussions in the process of holistic assessment may potentially change the way routine oncology clinic discussions are held.

Methods of improving both doctor and patient communication skills during cancer consultations may improve the overall quality of discussions. These interventions include the use of informational-based tools (i.e. prompt sheets, written summaries and audiorecordings of consultations) and coaching/communication skills building at the individual and community levels [**Parker et al, 2005**].

2.4.3.3. Prompt sheets

Prompt sheets are often designed in a list format, acting as an *aide-mémoire* during communication. Prompt sheets assist patients in articulating their needs and to get their views and message across to the health care provider [**Parker et al, 2005**]. The list could be composed of questions that may assist in information gathering during consultation, or tips/suggestions as to how to formulate questions they wish to be answered, or as itemized check list that enables patients to indicate their concerns, values and preferences relating to their care [**Parker et al, 2005**]. Prompt lists have been used extensively to aid communication in the oncology setting, and this subject has been reviewed elsewhere [**Brandes et al, 2016**; **Miller & Rogers, 2016**].

The availability and structured multidimensional format of a health-related quality of life (HRQOL) questionnaire makes it an attractive tool to exploit as a prompt sheet for screening of problems and communication in routine oncology follow-up clinics. HRQOL has been successfully adapted to screen for HNC survivors with significant problems, thereby triggering the need for healthcare intervention [**Rogers & Lowe, 2009**]. Routine use of HRQOL in oncology follow-up clinic consultations has also aided patient-clinician communication [**Detmar et al, 2002; Velikova et al, 2002; Velikova et al, 2004; Taylor et al, 2010; Takeuchi et al, 2011**]. By using HRQOL, more items of concern were discussed during patient-clinician consultations in clinic [**Velikova et al, 2004; Takeuchi et al, 2011**], suggesting the HRQOL tools can facilitate the expression of felt needs by directing the discussions toward the expressed need, thereby improving the efficiency of and satisfaction with the consultation.

There are some limitations in employing HRQOL as a tool to aid patient-clinician communication in regular follow-up clinics. Not all HRQOL assessment tools take into consideration the individual’s perception of the relative importance of some domains over others and this may be reflected in the weight given to specific concerns during consultation. HRQOL questionnaires may be restricted by the wording used and tend to focus on symptoms or dysfunction over a short period of time, typically over seven days, which only provides a snap-shot assessment of issues that are dynamic in nature.

The rigid structure of some HRQOL assessment tools may not accommodate the influence of coping and adaptation that occurs with time. Parallel cognitive and emotional processing during coping and adaptation [**Levanthal et al, 1980**] can result in incongruence between the degree of dysfunction and the significance patients place upon it [**Llewellyn et al, 2007**]. For example, patients with significant dysfunction will continue to indicate poor HRQOL scores in the related domains due to the way the questionnaire is constructed i.e. based on the assumption that poor function results in poor QOL, even though the patient has positively adapted to the condition and consequently, may not harbour any felt need to discuss this further. Alternatively, a patient with very mild dysfunction will score relatively good HRQOL scores but may hold significant felt need for supportive care in relation to this. In both scenarios, the

HRQOL tool fails to capture the patient's perception of their success in coping or adapting to the dysfunction present. Consequently, HRQOL tools may miss the presence of felt need to discuss the issue during consultation. The significant limitations with HRQOL tools in identifying individual patient concerns and priorities prompted the development of the Patients' Concerns Inventory.

2.5. The 'Patients' Concerns Inventory': A conceptual discussion

2.5.1. Similarities of the patient experience in chronic conditions and cancer survivorship: The 'patient empowerment' approach within patient-centred care

Cancer patients experiencing long-term survivorship bear similarities to those who live with irreversible or progressive chronic conditions. In both groups, patients experience diverse issues throughout their lives as a result of the disease and/or treatment, where the impact upon health outcomes is influenced by individual circumstances, especially psychosocial concomitants. Thus, it is useful to consider current concepts that underpin the management of chronic disease.

'Patient empowerment' is an important psychosocial concept in the management of chronic diseases. There is a lack of a universally accepted definition of patient empowerment, but most patient empowerment definitions focus on individuals' capacity to make decisions about their health (behaviour) and to have, or take control over aspects of their lives that relate to health [**McAllister et al, 2012**]. It is assumed that empowered individuals will be able to: (a) make more rational healthcare decisions to maximise their health and wellness; (b) decrease dependence on healthcare services; and (c) ultimately contribute to more cost-effective use of healthcare resources.

Improving patients' capacity to take control of their health and life means that patients need to be in a position to understand their disease, the diagnostic process, the treatment options and the side-effects, how to take their medications, and be able to cope with problems resulting from the disease and its treatment. These can be extremely challenging for many patients. **Chatzimarkakis** [**2010**] outlines the three principles of implementing the patient empowerment concept into practice. These principles are: (1) "Empowerment means Enablement", (2) "Empowered patients need strong partnerships with doctors and caregivers", and (3) "Patient empowerment is a paradigm, not a technique". In summary, patient empowerment is a (new) model of patient-doctor relationship, where patients' capacity for self-management is enabled by strong partnerships with doctors.

Enablement is an inextricable concept related to patient empowerment. **Chatzimarkakis** [**2010**] assert "*empowerment means enablement*" where patients need to 'know', 'be able' and 'want' to self-manage. The health care system supports patient empowerment by creating an environment of enablement. **Hudon et al, [2010**] defines enablement process as '*a professional intervention aiming to recognise, support and emphasise the patient's capacity to have control over their health and life*'. Steps to provide education and practical training, having tools and equipment for self-management, and motivational factors for patients to modify their health behaviour appropriately in context of self-managing their disease [**Chatzimarkakis, 2010**].

The quality of partnership between patients and doctors is fundamental to the enablement process. Continuity of care can foster the relationship that empowers patients because the partnership is negotiated with time, where doctors adjust to patients' capacities and their preferences [**Hudon et al, 2012**]. Doctors utilise their expertise and competencies to provide technical information in a way that patients can understand so as to find common ground, while patients are encouraged to participate in their own care stimulating them to ask questions, and engaging patients in discussions by creating ways through which patients can express their views, needs and concerns [**Hudon et al, 2012**]. One of the ways patients can be encouraged to express their views, preferences, needs and concerns is by using patient-reported outcome (PRO) measures.

McAllister et al [**2012**] considers PROs central to the concept of patient empowerment, because empowerment relies on an effective communicative process between health professionals and patients, which is the basis of a collaborative, patient-centred approach, and a fair and equal relationship [**McAllister et al, 2012**]. The ultimate goal of equitable/collaborative models of clinician-patient interaction based on patient empowerment is self-management and shared decision-making [**McAllister et al, 2012**].

Health care systems have started to recognise how the concept of patient empowerment sits comfortably within the philosophy of patient-centred care. This is particularly evident in the general practice setting, where the care of patients with chronic disease commonly takes place. Patient empowerment has been recognised as a characteristic of general practice, and is considered to lie within the core competency of person-centred care [**Rochford, 2015**]. The recent introduction of the 'New Care Models: Empowering Patients and Communities' in relation to the NHS in the UK also reflects this. This document outlines the paradigm shift in NHS policy towards personalising care and support, where the formation of partnerships through good communications between individuals living with long-term condition and their health care practitioners is considered the first key principle [**NHS England, 2015**].

2.5.2. "Patients' Concern": Clarifying the terminology in reference to 'patient empowerment'

Due to the diversity of issues that may be experienced at different time points of their lives, patients with chronic conditions must decide if these issues are of 'concern' to enable self-management and facilitate shared-decision making in managing chronic conditions.

From a linguistic standpoint, concern is used to describe 'worry or anxiety' [**Oxford dictionary, 2008B**]. The phrase '*a cause for concern'* echoes a range of related terms that express concern: care, disquiet, perturbation, apprehension, fear, unease, alarm, trouble, distress, upset, sorrow and grief [**Penguin Thesaurus, 2002**]. Concern is also used in reference to 'a matter of interest or importance' [**Oxford dictionary, 2008B**] where a matter is given thought, regard, attention and consideration because it has bearing or relevance, and is of consequence. Thus, the term 'concern' conveys an acknowledgement that a particular issue (of concern) is personally significant, and may, although not always, be associated with an adverse emotional response.

2.5.3. What is the relationship between needs and concern?

The relationship between patient concern and need in healthcare is not fully understood, and the terms are often used interchangeably. According to Bradshaw's sociological theory of need [**Bradshaw, 1972**], patient-assessed needs are composed of '*Felt need'* which refers to the perception of patients when they feel unwell, and '*Expressed needs*' which describes the process by which felt need is translated into the demands on health services.

Based on this understanding, it is proposed that when patients perceive a particular issue is of concern to their wellness, this may be considered as an expression of felt need. The consequential effort by patients to seek help from healthcare professionals may be considered as expressed need. Not all felt needs are ultimately expressed, as patients may choose not to disclose information when asked or given the opportunity to do so. However, it is of more significance if patients do not disclose their concerns or felt needs not out of choice but because of barriers (external and internal) that exist during the interaction between the patient and the health care professional.

2.5.4.What is the idea behind 'Patients' Concerns Inventory'?

The use of prompt sheets as a way of identifying patients' needs and concerns was discussed in **section 2.4.3.3.** The ease by which problems or concerns could be expressed by patients using prompt lists has seen the development of several problem- or concern-based tools in the oncology setting [**Miller & Rogers, 2016**]. These include the Problems List, which is used in conjunction with the Distress Thermometer, a screening tool for distress [**Holland & Bultz, 2007**] and the Patients Concerns Inventory (PCI), which is composed of a checklist of potential problems, issues or concerns that patients may experience due to their condition [**Rogers et al, 2009**].

These problem-based prompt lists are classified as a PRO measure based on the definition and criteria outlined by the **FDA [2009]**. PROs in a prompt sheet format can provide a simple but practical patient-reported tool, especially when it is designed to be holistic. This is particularly valuable in assisting cancer survivors identify their concerns, as holistic PROs considers all the domains of well-being [**Synder et al, 2010**].

'Patients' Concerns Inventory' (PCI) is essentially a checklist of key items of concerns that a cohort of patients with a particular condition may experience in their lives. It is essentially a PRO in a prompt sheet format. The idea of the checklist was to act as an *aide-mémoire* for patients, prompting them to disclose any concerns they may have about their condition during their encounter with the health care professionals. In this way, the PCI helps identify patient concerns.

During the process of completing the PCI, patients scan through the holistic PCI list, and discern which ‘felt need’ or concern will ultimately be expressed for attention. This thought process asks patients to reflect on the issue, their goals and priorities. The importance placed on a particular issue of concern may be relative and temporal. When the PCI is completed at regular intervals of their journey, it can provide a unique longitudinal record of patients’ concerns at specific time-points [**Synder et al, 2010**]. The process of going through the checklist can also be an educational experience. Patients may come to realise that some of the concerns listed are recognised issues that other patients with the condition may experience.

Once the PCI is completed, patients gain the opportunity to discuss these concerns further with the doctor/health care professionals. At best, the PCI can enable discussions that focus on the patients’ agenda and help patients gain better understanding of their concerns, empower patients to become more active participants in managing their condition, and facilitate joint decision making to maximise their health and wellness.

However, the extent by which the PCI data can empower patients i.e. facilitates discussions between patient and clinicians about their concerns, ultimately depends on upon the quality of partnership that exists between patients and doctors. The doctors’ acceptance of the PCI also plays a key role in this process.

2.5.5. What is the theoretical framework for PCI?

A formal theoretical framework for the PCI has never been proposed. There are two ways by which the PCI could be considered: (1). As a PRO used in identifying patients’ needs and concerns, and (2) As a tool that can enable better communication between patients and clinicians. Theoretical frameworks to explain both situations are presented as follows:

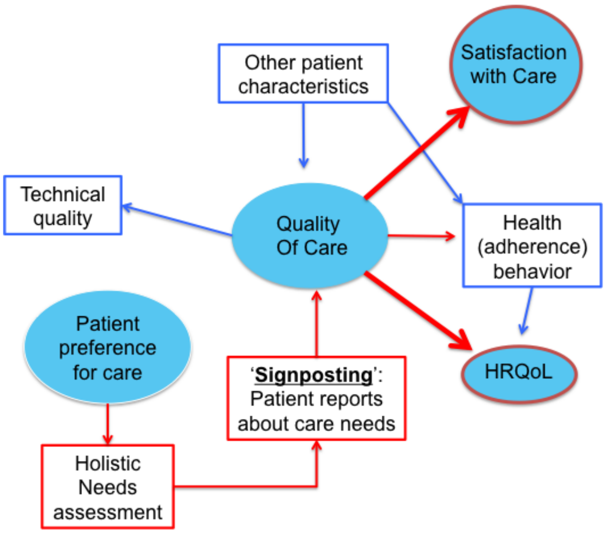
2.5.5.1. PCI as a PRO in identifying patients’ needs and concerns

Fung & Hays [2008] proposed a hypothesis on the relationship between different types of PROs used during patient-doctor encounters in healthcare (Figure 2.3). In their hypothesis, QOL and patient satisfaction are considered the core endpoints. In their hypothesis, PROs occupy the central role in the delivery of quality care during patient-doctor encounters.

According to this hypothesis, it is possible to identify a patient's problem during a patient-doctor encounter using a PRO. A PRO-based assessment of need i.e. 'Holistic assessment tool' could help identify patients' needs and concerns (i.e. number and type). The PRO empowers patients by providing the framework to help highlight their issues, and to also enable patients to engage with their clinicians in discussions during their encounter by focusing on these issues.

By empowering patients, through the identification of their needs and concerns, it is possible to then decide the appropriate action through discussions leading to joint decision-making, which can improve the quality of care. The quality of care delivered is influenced by patient factors, and the technical quality of health care professionals. The delivery of good quality of care can be reflected in better patient satisfaction and HRQOL.

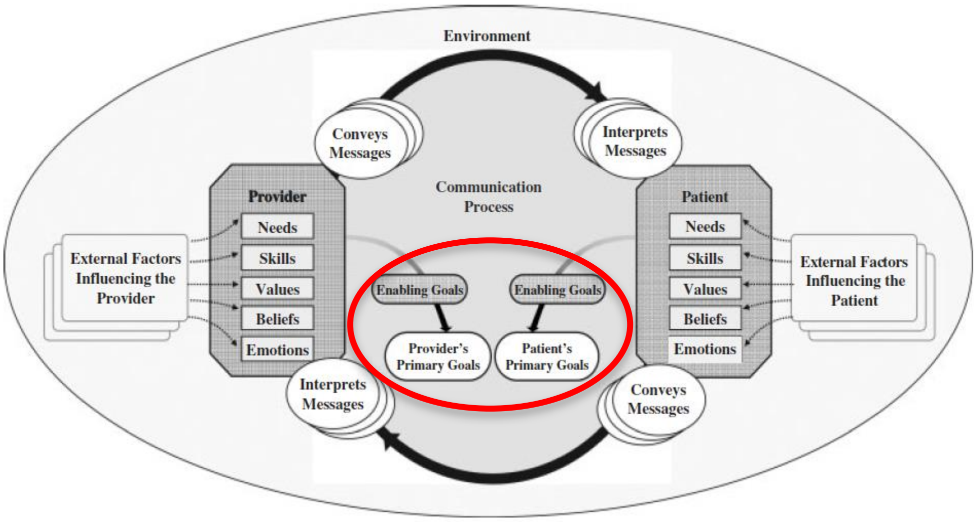
Figure 2.3. Inter-relationship of PROs and its core outcomes based on **Fung & Hays [2008]**



2.5.5.2. PCI as a tool that enables better communication between patients-doctors

The PCI intervention may help overcome some of the known potential barriers at the patient-healthcare interface. A model proposed by **Feldman-Stewart et al** [**2005**] (Figure 2.4) describing the dynamics of the patient-doctor communication during an encounter can help understand the role of the PCI in such situations. According to this model, the patient and the doctor enters the joint encounter by bringing into this encounter with their own agenda. These agenda may be considered the patients' and providers' primary goals during the communicative process. Internal barriers from within both parties may influence this process, as well as external barriers created by the environment.

Figure 2.4. Conceptual model describing the interaction or communication during a consultation in a cancer setting **[Feldman-Stewart et al, 2005]** Red circle: potential role of a PCI



The communication process involves conveying and interpreting messages by both parties, which may include expression of felt needs or concerns by patients, and also the doctors' concerns regarding treatment effects or physical problems. It is generally accepted that the quality of the patient-clinician interaction can determine the extent to which the concern is identified and addressed [**Mead & Bower, 2000**] but the quality of patient-doctor communication can vary.

A tool like a PCI can potentially change the dynamics of the patient-clinician interaction by enabling patients' concerns to be discussed. The PCI can help remind patients of their concerns, bring their issues to the attention of clinicians, thereby increasing the likelihood that their concerns are ultimately discussed and addressed. Where previously patients concerns and needs may have been dwarfed by the doctor's agenda and goals for the consultation, the PCI intervention can attempt to redress the imbalance by enabling patients' to highlight and convey their concerns and needs by reminding them of the items for discussion [**Synder et al, 2010**]. Nevertheless, as highlighted previously, this process only works as far as the clinician supports the PCI as part of a wider enablement process within the context of patient empowerment.

2.5.6. Application of the Patients Concerns Inventory in clinical settings

The PCI can help foster a collaborative approach as the basis of a personalised cancer care partnership. It is thought that the **'**PCI concept**'** could be relevant in the management of cancer survivors due to similarities of experience shared with patients with chronic disease.

The PCI concept was first used in the cancer setting by the introduction of the Head and Neck Cancer Patients' Concerns Inventory. This will be discussed in the following section (section 2.6). There is work in progress in adapting a PCI concept in breast cancer [**Kanatas et al, 2014**], neurosurgery and rheumatological conditions [**Ahmed et al**]. The 'concerns approach' has also been developed in chronic gastrointestinal conditions [**Drossman et al, 1991; Jorgensen et al, 2011**].

2.6. The Head and Neck Patient Concerns Inventory

This section reviews the literature encompassing the development and introduction of the HN-PCI in 2009 until present i.e. July 2017.

2.6.1. Development and Introduction of the HN-PCI

The Head and Neck Patient Concerns Inventory (HN-PCI) was introduced as a site-specific tool for routine use in the HNC outpatient setting [**Rogers et al, 2009**]. It was developed together with the Merseyside Region HNC support group and was designed to be a holistic, PRO that tries to disclose patients' needs and concerns by highlighting those concerns that they wish to discuss during the outpatient clinic.

To create a broad and holistic format, the content of the PCI was formulated through the synthesis of items from various PROs, HRQOL questionnaires, and discussions with local and national focus groups of HNC patients and professionals involved in the care of HNC patients, namely, the laryngectomy support group, HN support group, HN patient research forum, hospital volunteers, ward and outpatient staff and the multidisciplinary HNC team. The HN-PCI was first piloted on 1 August 2007 and originally introduced with 45 items of concerns and a list of 8 professionals whom patients would like to be seen or be referred to, to choose from. Content validity was evaluated by the Liverpool HNC support group and as a result of this exercise, a further 7 items were added in April 2008.

The content-validated HN-PCI (version 1) checklist composed of 45 items of concerns (including 'Anything else') (Appendix 2), ranging widely from dysfunction to psychosocial issues and also regarding the treatment and its after-effects. The HN-PCI (version 1) also allowed patients to choose individuals they wish to see or be referred to from a range of 15 professionals (including 'Anyone else') composed of those from HNC multidisciplinary teams to other non-medical professionals [**Rogers et al, 2009**]. In November 2008, a further addition of 10 items resulted in introduction of the HN-PCI (version 2) composed of 55 items of concern and 15 professionals (Appendix 3). The concerns checklist of the HN-PCI (version 2) was described in **Rogers et al [2012].**

The HN-PCI is administered along with the University of Washington Quality of Life version 4 (UWQOL) [**Rogers et al, 2002**] using touch-screen technology (TST) [**Millsopp et al, 2006**]. The digital TST format is advantageous because this permits self-completion of both questionnaires, provides a permanent record that can be included in electronic case notes, and can aid in service evaluation and audits. The completion time of the HN-PCI-UWQOL package averages 8 minutes of the pre-consultation waiting time [**Rogers et al, 2009A**]. The software summarises the HN-PCI and UWQOL scores immediately upon completion, allowing the information to be used during clinic consultation. The summarised PCI data sheet is printable and may be used addendum to the customary clinic letter to the general practitioner, facilitating the continuity of oncology care into the primary setting.

In a cohort of predominantly oral cancer patients in the post-treatment phase, the 5 most common concerns highlighted by patients on HN-PCI were the FOR (37%), dental health (27%), chewing and eating (24%), pain in the head and neck region (20%) and fatigue (19%) [**Rogers et al, 2009A**]. The median (IQR) number of concerns selected was 3 (1–6), range 0–21 with 82% selecting at least 1 item of concern. The three professionals patients most commonly selected were: dentist (19%), surgeon (10%) and speech and language therapist (10%). The median (IQR) number of professionals selected was 0 (0–1), range 0–8 with 42% selecting at least one professional. FOR is not an unexpected issue of concern to post-treatment patients, but it is frequently unexpressed openly by patients. Thus, concerns and fears of recurrences are seldom brought into discussion during consultation, despite this issue being the main concern for many patients as shown in this study. This finding insomuch demonstrates the permission-giving effect of the HN-PCI.

The HN-PCI prompt sheet format can encourage effective communication during in clinic consultations. Patients have commented that the HN-PCI **‘***reminds them of points they want discussed***’** at the clinic [**Rogers et al, 2009A**]. Through the checklist acting as a prompt, the HN-PCI helps focus and personalise consultations based on the specific concerns they have highlighted. The HN-PCI-directed consultation gives the clinician/multidisciplinary team a better understanding of the individual patient concerns, needs, and preferences, while patients can obtain the information they require regarding their concern, so as to help them participate actively in any clinical decision-making with the clinicians regarding their care.

2.6.2. Impact of HN-PCI on clinical outcomes

One criticism of routine screening of concerns and potential unmet needs in a clinic is that it may consequently increase onward referrals, thus, placing a bigger demand on existing healthcare services. However, a comparative study on the post-consultation referral trends in the time periods before and after introduction of HN-PCI did not show any increase in the overall numbers of such referrals [**Ghazali et al, 2011**]. The main reason for this was that the vast majority of HN-PCI-highlighted needs were dealt with immediately on the day of consultation because of the presence of multidisciplinary professionals during routine HNC outpatient clinics. This set up allows for a more prompt and efficient way of addressing supportive care needs and concerns. Detailed examination of the onward referrals made revealed an increased proportion of referrals to oral rehabilitation and psychological support, which are services that were not readily available during the HNC clinics.

2.6.3. Specific concerns identified by HN-PCI

Data generated from multiple, routine completion of the HN-PCI over time through outpatient clinics enabled further appreciation of particular issues experienced by post-treatment patients with the passage of time. There were two papers specifically relating to FOR identified by the HN-PCI, and these papers provided valuable insights into an area uncommonly explored in HNC [**Rogers et al, 2010; Ghazali et al, 2013B**]. The HN-PCI enables screening of FOR, being an item in the HN-PCI checklist. All UK-based HN-PCI-related studies to date indicate that FOR is the most common concern that HNC patients would like to be addressed in clinic, a finding that had never been previously reported. The ability of the HN-PCI to screen for FOR is extremely valuable because there are no predictive clinicopathological characteristics that could allow for effective routine screening of FOR **[Rogers et al, 2011B**]. Compared with a physical, symptom-type concern, it is far more difficult to broach a sensitive subject like FOR without a clear prompt like the HN-PCI. Using the HN-PCI-UWQOL, the prevalence of patients experiencing significant FOR was estimated at 35%, and longitudinal data indicates that this fear does not diminish with time [**Ghazali et al, 2013B**]. Independent predictors for significant FOR were personal characteristics of the survivor i.e. reporting significant problems with anxiety/mood, age and selecting FOR on PCI [**Ghazali et al, 2013B**]. This study indicates the value of the HN-PCI in disclosing a concern that can easily be overlooked because it is often undeclared by patients.

Apart from FOR, the HN-PCI-UWQOL combination was used to identify and quantify levels of emotional distress in post-treatment HNC patients attending routine FU clinics. This study found that the HN-PCI-UWQOL combination highlighted issues of mood, anxiety and depression in 10%, 23%, and 10% of patients, respectively [**Kanatas et al, 2012]**. In almost one-third of consultations, 44% patients reported significant problems with anxiety or mood on the UWQOL or highlighted issues of anxiety/mood/depression on the HN-PCI. It was noted that patients who highlighted emotional distress on the

HN-PCI frequently required referral for psychological support. In a more recent exploration of emotional distress using the HN-PCI-UWQOL in a larger cohort [**Kanatas et al, 2015**], FOR remained the most common concern selected by patients overall, and within the 14-item 'emotions' domain. This study found that just over half of patients (52%) were likely to choose FOR along with other items in the domain, and also other items in the HN-PCI. Patients who chose FOR and other items in the emotional domain also tended to be younger and had the poorest HRQOL status. This finding indicates that disclosing FOR in association with other emotional concerns may indicate the likelihood of a global distress compared with those who choose FOR alone. However, this study does not detail the outcomes of the consultations. It is possible that patients who report FOR alone could have their need addressed during the visit, but it is likely that patients who report FOR and other emotional concerns may require additional emotional supportive care to address the unmet needs, and this could place additional demand on existing services due to the size of this subset of patients (52%).

The HN-PCI-UWQOL combination screened for self-reported swallowing and/or speech problems in HNC patients [**Ghazali et al, 2012**]. These were prevalent, occurring in 39% of consultations involving 48% (n, 97) of patients overall. Of the 97 patients with self-reported swallowing and/or speech concerns, 74 (76%) were already known to the speech and language therapist, while the remaining 23 patients had their concerns addressed in the clinic. Three patients (3/23) required a referral for further specialized assessment and intervention for their speech and swallowing. This study demonstrates the ability of the HN-PCI to capture patients with significant problems that may have otherwise fallen through the net.

There are two studies evaluating the use of HN-PCI-UWQOL in screening for issues relating to oral health and function in those attending routine HNC clinics. The first is a study based in Aintree Hospital where the HN-PCI-UWQOL was used to screen for self-reported concerns with 'Chewing/eating' and 'Teeth/dental health', and the UWQOL Chewing domain [**Mahmood et al, 2014**]. This study found that 57% of patients (168/297) had oral health problems composed of those who indicated a significant chewing problem (40/297), those who wished to discuss perceived issues with their oral health and function but did not have a significant chewing problem (115/297), and those who wished to be referred to a dental health professional (i.e. dentist, dental hygienist or the oral rehabilitation team). Clinicopathological factors (i.e.

advanced staging, oropharyngeal tumours, RT, free-flap surgery, or worse overall UWQOL scores) were associated with poorer self-reported chewing function on UWQOL. Those reporting significant chewing problems were more likely to experience significant problems in other UWQOL domains (i.e. appearance, swallowing, speech, taste, saliva, pain and anxiety). Overall, those with self-reported concerns on HN-PCI with chewing or teeth concerns were more likely to report other concerns compared with those who did not. The dentist was the most frequent professional requested by patients with significant problems and concerns regarding their chewing or teeth. However, correspondence to the dentist only accounted for 10% of all letters evaluated, while correspondence with the oral rehabilitation team occurred in 31-33% of all clinic letters involving those with self-reported concerns on the HN-PCI related to their oral health and function. This study also showed how the UWQOL and HN-PCI can tease out patients with significant problems but who do not wish to discuss these (58%, 23/40) and those who could chew just as well but still wished to discuss the concern (21%, 22/103), providing a window into understanding patients’ preferences in terms of discussing certain concerns in the HNC clinic. In the second HN-PCI-UWQOL study screening for oral health and function issues of patients attending HNC clinics based in the University of Florida [**Aguilar et al, 2017**], items showing ≥ 10% prevalence that were related to oral health and function were salivation, chewing/eating, teeth/dental health and mouth opening. Interestingly, salivation was the most common concerns highlighted by this cohort, while FOR was the 5th most prevalent item.

In a study screening for self-reported pain in post-treatment period using the HN-PCI-UWQOL, up to 38% of patients experienced pain, of which 25% experienced significant pain [**Rogers et al, 2012**]. However, 55% who reported a significant problem with pain, did not wish to discuss this in clinics. A smaller proportion without significant pain problems (13%) wished to discuss pain during their consultation. Younger patients (<65 years) and those who received RT were more likely to have pain issues. Those with significant pain or those who wanted to discuss pain in clinic had greater problems in physical and social-emotional functioning, reported suboptimal QOL, and also had more additional HN-PCI items to discuss in clinic compared to those without significant pain issues. Those with significant pain, including those who did not wish to have this addressed at the clinic, were found to be on a regular prescription of analgesia. It is possible that this suggests that the concern is already comfortably self-managed by patients, or that such patients may prefer to discuss their pain-related concern elsewhere e.g. community setting or in a specialised pain clinic.

Facial disfigurement is a recognised consequence of HNC treatment. However, patients' concerns about appearance are often not discussed in clinic despite facial appearance being highly rated against other health-related issues impacting upon quality of life. In a HN-PCI-UWQOL study addressing facial disfigurement [**Flexen et al, 2012**], 14% met both the PCI and UWQOL criteria but almost half of those with significant appearance issues did not want to discuss this. The main factors associated with those who reported concerns about appearance were younger age, females, higher T-stage, and oropharynx subsite. Those who wanted to discuss facial disfigurement also frequently highlighted other concerns, namely, anxiety, depression, mood, sleeping, and self-esteem.

The combination of the HN-PCI-UWQOL and a single intimacy screening question was used to evaluate the prevalence of concerns relating to sexuality and intimacy [**Rogers et al, 2015A**]. This study found that the combined approach identified 31% (55/177) reported having 'Intimacy' and/or 'Sexuality' problems overall, and 14% (24/177) indicated having considerable/some concerns. Out of the 24 patients who had considerable/some intimacy concerns, the HN-PCI helped identify nine patients who wanted the topic to be discussed in clinic. Five out of the nine patients discussed intimacy concerns during their visit, where discussions led to onward referrals in four patients. This study indicates that while discussion surrounding this sensitive area was possible when highlighted by patients, not all of those who highlighted these on the HN-PCI wanted to discuss them when the matter was broached. Some felt that the clinical setting was not appropriate. Nevertheless, the HN-PCI enabled patients the choice to highlight a personal and sensitive matter if they so wished, and the tool enabled patients and doctors to make a shared decision regarding any clinical decisions/actions to address their unmet need as a result of their HN-PCI-facilitated discussions.

The concerns of elderly HNC patients (> 75 years) were studied by evaluating the HN-PCI responses in this subgroup of patients attending routine HNC follow-up clinics [**Rogers et al, 2015B]**. It was suggested that the elderly may have a general tendency to be forgetful and may not recall items of concern for discussion, and their advancing age and relatively higher comorbidity rates may present unique sets of concerns. Interestingly, this study found that the HRQOL status in the elderly was better than that reported by younger patients at the point when the HN-PCI was first completed. The selection profile by the elderly indicated that age did not influence the total number of items selected. However, elderly patients selected fewer items relating to the ‘emotional’ domain, which may be related to the better anxiety and mood scores and higher social-emotional subscale scores. More significantly, the > 75years age group showed a lower frequency of choosing to discuss FOR than that seen in all other younger age. The finding that the elderly are less likely to select FOR was also reported by **Ghazali et al [2013B]** in a longitudinal study of FOR with the HN-PCI. The dentist and surgeon were the two health professionals most often selected by elderly patients, and this may be unsurprising as ‘Chewing/eating’ and ‘Dental health/teeth’ remained high on the list of concerns of HNC patients in general, including the elderly.

There is a higher incidence of HNC in the lower socioeconomic group. It is known that patients from the lower socioeconomic group have lowered health literacy and recall of symptoms, and frequently have low self-esteem. These factors can be barriers towards expressing their needs during hospital visits. **Allen et al [2017]** undertook a study evaluating the influence of socioeconomic status on HN-PCI responses during routine HNC clinic visits. Based on the Indices of Deprivation ranks and scores for patients resident in England, 54% (47/87) of patients in this study cohort were living in the most deprived quartile of residential areas, with 15 % (13/87) in the 2nd quartile, 18 % (16/87) in the 3rd quartile, and 13 % (11/87) in the least deprived 4th quartile of areas, at the time of diagnosis. In regard to the HN-PCI selection profile, there were no significant differences seen in the number of items of concern or the professionals selected by patients between the deprivation quartiles. The two most common items of concern were FOR and sore mouth. However, there were significant differences seen in the UWQOL items, where patients from the most deprived quartile reported significantly more problems with recreation and mood than patients from other quartiles. This study suggests that levels of deprivation did not seem to influence feasibility of using the HN-PCI-UWQOL in general. The range of concerns of the more deprived HNC survivors were not significantly different to others, even though their HRQOL status was poorer.

2.6.4. Usage of the HN-PCI

A paper format for the HN-PCI was developed from the TST version [**Scott et al, 2013**]. Widespread adoption of the digital-based HN-PCI may be limited by financial and logistical constraints in other clinical units. Furthermore, patient confidentiality and data protection issues with electronic data are clinical governance concerns raised by other institutions. These provided the rationale for introducing a paper format. In a prospective study comparing TST and paper HN-PCI versions [**Scott et al, 2013**], no statistically significant differences were noted between paper and TST in how many HN-PCI concerns were selected by patients or discussed in consultation, nor in length of consultation. FOR, chewing/eating, dental health, swallowing and salivation issues were the 5 most common concerns across both HN-PCI versions. Only a small proportion (< 10%) encountered difficulties when completing either form of HN-PCI. Based on these findings, it was concluded that the paper HN-PCI was an acceptable and fitting alternative to the TST version.

At the time of when the current work was developed and planned i.e. October 2010 to February 2011, there was only a small collection of published HN-PCI-related studies for consideration. These studies were composed of data that were predominately generated from a cohort composed of oral cavity cancer survivors, and were based on the experience gained by a single physician who had originally introduced this PRO. Thereafter, two explorative studies of HN-PCI use by other doctors unfamiliar with the HN-PCI were published [**Scott et al, 2012; Ghazali et al, 2013A**]. The lack of data demonstrating the feasibility of using the HN-PCI in other HNC subsites remained. While one HN-PCI-related study of various HNC subsites was available, the items of concern identified using the paper HN-PCI in that study were not obtained through the outpatient setting but rather through a postal survey as part of a service audit exercise **[Kanatas et al, 2013]**. It can be argued that there was no evidence that the HN-PCI could be successfully used in a wider clinical setting, testing whether various doctors and patients who had never used the HN-PCI, could utilise this tool effectively. Thus, the next critical step in the development of the HN-PCI at that stage was to demonstrate that HN-PCI could be rolled out effectively in other HNC clinics outside of the circle of familiarity. This sets the stage for this current doctorate study.

While this current doctorate study was being undertaken, other developments relating to the HN-PCI occurred, and these are discussed henceforth. In September 2015, the tenth UK nationwide audit of HNC commissioned by the Healthcare Quality Improvement Partnership, was published [**DAHNO, 2015**]. For the first time this annual audit exercise evaluated the compliance of HNC units with the Cancer Reform Strategy

[DOH, 2007] recommendation regarding patients receiving holistic assessments during follow-up visits [**NCAT, 2011**] over a period from 1 November 2013 to 31 October 2014. In this audit, the HN-PCI was selected as a standard patient-reported HNC-specific measure suitable for national comparison based on the tool possessing the following features: (1) HNC-specific, (2) designed for routine use during follow-up visits, (3) enables patients to raise issues and concerns, (4) signposts access to other members of the MDT, and (5) enhances communication, and (6) provides support for holistic assessments [**DAHNO, 2014**]. The audit reported that not all HNC MDTs nationwide had used the HN-PCI. It estimated that only 539 patients (11.2%) had filled the HN-PCI within 6 months of their diagnosis compared with 754 patients (15.6%) who had not. The status was not recorded in 2859 patients (59.2%), and 680 (14.1%) patients were classified as being 'not applicable'.

The underwhelming application of the HN-PCI across-the-board highlighted fundamental issues, which suggested barriers to its comprehensive acceptance. A major issue is the lack of specific evidence documenting the ability of HN-PCI as a holistic assessment tool that could bring about measureable improvement in patient care, and also in service delivery. For this to occur, there has to be a meaningful engagement between the HNC MDT and the supportive services with the holistic assessment process and with the tool selected. In addition, patients' preferences for participating in holistic assessments need to be determined to ensure that this is useful from their perspectives. Common to other holistic assessment tools, many healthcare professionals were unfamiliar with the process and tools available [**NCAT, 2011**]. Other barriers to professionals' acceptance relate to their beliefs regarding their direct role in managing distress and unmet psychosocial needs.

Exploration of patients' views regarding the HN-PCI denotes a general favourable response [**Rogers et al, 2009; Hatta et al, 2014; Rogers & Lowe, 2016; Jungerman et al, 2017**]. Formal workshops and training sessions have been undertaken since November 2012 to provide healthcare professionals the theoretical and practical basis for using the HN-PCI [**Rogers & Lowe, 2014**]. However, there is still a lack of definitive guidelines for clinicians in managing concerns identified by the HN-PCI [**Rogers et al, 2016**]. The availability of a comprehensive 'rehabilitative/supportive care' guideline related to the HN-PCI can reassure cancer care professionals when using the tool. Having a template akin to the NCAT Rehabilitative Care Pathways (Head and

Neck) [**NCAT, 2010**] can help clinicians' in addressing complex biopsychosocial issues identified by the HN-PCI. However, the guidelines will depend on the services available locally and the critical support of multiprofessionals, who may not be directly related to the HNC MDT.

While the gold standard evidence for establishing the HN-PCI as the standard of care is still work-in-progress, adoption of the HN-PCI is gaining pace in in the UK. Several HNC MDTs are currently involved in a randomised control trial with the HN-PCI intervention [**Rogers et al, 2016**] and other units whose core members of the HNC MDT have undergone HN-PCI training have adopted this tool in their local practices. Inclusion of the HN-PCI in the 2014 national HNC audit has also resulted in the wider acknowledgement of the tool internationally. This development allowed for exploration of cross-cultural differences in HNC patients' concerns and needs.

The first non-UK HN-PCI application was reported in 2014, where the original HN-PCI version 1 was modified for use in Malaysia [**Hatta et al, 2014**]. The modification involved merging of several items into a single (i.e. 'sexuality' with 'intimacy'; and 'energy levels' with 'fatigue'), addition of two new items i.e. 'health supplements' and 'diet restrictions' and the removal of two items i.e. 'mood' and 'temperament/personality'. Furthermore, an attempt to create domains for the HN-PCI was undertaken producing 7 domains (i.e. physical status, emotional status, personal function, social/family relationships, economic status, diet-related function, and others), although the detailed methodology was not provided. The HN-PCI underwent forward-back translation method to enable cross-cultural adaptation, and was translated into Malay, Tamil and Chinese languages for use in a multiethnic cohort in Malaysia In this cohort, the top five items of concern were predominantly related to physical and functional concerns namely, Chewing/eating (48.6%), Pain in head/neck (43.1%), Salivation (30.6%), Limited mouth opening (30.6%) and Fatigue/Tiredness (20%). The prevalence of selecting FOR was only 6.9% in this cohort, suggesting a possible influence of the East versus Western cultural differences in patients' responses. This study reported high feasibility of the routine use of modified HN-PCI in the Malaysian setting. Most interviewed patients reported that the HN-PCI reminded them of the problems they needed to discuss, and majority agreed to use the HN-PCI in future visits. The majority of surgeons involved in this study felt that the HN-PCI helped guide them in addressing patients concerns in a more focused way during consultation [**Hatta et al,**

2014].

The HN-PCI (57-item) was recently translated into Portuguese language in a forward-back translation method, and was successfully adapted and validated in Brazil [**Jungerman et al, 2017**]. Modifications to the HN-PCI checklist were introduced to enable better understanding of the items and the terminology for professionals to suit the cultural/language and health service setting. The top five most prevalent items of concern were FOR (57%), dry mouth (45%), chewing/eating (44%), speech/voice/being understood (43%) and swallowing (40%). The median (IQR) number of HN-PCI items selected was 8 (5-13), range 0- 42 items, with 89% selecting at least one item of concern. The median and range of items selected by this cohort were generally higher than that originally reported by **Rogers et al [2009A**], although the top most prevalent concerns selected were similar. The top three specialists selected were speech therapist (26%), dentist (24%) and psychologists (18%). The median (IQR) number of specialists indicated was 1 (0-2), range 0-8 specialists, with 36% selecting at least one specialist. Compared with the findings reported by **Rogers et al [2009A]**, there was a very similar selection profile in regard to professionals/specialists by this cohort, and the only difference being the selection of psychologists in this cohort. The overall patient impression was favourable and authors concluded that there was good user acceptability/ feasibility of the HN-PCI Portuguese version. Finally, the first reported use of the HN-PCI in North America was by **Aguilar et al [2017]** based in University of Florida, which was discussed in the previous section on using the HN-PCI in screening for oral health and function. The original HN-PCI version 1 was used unmodified in their study. This study did not attempt to address the potential cross-cultural and health care systems differences. This may explain why no mention was made regarding the selection of professionals by patients in their study.

2.7 Conclusions

Identification of HNC patients' needs and concerns during survivorship is the main subject matter of this work. This chapter summarises the approach taken in considering this subject, where the subject matter was dealt with by an initial broad-brush approach. Fundamental ideas regarding patient-centred care in medicine, the concept of 'need' in healthcare, and the concept of patient empowerment were discussed.

Inward exploration of key concepts involved developing specific details, for example, clarifying the definition of inter-related terms relating to ‘need’. Key healthcare policies relating to identification of need in healthcare is presented, including holistic (need) assessments in cancer. The methods used in identifying patients’ concerns and needs were discussed, with particular reference to holistic (needs) assessment, where communication can be enhanced with a holistic PRO tool.

Chapter 3

3.0. HEAD & NECK CANCER SURVIVORSHIP

3.1. Introduction

With the diagnosis of head and neck cancer (HNC), patients begin their journey into the world of cancer survivorship. From this point henceforth, surviving HNC is their ultimate primary concern, and the priority is focused on treatment that offers the best chance of cure and survival [**Rogers et al, 2016C**]. However, the treatment options available for HNC (discussed in section 1.2), often lead to significant side-effects, which can be progressive and life-long. In this situation, well-being exists in the presence of disease and infirmary during HNC survivorship. HNC survivors and their caregivers will experience a wide range of physical, functional, cognitive and psychosocial problems throughout their cancer journey as the combined consequence of their disease and its treatment.

This chapter studies the experience of HNC survivors and their caregivers in their survivorship journey. The specific aim of this chapter was to provide a current and broad knowledge base of the key issues experienced by HNC patients and their caregivers, which can facilitate the qualitative work undertaken in this study.

Researchers have explored patients' and their caregivers' experience of HNC survivorship through two main research methodologies i.e. (1) self-reported health-related quality of life using various patient–reported outcome (PRO) measures [**Rogers et al, 2007A; Rogers et al, 2016B]** and (2) qualitative interviews [**Lang et al, 2013**].

3.2. Health-related quality of life in HNC survivorship

3.2.1. The conceptual basis of measuring health and its quality

The World Health Organization (WHO) regards health from a holistic standpoint, which is evident from its definition of health i.e. "*a state of physical, mental and social well-being, and not merely the absence of disease or infirmity"* [**WHO, 1948, page 1**]. From here, it follows that the measurement of health and the effects of health care must include not only an indication of changes in the frequency and severity of diseases but also an estimation of well-being, and this can be assessed by measuring the improvement in the quality of life related to health care [**WHO, 1997**]. In this respect, WHO defines quality of life as an "*individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns*" [**WHO, 1997, page 1**].

An individual's quality of life (QOL) is multidimensional in nature, consisting of but not limited by, a person's physical health and functioning, psychological state, level of independence, social relationships, occupation and finance, and personal beliefs (religion/spirituality) [**Saxena & Orley, 1997; Rogers et al, 2016**]. These factors interact with the salient features of external environment in a complex way that over-reaches beyond the small area of health care.

Health-related quality of life (HRQOL) may be considered as a component of overall QOL that is determined primarily by the person's health and that can be influenced by disease and clinical interventions. It is a more specific way of understanding the impact of a certain disease on the individual's QOL [**Wilson & Cleary, 1995**].

Measuring HRQOL enables healthcare professions to focus upon the assessment of the impact of the disease and its treatment on the physical, psychological and social aspects [**Rogers et al, 2016C**]. More specifically, HRQOL information may be valuable in helping patients decide on treatment choices, and also in identifying areas of need where supportive care interventions may be required [**Rogers et al, 2016C**].

3.2.2. Measuring QOL and HRQOL

Saxena and Orley [1997] describe the fundamental features of QOL measurement, i.e. individuals self-report their QOL assessment using a personal yardstick for judging how good or bad their quality of life is. The tool used for QOL assessment considers the multidimensional concept of QOL, and consists of a number of domains is necessary to derive a comprehensive view of a person's QOL.

Assessment of HRQOL is self-determined by patients, using instruments that ask questions about their health status, functional status and overall QOL. Within these broad constructs are questions that address physical health, psychological health, physical functioning, social functioning, role functioning, and general well-being. For HRQOL instruments/questionnaires to be useful, it has to demonstrate good psychometric performance properties i.e. validity, reliability, and responsiveness to change [**Linder et al, 2003**]. **Linder et al [2003]** succinctly summarises these performance properties as follows: "*An instrument is valid if it measures what it is purported to measure; reliable if repeated measures under the same conditions give similar results; and responsive if an instrument can detect important changes in the condition, even if those changes are small. Furthermore, changes should be interpretable, so that differences in the score of an instrument can be understood and assigned qualitative meaning*" (page 391).

3.2.3. HRQOL in HNC survivorship

Rogers et al [2016C] details the fundamentals of HRQOL assessment in HNC. A wide range of HNC-specific HRQOL instrument is available, and there is no single 'gold standard' instrument for use. Each HRQOL instrument carries its own strengths and limitations, and the choice and administration of the instrument depends on the purpose of the assessment. The assessment can be taken longitudinally, which allows the documentation of temporal changes in HRQOL status, or cross-sectionally, where an assessment is taken at a single time-point in the survivorship journey.

Laraway & Rogers [2012] classifies HNC-specific HRQOL instruments into four main categories: (i) Generic QOL, i.e. those asking about a range of broad issues unspecified to cancer; (ii) Cancer-specific QOL, i.e. those addressing issues common to all cancers; (iii) HNC-specific QOL, i.e. questionnaires with HNC-specific items; and (iv) HNC-specific issue i.e. those questionnaires that focus in detail on a particular aspect of HN function.

3.2.4. Review of HNC-specific HRQOL studies

HNC-specific HRQOL studies provide a window to understanding the key issues that patients and their carers experience in HNC survivorship [**Rogers et al, 2016C**]. There are two in-depth structured literature reviews of QOL-themed studies exploring issues relating to HNC self-reported HRQOL, and these reviews considered evidence from papers published during the period of 2000 to 2013 [**Rogers et al, 2007A; Rogers et al, 2016B**]. There has not been any updated review of the evidence published after 2013 other than a summarised list of key issues experienced by patients and their carers in HNC survivorship (**Table 3.1**) [**Rogers et al, 2016C**].

Thus, a literature review of QOL-themed studies published after 2013 was undertaken in this current work to explore for any new areas of knowledge within the body of evidence. This review also provides the knowledge base for the thematic framework approach during the assessment of patient concerns in the study.

The literature search methodology undertaken was based on the same methodology described in the previous in-depth reviews [**Rogers et al, 2007A; Rogers et al, 2016B**] to provide methodological continuity. The methodology used and the results obtained are shown in Appendix 1. Five additional themes i.e. breathing, sleep, taste, smell and self-management (**Table 3.1**) were identified during the literature review. A brief discussion of the key issues is presented in the section 3.2.5.

3.2.5. Key issues impacting HNC survivorship

i. Caregivers, children and family

The caregivers (or carers) of cancer patients are considered within the definition of the ‘cancer survivor’ in the UK [**NSCI, 2010**]. This definition recognises their role in providing support and assistance, thereby easing the burden for patients as they cope with the diagnosis and treatment of HNC. In a survey of HNC caregivers, **Hanly et al [2016]** found that the majority were females (76%), were not in paid employment (68%) and were caring for their spouses (67%). Females were also the most common primary caregivers [**Rigoni et al, 2016**]. **Nightingale et al [2016**] observed that the majority of caregivers lived with patient (88%) and provide daily care (73%).

The reported caregiving burden is variable. In one cohort, HNC caregivers reported low levels of burden [**Hanly et al, 2016**] while others report a heavy caregiving load [**Nightingale et al, 2016**]. Caregivers of HNC patients also provide emotional and instrumental support, most frequently with nutrition and assistance with speech, appearance, and addictions [**Sterba et al, 2017A**]. Experiences looking after trachestomy and tube feeding can be overwhelming for caregivers [**Sterba et al, 2017B**].

Table 3.1. Key issues impacting HNC survivorship

Based on Rogers et al, 2016	***Issues identified in current review***
Carer	Breathing
Comorbidity	Sleep
Coping	Taste
Dental status	Smell
Disfigurement	Self-management
Emotional distress	
Family and children	
Fatigue	
Fear of recurrence	
Financial and work	
Function	
Fungating wounds	
Information	
Intimacy	
Lifestyle choice	
Nutrition	
Osteoradionecrosis	
Pain	
Personality	
Self-esteem	
Socioeconomic Status	
Speech	
Swallowing	
Shoulder	
Trismus	
Unknown	
Xerostomia	

There are positive aspects of caregiving for cancer patients [**Li & Loke, 2013**], including increased self-identity [**Richardson et al, 2016**] and attainment of happiness [**Hanly et al, 2016**]. However, many HNC caregivers face challenges. Early studies suggest that psychological distress amongst family/caregivers were similar to those of patients [**Vickery et al, 2003**; **Zwahlen et al, 2008**]. More recent studies confirm that the high levels of distress and lowered QOL experienced by patients and caregivers were similar [**Rigoni et al, 2016**].

HNC caregivers report compromised psychosocial functioning, where symptoms of depression and anxiety are more prevalent than the normal population [**Longacre et al, 2012**; **Nightingale et al, 2016**]. HNC caregivers experience moderate to high levels of distress [**Ross et al, 2010**], suffer worry and fear of recurrence (FOR) [**Longacre et al, 2012**; **Lin et al, 2016**; **Maguire et al, 2017**], feel symptoms of anxiety, depression [**Terro & Crean, 2017**] and report suboptimal mental well-being [**Sterba et al, 2017A; 2017B**]. Psychological distress levels of caregivers are high during active treatment [**Lin et al, 2016; Ross et al, 2010; Badr et al, 2014],** which is related to coping with the physical effects related to treatment [**Badr et al, 2014**]. Higher levels of FOR are reported in female caregivers, those caring for younger patients, and those with survivors who had undergone less extensive forms of surgery [**Maguire et al, 2017**]. Furthermore, higher scores relating to worry and FOR was seen in caregivers who reported more loneliness, spent more time caring, and had greater financial stress [**Maguire et al, 2017**].

Not much is understood about the unmet needs of HNC caregivers. **Longacre et al [2012]** suggests that there is a perceived need for social support. **Nightingale et al [2016**] reports a demand by caregivers for wellness programmes that focus predominantly on diet/exercise, cancer education, stress reduction and finances, caregiving, and well-being. Such a programme may also help with lifestyle choices related to smoking and poor problem-solving ability among patients and caregivers [**Sterba et al, 2017A; Trunzo et al, 2016**].

Nevertheless, **Balfe et al [2016]'s** study of caregivers' self-reported unmet supportive care needs indicate that HNC caregivers had low levels of unmet needs. The highest levels of need were located in the emotional and the health services domains. Managing FOR was the most frequently reported individual need. Loneliness and financial stress were consistently and significantly associated with high levels of unmet need in this cohort. **Hanly et al [2016]** also reported on the unmet needs of caregivers, where healthcare needs was associated with carer burden, while their happiness was associated with psychological needs, healthcare service needs, informational needs, carer comorbidity and gender.

There is little known about the longer term impact on caregivers living with significant permanent disability in HNC patients. In a prospective study of spouses of laryngectomy patients over 3 years, there were high levels of distress, where the majority expressed wanting to learn relaxation methods [**Meyer et al, 2015**]. However, the need for psychosocial support and the use of professional support among spouses remained stable over time and there was low uptake of their own personal counselling.

ii. Comorbidity

Comorbidity is the presence of additional illnesses unrelated to the malignancy [**Paleri et al, 2010**]. In HNC, tobacco and alcohol abuse contributes greatly to comorbidity [**Boje et al, 2014**], which impacts significantly on the prognosis of HNC [**Paleri et al, 2010**]. Large cohort studies show that comorbidity increases the overall mortality in HNC [**Gollnitz et al, 2016; Boje et al, 2014**]. Six comorbidities, namely, congestive heart failure, cerebrovascular disease, chronic pulmonary disease, peptic ulcer disease, liver disease, and diabetes were significantly associated with reduced survival in HNC [**Boje et al 2014**].

Comorbidity may influence disease-specific survival negatively by way of its association with delayed diagnosis, and the presentation of more advanced stage disease [**Paleri et al, 2010**]. Comorbidity can be a determinant factor of HNC treatment, where higher comorbidity scores could prompt a less aggressive treatment [**Paleri et al, 2010**]. Furthermore, treatment complications are more frequently seen in patients with high comorbidity scores, resulting in a higher demand for health care.

Comorbidity influences HRQOL of HNC survivors. **Oozer et al [2008]** reported that patients with moderate to severe comorbidity had statistically significantly worse QOL at the start and at the midpoint of treatment, but not at the end of treatment. In HNC survivors, comorbidity score is a significant predictor of both the functional and the general symptom sum HRQOL scores obtained at 18-months follow-up [**Osthus et al, 2013**]. Comorbidity accounted for the proportion of variance seen in the functional and general symptom sum scores noted in longitudinal HRQOL scores. This study also found that lung disease appears to have an important and unique influence on HRQOL scores in HNC survivors [**Osthus et al, 2013]**. Addressing comorbidities during post-treatment survivorship may require input by the general practitioners and medical specialists in the hospital setting.

iii. Coping and personality

Coping and personality are two closely related key issues affecting HNC survivors. Coping may be defined as the constantly changing cognitive and behavioral efforts to manage specific external or internal demands (and conflicts between them) that are appraised as taxing or exceeding the resources of the person [**Aarstad et al, 2011**]. Coping styles include problem-focused, emotional-focused and avoidance coping, where more than one style can be used at a time [**Aarstad et al, 2011**]. Specialised types of coping include ‘drinking to cope’, ‘coping by humour’ and ‘coping by religion’ [**Aarstad et al, 2011**].

Sherman et al [2000] found a range of styles employed by HNC patients undergoing different phases of treatment (i.e. pretreatment versus on treatment versus post-treatment at < 6 months and >6 months) including acceptance, active coping and religion. Denial, disengagement, and suppression of competing activities were present in those receiving or recently completed treatment. This subgroup also employed a greater number of coping styles compared with others.

Coping strategies in HNC survivors may also vary according to their level of psychological distress experienced. **Sherman et al [2000]** found that increased distress was associated with general denial, behavioural disengagement and emotional ventilation. On the other hand, **Elani & Allison [2011]** found that patients with higher levels of anxiety and depression used more "blamed self", "wishful thinking", and "avoidance" coping strategies.

The type of coping style can influence HRQOL. **Aarstad et al [2002]** found that HNC patients who showed coping by humour and coping by problem-solving directly predicted low QOL. In the pretreatment phase, while a range of coping styles were employed, social support seeking behaviours representing the greatest proportion of total coping effort by HNC survivors [**List et al, 2002**]. Avoidance coping strategies resulted in poorer HRQOL in the pretreatment cohort.

The coping style employed may be related to the treatment previously received by HNC patients can influence HRQOL outcomes. In a cross-sectional study of coping styles of disease-free post-treatment HNC survivors, **Aarstad et al [2005]** found that using emotional focused coping was associated with low HRQOL among those treated with surgery only, while this method was associated with increased HRQOL among those treated with radiation therapy only. It is suggested that these associations may be indirectly related to coping with the treatment side –effects.

When measured longitudinally, avoidance focused, problem focused, drinking to cope and coping by humor all predicted HRQOL scores [**Aarstad et al, 2008**]. Coping by resorting to smoking and alcohol in HNC is not uncommon. While this type of behaviour carries a risk of adverse outcome to their HNC, patients who have this type of coping report good HRQOL.

Personality may be defined as those characteristics of the person that account for consistent patterns of feeling, thinking and behavior [**Aarstad et al, 2008**] and represents a person’s stable disposition [**Ran et al, 2014**]. There are only two studies of personality and coping in HNC [**Rana et al, 2014; Aarstad et al, 2008**]. While both studies approach personality from a different theoretical model, the overall findings indicate that personality type can influence how patients experience and cope during HNC survivorship.

Aarstad et al [2008] evaluated personality based on Eysenck’s model, which considers two personality types i.e. neuroticism and extraversion, and coping in HNC survivors. High neuroticism, but not extraversion, is associated with a lowered QOL [**Aarstad et al, 2008**].

Rana et al [2014] evaluated personality based on ten personality traits as assessed by the Frieburg Personality Inventory in disease-free HNC patients. This study demonstrated that certain personality traits correlated with coping styles. For example, lowered life satisfaction, inhibition and strain were predictors of depressive coping style. Social orientation and achievement were predictors of active problem-oriented coping, where there is seeking of social support or resorting to self-directed problem solving as ways of coping. However, this study did not directly relate the type of coping style with QOL outcomes.

Hope and optimism are related to post-traumatic growth and benefit finding in HNC survivors [**Ho et al, 2011; Harding et al, 2014**]. Benefit finding was facilitated by active coping strategies by patients [**Cavell et al, 2016**]. In a study of pretreatment coping styles in HNC patients, the use of negative coping styles was related to high anxiety levels, while low levels of optimism were related to higher levels of depression [**Horney et al, 2011**].

iv. Dental / Oral status and rehabilitation

Dental/oral health is one of the most common concerns of HNC patients [**Rogers et al, 2009; Jungerman et al, 2017**]. Post-treatment oral health status can result in negative functional and psychological repercussions [**Rogers et al, 1999**]. Direct damage to the oral structures (soft and hard tissues) frequently occurs from surgery, radio- and chemotherapy, and indirect damage may also arise from systemic toxicity [**Hong et al, 2010**]. HNC treatment can result in the loss of teeth. Dental extractions can occur in resectable oral cancer, where teeth are included as part of cancer clearance [**Pace-Balzan & Rogers, 2012**]. Teeth with poor prognosis are preemptively removed in view of chemo- and radiotherapy because patients with chronic dental disease and poor oral hygiene may be at an increased risk for the development of acute odontogenic infections and potentially life-threatening systemic infections during periods of chemotherapy-induced immunosuppression, and to prevent future need for dental extraction in teeth located within the radiation fields and the development of osteoradionecrosis [**Hong et al, 2010**]. Soft tissue health, i.e. mucositis (acute and chronic) is also affected by xerostomia. Replacement of normal mucosal lining by hair-bearing skin flaps changes the oral environment.

Changes to oral status result in multiple oral functional deficits i.e. chewing, swallowing and speech functions. Dental status has a persistent impact on subjective QOL [**Duke et al, 2005**]. The loss of teeth is a determinant of patient HRQOL, where reduced self-perceived oral health status is associated with greater numbers of missing teeth [**Korfage et al, 2011**]. Loss of teeth is also related to reduction in maximum bite force, overall masticatory function and poorer oral status compared with normal populations [**Speksnijder et al, 2011**]. Poor masticatory efficiency affected food choice and social life [**Pace-Balzan et al, 2009**]. Some patients are unable to wear dentures (22%) and this compounds poor functional outcomes [**Kamstra et al, 2011**]. Changes to the shape of oral/oropharyngeal soft tissue organs i.e. tongue, cheek and soft palate, can result in oral dysfunction due to loss of sensation, and abnormal/poor movement, strength and coordination [**Kamstra et al, 2011**]. Furthermore, loss of teeth and/or the basal bones (i.e. mandible or maxilla), can cause significant changes to orofacial appearance, with psychosocial implications [**Pace-Balzan & Rogers, 2012**]. **Hassel et al [2011]** reported the association of psychological distress (depression and/or anxiety) in disease-free survivors with poor self-reported oral health status. In a cross-sectional study of oral cancer survivors wearing dental prosthesis, 33% were somewhat or extremely depressed, 25% were anxious or very anxious, and 15% were both depressed and anxious [**Pace-Balzan et al, 2008**].

As a result of these issues, survivors frequently seek oral rehabilitation [**Ghazali et al, 2012**]. Oral rehabilitation strategies include aggressive oral health preventative programmes i.e. topical fluoride treatment, chlorhexidine mouth rinses [**Hong et al, 2010**], restoration of carious teeth, and prosthetic replacement of lost teeth [**Pace-Balzan & Rogers, 2012**]. The mainstay of dental rehabilitation of HNC survivors remains the provision of conventional fixed and removable prosthodontic appliances [**Pace-Balzan & Rogers, 2012**]. This process is complicated by the after effects of radiotherapy, diminished tongue function, changes to the soft-tissue and hard-tissue configuration, the presence and distribution of remaining teeth, the quality of tissue support, extent of mouth opening, the maxillomandibular relationship, and the quantity and quality of saliva available [**Pace-Balzan & Rogers, 2012**]. Because of this, not all survivors are suited to receive dental rehabilitation. Survivors who are able to receive oral rehabilitation are expected to attend multiple visits to the hospital/ dental clinics in the course of their treatment. Some require additional surgery to facilitate their oral rehabilitation.

Following completion of oral rehabilitation, most survivors report improvement in function and oral health-related QOL scores [**Dholam et al, 2017**]. This study also reported that despite good post-rehabilitation scores, a very small proportion of patients i.e. those who received a maxillary obturator still remained embarrassed about conversing, refused dinner invitation and lacked self-confidence because of embarrassment about their dentures. **Pace-Balzan et al [2009]** also reported this previously.

More recent studies document the outcomes and impact of implant-retained prostheses, particularly when implants were supported by microvascular bone flap reconstruction. Oral rehabilitation with implant-supported dental prostheses after reconstruction of segmental maxillofacial defects with vascularized flap resulted in good to excellent speech intelligibility and aesthetics [**Kumar et al, 2017**; **Wijbenga et al, 2017**].

v. Disfigurement

HNC and its treatment can result in facial disfigurement. Surgical access, curative surgical ablation, scarring and radio- and /or chemotherapy-related effects, can result in permanent loss of normal contours and integrity. Disfigurement is significantly related to a diagnosis of oral cancer, a history of adjunctive radiation, the type of surgical procedure performed, the degree of physical dysfunction, and the presence of postoperative complications [**Katz et al, 2000**]. The ability to re-integrate treatment-related changes into the body image is critical to optimal recovery and QOL after treatment [**Dropkin, 1999**]. About one quarter of HNC survivors have problems with appearance following treatment for oral or oropharyngeal cancer, and they rate appearance issues quite highly against other HRQOL issues [**Rogers et al, 2008; Katre et al, 2008; Millsopp et al, 2006**], where appearance can affect their activity and/or limit their social interactions [**Millsopp et al, 2006**; **Katre et al, 2008**].

HNC survivors experience significant negative psychosocial consequences from facial deformity. Survivors with greater disfigurement were more depressed [**Katz et al, 2003**]. Due to the central role of the face in self-expression and self-identity [**Penner, 2009**], changes to facial appearance can significantly influence their sense of body image [**White, 2000**]. In describing the impact of facial disfigurement, **Flexen et al [2012]** notes that the changes to facial appearance can act as persistent reminders of the disease, where visible disfigurement can profoundly shape social encounters. The distress experienced by a patient upon seeing in the mirror their ‘flawed’ image is re-lived through the reflected response of others, even during the briefest of contacts [**Macgregor, 1990**]. **Djan & Pennington [2013]** purports that the importance of facial appearance in self esteem and society's aversion to visible deformity means that its alteration can significantly impact on QOL, so much so HNC patients may fear facial disfigurement more than disease recurrence.

However, patient's concerns relating to appearance can go largely unrecognised in the outpatient clinics as patients are reluctant to burden clinicians with concerns about appearance and clinicians show poor awareness of patients' concern with disfigurement [**Djan & Pennington, 2013**]. **Millsopp et al [2006]** reported that 41% of HNC disease-free survivors were concerned with appearance and yet only seven patients (7/114, 6.1%) had appearance mentioned in their notes whilst only four (4/114, 3.5%) were considered for intervention.

Patients with appearance concerns are often overwhelmed with anxiety, distress, depression, and employ negative coping strategies [**Dropkin, 2001**]. Patients with disfigurement issues may benefit from further refinement surgery, prosthetic rehabilitation, participation in support groups, camouflage techniques including medical tattooing [**Drost et al, 2017**], and other holistic therapy, such as massage and in particular, psychosocial interventions, including education via self-help publications, social skills course, counselling and cognitive behavioural therapy [**Bessel, 2007**]. The opportunity for patients to discuss their body image issues in clinic must be facilitated to allow their rehabilitative needs to be addressed.

vi. Emotional distress and fear of recurrence (FOR)

In a systematic review of psychological variables associated with quality of life following primary treatment for head and neck cancer, **Dunne et al [2017]** found that distress-related variables (depression, anxiety, distress) were most frequently investigated, and mostly reported negative associations with QOL outcomes in HNC survivorship. Emotional distress is experienced throughout the survivorship trajectory, where depression [**Humphris & Rogers, 2004; Telfer et al, 1993; Espie et al, 1989; Wu et al, 2016**], anxiety [**Telfer et al, 1993; Espie et al, 1989; Chen et al, 2010; Chen et al, 2009A Chen et al, 2009C; Wu et al, 2016**] and mood disorders [**Espie et al, 1989**] are prevalent among HNC survivors. Over time, the experience of distress, anxiety and depression changes with time [**Wu et al, 2016; Ninu et al, 2016**, where improvement in post-treatment cohorts is generally reported [**Neilson et al, 2013**]. Various studies have identified specific factors that are related with/or predictive of distress, anxiety and/or depression in the HNC cohort [**Mucke et al, 2015**; **Almstahl et al, 2016; Moubayed et al, 2015;**], and the heterogeneity seen within and between studies suggest that assessment on an individual basis may be the most practical approach in understanding the prevalence, its potential association with other key HNC survivorship issues, and the overall impact of these emotional problems at specific time points during the survivorship trajectory.

Fear of recurrence (FOR) is a critical and central issue for patients because it relates to their survival. HNC patients and their caregivers fear cancer recurrence [**Humphris et al, 2003; Hodges & Humphris, 2009; Rogers et al, 2010; Ghazali et al, 2012; Wells et al, 2015; Maguire et al, 2017**] but this fear is infrequently disclosed [**Rogers et al, 2010]** and may cause significant psychosocial morbidity and affect their HRQOL negatively [**van Liew et al, 2014**; **Lin et al, 2016**]. Significant FOR occurs commonly among HNC survivors [**Rogers et al, 2010**]. When assessed longitudinally, 20% of patients reported significant FOR intermittently, whereas 30% experienced it consistently [**Ghazali et al, 2012**]. FOR has been shown to correlate with anxiety and mood [**Rogers et al, 2016A**], and occurred more frequently in those who continued to smoke after treatment [**van Liew et al, 2014**]. In addition, FOR is also associated with those who had poorer function and with those who felt that the information provided by health care professionals were inadequate [**Handschel et al, 2012**].

There is an increasing drive towards distress screening in HNC. Distress screening is often undertaken simultaneously with uncovering unmet needs through the process of holistic assessment [**NCAT, 2011**]. In a study surveying distress and unmet needs of post-treatment HNC survivors, one quarter reported experiencing significant distress, and the most common unmet need was psychological [**Henry et al, 2014**]. A higher level of overall unmet needs was found in patients who were divorced, had a high level of anxiety, in poor physical condition, or had a diminished emotional QOL [**Henry et al, 2014**]. A similar proportion of post-treatment HNC survivors reported clinically significant distress (22%) in a study by **Bornbaum et al [2011],** where distress was correlated with the presence of symptoms and HRQOL status. **Krebber et al [2016]** used touch-screen based screening tool for distress in HNC survivors and found that

29% of survivors reported psychological distress, where 19% fulfilled the criteria for significant distress and were undergoing psychological support. **Wells et al [2015]** found that one-third of post-treatment HNC survivors experienced moderate to severe distress, where 75% had at least one unmet need. The most common concerns and unmet needs included oral and eating problems, FOR and fatigue.

There are fewer studies evaluating levels of distress in patients HNC at pre-treatment than those currently undergoing treatment. **Chen et al, [2009**] suggests that the proportion of patients with distress may be higher in cohorts undergoing active treatment compared with those in the post-treatment group. **Ichikura et al [2016]** observes the persistence of psychological distress in hospitalized HNC patients, which correlated with their physical issues.

A range of psychosocial intervention have been proposed and evaluated to address the psychosocial distress [**Semple et al, 2013**]. While not all HNC survivors would accept professional intervention for their distress, some of those with significant distress were willing to consider psychological support [**Shiraz et al, 2014**].

vii. Fatigue

Fatigue is a common issue faced by cancer survivors. There is relatively little evidence base available on the experience of fatigue by HNC survivors. However, fatigue was one of the top five most common concerns of HNC survivors, accounting for one-fifth of those studied [**Rogers et al, 2009**].

Aynehchi et al [2013] found that cancer stage and comorbidity significantly correlated with fatigue in HNC survivors. The correlation of advanced cancer stage with fatigue was also reported by **Silviera et al [2015]** in a study of HNC patients that underwent non-surgical treatment i.e. chemoradiotherapy and/or radiotherapy. **Veldhuis et al [2016]** found that the oropharyngeal subsite treated by non-surgical means correlated with fatigue. **Singer et al [2014]** noted that post-laryngectomy patients never recovered their fatigue scores to pretreatment. **Sawada et al [2012]** noted that patients reporting fatigue along with depression increased during the course of radical radiotherapy. **Jereczek-Fossa et al [2007]** showed a similar pattern in their cohort receiving radiotherapy, where fatigue scores peaked at 6 weeks of radiotherapy improved thereafter. Fatigue was also reported in those who received postoperative radiotherapy [**Ch'ng et al, 2014**] and those who received chemoradiotherapy [**Ackerstaff et al, 2012; Pan et al, 2017**]. Pre-radiotherapy fatigue score, induction and/or concomitant chemotherapy, and need of cortisone during radiotherapy ($p < 0.005$) were correlated with higher post-radiotherapy fatigue level **[Jereczek-Fossa et al, 2007]**. Fatigue was the most common symptom of patients who were referred for palliative care [**Ullgren et al, 2017**]. Fatigue correlated with other key issues of HNC survivorship, including sleep disturbance/apnoea [**Loth et al, 2017**], distress [**Krebber et al, 2016**], and swallowing function [**Silviera et al, 2014**].

Interventions to reduce fatigue have been evaluated. Treatment with epoetin alfa was not found to influence fatigue in HNC patients treated by radiotherapy [**Hoskin et al, 2009**]. Intervention with 'guarana', a plant-based dietary supplement with stimulant effects, did not improve the management of fatigue [**Martins et al, 2016].** More recently, **Xiao et al [2016]** showed that inflammation could mediate the development of fatigue in survivors.

viii. Financial burden and employment

There are very few studies documenting the issues of financial burden and employment in relation to HNC survivorship. At diagnosis, more than half of UK HNC patients interviewed reported suffering financially, particularly in those who were retired, and whose occupation was directly affected by HNC [**Rogers et al, 2012C**]. A similar proportion of patients reported a decrease in their QOL as a result of the financial impact of the disease, which was most common in the unemployed, and in those whose work was affected by cancer [**Rogers et al, 2012C**].

The financial burden of UK HNC survivors and the impact on HRQOL was explored by **Rogers et al, 2012B]**. The most notable financial costs of moderate or large burden to patients were petrol, home heating, change in the type of food, and loss of earnings. Loss of income due to medical condition was significant in 15%. Patients with worse physical and socio-emotional functioning experienced more notable financial burden, and had more difficult life circumstances in the past month. In addition, this subgroup also had greater financial difficulty, and suffered loss of income due to their condition in the previous week. Furthermore, they reported more dissatisfaction with how well they took care of their own financial needs and were more likely to have sought statutory benefits.

Egestad et al, [2015] undertook an evaluation of the financial impact on HRQOL in Norwegian HNC patients, whose healthcare system is based on general taxpayer revenues. While this healthcare system is similar to the UK healthcare system, HNC patients did not report any significant financial difficulties at the end of treatment compared with the their status before commencement of treatment [**Egstad et al, 2015]**. However, they observed a trend of increasing financial difficulties during treatment in males, and those < 65 years i.e. before age of retirement.

Some survivors need help with managing their financial burden. About a quarter of patients reported moderate to significant dissatisfaction with how they addressed their financial burden [**Rogers et al, 2012C**]. Adequate help and information about finance was only received in a quarter of patients. Within this subgroup, financial advice/help was twice more frequently received by those who were fully employed (39%) compared with the unemployed (18%) [**Rogers et al, 2012B**]. Only two-thirds of survivors surveyed claimed benefits, where the most common benefits claimed were Disability Living Allowance and Incapacity Benefit. This study highlights the importance of providing patients with information about financial help in alleviating their financial burden.

Regarding employment, the majority of HNC patients (83-92%) were in employment at the time of their diagnosis [**Agarwal et al, 2017; Verdonck et al, 2010**]. Up to three-quarters (66-71%) returned to work after treatment [**Agarwal et al, 2017; Verdonck et al, 2010**] and the median time to work was 6 months [**Verdonck et al, 2010**]. **Agarwal el al [2017]** found that family structure (<2 male children, and eldest child age <20 years), a higher level of education (vocational or professional training), and the female gender were associated with higher return to work. **Verdonck et al [2010]** found that oral dysfunction, loss of appetite, deteriorated social functioning, and high levels of anxiety were barriers for HNC survivors returning to work after treatment. Furthermore, in previously employed HNC survivors who returned to employment, most resumed the same work, while others went into adapted work and/or into a different job. HNC survivors who returned to work had better global QOL and seemed to cope with the side-effects of treatment, including coughing and sticky saliva [**Agarwal et al, 2017**].

However, **Terkawi et al [2017]** reported that chronic pain interferes with normal work in post-treatment HNC survivors.

Koch et al [2015] evaluated employment and psychological factors in HNC survivors and found that current unemployment among was associated with harder physical work before cancer diagnosis, surgical treatment, and current risky alcohol consumption. This group of patients also reported decreased functional and social well-being and depression scores.

ix. Information

Information needs are important issues to HNC survivors [**Semple & McGowan, 2002**], and this is recognised by the government's drive for cancer patients to receive high quality information. Need for information is important at each stage of survivorship, especially when there is a sudden change in their disease status. Information can also be used as a form of intervention during survivorship, e.g. information about lifestyle choices relating to risk behaviour is valuable in secondary prevention [**Semple & McGowan, 2002**].

Many HNC survivors felt unprepared for the long-term lifestyle changes that occurred when their experience was evaluated retrospectively [**Newell et al, 2004**]. Satisfaction with information relates to the comprehensiveness of the information provided [**Semple & McGowan, 2002**]. The quality of information and satisfaction with the information provided was predictive of psychological distress (depression) [**Llewellyn et al, 2006**].

In a substantial review of informational needs and experiences of HNC survivors, **Ziegler et al [2004**] recommended that improvement to information giving is critical in light of the significant psychosocial and other functional disturbance reported among those who underwent surgery. **Rogers et al [2015C]** recently introduced a patient information sheet on the expected HRQOL outcomes based on a large, long-term database of HRQOL scores of HNC, and proposed that this HRQOL-based information can help patients decide on treatment options as they consider the potential after-effects of treatment on their quality of life based on the experience of other patients with similar clinicopathological and treatment characteristics.

Patients who have undergone surgery and their caregivers reported feeling adequately prepared about the surgery procedure [**Newell et al, 2004**]. This was similarly reported by HNC patients who were undergoing surgery in a prospective study of information given at presurgery, and in its relationship with HRQOL [**Bozec et al, 2016**]. This study found that HNC patients felt satisfied in all areas related to information, and this correlated with the HRQOL.

Llewellyn et al, [2006] studied the information received in the post-treatment period, where disease-free HNC patients reported being generally satisfied with information given. The key areas of information required by survivors related to support groups, financial advice and the long-term affects of treatment on ability to work, physical functioning and QOL. In a more recent work by **Jabbour et al [2017],** the majority of HNC patients surveyed across multiple institutions reported that the information received concerning the disease process (76%), prognosis (67%) and treatment (77%) were sufficient. However, half of patients reported receiving little or no information regarding coping with stress and anxiety, while more than half received minimal information about psychosexual health (56%) or the availability of patient support group (56%).

Jabbour et al [2017] also evaluated the methods by which patients' accessed/received the information**.** The majority of this cohort expressed a preference for a multiple mode of access to the information delivery (72%), while the rest preferred one-to-one modality, or internet-based information. In a large survey of informational needs and the preferred modality for delivery in a Canadian HNC cohort (n, 450), the top preferred educational modalities reported by patients were teaching with healthcare professionals and through pamphlets [**Papadakos et al, 2017**].

The value of written or similar forms of information as a reference for patients has been evaluated. In the palliative setting, **Ullgren et al [2017]** noted that patients were more satisfied when given written information regarding their self-care compared with those who did not receive the information in written form. There is an on-going clinical trial evaluating the DVD intervention of information for HNC patients and their caregivers [**Parker et al, 2016**].

Best et al [2015] evaluated the quality of information available on the internet for patients with HNC, and found that only 17.5% of websites evaluated partially or fully achieved the Journal of American Association of Medicine (JAMA) benchmarks criteria on the quality of medical information on the internet [**Silberg et al, 1997**]. This finding was similar to a previous survey undertaken in 2008 [**Ni Riordain & McCreary, 2008**]. Another survey using similar methodology for information regarding oral cancer also found that the majority of websites did not meet the JAMA criteria [**Lopez-Jornet & Camacho-Alonso, 2008],** indicating a need for vigilance by survivors when using these websites.

Support groups are excellent sources of information and support for survivors, who derive personal experience of others who have been diagnosed and treated that health care professionals are not able to provide. **Vakharia et al [2008]** evaluated the impact of support groups in HNC patients, and found that patients who participated in the HNC support group exhibited significantly better scores in the domains of eating, emotion, and pain as well as in the global QOL, compared with those patients who did not participate. Utilisation of web-based support groups can also provide similar improvements in HRQOL. **Algtewi et al [2017]** reported that participation in online support groups was found to be associated with better HRQOL either directly or indirectly through decreasing depression, anxiety and the negative adjustment behaviours and increasing self-efficacy and empowerment of the users.

In view of identifying gaps for improvement, **Fang & Heckman, [2016**] undertook a literature review of informational needs for HNC patients and observed several areas where information was reported inadequate or deficient by patients. These include informational needs of caregivers/family, lifestyle choices, particularly regarding smoking and alcohol dependency, involvement in clinical trials and information relating to HPV-related cancers. Other studies have also reported information gaps in areas relating to financial help [**Rogers et al, 2016C**]. Lack of information regarding diet and food was documented in laryngectomy cohorts [**Lennie et al, 2001**] and in obese HNC patients undergoing radiotherapy [**Egestad et al, 2015**].

x. Intimacy and sexuality

In cancer literature, sexuality and intimacy have been used interchangeably. According to the WHO, "*sexuality is a central aspect of being human throughout life and encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationships. While sexuality can include all of these dimensions, not all of them are always experienced or expressed. Sexuality is influenced by the interaction of biological, psychological, social, economic, political, cultural, ethical, legal, historical and religious and spiritual factors*" (page 1) [**WHO, 2005**]. In a review of sexuality and intimacy after cancer, **Hordern [2008]** notes that the term ''intimacy'' is rarely defined as a separate entity to sexuality, and is frequently been used as an euphemism for sexual function. However, HNC patients consider intimacy as multifaceted, relating to relationships, personal identify and re-establishing social networks [**Rogers et al, 2015**].

There is very little evidence available on the subject of intimacy and sexuality in HNC. The prevalence of intimacy and sexuality issues are unknown. In a study of unmet needs of psychological issues in HNC survivors, changes in sexual relationships, as well as changes in sexual feelings, were two of the most common unmet needs [**Henry et al, 2013**]. **Moreno et al [2012]** reported that all patients in their study reported that HNC negatively impacted their sexual relationships, while **Singer et al [2008]** reported that just over half of post-laryngectomy patients reported worse sex life after the diagnosis of HNC. **Low et al [2009]** reports that one-third of those answering the intimacy and sexuality questions reported substantial problems with sexual interest and enjoyment, and one-quarter reported problems with intimacy. Poor scores with sexuality were associated with distress [**Krebber et al**], in patients with trismus [**Lee et al, 2015**], in those with poor nutritional status [**He et al, 2017]** and predicted poor HRQOL [**Bajwa et al, 2016**].

Individuals with impaired sexuality have poorer QOL. However, the predictors of poor QOL related to sexuality/intimacy are not uniformly agreed across papers. **Low et al [2009]** and **Rogers et al [2015B]** showed that a younger age reported more problems but this was not noted in others [**Singer et al, 2008; Moreno et al, 2012**]. Regarding gender, males indicated a higher prevalence of problems [**Low et al, 2009**] but no gender-based differences were noted in other studies. **Singer et al** [2008] reported that more advanced tumours were related to higher sexual impairment but this was not noted by others [**Low et al, 2009**]. As HNC survival continues to improve, and patients are increasingly diagnosed with HNC at a younger age, there will be an increased need to support the unmet need relating to sexuality and intimacy of survivors of this disease.

xi. Lifestyle choices

It is estimated 35-50% of HNC patients were engaged in smoking at diagnosis [**Bloom et al, 2015**]. Most HNC survivors attempt to quit but a substantial proportion relapse and resume smoking. This carries the risk for adverse outcomes, including reduced treatment efficacy and poorer survival rates [**Simmons et al, 2013**]. In a longitudinal survey of HNC survivors at 1-year post-surgery, 60% of patients who smoked during the week prior to surgery had resumed smoking compared to only 13% who were abstinent prior to surgery. Predictors of smoking relapse in those who smoked before surgery included lower quitting self-efficacy, higher proneness to depression, and having greater fears about cancer recurrence [**Simmons et al, 2013**]. Continuous post-surgery abstinence was associated with lower levels of depressive symptoms [**Bloom et al, 2015],** indicating that smoking cessation/abstinence in HNC survivors can result in better psychological well-being. HNC survivors who continue to smoke after treatment report higher levels of distress and FOR [**Hodges & Humphris, 2009; van Liew et al, 2017].**

In regard to alcohol usage in HNC patients, **Potash et al, [2010]** reported that 45% of HNC survivors continued to drink alcohol after treatment, and 21% of this group were categorised as problem drinkers. At 12-months follow up, these survivors showed good HRQOL status, which was generally related to better oral health-related QOL scores. This study concluded that patients were more likely to indulge in alcohol drinking because of their good oral function, rather than alcohol drinking being directly related to the good HRQOL status. However, problem drinkers had 12-month eating scores in the low-functioning category, and this suggests the likelihood that alcohol dependency and its self-medicating properties may have contributed to why it very difficult for these individuals to quit drinking despite experiencing pain and/or poor oral functioning associated with swallowing [**Potash et al, 2010**].

A smaller prevalence of problem drinkers was found in a group of post-laryngectomy survivors, where 7% reported having alcohol-dependence [**Danker et al, 2011**]. When compared with non-alcohol dependent patients, this group had reported significantly higher levels of anxiety, problems in coping with illness, increased psychosocial care needs, fatigue, shortness of breath, diarrhoea and a worse emotional functioning level. Their alcohol consumption was independent of tumour stage, employment status, social class, the time interval since laryngectomy, and type of voice substitute. This study suggests that exploration of individual drinking behaviour may be valuable in addressing this problem adequately.

Psychological intervention and providing information regarding the risk of indulging in risk habits may be beneficial in managing patients' lifestyle choices. While the focus has predominantly been on smoking and alcohol, the abuse of other substances that may also increase the risk of HNC by HNS survivors e.g. opium [**Bakshaee et al, 2017; Razmpa et al, 2014**] and betel quid chewing, may also need similar attention. **Christensen et al [1999]** reported that continued smoking after HNC treatment was predicted by the interaction of behaviour specific self-blame and perceived control. Patients who attributed the cause of their HNC to their past substance use exhibited a lower likelihood of smoking but only if they also held the expectancy that their future cancer-related health was contingent on their own behaviour. Among patients not holding the belief that cancer recurrence was contingent on their own actions, self-blame was associated with a higher probability of continued smoking. Self-blame and perceived control had no effect on continued alcohol use. This study shows the importance of addressing health beliefs of patients. Coping styles also influence patients' relationship with smoking and alcohol dependence. In a study of coping styles in problem drinkers, **Petric et al [2011]** reported that problem drinkers of alcohol with HNC resorted to different defence mechanisms to life compared with problem drinkers who did not have malignancy.

xii. Nutrition

Patients with HNC are at risk of malnutrition because of the combination of cancer involvement of the upper digestive tract, the disease process and its treatment [**Talwar et al, 2016**]. Cancer cachexia may be present at diagnosis. It is a cancer-induced syndrome where there is decreased appetite, weight loss, metabolic alterations and an inflammatory state that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment [**Talwar et al, 2016**]. In addition, HNC patients may have long-standing dietary habits and detrimental lifestyle factors, particularly alcohol abuse that may exacerbate their risk of malnutrition [**Talwar et al, 2016**].

Their nutritional status may be worsened by treatment, which can reduce patients' appetite overall. Treatment can result in delayed return to oral intake, reduction in normal nutritional intake due to mucositis, pain and eating dysfunction (including dysphagia, mastication inefficiency and dry sticky saliva) [**Farhangfar et al, 2014**], and altered taste due to changes in salivary flow [**Bressen et al, 2017**]. These issues can lead to critical weight loss, which can occur in 20% of cases [**Jager-Wittnaar et al, 2009**]. Poor oral health and function is associated with malnutrition in HNC [**Barrios et al, 2014**].

Tube feeding support in patients with swallowing problems can be temporary in many, but a small proportion would require the tube permanently. Problems with tube feeding care and refeeding syndrome can occur [**Talwer et al, 2016**]. The presence of feeding tubes and enteral feeding in HNC survivors were not are associated with HRQOL changes [**Ehrsson et al, 2015**] but HNC survivors with long-term gastrostomy tube (PEG) reported poor HRQOL [**Rogers et al, 2007**]. Patients with PEGs reported significant deficits in all HRQOL domains and a much poorer QOL compared to patients without PEGs. The major problems reported by these patients were not PEG-related issues, but relate to interference with family life, intimate relationships, social activities, and hobbies [**Rogers et al, 2009**].

HNC survivors' weight and nutritional status changes can be influenced by the type of treatment received. Nutritional status decreased during IMRT treatment, which was accompanied with a reduction in HRQOL status [**He et al, 2017**]. The factors predicting nutritional status were multifactorial including the use of immunotherapy, tumour stage, the use of concurrent chemotherapy, pretreatment dental status, problems with sexuality, sensory deficits, and xerostomia [**He et al, 2017**]. In patients receiving IMRT, **Ma et al [2017]** reported a positive correlation between comprehensive nutritional status with QoL scores of functional and global QoL scales in patients.

Weight loss is a common problem encountered in post-treatment HNC patients despite aggressive nutritional support. There is a large variation in the reported value of nutritional intervention to prevent weight loss. However, a recent meta-analysis of randomised control trials of nutritional intervention in relation to radiotherapy in HNC found that there was no evidence for weight changes after radiotherapy, nor was there significant changes related to HRQOL by these intervention [**Roussel et al, 2017**]. Increased use of nutritional supplements in HNC was associated with trismus [**Lee et al, 2015**], and depression [**Wu et al, 2016**].

Weight loss is associated with depression in HNC survivors [**van Liew et al, 2017**], aspiration and HRQOL [**Campbell et al, 2004**]. **Languis et al [2013]** evaluated the influence of weight loss on HRQOL, where weight loss >10% was significantly associated with poor global QOL, reduced social eating and social contact. **Petruson et al [2005]** observes a similar finding but suggests that HRQOL status may predict survivors who will develop weight loss.

xiii. Osteoradionecrosis (ORN)

ORN is a major late complication of radiotherapy, representing a severe and significant wound healing deficiency. In ORN, there is devitalized bone, which may or may not be exposed through an ulcerated mucosa. ORN is associated with significant symptom burden. The associated symptoms and signs include pain, swelling, cellulitis, trismus, neuropathic pain, paraesthesia, fistula formation, and chronic purulent drainage [**Oh et al, 2009; Jacobson et al, 2010; Chronopoulos et al, 2015**]. When there is absence of exposed bone, patients often present with pain. The frequency of symptoms and signs can vary with the severity of ORN [**Chronopoulos et al, 2015**]. Patients may also often experience other radiation-related complications including xerostomia, dysgeusia, dysphagia and decreased tongue mobility [**Horiot et al, 1981**]. These issues compound ORN-related problems, creating an extremely challenging situation for patients, leaving some patients physically and emotionally disabled [**Jacobson et al, 2010**].

ORN is associated with a poor HRQOL score [**Rogers et al, 2015A**]. Patients experiencing pain with ORN reported worse scores for appearance, activity, recreation, swallowing, and chewing. Patients who had more severe grades of ORN and underwent major mandibular resection and reconstruction continued to report relatively poor HRQOL scores. This study suggests that survivors who develop ORN were unlikely to hugely benefit from active radical intervention, even though conservative treatment was unlikely to change their predicament either.

xiv. Pain

The head and neck area is highly sensitive to pain due to rich innervation and the confinement of many anatomical structures to a small space [**Macfarlane et al, 2012**]. In a systematic review of pain in HNC patients, **Macfarlane et al, [2012]** reports that survivors experience high levels of pain prevalence, which can be as high as 85% of those diagnosed with squamous cell carcinoma. The prevalence of pain may be influenced by the subsite, where patients with oral cavity and oropharyngeal subsites experienced pain in 60-70%. There are some factors associated with higher levels of pain, including age, gender, sociodemographic factors, the use of smoking/alcohol, psychological, cancer-related and treatment-related factors [**Macfarlane et al, 2012**].

The experience of pain improves with time but does not diminish completely even at long-term follow up. Just over a third of disease-free HNC patients self-reported pain issues, with 25% having significant pain problems despite medications, and about 13% self-reporting lesser or no problems with pain but wishing to discuss pain [**Rogers et al, 2012**]. Pain experienced by HNC patients may have a detrimental impact on their general well-being [**Chaplin & Morton, 1999**], cause dysfunction [**Chua et al, 1999; Chen et al, 2011**] and distress [**Bjordhal et al, 1999; Epstein et al, 2009**], is associated with poor sleep quality [**Shuman et al, 2010**] and poor health-related quality of life [**Macfarlane et al, 2012**], can mark the onset of malignant transformation [**Lam & Schimdt, 2011**] and recurrence [**Schrapf et al, 2009**], and reduces survival rate [**Sato et al, 2011**]. Although the impact of pain in HNC patients is significant, its management is difficult [**Sist et al, 2000**] and often inadequate [**Williams et al, 2010**].

xv. Self-esteem

Self-esteem may be defined as the summary judgement of everything a person can assess about him/herself, and these judgements concerns five main areas, namely, who one is (i.e. personal philosophy of life and character), what one does, what one has, the different levels in how one appears and to whom or what one is attached to [**Bailey et al, 2003**]. The final outcome of weighing of negative against positive judgment in the categories/areas will produce a value of self-esteem, which can be noted as low or high. Self-esteem is influenced by self-identify, body image, and social roles. All of these areas are affected by HNC. Disorders to self-esteem may include development of shame, stigma, self-hatred, self-harm and social isolation.

A proportion of HNC patients have preexisting low self-esteem at diagnosis and without intervention this may influence the HRQOL outcomes during treatment. **Kobayashi et al [2008]** reported that patients with low self-esteem were more likely to experience psychological distress during active treatment compared with those with high self-esteem. Patients who have undergone total laryngectomy were more often observed to have problems regarding depression, anxiety, self-esteem and sexual functions [**Batıoğlu-Karaaltın et al, 2017**].

Issues relating to disfigurement and body image [**Rhoten et al, 2013**]; loss of speech/impaired communication; failure to return to work after treatment; changes to relationships and intimacy; and social isolation can all lead to lowered self-esteem in HNC survivors. Continuing low self-esteem can impact upon the disclosure of concerns and needs by HNC survivors during the post-treatment period [**Rogers et al, 2009**]. This may lead to distress due to unmet needs and impacts upon their HRQOL.

HNC is associated with a negative stereotype image due to its association with addiction, substance abuse and risky sexual behaviour, and this can be stigmatising. HNC patients develop strategies to preserve their self-esteem by distancing i.e. construing oneself as dissimilar to a negatively-stereotyped group. **Devins et al [2015]** showed that self-perception of a negative stereotype was associated with poor sense of general well-being and distancing may be a productive strategy by patients.

xvi. Sleep

Sleep disturbances are a common complaint in cancer patients. The prevalence of sleep disturbance in HNC survivors is unknown but there is evidence to indicate that HNC patients are at even greater risk for sleep disorders than other cancer patients [**Mcmillan et al**] secondary to its association with pain [**Terkawi et al**], depression [**McCall et al**], nicotine and alcohol use [**Zhang et al; Lobo et al],** obstructive sleep apnea [**Huyett et al, 2017; Loth et al, 2017**], surgical alterations or radiation therapy, and xerostomia

[**Jellema et al, 2007**]. **Li et al [2017]** reported that sleep quality was worse in posttreatment patients who received neck dissection, scored poorly in mental and psychological domains. **Shuman et al, [2010]** also notes that pain, xerostomia, depression, presence of a tracheotomy tube, comorbidities, and younger age were significant predictors of poor sleep at 1-year following HNC diagnosis. The consequences of poor sleep include fatigue and poor HRQOL.

xvii. Sociodemographic

The prevalence of HNC survivors residing in the most deprived areas is estimated at 37% [**Rylands et al, 2016A**]. HNC patients from lower socio-economic backgrounds have worse outcomes of survival and HRQOL [**Wooley et al, 2006**]. In addition, HNC survivors from lower socioeconomic group living in deprived neighbourhoods were more likely to develop second primary malignancies [**Rietzel et al, 2012**]. **Ryland et al [2016B]** recently reported that those residing in more deprived areas had worse QOL outcomes in regard to social-emotional functioning and overall QOL but not in regard to physical oral function.

Lower level of education is related to less likelihood of returning to employment after HNC treatment [**Agarwal et al, 2017**]. Low levels of education may also influence the way HNC-related information is delivered [**Papakados et al, 2017]** and the impact this information has on HRQOL **[Bozec et al, 2016**]. Survivors with higher levels of education had a more positive attitude towards online self-management intervention [**Jansen et al, 2015**] while lower education level were less satisfied with online self – care education programmes in HNC survivorship [**Cnossen et al, 2016**].

Patients with high educational attainment and those who lived alone reported impaired QOL [**Rana et al, 2015**]. Marital status may positively influence HRQOL status in HNC survivors [**Bilal et al, 2015**]. **Jenewein et al [2008]** observed that self-reported overall QOL is considerably high in post-treatment HNC patients living in stable relationships compared to those who were not.

xviii. Speech

Speech is an integral means by which humans engage in social contact. Along with voice, speech forms the most important daily communication tool, shapes a person's identity and personality and contributes to well-being and overall QOL [**Jacobi et al, 2010**]. Speech difficulties encompass problems with speech production, intelligibility and acceptability of speech and inadequacy of speech in everyday life situations. These have significant psychosocial impact.

Oral cancer patients are particularly prone to speech dysfunction post-treatment. Despite organ preservation protocols, pharyngeal and laryngeal function is altered by treatment [**Rinkel et al, 2014**]. The problems reported encompass speech intelligibility, articulation, voice quality (hoarse voice), poor communication, and the associated psychosocial complications including social isolation, low self-esteem, inability to return to work and poor sleep. These problems continue and extend into long-term survivorship, with impacts on their long-term HRQOL [**Rinkel et al, 2014; Kraaijenga et al, 2016; Meyer et al, 2004**].

xix. Swallowing

Swallowing dysfunction is a multidimensional symptom-complex in which patients can experience a range of mechanical difficulties of bolus transfer through the oral cavity and pharynx, and also present with ineffective chewing and bolus formation, nasal regurgitation, oral leakage and aspiration [**Wallace et al, 2000**]. It can also significantly impact on overall and specific areas of HRQOL, including emotional, self-esteem, social functioning and is consequently, a survivorship issue [**Rinkel et al, 2014]**. It is one of the top ten most common concerns of HNC, with a prevalence of 18% [**Rogers et al, 2009**]. Radiation-induced pharyngoesophageal fibrosis, mucositis and dryness may account for the dysphagia experienced [**Eisbruch et al, 2004**] and improvement in delivery of radiotherapy i.e. IMRT can help reduce the severity of these effects [**Roe et al, 2010**].

Dysphagia is also related to other key issues including intake of food, nutritional status and aspiration. This may be exacerbated when dysphagia results in permanent dependence on tube feeding. Intervention with swallowing exercises may be considered as a preventative and/or therapeutic measure.

xx. Shoulder

Shoulder function is an important outcome after treatment. Patients who undergo surgery, particularly neck dissection (ND), are at risk of developing shoulder dysfunction. This is the result of damage to the accessory nerve, and denervation of the trapezius and sternocleidomastoid muscles. Loss of function in these muscles can impair shoulder movement and the development of secondary problems at the shoulder joint and the cervicofacial complex, e.g. adhesive capsulitis, rotator cuff impingement, and myofascial pain [**Eickmeyer et al, 2014**]. Damage to the cervical plexus can cause neuropathic pain in the neck region. Nerve damage results in reduced range of shoulder and neck motion, decreased the performance in activities of daily living, contributes to chronic pain and poor sleep. Subjective complaints of shoulder dysfunction and pain have a large impact on QOL. Shoulder dysfunction may also occur following non-surgical intervention, where radiation-induced fibrosis can cause changes in the musculature, innervation and joint.

Limiting the extent of ND, i.e. preservation of the accessory and cervical plexus nerves, preservation of sternocleidomastoid muscle and avoidance of Level 2B dissection in certain HNC subsites, is related to better shoulder symptomatology [**Gazaro et al, 2015; Nibu et al, 2010; Umeda et al, 2010**]. **Eickmeyer et al [2014]** studied long-term shoulder outcomes in survivors with 5 years disease-free status. Patient who had their accessory nerve sacrificed during ND had significantly poorer scores for disfigurement, level of activity, recreation and/or entertainment, speech and shoulder disability, and willingness to eat in public, and functional well-being. Furthermore, QOL scores were also reduced in the group who showed objective shoulder restriction.

When compared with HNC patients who did not undergo ND, those who received ND reported lower quality of life [**Spalthoff et al, 2017**]. The burdens reported by those who had less aggressive ND i.e. selective ND (SND) was lesser than those who underwent more aggressive ND procedure i.e. modified radical ND (MRND) or radical ND (RND). There were meaningful differences between the SND, MRND, and RND groups and those who did not undergo ND group in impairments in speech intelligibility for strangers and familiar persons, ingestion and swallowing, tongue mobility, opening of the mouth, lower jaw mobility, neck mobility, and shoulder and arm movement. Many patients with ND faced a lower functional status and negative professional and financial consequences.

These findings are significant for consideration during HNC treatment decision -making in the management of the neck, particularly in the scenario where there is no clinical evidence of regional involvement. In this instance, the option of avoiding ND in favour of ‘wait and watch’ policy or the option of a less aggressive option of sentinel node biopsy may be considered against the social and personal preference of patients. Shoulder exercise may be useful intervention to improve long-term shoulder outcomes in HNC survivors.

xxi. Trismus

Trismus is difficulty or restricted in mouth opening, and it is a recognised complication of the disease and its treatment i.e. surgery and/or radiotherapy treatment. Trismus can have a negative consequential impact on oral/dental health, chewing, swallowing, orofacial appearance, nutritional status and the psychosocial. While the objective definition can vary, a maximal interincisal opening < 3.5cm is generally the accepted cut off point, and the prevalence of trismus based on this criteria is approximately 38% [**Scott et al, 2011**]. When the masticatory muscles, in particular the pterygoid muscles, are involved by surgery and/or lie within the radiation fields, post-treatment scarring can predispose to trismus. Its development is usually progressive, and intervention by mouth opening exercises has been shown to help to reduce the severity of trismus.

xxii. Xerostomia and dysguesia

Xerostomia is a term used to describe the subjective symptoms of a dry mouth deriving from a lack of saliva [**Pinna et al, 2015**]. In the context of HNC, xerostomia is often the consequence of treatment e.g. radiotherapy and chemotherapy, but xerostomia may be preexist HNC diagnosis due to a range of causes including physiological reduction due to age, side effects of medication, and medical comorbidity i.e. autoimmune and other metabolic conditions [**Pinna et al, 2015**].

Radiation-induced damage to the salivary glands results in impairment of both the quantity and quality of saliva produced, and virtually all patients who receive radiotherapy will have xerostomia, albeit showing varying degrees of severity [**Chambers et al, 2004**]. Xerostomia causes oral discomfort and pain, increased dental caries and oral infection, dysgeusia, difficulty speaking and swallowing, and insomnia

[**Chambers et al, 2004; Jellema et al, 2007**]. This significantly impairs QOL and can compromise nutritional intake and continuity of cancer therapy. Patients with xerostomia experience distress, which is related to emotional functioning, sticky saliva and dyspnoea [**Almstahl et al, 2016].**

The natural progression is worsening of xerostomia immediately after completion of treatment. This continues well into 6-9 months post-treatment, after which salivary production recovers and salivary flow may return to pretreatment levels by 12-18 months. The changes are reflected also in HRQOL scores. Altered saliva-related symptoms are one of the most predictive factors for poor global QOL and HRQOL in HNC survivors. Treatment options that can reduce radiotherapy exposure to salivary glands e.g. IMRT, should be considered to reduce the impact of xerostomia on HRQOL.

3.3. Qualitative studies of HNC survivorship

There is comparatively less known about the patient's lived experience of HNC compared with the larger body of evidence on how HNC impacts upon QOL [**Lang et al, 2013**].

3.3.1. Qualitative studies

Qualitative research methods involve the systematic collection, organisation, and interpretation of textual material derived from talk or observation. It is used in the exploration of meanings of social phenomena as experienced by individuals themselves, in their natural context [**Malterud, 2001**].

3.3.2. Qualitative studies of HNC survivorship

Qualitative studies exploring the patients and their carers' day-to-day realities with HNC may provide an insight into how patients experience the survivorship journey. In a systematic and meta-synthesis review of multiple qualitative studies (1993-2011) reporting on HNC patients' lived experience, **Lang et al [2013]** identified six core concepts of the actuality of living with HNC emerged including 'uncertainty and waiting', 'disruption to daily life', 'the diminished self', 'making sense of the experience', 'sharing the burden' and 'finding a path'. This systematic review provided the basis for exploring the findings of succeeding qualitative studies published after 2013.

The dual concept of 'uncertainty and waiting' relates to the situation of '*being in limbo, i.e. the uncertainty of living with the disease and of the future, where patients oscillate between hope and despair'* (page 2651), while 'waiting' represents '*an urgent need to feel something is being carried out'* (page 2652) during their diagnostic, treatment and survivorship phases, which can aggravate anxiety and diminish hope [**Lang et al, 2013**]. 'Disruption to daily life' encompasses the global impact of HNC on aspects of their lives i.e. emotionally, physically and socially; and the sense of losing control, having fear and experiencing worry [**Lang et al, 2013**]. The disruption including the impact of symptoms [**Molassiotis & Rogers, 2012**] e.g. pain [**Schaller et al, 2015; Pattison et al, 2016],** mucositis **[Kartin et al, 2014],** forces patients to adjust and cope with a new normality, and life-long disruptions are tangible due to facial disfigurement, continuing physical disability, dysfunction (e.g. dysphagia, speech impediment, reduced hearing), pain and FOR [**Furness et al, 2006**; **Lang et al, 2013; Ganzer et al, 2015**; **Nund et al, 2015; Mortensen et al, 2012**].

HNC survivors often describe the theme of 'the diminished self', which encompasses the losses of identify [**Crossley et al, 2003**], confidence, self-esteem and self-image as a result of the diagnosis and/or treatment of HNC [**Lang et al, 2013**]. There is guilt for acquiring the disease [**Bjorkland et al, 2009**], stigmatisation [**Hu et al, 2009; Mertl et al, 2017; Mortensen et al, 2012**], and a sense of social rejection by relative/friends due to the illness. Their sense of self-esteem is strongly related to the ability to communicate i.e. speech and hearing difficulties knock their confidence [**Mortensen et al, 2012**]. Loss of ability to gain pleasure out of life, including eating, hobbies, travelling and doing sports and other activities related to loss of strength and fatigue, reduces their sense of self and result in withdrawal from social situations [**Ganzer et al; 2015; Mortensen et al, 2012**]. Some patients felt that the loss of enjoyment and inability to gain pleasure out of things in life is 'worse than being dead' [**Mortensen et al, 2012**].

Patients also acquire a new identity i.e. cancer patient/survivor, who inhabits the unfamiliar and disorientating hospitals, where there is a feeling of vulnerability. Returning to work is one way of re-structuring the disruption of their normality and also reinforces their sense of identity [**Issakson et al, 2016; Dewa et al, 2017**]. However, anxieties about returning to work were also expressed including the fear of accidentally spitting at others during speech, and the inability to communicate effectively [**Mortensen et al, 2012**].

Despite the difficulties, patients describe 'making sense of the experience' as a core experience of HNC, and these are the continual attempts to understand their cancer and what is happening to them. This results in acquiring new beliefs about their disease, experiencing fear and developing expectations, re-assessing their life priorities, and striving to manage the uncertainties inherent to the disease henceforth [**Lang et al, 2013**]. This theme is reflected in how some patients managed xerostomia, where they had to find their own solutions for their problems when they perceived help from professionals were not forthcoming [**Jiang et al, 2017**]. This was also seen in patients who were making sense of their HPV-positive status, by understanding its impact on their partners [**Baxi et al, 2013**] and in reducing the stigmatization of HNC as being a 'lifestyle disease' [**Mortensen et al, 2012**].

As a way of coping with the disease, HNC patients seek emotional and practical support by developing supportive connections with their immediate circle of family/friends, and also from a wider network of people, including health care professionals, support groups and others through the internet i.e. 'sharing the burden' [**Lang et al, 2013**]. **Lang et al [2013]** notes that in the relationship with healthcare professionals, '*patients have a great need to feel acknowledged, both as a person and as one who is suffering i.e. to have their suffering recognised,* but *patients are selective about what they disclose and seek help for, and often hide their distress, e.g. downplaying the difficulties of coping with treatment side effects'* (page 2657). In this sense, it is critical that the relationship with healthcare professional is one that instills hope, maintains self-worth and counteracts the vulnerability [**Lang et al, 2013**]. Laryngectomy patients describe having digital based-communication adjuncts e.g. instant messaging, email, web-based support groups and video messaging helps their communication and ability to gain psychosocial support [**Dooke et al, 2012**]. At the end of treatment or the secondary surveillance period, some HNC patients experience a sense of aloneness in managing their everyday life with the loss of regular contact with the healthcare professional [**Lang et al, 2013**]. Some patients are not able to process their new normality and resort to negative coping strategies, e.g. drinking alcohol. Failure to regain former intimacy in relationships has resulted in divorce [**Mortensen et al, 2012**].

The core theme of ‘Finding a path’ relates to the patient’s reflection of life beyond the diagnosis and/or treatment of HNC, where the future is often viewed as changed or diminished [**Lang et al, 2013**]. In this respect, a range of responses are reported including, focusing on the present i.e. ‘living in the here and now’ [**Bjorkland et al, 2009**]; adaptation to a new normality; acceptance of their mortality [**Chou et al, 2007**]; meaning- and benefit-finding [**Chou et al, 2007**; **Thambyrajah et al, 2010**]; adoption of a ‘battling’ attitude, i.e. fighting the cancer, not giving into the disease, rejection of the victim complex; changing to a more positive lifestyle i.e. exercise, better eating, cessation of risk habits and turning to religion/spiritual practices [**Chou et al, 2007**; **Agrawal et al, 2010**]. The bitter-sweet experience of HNC among survivors has also been described as ‘a blessing and a curse’, where the experience entails a deeper positive change from within to enable them to move forward n their lives [**Swore-Fletcher et al, 2012**]. Making new meanings of being in the world after HNC is important in patients’ sense of being human [**Roing et al, 2009**].

3.4. Stages of HNC survivorship

Based on the derived evidence discussed in the preceding sections of this chapter, a summary of key issues faced by HNC survivors based on specific phases of survivorship is presented.

3.4.1. At diagnosis

HNC and their caregivers may already be experiencing a multitude of symptoms related to HNC (e.g. pain, altered sensation, weight loss, trismus) and dysfunction (e.g. swallowing and speech difficulties). Furthermore, there maybe significant lifestyle issues that impact on comorbidity, and socioeconomic issues that predispose these patients to more advanced disease and poorer outcomes.

With confirmation of diagnosis, HNC survivors will experience significant psychological distress, particularly anxiety, worry and depression [**Chen et al, 2009A; Chen et al, 2010**]. This will impact on their immediate family. The cancer diagnosis will be considered a threat to their survival and they seek quick solutions to overcome this. Treatment decision-making will require patients to handle complex information, which may be difficult in patients from low socioeconomic background. Multiple hospital visits for various assessments, including dental and medical status, can impact upon their work and finances.

3.4.2. Peritreatment

The phase during treatment can be an extremely challenging time for HNC patients and is when the need for supportive care is greatest [**Chen et al, 2009C; Oskam et al, 2013**]. During treatment, patient and their caregivers continue to experience significant levels of distress, where the severity of distress may increase as active treatment progresses. Coping with treatment side-effects and worrying about the cancer response to treatment contributes to this distress. Loss of self through permanent changes to their facial appearance, the inability to speak and swallow normally can be significantly distressing. Sleep deprivation, inability to swallow normal food, loss of appetite and the systemic side-effects of chemoradiotherapy can result in fatigue, and depression. Prolonged hospitalisation can occur after surgery. This can occur due to the combination of the surgical complications, poor wound healing, patient comorbidities, and social circumstances where safe discharge cannot be guaranteed. At discharge, patients and their caregivers can be overwhelmed by the huge amount of information given regarding after-care. It is not uncommon for overall QOL and HRQOL scores to be at the lowest point during this time.

3.4.3. Posttreatment

Patients and their caregivers are not always able to imagine the potential impact of post-treatment changes, and may be under-prepared at this stage, which can be the longest phase during survivorship. Post-treatment HNC patients report varying levels of distress but most feel moderate to severe distress [**Chen et al, 2009A; Chen et al, 2009B; Henry et al, 2014; Wells et al, 2015**]. However, distress may be brought about by different things to different people, and it is critical that distress screening and holistic assessments are done repeatedly as appropriate during this long phase of survivorship.

Many will experience unmet needs, where the highest unmet needs are psychological [**Henry et al, 2014**]. They will also experience reduction in physical functioning of activities of daily living, where pain is a limiting factor towards physical rehabilitation, sleep and recovery [**Chen et al, 2011**]. Commonly reported problems were FOR, eating/chewing, dental health, fatigue and pain but overall, there were diverse concerns [**Rogers et al, 2009**; **Wells et al, 2015**]. **Chen et al [2009A]** reported high levels of unmet needs in the following needs domains: psychological, physical and daily living, health system/informational and patient care and support needs i.e. needs related to health care providers showing sensitivity to physical and emotional needs, privacy and choices. The highest level of unmet need was in the "physical and daily living" domain [**Chen et al, 2009A**].

Most concerns and problems are experienced keenly in the first two years of post-treatment survivorship. It is also the critical period where HNC recurrence frequently occurs. Regular surveillance for recurrence is as important as holistic assessments to support HNC patients. Addressing FOR is a very important aspect during this phase, and different interventions may be considered depending upon the severity of FOR.

Addressing lifestyle issues and global rehabilitation (i.e. psychological, physical and functional) are key issues during this phase. Nutritional assessments alongside swallowing evaluation and therapy are critical in the months after treatment completion. Patients may need to undergo smaller scale surgery as part of their rehabilitation. Supporting caregivers in their attempts to assist in HNC patients' after-care is important, particularly with information and education about diet, care of wounds/tubes, lifestyle choices. Supporting caregivers' psychological needs is also vital.

Supporting patients in returning to employment after treatment is important for their self-esteem and overall QOL, especially in the younger group. Financial difficulties can be an important issue for those having to pay for their treatment, the retired patient, and in caregivers who may have a reduced capacity to work due to their caregiving commitments. Involvement in HNC patient support groups may be beneficial to many patients, particularly laryngectomy patients. Patients need to be informed and counselled about the poor quality of information on HNC available on the world-wide web.

3.4.4. Long-term follow up

With time, the need for supportive care gradually changes, and the emphasis moves toward wellness. The perceived need for supportive care is higher at the time of treatment compared with at long-term follow-up [**Oskam et al, 2013**]. Long-term HNC patients and their carers report low levels of unmet need, where the highest needs remained in the emotional domain [**Balfe et al, 2016**]. Interestingly, the supportive needs of the carer may become more conspicuous at long-term follow up [**Balfe et al, 2016**]. Qualitative studies indicate that the quantity and quality of concerns recedes with time [**Mortensen et al, 2012**] as patient cope and transition into their new normality. Self-management may be appropriate in this group of patients who may be discharged from routine follow up at 5-years post-treatment. However, FOR can remain a persistent problem in some patients.

Long-term side effects of radiation, particularly ORN and oesophageal strictures, can be a feature of long-term survivorship. While many would advocate conservative treatment in addressing these conditions, surgery may still be undertaken as a last resort to overcome significant HRQOL issues related to these conditions.

3.4.5. End of life

A substantial proportion of HNC patients will succumb to their disease, and the end of life phase in their journey presents with unique challenges for care. Some of the newly diagnosed HNC patients will not receive radical treatment because they have either declined treatment, or are unable to receive radical treatment due to a combination of having advanced disease, significant comorbidity, poor performance status and advanced age. These patients go on to receive best supportive care.

Kowalski & Carvahlo [2000] documented the natural progression of HNC in those receiving best supportive care until their death, and observes that half of untreated HNC patients will die within 4 months of their diagnosis, but some patients survived up to 4 years. The majority of HNC patients who died of their disease show gradual deterioration over the months, and may suffer from various physical and psychological distresses with a completely *compos mentis* state [**Roland & Bradley, 2014**].

General principles of palliative care apply to HNC patients, where there is emphasis on alleviating pain, symptom control and enabling patients to live with dignity, respect and

QOL [**Sestherhan et al, 2008**]. Other than pain, the other symptoms experienced by HNC include nausea/vomiting, constipation, weight loss, psychological problems (i.e. anxiety, anger, withdrawal), 'acute confusional state', and fatigue [**Cocks et al, 2017; Roland & Bradley, 2014**]. Specific issues relating to HNC patients can include airway obstruction/stridor, dysphagia, communication issues (i.e. speech and hearing issues), oral problems (e.g. candidiasis, dry mouth, oral ulcers), nasal obstruction and facial nerve palsy causing weepy eyes, corneal abrasion and facial droopiness [**Goldstein et al, 2008**]. The presence of a trachestomy tube, feeding tube and maxillary obturator may be in place to deal with these issues.

Care of the oral cavity and the palliative HNC patient's oral health are important considerations of caregivers [**Ezenwa et al, 2016**]. HNC patients with inoperable recurrences can result in fungating wounds that can be malodorous, and create an orocutaneous fistula that is accompanied by salivary leak. Furthermore, recurrences in the neck can erode surrounding structures and predispose to a catastrophic hemorrhage via carotid artery blow out. Involvement of a multidisciplinary team, in particular, the palliative care professionals, can assist in undertaking holistic assessment and provide a suitable palliative care plan [**Cocks et al, 2016].**

In some instances, palliative surgery and/or radiotherapy are appropriate [**Cocks et al, 2017**]. **Roland & Bradley [2014]** list the most common reasons for undertaking palliative surgery, namely, nutritional support i.e. placement of gastrostomy tube; debulking of tumour; and placement of tracheostomy. Other reasons include closure of fistula, arresting haemorrhage, palliative embolization, photodynamic therapy, nerve ablation for pain control and tarsorrhaphy for corneal protection. Palliative radiotherapy is appropriate for local pain control and for painful bone metastasis [**Cocks et al, 2017**].

Patient and family involvement is critical in making decisions about the on-going management of symptoms/problems and in undertaking palliative surgery/radiotherapy. The overriding concern is maintenance of patient dignity, honouring the wishes of family and there is an emphasis in creating full understanding of all parties involved as to what the goals of treatment are at all times [**Sciubba, 2016**]. 'Do not attempt cardiopulmonary resuscitation' orders/code should be completed and discussed with the patient and/or family [**Cocks et al, 2017**]. At this stage, family members prefer full patient involvement in decision-making, but this may not always be the patients' point of view, which is divided among those wanting autonomy and those wanting passive acceptance [**O’sullivan & Higginson, 2016].**

Because of the uncertainty of death even in the palliative stage, this phase may be prolonged i.e. months rather than days in some patients. The main concerns of the patients at this stage were caregiver burden and symptom control [**O’Sullivan & Higginson, 2016**]. However, many also suffer from psychological distress, ranging from anger, anxiety, depression and mood disturbances, which are related significantly to existential issues. Existential distress is common among cancer survivors at the end of life [**Peteet & Balboni, 2013**]. According to **Sciubba [2016],** addressing the psychosocial and spiritual needs is necessary in the preparation for death as to make a "good death".

A significant change in circumstances in this survivorship phase is the stage where patients’ stable condition deteriorates, which may signify the closeness to death. The ideal scenario at the terminal point of their life is for patients to receive a ‘good death’. This is defined as death that is pain-free, peaceful, and dignified, at a place of choosing with the relatives present and without futile heroic interventions [**Cohen et al, 2001**]. The choice of place of death is an important aspect for consideration, although not much is known about the preferences of HNC patients. Only one study of HNC patient preference for end of life care is available in a Taiwanese cohort, where the preference to die at home or in the hospice was more common among males, those who reside in the capital city, and those who had received opioids [**Kuo et al, 2017**].

Some patients’ and their family’s preference is to meet death at the hospice. The most common symptoms of HNC patients admitted to the hospice were weight loss, followed by pain, cough, dysphagia, difficulties with feeding and communication [**Lin et al, 2011**]. Changes to pain symptom control can result in change to morphine dosage, where this correlated with survival time after hospice admission [**Lin et al, 2011**]. At the terminal stage, patients exhibit restlessness, followed by somnolence and irreversible coma. This can be distressing for caregivers, family and some hospital nursing staff, who are not accustomed to caring for dying patients [**Sasterham et al, 2008**].

However, the reality of HNC death is far from ideal. In Taiwan, the majority of HNC patients die in hospital [**Kou et al, 2017**]. In a UK-based study of the deaths of HNC patients over a time period, most died in an acute HNC ward, and the reason suggested for this is because the deterioration occurred unexpectedly and rapidly, and the hospital seemed to be the most appropriate place to address their complex care needs [**Kamisetty et al, 2014].** In another UK study, only 22% of patients had family members present at the time of death, and 35% did not have their resuscitation status documented [**Ethunandan et al, 2005**].

3.5. Conclusions

This chapter summarises the key issues HNC patients experience during their survivorship. In this journey, patients suffer significantly as a result of the disease and its treatment in many areas of their lives. Patients will journey through different stages of survivorship with the passage of time and may experience an abrupt change in their journey with a change in their disease status.

A review of the current HRQOL-related literature highlighted minor gaps in knowledge of the key issues experienced by HNC survivors, where more recent evidence focused on several new issues, e.g. sleeping, breathing, taste, smell, and self-management. Qualitative studies of patients' lived experience with HNC provided a different albeit valuable insight into their survivorship journey.

The review undertaken in this chapter allowed consolidated of new and existing evidence into a broad knowledge base of the key issues experienced by patients and their carers in HNC survivorship that is current. This can facilitate the thematic framework approach during the assessment of patient concerns during consultation in this study.

CHAPTER 4

4.0. MD STUDY OVERVIEW

This chapter presents the background of the MD study, including the rationale for the MD study, its conception, aims, and structure. The MD study is made up of 3 separate empirical studies i.e. the Main study and 2 other empirical studies that were undertaken to support the Main study.

A summary of each section/study is presented in this chapter, so as to provide a general overview of the MD work, and the flow of the work undertaken (**Table 4.1**). In addition, the patient-reported outcome measures that were commonly employed in the 3 empirical studies are also introduced in this chapter.

4.1. Background of the MD study

4.1.1. Rationale for the MD study

At the time this study was formulated *circa* October 2010, published HN-PCI data were limited to the original paper describing the PRO in August 2009 [**Rogers et al, 2009A**]. In this exploratory work, **Rogers et al** [**2009A**] the presented data consisting only of self-reported patients' concerns and self-selection of health care professionals patients wanted to speak to. This paper concluded that the HN-PCI '*helps focus the consultation onto patients' need*' even though there were no empirical data to support this other than comments obtained from patient feedback.

In addition, this pilot study data were obtained from the practice of one individual doctor from one surgical specialty within a single HNC unit. Evidence to suggest that the HN-PCI could be used and applied extensively was lacking. Consequently, the reported success of HN-PCI in identifying patients' concerns could arguably be related to the enabling character of that doctor or to the characteristics of a specific patient cohort, rather than the instrument *per se*. Finally, **Rogers et al** [**2009A**] concluded with a recommendation for '*undertaking a 'roll-out' study involving other doctors in HNC clinics'*.

4.1.2. Conception of the MD study

This study was primarily designed to evaluate the operationality of the HN-PCI as a PRO in helping to identify patients' concerns in subjects (patients and doctors) who are unfamiliar with the tool. The main question asked was: "*Can the HN-PCI be used by other doctors and patients in other HNC clinics to help disclose patients' concerns?"*

According to **Fung and Hayes'** [**2008**] framework for PROs (**section 2.5.5.1**), PROs help to identify patients' needs and concerns during patient—doctor encounters. If patients reveal their concerns by using the PRO, this indicates that the PRO is able to identify their concerns, and this could be measured by quantifying the number and type of concerns identified by the PRO used. This method of quantifying self-reported concerns' via PROs has been established in other like studies [**Heaven & McGuire, 1998; Parker et al, 2005]** as well as the original HN-PCI study [**Rogers et al, 2009A**].

Another question of research interest suggested by the original paper [**Rogers et al, 2009A**] was: "*Does the HN-PCI help focus the consultation to patients' need?"*

Feldman-Stewart et al [2005] model considers the interaction between the patient and the clinician as a two-way exchange of conveying and interpreting messages **(section 2.5.5.1; Figure 2.4).** Based on this model, the HN-PCI may fulfill an enabling role by bringing up or focusing on the patients' agenda i.e. their concerns during the consultation. It was postulated that if the HN-PCI can facilitate a more patients concern focused consultation, this may be reflected by a corresponding increase in the quantity of predisclosed items (i.e. self-selected on HN-PCI before the consultation) discussed during the consultation. It may be possible to examine this association by quantifying the number and type of concerns that patients and doctors discuss in consultation provided that the method of evaluation is robust and standardised, and comparing this with the self-reported items.

The term ‘discussion of concern’ during consultation needs clarifying. ‘Discussion of a concern’ during consultation may be considered as a ‘two-way exchange of conveying and interpreting messages’ suggested by **Feldman-Stewart et al [2005]**. It was recognised and acknowledged that the quality of the ‘discussion’ about the items of concern can vary considerably due to the influence of other factors e.g. patient-related factors, doctor-related factors, and environmental factors. This study was not designed to evaluate how the HN-PCI could influence the quality of the patient-doctor communication that occurred during consultations. This study was not intended to assess patient-doctor communication i.e. the behavioural and observational components through analysis of the recorded medical encounter for the purpose of coding behaviour using recognised observational instruments with respect to task and socioemotional behaviours [**Ha & Longnecker, 2010**].

Having identified patients’ concerns, secondary evaluation can be undertaken to test the associations of other variables with patients’ concerns, and also the impact of patients’ concerns on distress, length of consultations, clinic outputs, QOL status and patient satisfaction with the consultation.

4.2. Aims of the MD study

4.2.1. Primary Aim

The primary aim of this study was to evaluate the feasibility of using the HN-PCI in identifying the concerns of patients who were unfamiliar with the instrument in a multicenter setting, by measuring the number and type of self-reported concerns, and the concerns that were discussed during consultations.

In this study, a patient’s ‘concern’ was defined as ‘‘*a patient generated issue of current importance*’’ [**Heaven & McGuire, 1998**]. In terms of ‘*current importance*’, this study defines ‘currency’ as any concern that is raised by patients on the day of consultation, either by self-reporting on HN-PCI or by discussion with doctor during consultation.

The definition of patient's concern adopted in this study is meant to provide a broad understanding of issues that are highlighted by patients and/or discussed during their visit. This definition does not consider a 'concern' as inherently emotively negative or positive, other than how it is experienced and expressed by the patient on the day of consultation.

4.2.2. Secondary Aims

4.2.2.1. Undertake qualitative analysis using a thematic framework approach and content analysis to facilitate robust data collection and analysis for scoring patients' concerns and other outcome measures in the transcribed recordings of consultation;

4.2.2.2. Develop domains for the HN-PCI;

4.2.2.3. Evaluate the relationship between patients' concerns with distress;

4.2.2.2. Test the associations between clinicopathological factors with patients' concerns;

4.2.2.3. Determine the impact of HN-PCI intervention on outcomes of the consultation/encounter/visit i.e. length of consultation, patient satisfaction with consultation, clinic outputs, and HRQOL;

4.2.2.4. Determine the impact of the HN-PCI intervention on the content of the consultation.

4.3. Outline of the MD study

The MD work consists of 3 individual studies, which were undertaken in a time-line in the order shown:

a. Pilot study

b. HN-PCI Domain Generation
c. Main study

The Pilot and Domain Generation studies were undertaken prior to the Main study to facilitate the latter. A summary of each study is presented in the next sections of this chapter. A summary of the Main study methodology is presented first to enable the Pilot and the Domain generation studies to be understood in context. More detailed descriptions of each study are found in Chapters 5, 6 and 7.

4.4. Main study: A Summary of the Methodology

Subjects: A cohort consisting of four surgeons from two different surgical specialties working in two different centres, and their patients, who were unfamiliar with the HN-PCI, were recruited to the study.

Study design: A prospective, non-randomised study was planned and undertaken in 3 successive stages/blocks. The first block represented the ‘control’ group, where the HN-PCI was not used at all, and provided a baseline understanding of normal practice. The second block represented the ‘control in attention’ group, where patients completed the HN-PCI but the information was not available to the doctor during consultation. The third block represented the ‘intervention’ group, where patients completed the HN-PCI and both doctors and patients were able to access the information during consultation.

Data collected: The main data collected i.e. patients’ concerns, consisted of those provided by the patients through self-completion of HN-PCI, and also from the data derived during consultations, which were audiorecorded, transcribed and evaluated using a qualitative methodology. Other data collected were clinicopathological information, consultation length, and other PRO data.

Statistical analysis: The main statistical analysis was undertaken to determine the number and types of concerns identified and discussed. Associated analyses were undertaken to evaluate the secondary aims of the study i.e. relationships between patients' concerns and other variables including clinicopathological data, length of consultation, clinic outputs, distress, HRQOL and patient satisfaction scores.

4.5. Overview of the Pilot Study

Rationale: Data about patients' concerns that were discussed during consultations reported in previous HN-PCI studies relied upon the evaluation by a single assessor who was present during the consultation. This method is unreliable as it depends upon the interpretation of one individual only, and it is neither reproducible nor standardised.

To address this problem, the Main study design selected a more rigorous method of data collection and evaluation by adopting a qualitative method of assessment. This method involves audiorecording and transcribing the consultations, and having two independent assessors evaluate the transcribed consultations using a thematic framework approach.

Aim: The primary aim of the Pilot study was to test the feasibility of the method of data collection and data evaluation planned for the Main study. This includes a trial of the audiorecording equipment and the process of audiorecording, testing the logistics of questionnaire administration and its return, and the development of a robust and reliable way of scoring the items discussed during consultation through a thematic framework approach and content analysis.

Methodology: The subjects (patients and doctor) recruited to this study were from a convenience sample familiar with the HN-PCI. The Pilot study design was based the Block 3 'intervention' part of the Main study, where patients completed the HN-PCI before consultation and both patients and the doctor were able to access the information during consultation.

Patients filled in the HN-PCI (version 2), as well as all the other PROs planned for the Main study, before their consultations. Their consultations were audiorecorded, and transcribed. Patients were also given the post-consultation PROs to be used during the Main study for completion. Two assessors (including an experienced qualitative researcher) individually evaluated the transcribed consultation based on a thematic framework approach, and the level of agreement was determined to maintain scientific rigour.

Significant results impacting on Main study: The thematic framework approach and content analysis in assessing patients' concerns during consultation was feasible, and assessors showed very good levels of agreement. Two new items of patients' concern were identified during the Pilot study. These were incorporated into the HN-PCI (version 2), creating the HN-PCI (version 3) with 57 items of concern and 15 professionals (Appendix 4).

4.6. Overview of the Domain Generation study

Rationale: The holistic nature of the HN-PCI ensures that the total number of the items of concerns listed is relatively high (range, 55-57 items). This presents a technical difficulty in undertaking statistical analyses; particularly when addressing the secondary aims of the Main study i.e. to explore associations between patients' concerns and other variables. The study would require a significant number of recruited patients if individual HN-PCI items were considered as a single variable during statistical analyses, which would not be achievable in the timeframe set out for the MD work.

Having domains, where related items of concern are grouped together, can permit a more systematic method of summarising HN-PCI findings. It can facilitate comparative evaluations, and helps to construct an overall picture of the inter-relationship of various concerns in a defined cohort.

Aim: The primary aim of this study was to group related items of concern listed in the HN-PCI into domains, so as to facilitate statistical analysis of the Main study. This is particularly relevant when exploring the possible associations between patients' concerns and other variables.

Methodology: A Delphi approach was undertaken by a group of 10 healthcare professionals involved in the care of HNC patients who formed a convenience sample. Several rounds of consultation by this group suggested domains and groupings for the HN-PCI items. Moderation by the researcher finalised these into the accepted domains.

Significant results impacting on Main study: Five domains were generated for HN-PCI (version 3). These domains were not used in the HN-PCI questionnaire administered to patients during the Main study. The domain groupings were only used during statistical analysis of the Main study results.

4.7. Patient-Reported Outcome Measures used in the MD study

4.7.1. Head & Neck Patient Concerns Inventory (HN-PCI)

The HN-PCI was the intervention evaluated in this study. The HN-PCI (version 2) containing 55 items of concerns and 15 professionals was used in the Pilot study.

At the conclusion of the Pilot study, two additional items of concern were identified and these were incorporated into the HN-PCI (version 2). The new checklist i.e. HN-PCI (version 3) contained 57 items of concern and 15 professionals. The HN-PCI (version 3) was subsequently used in the domain generation exercise and also in the main study (Appendix 4).

4.7.2. University of Washington Quality of Life, version 4 (UWQOL)

The UWQOL is a validated HRQOL questionnaire (Appendix 8) [**Hassan & Weymuller, 1998; Rogers et al, 2002**]. The UWQOL comprises 12 domains, scaled from 0 (worst) to 100 (best) according to the hierarchy of response.

The UWQOL has two subscale composite scores i.e. 'Physical function' and 'Social-emotional function' and a single six-point 'overall' QOL measure [**Rogers et al, 2010**]. 'Physical function' is the simple average of the swallowing, chewing, speech, saliva, taste and appearance domain scores whilst 'Social-emotional function' is the simple average of the activity, recreation, pain, mood, anxiety and shoulder domains. In regard to the single item overall QOL scale, respondents were asked to consider not only physical & mental health, but also other factors, such as family, friends, spirituality or personal leisure activities important to their enjoyment of life.

To allow incorporation of UWQOL into routine clinical practice *viz.* screening for dysfunction, a ‘significant problem’ was considered present in a particular UWQOL domain when it fulfills either of the following criteria: (1) scores beyond a cut-off point specified in a domain, (2) (for some domains only) a score adjacent to the cut-off and respondents indicating the particular domain as being important during the previous week [**Rogers & Lowe, 2009B**]. This is detailed in the **Table 4.2**

Table 4.1. Summary of MD study. The 3 empirical studies (Main study, Pilot study, Domain generation study) are shown in context of the aims of the overall MD study

	Where is this addressed?	**Method**	**PROs used**	**Outcomes**
OVERALL MD STUDY: **Primary Aim**				
1. To evaluate the feasibility of using the HN-PCI in identifying the concerns of patients' who were unfamiliar with the instrument in a multicenter setting, by measuring the number and type of self-reported concerns, and the concerns that were discussed during consultations.	Main study	Prospective, non-randomised study composed of 3 successive study blocks: Blk 1 "control"; Blk 2 "control in attention"; Blk 3 "HN-PCI v3 intervention". All consultations were recorded and transcribed.	**At pre-consultation:** Blocks 1: UWQOLv4; DT Blocks 2 and 3: UWQOLv4; DT; HN-PCI v3 **Post-consultation:** PROC; DT; PSQ-MD	Described in Chapter 7

	Where is this addressed?	Method	PROs used	Outcomes
OVERALL MD STUDY: **Secondary Aims**				
1. Undertake qualitative analysis using a thematic framework approach and content analysis to facilitate robust data collection and analysis for Main study	Pilot study Undertaken before the Main study	Prospective study based on Block 3 of Main study. Convenience sample of surgeon and patients familiar with HN-PCI. PROs are completed before and after consultations. Consultations recorded and transcribed. Qualitative analysis of transcriptions.	**At pre-consultation:** UWQOLv4; DT; HN-PCI v2 **Post-consultation:** PROC; DT; PSQ-MD	Described in Chapter 5. 1. Successful trial of audiorecording equipment and transcription 2. Development of thematic framework approach and content analysis to evaluate transcribed consultation 3. Development of HN-PCI v3
2. Develop domains for the HN-PCI	Domain generation study Undertaken before the Main study	Delphi method. Convenience sample of 10 health care professionals, moderated by researcher. 3 rounds of consultations, level of agreement set to >70%.	HN-PCI v3	Described in Chapter 6. Developed 5 domains for HN-PCI v3 i.e. (A) Physical & functional well-being; (B) Social care/Social well-being, (C) Psychological & Emotional well-being /Spirituality; (D) Treatment-related; and (E) Others. This is used in the analysis of results of the Main study.

	Where is this addressed?	Method	PROs used	Outcomes
3. Evaluate the relationship between HN-PCI data and levels of self-reported distress.	Main study	Statistical analysis of variable	HN-PCI v3; DT; UWQOL	Described in Chapter 7
4. Test the associations between clinicopathological factors with patients' concerns identified by the HN-PCI intervention.	Main study	Statistical analysis of variables		Described in Chapter 7
5. Determine the impact of HN-PCI intervention on outcomes i.e. length of consultation, patient satisfaction with consultation, clinic outputs, and HRQOL.	Main study	Compare 'Control' group with HN-PCI intervention groups		Described in Chapter 7
6. Determine the impact of the HN-PCI intervention on content of consultation.	Main study	Compare the self-reported concerns with the concerns discussed during in the HN-PCI intervention groups.		Described in Chapter 7

Table 4.2. UWQOL criteria for 'significant problem' [**Rogers & Lowe, 2009B**].

UWQOL domain	Score	Score + importance
Pain	0, 25	50 + importance
Appearance	0, 25	50 + importance
Activity	0, 25	50 + importance
Recreation	0, 25	50 + importance
Swallowing	0, 30	
Chewing	0	
Speech	0, 30	
Shoulder	0	30 + importance
Taste	0	30 + importance
Saliva	0	30 + importance
Mood	0, 25	50 + importance
Anxiety	0 or 30	

The UWQOL has been validated against several established patient-reported outcome measures [**Pusic et al, 2007**]. It showed good correlation with the European Organization for Research and Teaching Centre global Quality of Life (EORTC QLQC-30) and the HN subsite-specific questionnaire (H&N-35). Against the Sickness Impact Profile and Karnofsky scale, UWQOL showed high reliability, validity, responsiveness and acceptability. Internal consistency reliability demonstrated Cronbach alpha > 0.7; and intrarater test-retest reliability was > 0.8 in all domains [**Pusic et al, 2007**].

4.7.3. Distress thermometer (DT)

The DT is a single item self-report measure of distress **[Roth et al, 1998]** (Appendix 9). Since its introduction, the DT has been used worldwide [**Donovan et al, 2014**] both routinely in clinical practice and in research to detect significant distress in various types of cancer diagnoses [**Jacobsen et al, 2005; Kier et al, 2008; Hegel et al, 2006; Patrick-Miller et al, 2004; Hegel et al, 2008**]. It is scaled from 0 (no distress) to 10 (severe distress) in a thermometer layout to rate the level of distress experienced.

As a short screening tool for measuring distress, the DT has been validated against established tools, where suitable cut-off points were determined using the receiver operating curve for optimal sensitivity and specificity. A cut-off DT score of ≥ 4 is used to denote level of significant distress as it correlates with optimal sensitivity and specificity to the established cut-offs for significant distress for the Hospital Anxiety Depression Scale, HADS (sensitivity, 0.77; specificity, 0.68) and the Brief Symptom Inventory, BSI-18 (sensitivity & specificity, 0.7) in a multisite cancer cohort [**Jacobsen et al, 2005**]. With a cut-off score of 4, other studies also found optimal combination of sensitivity and specificity against HADS scores [**Ozlap et al 2007; Shim et al, 2008]** and with the EORTC QLQ-C30 [**Ozlap et al, 2007**]. In addition, this cut-off is able to identify patients reporting elevated levels of physical, emotional, practical, and family problems [**Donovan et al, 2004; Jacobsen et al, 2004; Kier et al, 2008**].

The DT has also been validated for distress screening in the UK [**Gessler et al, 2008**] in this large, prospective study. When the DT cut off point was set to 4 vs 5, the sensitivity against HADS was 79%, specificity 81%; against General Health Questionnaire-12 (GHQ-12,) sensitivity was 63%, specificity 83%; and against BSI-18, sensitivity was 88%, specificity74%.

4.7.4. Princess Margaret Hospital Patient Satisfaction with Physician (PSQ-MD)

The Princess Margaret Hospital Patient Satisfaction with Doctor Questionnaire, PSQ-MD is a patient-reported outcome measure used to quantify patient satisfaction with a visit-specific consultation [**Loblaw et al, 1999**] (Appendix 10). It has been validated for evaluating patient satisfaction with patient-doctor consultations in an oncology outpatient setting [**Loblaw et al, 2004**], with a Cronbach α score of 0.94. This 24-item questionnaire is scored using a four-point Likert-type response. Patients responded to statements from “strongly disagree” to “strongly agree,” scoring 1 to 4. For items that elicit negative responses, scores are reversed. Each patient’s score is an average of 24 equally weighted responses.

4.7.5. Non-validated patient-reported outcomes of consultation

> One non-validated questionnaire (Appendix 11) was used after the consultation to determine patient's perception of (a) what their concerns were; (b) the extent to which these concerns were addressed; (c) if they were able to see or be referred to the professional they had wanted to see; and (d) the degree of fulfillment felt by the patient from the consultation. Questions (b) and (d) were gauged using a Likert-type scale. The first question was recorded in a free text form and question (c) was a binary yes/no response.

Ethics approval for the entire MD study was granted from the North West Research ethics committee (study reference: 11/H1002/7). The study research ethics application including patient information sheet, patient consent form, and letter of research ethics approval are located in the Appendix. All the PROs used in the MD study including the versions of the HN-PCI, are also available in the Appendix.

5.0. PILOT STUDY

5.1.1. Introduction

A Pilot study was undertaken to test the feasibility of undertaking the Main study. This work was published in a peer-reviewed journal [**Ghazali et al, 2013A].** (Appendix 13).

5.2. Aims of study

5.2.1. Develop a thematic framework approach and content analysis to score items discussed during consultations for agreement and standardisation;

5.2.2. To test the audiorecording equipment, the process of audiorecording during consultation and the transcription of recordings;

5.2.3. To determine and compare the number of items highlighted on the HN-PCI with those discussed,

5.2.4. To report the clinical outcomes and satisfaction reported by patients.

5.3. Material and Method

5.3.1. Subjects

Patients were prospectively recruited were from those attending routine clinics of one OMF surgeon from 1 February to 15 May 2011. The OMF surgeon was trained and very familiar with the HN-PCI.

Recruitment to the Pilot study was based on the following criteria: The inclusion criteria were (1) diagnosis of HNC; and (2) disease-free survivors who have completed primary treatment of at least 6 weeks. The exclusion criteria were (1) pre-treatment HNC; (2) HNC patients with palliative status; and (3) non-HNC diagnosis.

On the day of appointment, patients were approached for recruitment in the waiting area while they were waiting for their appointment. Informed consent was formalised using the study consent form (Appendix 7) prior to data collection.

5.3.2. Patient-reported outcome measure

The HN-PCI (version 2) was used in this study. There were 55 items of concern and 15 professionals on the checklist (Appendix 4). The UWQOL, DT, PSQ-MD and other PROCs have been described previously in **sections 4.7**.

5.3.3. Study design

Recruited patients were given the preconsultation PROs to complete before their consultation. Patients completed the UWQOL and HN-PCI (version 2) using the TST-format. Both questionnaires were written as Microsoft Access-based software application packages and were filled in using a touch-screen computer linked to the hospital mainframe. After completion, the clinician retrieved a summarised report [**Rogers et al, 2009**]. On one occasion when the touch-screen computer was inaccessible (hardware malfunction), 6 paper versions of the UWQOL-HN-PCI were used. The complted HN-PCI (version 2) was available to both the patient and the doctor during consultation.

The consultation was audiorecorded using a Tascam DR-100 (TEAC UK Ltd., Watford, UK) recorder. The handling of the Tascam recorder was undertaken by the OMF surgeon. Audiorecording began at the start of the consultation and ends at the completion of the consultation. Each recorded consultation was saved on an individual file in MP3 format.

Patients are given the post-consultation questionnares consisting of the DT, PROC and the PSQ-MD, along with a stamped-envolope addressed to the researcher. Patients were instructed to complete the questionnaires and return them within 1 week following their consultation. Patients were contacted by a postcard reminder and latterly by a telephone call reminder, if the FU survey forms were not received at 2- and 4-weeks respectively, following consultation.

5.3.4. Transcription of recorded consultations

All identifiable information relating to the surgeon and patients were removed to maintain confidentiality. Only recordings of complete consultations were used and transcribed. Transcription was undertaken by medical secretaries at Aintree University Hospital. Each transcription was checked for accuracy by researcher (NG).

5.3.5. Clinical outcomes

The clinical outcomes measured in this study were:

a. Clinic outputs: Clinical outputs are the clinical decision or action taken related to the consultation, and are broadly considered as medical or non-medical clinical decisions/actions [**Velikova et al, 2004].** Medical actions comprised of physical examination, being placed on the waiting list for operations to aid rehabilitation, symptomatic or supportive medical treatment, investigations, and referrals. Non-medical actions included provision of information, advice on lifestyle, strategies for coping, and reassurance.

b. Length of consultation: This was measured from the duration of audiorecording of each consultation (minutes).

5.3.6. Patient satisfaction

Patient satisfaction was measured using the PROC (including PSQ-MD, and non-validated questionnaire). An overall PSQ-MD score is obtained by the sum of the individual 24-item scored. (**section 4.7.4 and 4.7.5**)

5.3.7. Thematic Coding Framework and Content Analysis

The aim of developing the thematic coding framework in this study was to create a standardised evaluation of spoken phrases or terms used by patients and clinicians during consultation. This method was specifically devised to enable a thematic framework based content analysis of the consultation in relation to the outcomes measures of the Main study i.e. patients' concerns, health care professionals, and clinic outputs.

The development of the thematic coding framework [**Miles & Huberman, 1994]** involves several steps (**Table 5.1**). Based on the principles described by **Miles & Huberman [1994], t**he process of developing the thematic coding framework and content analysis in this study was undertaken as follows:

1. The first stage is "Familiarisation".
   This involves becoming acquainted and conversant with the themes related to patients concerns, health care professionals and clinic outputs, by listening to the audiorecordings and reading through the transcripts.

2. The second stage is "Identification of Thematic Framework".
   This involves formally constructing the individual themes that will make up the framework. This is based on existing knowledge or evidence obtained through a literature review (**Chapter 3**) and/or established medical practices. For example, some themes could be derived from the HN-PCI checklist, and other themes were derived from **Chapter 3,** while themes surrounding clinic outputs were based on accepted conventional practices in oncology. The themes were expanded, by providing words or terms that explain or have similar meanings within a theme. For example, 'lethargy', 'exhausted', 'run down' could be considered individual codes, but were related under the theme of 'Fatigue/Tiredness'. The thematic framework forms the basis of a standardised coding definition.

3. The third stage is "Indexing".
   This involves both assessors evaluating the transcriptions independently using the thematic coding i.e. directed content analysis. The areas of the transcription were highlighted in the text, and the corresponding theme is annotated in the margin for indexing.

4. The fourth stage is "Charting".

The annotated themes that are indexed are charted to report the findings i.e. a list of all the identified themes in the transcription. Both assessors undertook this independently.

5. The final stage is "Mapping and Interpretation".
   This involves tabling and mapping the themes identified to allow better understanding of how individual themes relate to one another. This global analysis of themes also provided an understanding of how the items of concerns were handled during the consultation.

   From this exercise, it is possible to ascertain if the item of concern was simply mentioned in passing or expanded during the interaction. A concern was considered 'discussed' when there was evidence of expansion of themes or themes inter-relating in the transcription. As indicated in **Chapter 4 (Overview of MD study) section 4.1.2**, this content analysis based on a thematic framework was not designed to analyse the quality of the patient-doctor communication.

   Once the final stage is undertaken, both assessors meet to evaluate agreement for each transcription. This is detailed in the next **section 5.3.8. Scientific Rigour.**

5.3.8. Scientific Rigour

The reliability of qualitative data analysis i.e. rigour was enhanced with an independent assessment of transcripts by an additional skilled qualitative researcher (BR) and comparing agreement between raters for agreement of themes identified [**Mays & Pope, 1995**].

When the content analyses of all transcriptions were completed and available, assessor agreement was determined, where both raters (NG and BR) evaluated every 1 of 4 transcriptions selected randomly.

Assessor agreement was determined as follows. When an item was identified by one and missed by the other, it was discussed until resolved. This involved building a holistic picture of the patient or clinician, or both, on which to base analysis of the words used, and to identify key ideas and themes that were ultimately agreed by both assessors. This is particularly relevant in regard to ‘item missed’ that were not in the HN-PCI-based framework, which were carefully considered for the potential of new codings for addition to the HN-PCI-based thematic framework. However, for the purpose of this pilot study, these items were considered under ‘Others’. The overall level of agreement per consultation assessed was derived as a percentage from the formula: number of ‘item agreed’ / total number of items identified.

This evaluation also enabled formation of an agreed thematic framework, which was used by one assessor (NG) to evaluate the remaining number of transcriptions included in this study.

Table 5.1. The steps undertaken in developing the thematic coding framework and content analysis

Step	Definition	Process undertaken
1. Familiarisation	The process through which the researcher becomes familiarised with the datum.	1. Listening to the audio-recordings 2. Reading through the transcripts
2. Generating codes	The process of putting tags, labels or names against pieces of data. Sorting out descriptive and pattern codes. Develop operational definitions for codes based on HN-PCI checklist	Start codes are listed based on HN-PCI checklist. Pattern codes are generated. Test pattern codes against new data. Generation of other descriptive codes i.e. not on the HN-PCI checklist. Memoing was also undertaken to record ideas and potential relationships of codes as they are being analysed.
3. Identifying themes	Identification of portions or sections of the data that correspond to a particular theme	Portions of data representing a theme were identified by highlighting this in the text, with the corresponding theme annotated in the margin for indexing purposes.
4. Construction of thematic framework	Indexed data is organised into charts i.e. the portions of highlighted text are organised systematically, to identify the best way to report the findings.	Evaluate how themes support data and the overarching theoretical premise. At this stage, the framework can be tentative and open to further changes for refinement based on logical and intuitive thinking.
5. Integration and interpretation	Analysis of key characteristics as laid out in tables.	The indexed themes from the transcription were tabled according to types of themes identified.

5.4. Results

63 consultations of 56 patients derived from 6 clinics were eligible for this study. 67% (42 consultations) were enrolled whilst 33% (21) were missed. The losses resulted from lack of opportunity to recruit during a busy clinic (14/21) and refusal to participate (7/21). Those enrolled were on average 5 years younger (mean 61.6 versus 66.4 years) at clinic than those missed and in regard to primary diagnosis, they had more advanced T-stage (i.e. T3-4) tumours (38% versus 15%) but less flap surgery (29% versus 61%); otherwise there were no notable differences in the demographic and clinicopathological data.

Of the 42 enrolled consultations of 40 patients, 69% (29) were males, and mean (SD) age was 61.6 (11.3) years. The primary diagnosis was SCC for 37. The primary tumour site was: oral (28), pharyngeal (11), salivary (2) and skin (1). The pathological disease staging was: Stage 1 (14), Stage 2 (12), Stage 3 (8) and Stage 4 (8). The primary treatment received was: surgery (34), primary radiation and/or chemo-radiotherapy (7), flap surgery as part of treatment (12) and adjuvant post-operative radiotherapy (14). The median (IQR) time from first diagnosis to study clinic consultation was 22 (10-53) months.

5.4.1. Patient-reported concerns on HN-PCI

HN-PCI data was available from all 42 consultations (TST, 36; paper, 6). The mean number of concern and of professionals highlighted on the PCI was 5.52 and 0.50 respectively, with median (IQR) of 4 (2-8) and 0 (0-1). Almost all (88%, 37/42) selected at least one HN-PCI concern whilst a minority (38%, 16/42) selected at least one healthcare professional. HN-PCI concerns chosen by at least 20% were FOR (33%, 14), Dental health/teeth (31%, 13), Swallowing (29%, 12), Chewing (26%, 11), Speech/Voice/Being understood (21%, 9), Pain in head and neck (21%, 9), and Pain elsewhere (21%, 9). The only healthcare professional selected by at least 10% was dentist (21%, 9).

5.4.2. Audiorecordings

Overall, the audiorecording equipment was found to be ‘fit-for-purpose’ after a short learning curve. Recordings were complete in 19 consultations from 42 consultations (45%). The recordings that were rejected were either due to ‘an incomplete recording’ or ‘no recording at all’. The reasons for this were lack of consent (12 cases), seeing a different surgeon (5 cases), forgetting to record (3 cases) and equipment failure (3 cases).

There were some differences between those with audiorecordings and those without audiorecodings (**Table 5.2**). Patients with audiorecordings were 5 years younger on average (mean, 59 versus 64 years), and were closer to the time they were treated (median, 16 versus 45 months) and fewer had had adjuvant postoperative RT (16% Versus 52%). There were no notable differences in number of HN-PCI items selected before consultation (median 4, IQR 3-8 versus median 4, IQR 1-8) or in the number of HN-PCI health professions selected.

Table 5.2. Characteristics of the 19 with consultation audio recorded transcripts and 23 without transcripts

		WITH TRANSCRIPT	WITHOUT TRANSCRIPT	P Value *
Age	Mean (SD)	59 (13) years	64 (9) years	0.14
	% 65 years & over	32% (6/19)	39% (9/23)	0.85
Sex	% male	58% (11/19)	78% (18/23)	0.28
pT	% 3-4	32% (6/19)	17% (4/23)	0.48
pN	% Positive	42% (8/19)	17% (4/23)	0.16
pStage	% 3-4	47% (9/19)	30% (7/23)	0.42
Diagnosis	% scc	95% (18/19)	83% (19/23)	0.47
Tumour site	% oral	63% (12/19)	70% (16/23)	0.91
Treatment	% surgery	79% (15/19)	83% (19/23)	0.76
	% flap	21% (4/19)	35% (8/23)	0.52
	% adjuvant PORT / RND	16% (3/19)	52% (12/23)	0.03
Months from diagnosis to clinic	Median (IQR)	16 (8-34)	45 (16-76)	0.02
# HN-PCI items	Median (IQR)	4 (3-8)	4 (1-8)	0.54
# HN-PCI healthcare professionals	Median (IQR)	0 (0-1)	0 (0-1)	0.16
UWQOL physical function subscale score	Median (IQR)	75 (62-95)	76 (59-88)	0.73
UWQOL social-emotional function subscale score	Median (IQR)	83 (53-91)	80 (65-91)	0.89

*t-test (age), chi-squared test with Yates correction or Mann-Whitney test as appropriate

Abbreviations: PORT, postoperative RT; scc: squamous cell carcinoma; RND, radical neck dissection

5.4.3. *Thematic Content Analysis*

The main assessor (NG) reviewed all 19 transcriptions. From these, 5 transcriptions were randomly selected to assure scientific rigour independently by two assessors (NG and BR) (**Table 5.3**). The rate of overall rate of agreement between the main assessor (NG) and second assessor (BR) was 80.2%.

The thematic content analysis in this study identified potentially new themes for coding including themes of ‘well-being’, ‘dizziness’, ‘skin rash’ and ‘further surveillance’.

Table 5.3. Thematic content analysis and level of agreement between 2 assessors.

	Consultations					SUM 1-5
	1	2	3	4	5	
Total number of items	17	15	14	15	20	81
Missed items	2	4	2	4	1	13
Change definition of coding	1	1	1	0	0	3
Agreement	14	10	11	11	19	65
Percentage agreement	82.3%	66.7%	78.5%	73.3%	95.0%	80.2%

5.4.4. *Clinical outcomes*

The median length of consultation analyed by audiorecording was 8.4 minutes (IQR, 5.6-10.3 minutes).

In terms of clinic output, the median number of clinical decisions/actions taken during consultations was 2.8 (range, 2-5). Non-intervention action was the predominant decision made with ‘further surveillance appointment’, ‘provision of information’ and ‘reassurance’ being the most common action taken. Onward referrals occurred in only 2/19 (11%) consultations.

5.4.5. *Comparison of self-reported data with those discussed*

The mean number of items of concern and professionals highlighted on the HN-PCI was 5.95 and 0.74 respectively, with median IQR of 4 (3-8) and 0 (0-1). In contrast, content analysis of the consultation audiorecordings gave a mean number of 6.47 and 2.63 respectively, median 6 (4-9) and 3 (1-4).

A contrast between what patients selected on the HN-PCI and the content of their discussions is shown in **Figure 5.1 and 5.2**. There were clearly more items discussed than raised on the HN-PCI particularly in regard to health care professionals. Of the HN-PCI items, ‘FOR’ was prominent in being selected on the HN-PCI by 42% (8/19) patients and being discussed with 47% (9/19) patients.

The detailed breakdown of FOR is as follows: FOR was selected on the HN-PCI but was not discussed (2 patients), FOR was discussed despite having not selected this on HN-PCI (3 patients) and FOR selected and discussed (6 patients). **Table 5.4** summaries these relationships in more detail for the 20 most cited items.

5.4.6. Patient-reported post-consultation outcomes

Post-consultation questionnaires were distributed following 22 consultations (15 patients), of which 11 were audio-recorded. Post-consultation questionnaires were distributed following 15 consultations, of which 11 were audio-recorded. Questionnaire returns for 15 patients were completed within a median of 1 day (range, 0- 12 days from consultation day). 93% (14) felt that they were able to see the professional or individual they had hoped to see on the consultation day.

Other post-consultation results are summarised in **Table 5.5**. The vast majority of responses described positive experiences, i.e. patients were agreeing to statements on the PSQ-MD indicating satisfaction with consultation and disagreeing with those that contradict satisfaction.

Figure 5.1. Items were selected on the HN-PCI (LEFT graph) and which items were noted from the audio recordings of the consultations (RIGHT graph) (19 cases)

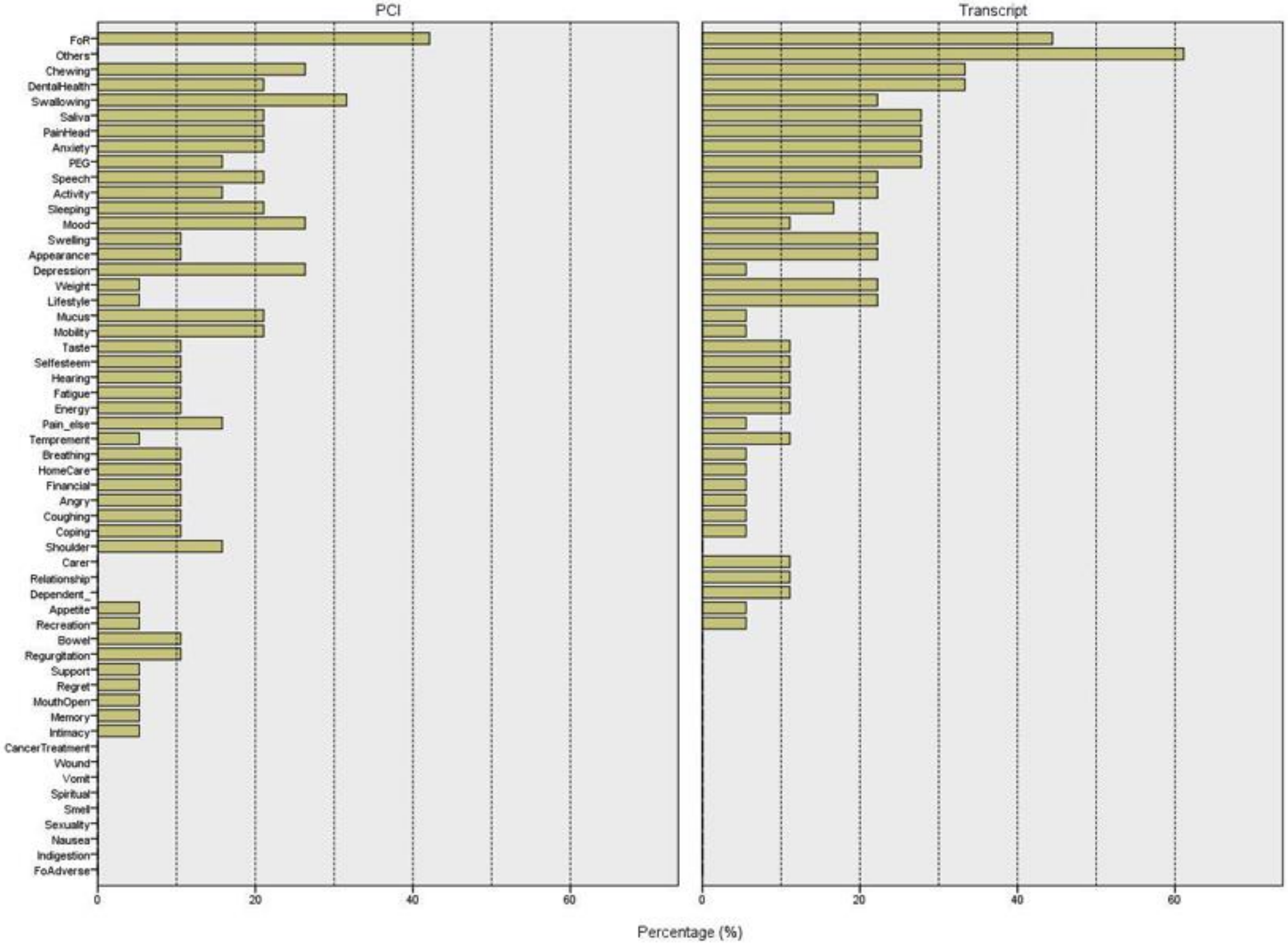


Figure 5.2. Healthcare professionals were selected on the HN-PCI (LEFT graph) and which were noted from the audio recordings of the consultations (RIGHT graph) (19 cases)

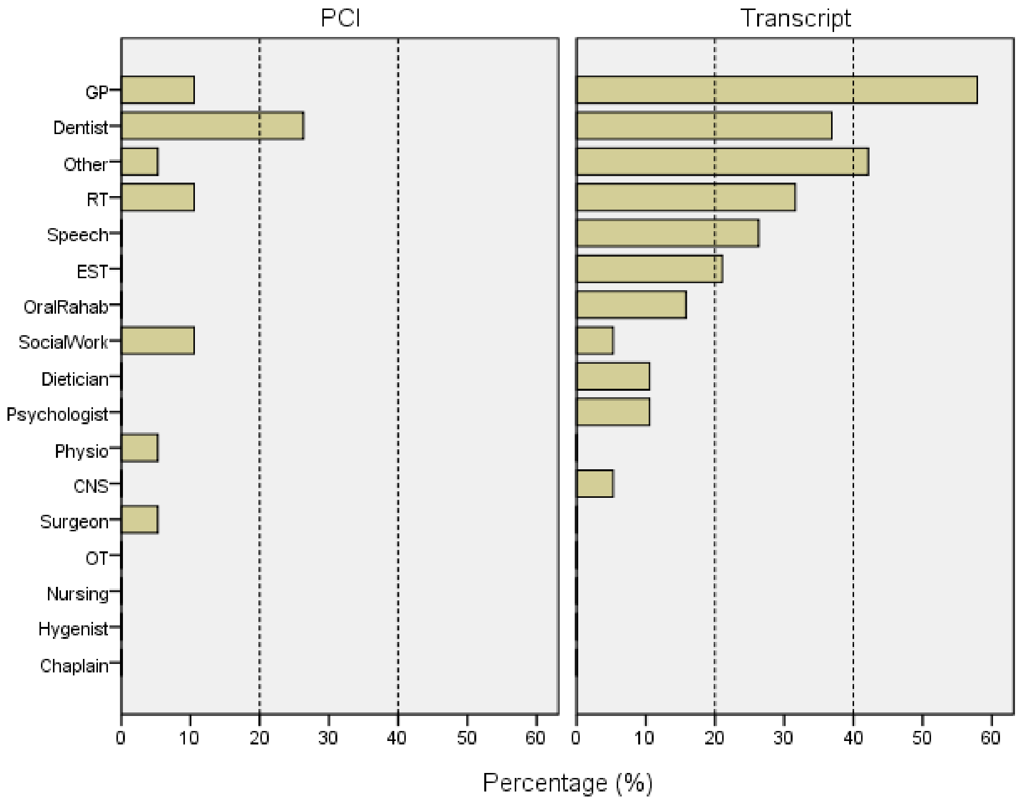


Table 5.4. The 20 items shown here are those that involved 4 or more (ie. >20%) of the 19 cases, whereas health professionals shown are all those noted on the HN-PCI or in consultation.

	On HN-PCI	Discussed	On HN-PCI & not discussed	On HN-PCI & Discussed	Not on HN-PCI but discussed
Fear of recurrence	8	9	2	6	3
Others*	0	12	0	0	12
Chewing	5	7	1	4	3
Dental health	4	6	1	3	3
Swallowing	6	5	1	5	0
Saliva	4	6	1	3	3
Pain in H&N	4	5	4	0	5
Anxiety	4	6	1	3	3
PEG	3	5	0	3	2
Speech	4	5	1	3	2
Activity	3	4	1	2	2
Sleeping	4	3	1	3	0
Mood	5	2	4	1	1
Swelling	2	4	1	1	3
Appearance	2	4	0	2	2
Depression	5	1	4	1	0
Weight	1	4	1	0	4
Lifestyle	1	5	0	1	4
Mucus	4	1	3	1	0
Mobility	4	1	4	0	1
SUM over these 20 items	73	95	31	42	53
SUM over the other 35 items	40	28	28	12	16
SUM over all 55 items	113	123	59	54	69
General practitioner	2	11	0	2	9
Dentist	5	7	3	2	5
Other**	1	8	1	0	8
Oncologist	2	6	1	1	5
Speech & Language Therapist	0	5	0	0	5
Emotional support therapist	0	4	0	0	4
Oral Rehabilitation	0	3	0	0	3
Social worker	2	1	1	1	0
Dietician	0	2	0	0	2
Psychologist	0	2	0	0	2
Physiotherapist	1	0	1	0	0
Clinical nurse specialist	0	1	0	0	1
Surgeon	1	0	1	0	0
SUM over all these health professionals	14	50	8	6	44

*Wellbeing (7), wellbeing & dizziness (1), new cancer (1), jaw deformity (1), altered sensation (1), skin rash (1)

**Psychiatrist (1), dermatologist (1), financial advisor (2), alcohol nurse (1), ENT consultant (1), medical specialty doctor (1), respiratory consultant (1)

Table 5.5. Post-consultation questionnaire results for 15 patients, comprising of the PSQ-MD and the non-validated questionnaire specific to this study

	Strongly Agree	Agree	Disagree	Strongly disagree	Does not apply	%positive response*
PSQ-MD						
I will follow the doctor's advice because I think s/he is absolutely right.	11	3	-	-	1	100% (14/14)
The doctor did not take my problems very seriously.	-	-	4	10	1	100% (14/14)
The doctor considered my individual needs when treating my condition.	10	3	-	1	1	93% (13/14)
The doctor did not give me all the information I thought I should have been given.	-	-	4	10	1	100% (14/14)
The doctor went straight to my medical problem without greeting me first.	-	-	3	12		100% (15/15)
The doctor used words I did not understand.	1	-	5	9		93% (14/15)
There was not enough time to tell the doctor everything I wanted.	1	-	5	8	1	93% (13/14)
I feel the doctor did not spend enough time with me.	-	-	3	12		100% (15/15)
It seemed to me that the doctor was not really interested in my emotional well-being.	-	-	3	12		100% (15/15)
I really felt understood by my doctor.	11	4	-	-		100% (15/15)
After my last visit with my doctor, I feel much better about my concerns.	5	8	1	-	1	93% (13/14)
The doctor was not friendly to me.	-	-	2	13		100% (15/15)
I understand my illness much better after seeing this doctor.	5	6	1	-	3	92% (11/12)
This doctor was interested in me as a person and not just my illness.	10	4	-	1		93% (14/15)
I feel I understand pretty well the doctor's plan for helping me.	8	4	-	2	1	86% (12/14)
I would not recommend this doctor to a friend.	1	-	-	14		93% (14/15)
The doctor seemed to brush off my questions.	-	-	1	14		100% (15/15)
The doctor should have told me more about how to care for my condition.	2	-	2	10	1	86% (12/14)
After talking with the doctor, I have a good idea of what changes to expect in my health over the next few weeks and months.	6	6	-	-	3	100% (12/12)
The doctor told me to call back if I had any questions or problems.	9	4	1	-	1	93% (13/14)
I felt the doctor was being honest with me.	11	4	-	-		100% (15/15)
The doctor explained the reason why the treatment was recommended for me.	7	5	-	-	3	100% (12/12)
It seemed to me that the doctor was not really interested in my physical well-being.	-	-	1	14		100% (15/15)
The doctor should have shown more interest.	-	-	2	13		100% (15/15)
Non-validated questions specific to this study:						
How would you rate the extent to which these concerns were addressed?	8	7				100% (15/15)
To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient visit.	10	4	-	1		93% (14/15)
To what degree would you agree to this statement: I felt the PCI was intrusive	2	-	8	5		87% (13/15)
To what degree would you agree to the statement: I felt the PCI was unhelpful	-	1	8	6		93% (14/15)

* Strongly agree / agree, OR strongly disagree / disagree, as appropriate and applicable

5.5. Discussion

This main aim of this Pilot study was to develop a standardised method of evaluating the content of consultations through a thematic framework -based content analysis. This involved accurately recording of the consultation using a reliable audiorecording device, precise transcription of the recording, development of a thematic framework approach to content analysis, and applying scientific rigour of the content analysis method.

This study observed that the audiorecording equipment was “fit for purpose”. Failure to record consultation was predominantly due to issues unrelated to the handling of the equipment i.e failure to consent (12/23, 52%) and others (5/23, 22%). Equipment failure (3/23, 13%) and Surgeon did not record (3/23,13%) were both due to initial unfamiliarity with the equipment. The handling of the equipment improved after a short learning curve. Professional medical secretaries, who were experienced and reliable, accurately transcribed the audiorecordings.

This study developed a method of content analysis of the transcriptions using a thematic framework [**Miles & Huberman, 1994**]. The method employed in this study was suitable for exploring consultations of patients whose needs and concerns are diverse, because it considered the themes within the experience of the subjects involved. Other valuable features of this approach were dynamism (i.e. allows for amendments to the thematic framework during the analytical process), systematic (i.e. permits standardised approach to handling data) and comprehensive (facilitates a full review of the datum). Using this approach, more items were discussed in comparison to those highlighted originally by patients. This is may be in part due to the introduction of new themes that were not found in the HN-PCI (version 2) checklist .

The new themes identified relating to patients’ concern include ‘Dizziness’ and ‘Skin rash’, and these were not part of the original HN-PCI (version 2) checklist in this study. Under the theme of ‘Dizziness’, the coding included the words ‘*dizziness*’, ‘*light-headedness*’, ‘*giddy*’, ‘*woozy*’ and ‘*vertigo*’. The theme ‘Skin rash' includes the words describing skin symptoms e.g. '*rash*', '*eczema*' and '*dry, flaky skin'*. In regard to clinic output, the theme 'Further surveillance' was identified and incorporated into the existing thematic framework for use in further studies.

Another new theme identified during the development of the thematic framework in this study was 'Well-being'. This theme was the most frequently discussed during the clinical encounters. The complexity of the linguistic implications of the term 'well-being' is recognised. 'Well-being' may be considered as a social construct that is fluid and subject to primary cultural judgment [**Ereaut et al, 2008**]. To provide an operational definition for coding, 'well-being' was deliberated as the subjective notion of how well a person's life is going, and the words used to categorise this theme includes '*doing well'*, '*feeling great in me-self*' and '*super*'. The frequency with which this theme is discussed may reflect an overall expression of how well a patient feels he/she has coped with their condition and thereby does not have any items of concerns. In others, this could simply be an automatic response to enquiries about their condition because in these patients, further exploratory HN-PCI-led discussions identified various items of concerns. **Fagerlind et al, [2008]** also identified the 'well-being' theme in their qualitative evaluation of audiorecordings of routine HNC clinic consultations.

The increased number of items discussed in comparison to those highlighted may also be related to how the HN-PCI is used during consultation. This process is observed through the mapping of the themes derived from individual transcripts. One way is by association of themes. This is exemplified in an excerpt from the consultation with patient JC:

Surgeon: You mentioned on the computer about Anxiety..
Patient: I've always been anxious..
Surgeon: …and the fear of it coming back. Have you seen Jimmy in the past? The emotional support therapist?
Patient: Yeah, I've seen him. Its just that, over this last year I've buried me mum, buried me dad, buried me brother..

This patient did not indicate FOR but instead indicated anxiety on the HN-PCI. The clinician was able to bring up the issue of FOR based on the understanding of the association of anxiety with FOR [**Rogers et al, 2011; Ghazali et al, 2013B**], thereby allowing the patient the opportunity to disclose this concern if he/she so wished. Other thematic associations include swallowing-PEG tube, saliva-chewing-swallowing and FOR-depression.

Another way is based on the permission-giving impact of the HN-PCI. This is exemplified in an excerpt from the consultation with patient AR:

Surgeon: Did you mention about appearance (on the HN-PCI)?
Patient: It's just that I feel great about my appearance now, you know. Now I'm back to me confidence again. And it's really fine.
Surgeon: You feel stronger, you mean?
Patient: Yeah, much, much. As I said to you before, I was worried sick about it coming back again and all this, that is still at the back of me mind. (But) It's (now) not a major issue or anything.
Surgeon: Do you think about it a lot?
Patient: No, not a lot..

This patient did not indicate FOR on the HN-PCI on this occasion but had done so in the past. But having done so in the past has allowed the patient to freely bring this issue up once again for discussion. This example also demonstrates another way the HN-PCI can increase the number of items discussed, which is by further exploration of one HN-PCI-highlighted item would lead on to uncovering other hidden issues of concern.

Some items were infrequently indicated on the HN-PCI but were frequently touched upon during consultations, for example, 'Relationships'. Other items may have been indicated on the HN-PCI but not discussed. This may be due to the patients selecting too many items at one time, particularly when significant distress is experienced [**Ghazali et al, 2012**] and/or when restrictions to clinic time may have prevented these items to be broached. In this situation, the HN-PCI can sign-post the patients who may need more time for unpacking of these concerns. This could be provided by seeing the Clinical Nurse Specialist after the consultation with the doctor.

A higher number of professionals were discussed during the consultation in comparison to what was indicated on the HN-PCI. This finding may reflect the lack of understanding on the part of patients regarding each professional's scope of practice or expertise, and also not knowing what services are available to them. For example, in patient TD:

> Surgeon: You mentioned about financial side as well, do you need some help with that as well?
> Wife: Well, we've been trying to sort something out with our mortgage now. It does seem like we're going round in circles.
> Surgeon: Absolutely. So you don't need anyone from this end to see you?
> Wife: Is it possible you can get help from here (hospital)?
> Surgeon: Yes, that's right.
> Wife: Well, I just want to see if we can get this one first.

The nature of the multidisciplinary team approach, and the important role played by the GP in the community, has also resulted in more professionals being discussed during consultations. This is evident in the frequency with which the GP and oncologist is mentioned in consultations. However, this has not resulted in an increase in the number of referrals (2 per 19 patients seen) in comparison to a previous study (21 per 100 patients seen) [**Ghazali et al, 2011**].

Regarding patient satisfaction with consultations, the results indicate that the majority of patients were satisfied with the consultation. Although patient satisfaction surveys are thought to favour the clinician, visit-specific scales measure different attributes than those that ask respondents to integrate their perceptions over the duration of the patient–physician relationship [**Epstein et al, 2006**]. However, the PSQ-MD visit-specific oncology patient satisfaction questionnaire has never been used in HNC setting and precludes any potential comparisons in other cohorts to be made. This early data provides a measure of its feasibility and an understanding of how this questionnaire could translate into a real measure of satisfaction.

The limitations of this pilot study relates to the small numbers of transcriptions available for statistical analysis of the results obtained. However, it was a feasibility study to test methods of recruitment, audio-recording process and data collection from the transcribed recordings. Furthermore, the choice of a visit-specific oncology patient satisfaction with consultation has never been used in a HNC setting and precludes any potential comparisons in other cohorts to be made.

5.6. Conclusions

In conclusion, the Pilot study showed that the audiorecording of consultations and its transcription was a reliable method for data collection for further analysis. The Pilot study also developed a standardised method for content analysis of consultations using the thematic framework approach. Analyses of the Pilot study findings suggest that more items of concerns' were discussed in comparison to those self-selected by patients. This observation was also noted in regard to health care professionals. Meaningful conclusions could not be made from the data regarding clinical outcomes and patient satisfaction due to the small numbers obtained in this study. These issues will be addressed in the Main study.

CHAPTER 6

6.0. GENERATION OF HN-PCI DOMAINS

6.1. Introduction

The two new items of concern identified during the Pilot study i.e. 'Dizziness' and 'Skin Rash' [**Ghazali et al, 2013A**] was incorporated into the HN-PCI, creating a new version i.e. HN-PCI (version 3) with 57 items of concern and 15 professionals (Appendix 4). However, the current HN-PCI (version 3) or previous versions are not organised or grouped into categories or domains.

Previous reporting of patients' expressed needs/concerns identified using HN-PCI have been summarised as an extensive bar chart and this is often cumbersome due to the long checklist of individual items [**Rogers et al, 2009A; Rogers et al, 2012; Ghazali et al; 2013B**]. Alternatively, HN-PCI results are sometimes presented as a list of all selected items or the top most ranked items [**Scott et al, 2013; Flexen et al, 2012; Jungerman et al, 2017**]. While this is succinct, the narrowed focus on more common concerns can result in missing less frequently reported but nonetheless significant concerns, e.g. regret of treatment.

It is hypothesised that having domains can permit a more systematic method of summarizing HN-PCI findings, facilitates comparative evaluations and helps to construct an overall picture of the inter-relationship of various concerns in a defined cohort. This work has been published in a peer-reviewed journal [**Ghazali et al, 2015**] (Appendix 14).

6.2. Aim of study

The primary aim was to generate domains for the HN-PCI (version 3) through a systematic methodology.

The secondary aim of this study was to apply the domains to an existing database of HN-PCI data established at the OMF department, Aintree University

Hospital, and evaluate the associations between HN-PCI data with demographic and clinical parameters.

6.3 Materials and Method

6.3.1. Domain generation

The Delphi method [**Linstone & Turnoff, 1975**; **Powell, 2003**] of achieving consensus was used. A convenience panel of experts was set up *ad hoc* through selection of 10 healthcare workers caring for HNC patients within the Merseyside and Cheshire HNC service. The panel of experts consisted of two doctors, two Clinical Nurse Specialists, one Speech & Language therapist plus three outpatient clinic nurses, one research nurse and one HN-PCI hospital volunteer.

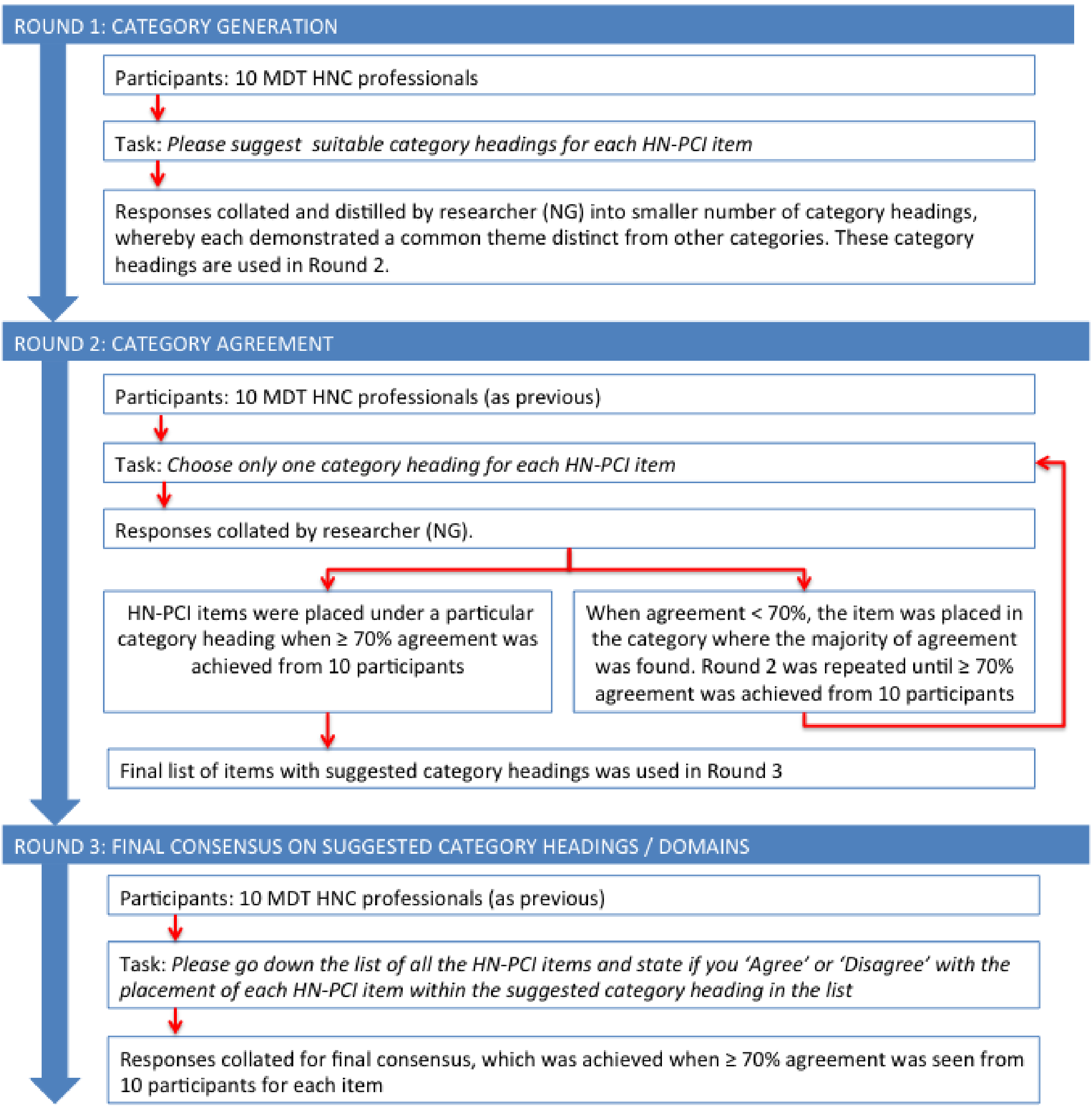
Domain generation was undertaken in a 3-step process (Figure 6.1). Participants were given a sheet of paper, indicating the specific task according to the stage of the process. They were instructed to complete the task within 7 days of its receipt and to post their responses in with a self-return envelope addressed to the researcher (NG). The researcher was blinded to the identity of the participant. All 10 participants took part at each stage of the process (100% response rate).

In order to achieve a consensus in Rounds 2 and 3, a minimal percentage of 70% agreement among panelists had to be established per item based on the recommendation by **Sumsion [1998**]. When an item achieved <70% agreement, the checklist with the related items was re-distributed until the expected level of agreement was achieved.

6.3.2. Application of domains to existing HN-PCI data

The HN-PCI database was started in 1 August 2007 with the introduction of the HN-PCI in routine clinical practice [**Rogers et al, 2009A**]. The database also includes HN-PCI data completed as part of a wider HNC service audit [**Kanatas et al, 2013**]. Relationships between HNC-PCI domain and patient/clinical characteristics were investigated for the 674 patients completing the HN-PCI for the first time, with statistical significance obtained using Fishers Exact test (two by two tables) or chi-squared test (three by two or four by two tables) as appropriate. Because of the large number of significance tests performed, statistical significance was regarded as p<0.01.

Figure 6.1. Step-wise process of domain generation



ROUND 1: CATEGORY GENERATION

Participants: 10 MDT HNC professionals

Task: *Please suggest suitable category headings for each HN-PCI item*

Responses collated and distilled by researcher (NG) into smaller number of category headings, whereby each demonstrated a common theme distinct from other categories. These category headings are used in Round 2.

ROUND 2: CATEGORY AGREEMENT

Participants: 10 MDT HNC professionals (as previous)

Task: *Choose only one category heading for each HN-PCI item*

Responses collated by researcher (NG).

HN-PCI items were placed under a particular category heading when ≥ 70% agreement was achieved from 10 participants

When agreement < 70%, the item was placed in the category where the majority of agreement was found. Round 2 was repeated until ≥ 70% agreement was achieved from 10 participants

Final list of items with suggested category headings was used in Round 3

ROUND 3: FINAL CONSENSUS ON SUGGESTED CATEGORY HEADINGS / DOMAINS

Participants: 10 MDT HNC professionals (as previous)

Task: *Please go down the list of all the HN-PCI items and state if you 'Agree' or 'Disagree' with the placement of each HN-PCI item within the suggested category heading in the list*

Responses collated for final consensus, which was achieved when ≥ 70% agreement was seen from 10 participants for each item

6.4. Results

6.4.1. Domain generation

Round 1: The suggested category headings suggested by panelists at Round 1 are shown in **Table 6.1**. These items were analysed and distilled into 5 groups based on thematic considerations by researcher (NG), namely, (A) Physical and functional well-being; (B) Social care/Social well-being, (C) Psychological and Emotional well-being /Spirituality; (D) Treatment-related; and (E) Others. These were subsequently used as the HNC-PCI domain headings.

Round 2: **Table 6.2** shows the frequency by which each category heading was chosen by each panelist per item at the first stage of Round 2. 100% agreement was seen in 21/57 items (36.8%) (category A: 14/21; C: 6/21; and E: 1/21). However, most items (87%, 50/57) showed an agreement ≥ 70%. Seven items with < 70% agreement at this stage were ‘Appearance’, ‘Dependents/Children’, ‘PEG tube’, ‘Speech/voice/being understood’, ‘Sexuality’, ‘Regret about treatment’, and ‘Relationships’. Round 2 was repeated once when the minimum level of agreement was reached (**Table 6.3**).

Round 3: At the first stage of Round 3, 100% agreement was achieved in almost all items (94%, 53/57). This was repeated once and ≥ 70% agreement was achieved at the second stage of Round 3 in the remaining items. **Table 6.4** shows the final consensus reached in Round 3 for the items within final domain.

Table 6.1. Suggested categories by 10 panelists and facilitated by researcher

Items suggested for category headings by panelists	Frequency (n=10)	Thematic category	Suggested categories after collation by researcher
Fitness	2	A	Physical and functional well-being
Rehabilitation	2	A	
Physical	7	A	
Social care/support	4	B	Social care / Social well-being
Practical	1	B	
Lifestyle	1	B	
Support	6	B	
Social life	3	B	
Spiritual	5	C	Psychological and Emotional well-being / Spirituality
Emotional	8	C	
Feelings	6	C	
Treatment	4	D	Treatment-related
Treatment-related	4	D	
Side-effects	8	D	
Body image	1	E	Others
Personal	2	E	
Symptoms	1	E	
Illness	1	E	
Others	7	E	

Table 6.2. Suggested category headings and agreement by 10 panelists after Round 2 (continued next page)

	PCI item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Agreement**
1.	Activity	A	A	A	A	B	B	A	A	A	B	A (70%); B (30%)
2	Angry	C	C	C	C	C	C	C	C	C	C	C (100%)
3	Anxiety	C	C	C	C	C	C	C	C	C	C	C (100%)
4	Appearance	C	B	B	C	B	C	A	B	A	B	B (50%); C (30%); A (20%)
5	Appetite	A	A	A	A	A	A	A	A	C	A	A (90%); C (10%)
6	Bowel habit	A	A	A	A	A	A	A	A	A	A	A (100%)
7	Breathing	A	A	A	A	A	A	A	A	A	A	A (100%)
8	Cancer treatment	D	D	D	D	D	D	D	A	D	D	D (90%); A (10%)
9	Carer	B	A	E	C	B	B	B	B	B	B	B (70%); C, E, A (10% each)
10	Chewing/eating	A	A	A	A	A	A	A	A	A	B	A (90%); B (10%)
11	Coping	C	C	C	C	B	C	C	C	C	C	C (90%); B (10%)
12	Coughing	A	A	A	A	A	A	A	A	A	A	A (100%)
13	Dental health/teeth	A	C	A	A	A	A	A	A	A	A	A (90%); C (10%)
14	Dependents/children	B	C	E	C	B	B	B	B	E	B	B (60%); C (20%); E (20%)
15	Depression	C	C	C	C	C	C	C	C	C	C	C (100%)
16	Dry mouth	A	A	A	A	A	A	A	A	A	A	A (100%)
17	Energy levels	C	A	A	A	A	C	A	A	C	A	A (70%); C (30%)
18	Fatigue/tiredness	C	A	A	A	A	C	A	A	A	A	A (80%); C (20%)
19	Fear of the cancer coming back	C	C	C	C	C	C	C	C	C	C	C (100%)
20	Fear of adverse events	C	C	C	C	C	C	C	C	C	C	C (100%)
21	Financial/ benefits	B	B	B	E	B	B	C	B	B	B	B (80%); C, E (10% each)
22	Hearing	A	C	A	A	A	A	A	A	A	B	A (80%); B (10%); C (10%)
23	Home care/district nurse	B	B	B	E	B	B	A	B	B	B	B (80%); A, E (10% each)
24	Indigestion	A	A	A	A	A	A	A	A	A	A	A (100%)
25	Intimacy	C	C	E	C	C	C	C	B	C	B	C (70%); B (20%); E (10%)
26	Lifestyle issues	B	B	B	E	B	B	B	A	B	A	B (70%); A (20%); E (10%)
27	Memory	C	C	A	C	C	C	C	C	C	C	C (90%); A (10%)
28	Mobility	A	A	A	A	A	A	C	B	A	A	A (80%); C,B (10% each)
29	Mood	C	B	C	C	C	C	C	C	C	C	C (90%); B (10%)

	PCI item	1	2	3	4	5	6	7	8	9	10	Agreement
30	Mouth opening	A	A	A	A	A	A	A	A	A	A	A (100%)
31	Mucus	A	A	A	A	A	A	A	A	A	A	A (100%)
32	Nausea	A	A	A	A	A	A	B	A	A	A	A (100%)
33	Pain in head and neck	A	A	A	A	A	A	C	A	A	A	A (90%); C (10%)
34	Pain elsewhere	C	A	A	A	A	A	C	A	A	A	A (80%); C (20%)
35	PEG tube	D	A	A	D	A	D	D	B	E	D	D (50%); A (30%); B, E (10% each
36	Recreation	B	B	B	B	B	B	A	B	B	B	B (90%); A (10%)
37	Regret about treatment	D	C	D	D	C	C	D	C	D	D	D (60%); C (40%)
38	Relationships	C	C	B	C	B	C	C	B	B	B	C (50%); B (50%)
39	Regurgitation	A	A	A	A	A	A	A	A	A	A	A (100%)
40	Salivation	A	A	A	A	A	A	A	A	A	A	A (100%)
41	Self-esteem	C	C	C	C	C	C	A	C	C	C	C (90%); A (10%)
42	Sexuality	C	C	C	C	E	C	B	B	C	B	C (60%); B (30%); E (10%)
43	Shoulder	A	A	A	A	A	A	A	A	A	A	A (100%)
44	Sleeping	C	A	A	A	A	A	A	B	C	A	A (70%); C (20%); B (10%)
45	Smell	A	B	A	A	A	B	A	A	A	A	A (80%); B(20%)
46	Sore mouth	A	A	A	A	A	A	A	A	A	A	A (100%)
47	Speech/voice/being understood	C	B	A	A	B	B	B	B	A	B	B (60%); A 30%); C (10%)
48	Spiritual/religious aspects	C	C	C	C	C	C	C	C	C	C	C (100%)
49	Support for my family	B	B	B	C	B	B	B	B	E	B	B (80%); C, E (10% each)
50	Swallowing	A	A	A	A	A	A	A	A	A	A	A (100%)
51	Swelling	A	A	A	A	A	A	B	A	A	A	A (90%); B (10%)
52	Taste	A	A	A	A	A	A	A	C	A	A	A (90%); C (10%)
53	Temperament and personality	C	B	C	C	C	C	C	E	C	C	C (80%); B,E (10% each)
54	Vomiting/sickness	A	A	A	A	A	A	B	A	A	A	A (90%); B (10%)
55	Weight	C	A	A	A	A	A	C	A	A	A	A (80%); C (20%)
56	Wound healing	D	D	D	D	D	A	A	D	D	D	D (80%); A (20%)
57	Anything else	E	E	E	E	E	E	E	E	E	E	E (100%)

Table 6.3. Suggested category headings and agreement between panelists after repeating Round 2 (Pink rows showing items that had agreement < 70% in previous round) continued next page

	PCI item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Agreement**
1.	Activity	A	A	A	A	B	B	A	A	A	B	A (70%); B (30%)
2	Angry	C	C	C	C	C	C	C	C	C	C	C (100%)
3	Anxiety	C	C	C	C	C	C	C	C	C	C	C (100%)
4	Appearance	C	C	C	A	C	A	C	C	C	A	C (80%); A (30%)
5	Appetite	A	A	A	A	A	A	A	A	C	A	A (90%); C (10%)
6	Bowel habit	A	A	A	A	A	A	A	A	A	A	A (100%)
7	Breathing	A	A	A	A	A	A	A	A	A	A	A (100%)
8	Cancer treatment	D	D	D	D	D	D	D	A	D	D	D (90%); A (10%)
9	Carer	B	A	E	C	B	B	B	B	B	B	B (70%); C, E, A (10% each)
10	Chewing/eating	A	A	A	A	A	A	A	A	A	B	A (90%); B (10%)
11	Coping	C	C	C	C	B	C	C	C	C	C	C (90%); B (10%)
12	Coughing	A	A	A	A	A	A	A	A	A	A	A (100%)
13	Dental health/teeth	A	C	A	A	A	A	A	A	A	A	A (90%); C (10%)
14	Dependents/children	B	C	B	C	B	B	B	B	B	B	B (80%); (20%)
15	Depression	C	C	C	C	C	C	C	C	C	C	C (100%)
16	Dry mouth	A	A	A	A	A	A	A	A	A	A	A (100%)
17	Energy levels	C	A	A	A	A	C	A	A	C	A	A (70%); C (30%)
18	Fatigue/tiredness	C	A	A	A	A	C	A	A	A	A	A (80%); C (20%)
19	Fear of the cancer coming back	C	C	C	C	C	C	C	C	C	C	C (100%)
20	Fear of adverse events	C	C	C	C	C	C	C	C	C	C	C (100%)
21	Financial/ benefits	B	B	B	E	B	B	C	B	B	B	B (80%); C, E (10% each)
22	Hearing	A	C	A	A	A	A	A	A	A	B	A (80%); B (10%); C (10%)
23	Home care/district nurse	B	B	B	E	B	B	A	B	B	B	B (80%); A, E (10% each)
24	Indigestion	A	A	A	A	A	A	A	A	A	A	A (100%)
25	Intimacy	C	C	E	C	C	C	C	B	C	B	C (70%); B (20%); E (10%)
26	Lifestyle issues	B	B	B	E	B	B	B	A	B	A	B (70%); A (20%); E (10%)
27	Memory	C	C	A	C	C	C	C	C	C	C	C (90%); A (10%)
28	Mobility	A	A	A	A	A	A	C	B	A	A	A (80%); C, B (10% each)
29	Mood	C	B	C	C	C	C	C	C	C	C	C (90%); B (10%)
30	Mouth opening	A	A	A	A	A	A	A	A	A	A	A (100%)
31	Mucus	A	A	A	A	A	A	A	A	A	A	A (100%)

	PCI item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Agreement**
32	Nausea	A	A	A	A	A	A	B	A	A	A	A (100%)
33	Pain in head and neck	A	A	A	A	A	A	C	A	A	A	A (90%); C (10%)
34	Pain elsewhere	C	A	A	A	A	A	C	A	A	A	A (80%); C (20%)
35	PEG tube	D	A	D	D	A	D	D	D	D	D	D (80%); A (20%)
36	Recreation	B	B	B	B	B	B	A	B	B	B	B (90%); A (10%)
37	Regret about treatment	D	C	D	D	C	D	D	C	D	D	D (70%); C (30%)
38	Relationships	C	C	B	C	B	B	B	B	B	B	C (30%); B (70%)
39	Regurgitation	A	A	A	A	A	A	A	A	A	A	A (100%)
40	Salivation	A	A	A	A	A	A	A	A	A	A	A (100%)
41	Self-esteem	C	C	C	C	C	C	A	C	C	C	C (90%); A (10%)
42	Sexuality	C	C	C	C	C	C	B	B	C	B	C (70%); B (30%)
43	Shoulder	A	A	A	A	A	A	A	A	A	A	A (100%)
44	Sleeping	C	A	A	A	A	A	A	B	C	A	A (70%); C (20%); B (10%)
45	Smell	A	B	A	A	A	B	A	A	A	A	A (80%); B (20%)
46	Sore mouth	A	A	A	A	A	A	A	A	A	A	A (100%)
47	Speech/voice/being understood	C	B	B	A	B	B	B	B	A	B	B (70%); A (20%); C (10%)
48	Spiritual/religious aspects	C	C	C	C	C	C	C	C	C	C	C (100%)
49	Support for my family	B	B	B	C	B	B	B	B	E	B	B (80%); C, E (10% each)
50	Swallowing	A	A	A	A	A	A	A	A	A	A	A (100%)
51	Swelling	A	A	A	A	A	A	B	A	A	A	A (90%); B (10%)
52	Taste	A	A	A	A	A	A	A	C	A	A	A (90%); C (10%)
53	Temperament and personality	C	B	C	C	C	C	C	E	C	C	C (80%); B,E (10% each)
54	Vomiting/sickness	A	A	A	A	A	A	B	A	A	A	A (90%); B (10%)
55	Weight	C	A	A	A	A	A	C	A	A	A	A (80%); C (20%)
56	Wound healing	D	D	D	D	D	A	A	D	D	D	D (80%); A (20%)
57	Anything else	E	E	E	E	E	E	E	E	E	E	E (100%)

Table 6.4. Results of Round 3. (Yellow rows showing items with agreement < 100%)
A: Agree; D: Disagree

	PCI item	A	D
A	Physical and functional well-being		
1.	Activity	100%	
5	Appetite	100%	
6	Bowel habit	100%	
7	Breathing	100%	
10	Chewing/eating	100%	
12	Coughing	100%	
13	Dental health/teeth	100%	
16	Dry mouth	100%	
17	Energy levels	100%	
18	Fatigue/tiredness	100%	
22	Hearing	100%	
24	Indigestion	100%	
28	Mobility	100%	
30	Mouth opening	100%	
31	Mucus	100%	
32	Nausea	100%	
33	Pain in head and neck	100%	
34	Pain elsewhere	100%	
39	Regurgitation	100%	
40	Salivation	100%	
43	Shoulder	100%	
44	Sleeping	100%	
45	Smell	100%	
46	Sore mouth	100%	
50	Swallowing	100%	
51	Swelling	100%	
52	Taste	100%	
54	Vomiting/sickness	100%	
55	Weight	100%	
B	Social care/ Social well-being		
9	Carer	100%	
14	Dependents/children	100%	
21	Financial/ benefits	100%	
23	Home care/district nurse	100%	
26	Lifestyle issues	100%	
36	Recreation	100%	
38	Relationships	90%	10%
47	Speech/voice/being understood	70%	30%
49	Support for my family	100%	

	PCI item	A	D
C	Psychological/ Emotional/ Spirituality well-being		
4	Appearance	70%	30%
2	Angry	100%	
3	Anxiety	100%	
11	Coping	100%	
15	Depression	100%	
19	Fear of the cancer coming back	100%	
20	Fear of adverse events	100%	
25	Intimacy	100%	
27	Memory	100%	
29	Mood	100%	
41	Self-esteem	100%	
42	Sexuality	100%	
48	Spiritual/religious aspects	100%	
53	Temperament and personality	100%	
D	Treatment-related		
8	Cancer treatment	100%	
37	Regret about treatment	100%	
35	PEG tube	80%	20%
56	Wound healing	100%	
E	Others		
57	Anything else	100%	

6.4.2. Application of domain

The 674 patients analysed had a mean age of 64 years (SD, 11) and 67% (449/674) were male. Primary diagnosis was made between 1 August 2007 and 31 December 2011 (median, May 2007; IQR, October 2004 to December 2008) and was SCC for 91% (616). Tumour site was oral cavity for 50% (340/674), pharyngeal for 25% (170/674), laryngeal for 17% (115/674), other HNC locations for 6% (40/674), unknown for 1% (9/674). Cancer TN-stage was advanced T3-4 for 25% (164/647), and N-positive for 28% (180/652). Primary treatment was surgery alone for 50% (335/674), surgery with adjuvant RT for 33% (225/674), (chemo)RT alone for 14% (96/674), and unknown for 3% (18/674). Of those treated with surgery, 42% (237/560) had free-flaps (179 soft tissue, 58 composite). The median time from primary surgery (or from primary diagnosis if no surgery) to first completion of the HN-PCI was 32 (IQR, 14-58) months, n=660. Most (70%, 472) completed the HN-PCI only once at a median (IQR) 39 (range, 20-69) months. Just under one-third (30%, 202) completed it more than once.

For those 674 completing the HN-PCI for the first time, 81% selected items in the Physical and Functional well-being domain, 30% in the Social care/Social well-being domain, 58% in the Psychological and Emotional well-being/Spiritual domain and 15% in the Treatment-related domain (**Table 6.5**). 'Other' items raised by patients were relative rare at 4%. On subsequent HN-PCI completions, more patients chose not to select items, evident for all domains and reflected through to both the number of domains and domain combinations selected. Specifically, on first HN-PCI, 11% did not select any HN-PCI item and on subsequent HN-PCI completions this had doubled to 23%.

Relationships between domain selection and patient/clinical characteristics were investigated for 674 patients completing the HNC-PCI for the first time (**Table 6.6**). Younger patients (<65 years) were more likely to select items within the Psychological and Emotional well-being/Spiritual domain (66% versus 48% for 65+ years), and also items in the Social care/Social well-being domain (36% versus 24% for 65+ years). Of borderline statistical significance was that more women than men (64% versus 55%) chose items in the Psychological and

Emotional well-being/Spiritual domain. Patients having surgery alone as primary treatment were less likely to select within the Physical and Functional well-being domain (74%) than patients having surgery-RT combination (89%) or (chemo)RT alone (86%). Patients with surgery-RT combination were also more likely (39%) to select within the Social care/Social well-being domain than other patients. More patients with laryngeal tumours selected within the Social care/Social well-being domain. There were no notable patterns of association seen with other clinicopathological parameters with domains.

Table 6.5. HN-PCI item response grouped by domain

	Items chosen	First PCI (674 patients)	Subsequent PCI (602 PCI from 202 patients)
Domain A: Physical and functional well-being	0	19% (128)	30% (181)
	1	18% (122)	17% (104)
	2	14% (92)	15% (88)
	3-4	21% (139)	17% (105)
	5-9	23% (153)	18% (106)
	10 or more	6% (40)	3% (18)
Domain B: Social care / Social well-being	0	70% (470)	80% (480)
	1	23% (156)	15% (92)
	2 or more	7% (48)	5% (30)
Domain C: Psychological/Emotional/Spirituality well-being	0	42% (286)	57% (343)
	1	29% (197)	22% (133)
	2-3	20% (132)	13% (81)
	4 or more	9% (59)	7% (45)
Domain D: Treatment related	0	85% (573)	93% (557)
	1	13% (85)	7% (40)
	2 or more	2% (16)	<1% (5)
NUMBER OF DOMAINS SELECTED	None	11% (76)	23% (140)
	One	26% (177)	32% (191)
	Two	35% (236)	28% (170)
	Three	22% (150)	15% (88)
	ALL Four	5% (35)	2% (13)
MAIN DOMAIN COMBINATIONS SELECTED	None	11% (76)	23% (140)
	A only	20% (137)	26% (155)
	A&C only	26% (172)	21% (125)
	A&B&C only	17% (115)	11% (68)
	Other combinations	26% (174)	19% (114)

Table 6.6: HN-PCI domains selected on first use of HNC-PCI (N=674), by patient characteristics

Items chosen		Patients	Domain A: Physical and functional well-being	P value	Domain B: Social care / Social well-being	P value	Domain C: Psychological/Emotional/Spirituality well-being	P value	Domain D: Treatment related	P value
ALL PATIENTS		674	81% (546)		30% (204)		58% (388)		15% (101)	
Gender	Male	449	82% (370)	0.21	31% (139)	0.60	55% (245)	0.03	16% (71)	0.43
	Female	225	78% (176)		29% (65)		64% (143)		13% (30)	
Age in years	<55	129	82% (106)	0.40	35% (45)	0.007	60% (78)	<0.001	18% (23)	0.06
	55-64	242	84% (203)		36% (87)		69% (166)		19% (45)	
	65-74	209	78% (163)		22% (46)		49% (103)		11% (22)	
	75+	94	79% (74)		28% (26)		44% (41)		12% (11)	
Primary treatment	Surgery & RT	225	89% (201)	<0.001	39% (87)	0.005	58% (130)	0.83	15% (34)	0.52
	Surgery alone	335	74% (249)		26% (87)		56% (188)		14% (47)	
	Chemo/RT alone	96	86% (83)		28% (27)		59% (57)		19% (18)	
Free-flap (if surgery)	No free-flap	312	79% (245)	0.27	30% (94)	0.65	59% (183)	0.69	14% (44)	0.60
	Soft	179	84% (151)		32% (57)		55% (98)		17% (30)	
	Composite	58	83% (48)		36% (21)		59% (34)		12% (7)	
Months from surgery (or diagnosis if no surgery)	Within 12 months	149	81% (121)	0.83	32% (48)	0.57	59% (88)	0.02	21% (31)	0.13
	12-23 months	124	83% (103)		34% (42)		69% (85)		15% (19)	
	24-59 months	230	79% (182)		30% (68)		54% (124)		13% (29)	
	60+ months	157	82% (128)		27% (42)		51% (80)		13% (20)	
Diagnosis	SCC	616	81% (502)	0.35	31% (190)	0.53	57% (351)	0.55	16% (97)	0.22
	Other	50	76% (38)		26% (13)		62% (31)		8% (4)	
Tstage	Tis, T1	256	78% (200)	0.06	30% (77)	0.35	57% (147)	0.20	15% (39)	0.97
	T2	227	81% (183)		27% (62)		54% (122)		15% (34)	
	T3, T4	164	87% (143)		34% (56)		63% (103)		16% (26)	
Nstage	N0	472	79% (375)	0.19	31% (145)	0.67	57% (269)	0.97	14% (65)	0.04
	N1	70	84% (59)		30% (21)		57% (40)		11% (8)	
	N2-3	110	86% (95)		26% (29)		58% (64)		23% (25)	
Tumour location	Oral	340	79% (268)	0.20	32% (109)	0.002	55% (187)	0.43	14% (47)	0.73
	Pharyngeal	170	86% (147)		21% (36)		59% (101)		18% (30)	

	Laryngeal	115	79% (91)		42% (48)		57% (66)		15% (17)	
	Other H&N	40	83% (33)		25% (10)		68% (27)		15% (6)	

Items chosen		Patients	Domain A: Physical and functional well-being	P value	Domain B: Social care / Social well-being	P value	Domain C: Psychological/Emotional/Spirituality well-being	P value	Domain D: Treatment related	P value
UWQOL Physical function subscale score	<50	78	95% (74)	<0.001	45% (35)	<0.001	67% (52)	0.006	32% (25)	<0.001
	50-74	230	89% (205)		35% (81)		62% (143)		13% (31)	
	75-89	141	86% (121)		27% (38)		60% (84)		13% (18)	
	90-100	204	65% (132)		21% (43)		48% (98)		11% (23)	
UWQOL Social-emotional subscale score	<50	68	97% (66)	<0.001	50% (34)	<0.001	81% (55)	<0.001	29% (20)	0.001
	50-74	205	93% (190)		39% (79)		67% (137)		17% (35)	
	75-89	199	83% (165)		26% (52)		57% (114)		13% (25)	
	90-100	182	62% (112)		18% (32)		39% (71)		9% (17)	
UWQOL overall QOL	Outstanding/V Good	243	71% (173)	<0.001	21% (52)	<0.001	44% (107)	<0.001	12% (28)	0.001
	Good	224	83% (186)		29% (65)		59% (133)		15% (33)	
	Fair	131	95% (124)		40% (52)		73% (95)		15% (19)	
	Poor/V Poor	47	96% (45)		51% (24)		77% (36)		34% (16)	
UWQOL ‘problem’ as identified from UWQOL algorithm*	Pain	115	97% (111)	<0.001	39% (45)	0.03	75% (86)	<0.001	23% (27)	0.006
	Appearance	65	92% (60)	0.02	48% (31)	0.002	85% (55)	<0.001	28% (18)	0.005
	Activity	87	93% (81)	0.003	47% (41)	<0.001	64% (56)	0.20	29% (25)	<0.001
	Recreation	49	94% (46)	0.02	49% (24)	0.005	76% (37)	0.01	24% (12)	0.06
	Swallowing	88	92% (81)	0.005	41% (36)	0.02	58% (51)	0.99	28% (25)	<0.001
	Chewing	55	91% (50)	0.07	40% (22)	0.13	62% (34)	0.57	40% (22)	<0.001
	Speech	41	95% (39)	0.02	63% (26)	<0.001	73% (30)	0.05	32% (13)	0.005
	Shoulder	65	97% (63)	<0.001	40% (26)	0.09	69% (45)	0.05	28% (18)	0.005
	Taste	74	93% (69)	0.004	34% (25)	0.50	62% (46)	0.45	26% (19)	0.009
	Saliva	138	93% (129)	<0.001	26% (36)	0.34	64% (89)	0.07	20% (28)	0.06
	Mood	87	97% (84)	<0.001	53% (46)	<0.001	87% (76)	<0.001	20% (17)	0.20
	Anxiety	88	93% (82)	0.002	44% (39)	0.003	81% (71)	<0.001	22% (19)	0.07

P values: Fishers exact or chi-squared test as appropriate * Significant problem trigger criteria (see Table 5.1) Results for those not triggered by the algorithm are not shown in the above table.

6.5. Discussion

Development of the HN-PCI checklist involved a combination of item generation from the medical literature of various HRQOL items, and item selection for the checklist based on discussions with various patient and professional bodies [**Rogers et al, 2009A**]. Because the HN-PCI was designed as a prompt for disclosing concerns, psychometric development of the tool was not undertaken as it was not required. Furthermore, as a new concept, the theoretical framework underlying the PCI was evolving. Therefore, the urgency of identifying appropriate categories or domains for the HN-PCI was not immediate at the time of its inception.

Subgrouping items within distinct domains can help researchers use domains as a way of exploring the inter-relationships of domains and ultimately construct an overall picture to explain a phenomenon or answer a research question [**Atkinson & Abu el-Haj, 1996**]. While primarily a prompt sheet, the HN-PCI is designed to be holistic and when combined with other psychometric PROs, can inform clinicians as a screening tool for levels of distress [**Ghazali et al, 2017**], and HRQOL status [**Rogers et al, 2002; 2009B; 2010**]. Further understanding of the PCI concept, particularly with the HN-PCI, in a wider cancer survivorship setting will benefit from having similar domains that reflect the holistic nature of the HN-PCI.

Hatta et al [2014] attempted to generate domains for the HN-PCI they have modified to meet with cross-cultural differences for use in feasibility study in a multiethnic cohort in Malaysia. The modification includes the combination of related HN-PCI items into a single item (e.g. Fatigue/Tiredness and Energy levels) and the introduction of two new items relating to dietary (i.e. ‘Health supplements’ and ‘Diet restrictions’). There were 7 domains suggested i.e. physical status, emotional status, personal function, social/family relationships, economic status, diet-related function, and others. Categorisation of items into seven main domains allowed for descriptive analyses intended in their study. However, the process and rigour of generating the domains was not detailed in their paper.

Five HN-PCI domains were generated from this exercise. The ‘Physical and Functional well-being’ dimension consisted of items covering activity (of daily living), physical symptoms (including pain) and functional impairment. The ‘Social care/Social well-being’ domain involved areas relating to practical support where help may be needed, access to medical support and care, financial security (including occupation), involvement of family and friends, lifestyle choices, interactions in social settings i.e. recreational or social groups. The ‘Psychological and Emotional well-being/Spiritual’ domain assessed issues relating to psychological adjustments, feelings toward diagnosis/treatment, the influence of diagnosis/treatment on personality and sexual relationships, and religious/spiritual fulfillment. Two additional domains were created to account for items that were deemed ‘Treatment-related’ and a single item domain of ‘Others’ to account for any potential items that have not been considered, such as Informational needs. The domains generated fulfilled the national recommendations for holistic assessment tools by having items that assess domains of physical, social and occupational, psychological and spiritual well-being [**Richardson et al, 2007**].

Arguably, the generated HN-PCI domains may be considered a reflection of the healthcare professional’s opinion on how individual patient concerns may be addressed, which is framed in reference to the potential services on offer. Individual difference in interpretation of a concern by professionals regarding an item may have also been complicated by the complex nature of the disease and treatment-related changes related to HNC. This may have posed a challenge during the process of achieving consensus, e.g., ‘Appearance’ could relate to concerns about physical and function, or the psychological distress experienced with disfigurement, or the impact of facial appearance on social well-being and/or reflecting patient interest in further treatment. Any disagreement between participants have had was addressed by the Delphi process used in this study. The process was augmented by enabling each participant to provide their view’s impersonally through the post, and its reliability was increased by a reasonable sized expert panel, and with repeated rounds [**Fink et al, 1984**].

In this study, the highest frequency of concerns was encountered within the

Physical and Functional wellbeing (81%), followed by the Psychological and Emotional wellbeing/Spiritual (53%) and Social care/social wellbeing (30%) domains. An overall reduction in the number of items selected across all domains was observed longitudinally. The results are valuable data for comparison with the forthcoming results of the main study.

Treatment modality is associated with concerns within the Physical and Functional domain. Recognised RT-related complications may account for the less likelihood of surgery only patients in highlighting concerns within this domain. Younger patients (<65years) were more likely to voice concerns in Psychological and Emotional well-being/Spiritual, and Social care/Social well-being domains. This may have significant implications in supportive care planning considering the rising oropharyngeal cancer incidence in younger populations [**Mourad et al, 2017**]. The direct impact of laryngeal disease and treatment on voice/speech, communication, swallowing and breathing may explain the higher number of expressed concerns under the Social care/Social well-being domain.

This study suggests a clear association between poor HRQOL outcomes with perceived needs/concerns of long-term HNC survivors in remission (median FU, 34 months; IQR, 14-58). HNC patients more likely to select HN-PCI items for discussion during consultation were those who reported poor overall QOL, poor UWQOL Physical function and Socio-emotional function outcomes, and those screened as having significant problems on UWQOL. This finding indicates that concerns, based on their disclosure via HN-PCI, are related to HRQOL status in HNC patients. The clustering pattern of certain perceived needs and their association with HRQOL outcomes can help healthcare professionals identify at-risk patients who may benefit from tailored supportive care to improve HRQOL outcomes.

One study limitation relates to the Delphi methodology. Firstly, selection of the expert panel did not include patients, and therefore, their input, as users of the tool, were not considered. Secondly, a universally agreed proportion of the level of agreement for consensus does not exist for the Delphi, as the range of reported values are between 51-80% [**Hasson et al, 2000**]. The proportion of level of agreement for consensus used in this study was 70%, which is based on previous recommendation [**Sumsion, 1998**]. While **Green et al [1999]** suggested 80%, the decision to set to the level of 70% for this study was achieved on balance by considering the study characteristics i.e. sample numbers, the aim of the work and resources available. Another limitation to this study relates to the inherent variability in the individual interpretation of the items on the checklist, which may introduce bias in this work, while at the clinical level, miscommunication could occur. There may be some merit in providing additional information to guide HN-PCI users on what each item refers to. Without a standardized definition for guidance, a certain amount of ambiguity may exist at the pre-consultation stage. However, any vagueness could be cleared up during consultation as the HN-PCI itself can facilitate patient-doctor communication [**Rogers et al, 2009**].

Examination of the association between HN-PCI with HRQOL status is limited by a cross-sectional design. A baseline level of perceived need at diagnosis or in the immediate post-treatment was unavailable for comparison. A glimpse of possible changing trend of needs over time is offered because the vast majority (70%) completed the HNC-PCI only once. In addition, other reported factors that can influence perceived need, including comorbidity, psychological state, education level, socioeconomic status, may also be considered in future prospective studies.

6.6. Conclusions

HN-PCI item categorisation into 5 domains can help summarise future HN-PCI data in a way that may present and help understand trends better. This study found that certain clinical-pathological factors are associated with the presentation of perceived needs/concerns in specific domains. Close associations between HNC-PCI domains with HRQOL outcomes were observed. Further work may help clarify some of the emerging trends identified and evaluate the potential for HN-PCI as a routine screening tool for HRQOL status.

<u>*Chapter 7:*</u>

7.0. MAIN STUDY

This chapter contains the work relating to the Main study. The chapter is considered under the following sections: Study Aims and Objectives, Study Hypothesis, Methodology, Results and Discussion.

7.1. Study aims

7.1.1. The primary aim of this study was to evaluate the HN-PCI as a tool for identifying patient concerns during routine outpatient consultations in a cohort of subjects unfamiliar with the tool.

7.1.2. The secondary aims of this study were:

a. Describe the characteristics of a 'normal' consultation visit i.e. when HN-PCI was not used routinely, to provide baseline values before introduction of the HN-PCI.

The characteristics evaluated were the distress levels, HRQOL scores, the concerns discussed during consultation, length of consultation, level of patient satisfaction and the clinic output.

b. Evaluate the impact of HN-PCI intervention on clinical outcomes routine HNC visits.

Compare 'Control' group with HN-PCI intervention groups to evaluate consultation length, clinic output and patient satisfaction.

c. Examine the relationship between patients' concerns with cancer-related distress.

Cancer-related distress is defined as an "*unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment*" [**NCCN, 2010**].

d. Examine the associations between clinicopathological factors and patients' concerns.

e. Explore the impact of HN-PCI intervention on patient-doctor encounter.

Compare the self-reported concerns against the concerns discussed during the consultation in the HN-PCI intervention groups.

7.2. Study hypothesis

The study hypotheses are:

7.2.1. The HN-PCI can help identify patients' concerns in cohorts unfamiliar with the instrument;

7.2.2. The HN-PCI intervention will raise more items and/or a broader range of concerns:

    7.2.2.1. The HN-PCI intervention will increase the number of concerns discussed during consultations;

    7.2.2.2. The HN-PCI intervention will increase the type of concerns discussed during consultations;

7.2.3. The HN-PCI will result in more congruence between self-reported concerns and those discussed during consultation;

7.2.4. The HN-PCI intervention will change the characteristics of consultations:

    7.2.4.1. Consultations will lengthen

    7.2.4.2. Clinical outputs will increase in number

    7.2.4.3. Patients will be more satisfied with consultations

7.2.5. Patients' concerns are related to distress

7.2.6. Patients’ concerns are not related to clinicopathological factors

7.3. Study methodology

7.3.1. Patient-reported outcome measures

The PROs used in the main study are the HN-PCI (version 3), UWQOL DT, PSQ-MD and PROC. These have been discussed in section 4.7. Administration of the PROs to patients depends on the Main study design (**section 7.2.2**).

7.3.2. Main Study Design

A prospective, non-randomised study design was used. The study was set up into three individual study blocks organised sequentially (Appendix 12).

(a) Block 1 (Control group): Block 1 represents ‘normal’ practice, where patients are not asked to complete the HN-PCI before their consultation.

(b) Block 2 (Control in attention group): In Block 2, patients were asked to complete the HN-PCI at the pre-consultation stage but the HN-PCI questionnaire was withheld from clinicians during consultation.

(c) Block 3 (Intervention group): In Block 3, patients were asked to complete the PCI at the pre-consultation stage and the HN-PCI questionnaire was passed on to the clinicians before the patient entered the consultation room and was made available for use during the consultation.

Recruitment continued until the target recruitment number was achieved and study recruitment closed. Patient recruitment into the study blocks followed the order of the date of their clinic attendance. The study commenced with recruitment into Block 1. Recruitment to each block continued until the target recruitment number was achieved based on proposed sample size (**section 7.3.4.),** whereby the succeeding block commenced.

All recruited patients completed the DT and UWQOL before they entered the clinic consultation. The intervention with the HN-PCI was completed in the second and final blocks. All questionnaires were administered in a paper format.

7.3.3. Study Participants

Study participants comprised of surgeons and patients.

Surgeons: A convenience sample of four consultant HNC surgeons without prior experience of using the HN-PCI i.e. two Oral & Maxillofacial (OMF) surgeons and two Otolaryngology, Head and Neck (ENT) surgeons, were invited to participate in this study. All participating surgeons were given a Microsoft Power Point demonstration covering the study protocol and how the HN-PCI is used before the start of the study.

Patients: Patient recruitment was based on the inclusion and exclusion criteria. The inclusion criteria were (1) diagnosis of HNC; (2) disease-free survivors who have completed primary treatment of at least 6 weeks; and (3) have never used the HN-PCI before. The exclusion criteria were (1) pre-treatment HNC; (2) HNC patients with palliative status; and (3) non-HNC diagnosis.

Details regarding patient sample size calculation and recruitment are explained in the sections **7.3.4 and 7.3.5**, respectively.

7.3.4. Study Sample Size Calculation

Statistical power analysis was performed *a priori* to ensure an adequate estimated study number recruitment capable of detecting a significant effect while reducing both types I and II errors. Previously published results in a similar study population [**Rogers et al, 2009**] indicated that the items raised on the HN-PCI at pre-consultation can vary considerably up to about 40% (range, 5-25%). It was not known how many of these would be discussed during the consultation.

Initial sample size calculations indicated 400 per block to detect a clinically significant impact based on percentages between groups with 80% power and 5% significance level (α). Typically this number would allow differences in outcome such as 30% versus 40%, 20% versus 29%, 15%versus 23%, 10% versus 17% and 5% versus 11% to be detected at $p<0.05$ with 80% power should they exist. Numerical data comparisons generally require fewer numbers and so would be guaranteed by the same sample size calculations.

The study sample size has to balance recruitment of adequate patient numbers to detect moderately sized differences should they exist with the logistics of completing the study in a reasonable time scale and 200 per block was chosen as the pragmatic compromise. For 200 per group, the power to detect such differences in outcome as those specified here would have been about 50%. For 108 per group (the 'reality') the power was about 30%.

7.3.5. Study Recruitment

The study was conducted in 1 February 2011 to 9 January 2013 the HNC outpatient clinics of two NHS Hospitals Trusts run by two OMF surgeons at the University Hospital Aintree, Liverpool, and two ENT surgeons at the Whiston hospital, St Helens. The study opened once research ethics approval was obtained from the North West Research ethics committee (study reference: 11/H1002/7; Appendix 5).

Potential patients were identified from the outpatient clinic patient list of each participating consultant. Eligible patients were identified based on the inclusion and exclusion criteria in the study protocol (**section 7.2.3**). All eligible patients were sent the study patient information sheet (Appendix 6) together with their clinic appointment letter 6 weeks before the appointment date. On the day of appointment, once the patient has been booked into the clinic, eligible patients were approached in the waiting area. Patients were asked if they received both the letter of invitation to the study as well as the patient information sheet (Appendix 6). Upon acknowledgement of receipt of both documents, patients were asked if they wished to participate in the study. Patients who expressed their wish to participate were invited to a private room, and the process of obtaining formal informed consent was undertaken using the study consent form (Appendix 7) before data was collected. Patients who declined to participate were recorded.

7.3.6. Recording of Clinic Consultations

The method used in the Main study was established in the Pilot study (section A Tascam DR-100 (TEAC UK Ltd., Watford, UK) recorder was used to record each consultation in MP3 format. The interview was recorded by the doctor from the start of consultation, defined as the moment patient entered the consultation room, until the end of the consultation, defined as the moment the patient left the room. All patient and doctor identifiable information was removed to maintain confidentiality. Only recordings of complete consultations were used and transcribed.

7.3.7. Patient-reported Outcomes of Consultation (PROC)

At the end of the consultation, patients were given FU survey questionnaires by the researcher (NG) consisting of the DT, PSQ-MD and a non-validated questionnaire (**section 4.7.5**) together with a stamped return-addressed envelope for completion at home. Patients were instructed to complete the questionnaires and return them within 1 week following their consultation. Patients were contacted by a postcard reminder and latterly by a telephone call reminder, if the FU survey forms were not received at 2- and 4-weeks respectively, following consultation.

7.4. Data Collection

7.4.1. Clinical data

Relevant clinical data were obtained from the Liverpool HNC database and patient hospital records. The data collected include demographic data (age, gender), definitive diagnosis, tumour characteristics (primary site, T-stage, N-stage, overall TNM stage) and treatment details (type of surgery and surgical date; radiotherapy (dosimetry, addition of chemotherapy).

The data were collected in a database using the Microsoft Office Excel software (version 2007) i.e. Main study database. The data were exported into SPSS, and analysed in SPSS v19.

7.4.2. Data from audiorecordings of consultations

All audiotaped consultations were transcribed word-for-word by medical secretaries at Aintree University Hospital. Each transcription was evaluated for accuracy by the researcher (NG). The transcribed audiotaped consultations were content analysed using a thematic coding framework using the method established in the Pilot study (**Chapter 5**).

7.4.3. Data from PROs

All the data obtained from the PROs used in the Main study were input into the Main study database described previously (**section 7.4.1**).

7.5. Study Outcome Measures

The variables chosen for outcome measures selected were based on standard outcome measures used for prompt sheet interventions previously established in the literature [**Parker et al, 2005; Rogers et al, 2009A**].

7.5.1. Primary outcome measure

a. Number and category of items of concerns

7.5.2. Secondary outcome measures

a. Number of professionals requested
b. Patient satisfaction with consultation (discussed in **section 5.3.6**)
c. Length of consultation (discussed in **section 5.3.5**)
d. Distress levels (discussed in **section 4.7.3**)
e. Clinical output (discussed in **section 5.3.5**)

7.6. Statistical Analysis

7.6.1. Main statistical analysis

Summary statistics of the quantitative and categorical data of each block were computed. These include the number of items discussed, satisfaction scores, distress levels, types of items discussed and types of clinical decision made and referral practices.

7.6.2. Hypothesis testing

Comparative analysis between the study blocks was performed to test the null hypothesis ($\boldsymbol{H_0}$) i.e. there is no difference between the blocks (Block 1 versus Block 2 versus Block 3) in what is being measured, in a two-tailed test with a significance level set at 5% (***P***-value <0.05).

For numerical data, e.g. length of consultation, distress level, number items of concern discussed, number of healthcare professionals selected and number of clinical decisions made, the Kruskal-Wallis test (between 3 blocks) or the Mann-Whitney test (between 2 blocks) was used. For categorical data, e.g. types of items discussed, types of clinical decision made, the chi-squared test (3 blocks) or Fisher's exact test (2 blocks) was used.

To examine the relationship between significant distress and other variables, Fishers Exact test, the chi-squared test or Mann-Whitney analysis were applied as appropriate.

Comparative analysis was also undertaken to determine if the HN-PCI influenced the content of consultations by measuring the level of agreement between what items the patient selected on the HN-PCI and what was actually discussed during clinic consultations. The Kappa coefficient of agreement was calculated and the interpretation of Kappa used is shown in **Table 7.1**.

Table 7.1. Interpretation of kappa values [Oxford handbook of medical statistics]

Value of Kappa	**Strength of agreement**
<0.00	Poor (worse than chance)
0.00-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very good

In addition, McNemar test was undertaken to evaluate the shift of proportions of items selected by patients on HN-PCI against the proportion of items discussed.

7.6.4. Subgroup analysis of the intervention group

These are secondary analyses to identify if any patient features stratified by HRQOL, primary site, clinicopathological stage, sociodemographic, treatment or specialty may associate with the study outcome measures in the intervention block. For numerical outcomes the Mann Whitney or Kruskal-Wallis test was used. For categorical outcomes, the Fisher's exact test or chi-squared test was used.

Multiple statistical testing was undertaken in the main study and the subgroup section. Due to the number of tests performed, the statistical significance was regarded as $p<0.01$. It is recognised that in smaller samples, clinically significant differences may not be statistically significant. Therefore, interpretation of these tests was taken on balance between what is observed from descriptive data and how likely any differences seen or something more extreme could have occurred if the assumptions underlying the Null hypothesis were true.

7.7. Study Reliability

The reliability of the data obtained in the main study was assured by the use of standardized validated tools for comparison, rigorous sample recruitment, and the method of data collection was developed and tested during the pilot work, where inter-rater agreements are reported.

7.8 Results

7.8.1. Overview of Results

The main study opened for recruitment on 15 June 2011 and closed on 9 January 2013 (Block 1 recruitment: 15 June 2011 to 23 Nov 2011; Block 2 recruitment: 23 Nov 2011 to 25 April 2012; and Block 3 recruitment: 25 April 2012 to 9 January 2013).

A total of 261 patients were recruited to the study across the 3 study blocks, which generated 346 consultations. 61 patients appeared more than once during the entire study, either in the same block or across different blocks due to the nature of regular repeat attendances to the follow-up clinic.

According to protocol any between block duplication was acceptable but any within block duplication was not as it undermines the assumption of independence of the unit of analysis within block. Therefore, for subsequent analyses if there was within block duplication then only the first consultation was included. Thus, there were 261 patients (325 consultations) recruited in all.

In Block 1, from 182 eligible patients, 136 patients (74.7%) were recruited, resulting in 136 consultations. In Block 2, from 110 eligible patients, 78 patients (70.9.%) were recruited, resulting in 78 consultations. In Block 3, from 155 patients, 111 patients (71.6%) were recruited, resulting in 111 consultations.

7.8.2. Baseline data

7.8.2.1. Baseline clinical characteristics

The baseline clinical characteristics of study participants across the 3 Blocks are shown in **Table 7.2**. No significant differences were seen between blocks regarding the clinical characteristics of participants, indicating that the three

Blocks are reasonably comparable groups. The distribution of patients seen by the respective surgeons is shown in **Table 7.3.**

Table 7.2. Baseline characteristics

		Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)	P value*
Sex	Male	69% (94)	68% (53)	66% (73)	0.76
	Female	29% (40)	31% (24)	34% (38)	
	Not known	2% (2)	1% (1)	-	
Age	Mean (SD)	62.1 (13.8)	64.5 (11.4)	65.0 (11.1)	0.36
	Median (IQR)	63 (54-71)	64 (58-73)	65 (59-73)	
	<55	27% (37)	15% (12)	14% (15)	0.13
	55-64	25% (34)	36% (28)	35% (39)	
	65-74	32% (44)	31% (24)	33% (37)	
	75+	14% (19)	15% (12)	16% (18)	
	Not known	2% (2)	3% (2)	2% (2)	
Specialty	OMF	50% (68)	65% (50)	50% (55)	0.07
	ENT	50% (68)	35% (27)	50% (56)	
	Not known	-	1% (1)	-	
Tumour site	Oral	34% (46)	46% (36)	33% (37)	0.47
	Oro-pharyngeal	21% (29)	19% (15)	22% (24)	
	Laryngeal	18% (24)	17% (13)	23% (25)	
	Other	27% (37)	18% (14)	23% (25)	
Histology	SCC	85% (116)	86% (67)	84% (93)	0.83
	Not SCC	15% (20)	13% (10)	16% (18)	
	Not known	-	1% (1)	-	
Overall P stage	1	30% (41)	28% (22)	31% (34)	0.96
	2	19% (26)	19% (15)	17% (19)	
	3	10% (13)	8% (6)	13% (14)	
	4	29% (39)	31% (24)	29% (32)	
	Not known	13% (17)	14% (11)	11% (12)	
Primary Treatment	Surgery only	44% (60)	54% (42)	41% (45)	0.47
	Surgery + RT/CRT	39% (53)	33% (26)	41% (46)	
	RT/CRT only	14% (19)	10% (8)	15% (17)	
	Not known	3% (4)	3% (2)	3% (3)	
Free-flap	No surgery	14% (19)	10% (8)	15% (17)	0.36
	Surgery without FF	58% (79)	56% (44)	62% (69)	
	Surgery with FF	25% (34)	31% (24)	18% (20)	
	Not known	3% (4)	3% (2)	5% (5)	
Years from Primary diagnosis to consultation	Median (IQR)	2.2 (0.9-3.8	2.4 (1.2-3.8)	2.3 (1.3-3.7)	0.64
	< 1 year	27% (37)	21% (16)	17% (19)	0.35
	1.0-2.9 years	35% (47)	40% (31)	44% (49)	
	≥ 3 years	37% (50)	38% (30)	38% (42)	
	Not known	2% (2)	1% (1)	1% (1)	

*chi-squared comparing blocks for categorical data after excluding the not known category; Kruskal-Wallis test comparing blocks for age in years and for years from primary diagnosis to study consultation.

Abbreviation: OMF, oral & maxillofacial; ENT: otorhinolaryngology; SCC, squamous cell carcinoma; RT, radiotherapy; CRT, chemoradiotherapy, FF, free flap

Table 7.3. Distribution of patients according to the respective surgeons

Surgeon	Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)
A	34% (46)	42% (33)	23% (26)
B	16% (22)	22% (17)	26% (29)
C	24% (32)	10% (8)	22% (24)
D	26% (36)	23% (18)	29% (32)

7.8.2.2. Baseline Distress Thermometer (DT) scores

The levels of self-reported distress recorded at recruitment using the DT are shown in **Table 7.4.** The mean DT scores for Blocks 1, 2 and 3 were 2.7, 2.5 and 3.0, respectively, while the median (IQR) scores were 2 (0-5) for every Block. The proportion of patients reporting severe distress (DT scores, 6-10) in Blocks 1,2 and 3 were 18%, 18% and 20%, respective. Overall, the 3 groups were comparable (Kruskal-Wallis test of DT scores between blocks, P=0.58).

Table 7.4. Baseline Distress Thermometer scores

DT score	Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)
0 No distress	35% (48)	35% (27)	32% (35)
1	10% (13)	14% (11)	8% (9)
2	11% (15)	10% (8)	13% (14)
3	12% (16)	9% (7)	11% (12)
4	5% (7)	6% (5)	5% (6)
5	9% (12)	8% (6)	12% (13)
6	6% (8)	3% (2)	5% (5)
7	5% (7)	12% (9)	5% (6)
8	5% (7)	3% (2)	4% (4)
9	1% (1)	1% (1)	-
10 Extreme distress	2% (2)	-	6% (7)
Mean	2.7	2.5	3.0
Median (IQR)	2 (0-5)	2 (0-5)	2 (0-5)
% ≥ 4	32% (44)	32% (25)	37% (41) p,0.70
% ≥ 6	18% (25)	18% (14)	20% (22)

7.8.2.3. Baseline University of Washington Quality of Life (UWQOL) scores

The baseline UWQOL data recorded at recruitment are shown in **Tables 7.5-7.7**. Overall, there were no significant statistical differences seen in UWQOL data between Blocks. UWQOL status was comparable between study blocks.

Table 7.5 shows the individual scores, composite subscores and QOL scores, which were similar between blocks.

Table 7.6 shows the section of issues that were important to patients in the last 7 days. **Table 7.7** shows the range of ‘significant problem’ based on the UWQOL algorithm. In both **Tables 7.7 and 7.8,** there were few differences between blocks.

Table 7.5. Baseline UWQOL showing the scores, composite subscores and QOL scores

	Block 1 (n=136)		Block 2 (N=78)		Block 3 (n=111)		
	Mean	SE of Mean	Mean	SE of Mean	Mean	SE of Mean	P value*
Physical function subscale score	76.3	1.7	77.3	2.2	76.4	1.9	0.95
Appearance	79.2	1.9	80.8	2.5	81.8	1.9	0.74
Swallowing	80.1	1.9	84.7	2.3	81.6	2.1	0.32
Chewing	73.2	2.7	69.9	3.6	69.4	3.2	0.63
Speech	80.4	2.0	82.8	2.4	83.5	1.8	0.64
Taste	75.5	2.6	75.5	3.3	73.4	3.0	0.93
Saliva	69.1	3.0	69.9	3.9	68.8	3.3	0.96
Social - Emotional subscale score	75.8	1.6	79.6	1.8	74.9	1.7	0.22
Pain	77.6	2.3	79.5	2.6	77.7	2.2	0.88
Activity	71.5	2.1	76.9	2.5	68.5	2.2	0.06
Recreation	75.2	2.1	78.5	2.3	71.8	2.4	0.25
Shoulder	81.3	2.5	85.5	3.0	79.7	2.7	0.21
Mood	76.1	2.4	82.1	2.5	75.9	2.5	0.26
Anxiety	73.2	2.5	75.3	2.9	75.9	2.4	0.89
Compared to the month before you developed cancer, how would you rate your health-related quality of life?	56.1	2.4	56.7	2.8	60.1	2.9	0.55
In general, would you say your health-related quality of life during the past 7 days has been	61.3	2.0	62.3	2.2	59.3	1.8	0.48
Overall QOL during the past 7 days	64.4	2.1	62.1	2.3	61.8	1.8	0.47

*Kruskal-Wallis test of distribution of scores between blocks

		Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)	P value*
Physical function subscale score	Mean (SD)	76.3 (19.6)	77.3 (19.3)	76.4 (19.7)	0.95
	Median (IQR)	78 (63-95)	82 (65-95)	78 (63-95)	
	<50	8% (11)	6% (5)	10% (11)	
	50-59	9% (12)	8% (6)	14% (15)	
	60-69	18% (25)	24% (19)	7% (8)	
	70-79	15% (21)	9% (7)	21% (23)	
	80-89	18% (24)	19% (15)	11% (12)	
	90-100	32% (43)	33% (26)	38% (42)	
Social - Emotional subscale score	Mean (SD)	75.8 (19.2)	79.6 (16.2)	74.9 (17.9)	0.22
	Median (IQR)	80 (65-91)	83 (70-93)	78 (63-91)	
	<50	10% (14)	5% (4)	12% (13)	
	50-59	10% (14)	8% (6)	6% (7)	
	60-69	11% (15)	10% (8)	17% (19)	
	70-79	18% (24)	24% (19)	23% (25)	
	80-89	24% (32)	23% (18)	16% (18)	
	90-100	27% (37)	29% (23)	26% (29)	

*Kruskal-Wallis test of distribution of scores between blocks

Table 7.6: UWQOL selection of issues importance

	Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)	P value*
Appearance	13% (18)	8% (6)	11% (12)	0.46
Swallowing	28% (38)	18% (14)	26% (29)	0.25
Chewing	15% (21)	18% (14)	18% (20)	0.83
Speech	20% (27)	14% (11)	17% (19)	0.56
Taste	11% (15)	13% (10)	16% (18)	0.49
Saliva	29% (39)	38% (30)	26% (29)	0.19
Pain	22% (30)	17% (13)	16% (18)	0.44
Activity	10% (13)	5% (4)	11% (12)	0.38
Recreation	7% (9)	5% (4)	5% (5)	0.76
Shoulder	16% (22)	13% (10)	12% (13)	0.57
Mood	12% (16)	8% (6)	11% (12)	0.64
Anxiety	13% (18)	12% (9)	16% (18)	0.63
Count ZERO	17% (23)	26% (20)	16% (18)	0.22**
ONE	18% (24)	15% (12)	25% (28)	
TWO	18% (25)	24% (19)	16% (18)	
THREE	47% (64)	35% (27)	42% (47)	

*chi-squared comparing blocks; **Kruskal-Wallis comparing number of domains selected as important

Table 7.7: UWQOL algorithm ‘significant problem’

	Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)	P value*
Appearance	9% (12)	8% (6)	5% (5)	0.41
Swallowing	9% (12)	6% (5)	8% (9)	0.82
Chewing	7% (10)	8% (6)	11% (12)	0.60
Speech	8% (11)	6% 5)	5% (6)	0.70
Taste	10% (14)	10% (8)	14% (16)	0.55
Saliva	24% (32)	23% (18)	21% (23)	0.86
Pain	19% (26)	14% (11)	14% (15)	0.43
Activity	8% (11)	4% (3)	11% (12)	0.22
Recreation	9% (12)	5% (4)	10% (11)	0.48
Shoulder	11% (15)	9% (7)	9% (10)	0.83
Mood	16% (22)	6% (5)	13% (14)	0.12
Anxiety	18% (25)	17% (13)	17% (19)	0.94
Count ZERO	39% (53)	46% (36)	41% (46)	0.44**
ONE	25% (34)	26% (20)	23% (25)	
TWO	13% (18)	12% (9)	14% (16)	
THREE	10% (13)	8% (6)	9% (10)	
FOUR	9% (12)	5% (4)	8% (9)	
FIVE or more	4% (6)	4% (3)	5% (5)	

*chi-squared comparing blocks; **Kruskal-Wallis comparing number of significant problem domains

7.8.2.4. Baseline HN-PCI data

Based on the study design, baseline self-reported HN-PCI data were available only from Blocks 2 and 3. The numbers of items selected based on HN-PCI domains are shown in **Table 7.8**, while a detailed list of the items selected are shown in **Table 7.9** (items of concern) and **Table 7.10** (professionals).

When HN-PCI domains were considered, the most common items of concern reported fell into the Physical and functional well-being domain (i.e. Block 2, 69% and Block 3, 65%), followed by the Psychological/emotional and Spiritual well-being domain (i.e. Block 2, 37% and Block 3, 43%). When the number of HN-PCI items selected was considered, the mean and median (IQR) values in Block 2 were 3.15 and 2 (1-5) and in Block 3 were 3.79 and 2 (0-6), respectively. When the number of professionals selected was considered, the mean and median (IQR) values in Block 2 were 0.41 and 0 (0-1), and in Block 3 were 0.39 and 0 (0-1), respectively. In summary, the number of HN-PCI items chosen by patients (by domain and individual items) and the number of professional selected were comparable between blocks (Mann-Whitney, p >0.16).

In Block 2, the five most common items of concern selected were dry mouth (23%), FOR (21%), dental health/teeth (19%) chewing (18%) and mouth opening (17%). In Block 3 the five most common item of concern selected were FOR (31%), dry mouth (25%), fatigue/tiredness (22%), swallowing (21%) and pain in head and neck (16%). These accounted for the marginal differences seen in the individual items selected by patients between the two blocks, which were not statistically significant. The surgeon was the professional most selected by patients in both blocks.

Table 7.8: Number of HN-PCI items selected

	Block 2 (N=78)			**Block 3 (n=111)**			P value*
	%1 or more	Mean	Median (IQR)	%1 or more	Mean	Median (IQR)	
Physical and functional well-being	69% (54)	2.32	2 (0-3)	65% (72)	2.78	2 (0-5)	0.74
Treatment related	9% (7)	0.10	0 (0-0)	10% (11)	0.10	0 (0-0)	0.85
Social care and social well-being	8% (6)	0.10	0 (0-0)	14% (16)	0.16	0 (0-0)	0.16
Psychological emotional and spiritual well-being	37% (29)	0.63	0 (0-1)	43% (48)	0.75	0 (0-1)	0.53
Total number of HN-PCI items selected	82% (64)	3.15	2 (1-5)	75% (83)	3.79	2 (0-6)	0.72
Total number of HN-PCI health professionals selected	35% (27)	0.41	0 (0-1)	28% (31)	0.39	0 (0-1)	0.41

*Mann-Whitney test comparing Blocks 2 & 3 in the number of HN-PCI items selected.

Table 7.9: Selection of HN-PCI items

	Block 2 (N=78)	**Block 3 (n=111)**
Activity	4%	5%
Angry	3%	3%
Anxiety	5%	8%
Appearance	6%	5%
Appetite	1%	7%
Breathing	5%	4%
Bowel habit (diarrhoea or constipation)	5%	6%
Cancer treatment	3%	6%
Carer	-	-
Chewing/eating	18%	14%
Coping	-	-
Coughing	-	10%
Dental health/teeth	19%	13%
Dependents/children	-	-
Depression	4%	5%
Dry mouth	23%	25%
Energy levels	1%	8%
Fatigue/tiredness	14%	22%
Fear of the cancer coming back	21%	31%
Fear of adverse events	1%	4%
Financial / benefits	-	2%
Hearing	13%	9%
Home care/district nurse support	1%	-
Indigestion	1%	5%
Intimacy	4%	2%
Lifestyle issues (smoking/alcohol)	1%	1%
Memory	6%	8%
Mobility	3%	5%
Mood	6%	5%
Mouth opening	17%	11%
Mucus production	13%	10%
Nausea	-	1%
Pain in head and neck	13%	16%
Pain elsewhere	8%	8%
PEG tube	4%	2%
Recreation	-	-
Regret about treatment	1%	-
Regurgitation	1%	2%
Relationships	-	2%
Salivation	9%	12%
Self-esteem	3%	2%
Sexuality	3%	1%
Shoulder	6%	11%
Sleeping	6%	15%
Smell	1%	1%
Sore mouth	14%	12%
Speech/voice/being understood	8%	9%
Spiritual /religious aspects	-	1%
Support for my family	-	3%
Swallowing	13%	21%
Swelling	13%	6%
Taste	3%	11%
Temperament and personality	1%	2%
Vomiting/sickness	-	-
Weight	8%	10%
Wound healing	3%	2%
Anything else*	6%	4%

* Anything else (items of concern)

Block 2 (N=78)		Block 3 (n=111)	
Blood test results	1	Blank	2
Difficulties in blowing air	1	Depression	1
Issues about permanent non-peroral intake status	1	Itchy skin	1
Itchy skin, tingly lip	1	Total	4
Vision	1		
Total	5		

Table 7.10: Selection of professionals

	Block 2 (N=78)	Block 3 (n=111)
Chaplain	-	-
Clinical nurse specialist	-	4%
Dental hygienist	-	1%
Dentist	8%	4%
Dietician	1%	3%
Nursing staff	1%	-
Occupational therapist	-	-
Oral rehabilitation team	1%	-
Physiotherapist	4%	3%
Radiotherapist/oncologist	4%	2%
Speech and language therapist	3%	1%
Social worker	-	-
Surgeon	13%	14%
Family doctor	4%	6%
Clinical psychologist	1%	2%
Emotional support therapist	1%	1%
Financial advisor	-	-
Anyone else*	-	3%

* Anyone else (professionals)

Block 2 (N=78)	Block 3 (n=111)	
-	blank	1
	Pain team	1
	PEG nurse	1
	Total	3

7.8.3. Characteristics of clinic consultations

Evaluations of the clinic consultation were based on the recorded consultations at the time of the visit. Because of repeat visits to the outpatient clinics, duplications i.e. different recordings related to an individual patient at different attendances, could occur. When duplications occurred within each Block, these were not accepted for evaluation because inclusion of this data could undermine the assumption of independence of the unit of analysis within block. However, any duplication made at different time-points between blocks was included. Therefore, from a total of 261 patients recruited to this study, a total of 325 consultations (i.e. Block 1, 136 consultations; Block 2, 78 consultations and Block 3, 111 consultations) were expected.

7.8.3.1. Audiorecordings

When the study closed, a total of 262 audiorecordings were made from 325 consultations (84%), and the individual breakdown per Block is shown in **Table 7.11**.. 10% of audiotape recordings were unavailable in Block 3, 19% in Block 1 and 28% in Block 2. The differences were statistically significant (p=0.007). The reasons why audiorecording was unavailable are detailed in **Table 7.12**.

Table 7.11. Number of audiorecordings made in each study Block

	Block 1 (n=136)	**Block 2 (n=78)**	**Block 3 (n=111)**	**P value***
Audiotaped examined recording	81% (107)	72% (55)	90% (100)	0.007

*chi-squared test

Table 7.12. Reasons why audiorecording was not done or unavailable

	Block 1 (n=29/136)	**Block 2 (N=23/78)**	**Block 3 (n=11/111)**
Not known	1	2	2
Equipment error	2	4	0
Surgeon forgot to record	13	12	7
Patient left clinic before consultation	1	0	1
Recurrence, stop tape	0	0	1
Saw other doctor	12	5	0
Total	29	23	11

7.8.3.2. Length of consultation

The length of consultation was determined from the start and end time of the audiorecordings. Details of the length of consultation (seconds) according to Blocks are shown in **Table 7.13**.

The mean length of consultation in Blocks 1,2 and 3 was 354 seconds (5.9 minutes), 307 seconds (5.1 minutes) and 425 seconds (7.1 minutes). The distributions were not statistically significant, but the trend suggests that full implementation of the HN-PCI intervention had increased lengths of consultations (**Table 7.13**).

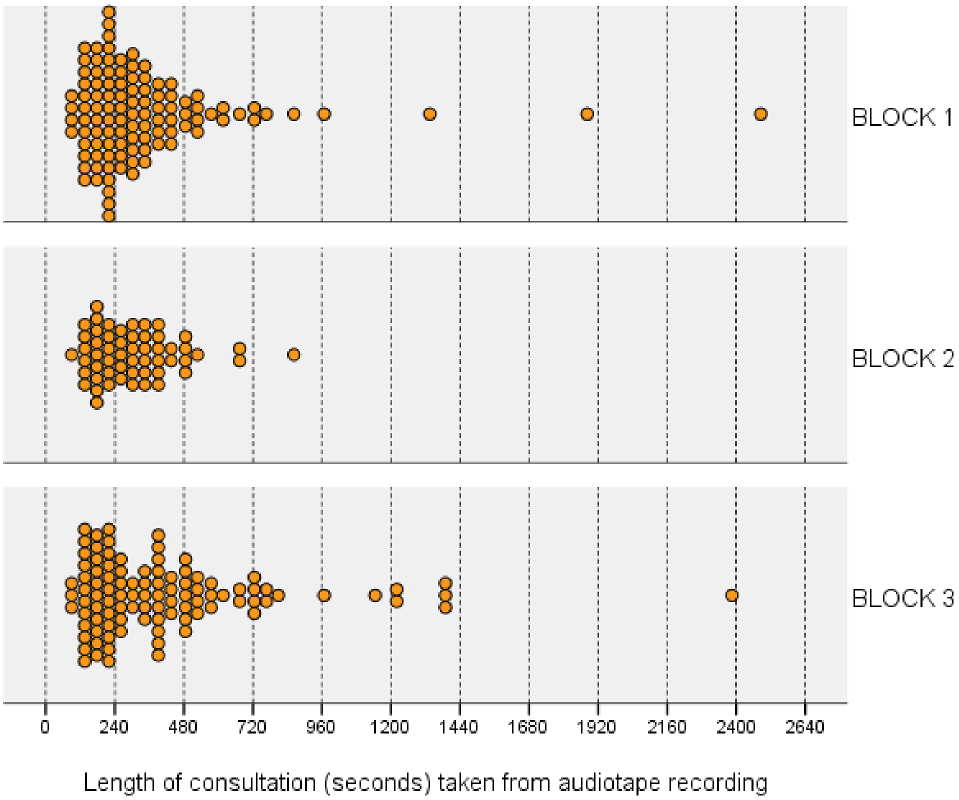
Distribution of individual consultations within each Block is shown in **Table 7.14**.

Table 7.13: Length of clinic consultation based on study Blocks (seconds)

	Block 1 (n=107/136)	Block 2 (N=55/78)	Block 3 (n=100/111)	P value**
Median (IQR) score	268 (193-401)	283 (192-376)	333 (192-509)	0.17
Mean	354	307	425	
% < 2min (120s)	5% (5)	2% (1)	4% (4)	
121-240s	38% (41)	38% (21)	34% (34)	
241-360s	26% (28)	27% (15)	15% (15)	
361-480s	13% (14)	18% (10)	16% (16)	
>8min (480s)	18% (19)	15% (8)	31% (31)	

**Kruskal-Wallis test

Table 7.14. Dot plot demonstrating the length of each audiorecorded consultation in Blocks



7.8.3.3. ‘Items of patients’ concern’ and ‘patient request for professionals’ discussed at consultation

The items of concern discussed in the audiorecorded consultations were examined and coded by a single researcher (NG) using the thematic framework developed in the Pilot study (**section 5.3.7**). Another researcher (BR) independently evaluated coding for 1 in 4 transcriptions in the same manner for the patient completed HN-PCI and transcription of the audiorecording of the consultation. Comparison was then made for coding of themes undertaken by NG and BR. Assessor agreement was evaluated for all items coded and is shown in **Table 7.15.**

Table 7.15: Inter-assessor agreement for thematic coding of items for transcribed audiorecordings

	Block 1	Block 2	Block 3
Inter-rater agreement for coding (%)	95.2%	97.6%	100%

The items of patients' concern and professionals discussed by patients are detailed in **Table 7.16**. The mean (median; IQR) total number of concerns discussed was 3.64 (3; 2-5) in Block 1, 2.85 (2; 1-4) in Block 2 and 4.62 (3; 2-6) in Block 3. While the differences were not statistically significant (p=0.12), there was a trend towards higher numbers of concerns discussed with full implementation of HN-PCI. There were notable increases in discussion of the certain items of concern during consultations with HN-PCI intervention, including FOR (p<0.001), fatigue/tiredness (p<0.001), energy levels (p=0.004) and dry mouth (p=0.01). The breakdown of individual items of concern discussed is shown in **Table 7.17**.

The mean (median; IQR) number of discussions about requests for other health professionals was 0.74 (0; 0-1) in Block 1, 0.49 (0;0-1) in Block 2 and 0.60 (0; 0-1) in Block 3. While the differences seen were not statistically significant, there was a trend suggesting a lowered rate of discussion regarding referrals/requests for other healthcare professionals with the HN-PCI intervention. However, there was notable increase in the requests for the CNS (p=0.003) and a notable reduction in the requests for oral rehabilitation specialists (p< 0.001). The breakdown of patient request for professionals is shown in **Table 7.18.**

Table 7.16. Number of items discussed during consultations according to HN-PCI domains

	Block 1 (N=107/136)			**Block 2 (N=55/78)**			**Block 3 (n=100/111)**			**P value***
	%1 or more	Mean	Median (IQR)	%1 or more	Mean	Median (IQR)	%1 or more	Mean	Median (IQR)	
Physical and functional well-being	79% (84)	1.99	2 (1-3)	73% (40)	1.65	1 (0-2)	81% (81)	2.76	2 (1-4)	0.04
Treatment related	59% (63)	0.65	1 (0-1)	67% (37)	0.71	1 (0-1)	55% (55)	0.60	1 (0-1)	0.45
Social care and social well-being	43% (46)	0.63	0 (0-1)	33% (18)	0.33	0 (0-1)	36% (36)	0.50	0 (0-1)	0.18
Psychological and emotional well-being / spirituality	26% (28)	0.36	0 (0-1)	13% (7)	0.16	0 (0-0)	41% (41)	0.76	0 (0-1)	<0.001
Total number of HN-PCI items discussed	96% (103)	3.64	3 (2-5)	93% (51)	2.85	2 (1-4)	95% (95)	4.62	3 (2-6)	0.12
Total number of HN-PCI health professionals discussed	47% (50)	0.74	0 (0-1)	38% (21)	0.49	0 (0-1)	40% (40)	0.60	0 (0-1)	0.28

*Kruskal-Wallis test comparing Blocks in the number of PCI items selected.

Table 7.17: Individual items discussed at consultation

	Block 1 (N=107/136)	Block 2 (N=55/78)	Block 3 (n=100/111)	Chi-squared test P value
Activity	**9% (10)**	**5% (3)**	**18% (18)**	**0.04**
Angry	1% (1)	-	3% (3)	0.28
Anxiety	**5% (5)**	**4% (2)**	**12% (12)**	**0.07**
Appearance	8% (9)	4% (2)	7% (7)	0.52
Appetite	5% (5)	-	7% (7)	0.14
Breathing	5% (5)	2% (1)	6% (6)	0.49
Bowel habit (diarrhoea or constipation)	1% (1)	5% (3)	5% (5)	0.18
Cancer treatment	53% (57)	62% (34)	48% (48)	0.26
Carer	4% (4)	2% (1)	4% (4)	0.76
Chewing/eating	11% (12)	18% (10)	16% (16)	0.42
Coping	4% (4)	2% (1)	8% (8)	0.18
Coughing	7% (7)	2% (1)	9% (9)	0.22
Dental health/teeth	21% (23)	27% (15)	25% (25)	0.69
Dependants/children	3% (3)	-	4% (4)	0.33
Depression	3% (3)	-	4% (4)	0.33
Dry mouth	**7% (8)**	**9% (5)**	**24% (24)**	**0.01**
Energy levels	**1% (1)**	**2% (1)**	**10% (10)**	**0.004**
Fatigue/tiredness	**3% (3)**	**-**	**18% (18)**	**<0.001**
Fear of the cancer coming back	**8% (9)**	**5% (3)**	**30% (30)**	**<0.001**
Fear of adverse events	3% (3)	2% (1)	1% (1)	0.64
Financial / benefits	2% (2)	-	2% (2)	0.58
Hearing	1% (1)	7% (4)	6% (6)	0.09
Home care/district nurse support	1% (1)	2% (1)	1% (1)	0.87
Indigestion	-	-	1% (1)	-
Intimacy	-	-	-	-
Lifestyle issues (smoking/alcohol)	20% (21)	11% (6)	11% (11)	0.15
Memory	1% (1)	-	2% (2)	0.52
Mobility	3% (3)	7% (4)	3% (3)	0.32
Mood	2% (2)	-	5% (5)	0.15
Mouth opening	7% (8)	2% (1)	10% (10)	0.17
Mucus production	7% (7)	5% (3)	6% (6)	0.96
Nausea	1% (1)	-	1% (1)	-
Pain in head and neck	28% (30)	16% (9)	21% (21)	0.21
Pain elsewhere	4% (4)	5% (3)	5% (5)	0.86
PEG tube	**-**	**2% (1)**	**5% (5)**	**0.05**
Recreation	11% (12)	5% (3)	6% (6)	0.28
Regret about treatment	-	-	-	-
Regurgitation	**8% (9)**	**-**	**-**	**0.001**
Relationships	2% (2)	-	2% (2)	0.58
Salivation	4% (4)	4% (2)	5% (5)	0.88
Self-esteem	1% (1)	-	1% (1)	-
Sexuality	-	-	-	-
Shoulder	7% (8)	4% (2)	7% (7)	0.62
Sleeping	4% (4)	-	5% (5)	0.26
Smell	-	-	1% (1)	-
Sore mouth	6% (6)	7% (4)	14% (14)	0.10
Speech/voice/being understood	21% (22)	13% (7)	20% (20)	0.44
Spiritual /religious aspects	1% (1)	-	1% (1)	-
Support for my family	-	-	-	-
Swallowing	24% (26)	15% (8)	27% (27)	0.20
Swelling	10% (11)	7% (4)	9% (9)	0.82
Taste	1% (1)	4% (2)	5% (5)	0.23
Temperament and personality	-	-	2% (2)	-
Vomiting/sickness	-	-	-	-
Weight	14% (15)	11% (6)	12% (12)	0.83
Wound healing	12% (13)	7% (4)	7% (7)	0.38
General well-being	82% (88)	87% (48)	90% (90)	0.26
Anything else*	**55% (59)**	**36% (20)**	**44% (44)**	**0.06**

*Anything else:

Block 1 (N=107/136)		Block 2 (N=55/78)		Block 3 (n=100/111)	
blank	1	Bad odour, Nasal blockage	1	Alopecia	1
Breast cancer diagnosis & treatment	1	IxRes	5	Bereavement	1
Research/Clinical trial	1	Pending investigations	1	Crusty nose	1
Dizziness	1	Ear infection	1	Diagnosis	2
Dysesthesia	1	Job	1	Watery eyes	1
Eye tumour	1	Medication	1	Further Treatment	1
Gynae problems	1	Nasal congestion, Diplopia	1	HPV virus infection	1
Housing	1	Numb lip	1	IX results, Txcompl, Cancer risk	1
Improvement in numb lip	1	Numb tongue	1	IxRes	2
Infection	1	Recent fall	1	IxRes, TxCompl	1
Infection, Donor site problems, Job	1	Research	1	Jaw pain	1
Info, Speech valve, Medications	1	Travel problems, Bipolar disorder	1	Job	1
IxRes	6	TxCompl	2	Leaking valve	1
IxRes, Job	1	Urinary problems	1	Leaking valve, New lump in spine	1
IxRes, New diagnosis	2	Watery eyes	1	Liver issues, Stiff neck	1
Job	6	Total	20	Medical prosthesis	1
Job, Numb ear	1			Medication, IxRes, Hair loss	1
Leaking valve	1			Meds	1
Limited tongue movement	1			Metalwork exposed	1
Med, Job, TxCompl	1			Neck stiff	1
Medications	2			Numb donor site	1
Medications,	1			Numb lip	1
Medications, IxRes	1			Numb skin, Dizziness	1
Nasal secretion, Restless legs	1			Osteoporosis	1
Neck stiffness	1			Recent admission	2
NO	2			Recent heart surgery	1
Recent dilatation	1			Recent infection, medication	1
Recent eye surgery, therabite	1			Reflux	1
Recent surgery, Meds	1			Research, TxComp	1
Reflux	1			Skin irritation, Cataract	1
Research	1			Skin lesion	1
Sneezing	1			Skin lesion, Job	1
Throat irritation	1			Stiff neck	1
TMJ problems	1			Stiff neck, Research	1
Tongue stiffness, Job	1			Stroke	1
Tracheostomy tube	1			Temperature regulation	1
Twitching, TxCompl, Job	1			Testicle problems	1
TxCompl	4			TxCompl	2
TxCompl & Meds	2			TxCompl, Acid reflux	1
TxCompl; Numb donor site	1			Valve	1
TxCompl; Numb lip	1			Total	44
TxCompl; Numb lip/tongue	1				
Total	59				

Abbreviations: TxCompl, treatment complications; IxRes, investigation results; TMJ, temporomandibular joint

Table 7.18: Details of patient requests for professionals discussed during consultation

	Block 1 (N=107/136)	Block 2 (N=55/78)	Block 3 (n=100/111)	Chi-squared test P value
Chaplain	-	-	-	-
Clinical nurse specialist	**8% (9)**	**7% (4)**	**23% (23)**	**0.003**
Dental hygienist	2% (2)	2% (1)	1% (1)	0.86
Dentist	6% (6)	13% (7)	4% (4)	0.10
Dietician	2% (2)	4% (2)	3% (3)	0.78
Nursing staff	3% (3)	-	2% (2)	0.46
Occupational therapist	-	-	-	-
Oral rehabilitation team	**13% (14)**	**2% (1)**	**1% (1)**	**<0.001**
Physiotherapist	4% (4)	7% (4)	3% (3)	0.43
Radiotherapist/oncologist	**7% (7)**	**2% (1)**	**-**	**0.02**
Speech and language therapist	6% (6)	-	5% (5)	0.21
Social worker	-	-	-	-
Surgeon	1% (1)	-	-	-
Family doctor	13% (14)	13% (7)	12% (12)	0.97
Clinical psychologist	2% (2)	-	2% (2)	0.58
Emotional support therapist	**8% (9)**	**-**	**4% (4)**	**0.05**
Anyone else**	12% (13)	16% (9)	13% (13)	0.76

*Anyone else:

Block 1 (N=107/136)		**Block 2 (N=55/78)**		**Block 3 (n=100/111)**	
Camouflage nurse	1	Colorectal surgeon	1	Audiology	1
ENT surgeon	1	ENT	1	Audiology, Smoking cessation nurse	1
Eye surgeon	1	ENT, Ophthalmologist	1	Chest physician	1
Gastroenterologist	1	Gastroenterology, ENT	1	Chest Physician, Neurosurgeon	1
Hypnotherapy	1	Neurologist	1	Chest rehab	1
Lung oncology	1	Radiologist	1	Counselor	1
Neurosurgeon	1	Thyroid oncology	1	Endocrinologist	1
Pain team, TMJ surgeon	1	Urologist	2	ENT	1
Thyroid oncology	4	Total	9	HNC support group	1
Thyroid oncology, Financial advisor	1			Jaw specialist	1
Total	13			Neurologist	1
				Thyroid oncologist	1
				Thyroid oncologist, ENT, Cardiologist	1
				Total	13

7.8.3.4. Clinical outputs of consultations

The clinical outcomes (medical and non-medical) related to the consultation are shown in this section. All recruited patients attending outpatient clinics received medical attention irrespective of the HN-PCI intervention (**Table 7.19**). In Block 3, there was a greater proportion ≥ 3 medical actions (12%) compared with other blocks. Details of the medical actions undertaken in each block are shown in **Table 7.20**.

Table 7.19. Medical actions resulting from the consultation

	Block 1 (N=107/136)	**Block 2 (N=55/78)**	**Block 3 (n=100/111)**
%YES	99% (106)	100% (55)	100% (100)
1 action	67% (71)	76% (42)	57% (57)
2 actions	26% (28)	22% (12)	31% (31)
3 actions	7% (7)	2% (1)	10% (10)
4 actions	-	-	2% (2)

Kruskal-Wallis P=0.03, number of actions

Table 7.20. What medical actions were undertaken

Block 1 (N=107/136)		**Block 2 (N=55/78)**		**Block 3 (n=100/111)**	
Exam	67	Exam	40	Exam	58
Exam, Investigation	11	Exam, Investigation	3	Exam, Investigation	5
Exam, Investigation, Meds	1	Exam, Letter	3	Exam, Investigation, Letter	1
Exam, Letter	6	Exam, Letter, Investigation	1	Exam, Investigation, Photo	1
Exam, Medical device, Investigation	1	Exam, Medication	1	Exam, Investigation, WL surgery	1
Exam, Medical device, Referral	2	Exam, Photo	1	Exam, Letter	3
Exam, Medication	4	Exam, Referral	3	Exam, Medical device	1
Exam, Medication, Referral	1	Exam, Wound inspection	1	Exam, Medication	7
Exam, Perform procedure	1	Letter	2	Exam, Medication, Letter	2
Exam, Photo	1	Total	55	Exam, Organise MDT	1
Exam, Referral	4			Exam, Organise MDT, WL cancer surgery, Letter	1
Exam, WL surgery	4			Exam, Photo, Medication	1
Exam, WL surgery, Letter	1			Exam, Referral	10
Exam, WL surgery, Referral	1			Exam, Referral, Investigation	2
WL surgery	1			Exam, Referral, Medication, Letter	1
Total	106			Exam, WL non-cancer	2
				Exam, WL surgery	1
				Exam, Wound inspection, Letter	1
				Referral, Investigation	1
				Total	100

Abbreviation: WL, waiting list; MDT, multidisciplinary team

In regard to non-medical actions taken related to the consultation, similar results were obtained (**Table 7.21**), where all recruited patients received non-medical actions. Details of the non-medical actions undertaken are shown in **Table 7.22**.

Table 7.21: Non-Medical actions resulting from the consultation

	Block 1 (N=107/136)	**Block 2 (N=55/78)**	**Block 3 (n=100/111)**
%YES	98% (106)	100% (55)	100% (100)
1 action	-	-	-
2 actions	74% (78)	78% (43)	72% (72)
3 actions	26% (27)	22% (12)	28% (28)
4 actions	1% (1)	-	-

Kruskal-Wallis P=0.70, number of actions

Table 7.22. What non-medical action taken

Block 1 (N=107/136)		**Block 2 (N=55/78)**		**Block 3 (n=100/111)**	
Bad news, Discuss Tx options, Reassure	1	Educate, Reassure, FU	2	Reassure, DC	6
Bad news, Explain Tx option, Reassure	2	Reassure, DC	1	Reassure, Educate, FU	21
Bad news, Explain Tx plan	1	Reassure, Educate, FU	9	Reassure, FU	66
Educate, Reassure, DC	1	Reassure, FU	43	Reassure, FU, education	3
Educate, Reassure, Encourage, FU	1	Total	55	Reassure, Tx Plan, FU	4
Educate, Reassure, FU	19			Total	100
Examination, Reassure, FU	1				
Explain Tx options, FU	1				
Reassure, DC	3				
Reassure, Educate, FU	1				
Reassure, FU	74				
Reassure, FU, education	1				
Total	106				

Abbreviation: Tx, treatment; FU, follow up; DC, discharge

7.8.4. Patient-reported outcomes of consultation (PROC)

Patient distress levels and satisfaction with consultation were measured using the DT, PSQ-MD and post-consultation questionnaires, which were self-reported and returned to the researcher with a postage-paid reply envelope after their consultation. The proportion of PROC questionnaires received for each category is shown in **Table 7.23**. The clinical characteristics of patients who returned the PROC questionnaires were considered (**Table 7.24**). There were no significant differences seen between Blocks.

Table 7.23: Self-reported outcomes of consultation received from patients

	Block 1 (n=136)	Block 2 (N=78)	Block 3 (n=111)	P value*
DT score	82% (111)	77% (60)	84% (93)	0.49
Post consultation Q	82% (111)	80% (62)	83% (92)	0.84
PSQ-MD	82% (111)	80% (62)	83% (92)	0.84

*chi-squared test

The time lapse between completion of PROC questionnaires from the day of consultation is shown in **Table 7.25**. Evidence here to indicate the time between consultation and post consultation data completion increased over the course of the study.

Post-consultation questionnaires were also considered from the surgeon seen at the consultation, and the results are shown in **Table 7.26**.

Self-recorded level of distress at post-consultation using the DT is shown in **Table 7.27**. There were no significant differences between the Blocks.

Table 7.24. Clinical characteristics of patients who returned PROC questionnaires

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=94/111)	P value*
Sex	Male	69% (76)	65% (40)	65% (61)	0.74
	Female	30% (33)	34% (21)	35% (33)	
	Not known	2% (2)	2% (1)	-	
Age	Mean (SD)	63.0 (13.3)	64.6 (10.1)	65.1 (11.2)	0.71
	Median (IQR)	65 (56-71)	64 (58-71)	65 (58-73)	
	<55	23% (26)	13% (8)	14% (13)	0.49
	55-64	28% (31)	37% (23)	35% (33)	
	65-74	32% (35)	34% (21)	32% (30)	
	75+	15% (17)	13% (8)	17% (16)	
	Not known	2% (2)	3% (2)	2% (2)	
Specialty	OMF	53% (59)	67% (41)	48% (45)	0.06
	ENT	47% (52)	33% (20)	52% (49)	
	Not known	-	1% (1)	-	
Tumour site	Oral	37% (41)	47% (29)	34% (32)	0.74
	Oro-pharyngeal	21% (23)	16% (10)	19% (18)	
	Laryngeal	17% (19)	18% (11)	22% (21)	
	Others	25% (28)	19% (12)	24% (23)	
Histology	SCC	85% (94)	84% (52)	83% (78)	0.92
	Not SCC	15% (17)	15% (9)	17% (16)	
	Not known	-	2% (1)	-	
Overall P stage	1	30% (33)	31% (19)	31% (29)	0.98
	2	18% (20)	19% (12)	20% (19)	
	3	11% (12)	6% (4)	9% (8)	
	4	27% (30)	27% (17)	30% (28)	
	Not known	14% (16)	16% (10)	11% (10)	
Primary Treatment	Surgery only	46% (51)	55% (34)	44% (41)	0.67
	Surgery + RT/CRT	36% (40)	31% (19)	40% (38)	
	RT/CRT only	14% (16)	11% (7)	14% (13)	
	Not known	4% (4)	3% (2)	2% (2)	
Free-flap	No surgery	14% (16)	11% (7)	14% (13)	0.62
	Surgery without FF	56% (62)	56% (35)	64% (60)	
	Surgery with FF	26% (29)	29% (18)	19% (18)	
	Not known	4% (4)	3% (2)	3% (3)	
Years from Primary diagnosis to consultation	Median (IQR)	2.2 (0.8-3.6)	2.5 (1.2-3.8)	2.2 (1.2-3.8)	0.61
	< 1 year	30% (33)	21% (13)	18% (17)	0.23
	1.0-2.9 years	32% (36)	39% (24)	46% (43)	
	≥ 3 years	36% (40)	39% (24)	35% (33)	
	Not known	2% (2)	2% (1)	1% (1)	

*chi-squared comparing blocks for categorical data after excluding the not known category; Kruskal-Wallis test comparing blocks for age in years and for years from primary diagnosis to study consultation.

Table 7.25. Days questionnaire were completed from day of consultation

		Block 1 (n=111/136)	**Block 2 (N=62/78)**	**Block 3 (n=93/111)**
Number of days between consultation and completion of PROC data	0	45% (50)	35% (22)	29% (27)
	1	41% (46)	40% (25)	41% (38)
	2	11% (12)	16% (10)	14% (13)
	3	1% (1)	2% (1)	5% (5)
	4	2% (2)	3% (2)	2% (2)
	5	-	3% (2)	2% (2)
	6	-	-	2% (2)
	8	-	-	2% (2)
	11	-	-	1% (1)
	16	-	-	1% (1)
Median (IQR)		1 (0-1)	1 (0-1)	1 (0-2)
Mean		0.73	1.06	1.63

*Kruskal-Wallis test comparing the 3 blocks: P=0.005

Table 7.26. Post-consultation questionnaire completion based on surgeon

Surgeon	**Block 1 (n=111/136)**	**Block 2 (N=62/78)**	**Block 3 (n=94/111)**
1	36% (40)	40% (25)	23% (22)
2	17% (19)	26% (16)	24% (23)
3	23% (25)	8% (5)	23% (22)
4	24% (27)	23% (14)	29% (27)
SpR	-	2% (1)	-
Not known	-	2% (1)	-

Table 7.27. Levels of distress post-consultation

DT score	**Block 1 (n=111/136)**	**Block 2 (N=60/78)**	**Block 3 (n=93/111)**
0 No distress	41% (45)	48% (29)	48% (45)
1	14% (15)	13% (8)	16% (15)
2	17% (19)	5% (3)	10% (9)
3	11% (12)	13% (8)	6% (6)
4	2% (2)	5% (3)	8% (7)
5	6% (7)	5% (3)	5% (5)
6	5% (5)	2% (1)	3% (3)
7	3% (3)	8% (5)	-
8	3% (3)	-	3% (3)
9	-	-	-
10 Extreme distress	-	-	-
Mean	1.9	1.8	1.6
Median (IQR)	1 (0-3)	1 (0-3)	1 (0-3)
% 6-10	10% (11)	10% (6)	6% (6)

Kruskal-Wallis test of DT scores between blocks, P=0.52

7.8.4.1. Non-validated post-consultation questionnaire

Non-validated post-consultation questionnaires composed of 6 questions and the results are shown in **Tables 7.28-.7.34**. In question 1, (*From your perspective, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation?),* the proportion of patients who replied ‘None’ was 48/111 (43%), 20/59 (34%), and 16/88 (18%) in Blocks 1,2 and 3, respectively (**Table 7.28**). When the details of the self-reported items in question 1 were counted (**Table 7.29**), the mean number of items indicated was 0.87 (Block 1), 1.34 (Block 2) and 1.42 (Block 3), where the difference seen is statistically significant (p=0.002).

In question 2 (*How would you rate the extent with which these concerns were addressed?),* the proportion who strongly agreed was higher in the intervention blocks though the differences across blocks were not statistically significant. (**Table 7.30**).

In question 3 (*Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation?*), almost all patients replied ‘Yes’ i.e. Block 1 (100/102, 98%), Block 2 (55/57, 96%) and Block 3 (85/86, 99%). (**Table 7.31**)

In question 4 (*To what degree would you agree with the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit*), those who replied “Strongly agree” accounted for 40% (43/108), 59% (33/56) and 58% (53/92) in Blocks 1, 2 and 3 respectively. This difference seen across the blocks was not statistically significant (p=0.02). (**Table 7.32**)

In question 5 (*To what degree would you agree with the statement: I felt the HN-PCI was intrusive*), those who replied “Strongly disagree” accounted for 40% (21/53) and 46% (41/90) in Blocks 2 and 3, respectively. The difference was not statistically significant. Those who replied “Agree” and/or “Strongly agree” accounted for 24% (13/53) and 6/41 (14%) in Blocks 2 and 3, respectively. (**Table 7.33**)

In question 6 (*To what degree would you agree with the statement: I felt the HN-PCI was unhelpful*), those who replied “Strongly disagree” accounted for 34% (17/50) and

54% (48/89) in Blocks 2 and 3, respectively. The difference was not statistically significant (p=0.03). (**Table 7.34**)

Table 7.28. Question 1: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation?

BLOCK 1 (N=111/136)	N
Blood test results	1
Breathing problems, mouth yness	1
Candidal infection	1
Cough, mucous secretions	1
Dental pain, ulcer on cheek	1
Dentures	1
Drooling	1
Dry mouth, chewing	1
Follow up visit	1
FOR	1
Gum lesion, Implants	1
Jaw pain, dental	1
Life	1
Medication	1
Mouth ulcer	1
Nasal discharge	1
Neck lump	1
Neck lump, neck pain	1
Neck pain, mucus secretions	1
New cancer	1
None	48
Pain in neck & jaw, sore roat	1
Pain neck & tongue	1
Prognosis	1
Progress	8
Progress, FoR	1
Progress, Prognosis	2
Reassurance	1
Reassurance FoR	1
Recent chest infection	1
Recent surgery, results	1
Recurrence	1
Recurrence, Rehabilitation	1
Restorative dentistry	1
Scan results	1
SE treatment, after-care	1
Self-care	1
Shoulder, lip deformity	1
Sore mouth, progress	1
Sore throat, CT request	1
Sore tongue, neck pain	1
Speech valve leak	1
Speech, oral disfigurement, normal sensations in mouth, outh lesions	1
Speech, swallowing, loss of nsation to hand & mouth	1
Swallowing problem	1
Swallowing, self-monitoring	1
Teeth	1
Thyroxine dosage	1
Treatment	1
Treatment outcome, progress	1
Trismus, Further surgery	1
Trismus, mouth pain, pain sewhere	1
Upcoming breast cancer eration and potential ifficulties with intubation	1
Update on condition	1
Voice, eating	1
Weight problems, edications, blood test	1

BLOCK 2 (n=62/78)	N
blank	3
Abnormal lip sensation, leg ar itch	1
APPEARANCE, CHEWING, REATHING, DENTAL, ATIGUE, SWELLING, EIGHT, SWALLOWING	1
Blood test, teeth	1
BREATHING, WALLOWING	1
CHEW, TASTE, DENTIST, ORE MOUTH	1
DENTAL CARE, PROGRESS	1
Eating, psysio for shoulder, ncer recurrence	1
FOR	3
FOR, mood, swelling, wallowing, dry mouth	1
GWB, CANCER TX	1
GWB, Check for recurrence	1
Hearing, chewing	1
mouth opening, dry mouth, ewing	1
mouth opening, prognosis	1
MOUTH OPENING, ROGRESS	1
mucus, activity	1
Neck tightness, drooling	1
next surgery, wound healing	1
None	20
PAIN, FOR	1
PEG, no oral intake for life	1
Progress	1
PROGRESS	5
REASSURANCE	1
RT side effects	1
SORE MOUTH, CHEEK WELLING	1
Sore mouth, pain	1
SWELLING	2
Swelling, pain	1
teeth, recovery, GWB	1
Test result	1
WORK	1
WOUND, TX REGRETS, WELLING,EMOTIONAL	1

BLOCK 3 (N=92/111)	
blank	4
APPEARANCE, NUMB SKIN	1
CHEWING, TEETH, MUCUS, FOR	1
COUGH, CHOKING, MUCUS	1
DEPRESSION, FOR	1
DRY MOUTH	2
DRY MOUTH TEETH	1
DRY MOUTH, BOWELS, EMOTIONAL	1
DRY MOUTH, DENTAL HEALTH	1
DRY MOUTH, SWALLOWING	1
DRY MOUTH, SWALLOWING, APETITE	1
FATIGUE, MOUTH OPENING, JAW PAIN	1
FEELING LOW, ANXIETY, COPING	1
FOR	6
FOR, PROGNOSIS	1
FOR, SIDE-EFFECTS TX	1
FOR. PROGRESS	1
HEARING, MOUTH OPENING	1
HEARING, MUCUS	1
INDIGESTION	1
JAW PAIN	2
MEDICATION, THROAT TIGHTENING	1
MRI RESULT, FATIGUE, PAIN, REFERRALS, JOINT PAIN	1
NECK STIFFNESS/PAIN	2
NEW CANCER	1
None	16
PAIN	1
PAIN, FOR	1
PAIN, MUCUS	1
PAIN, SWALLOWING	1
PEG	1
PHYSICAL STATE OF TONGUE	1
PHYSICAL STATE OF VOCAL CORDS	1
PROGNOSIS, FOR	1
PROGRESS	2
REASSURANCES	4
SCAN RESULTS	1
SHOULDER	1
SIDE-EFFECTS OF RT	2
SKIN ITCH	1
SORE MOUTH, EATING	1
SPEECH VALVE	1
SPEECH, TIREDNESS	1
SURGERY	1
SWALLOWING	2
TEETH	1
TEETH, CHEWING, FOR	1
TEETH, MOUTH OPENING	1
TIREDNESS	1
TIREDNESS, FEELING LOW, SWALLOWING	1
TIREDNESS, MEMORY, DRY MOUTH	1
VOICE	1
VOICE, SIDE-EFFECTS TX	1
WEIGHT, FOR, CHILDREN, DIET	1
WEIGHT, SLEEPING, TIREDNESS	1
WIFE UNWELL	1
WOUND	6

Abbreviation: GWB, general wellbeing; Tx, treatment; FOR/FoR, fear of recurrence

Table 7.29. Number of items of concerns that patient wanted discussing based on Question 1.

		Block 1 (n=111/136)	**Block 2 (N=59/78)**	**Block 3 (n=88/111)**
Number of items	0	43% (48)	34% (20)	18% (16)
	1	31% (34)	25% (15)	43% (38)
	2	23% (25)	29% (17)	24% (21)
	3	3% (3)	5% (3)	9% (8)
	4	1% (1)	3% (2)	5% (4)
	5	-	2% (1)	1% (1)
	8	-	2% (1)	-
	Median (IQR)	1 (0-2)	1 (0-2)	1 (1-2)
	Mean	0.87	1.34	1.42

Kruskal-Wallis test of number of items between blocks, P=0.002

Table 7.30. Question 2. How would you rate the extent with which these concerns were addressed?

	Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
Strongly agree	31% (34)	42% (26)	48% (44)
Agree	34% (38)	32% (20)	34% (31)
Disagree	1% (1)	2% (1)	-
Strongly disagree	-	-	-
Does not apply	29% (32)	19% (12)	16% (15)
Missing data	5% (6)	5% (3)	2% (2)
%Strongly agree*	**47% (34/73)**	**55% (26/47)**	**59% (44/75)**

*Chi-squared test of % strongly agree: P=0.32, after excluding 'Does not apply' and 'missing data'.

Table 7.31. Question 3. Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation?

	Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
Yes	90% (100)	89% (55)	92% (85)
No	2% (2)	3% (2)	1% (1)
Missing data	8% (9)	8% (5)	7% (6)
%Yes*	**98% (100/102)**	**96% (55/57)**	**99%(85/86)**

* after excluding 'missing data'.

Table 7.32. Question 4. To what degree would you agree with the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit.

	Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
Strongly agree	39% (43)	53% (33)	58% (53)
Agree	56% (62)	35% (22)	42% (39)
Disagree	2% (2)	2% (1)	-
Strongly disagree	1% (1)	-	-
Does not apply	-	6% (4)	-
Missing data	3% (3)	3% (2)	-
%Strongly agree*	**40% (43/108)**	**59% (33/56)**	**58% (53/92)**

*Chi-squared test of % strongly agree: P=0.02, after excluding 'Does not apply' and 'missing data'.

Table 7.33. Question 5. To what degree would you agree with the statement: I felt the HN-PCI was intrusive.

	Block 2 (N=62/78)	Block 3 (n=92/111)
Strongly agree	11% (7)	2% (2)
Agree	10% (6)	4% (4)
Disagree	31% (19)	47% (43)
Strongly disagree	34% (21)	45% (41)
Does not apply	15% (9)	2% (2)
Missing data	-	-
%Strongly disagree*	40% (21/53)	46% (41/90)

*after excluding 'Does not apply' and 'missing data'. Fishers exact test P=0.30

Mann-Whitney test of number of items between blocks, P=0.0.09, after excluding 'Does not apply' and 'missing data'.

Table 7.34. Question 6. To what degree would you agree with the statement: I felt the HN-PCI was unhelpful.

	Block 2 (N=62/78)	Block 3 (n=92/111)
Strongly agree	8% (5)	1% (1)
Agree	3% (2)	2% (2)
Disagree	42% (26)	41% (38)
Strongly disagree	27% (17)	52% (48)
Does not apply	16% (10)	3% (3)
Missing data	3% (2)	-
%Strongly disagree*	34% (17/50)	54% (48/89)

*after excluding 'Does not apply' and 'missing data'. Fishers exact test P=0.02

Mann-Whitney test of number of items between blocks, P=0.008, after excluding 'Does not apply' and 'missing data'.

7.8.4.2. Princess Margaret Hospital Satisfaction with Physician Questionnaire (PSQ-MD) data

PSQ-MD data is summarised in **Tables 7.35-7.37**. The 24 questions are mixed in terms of the direction of the wording, thus Strongly Agree could either be the best or worst response depending on the wording of the stem of the question. "Strongly Agree" is the best response for questions 1,3,10,11,13,14,15,19,20,21 and 22. "Strongly Disagree" is the best response for questions 2,4,5,6,7,8,9,12,16,17,18,23 and 24.

For scoring purposes, scores were allocated to the responses 'Strongly Agree', 'Agree', 'Disagree', 'Strongly Disagree' so that the best response scores 4 and the worse scores 1. Any question with 'Does not apply' or 'Missing data' did not get scored. The average score for relevant questions was computed for each patient and then scaled from 0 to 100 where 100 is the best score and 0 the worst score.

Table 7.35. Results of the PSQ-MD detailing individual question

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM1. I will follow the doctor's advice because I think s/he is absolutely right.	1 Strongly Agree	48	31	36
	2 Agree	51	21	43
	3 Disagree	0	0	1
	5 Does Not Apply	10	10	12
	9 Missing data	2	0	0
	% Strongly Agree*	48% (48/99)	60% (31/52)	45% (36/80)

* after excluding 'Does not Apply' and 'Missing data'
Kruskal-Wallis test P=0.23, after excluding 'Does not Apply' and 'Missing data'

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM2. The doctor did not take my problems very seriously.	1 Strongly Agree	2	0	0
	2 Agree	2	2	1
	3 Disagree	43	13	40
	4 Strongly Disagree	45	41	45
	5 Does Not Apply	16	5	6
	9 Missing data	3	1	0
	% Strongly Disagree*	49% (45/92)	73% (41/56)	52% (45/86)

* after excluding 'Does not Apply' and 'Missing data'
Kruskal-Wallis test P=0.02, after excluding 'Does not Apply' and 'Missing data'

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM3. The doctor considered my individual needs when treating my condition.	1 Strongly Agree	41	28	34
	2 Agree	50	25	49
	3 Disagree	4	0	1
	5 Does Not Apply	14	8	7
	9 Missing data	2	1	1
	% Strongly Agree*	43% (41/95)	53% (28/53)	40% (34/84)

* after excluding ‘Does not Apply’ and ‘Missing data’Kruskal-Wallis test P=0.30, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM4 .The doctor did not give me all the information I thought I should have been given.	1 Strongly Agree	2	1	1
	2 Agree	2	1	0
	3 Disagree	55	19	42
	4 Strongly Disagree	35	37	43
	5 Does Not Apply	13	4	4
	9 Missing data	4	0	2
	% Strongly Disagree*	37% (35/94)	64% (37/58)	50% (43/86)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.007, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM5. The doctor went straight to my medical problem without greeting me first.	2 Agree	1	1	0
	3 Disagree	52	17	44
	4 Strongly Disagree	53	39	44
	5 Does Not Apply	3	5	3
	9 Missing data	2	0	1
	% Strongly Disagree*	50% (53/106)	68% (39/57)	50% (44/88)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.06, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM6. The doctor used words I did not understand.	1 Strongly Agree	1	0	0
	2 Agree	7	1	2
	3 Disagree	52	14	50
	4 Strongly Disagree	44	42	38
	5 Does Not Apply	5	3	2
	9 Missing data	2	2	0
	% Strongly Disagree*	42% (44/104)	74% (42/57)	42% (38/90)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P<0.001, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM7. There was not enough time to tell the doctor everything I wanted.	1 Strongly Agree	2	0	1
	2 Agree	3	0	0
	3 Disagree	56	20	42
	4 Strongly Disagree	42	38	47
	5 Does Not Apply	5	3	2
	9 Missing data	3	1	0
	% Strongly Disagree*	40% (42/103)	66% (38/58)	52% (47/90)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.005, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM8. I feel the doctor did not spend enough time with me.	1 Strongly Agree	3	0	0
	2 Agree	5	2	0
	3 Disagree	55	20	52
	4 Strongly Disagree	44	39	39
	5 Does Not Apply	1	1	1
	9 Missing data	3	0	0
	% Strongly Disagree*	41% (44/107)	64% (39/61)	43% (39/91)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.01, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM9. It seemed to me that the doctor was not really interested in my emotional well-being.	1 Strongly Agree	2	0	0
	2 Agree	4	0	4
	3 Disagree	53	15	26
	4 Strongly Disagree	47	43	59
	5 Does Not Apply	4	3	3
	9 Missing data	1	1	0
	% Strongly Disagree*	44% (47/106)	74% (43/58)	66% (59/89)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P<0.001, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM10. I really felt understood by my doctor.	1 Strongly Agree	43	29	47
	2 Agree	59	31	39
	3 Disagree	4	0	4
	4 Strongly Disagree	2	1	0
	5 Does Not Apply	2	1	2
	9 Missing data	1	0	0
	% Strongly Agree*	40% (43/108)	48% (29/61)	52% (47/90)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.20, after excluding ‘Does not Apply’ and ‘Missing data

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM11. After my last visit with my doctor, I feel much better about my concerns.	1 Strongly Agree	32	18	39
	2 Agree	57	40	42
	3 Disagree	8	0	8
	4 Strongly Disagree	1	1	1
	5 Does Not Apply	12	3	1
	9 Missing data	1	0	1
	% Strongly Agree*	33% (32/98)	31% (18/59)	43% (39/90)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.44, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM12 .The doctor was not friendly to me.	1 Strongly Agree	1	0	0
	2 Agree	2	0	0
	3 Disagree	46	21	32
	4 Strongly Disagree	59	40	59
	5 Does Not Apply	1	0	1
	9 Missing data	2	1	0
	% Strongly Disagree*	55% (59/108)	66% (40/61)	65% (59/91)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.18, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM13. I understand my illness much better after seeing this doctor.	1 Strongly Agree	30	18	22
	2 Agree	55	26	43
	3 Disagree	4	0	13
	5 Does Not Apply	21	17	14
	9 Missing data	1	1	0
	% Strongly Agree*	34% (30/89)	41% (18/44)	28% (22/78)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.04, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM14. This doctor was interested in me as a person and not just my illness.	1 Strongly Agree	29	24	41
	2 Agree	73	30	42
	3 Disagree	6	3	2
	4 Strongly Disagree	1	2	0
	5 Does Not Apply	1	2	7
	9 Missing data	1	1	0
	% Strongly Agree*	27% (29/109)	41% (24/59)	48% (41/85)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.007, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM15. I feel I understand pretty well the doctor’s plan for helping me.	1 Strongly Agree	33	25	37
	2 Agree	65	26	39
	3 Disagree	2	0	0
	4 Strongly Disagree	0	1	0
	5 Does Not Apply	10	10	16
	9 Missing data	1	0	0
	% Strongly Agree*	33% (33/100)	48% (25/52)	49% (37/76)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.06, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM16. I would not recommend this doctor to a friend.	2 Agree	1	1	1
	3 Disagree	39	12	25
	4 Strongly Disagree	66	45	63
	5 Does Not Apply	4	3	3
	9 Missing data	1	1	0
	% Strongly Disagree*	62% (66/106)	78% (45/58)	71% (63/89)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.13, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM17. The doctor seemed to brush off my questions.	1 Strongly Agree	1	1	0
	2 Agree	0	1	0
	3 Disagree	45	15	43
	4 Strongly Disagree	59	43	45
	5 Does Not Apply	4	1	4
	9 Missing data	2	1	0
	% Strongly Disagree*	56% (59/105)	72% (43/60)	51% (45/88)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.07, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM18. The doctor should have told me more about how to care for my condition.	2 Agree	8	2	0
	3 Disagree	52	17	48
	4 Strongly Disagree	39	33	35
	5 Does Not Apply	11	10	9
	9 Missing data	1	0	0
	% Strongly Disagree*	39% (39/99)	63% (33/52)	42% (35/83)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.02, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM19. After talking with the doctor, I have a good idea of what changes to expect in my health over the next few weeks and months.	1 Strongly Agree	25	22	31
	2 Agree	61	21	48
	3 Disagree	4	1	3
	4 Strongly Disagree	1	2	0
	5 Does Not Apply	19	16	10
	9 Missing data	1	0	0
	% Strongly Agree*	27% (25/91)	48% (22/46)	38% (31/82)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.10, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM20 .The doctor told me to call back if I had any questions or problems.	1 Strongly Agree	32	25	47
	2 Agree	53	25	40
	3 Disagree	6	1	4
	5 Does Not Apply	17	8	1
	9 Missing data	3	3	0
	% Strongly Agree*	35% (32/91)	49% (25/51)	52% (47/91)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.06, after excluding ‘Does not Apply’ and ‘Missing data

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM21. I felt the doctor was being honest with me.	1 Strongly Agree	41	29	53
	2 Agree	64	28	39
	3 Disagree	0	1	0
	4 Strongly Disagree	2	0	0
	5 Does Not Apply	3	4	0
	9 Missing data	1	0	0
	% Strongly Agree*	(41/107)	50% (29/58)	(53/92)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.02, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM22. The doctor explained the reason why the treatment was recommended for me.	1 Strongly Agree	29	20	31
	2 Agree	58	22	44
	4 Strongly Disagree	0	2	0
	5 Does Not Apply	23	18	17
	9 Missing data	1	0	0
	% Strongly Agree*	(29/87)	(20/44)	(31/75)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.48, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM23. It seemed to me that the doctor was not really interested in my physical well-being.	1 Strongly Agree	1	1	0
	2 Agree	1	0	1
	3 Disagree	46	16	30
	4 Strongly Disagree	58	41	55
	5 Does Not Apply	4	4	6
	9 Missing data	1	0	0
	% Strongly Disagree*	(58/106)	(41/58)	(55/86)

* after excluding ‘Does not Apply’ and ‘Missing data’
Kruskal-Wallis test P=0.12, after excluding ‘Does not Apply’ and ‘Missing data’

		Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)
PM24. The doctor should have shown more interest.	2 Agree	2	1	0
	3 Disagree	46	14	29
	4 Strongly Disagree	61	39	61
	5 Does Not Apply	1	5	1
	9 Missing data	1	3	1
	% Strongly Disagree*	(61/109)	(39/54)	(61/90)

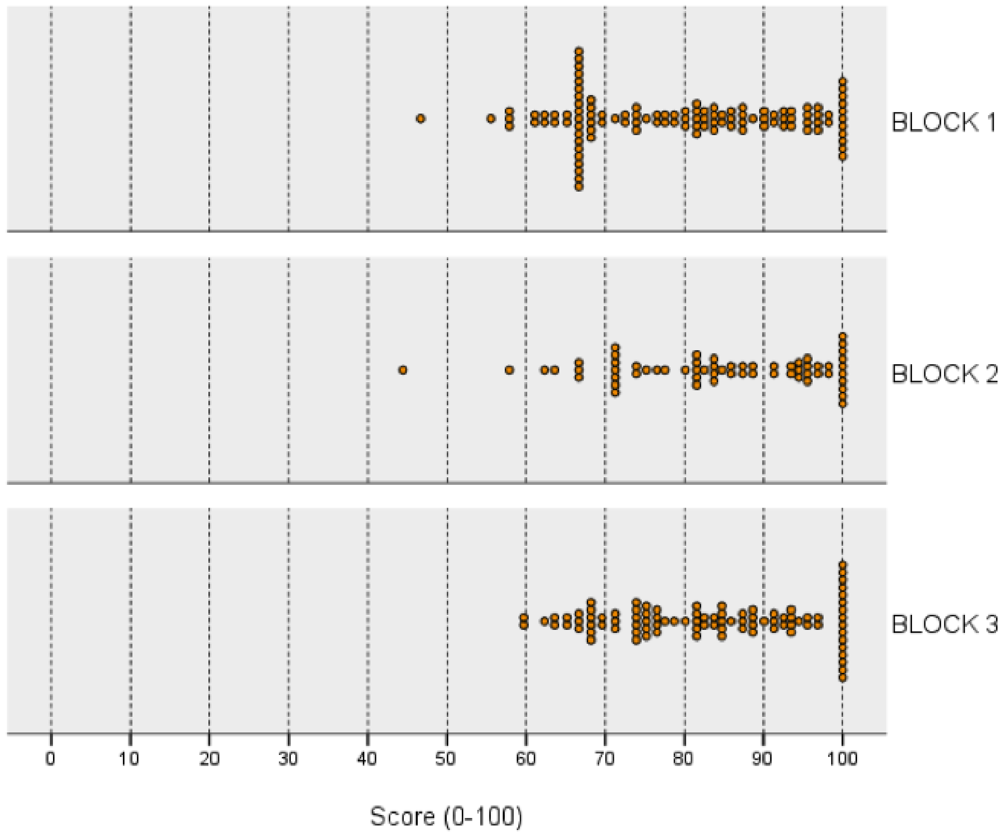
* after excluding 'Does not Apply' and 'Missing data'
Kruskal-Wallis test P=0.07, after excluding 'Does not Apply' and 'Missing data'

Table 7.36. Scoring system for PSQ-MD

	Block 1 (n=111/136)	Block 2 (N=62/78)	Block 3 (n=92/111)	P value **
Median (IQR) score	80 (67-91)	86 (74-96)	83 (74-93)	0.02
Mean	79.4	84.6	82.9	
Median (IQR) N of questions with scoreable* responses	23 (21-24)	23 (21-24)	24 (22-24)	0.05
Mean	21.8	21.4	22.5	

* 'Strongly Agree', 'Agree', 'Disagree', 'Strongly Disagree'
**Kruskal-Wallis test

Table 7.37. Drop-plot showing PSQ-MD scores across Blocks



7.8.5. Relationship between HN-PCI and Distress

In this section, analysis was restricted to one consultation per patient to reduce the bias introduced by repeated exposure to the HN-PCI. The consultation selected was the patient’s first attendance at clinics in study Blocks 2 and 3 during which they first used the PCI. Based on this criteria, one-hundred and seventy patients (n=170) were considered for analysis.

The mean DT score overall was 2.9 and the median (IQR) was 2 (0-5). The overall rate of significant distress (i.e. DT cut-off score of ≥4) was 36% (62/170). Thus, about two-thirds (64%, 108/170) of this cohort at clinic did not report significant distress.

Overall, the number of HN-PCI items of concern selected ranged from 0-18, mean 3.63, median 2 (IQR, 1-5). Patients with significant distress selected more items overall than patients without distress (Significant distress: mean, 5.4; median, 5; IQR, 2-8 versus no distress: mean, 2.61; median, 2; IQR, 0-4) (Mann-Whitney test $p<0.001$). More specifically, patients with significant distress had more concerns from within the Physical and Functional well-being domain (mean, 3.87 versus 1.96) and the Psychological and Emotional well-being domain (1.16 versus 0.46) than from the Social care/Social well-being domain (0.21 versus 0.10) and Treatment-related domain (0.16 versus 0.08). The association between HN-PCI items of concern and significant distress is summarised in **Table 7.38.**

There were trends within each domain for the likelihood of significant distress to increase with the number of concerns selected and for this to be compounded within the total score. In stepwise logistic regression to predict significant distress using the category variables within **Table 7.38**, the total number of concerns was the only variable selected (at $p<0.001$) in regression modelling with $p<0.01$ inclusion criteria. Three distinct predictive groups were apparent: 20% of patients selecting zero items of concern - 9% (3/35) distressed, 47% selecting 1-4 items - 30% (24/80) distressed, and 32% selecting 5 or more items - 64% (35/55) distressed. Possible cut-offs in the number of HN-PCI items of concern selected in relation to significant distress are explored in **Table 7.39**. Specific HN-PCI items of concern associated with significant distress are shown in **Table 7.40**.

Table 7.38. Number of HN-PCI items selected and significant distress (DT≥4)

	Significant distress (DT≥4) %	n	P value*
Physical & functional well-being			
0	20%	11/56	<0.001
1-2	32%	16/50	
3-4	42%	13/31	
5-9	71%	17/24	
≥10 (range 10-15)	56%	5/9	
Treatment related			
0	35%	53/152	0.30
≥1 (range 1-2)	50%	9/18	
Social care & social well-being			
0	33%	50/150	0.03
≥1 (range 1-3)	60%	12/20	
Psychological, emotional & spiritual wellbeing			
0	28%	28/100	0.001
1-2	42%	24/57	
≥3 (range 3-6)	77%	10/13	
Total number of items			
0	9%	3/35	<0.001
1-2	30%	17/56	
3-4	29%	7/24	
5-9	61%	25/41	
≥10 (range 10-18)	71%	10/14	
Health professionals			
0	31%	37/121	0.01
≥1 (range 1-4)	51%	25/49	

*chi-square test (physical & functional, psychological emotional & spiritual well-being, total number), otherwise Fisher's exact test.

Table 7.39. Possible cut-offs in the number of HN-PCI items in relation to significant distress

Number of total PCI items as cut-off	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
≥1	95% (59/62)	30% (32/108)	44% (59/135)	91% (32/35)
≥2	82% (51/62)	49% (53/108)	48% (51/106)	83% (53/64)
≥3	68% (42/62)	66% (71/108)	53% (42/79)	78% (71/91)
≥4	61% (38/62)	72% (78/108)	56% (38/68)	76% (78/102)
≥5	56% (35/62)	81% (88/108)	64% (35/55)	77% (88/115)
≥6	42% (26/62)	88% (95/108)	67% (26/39)	73% (95/131)
≥7	34% (21/62)	90% (97/108)	66% (21/32)	70% (97/138)

Table 7.40. Specific HN-PCI items associated with significant DT distress

PCI item	PCI item selected		PCI item not selected		P value*
	%DT score ≥4		%DT score ≥4		
Anxiety	77	10/13	33	52/157	0.005
Bowel	78	7/9	34	55/161	0.01
Depression	88	7/8	34	55/162	0.004
Fatigue	62	21/34	30	41/136	0.001
Mood	78	7/9	34	55/161	0.01
Pain in head/neck	65	17/26	31	45/144	0.002
Sleeping	65	13/20	33	49/150	0.007
Swallowing	67	20/30	30	42/140	<0.001

*Fishers exact test

Distress and patient concerns and length of consultation

The median (IQR) number of concerns discussed in consultations was 3 (2-5) items, n=141. When patients were distressed and ≤ 3 items of concern were discussed (19 patients), the median (IQR) length of consultation was 4.2 (3.1-6.0) minutes; when ≥ 4 items of concern were discussed (33 patients), the median (IQR) consultation length was 8.4 (5.5-12.1) minutes (Mann-Whitney test, p<0.001). In the absence of distress and ≤ 3 items were discussed (63 patients), the median (IQR) length of consultation was 3.3 (2.6-6.2) minutes; when ≥ 4 items were discussed (26 patients) the median (IQR) consultation length was 6.4 (4.3-8.9) minutes (Mann-Whitney test, p<0.001).

Distress and perceived need for services

Overall, the number of professionals selected ranged from 0-4, mean 0.38, median (IQR) 0 (0-1), n=170, with a mean 0.53 selected in those with significant distress and a mean 0.30 without significant distress. No strong associations were found with type of professional selected, though it was noted that 52% (11/21) of those wanting to see the surgeon were distressed, 83% (5/6) of those wanting to see the physiotherapist, and all those wanting to see either a psychologist (2/2) or Emotional Support therapist (2/2).

The number of medical actions taken based on audiotaped consultations (n=141) ranged from 1 to 4, and the percentage when ≥ 2 actions was 52% (27/52) for those with significant distress and 29% (26/89) without distress (Fishers exact test, p=0.01). In regard to non-medical actions (range 2-4), the percentage when ≥ 3 actions was 37% (19/52) for those with significant distress and 21% (19/89) without distress (Fishers exact test, p=0.18).

7.8.6. Relationship between clinical variables in relation to consultations with HN-PCI intervention

More detailed analysis was undertaken in Block 3. The clinical variables considered were gender, age, diagnosis, tumour site, overall stage, treatment, free flap reconstruction, years from diagnosis, surgeons/doctors, and specialty. The outcomes of consultation considered include HN-PCI domains and items, the PROC and the PSQ-MD scores. Each clinical variable was analysed in turn against summarised outcomes. The most appropriate statistical test was undertaken during analysis across all categories and this is detailed in the table showing the results.

Results of clinical significance (while showing either significant or borderline statistical significance) are summarised as follows:

a. Gender (**Table 7.41**): Females were more likely to discuss items within the Psychological emotional or spiritual wellbeing, and were more likely to give favourable responses to the post-consultation question 2.

b. Age-group (**Table 7.42**): Patients <55 years had longer consultation length, had more discussions of Psychological/emotional or spiritual wellbeing, had more discussions about Pain in head and neck, and received more medical actions.

c. Specialty (**Table 7.43**): Compared with OMF patients, ENT patients had fewer discussions in the Treatment-related domain and ‘Dental health/teeth’, more discussions of Psychological/emotional or spiritual wellbeing, and ‘Dry mouth’. ENT patients also had more discussion of referral to other health professionals. ENT patients were more likely to give favourable responses to the post-consultation question, and had better overall PSQ-MD scores.

d. Surgeons (**Table 7.44**): There were notable inter-surgeon differences in consultation length, Treatment-related discussions, and in discussions of referral to other health professionals, and medical actions.

e. Tumour site (**Table 7.45**): Patients with primary larynx tumours were more likely to have more Social care and social well-being discussions, and have more discussions regarding ‘Speech/voice/understood’. Patients with oral cavity and oropharynx primary sites had more discussions regarding ‘Swallowing’, and ‘Dental health/teeth’. Patients with oropharynx primary had more discussions with ‘Dry mouth’.

f. Overall p-stage (**Table 7.46**): Consultation length increased with stage, as did discussions about Physical and functional wellbeing, and overall number of HN-PCI items discussed.

g. Years from primary diagnosis (**Table 7.47**): Consultation length fell with time, less discussion > 3 years about Physical and functional wellbeing, and in overall number of HN-PCI items discussed.

h. Free flap reconstruction (**Table 7.48**): Patients who received free flap reconstruction had longer length of discussion, and had more discussions about ‘Dental health/teeth’ compared with those who did not have surgery and/or those who underwent surgery without free flap reconstruction.

g. Treatment (**Table 7.49**): Those receiving RT had more discussions about ‘Dry mouth’ than those who did not receive RT.

There were no notable associations seen in Diagnosis (**Table 7.50**).

Table 7.41. Gender

		Male	Female	P value*
Distress	Mean (SE) %6-10	1.45 (0.28) 5% (3/60)	1.79 (0.36) 9% (3/33)	0.25
Post consultation Q # on Q1A	Mean (SE) % 2 or more	1.49 (0.14) 42% (24/57)	1.29 (0.22) 32% (10/31)	0.24
Post consultation Q	% Q2 SA	52% (27/52)	74% (17/23)	0.08
	% Q3 YES	98% (55/56)	100% (30/30)	-
	% Q4 SA	59% (35/59)	55% (18/33)	0.66
	% Q5 SD	46% (27/59)	45% (14/31)	0.97
	% Q6 SD	53% (30/57)	56% (18/32)	0.74
Princess Margaret Q score 0-100	Mean (SE) Median (IQR)	83.1 (1.5) 83 (74-93)	82.7 (2.3) 84 (71-95)	0.86
Consultation Length (sec)	Mean (SE) Median (IQR)	403 (39) 302 (191-501)	469 (74) 393 207-534)	0.28
Audio taped # Items discussed	D1 mean (SE), %≥1 item	2.63 (0.34) 84% (56/67)	3.03 (0.51) 76% (25/33)	0.57
	D2 mean (SE), %≥1 item	0.58 (0.07) 54% (36/67)	0.64 (0.11) 58% (19/33)	0.68
	D3 mean (SE), %≥1 item	0.48 (0.09) 36% (24/67)	0.55 (0.15) 36% (12/33)	0.81
	D4 mean (SE), %≥1 item	0.55 (0.12) 36% (24/67)	1.18 (0.31) 52% (17/33)	0.06
	PCI mean (SE), %≥1 item	4.24 (0.43) 94% (63/67)	5.39 (0.80) 97% (32/33)	0.27
	PCI-HP mean (SE), %≥1 item	0.63 (0.10) 45% (30/67)	0.55 (0.19) 30% (10/33)	0.24
Discussion of	% Cancer treatment	43% (29/67)	58% (19/33)	0.21
Common items	% FOR	25% (17/67)	39% (13/33)	0.17
	% Swallowing	27% (18/67)	27% (9/33)	>0.99
	% Dental health/teeth	21% (14/67)	33% (11/33)	0.22
	% Dry mouth	25% (17/67)	21% (7/33)	0.80
	% Pain in head/neck	19% (13/67)	24% (8/33)	0.61
	% Speech/voice/understood	22% (15/67)	15% (5/33)	0.44
	% Fatigue/tiredness	16% (11/67)	21% (7/33)	0.59
Medical actions	% 2 or more	46% (31/67)	36% (12/33)	0.32
Non-medical actions	% 3 or more	28% (19/67)	27% (9/33)	0.91

*Fishers exact test for Post consultation Q3, discussion of common items; otherwise Mann-Whitney test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.42. Age group

		<55	55-64	65-74	75+	P value *
Distress	Mean (SE)	2.85 (0.72)	1.38 (0.37)	1.13 (0.31)	1.50 (0.56)	0.14
	%6-10	15% (2/13)	6% (2/32)	0% (0/30)	13% (2/16)	
Post consultation Q	Mean (SE)	2.08 (0.43)	1.34 (0.18)	1.25 (0.16)	1.37 (0.32)	0.38
# on Q1A	% 2 or more	62% (8/13)	31% (9/29)	36% (10/28)	44% (7/16)	
Post consultation Q	% Q2 SA	55% (6/11)	56% (15/27)	70% (16/23)	50% (6/12)	0.65
	% Q3 YES	100% (13/13)	100% (29/29)	96% (26/27)	100% (15/15)	-
	% Q4 SA	54% (7/13)	55% (17/31)	57% (17/30)	69% (11/16)	0.81
	% Q5 SD	62% (8/13)	40% (12/30)	45% (13/29)	44% (7/16)	0.55
	% Q6 SD	62% (8/13)	45% (13/29)	70% (21/30)	40% (6/15)	0.08
Princess Margaret	Mean (SE)	85.6 (3.9)	80.3 (2.0)	84.7 (2.3)	81.5 (3.1)	0.43
Q score 0-100	Median (IQR)	89 (70-99)	80 (72-89)	86 (74-96)	80 (74-93)	
Consultation	Mean (SE)	706 (154)	350 (48)	380 (40)	438 (83)	
length	Median (IQR)	496 (327-792)	226 (154-484)	376 (205-438)	393 (174-511)	0.02
Audio taped	D1 mean (SE),	3.20 (0.69)	2.38 (0.41)	2.81 (0.49)	3.33 (0.97)	0.66
# Items discussed	%≥1 item	80% (12/15)	78% (29/37)	91% (29/32)	73% (11/15)	
	D2 mean (SE),	0.47 (0.13)	0.65 (0.10)	0.59 (0.11)	0.67 (0.16)	0.77
	%≥1 item	47% (7/15)	59% (22/37)	53% (17/32)	60% (9/16)	
	D3 mean (SE),	0.47 (0.26)	0.49 (0.11)	0.50 (0.13)	0.40 (0.16)	0.82
	%≥1 item	20% (3/15)	41% (15/37)	38% (12/32)	33% (5/16)	
	D4 mean (SE),	2.13 (0.64)	0.49 (0.14)	0.63 (0.15)	0.40 (0.13)	0.06
	%≥1 item	60% (9/15)	32% (12/37)	44% (14/32)	40% (6/15)	
	PCI mean (SE),	6.27 (1.46)	4.00 (0.51)	4.53 (0.61)	4.80 (1.22)	0.70
	%≥1 item	93% (14/15)	97% (36/37)	97% (31/32)	87% (13/15)	
	PCI-HP mean (SE),	1.07 (0.38)	0.57 (0.13)	0.53 (0.14)	0.40 (0.16)	0.57
	%≥1 item	53% (8/15)	41% (15/37)	38% (12/32)	33% (5/15)	
Discussion of	% Cancer treatment	33% (5/15)	49% (18/37)	50% (16/32)	60% (9/15)	0.53
Common items	% FOR	53% (8/15)	24% (9/37)	28% (9/32)	27% (4/15)	0.21
	% Swallowing	33% (5/15)	30% (11/37)	22% (7/32)	27% (4/15)	0.83
	% Dental health/teeth	27% (4/15)	24% (9/37)	25% (8/32)	27% (4/15)	0.98
	% Dry mouth	13% (2/15)	24% (9/37)	28% (9/32)	27% (4/15)	0.73
	% Pain in head/neck	33% (5/15)	19% (7/37)	9% (3/32)	40% (6/15)	0.06
	% Speech/voice/understood	7% (1/15)	19% (7/37)	25% (8/32)	20% (3/15)	0.53
	% Fatigue/tiredness	27% (4/15)	19% (7/37)	9% (3/32)	27% (4/15)	0.37
Medical actions	% 2 or more	73% (11/15)	35% (13/37)	38% (12/32)	47% (7/15)	0.05
Non-medical actions	% 3 or more	33% (5/15)	30% (11/37)	28% (9/32)	20% (3/15)	0.87

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.43. Specialty

		OMF	ENT	P value*
Distress	Mean (SE)	1.53 (0.27)	1.60 (0.35)	0.73
	%6-10	2% (1/45)	10% (5/48)	
Post consultation Q # on Q1A	Mean (SE)	1.18 (0.14)	1.66 (0.19)	0.07
	% 2 or more	30% (13/44)	48% (21/44)	
Post consultation Q	% Q2 SA	49% (18/37)	68% (26/38)	0.08
	% Q3 YES	97% (38/39)	100% (47/47)	-
	% Q4 SA	44% (20/45)	70% (33/47)	0.01
	% Q5 SD	44% (20/45)	47% (21/45)	0.96
	% Q6 SD	50% (22/44)	58% (26/45)	0.42
Princess Margaret Q score 0-100	Mean (SE)	80.4 (1.8)	85.2 (1.7)	0.06
	Median (IQR)	82 (70-91)	88 (75-96)	
Consultation Length (sec)	Mean (SE)	399 (41)	447 (56)	0.87
	Median (IQR)	333 (191-492)	332 (198-547)	
Audio taped # Items discussed	D1 mean (SE), %≥1 item	2.45 (0.40)	3.04 (0.39)	0.24
		79% (37/47)	83% (44/53)	
	D2 mean (SE), %≥1 item	0.81 (0.09)	0.42 (0.07)	0.001
		70% (33/47)	42% (22/53)	
	D3 mean (SE), %≥1 item	0.47 (0.11)	0.53 (0.11)	0.55
		32% (15/47)	40% (21/53)	
	D4 mean (SE), %≥1 item	0.49 (0.13)	1.00 (0.22)	0.06
		32% (15/47)	49% (26/53)	
	PCI mean (SE), %≥1 item	4.21 (0.51)	4.98 (0.58)	0.41
		96% (45/47)	94% (50)	
	PCI-HP mean (SE), %≥1 item	0.26 (0.09)	0.91 (0.14)	<0.001
		19% (9/47)	58% (31/53)	
Discussion of Common items	% Cancer treatment	62% (29/47)	36% (19/53)	0.02
	% FOR	23% (11/47)	36% (19/53)	0.20
	% Swallowing	17% (8/47)	36% (19/53)	0.04
	% Dental health/teeth	36% (17/47)	15% (8/53)	0.02
	% Dry mouth	15% (7/47)	32% (17/53)	0.06
	% Pain in head/neck	15% (7/47)	26% (14/53)	0.22
	% Speech/voice/understood	11% (5/47)	28% (15/53)	0.04
	% Fatigue/tiredness	13% (6/47)	23% (12/53)	0.30
Medical actions	% 2 or more	32% (15/47)	53% (28/53)	0.06
Non-medical actions	% 3 or more	23% (11/47)	32% (17/53)	0.34

*Fishers exact test for Post consultation Q3, discussion of common items; otherwise Mann-Whitney test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.44. Surgeon

		Surgeon 1	**Surgeon 2**	**Surgeon 3**	**Surgeon 4**	**P value***
Distress	Mean (SE) %6-10	0.95 (0.30) 0% (0/22)	2.09 (0.42) 4% (1/23)	2.14 (0.58) 18% (4/22)	1.15 (0.40) 4% (1/26)	0.09
Post consultation Q # on Q1A	Mean (SE) % 2 or more	1.19 (0.18) 33% (7/21)	1.17 (0.21) 26% (6/23)	2.05 (0.30) 64% (14/22)	1.27 (0.20) 32% (7/22)	0.06
Post consultation Q	% Q2 SA	56% (10/18)	42% (8/19)	68% (13/19)	68% (13/19)	0.30
	% Q3 YES	100% (20/20)	95% (18/19)	100% (22/22)	100% (25/25)	-
	% Q4 SA	45% (10/22)	43% (10/23)	59% (13/22)	80% (20/25)	0.04
	% Q5 SD	45% (10/22)	43% (10/23)	45% (10/22)	48% (11/23)	>0.99
	% Q6 SD	50% (11/22)	50% (11/22)	59% (13/22)	57% (13/23)	0.89
Princess Margaret Q score 0-100	Mean (SE) Median (IQR)	78.7 (2.6) 79 (68-85)	82.1 (2.6) 83 (71-92)	84.2 (2.7) 82 (73-98)	86.1 (2.2) 88 (75-95)	0.22
Consultation length	Mean (SE) Median (IQR)	285 (38) 214 (157-386)	509 (66) 454 (288-674)	561 (101) 400 (250-684)	353 (56) 241 (158-414)	0.002
Audio taped # Items discussed	D1 mean (SE), %≥1 item	2.09 (0.50) 78% (18/23)	2.79 (0.63) 79% (19/24)	3.92 (0.66) 88% (21/25)	2.31 (0.43) 79% (23/29)	0.15
	D2 mean (SE), %≥1 item	0.87 (0.11) 78% (18/23)	0.75 (0.14) 63% (15/24)	0.21 (0.09) 21% (5/24)	0.59 (0.09) 59% (17/29)	0.001
	D3 mean (SE), %≥1 item	0.48 (0.17) 35% (8/23)	0.46 (0.16) 29% (7/24)	0.58 (0.17) 42% (10/24)	0.48 (0.14) 38% (11/29)	0.91
	D4 mean (SE), %≥1 item	0.30 (0.15) 22% (5/23)	0.67 (0.21) 42% (10/24)	1.46 (0.41) 54% (13/24)	0.62 (0.19) 45% (13/29)	0.06
	PCI mean (SE), %≥1 item	3.74 (0.60) 100% (23/23)	1.67 (0.83) 92% (22/24)	6.17 (1.06) 92% (22/24)	4.00 (0.56) 97% (28/29)	0.35
	PCI-HP mean (SE), %≥1 item	0.09 (0.06) 9% (2/23)	0.42 (0.16) 29% (7/24)	1.13 (0.26) 63% (15/24)	0.72 (0.15) 55% (16/29)	<0.001
Discussion of	% Cancer treatment	70% (16/23)	54% (13/24)	21% (5/24)	48% (14/29)	0.008
Common items	% FOR	13% (3/23)	33% (8/24)	38% (9/24)	35% (10/29)	0.24
	% Swallowing	26% (6/23)	8% (2/24)	29% (7/24)	41% (12/29)	0.06
	% Dental health/teeth	17% (4/23)	54% (13/24)	21% (5/24)	10% (3/29)	0.002
	% Dry mouth	9% (2/23)	21% (5/24)	25% (6/24)	38% (11/29)	0.10
	% Pain in head/neck	13% (3/23)	17% (4/24)	29% (7/24)	24% (7/29)	0.52
	% Speech/voice/ understood	17% (4/23)	4% (1/24)	29% (7/24)	28% (8/29)	0.10
	% Fatigue/tiredness	9% (2/23)	17% (4/24)	33% (8/24)	14% (4/29)	0.14
Medical actions	% 2 or more	17% (4/23)	46% (11/24)	79% (19/24)	31% (9/29)	<0.001
Non-medical actions	% 3 or more	26% (6/23)	21% (5/24)	38% (9/24)	28% (8/29)	0.63

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.45. Tumour site

		Oral	Oro-pharyngeal	Laryngeal	Other	P value*
Distress	Mean (SE)	1.78 (0.33)	0.94 (0.38)	1.19 (0.52)	2.14 (0.52)	0.09
	%6-10	3% (1/32)	0% (0/18)	10% (2/21)	14% (3/22)	
Post consultation Q # on Q1A	Mean (SE)	1.19 (0.16)	1.89 (0.29)	1.28 (0.20)	1.48 (0.30)	0.25
	% 2 or more	29% (9/31)	56% (10/18)	39% (7/18)	38% (8/21)	
Post consultation Q	% Q2 SA	52% (14/27)	63% (10/16)	53% (8/15)	71% (12/17)	0.62
	% Q3 YES	96% (26/27)	100% (18/18)	100% (20/20)	100% (21/21)	-
	% Q4 SA	44% (14/32)	61% (11/18)	85% (17/20)	50% (11/22)	0.03
	% Q5 SD	38% (12/32)	56% (10/18)	42% (8/19)	52% (11/21)	0.59
	% Q6 SD	42% (13/31)	72% (13/18)	44% (8/18)	64% (14/22)	0.10
Princess Margaret Q score 0-100	Mean (SE)	81.6 (2.1)	81.3 (3.3)	87.9 (2.4)	81.7 (2.4)	0.23
	Median (IQR)	83 (70-91)	82 (68-94)	89 (76-99)	81 (71-93)	
Consultation length	Mean (SE)	384 (47)	498 (68)	323 (49)	524 (124)	0.13
	Median (IQR)	305 (195-499)	434 (218-685)	232 (157-385)	340 (230-504)	
Audio taped # Items discussed	D1 mean (SE), %≥1 item	2.19 (0.50) 72% (23/32)	3.79 (0.69) 88% (21/24)	2.17 (0.38) 83% (20/24)	3.15 (0.63) 85% (17/20)	0.11
	D2 mean (SE), %≥1 item	0.75 (0.11) 66% (21/32)	0.75 (0.12) 67% (16/24)	0.46 (0.10) 46% (11/24)	0.35 (0.11) 35% (7/20)	0.04
	D3 mean (SE), %≥1 item	0.66 (0.17) 38% (12/32)	0.17 (0.08) 17% (4/24)	0.75 (0.14) 63% (15/24)	0.35 (0.17) 25% (5/20)	0.009
	D4 mean (SE), %≥1 item	0.47 (0.16) 31% (10/32)	0.83 (0.27) 42% (10/24)	0.50 (0.16) 38% (9/24)	1.45 (0.46) 60% (12/20)	0.13
	PCI mean (SE), %≥1 item	4.06 (0.66) 94% (30/32)	5.54 (0.89) 88% (21/24)	3.88 (0.49) 100% (24/24)	5.30 (1.12) 100% (20/20)	0.51
	PCI-HP mean (SE), %≥1 item	0.34 (0.13) 22% (7/32)	0.67 (0.16) 54% (13/24)	0.79 (0.20) 50% (12/24)	0.70 (0.27) 40% (8/20)	0.11
Discussion of	% Cancer treatment	63% (20/32)	50% (12/24)	46% (11/24)	25% (5/20)	0.07
Common items	% FOR	25% (8/32)	33% (8/24)	21% (5/24)	45% (9/20)	0.31
	% Swallowing	9% (3/32)	50% (12/24)	29% (7/24)	25% (5/20)	0.009
	% Dental health/teeth	38% (12/32)	38% (9/24)	4% (1/24)	15% (3/20)	0.01
	% Dry mouth	9% (3/32)	46% (11/24)	25% (6/24)	20% (4/20)	0.02
	% Pain in head/neck	16% (5/32)	21% (5/24)	25% (6/24)	25% (5/20)	0.81
	% Speech/voice/ understood	9% (3/32)	8% (2/24)	50% (12/24)	15% (3/20)	<0.001
	% Fatigue/tiredness	13% (4/32)	21% (5/24)	8% (2/24)	35% (7/20)	0.10
Medical actions	% 2 or more	34% (11/32)	54% (13/24)	29% (7/24)	60% (12/20)	0.10
Non-medical actions	% 3 or more	22% (7/32)	33% (8/24)	21% (5/24)	40% (8/20)	0.40

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.46. Overall P stage

		1	2	3	4	P value*
Distress	Mean (SE)	0.86 (0.25)	1.63 (0.48)	2.75 (1.29)	1.96 (0.44)	0.29
	%6-10	0% (0/29)	11% (2/19)	25% (2/8)	7% (2/27)	
Post consultation Q # on Q1A	Mean (SE)	1.07 (0.17)	1.50 (0.28)	1.17 (0.48)	1.67 (0.21)	0.30
	% 2 or more	36% (10/28)	39% (7/18)	33% (2/6)	41% (11/27)	
Post consultation Q	% Q2 SA	64% (14/22)	71% (10/14)	50% (2/4)	42% (11/26)	0.28
	% Q3 YES	100% (26/26)	100% (18/18)	100% (6/6)	96% (25/26)	-
	% Q4 SA	55% (16/29)	63% (12/19)	86% (6/7)	48% (13/27)	0.32
	% Q5 SD	36% (10/28)	42% (8/19)	50% (3/6)	56% (15/27)	0.53
	% Q6 SD	52% (15/29)	56% (10/18)	60% (3/5)	59% (16/27)	0.96
Princess Margaret Q score 0-100	Mean (SE)	85.0 (2.4)	82.9 (2.6)	85.4 (4.7)	80.5 (2.3)	0.54
	Median (IQR)	87 (74-99)	82 (74-93)	83 (75-100)	81 (70-91)	
Consultation length	Mean (SE)	306 (33)	378 (67)	427 (97)	543 (69)	0.04
	Median (IQR)	230 (170-412)	327 (189-427)	327 (142-632)	485 (237-698)	
Audio taped # Items discussed	D1 mean (SE),	1.27 (0.21)	3.17 (0.76)	2.85 (0.90)	4.03 (0.56)	<0.001
	%≥1 item	70% (21/30)	72% (13/18)	85% (11/13)	97% (28/29)	
	D2 mean (SE),	0.53 (0.09)	0.56 (0.15)	0.69 (0.18)	0.76 (0.12)	0.53
	%≥1 item	53% (16/30)	50% (9/18)	62% (8/13)	66% (19/29)	
	D3 mean (SE),	0.73 (0.16)	0.33 (0.14)	0.46 (0.14)	0.21 (0.10)	0.02
	%≥1 item	50% (15/30)	28% (5/18)	46% (6/13)	14% (4/29)	
	D4 mean (SE),	0.60 (0.18)	1.22 (0.36)	0.15 (0.10)	0.72 (0.22)	0.09
	%≥1 item	40% (12/30)	56% (10/18)	15% (2/13)	41% (12/29)	
	PCI mean (SE),	3.13 (0.45)	5.28 (1.05)	4.15 (1.03)	5.72 (0.71)	0.03
	%≥1 item	90% (27/30)	94% (17/18)	92% (12/13)	100% (29/29)	
	PCI-HP mean (SE), %≥1 item	0.63 (0.18) 37% (11/30)	0.28 (0.11) 28% (5/18)	0.69 (0.31) 38% (5/13)	0.69 (0.13) 55% (16/29)	0.31
Discussion of Common items	% Cancer treatment	53% (16/30)	44% (8/18)	54% (7/13)	48% (14/29)	0.93
	% FOR	30% (9/30)	33% (6/18)	8% (1/13)	34% (10/29)	0.32
	% Swallowing	7% (2/30)	39% (7/18)	31% (4/13)	41% (12/29)	0.02
	% Dental health/teeth	13% (4/30)	28% (5/18)	31% (4/13)	34% (10/29)	0.28
	% Dry mouth	10% (3/30)	33% (6/18)	23% (3/13)	34% (10/29)	0.12
	% Pain in head/neck	10% (3/30)	17% (3/18)	31% (4/13)	31% (9/29)	0.18
	% Speech/voice/understood	27% (8/30)	22% (4/18)	15% (2/13)	7% (2/29)	0.23
	% Fatigue/tiredness	3% (1/30)	22% (4/18)	8% (1/13)	24% (7/29)	0.09
Medical actions	% 2 or more	37% (11/30)	33% (6/18)	38% (5/13)	52% (15/29)	0.40
Non-medical actions	% 3 or more	17% (5/30)	17% (3/18)	31% (4/13)	38% (11/29)	0.22

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.47. Years from primary diagnosis to consultation

		<1 year	1.0-2.9 years	≥3.0 years	P value*
Distress	Mean (SE)	1.41 (0.38)	1.67 (0.36)	1.44 (0.37)	0.80
	%6-10	0% (0/17)	9% (4/43)	6% (2/32)	
Post consultation Q # on Q1A	Mean (SE)	1.41 (0.23)	1.71 (0.19)	1.00 (0.16)	0.04
	% 2 or more	47% (8/17)	48% (20/42)	21% (6/28)	
Post consultation Q	% Q2 SA	57% (8/14)	62% (23/37)	52% (12/23)	0.75
	% Q3 YES	100% (15/15)	100% (41/41)	97% (28/29)	-
	% Q4 SA	47% (8/17)	55% (23/42)	66% (21/32)	0.42
	% Q5 SD	59% (10/17)	48% (20/42)	33% (10/30)	0.22
	% Q6 SD	71% (12/17)	60% (24/40)	39% (12/31)	0.10
Princess Margaret Q score 0-100	Mean (SE)	83.9 (2.9)	84.1 (1.9)	80.5 (2.1)	0.39
	Median (IQR)	83 (76-93)	85 (74-95)	77 (69-90)	
Consultation length	Mean (SE)	614 (101)	490 (64)	276 (22)	0.001
	Median (IQR)	543 (211-880)	377 (226-571)	226 (161-386)	
Audio taped # Items discussed	D1 mean (SE), %≥1 item	3.35 (0.92)	3.60 (0.45)	1.64 (0.25)	0.003
		82% (14/17)	88% (38/43)	74% (29/39)	
	D2 mean (SE), %≥1 item	0.71 (0.19)	0.60 (0.09)	0.56 (0.08)	0.91
		53% (9/17)	56% (24/43)	56% (22/39)	
	D3 mean (SE), %≥1 item	0.76 (0.24)	0.47 (0.12)	0.36 (0.09)	0.35
		47% (8/17)	33% (14/43)	33% (13/39)	
	D4 mean (SE), %≥1 item	0.94 (0.36)	0.93 (0.23)	0.51 (0.16)	0.33
		47% (8/17)	47% (20/43)	33% (13/39)	
	PCI mean (SE), %≥1 item	5.76 (1.26)	5.60 (0.64)	3.08 (0.35)	0.004
		88% (15/17)	95% (41/43)	97% (38/39)	
	PCI-HP mean (SE), %≥1 item	0.88 (0.26)	0.72 (0.17)	0.36 (0.09)	0.18
		53% (9/17)	42% (18/43)	33% (13/39)	
Discussion of Common items	% Cancer treatment	41% (7/17)	49% (21/43)	51% (20/39)	0.78
	% FOR	41% (7/17)	33% (14/43)	23% (9/39)	0.36
	% Swallowing	35% (6/17)	33% (14/43)	18% (7/39)	0.24
	% Dental health/teeth	41% (7/17)	28% (12/43)	15% (6/39)	0.11
	% Dry mouth	18% (3/17)	33% (14/43)	18% (7/39)	0.24
	% Pain in head/neck	6% (1/17)	30% (13/43)	18% (7/39)	0.09
	% Speech/voice/understood	18% (3/17)	21% (9/43)	18% (7/39)	0.93
	% Fatigue/tiredness	18% (3/17)	28% (12/43)	8% (3/39)	0.06
Medical actions	% 2 or more	53% (9/17)	53% (23/43)	28% (11/39)	0.04
Non-medical actions	% 3 or more	53% (9/17)	23% (10/43)	23% (9/39)	0.05

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.4. Free-Flap (FF) reconstruction

		No surgery	Surgery without FF	Surgery with FF	P value*
Distress	Mean (SE) %6-10	0.85 (0.37) 0% (0/13)	1.63 (0.30) 8% (5/59)	1.89 (0.45) 6% (1/18)	0.27
Post consultation Q # on Q1A	Mean (SE) % 2 or more	1.92 (0.36) 67% (8/12)	1.25 (0.14) 31% (17/55)	1.44 (0.23) 39% (7/18)	0.12
Post consultation Q	% Q2 SA	50% (5/10)	61% (28/46)	50% (8/16)	0.67
	% Q3 YES	100% (13/13)	98% (52/53)	100% (17/17)	-
	% Q4 SA	69% (9/13)	57% (33/58)	50% (9/18)	0.57
	% Q5 SD	25% (3/12)	45% (26/58)	56% (10/18)	0.08
	% Q6 SD	36% (4/11)	55% (32/58)	59% (10/17)	0.58
Princess Margaret Q score 0-100	Mean (SE) Median (IQR)	87.8 (3.9) 93 (76-100)	82.5 (1.6) 82 (74-93)	80.1 (2.5) 82 (73-91)	0.18
Consultation length	Mean (SE) Median (IQR)	351 (51) 377 (172-547)	411 (51) 310 (184-442)	534 (80) 475 (254-746)	0.08
Audio taped # Items discussed	D1 mean (SE), %≥1 item	3.35 (0.82) 82% (14/17)	2.30 (0.31) 80% (48/60)	3.61 (0.76) 89% (16/18)	0.11
	D2 mean (SE), %≥1 item	0.71 (0.14) 65% (11/17)	0.55 (0.07) 52% (31/60)	0.67 (0.14) 61% (11/18)	0.53
	D3 mean (SE), %≥1 item	0.53 (0.17) 41% (7/17)	0.43 (0.10) 32% (19/60)	0.56 (0.19) 39% (7/18)	0.68
	D4 mean (SE), %≥1 item	0.65 (0.23) 41% (7/17)	0.82 (0.19) 42% (25/60)	0.61 (0.24) 39% (7/18)	0.95
	PCI mean (SE), %≥1 item	5.24 (0.97) 94% (16/17)	4.10 (0.49) 95% (57/60)	5.44 (1.01) 94% (17/18)	0.15
	PCI-HP mean (SE), %≥1 item	0.59 (0.15) 53% (9/17)	0.58 (0.13) 35% (21/60)	0.44 (0.19) 33% (6/18)	0.58
Discussion of Common items	% Cancer treatment	59% (10/17)	47% (28/60)	44% (8/18)	0.63
	% FOR	35% (6/17)	27% (16/60)	33% (6/18)	0.73
	% Swallowing	41% (7/17)	22% (13/60)	28% (5/18)	0.27
	% Dental health/teeth	6% (1/17)	22% (13/60)	56% (10/18)	0.002
	% Dry mouth	47% (8/17)	18% (11/60)	22% (4/18)	0.05
	% Pain in head/neck	24% (4/17)	22% (13/60)	22% (4/18)	0.99
	% Speech/voice/understood	35% (6/17)	17% (10/60)	17% (3/18)	0.22
	% Fatigue/tiredness	18% (3/17)	17% (10/60)	22% (4/18)	0.86
Medical actions	% 2 or more	41% (7/17)	42% (25/60)	44% (8/18)	0.92
Non-medical actions	% 3 or more	24% (4/17)	25% (15/60)	39% (7/18)	0.48

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.49. Primary Treatment

		Surgery only	Surgery + RT/CRT	RT/CRT only	P value*
Distress	Mean (SE)	1.54 (0.30)	1.84 (0.42)	0.85 (0.37)	0.48
	%6-10	5% (2/41)	11% (4/37)	0% (0/13)	
Post consultation Q # on Q1A	Mean (SE)	1.20 (0.15)	1.50 (0.21)	1.92 (0.36)	0.16
	% 2 or more	35% (14/40)	32% (11/34)	67% (8/12)	
Post consultation Q	% Q2 SA	55% (17/31)	63% (20/32)	50% (5/10)	0.73
	% Q3 YES	100% (35/35)	97% (35/36)	100% (13/13)	-
	% Q4 SA	51% (21/41)	58% (21/36)	69% (9/13)	0.51
	% Q5 SD	41% (17/41)	54% (19/35)	25% (3/12)	0.07
	% Q6 SD	56% (23/41)	57% (20/35)	36% (4/11)	0.55
Princess Margaret Q score 0-100	Mean (SE)	82.6 (1.9)	80.8 (1.8)	87.8 (3.9)	0.19
	Median (IQR)	82 (74-94)	82 (72-91)	93 (76-100)	
Consultation length	Mean (SE)	357 (40)	526 (73)	351 (51)	0.22
	Median (IQR)	317 (181-483)	393 (226-727)	377 (172-547)	
Audio taped # Items discussed	D1 mean (SE), %≥1 item	2.26 (0.47)	3.00 (0.36)	3.35 (0.82)	0.08
		72% (28/39)	93% (38/41)	82% (14/17)	
	D2 mean (SE), %≥1 item	0.59 (0.10)	0.59 (0.09)	0.71 (0.14)	0.73
		54% (21/39)	54% (22/41)	65% (11/17)	
	D3 mean (SE), %≥1 item	0.62 (0.13)	0.29 (0.10)	0.53 (0.17)	0.09
		44% (17/39)	22% (9/41)	41% (7/17)	
	D4 mean (SE), %≥1 item	0.82 (0.19)	0.80 (0.25)	0.65 (0.23)	0.65
		49% (19/39)	37% (15/41)	41% (7/17)	
	PCI mean (SE), %≥1 item	4.28 (0.65)	4.68 (0.60)	5.24 (0.98)	0.46
		90% (35/39)	100% (41/41)	94% (16/17)	
	PCI-HP mean (SE), %≥1 item	0.46 (0.15)	0.68 (0.15)	0.59 (0.15)	0.19
		26% (10/39)	46% (19/41)	53% (9/17)	
Discussion of Common items	% Cancer treatment	54% (21/39)	39% (16/41)	59% (10/17)	0.27
	% FOR	41% (16/39)	20% (8/41)	35% (6/17)	0.11
	% Swallowing	18% (7/39)	29% (12/41)	41% (7/17)	0.18
	% Dental health/teeth	28% (11/39)	32% (13/41)	6% (1/17)	0.11
	% Dry mouth	8% (3/39)	29% (12/41)	47% (8/17)	0.003
	% Pain in head/neck	23% (9/39)	20% (8/41)	24% (4/17)	0.91
	% Speech/voice/understood	21% (8/39)	12% (5/41)	35% (6/17)	0.13
	% Fatigue/tiredness	15% (6/39)	22% (9/41)	18% (3/17)	0.75
Medical actions	% 2 or more	38% (15/39)	49% (20/41)	41% (7/17)	0.44
Non-medical actions	% 3 or more	23% (9/39)	34% (14/41)	24% (4/17)	0.50

*Chi-squared test for Post consultation Q3, discussion of common items; otherwise Kruskal-Wallis test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

Table 7.50. Diagnosis

		SCC	Other	P value*
Distress	Mean (SE)	1.49 (0.24)	1.94 (0.55)	0.33
	%6-10	5% (4/77)	13% (2/16)	
Post consultation Q	Mean (SE)	1.38 (0.13)	1.60 (0.27)	0.45
# on Q1A	% 2 or more	38% (28/73)	40% (6/15)	
Post consultation Q	% Q2 SA	54% (33/61)	79% (11/14)	0.10
	% Q3 YES	99% (71/72)	100% (14/14)	-
	% Q4 SA	57% (43/76)	63% (10/16)	0.67
	% Q5 SD	46% (34/74)	44% (7/16)	0.91
	% Q6 SD	55% (40/73)	50% (8/16)	0.85
Princess Margaret	Mean (SE)	83.1 (1.4)	81.9 (2.8)	0.67
Q score 0-100	Median (IQR)	84 (74-9)	81 (72-88)	
Consultation	Mean (SE)	404 (33)	519 (128)	0.45
Length (sec)	Median (IQR)	322 (189-518)	365 (231-463)	
Audio taped	D1 mean (SE), %≥1 item	2.61 (0.31)	3.44 (0.62)	0.10
# Items discussed		78% (64/82)	94% (17/18)	
	D2 mean (SE), %≥1 item	0.65 (0.06)	0.39 (0.14)	0.06
		60% (49/82)	33% (6/18)	
	D3 mean (SE), %≥1 item	0.52 (0.09)	0.39 (0.18)	0.40
		38% (31/82)	28% (5/18)	
	D4 mean (SE), %≥1 item	0.61 (0.11)	1.44 (0.51)	0.10
		38% (31/82)	56% (10/18)	
	PCI mean (SE), %≥1 item	4.39 (0.40)	5.67 (1.12)	0.35
		94% (77/82)	100% (18/18)	
	PCI-HP mean (SE), %≥1 item	0.60 (0.09)	0.61 (0.29)	0.57
		41% (34/82)	33% (6/18)	
Discussion of	% Cancer treatment	51% (42/82)	33% (6/18)	0.20
Common items	% FOR	28% (33/82)	39% (7/18)	0.40
	% Swallowing	27% (22/82)	28% (5/18)	>0.99
	% Dental health/teeth	24% (20/82)	28% (5/18)	0.77
	% Dry mouth	23% (19/82)	28% (5/18)	0.76
	% Pain in head/neck	21% (17/82)	22% (4/18)	>0.99
	% Speech/voice/understood	21% (17/82)	17% (3/18)	>0.99
	% Fatigue/tiredness	15% (12/82)	33% (6/18)	0.09
Medical actions	% 2 or more	41% (34/82)	50% (9/18)	0.36
Non-medical actions	% 3 or more	28% (23/82)	28% (5/18)	0.98

*Fishers exact test for Post consultation Q3, discussion of common items; otherwise Mann-Whitney test using numerical/ordinal values

SE: Standard Error of mean. IQR: inter-quartile range

SA: Strongly Agree, SD: Strongly Disagree.

D1: Physical and functional wellbeing, D2: Treatment related, D3: Social care and social wellbeing, D4: Psychological emotional and spiritual wellbeing, PCI: total of PCI items, PCI-HP total of health professionals.

Q1A: From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Q2: How would you rate the extent to which these concerns were addressed? Q3: Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation? Q4: To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit? Q5: To what degree would you agree to the statement: I felt the PCI was intrusive? Q6: To what degree would you agree to the statement: I felt the PCI was unhelpful?

7.8.7. Pattern of consultations pre-intervention versus intervention

Analysis was undertaken to determine the level of agreement between what patients selected on the HN-PCI and what was discussed at the consultation. Individual data were analysed from Blocks 2 and 3 separately. To facilitate analysis, the raw data was classified into 4 categories: YY: item selected on HN-PCI and discussed; YN: item selected on HN-PCI but not discussed; NY: item not selected on HN-PCI but discussed, and NN: item not selected on HN-PCI and was not discussed. Kappa coefficient of agreement and McNemar test for paired proportions were calculated.

Generally, the kappa values for items of concern were low across both Blocks 2 and 3, indicating a weak level of agreement between items selected by patient on HN-PCI and those being discussed (**Table 7.51**). When the HN-PCI items were summarised based on their domains, the overall agreement between selection of an item and discussion was only fair to moderate; there was some evidence of greater agreement in Block 3 than in Block 2 (**Table 7.52**).

In Block 2, the median (IQR) of the 27 HN-PCI item kappa values was 0.25 (0.02-0.48). For Block 3, the median (IQR) of 44 item kappa values was 0.42 (0.24-0.49), and when the same 27 items as Block 2 were considered, the median score was also 0.42 (0.27-0.49). Of these 27 items with kappa values in both Blocks 2 and 3, the kappa for block 3 was higher for 16 items, was the same for 1 and was lower for 10 items, median (IQR) difference in kappa values between blocks was 0.05 (-0.07 to 0.34) Wilcoxon related samples test p=0.05.

Further evaluation was undertaken on the data where the largest disagreement had occurred between patient-selected data and the discussion data i.e. the NY and YN subgroups using the McNemar test for paired proportions within a two-by-two table. In general, analysis was difficult due to the gaps introduced by the less common HN-PCI items within the tables particularly in Block 2 (**Table 7.53**).

The relationship between the numbers of items selected grouped into domains with the items discussed was considered. The results are shown in Tables **7.54**. When no items were selected, there was a greater likelihood of domain-related items being discussed in Block 3 as compared with Block 2 for the following domains: Physical and Functional wellbeing (56%, 10/18 versus 67%, 22/33), Social care and social well-being (27%, 14/51 versus 33%, 28/85) and Psychological/emotional and spiritual well-being (10%, 4/39 versus 25%, 14/55), but less so for Treatment-related domain (67%, 35/52 versus 53%, 47/89). In regard to professionals selected, overall, there was a total lack of agreement between what was selected by patients and what was discussed (Table 7.54.). Details of the numbers selected and discussed are shown in Table 7.55. A similar trend for request for healthcare selected by patients and those discussed with that seen with items of concern detailed above.

Table 7.51. Agreement between items selected by patient on HN-PCI and those discussed (continued next page)

	BLOCK 2						BLOCK 3					
	NN	YN	NY	YY	Kappa	McNemar P	NN	YN	NY	YY	Kappa	McNemar P
ANY D1: Physical and functional well-being	8	7	10	30	0.27	0.63	11	8	22	59	0.24	0.02
Activity	51	1	2	1	0.37	>0.99	82	-	15	3	0.25	<0.001
Appetite	55	-	-	-	-	-	91	2	1	6	0.78	>0.99
Breathing	52	2	1	-	-0.03	>0.99	93	1	3	3	0.58	0.63
Bowel habit (diarrhoea/constipation)	51	1	1	2	0.65	>0.99	93	2	1	4	0.71	>0.99
Chewing/eating	39	6	5	5	0.53	>0.99	77	7	7	9	0.48	>0.99
Coughing	54	-	1	-	-	-	83	8	6	3	0.22	0.79
Dental health/teeth	37	3	8	7	0.44	0.23	70	5	17	8	0.30	0.02
Dry mouth	45	5	-	5	0.62	0.06	66	10	7	17	0.55	0.63
Energy levels	53	1	1	-	-0.02	>0.99	86	4	5	5	0.48	>0.99
Fatigue/tiredness	46	9	-	-	-	-	73	9	5	13	0.56	0.42
Hearing	46	5	1	3	0.45	0.22	89	5	1	5	0.60	0.22
Indigestion	54	1	-	-	-	-	95	4	-	1	0.33	0.13
Mobility	49	2	4	-	-0.05	0.69	92	5	2	1	0.19	0.45
Mouth opening	46	8	1	-	-0.03	0.04	85	5	3	7	0.59	0.73
Mucus production	46	6	2	1	0.13	0.29	89	5	-	6	0.68	0.06
Nausea	55	-	-	-	-	-	98	1	1	-	-0.01	>0.99
Pain in head and neck	43	3	7	2	0.19	0.34	73	6	10	11	0.48	0.45
Pain elsewhere	49	3	2	1	0.24	>0.99	88	7	3	2	0.24	0.34
Regurgitation	54	1	-	-	-	-	98	2	-	-	-	-
Salivation	48	5	2	-	-0.06	0.45	85	10	2	3	0.28	0.04
Shoulder	49	4	1	1	0.25	0.38	85	8	4	3	0.27	0.39
Sleeping	52	3	-	-	-	-	82	13	2	3	0.23	0.007
Smell	55	-	-	-	-	-	99	-	-	1	-	-
Sore mouth	47	4	1	3	0.50	0.38	80	6	8	6	0.38	0.79
Swallowing	43	4	5	3	0.31	>0.99	66	7	12	15	0.49	0.36
Swelling	46	5	1	3	0.45	0.22	88	3	5	4	0.46	0.73
Taste	52	1	1	1	0.48	>0.99	88	7	1	4	0.46	0.07
Vomiting/sickness	55	-	-	-	-	-	100	-	-	-	-	-
Weight	46	3	5	1	0.12	0.73	84	4	6	6	0.49	0.75

	BLOCK 2						BLOCK 3					
	NN	YN	NY	YY	Kappa	McNemar		NN	YN	NY	YY	Kappa
ANY D2: Treatment related	17	1	35	2	0.00	<0.001	42	3	47	8	0.07	<0.001
Cancer treatment	21	-	33	1	0.02	<0.001	50	2	43	5	0.07	<0.001
Regret about treatment	55	-	-	-	-	-	100	-	-	-	-	-
PEG tube	53	1	-	1	0.66	>0.99	94	1	4	1	0.27	0.38
ANY D3: Social care and social well-being	37	-	14	4	0.28	<0.001	57	7	28	8	0.13	0.001
Carer	54	-	1	-	-	-	96	-	4	-	-	-
Dependants/children	55	-	-	-	-	-	96	-	4	-	-	-
Financial / benefits	55	-	-	-	-	-	97	1	1	1	0.49	>0.99
Home care/district nurse support	54	-	1	-	-	-	99	-	1	-	-	-
Lifestyle issues (smoking/alcohol)	49	-	6	-	-	-	89	-	10	1	0.15	0.002
Recreation	52	-	3	-	-	-	94	-	6	-	-	-
Relationships	55	-	-	-	-	-	97	1	1	1	0.49	>0.99
Speech/voice/being understood	46	2	5	2	0.30	0.45	75	5	16	4	0.17	0.03
Support for my family	55	-	-	-	-	-	97	3	-	-	-	-
ANY D4: Psychological emotional and spiritual well-being	35	13	4	3	0.10	0.05	41	18	14	27	0.35	0.60
Appearance	52	1	1	1	0.48	>0.99	90	3	5	2	0.29	0.73
Angry	53	2	-	-	-	-	96	1	2	1	0.39	-
Anxiety	52	1	2	-	-0.03	>0.99	84	4	7	5	0.42	0.55
Coping	54	-	1	-	-	-	92	-	8	-	-	-
Depression	54	1	-	-	-	-	94	2	1	3	0.65	>0.99
Fear of the cancer coming back	46	6	2	1	0.13	0.29	56	14	11	19	0.42	0.69
Fear of adverse events	54	-	1	-	-	-	96	3	1	-	-0.02	0.63
Intimacy	53	2	-	-	-	-	98	2	-	-	-	-
Memory	52	3	-	-	-	-	92	6	-	2	0.38	0.03
Mood	51	4	-	-	-	-	93	2	3	2	0.42	>0.99
Self-esteem	55	-	-	-	-	-	98	1	-	1	0.66	>0.99
Sexuality	54	1	-	-	-	-	99	1	-	-	-	-
Spiritual /religious aspects	55	-	-	-	-	-	98	1	1	-	-	-
Temperament and personality	55	-	-	-	-	-	97	1	1	1	0.49	>0.99
Anything else	33	2	18	2	0.05	<0.001	54	2	42	2	0.01	<0.001

Table 7.52. Summary of the level of agreement between items selected by patient on HN-PCI and those discussed based on HN-PCI domains

	BLOCK 2						BLOCK 3					
	NN	YN	NY	YY	Kappa	95% CI kappa	NN	YN	NY	YY	Kappa	95% CI kappa
D1: Physical and functional well-being	1418	86	52	39	0.32	0.21-0.43	2478	146	127	149	0.47	0.41-0.53
D2: Treatment related	180	1	37	2	0.07	0-0.34	336	4	53	7	0.16	0-0.36
D3: Social care and social well-being	475	2	16	2	017	0-0.55	840	10	43	7	0.19	0-0.40
D4: Psychological emotional and spiritual well-being	740	21	7	2	0.11	0-0.43	1283	41	40	36	0.44	0.32-0.56
D1-D4 total # items	2813	110	112	45	0.25	0.16-0.35	4937	201	263	199	0.42	0.37-0.47

Table 7.53. Numbers of items selected by patients and the items discussed by domains

			Physical and functional well-being: Items discussed												
			0	1	2	3	4	5	6	7	8	9	11	14	Total
BLOCK 2: HN-PCI completed but retained by researcher and not seen by doctor	Physical and functional well-being: Items selected	0	8	6	3	-	-	-	1	-	-	-	-	-	18
		1	1	2	3	-	-	-	-	-	-	-	-	-	6
		2	3	6	1	2	-	-	-	-	-	-	-	-	12
		3	1	2	-	2	1	-	-	-	-	-	-	-	6
		4	1	1	2	-	2	1	-	-	-	-	-	-	7
		6	-	-	-	-	1	-	-	1	-	-	-	-	2
		7	1	-	-	-	1	-	-	-	-	-	-	-	2
		8	-	-	-	-	1	-	-	-	-	-	-	-	1
		15	-	-	1	-	-	-	-	-	-	-	-	-	1
		Total	15	17	10	4	6	1	1	1	-	-	-	-	55
BLOCK 3: HN-PCI completed and given to doctor before consultation	Physical and functional well-being: Items selected	0	11	10	5	3	3	1	-	-	-	-	-	-	33
		1	4	5	1	1	-	-	-	-	-	-	-	-	11
		2	1	2	5	3	4	-	-	-	-	-	-	-	15
		3	2	1	2	4	1	-	1	1	-	-	-	-	12
		4	-	-	1	-	-	-	-	-	-	-	1	-	2
		5	-	1	-	-	2	2	-	-	-	1	-	-	6
		6	-	1	-	-	-	-	-	-	1	-	-	-	2
		7	1	-	1	1	-	1	2	1	-	1	-	-	8
		8	-	2	-	-	1	1	-	-	-	-	-	-	4
		10	-	1	-	1	-	-	-	-	-	-	-	-	2
		11	-	-	-	-	-	-	-	-	-	-	1	1	2
		12	-	-	-	-	-	-	1	-	-	-	1	-	2
		14	-	-	-	-	1	-	-	-	-	-	-	-	1
		Total	19	23	15	13	12	5	4	2	1	2	3	1	100

			Treatment related: Items discussed			
			0	1	2	Total
BLOCK 2: HN-PCI completed but retained by researcher and not seen by doctor	Treatment related: Items selected	0	17	34	1	52
		1	1	1	1	3
		Total	18	35	2	55
BLOCK 3: HN-PCI completed and given to doctor before consultation	Treatment related: Items selected	0	42	45	2	89
		1	3	5	3	11
		Total	45	50	5	100

			Social care and social wellbeing: Items discussed				
			0	1	2	3	Total
BLOCK 2 HN-PCI completed but retained by researcher and not seen by doctor	Social care and social wellbeing: Items selected	0	37	14	-	-	51
		1	-	4	-	-	4
		Total	37	18	-	-	55
BLOCK 3: HN-PCI completed and given to doctor before consultation	Social care and social wellbeing: Items selected	0	57	20	7	1	85
		1	6	5	1	1	13
		2	1	-	-	1	2
		Total	64	25	8	3	100

			Psychological emotional and spiritual wellbeing: Items discussed							
			0	1	2	3	4	5	8	Total
BLOCK 2: HN-PCI completed but retained by researcher and not seen by doctor	Psychological emotional and spiritual wellbeing: Items selected	0	35	4	-	-	-	-	-	39
		1	8	1	-	-	-	-	-	9
		2	5	1	-	1	-	-	-	7
		Total	48	6	-	1	-	-	-	55
BLOCK 3: HN-PCI completed and given to doctor before consultation	Psychological emotional and spiritual wellbeing: Items selected	0	41	11	3	-	-	-		55
		1	14	12	3	1	-	1	-	31
		2	1	2	1	-	1	-	-	5
		3	1	-	-	1	1	-	1	4
		4	1	-	-	1	-	-	-	2
		5	-	-	1	-	-	1	-	2
		6	1	-	-	-	-	-	-	1
		Total	59	25	8	3	2	2	1	100

Table 7.54. Agreement between professionals selected on HN-PCI by patients and what was discussed

	BLOCK 2						BLOCK 3					
	NN	YN	NY	YY	Kappa	McNemar P	NN	YN	NY	YY	Kappa	McNemar P
Chaplain	55	-	-	-	-	-	100	-	-	-	-	-
Clinical nurse specialist	51	-	4	-	-	-	74	3	23	-	-0.06	<0.001
Dental hygienist	54	-	1	-	-	-	98	1	1	-	-	-
Dentist	45	3	7	-	-0.08	0.34	92	4	4	-	-0.04	>0.99
Dietician	53	-	2	-	-	-	95	2	3	-	-0.03	>0.99
Nursing staff	54	1	-	-	-	-	98	-	2	-	-	-
Occupational therapist	55	-	-	-	-	-	100	-	-	-	-	-
Oral rehabilitation team	53	1	1	-	-	-	99	-	1	-	-	-
Physiotherapist	50	1	4	-	-0.03	0.38	94	3	3	-	-0.03	>0.99
Radiotherapist/oncologist	52	2	1	-	-0.03	>0.99	98	2	-	-	-	-
Speech and language therapist	54	1	-	-	-	-	94	1	5	-	-0.02	0.22
Social worker	55	-	-	-	-	-	100	-	-	-	-	-
Surgeon	47	8	-	-	-	-	86	14	-	-	-	-
Family doctor	46	2	7	-	-0.06	0.18	84	4	10	2	0.16	0.18
Clinical psychologist	54	1	-	-	-	-	96	2	2	-	-0.02	>0.99
Emotional support therapist	55	-	-	-	-	-	96	-	3	1	0.39	0.25
Anyone else	46	-	9	-	-	-	84	3	13	-	-0.05	0.02

Table 7.55. Numbers of healthcare professionals selected by patients and the items discussed by domains

			Number of Health professionals: Items discussed					
			0	1	2	3	5	Total
BLOCK 2: HN-PCI completed but retained by researcher and not seen by doctor	Number of Health professionals selected	0	23	8	4	1	-	36
		1	10	8	-	-	-	18
		2	1	-	-	-	-	1
		Total	34	16	4	1	-	55
BLOCK 3: HN-PCI completed and given to doctor before consultation	Number of Health professionals selected	0	42	22	6	2	-	72
		1	13	3	2	2	1	21
		2	3	1	-	-	-	4
		3	1	1	-	-	-	2
		4	1	-	-	-	-	1
		Total	60	27	8	4	1	100

7.9. Discussion

7.9.1. Main findings of the study

This study achieved its primary aim by demonstrating that the HN-PCI can be successfully introduced in a population of doctors and patients who were unfamiliar with the tool, its handling and the practical elements of its usage in routine outpatient clinics.

The results showed that HN-PCI was able to help patients disclose their concerns during their visits, enable doctors to deliver a patient-centred consultation by addressing their specific concerns during clinic visits, while maintaining the usual medical and non-medical outputs expected during routine outpatient clinic consultations. In general, the introduction of the HN-PCI had generated a trend towards an increase in the number of concerns discussed in clinic when compared to control consultations. Furthermore, the types of concerns discussed had changed with the intervention. Higher numbers of items within the Psychological/ emotional and spiritual well-being domain were discussed in the HN-PCI intervention groups, suggesting that a broader range of expressed concerns were addressed in clinic as a result of this intervention. With the HN-PCI intervention, doctors were fair to moderately more likely to take on the patient's agenda for discussion during consultation by addressing the items selected on the HN-PCI compared with non-HN-PCI facilitated consultations. These findings were achieved with a trend towards longer consultations, and a higher usage of medical interventions. When HN-PCI driven consultations were analysed in more detail, it was observed that the characteristics of the consultations were significantly associated with certain clinical factors. Following the consultation, patient having the HN-PCI intervention had higher scores of satisfaction with consultations than those without. Furthermore, the HN-PCI intervention group also reported higher levels of agreement with statements indicating that the consultation had fulfilled their expectations. There was good acceptance of the HN-PCI, where patients did not find the HN-PCI intrusive.

This study also demonstrated that the HN-PCI was able to indirectly predict patients who experienced distress based on the number of items selected. However, this study did not find any indications that the HN-PCI could reliably inform clinicians about the patient's perceived need for supportive care services.

Study limitations

Before the specific study findings are discussed, the limitations of this study are presented. Firstly, the study design did not include randomisation at patient recruitment. While randomisation was considered initially, it was felt that this process could significantly disrupt the flow of busy outpatients clinics, which could impact negatively on study recruitment uptake (doctors and patients). Furthermore, recruitment difficulties were expected with randomization because many patients attend regularly and see a designated doctor, usually the surgeon who provided their cancer treatment. Furthermore, the study was undertaken across two different sites. Due to these restrictions, randomisation was abandoned. To provide a control population against the HN-PCI intervention, the study design included the 'normal' consultation group i.e. Block 1. This Block was done at the start of the study to avoid cross-contamination of patients in the successive intervention phase as they return for their repeat visits to the clinic.

Secondly, the recruitment numbers to the study did not reach the target numbers indicated by sample size calculation, and is therefore under-powered. This is particularly evident in Block 2, where the recruited number (n, 78) was less than Blocks 1 (n, 136) and Block 3 (n, 111). The practical decision to stop recruitment and proceed into Block 3 from Block 2 was made due to time pressures to facilitate study completion. Furthermore, it was thought that shortening Block 2 would not impact significantly to the study as the purpose of this Block was to provide control in attention i.e. introduce the HN-PCI to patients, without it being exposed to the doctor in the actual consultation.

Thirdly, there is a lack of data from eligible patients who were not recruited to the study. Thus, it is not possible to comment if these patients were significantly different from those recruited, and if this has introduced a bias to the overall results of this study. This data was not included in this current work due to incomplete data in some of the parameters. Fourthly, there was data loss of those recruited to the study due to failure to audiorecord the consultation. The main reason for this was the ‘surgeon forgetting to record the consultation’. This was particularly significant in Block 1, where there was also the problem of seeing the wrong doctor i.e. one not involved in this study.

Fourthly, assessor bias may have been introduced during the assessment of the recorded consultations. It was not possible to blind the assessors to the consultation in the respective blocks because of how the HN-PCI would have been used during the consultation i.e. the HN-PCI would have been referenced explicitly by the doctor during the consultations in Block 3. Therefore, a decision was made to undertake the evaluation of the recorded consultation in order of recruitment.

Finally, the statistical analysis undertaken in this study involved large number of tests. There were also noticeable gaps in the HN-PCI data due to the inherent nature of some concerns being relatively less commonly expressed by patients. While the accepted statistical level of significance was set to $p<0.01$, interpretations of statistical analysis also included results with borderline statistical significance i.e. $0.01<p<0.10$ when this allowed demonstration of trends of clinical significance. Thus, the results presented must not be over-estimated.

Objectives of the study

a. *“What constitutes a normal HNC outpatient consultation?”*

This study describes aspects of a ‘normal’ consultation i.e. before HN-PCI intervention. Without the HN-PCI intervention, it is likely that this group represents the typical consultation that occurs in routine HNC FU clinics. This finding provides formative baseline data because this has never been previously explored, particularly in a large cohort (n, 111). The post-treatment survivors attending these clinics were at 2.2 years post-diagnosis (mean), had low levels of distress (mean DT score 2.7), and reported reasonably good HRQOL/UWQOL scores (mean, Physical function subscale, 76.3; Social/Emotional subscale 75.8; current HRQOL compared to pre-diagnosis, 56.1; HRQOL in the past 7 days, 61.3; QOL in the past 7 days, 64.4). The median length of clinic consultation was 268 seconds (4.5 minutes), and the median (IQR) number of items of concern discussed during consultation was 3 (2-5). The median (IQR) number of professionals requested per visit was 0 (0-1).

The Physical and functional well-being domain was the domain that had the types of concerns most frequently discussed. The five most common item of concern discussed was General wellbeing (82%), ‘Anything else’ (55%), Cancer treatment (53%), Pain in head and neck (28%) and Swallowing (24%). There was a range of professionals whom patients requested for referral/input, the most common being the oral rehabilitation specialist, family doctor and the CNS. All patients received medical and non-medical input during the visit. After the consultation, patients reported a lesser level of distress compared to pre-consultation level (mean DT score, 1.9) and on average, recalled discussing 1 item of concern (median, 1; IQR, 0-2) that they wanted to discuss at consultation.

A previous small, observational study of consultations in routine HNC FU clinics (n, 25) without the adjunctive use of HN-PCI [**Ghazali et al, 2013B**] provided valuable data for comparison. Interestingly, the results obtained from the two cohorts were not markedly different overall. The median length of control consultation in the observational study was 5.3 minutes (IQR, 3.2-8.1), which is comparable to 4.5 minutes (IQR, 3.2- 6.7) noted in this study. When mean lengths of consultations were considered, both the observational study (5.4 minutes) and the current study (5.9 minutes) were considerably shorter than that reported in **Fagerlind et al [2008]**’s study of consultations in routine gastrointestinal oncology clinics, where longer consultation times were noted i.e. mean length, 19 minutes (range, 9-36).

Regarding the number of concerns discussed, the median (IQR) number identified during consultation in this current cohort was 3 (2-5), which was slightly higher than 2 (1-3) reported in the observational study [**Ghazali et al, 2013B**]. While both cohorts commonly requested referrals to the oral rehabilitations specialist, the observational study cohort also requested input by the dietitian, physiotherapist, speech therapist and radiotherapist as opposed to the current cohort who requested the family doctor and CNS. The difference may represent the slightly different supportive care needs between the two cohorts, where the current study includes a wider range of primary cancer sites, including larynx and thyroid, as compared with the pilot study, which is predominantly composed of oral cavity cancers.

In this current study, patients recalled having discussed much less concerns (mean, 0.87; median, 1) compared with the numbers of concerns actually discussed (mean, 3.64; median, 3). The difference may be accounted for by incomplete recall of conversations by patients, including misinformation due to memory lapses and/or may be distorted when sensitive issues were discussed, by the addition of items from the doctor's agenda, and the inclusion of 'General wellbeing' as an item based on the thematic framework-based assessment of consultations [**Ghazali et al, 2013A]**. The presence of this theme during consultation was also recognised by **Fagerlind et al [2008]**'s study. Overall, doctors have interest in acquiring information about the patients' general well-being and in non-medical areas of their lives and often spend time on this during clinic visits [**Velikova et al, 2008]**. 'General wellbeing' covers themes of general welfare or condition, which can represent common salutations that help initiate or begin conversations, facilitating the subsequent discussions during the visit. This theme also covers topics discussed based on pre-existing rapport already established between doctor and patient from previous visits i.e. 'catching up' [**Ghazali et al, 2013A**]. Thus, it is unsurprisingly the most common item discussed during consultation (82%) in this study.

'Anything else' (55%) and 'Cancer treatment' (53%) were the next two most common themes discussed. The finding of 'Cancer treatment' being the most common item for discussion in routine FU clinics was also reported previously in the observational study [**Ghazali et al, 2013B]**. Even after the HN-PCI was introduced to that cohort, 'Cancer treatment' was still discussed significantly during consultation despite the item not being selected by patients. This suggests that this topic of discussion may have been initiated by the doctor in keeping with their focus is on disease and treatment [**Fagerlind et al, 2008; Rodriguez et al, 2010]**. Such topics are known to form the largest proportion of consultation time [**Fagerlind et al, 2008; Detmar et al, 2001**]. The doctor's agenda is composed of undertaking discussions on treatment response, its adverse effects and management, and also undertaking physical examination relating to cancer recurrence and wounds. This is sometimes pursued at the expense of psychosocial issues even when doctors have access to HRQOL-based PROs filled by patients prior to their consultations [**Detmar et al, 2002**]. This finding suggests that a typical routine oncology FU clinic consultation is generally doctor/physician-led rather than patient-centred.

The theme of ‘Anything else’, which was commonly discussed, reveals the potential limitless types of concerns that could be discussed during routine FU clinics that are not found on the HN-PCI checklist. This finding was not noted in the pilot observational study referenced previously [**Ghazali et al, 2013A**]. This was probably due to the difference of methodology where the previous study only used the items present on the HN-PCI checklist (n, 55) to evaluate the items discussed during consultation.

b. “Has the HN-PCI intervention changed outcomes of clinic?”

Clinic outputs: One of the criticisms of routine adoption of PROs in routine clinical practice is the lack of data demonstrating that its usage has translated into a clinically meaningful outcome and it does not influence patient care [**Greenhalgh et al, 2005; Luckett et al, 2009**]. This study hypothesised that the HN-PCI intervention would cause an increase in clinical outputs. Study findings agree with the study hypothesis as the HN-PCI intervention had significantly increased the number of clinical outcomes (**Table 7.19**) and also showed a trend for lower distress levels post-consultation, and a significant increase in patient-reported satisfaction with consultations in HN-PCI intervention groups.

The rationale for measuring clinical outputs in this study was based on the assumption that HN-PCI information can influence on clinical decision-making by measuring the clinical outcomes. The clinical outputs following HN-PCI intervention has to be taken in context of the usual temporal structure of clinic visit i.e. a routine oncology outpatient visit begins with identifying the reasons for the visit, updating patient’s medical history, undertaking a physical examination and conclusion of the visit with discussions about treatment, requirement for investigations, arranging FU and possible referrals to other healthcare professionals [**Clayton & Dudley, 2009**]. The data showed that all patients underwent physical examination as part of their consultation (**Table 7.20**), which is reassuring for patients because in some ways it addressed their concerns and FOR [**Ghazali et al, 2013C; Clayton & Dudley, 2009**]. With this considered, there was still notably higher numbers of medical actions undertaken in the HN-PCI intervention groups when compared with control (p=0.03) (**Table 7.19**). The increased medical actions may be associated to higher numbers of referrals and investigation requests with

HN-PCI intervention, especially in Block 3 (**Table 7.20**). In a randomised controlled trial, **Velikova et al [2004]** investigated the influence of HRQOL data in routine oncology practice and reported that while doctors reported PRO data contributed to management decisions in only 11% while indicating this data to be useful in > 90% of intervention encounters. **Greenhalgh et al [2005]** notes that the impact of routine use of HRQOL data on clinical decision-making may be more prominent among cancer patients who are undergoing care with palliative rather than curative intent.

On the other hand, there were no discernable changes relating to non-medical actions with HN-PCI intervention. The vast majority of patients had reassurances and their next FU arranged during their visit. Based on a content analysis study of routine oncology consultations, **Clayton & Dudley [2009]** suggested that "reassurances conversations", which involved offering, giving and seeking reassurance, occurred regularly in consultations. Interestingly, they found that the more specificity of the patients plan for discussion with the doctor, the less likely the overall discussion time is spent in illness exploration and in reassurances. Time spent exploring and understanding the patient within the context of their life was a significant factor that enhances patient's perception of patient-centredness approach to the visit. In a study of routine use of HRQOL in nurse-led chemotherapy outpatient clinics, **Hilarius et al [2008]** found that the intervention resulted in modest changes in patient management by nurses relating to counselling behavior.

Evaluation of PROs in routine oncology clinical settings has largely focused on measuring HRQOL status as an outcome [**Velikova et al, 2004**; **Rosenbloom et al, 2008**; **Hilarius et al, 2008**]. However, this health status was not chosen for this study because most HRQOL tools measure health status within the 7 days and because patients complete the UWQOL questionnaire on the day of consultation and the HN-PCI intervention was assessed as a single event rather than longitudinally, repeating the UWQOL post-consultation would not provide a meaningful assessment due to the overlap of timings. Instead, we evaluated patient distress as an outcome following the HN-PCI intervention as a tool to help disclose concerns. This is based on evidence indicating higher distress levels in cancer patients are related to unmet needs, which are often missed because they were not enquired about or disclosed. While the distress levels were generally low after consultations, there was a trend towards lower distress levels being recorded in HN-PCI intervention group compared with the control group. The mean DT score (median; IQR) for the control group was 1.9 (1; 0-3), for Block 2 was 1.8 (1; 0-3) and in Block 3 was 1.6 (1; 0-3) (p=0.52). Furthermore, these scores were generally lower that the mean scores reported at baseline in all blocks i.e. control group was 2.7 (2; 0-5), Block 2 was 2.5 (2; 0-5) and Block 3 was 3.0 (2; 0-5). It is possible that this observation may be influenced by the increasing length of time taken to complete the patient-reported outcomes consultation (PROC) from the date of consultation with successive blocks. The mean days between completion of PROC and day of consultation was 0.73 days (median, 1; IQR, 0-1), in Block 2 was 1.06 (1; 0-1) and in Block 3 was 1.63 (1; 0-2) (p=0.005).

Patient satisfaction: Patient satisfaction is the most recognised and widely used measure for gauging the effectiveness of patient-doctor communication [**Ong et al, 2000; Takayama et al, 2001**], particularly patient-centred interventions [**Epstein et al, 2005**; **Fung & Hays, 2008**]. The Princess Margaret Satisfaction with Physician questionnaire (PSQ-MD) was used in this study because the questionnaire was specifically developed for evaluating satisfaction with consultations in the oncology setting. An overall score was calculated from the responses ranging from 0 (worse) to 100 (best). In addition, non-validated questionnaire was also used.

This study hypothesised that patient satisfaction scores will improve with HN-PCI intervention. This study found that there was a trend for better patient satisfaction scores with HN-PCI intervention. The overall PSQ-MD scores (median; IQR) for HN-PCI intervention in Block 2 (86; 74-96) and Block 3 (83; 74-93) were higher than in control (80; 67-91) (p=0.02). Nine from 24 individual questions of the PSQ-MD showed a statistically significant difference between HN-PCI intervention compared with the control group, where favourable responses were noted in the HN-PCI intervention group. Interestingly, the overall PSQ-MD score and the responses for individual questions in the PSQ- MD were better in Block 2 compared with Block 3 in the HN-PCI intervention group. The significance of this is unclear. While the number of recruited patients in Block 2 is comparatively smaller, there were no statistically significant differences in clinicopathological features (Table 8.23), median length of consultation and in the median number of PCI items selected and/or discussed between the blocks.

Non-validated post-consultation questionnaires helped detail the overall satisfaction between blocks. Patients in HN-PCI intervention groups were able to recall more items of concern discussed during their recent consultation compared with control group. The mean number of items recalled for control block was 0.87 (median 1; IQR, 0-2), while for Block 2 was 1.34 (1; 0-2) and in Block 3 was 1.42 (1, 1-2) (p=0.002). In regard to the statement: *My expectations of the consultation were fulfilled in the most recent outpatient clinic visit*, the proportion of those responding 'Strongly Agree' were statistically significantly higher in the HN-PCI intervention group i.e. Block 1: 34% versus Block 2: 59% versus Block 3: 58% (p=0.02). To the statement: *I felt the PCI was intrusive*, the proportion of those responding 'Strongly disagree' in the HN-PCI intervention group was Block 2: 40% and Block 3: 46%, respectively. To the statement: *I felt the PCI was unhelpful*, the proportion of those responding 'Strongly disagree' in the HN-PCI intervention group was Block 2: 34% and Block 3: 54%, respectively. This finding suggests that there is reasonably good overall acceptance by patients of the HN-PCI. In the original HN-PCI study, when patients were asked: '*How much difference has the HN-PCI made to their consultation?',* 50% (62/123) reported 'Quite a bit' (28, 23%) or 'Very much' (34, 28%) compared with 'A little' (14, 11%,) or 'No difference' (34, 28%) (result not known: 13, 11%).

A limitation of this study is the use of patient satisfaction as an outcome measure. While this outcome is established in evaluating patient-empowerment, patient satisfaction with the consultation can be influenced by other issues, including their preferences and expectations of the consultation, which were not assessed in in this study. There is also a lack of studies that can offer direct comparison with the level of patient satisfaction. This is related to the tool selected in this study, which is not widely used. Only two studies that evaluated patient satisfaction with the intervention of HRQOL in routine oncology practice [**Rosenbloom et al, 2008; Detmar et al, 2002**]. The first study was a longitudinal study set in nurse-led clinics. The patient satisfaction used was the Medical Outcomes Study Patient Satisfaction Questionnaire-III, a validated questionnaire measuring domains of general satisfaction, technical quality, time spent with doctor, interpersonal aspects, access/availability/convenience, communication and financial aspects. This study did not find any change in the level of satisfaction in the HRQOL intervention group compared with control. Authors cited the lack of impact on patient satisfaction was likely to be that the control care given had already reached the ‘ceiling effect’, whereby further interventions would not have made any difference. Another reason given was that this study involved nurses (rather than doctors), and as such, they were not able to make changes to the clinical care in the same way that doctors can. The second reason appears to suggest that patients require medical intervention to deal with symptoms, where ‘real’ improvements in symptom control would translate into improvements in HRQOL status rather than the traditional supportive roles given by nurses, who are more comfortable at addressing and discussing emotional and social issues than doctors [**Morgan et al, 2010**]. The other study measured the satisfaction relating to the supportive care received. An increased level of patient satisfaction was reported in the HRQOL intervention group, where they recorded high satisfaction scores for support and care that they received [**Detmar et al, 2002**].

c. “*How are self-reported HN-PCI data related to distress?*”

This study hypothesised that self-reported cocnerns were related to patient distress. The majority of patients examined in this cohort did not experience significant distress (64%, 108/170). However, patients with significant distress selected more concerns overall than patients without distress (mean, median (QR) of 5.40, 5 (2-8) *versus* 2.61, 2 (0-4); Mann-Whitney test, p<0.001). This finding corroborates other studies [**Maguire, 2002**; **Chaturvedi et al, 1996**], where patient concerns were related with the development of distress. The potential relationship between the number of concerns with the likelihood of experiencing significant distress was further evaluated, where it was possible to suggest a cut-off point indicating significant distress with a reasonable degree of sensitivity and specificity. On balance, cut-off points of either ≥4 or ≥5 items of concern selected on the HN-PCI demonstrated an acceptable level of sensitivity, specificity and predictive values (**Table 7.38**) for likelihood of experiencing significant distress. From a clinical perspective, using either ≥4 or ≥5 cut-off score can help guide clinicians in risk assessing patients for significant distress, who may benefit from more in depth evaluation and intervention, at pre-consultation.

Those experiencing significant distress were more likely to select items from the Physical and Functional well-being domain (p<0.001) and the Psychological and

Emotional well-being domain (p=0.001). This finding suggests that emotional distress may not be the only significant contributing factor in cancer-related distress in HNC population predominantly treated with surgery (84%, 142/170). Severe distress, in particular physical distress related to oral cavity dysfunction, has been reported in another HNC cohort treated by ablative surgery and immediate reconstruction [**Chen et al, 2009**]. Furthermore, the use of RT [**Lewis et al, 2013**] and chemoRT [**Chen et al, 2013]** were also strongly associated with significant distress in this population. HNC survivors struggling to cope with the after-effects of HNC treatment are likely to express significant distress and require physical support more than any other cancer types [**Chen et al, 2009; Chen et al, 2016**]. Addressing significant distress related to physical concerns can be initiated in clinic. This includes both non-medical (e.g. education, advice, reassurances) and medical actions (e.g. investigations, surgery, medications, referrals). Treatment-related domain was not associated with significant distress (p=0.3) although the trend was there as in all the domains. It is possible that disease-free, post-treatment HNC patients were less likely to be significantly distressed about these issues following the completion of treatment. Comparisons with other studies are not possible due to methodological differences in assessing concerns [**Jacobsen et al, 2004**; **Grassi et al, 2013**].

When individual HN-PCI items of concern were evaluated, Anxiety (p=0.005), Depression (p=0.004), Mood (p=0.01), Pain in head/neck (p=0.002), Sleeping (p=0.007), Fatigue/tiredness (p=0.001), Swallowing (p<0.001) and Bowel habit (p=0.01) were related to significant distress. Apart from bowel habit, the other concerns associated with significant distress in this study have been consistently been reported by HNC patients previously [**Rogers et al, 2009; Kanatas et al, 2012; Ghazali et al, 2013A**]. It is recognised that Anxiety, Mood and Depression are essential components of, and possible overlapping elements of emotional distress in cancer [**Holland & Bultz, 2007**; **Panday et al, 2006**]. Post-treatment dysphagia is related to weight loss, progressive reduction in swallowing function, narrowing range of oral dietary intake and reliance on gastrostomy tube feeding [**Oozeer et al, 2011**], and these confer a global impact on the long-term day-to-day functioning and QOL [**Cartmill et al, 2012**]. Altered bowel function is related to distress in colorectal, urological and gynaecological cancer survivors but this has never been reported previously in HNC cohorts. This finding may be related to complications of opiate analgesia use, alterations to bowel function due to full reliance on enteral feeding and also secondary to hormonal imbalances in a subgroup of thyroid cancers included within this study cohort. Pain is highly correlated to significant distress in HNC patients throughout the survivorship trajectory [**Lewis et al, 2013; Maher et al, 2013**]. Cancer-related fatigue is a common problem in cancer survivors [**Carlson et al, 2004; Brown & Kroenke, 2009**] and is linked to emotional reactivity [**Rissanen et al, 2014**]. Like pain, sleep disturbances and insomnia can occur throughout the survivorship trajectory in HNC survivors [**Scarpa et al, 2014**; **Zhou & Jolly, 2014**]. While individual symptom/concern was related to significant distress in its own right, there is increasing interest in the prevalence of symptoms that frequently co-occur in symptom clusters with distress. For example, sleep disturbances and insomnia occur commonly with other frequently reported side effects of cancer and/or its treatment, namely pain, fatigue, depression and distress [**Butt et al, 2008**;**Garland et al, 2014**]. It is postulated that the clustering of co-occurring symptoms might be related to underlying inflammatory processes common to these concerns [**Garland et al, 2014**].

Overall, the number of professionals selected ranged from 0-4, mean 0.38, median (IQR) 0 (0-1), n=170. From the patients' perspectives, the attending doctor in clinic is often seen as the main clinician managing their cancer care. Thus, it is unsurprising that patients have indicated this professional as the one they would like to see or meet during their appointment, particularly those experiencing significant distress (52%, 11/21). Furthermore, those who were significantly distressed were more likely to select health professionals compared with those not experiencing significant distress (mean 0.53 versus 0.30). In this scenario, perhaps the attending doctor needs to be more proactive in suggesting onward referral or having direct access to the other professionals' support in clinic. However, it remains unclear why so few additional HNC multidisciplinary personnel are ticked generally on the HN-PCI and this is a subject for future research.

Those significantly distressed with larger numbers of concerns were more likely to have had longer consultations compared with patients not reporting significant distress with fewer concerns. Apart from increasing the length of consultation, significant distress impacts upon the individual management of these patients. Overall, those with significant distress were more likely to receive both medical and non-medical actions related to their consultation compared to those without distress.

While this finding is unsurprising, it places huge demand upon resources and outpatient clinic management. A different approach may be required to meet the concerns of significantly distressed patients in clinics where the HN-PCI is used. Suggestions include asking patients to prioritise their list of concerns for discussion during clinic, referral to the most appropriate professional who may be present at the clinic or at another appointment and self-referral through a web-based HN-PCI application. Future work should focus on the impact of HN-PCI-directed pathways in managing distress.

d. *"Is there an association between clinicopathological factors with outcomes of consultations with HN-PCI intervention?"*

An examination of the associations of multiple patient, doctor and contextual factors with the content and outcomes of consultations with HN-PCI intervention (Block 3 only) was undertaken. These factors include gender, age, surgical specialty, surgeon, tumour primary site, overall cancer p-Stage, length of time from primary diagnosis, treatment rendered, and utilisation of free flaps. The results of this study proved the study hypothesis wrong as the study results found that showed certain clinicopathological factors were significantly associated or showed a trend towards an association with concerns discussed during consultation.

Overall, a larger number of concerns were discussed in consultations involving patients with a more advanced cancer stage, where more discussions were related to Physical and Functional wellbeing. These findings are unsurprising as patients with late stage tumours were more likely to receive multimodality treatment, experience complex side-effects and report poorer HRQOL [**Hammerlid et al, 2001**]. Due to the higher number of concerns, patients with higher overall cancer stage were also more likely to have longer consultations.

A lesser number of concerns were discussed in those with > 3 years FU from diagnosis. Most concerning issues were typically experienced in the first year post-diagnosis, particularly during the treatment period [**Hammerlid et al, 2001**], coinciding with the period when supportive care is most needed. Thereafter, only few significant improvements are seen between 1- and 3-year FU, during which issues of dry mouth, restricted mouth opening, sticky saliva and teeth problems persist

[**Hammerlid et al, 2001**]. Even though these could progress beyond 5 years post-diagnosis [**Abendstein et al, 2005**], patient coping and adaptability to their dysfunction may explain why there is less discussion about concerns related to the Physical and functional well-being. This is corroborated by findings of a reduction in the need and request for supportive care at long-term FU [**Oskam et al, 2013**].

There was a trend towards more discussions about concerns within the Psychological/emotional and spiritual well-being domain among females, younger (< 55 years) patients and ENT patients. The reasons behind this finding are likely to be multifactorial, where multiple concerns are inter-related and clustered together. For example, in a previous study, the ‘Appearance’ concerns, being an item within the Psychological/emotional and spiritual wellbeing domain, was more frequently reported as a significant issue by females, those < 65 years and by patients with oropharyngeal primary site who are commonly under the care of ENT [**Ghazali et al, 2013A**]. In addition, compared with those without appearance issues, patients with appearance concerns also wanted to discuss during consultations the following items i.e. anger, anxiety, depression, mood, sleeping and self-esteem. Interestingly, all of these items are clustered within the Psychological/emotional and spiritual well-being domain [**Ghazali et al, 2013A**].

Survivors of primary larynx cancers were more likely to discuss concerns from the Social care and social wellbeing domain. This may be related to the ‘Speech/Voice/Being understood’ concern, an item clustered within the Social care and social well-being domain, is significantly discussed more frequently in patients with laryngeal cancer. A similar finding has been reported previously [**Kanatas et al, 2013**], where ‘Speech/voice/understood’ is one of the top two most common HN-PCI concerns selected by laryngeal cancer survivors. Significant voice changes occurring after cancer treatment [**Rzepakowska et al, 2017**], including complete loss of voice though laryngectomy can cause depression and social isolation which impacts upon their quality of life [**Mertl et al, 2017**] and their ability to return to work [**Costa et al, 2017**].

In general, ENT patients showed a trend towards having a certain pattern of consultation that is different to non-ENT consultations. They had fewer discussions of concerns relating to Treatment-related domains. There was a trend towards more discussions regarding ‘Dry mouth’ and also concerns within the Psychological/emotional and spiritual well-being domain. On the other hand, ‘Dental health/teeth’ were less likely to be discussed in ENT cohort even though the oral cavity including teeth, commonly demonstrate side-effects of RT due overlapping radiation fields for primary tumours that are usually managed by ENT i.e. nasopharynx, oropharynx, larynx, hypopharynx and cervical oesophagus. ENT patients also had notably more discussions about referral/requests for other professionals. A greater number of medical outcomes from the ENT consultations may be related with actual referrals made by the doctors as a result of the discussion. The ENT HNC clinics enrolled in this study are not always supported by the presence of speech and language therapist and/or dietitians in the same way that maxillofacial HNC clinics are set up. Furthermore, maxillofacial HNC surgeons who are also qualified dentists, may be able to address some of the more simple dental health/teeth related issues in clinic without resorting to referrals to dentists. These factors may explain the significantly higher number of referrals/requests for other healthcare professionals in non-maxillofacial HNC clinics. ENT patients reported better patient satisfactions with consultations, where they scored favourable responses to the post-consultation questions and had better overall PSQ-MD scores.

Longer consultation times were recorded in those < 55 years old, in those with late stage cancers, and in survivors with < 1 year FU since diagnosis. Longer consultations may be required in younger HNC patients to address their numerous and varied concerns. Younger HNC patients are known to report higher pain concerns [**Rogers et al, 2012**] which is also found in this study where they were more likely to discuss ‘Pain in head and neck’, experience chronic, significant FOR [**Ghazali et al, 2013C**], have a significant problem with anxiety and/or mood [**Kanatas et al, 2012**], have more appearance concerns [**Flexen et al, 2012**] and concerns about sexual health, particularly those with HPV-related cancers [**Taberna et al, 2017]**. Among cancer survivors in general, the younger aged subgroup also have specific concerns relating to parenting dependent children [**Moore et al, 2015**], returning to work [**Stones et al, 2017**], finances [**Landwehr et al, 2016**], concerns about fertility, relationships with others, spirituality and future outlook [**Sodergren et al, 2017**].

The relationship between more advanced cancer stage with longer consultations was due to the higher number of concerns reported by these patients. Longer consultations in those with < 1 year FU from diagnosis is also explained by the higher number of concerns discussed. In addition, physical recovery is still on going during this acute survivorship period, which is related to the higher recorded discussion relating to the Physical and functional wellbeing domain. While the difference was not statistically significant, those with < 1 year FU were more likely to have more discussions about referral/request for other healthcare professionals i.e. 53% versus 33-42%. This fits in with the finding that younger patients were more likely to receive more medical actions that older patients at consultations.

A trend towards longer consultations was seen in patients who received free flap reconstruction. As a group, free flap reconstruction may be a surrogate marker of extensive local disease, where the post-resection defect is likely to result in direct orocutaneous communication, or when direct closure would result in dysfunction of remaining tissues. Complications with free flaps are not uncommon due to the complexity of the procedure and patient characteristics [**Al-Haydar et al, 2017**], and this may cause a protracted period of wound healing, impacting significantly on quality of life [**Momeni et al, 2013**]. These issues require additional visits for continued outpatient management after in-patient care. Changes to the tongue, floor of mouth and cheek with the placement of soft tissue free flaps can change the way food is managed during eating and with wearing of dentures. Providing dental implant/prosthetic rehabilitation based on vascularized bone flaps is an inherently long process, and patients may continue to have issues with lack of teeth and chewing until its completion. Furthermore, the risk of vascularised tissues of developing osteoradionecrosis [**Al-Haydar et al, 2017]** may preclude some patients being offered dental implants indefinitely. These factors may explicate why free flap patients were more likely to discuss ‘Dental health/teeth’ concerns.

Interestingly, this study found striking inter-surgeon differences impacting upon consultations. These differences were particularly evident in the consultation length, Treatment-related discussions, discussion of referral to other health professionals, and medical actions. In particular, Surgeon 1 had the shortest length of consultations, discussed predominantly Treatment-related issues, particularly the item ‘Cancer treatment’, and was least likely to discuss patient referrals/requests for other healthcare professionals compared with other surgeons. On the other hand, Surgeon 3 had the longest consultation time but discussed more number of concerns overall, also had more discussions about patient referral/requests for other healthcare professionals, and showed a higher number of medical outcomes.

Studies of patient-doctor interactions indicate that consultations may be influenced by doctor-related factors which are related to individual surgeons' perceptions of patients [**Street et al, 2007**], their belief regarding aspects of psychosocial care [**Levinson & Roter, 1997**], belief about their professional remit and preferences related to such consultations [**Detmar et al, 2000**], consultation style [**Street et al, 2007; Takayama et al, 2001**], possession of advanced communication training/skill [**Parker et al, 2005**], and the patient-doctor relationship. **Rodriguez et al [2011]** showed that longer duration of discussions related to QOL during consultation was significantly related to the length of patient-doctor relationship measured by the number of previous visits, indicating that existing and continuing rapport helped facilitate this. It may be argued that the HN-PCI intervention should iron out striking differences introduced by individual surgeon variable, and this is investigated and discussed in depth in the next section.

The findings of this study may be limited by the exclusion of other patient factors that have been shown to influence cancer communication behavior such as ethnicity, education, and income level [**Siminoff et al, 2006**]. Critically, this study did not enquire about patients' preference regarding the style of consultation at baseline. Furthermore, multivariate analysis was not undertaken. There may be some value in undertaking this analysis because it is more likely to be influenced by a multitude of other competing factors during a dynamic process of the clinical encounter [**Street et al, 2007**].

e. "Does the HN-PCI intervention change the content of the consultation?"

This study hypothesised that the HN-PCI intervention would raise more items and/or a broader range of expressed concerns during consultations. The findings of this study showed that the intervention had significantly changed the content of consultations, whereby concerns from the Psychological/emotional and Spiritual well-being domains were more commonly discussed following the intervention (**Table 7.16**).

The trend towards an increase in the number of concerns and a broader range of items discussed at consultation with HN-PCI PRO found in this study was also reported when HRQOL PROs were utilized in routine oncology practice settings in two randomised-controlled trials [**Velikova et al, 2002; Detmar et al, 2002],** a longitudinal, cross-sectional study of various cancer survivors **[Takeuchi et al, 2011**], a controlled trial of paediatric haematological cancer survivors [**Engelen et al, 2012**] and a controlled trial of patients attending outpatient chemotherapy clinic run by nurses [**Hilarius et al, 2008**].

The trend for more discussions of items was observed across the board even when patients do not select these items (**Tables 7.51 and 7.52**). These items may have been were brought up by one or several ways. The patient may have generated the items for discussion despite not selecting the item on the HN-PCI as a result of being primed to the HN-PCI checklist. This effect was observed in previous studies [**Velikova et al, 2004**; **Takeuchi et al, 2011**]. Alternatively, it may have been initiated by the doctor, or arisen from discussions surrounding other items as demonstrated in the pilot study [**Ghazali et al, 2013A**]. Overall, there were a higher number of items selected and discussed in Block 3 than in Block 2 in all domains (**Table 7.53**), where full HN-PCI implementation may have played a contributory role. However, there was more likelihood of lesser items being discussed as the number of items selected increased (**Table 9.53**).

A previous study showed a tendency for some patients to select large numbers of concerns for discussion, particularly when filling in the HN-PCI for the first time [**Ghazali et al, 2015**]. It is probable that patients may have felt ‘spoilt for choice’ where the novelty of the opportunity to express their concern was met with an excess number of selected items, because this tendency is not repeated as the numbers selected reduced with succeeding visits. The reduction in the number of symptom with succeeding visits was also observed in a longitudinal study of using HRQOL PRO in routine oncology setting [**Takeuchi et al, 2011**]. As indicated in the pilot study discussion, when patients select too many items to be addressed in single visit, this may sign post the patient for an additional visit with the doctor or with the CNS to help address any remaining concerns [**Ghazali et al, 2013A**]. Nevertheless, in this situation, it may not be practically possible for the doctor to address all of the items selected in a single visit due to clinic appointment constraints. This may account for why fewer numbers of items were discussed with increasing number selected by patients (**Table 7.53**). However, it is still unclear why from a collection of items selected, some items were chosen for discussion, while others were disregarded.

To determine if the HN-PCI helped to bring the patient’s agenda up for discussion, the level of agreement between self-reported HN-PCI data and consultation-assessed data was evaluated. The overall agreement between patient selection of an item and discussion with doctor with HN-PCI intervention was only fair to moderate. There was improvement in the levels of agreement when the HN-PCI was fully implemented (Block 3) then with partial implementation (Block 2). In Block 2, where self-reported data were not available to the doctor during discussion, the median (IQR) level of agreement for 27 items of concerns was recorded as fair i.e. 0.25 (0.02-0.48). In Block 3, where self-reported data were available to the doctor during discussion, the median levels of agreement for both 27- and 44 items of concerns were recorded as moderate i.e. 0.42 (0.27-0.49) and 0.42 (0.24-0.49), respectively. When the level of agreement was compared by domain across Blocks 2 and 3, better levels of agreement were seen in all domains in Block 3.

A closer look at the level of disagreement between the proportions of items selected and those discussed (i.e. YN: ‘patient selected but not discussed’ and NY: ‘not selected by patient but discussed’) in relation to the proportion where there was agreement (i.e. NN: ‘item not selected and not discussed’, and YY: ‘item selected and was discussed’) may provide a window into how items of concerns may have been handled during consultations in Block 3. With items in the Treatment-related domain, a vast gap was observed when the proportion of disagreement (i.e. NY=47 and YN=3) was considered alongside the proportion of agreement (i.e. NN=42 and YY=8), thereby, producing a kappa value that was barely above zero. Thus, the dominating feature here was that treatment-related items were not being selected by patients, but treatment-related items were discussed. For the Social care and social wellbeing domain, there is tendency to discuss one or more items from this domain even when none has been selected than vice versa. But because the dominant feature here is for none to be raised or discussed (NN=57), the level of agreement is somewhat raised. On the other hand, the items in the Psychological/emotional and Spiritual wellbeing domain showed a near balance between NY (14) and YN (18), but when this is considered in relation to the proportion of agreed items (NN=41 and YY=27), the dominant feature overall is of agreement, producing a better kappa level of agreement.

There are 4 items in the Treatment-related domain. ‘Cancer treatment’ was most likely to be discussed during consultations even when patients did not select this. ‘Cancer treatment’ is often a doctor-directed item during discussion as this enables doctors to familiarise themselves with where patients are in terms of their post-treatment progress [**Fagerlind et al, 2008; Detmar et al, 2001; Takeuchi et al, 2011**]. While this may help open further discussions relating to treatment-related concerns that patients may have, there is a danger that the proportion of discussion time will be spent here rather than other areas more important to patients. Although there was no definitive evidence to validate this in the current study, the discussions about other items in the Treatment-related domain that were not selected by patients (NY items) such as ‘Wound healing’ and ‘PEG tubes’ may suggest that this could have occurred. The remaining item in this domain i.e. ‘Regret about treatment’ is considered an important concern to both patient and clinicians. While post-treatment regret is not unusual among cancer patients [**Connoly & Reb, 2005**], the prevalence of post-treatment regret among HNC patients and their carers is reportedly low [**Gill et al, 2011**], which may to some extent explain why this concern was not highlighted by this study cohort or discussed in clinics.

There is further evidence suggesting that doctor-directed discussions may have also occurred in items within the Social care and social wellbeing domain. There were more discussions relating to some items in this domain even though there was a general trend for patients choosing not to select items within this domain. Kappa values were obtained only in 4/9 items in this domain. ‘Financial /benefits’ and ‘Relationships’ showed moderate level of agreement (κ =0.49), indicating that these concerns were likely to be discussed if they were initiated by selection on the HN-PCI. ‘Speech/Voice/Being understood’ and ‘Lifestyle issues (smoking/alcohol)’ showed less than fair kappa values (κ <0.20). In both items, the kappa value was the result of the gap seen when the proportion of disagreement (Speech/Voice/Being understood: NY=16 and YN=5; Lifestyle issues: NY=10 and YN=0) was considered alongside the proportion of agreement (Speech/Voice/Being understood: NN=75 and YY=4; Lifestyle issues: NN=89 and NN=1) in both concerns, respectively. This finding indicates that discussions of these two concerns were more likely to occur even if they were not selected for discussion by patients. It is reported that doctors felt more comfortable discussing social concerns when these were related to dysfunction and its impact on performance status, as many social activities are reliant upon on physical functioning **[Taylor et al, 2011]**. This may account for the increased likelihood of discussion related to 'Speech/Voice/being understood' and 'Recreation'. It is highly probable that doctors had also initiated 'Lifestyle issues (smoking/alcohol)' discussions because doctors are trained to undertake secondary prevention of HNC [**Detmar et al, 2001; Fagerlind et al, 2008; Rodriguez et al, 2010**]. On the other hand, the overall trend of patients choosing not to select items within this domain perhaps reflects this cohort's preference for not wanting to discuss social concerns in clinic. **Taylor et al [2011]** reported that only 44% of their cancer patients expressed a willingness to discuss social concerns in clinic while 39% would only do so at the doctors' prompting, and 11% would not rather not discuss these concerns in clinic. Despite a lowered trend for patients selecting items in the Social care and social wellbeing domain in Block 3, 8/9 items (89%) in this domain (except 'Support for my family') were discussed in clinic. This may suggest that doctors' willingness to broach social concerns may have helped bring NY social concerns into discussion, even if the initiating factor to discussion may have been related to treatment side-effect.

In regard to the Psychological/emotional and Spiritual wellbeing domain, 9/14 items showed fair to moderate level of agreement, while kappa value was not obtained 4/14 items and a negative kappa value was obtained in 1 item. Items showing fair to moderate kappa values include those related to psychological distress (i.e. 'FOR', 'Anxiety', 'Anger', 'Depression' and 'Mood') and those related to the individual's character/quality (i.e. 'Self-esteem' and 'Temperament/Personality'). This finding indicates that both patients and doctors were willing to discuss these issues when patients choose to disclose them in clinic on the HN-PCI. Kappa values were unobtainable with 'Spirituality/religious aspects', 'Sexuality', 'Intimacy' and 'Coping'. In general, the vast majority of patients did not choose to discuss any of the items without kappa values. When these weren't chosen, these items were unlikely to be discussed other than 'Coping' (NY=8 versus NN=92). Coping may be discussed when addressing other ‘stressful’ concerns that patients may have.

Sexual dysfunction is a significant problem in people with cancer, but discussions about sexual dysfunction and sexual health remain taboo subjects [**Barbera et al, 2017**]. The items, ‘Intimacy’ and ‘Sexuality’ are difficult subjects to discuss in clinic, and these concerns are believed to be under-reported in HNC [**Low et al, 2009**; **Rogers et al, 2015**]. In Block 3 of this study, ‘Intimacy’ was highlighted in 2% (2/100) while ‘Sexuality’ was highlighted in 1% (1/100), which was smaller when compared with a previous HN-PCI study, where the proportions were 5% (9/177) and 2% (4/177), respectively [**Rogers et al, 2015**]. This finding supports the notion that having a prompt like the HN-PCI, patients can take the initiative and highlight their interest in having open discussions about them in clinic. However, there were three instances in Block 3 where both concerns were highlighted, but these were not discussed (YN=3), indicating that these concerns remained unaddressed. Blocking these concerns from open discussion means that the unmet need persists. **Rogers et al [2015]** suggests that doctors may not be willing and/or express lack of confidence in dealing with these concerns. Training is paramount in overcoming these issues, and this is essential as doctors increasingly confront more cases of HPV-related cancers, a sexually-transmitted disease, in their practice [**Chu et al, 2013**]. HPV screening in HNC is becoming a standard of care, and a patient-centered approach is warranted in dealing with the aftermaths of HPV screening, which may bring up a unique set of anxieties and stresses on patients and their interpersonal relationships [**Chu et a, 2013**]. Awareness of and access to specific services that can support sexual health needs with may help facilitate its open discussion in routine oncology clinic. Addressing these concerns in routine HNC clinics has led to referrals to other professionals [**Rogers et al, 2015**] with psychosexual training, who may be better equipped in dealing with these issues with patients and their carers [**Manne & Badr, 2010; Hoole et al, 2015**].

The recognition of the importance of ‘Spirituality/Religious aspects’ in oncology and survivorship is increasing [**Pereet & Balboni , 2013**], particularly in terms of its central role in helping cancer patients cope, providing comfort, hope and meaning with the existential crises at diagnosis, during treatment [**Becker et al, 2006**], and also in the palliative care setting [**Williams, 2006**]. Patients describe having ‘spiritual pain’ as a major factor that influences their sense of religiosity and their spiritual wellbeing [**Delgado-Guay et al, 2011**]. Maintaining good spiritual wellbeing is critical because of its impact on QOL, not only at the concluding stages of their journey [**Kandasamy et al, 2011]** but also in long-term cancer survivorship. ‘Spirituality/Religious aspects’ are linked with post-traumatic growth where benefit-finding and making meanings are ways that can help patients create a more positive revised worldview after a significant adverse event i.e. cancer diagnosis, [**Kandasamy et al, 2011; Pereet & Balboni, 2013**]. **Pereet & Balboni [2013]** broadly indicates spiritual needs to include *‘distressing spiritual struggles (e.g. feeling abandoned by God) and spiritual seeking (e.g. seeking forgiveness, thinking about what gives meaning to life)’* [page 281] and unmet spiritual needs may include negative religious coping (e.g. anger at God). Traditionally, the clergy (i.e. chaplains, priests, imams, rabbi, monks or other religious ministers) have been responsible for the spiritual care of patients [**Best et al, 2014**]. However, irrespective of their religious background, the majority of cancer patients wanted their doctor to ask about their source of spiritual support and facilitate access to it, even though doctors felt that they would not broach this subject without patient initiating it **[Best et al, 2014]**. This study also specified that cancer patients did not want spiritual guidance from their doctors, but discussions about spirituality by doctors were perceived as fulfilling their expectations to be treated holistically, and as the basis of a good patient-doctor relationship, which enabled them to discuss their fears [**Best et al, 2011**].

In Block 3, this concerns was identified in 2/100 consultations (2%), where there were one case each of YN and NY. The rarity of this concern being highlighted may represent either the lack of need, or patient preference not to discuss the issue in clinic. Studies have shown that spirituality concerns are infrequently discussed in clinics, and while patients welcome the idea of doctors discussing spirituality in clinics, there maybe a mismatch between patients and doctors regarding what constitutes this discussion [**Best et al, 2016**]. Multiple issues underlie this, which includes the lack of universal definition of spirituality and/or religion; ethnocultural differences; individual personality; doctors’ beliefs regarding who should best address these concerns; some doctors’ preference for not discussing this concern even when broached by patients; the lack of knowledge/training in dealing with this concern; doctors’ belief that they lack capacity to help with such concerns; doctors’ belief that discussing this concern can exceed professional boundaries and/or cause a negative impact on patient outcomes; doctors' discomfort discussing concerns that 'did not have a scientific basis'; discordance between the doctors' and patients' personal religious beliefs; the strength of patient-doctor relationship; and practical considerations i.e. lack of time [**Best et al, 2016**]. It is unclear how the discussion relating to this concern was broached in the single case of NY seen in Block 3.

In Block 3, most items in the Physical and Functional wellbeing domain (24/29, 83%) showed at least fair kappa values ($\kappa \geq 0.20$). This finding indicates that patients want to discuss concerns relating to their function, and there was a fair chance that these concerns were addressed during their visit. These items were issues brought about as a consequence of their treatment, which are of interest to both parties. This has been reported previously in other studies, where patients and doctors express preference for discussing physical concerns during clinic visits [**Detmar et al, 2000; Fagerlind et al, 2008].** In this subset, some items showed better kappa values than others, e.g. 'Appetite' κ= 0.78 and 'Bowel habit (diarrhoea/constipation)' κ= 0.71 while 'Sleeping' κ= 0.23 and 'Activity' κ=0.25. The imbalance seen in Sleeping i.e. YN=13 and NY=2; and with Activity i.e. YN=0 and NY=15 may account for the kappa agreement value of being only fair. 'Mobility' showed less than fair kappa value, where a reasonable gap is seen between the proportion showing agreement (NN=92 and NN=1) in comparison to the proportion of disagreement (YN=5 and NY=2). This indicates that this concern is infrequently discussed and was particularly less likely to be discussed even if selected by patients. Kappa value was not available from 3 items i.e. 'Vomiting/Sickness', 'Regurgitation', and 'Smell', where these were hardly selected and/or discussed at all in Block 3. 'Vomiting/sickness' and 'Nausea' are more common concerns in HNC patients who are undergoing active treatment, particularly with chemotherapy, in comparison to those who have completed their treatment, and this may explain why these concerns were hardly an issue in this post-treatment cohort.

It is not possible to determine definitively how discussions regarding concerns were initiated with the HN-PCI in place, as this study was not designed to explore the specific dynamics of the discussion. Without qualitative analysis, it is impossible to examine thoroughly how patients and doctors use the HN-PCI in eliciting patient concerns and how discussions about these concerns were initiated or otherwise during the visit. This is a subject for future work.

Therefore, the following observations are tentative based on existing data. For items not addressed, it may be speculated that patients may not have taken the initiative to broach these subjects during consultation having completed the prompt sheet, and/or doctors had blocked discussion of patient-selected topics, or there was simply no time to address all of the concerns selected. Even with the HN-PCI intervention, there was a trend indicating that consultations continue to focus on medical/technical issues despite an increase in psychosocial discussions. Some of these issues were related to the patient selecting these items on the HN-PCI but some were discussed irrespective of patient selection. Perhaps, these discussed items were due to its relatedness to medical/technical issues (e.g. 'Speech/Voice/Being understood as an issue related to treatment), and these are concerns that doctors are more familiar with. Doctors may also preferentially address symptoms they are able to alleviate or manage. Clinicians using PROs in cancer clinics have expressed their reservations about initiating discussions about issues that they would not personally be able to deal with or could not do anything about [**Velikova et al, 2008; Takeuchi et al, 2011**]. In addition, with concerns of complex and multifactorial nature, doctors may not directly address those concerns but rather approach this by discussing other symptoms/concerns that are often clustered together. Take the example of 'Sleeping', a concern is not commonly discussed in Block 3 (NN=82; YN=13 versus NY=2; YY=3; κ=0.23). Other concerns that are often clustered with 'Sleeping' were discussed more commonly in Block 3 with moderate levels of agreement: 'Fatigue/tiredness' (κ=0.56); 'Energy levels' (κ=0.48); 'Dry mouth' (κ=0.55); and 'Breathing' (κ= 0.58). This method of discussion may not easily or necessarily translate into the method of assessment used in this study.

Perhaps, the crux of the problem i.e. the mismatch seen between what the patient selects and what is discussed lies in the doctor's willingness to take on the discussion. This is succinctly summarised by **Greenhalgh et al** [**2005, page 840**]: '*Even if patients raise their concerns within the consultation, this must be taken on board by clinicians if it is to have any influence on their decision making'*. The fair to moderate level of agreement may suggest the possibility that some surgeons in this study have not consistently utilised the HN-PCI prompt sheet when it was available to them. This finding was recorded in another study [**Greenhalgh et al, 2013; Hatta et al, 2014**]. These are several issues that may account for this: (1) time and resource constraints; (2) unfamiliarity with instrument; (3) belief that doctors' subjective assessment is better; (4) belief that PROs can interfere with the patient-doctor relationship; and (5) the belief that PROs do not contribute towards clinical decisions due to the lack of clear guidance or pathways that can guide doctors in dealing with types of concerns raised [**Hayland & Ferrans, 2008**; **Velikova et al, 2008; Luckett et al, 2009; Takeuchi et al, 2011; Greenhalgh et al, 2013**].

Clinicians are still uncertain on how to use HRQOL PROs in routine clinical practice despite increasing enthusiasm to do so [**Greenhalgh et al, 2005**; **Hayland & Ferrans, 2008; Luckett et al, 2009]**. **Greenhalgh et al [2013]** undertook a detailed qualitative study of how clinicians used HRQOL as prompt sheets in routine oncology clinics. They found that by simply making explicit reference to the prompt sheet at the start of the consultation, clinicians have strengthened patients by allowing them the opportunity to clarify and explain the disclosed concerns on the prompt sheet. This 'permission-giving' effect by referencing to the PRO data at consultation was also noted during the development of thematic framework of this study [**Ghazali et al, 2013A**]. Interestingly, **Greenhalgh et al, [2013**] notes that doctors may not always know how to do this even when the PRO is accessible to them.

Greenhalgh et al [2013] observed that initial references to the prompt sheet during consultations tend to be general, mainly as recognition of its completion, and to acknowledge the patient's self-reported responses. When direct references are made to a particular concern selected, patients usually attempt to explain their experience of the concern. In response, the doctor often tries to explain away the concern, particularly if the concern was a symptom. The explanations given i.e. the reasons and purported cause for why those concerns may have been experienced i.e. 'candidate cause' are usually based on the disease or treatment. On the occasion that the patient concern did not seem to fit in with the understanding of the disease or treatment, it is deemed 'not cancer-related'. Consequently, the doctor terminates further discussion relating to that concern, and the next concern on the list is approached. For some symptom-type concerns where the candidate cause is determined, doctors often resort to medical symptomatic treatment by way of addressing them. Doctors have a tendency to close down further discussions regarding a concern once the candidate caused is provided, even if their explanation sometimes contradicts the patient experience. At this point, when patients attempt to continue the discussion, the doctor may block or change discussions to another topic. The only time a candidate cause is abandoned is when there is objective evidence e.g. blood investigation, etc. is available. Therefore, further exploration of the psychosocial impact of the concern is blocked. This finding suggests that while PROs may be able to help disclose a concern and initiate its discussion, the quality of that discussion may still be influenced by other factors.

An interesting observation in the MD Pilot study [**Ghazali et al, 2013**] was how the inter-relatedness of individual concerns can influence the way patients select items on PROs and how they are discussed. Some clustering of items of concern are intuitive, for example, clustering of the following concerns: ‘Teeth/Dental health’, ‘Chewing/eating’, ‘Appearance’, ‘Speech/Voice/being understood’ and request for ‘Dentist’ and ‘Oral rehabilitation’ support may relate to issues surrounding loss of teeth. These types of clusters are often based on the understanding of anatomy, function and the impact of treatment. Initiating discussions about these concerns are relatively easier because it is immediately clear to both patients and doctors.

In an exploration of symptoms, function and supportive care needs, **Synder et al [2008]** showed that some concerns e.g. sleeping problems have greater unmet needs than others. **Greenhalgh et al [2013]** provides the example of how doctors dealt with the concern ‘Fatigue’, a complex item with multifactorial causes. Doctors tend to approach this concern with their medical/technical understanding, including enquiring about the problem with closed ended questions, offering a candidate cause (e.g. chemotherapy), probes other candidate cause related issues (e.g. pain, breathing problems, appetite), suggest medical interventions based on their candidate causes (e.g. high-energy drinks for perceived loss of appetite) while blocking patients explanation of the concern (e.g. changes topic of discussion to other related/known causes of tiredness) with consequential impact on access to supportive care (e.g. ‘tiredness is an inevitable chemotherapy side-effect, therefore nothing can be done’) and preferring to rely on objective medical evidence before changing management (e.g. only intervene when blood results indicate deficiency). Doctors failed to explore possible psychosocial reasons or impact of fatigue, for example, psychological distress, social isolation, inability to return to work, and in doing so may inadvertently block access to supportive care.

The data regarding discussions on patient request for referrals to healthcare professionals was not forthcoming. There was hardly any discernable level of agreement seen across both blocks, mainly because of the relatively few requests selected by patients in the first place. When patients did indicate a request, there was very little acknowledgement of that during discussions. Interestingly, there were significantly more discussions about the CNS input despite patients not selecting that in Block 3. With the trend of discussing more items, particularly in the Psychological/Emotional and Spiritual wellbeing in this block, discussion surrounding the CNS may be a way by which the doctor enlists additional help to deal these types of concerns. Overall, these results did not provide any strong evidence for the potential role of the HN-PCI as a prompt for access to supportive or additional care. It is unclear if this is because there is lack of need for additional supportive help, or if patients preference is to self-manage their concerns/issues.

There are several limitations to this section of the study. The main limitation relates to the statistical analysis. Multiple statistical analyses were undertaken on underpowered data, and on HN-PCI where there were large gaps were seen in items that were less commonly selected. Interpretation of the statistical analyses also included borderline statistical significant findings, which allowed the formulation of trends that are clinically relevant. Existing data was obtained from a single clinic encounter only. The coding data were not adequate to allow in depth content and conversational analysis of discussions to elucidate how the HN-PCI may have changed the discussions during consultation. While this is not an objective of this current study, an opportunity for future qualitative evaluation is possible as the consultations were audiorecorded.

CHAPTER 8

8.0. MD STUDY CONCLUSIONS

8. 1. Implications for clinical practice and future research

In this study, normal consultations that occur in routine HNC clinics without the HN-PCI intervention were found to retain the traditional, doctor-centric approach, where medical/technical-based discussions predominate within the expected temporal and structure of the visit. This falls short of the overall concept of patient-centred care in cancer, which is unlikely to occur without a good understanding of patient needs and factors that influence them [**Richardson et al, 2007**]. Without engaging the patient in the process of disclosing their concerns, needs and problems and the discussions that can help explore and address these issues, it would be impossible to personalise their care.

This study provided evidence for the introduction of HN-PCI as a PRO in routine multispecialty HNC practices. The intervention of HN-PCI as a prompt sheet helped patients to disclose their concerns by demonstrating a trend towards a higher number of concerns discussed compared to control. Furthermore, a broader range of concern was discussed, particularly concerns relating to the psychological-emotional domain. These resulted in a trend towards slightly longer consultations. As a prompt for requesting referrals for other health care professionals to support their care, the impact of HN-PCI intervention was less clear. There was no increase in the request for referrals or access to supportive care seen at both the self-completed data and the discussion stages. While primarily used as a prompt sheet for discussions in clinic, the HN-PCI was also able to indirectly screen for those with significant levels of distress based on a cut–off point of the numbers of concerns selected. This finding suggests that the HN-PCI may also be deployed as a quick screening tool not only for identifying significant distress, but it may also simultaneously identifying the concerns that may be associated with this.

This study showed that patients did not reject the HN-PCI, where trends suggested favourable acceptance by patients who used the HN-PCI. Favourable responses by patients who used the HN-PCI were also recorded in studies by **Rogers et al [2009**], **Hatta et al, [2014]** and **Jungerman et al [2017].** First time users of the HN-PCI in Brazil comment on the impact of the HN-PCI in acknowledging their often unrecognised concerns, enables them to indicate their complete list of concerns, preempts the dialogue they will have with the doctors, empowers patients by giving them an outlet to voice their concerns, and how it provides reassurances that their concerns mattered [**Jungerman et al, 2017**]. In a detailed review of patient's perspectives as users of the HN-PCI tool, **Rogers & Lowe [2016]** reported that almost two-thirds of patients surveyed felt that the HN-PCI was helpful in enabling all or most of their concerns to be discussed, and in their communication with the doctor. Favourable responses regarding the HN-PCI as a communication prompt includes reminding patients the items for discussion, opens door for discussion of items not normally discussed in clinic, assist patients to mentally prepare for the discussion, inform doctors of patients concerns, help doctors to initiate items for discussion, focus the discussion, and enable patients to speak with different people for help. In addition, patients also report on the positive effect of filling the HN-PCI as providing an opportunity for them to concentrate on thinking about what concerns they may have and to determine if any of the concerns on the list constitutes a problem that requires addressing, and for some, the process enables them to make a mental note about their health. Some patients indicate a sense of relief after consultations, and this seems to relate to having their worries addressed and talked about through discussions.

Rogers & Lowe [2016] reports that a small percentage (11%) did not feel the HN-PCI made a difference to their communication during consultation, and based on the verbatim comments made, these patients could be categorized into (1) those who did not have any concerns; (2) those who are self-aware and feel able to initiate the discussions with doctors without help; (3) those who have their concerns unacknowledged or blocked from discussion; (4) those who have a preference to discuss non-medical/technical concerns with nurses rather than doctors; and (5) those who are unfamiliar or uncomfortable with self-directed questionnaires/tools.

For the HN-PCI to become a useful tool in assisting patient-centred consultations, both patients and doctors have to buy into the idea, and be willing participants in the process. This is a prerequisite before HN-PCI data can be of any value in decision-making of patient care. This study offered a broad perspective of how patient-reported concerns highlighted by the HN-PCI are managed by the patient and doctor during consultations. The HN-PCI intervention improved the level of agreement between patient-reported concerns and concerns discussed slightly from fair to moderate. Any mismatch seen between patient-reported concerns and concerns discussed reflects multiple reasons influenced by patient-, doctor-, and contextual-related factors.

For the HN-PCI to be accepted more widely, there remain several barriers to be overcome. With the potential for HN-PCI to increase consultation times, time constraints expected from a busy HNC clinic are a major consideration. This is particularly relevant in situations where longer consultation times than normal may be expected, such as those identified in this study i.e. when large number of items of concern are selected, in younger patients, those with late stage cancers, patients who received free flaps, and in survivors with < 1 year FU from diagnosis. Continued commitment of the HN-PCI usage in routine clinical practice is largely driven by patient acceptance. This study, as well as previous studies [**Rogers et al, 2009; Hatta et al, 2014; Jungerman et al, 2017**] have shown that there is favourable acceptance of the HN-PCI, but these are based on a one-off assessment of the HN-PCI, and longitudinal reception of the HN-PCI by patients remains unproven. This may be influenced by the extent of respondent burden per visit, the relevance of the HN-PCI at long-term FU with decreasing needs, and the patient perception of its efficacy in addressing their concerns. The question of whether having completed the HN-PCI before the consultation may have raised expectations of the imminent consultation was explored by **Rogers & Lowe [2016].** While almost half (45%) thought that the HN-PCI may, or had definitely raised expectations of the consultation, only a minority (12%) felt that raised expectations had possibly or definitely led to disappointment because their needs had not been met. Thus, it was unsurprising that a similar proportion (47%) thought that the HN-PCI had made a positive difference to their appointment. More than half (58%) felt that they would definitely like to continue using the HN-PCI compared with 17% who thought they might, and 5% who thought they definitely would not.

Doctor acceptance of the HN-PCI is also a pre-requisite for the regular and long-term commitment towards the HN-PCI implementation. In regard to this, it can be argued that doctor-related barriers are far more critical than those presented by patients [**Mitchell, 2013**]. The barriers for PROs use in routine clinical practice noted in other studies [**Synder et al, 2010**; **Takeuchi et al, 2011**] and these are also applicable to the HN-PCI, and include (1) doctors' preferences; (2) doctors' ability to discuss psychosocial issues; (3) doctors' tendency to minimise or ignore psychosocial concerns based on their belief that these are unavoidable consequences of cancer diagnosis; (4)

doctors' belief that they are unable to provide appropriate management i.e. advice and/or solutions; and (5) doctors' unfamiliarity with PROs and how to use them. It is also suggested that having a structured questionnaire/form to guide communication between patients and doctors may reduce the value of the conversational approach, particularly when there is already a long established patient-doctor relationship [**Takeuchi et al, 2011**].

In regard to the HN-PCI, doctors' views have not been explored in detail. This current study failed to evaluate the views of the doctors who participated in this study. In the UK, there were only two verbatim comments made by doctors who have used the HN-PCI, where comments were positive and supportive of the tool, indicating that the tool helped to focus discussions and also facilitated discussion of items that were never talked about before [**Rogers & Lowe, 2016**]. Malaysian doctors who used the HN-PCI were surveyed at the end of the study [**Hatta et al, 2014**]. All the surgeons in that study had referred to the HN-PCI before the consultation. All surgeons were of the opinion that referring to the HN-PCI checklist helped prompt patients to recall the issues that they had selected for discussion. Nine out of 10 surgeons felt that the HN-PCI helped to focus the consultations, and most (70%, 7/10) did not think that using the HN-PCI lengthened the consultation. Overall, the vast majority (90%) indicated that they would agree to use the HN-PCI in future consultations. Specialist HNC nurses, who are often keyworkers of HNC patients, expressed positive feedback regarding the use of HN-PCI relating to its ability screen more holistically, and its empowering effect on patients as they take ownership of their condition. There were some reservations regarding potential duplication of work as nurses are expected to undertake a more formal holistic needs assessment during separate visits for patients [**Rogers & Lowe, 2016**].

Nurses have also highlighted logistical issues with implementing the HN-PCI in busy HNC clinics, due to the lack of suitable space for patients to complete the HN-PCI, and the sheer volume of patients attending those clinics [**Rogers & Lowe, 2016**]. Despite some disruption at the registration area where Malaysian patients complete the questionnaire, more than half of the clinic registration staff felt that it was suitable to give patients the questionnaire at the registration area [**Hatta et al, 2014**], indicating that these were simply early, teething problems. From the patients' perspectives, the appointment was time-efficient due to the focused consultation [**Rogers & Lowe, 2016**] and the process of filling in the HN-PCI did not amount to additional difficulties, although a small number of some patients had trouble with the TST [**Hatta et al, 2014**].

A major problem that may hinder the implementation of the HN-PCI is the way the health care system is currently structured, as it is not geared up to meet with some of the concerns on the HN-PCI checklist. Individual HNC services need to have a strategy, structure and care pathways in place to cater for the concerns that are being potentially screened with the checklist. Failure to plan for and organise pathways of care based on the HN-PCI prompt list can result in doctors feeling out of depth to deal with unfamiliar problems, and frustrations on the part of doctors and patients with the lack of services that can support the concerns highlighted.

In the UK, the endorsement of the Macmillan Recovery package [**Macmillan, 2013**] within the national strategy for cancer [**NHS England, 2014; NHS England, 2017**] may help address the fundamental issue with a health care system that is currently not organised to achieve the full implementation of personalised care through holistic assessment. Being one of the four interventions of the Macmillan Recovery package, all cancer services services will need to adopt a suitable holistic assessment process, and develop a local/regional strategy and structure to to support its implementation. This MD study demonstrates that the HN-PCI could be used as a holistic assessment tool in routine HNC clinic setting. In considering this finding, the MD study discussion has highlighted some of the practical issues that could occur with its implementation, especially when it is implemented in isolation i.e. without the accompanying paradigm change in cancer strategy, health care system and structure. Longer consultation times, higher clinic outputs and an increased range of patients' concerns they want to discuss during consultation can put extra demands on health care providers and the cancer services.

Rolling out holistic needs assessment also requires careful consideration of practicalities i.e. who undertakes holistic assessments, how and when is it best done. While this MD study cannot definitively comment on the role of doctors in enabling a patient-centred consultation with the help of a holistic prompt sheet (HN-PCI), there is a suggestion from this work that this is an area that needs addressing e.g. work in educating and changing the minds of doctors, if the model of holistic assessment described in this MD study is to adopted more widely.

Other than the problem strategy and health care systems, another fundamental question regarding the routine use PROs relates to a skepticism as to whether the theory of routine PRO use can be translated clinically [**Greenhalgh et al, 2005].** Several authors have questioned if PROs could be a meaningful tool that plays a valuable role in shaping a shared decision regarding treatment, and in personalising care [**Greenhalgh et al, 2005; Luckett et al, 2009**]. From only a handful of studies, there is only one oncology-based study on the routine use of PROs, which had a positive impact on clinical outcomes [**Velikova et al, 2004**]. This lack of consistent evidence does little to allay the skepticism. In this context, the finding in this current study that HN-PCI intervention resulted in an increase in medical actions without compromising the normal temporal structure of the FU visit provides new evidence supporting the value of PROs in reaching shared-decisions about patient care. Furthermore, patients in the HN-PCI intervention group reported lower levels of distress and better satisfaction with the consultations in compared with the control group.

Steps to overcome known barriers should be considered to improve the efficacy of HN-PCI. Longer appointment slots can be built-in to the clinical template to accommodate patients who require longer consultation times, which can be predicted by their demographic and clinical factors. Also, preempting the concerns profile prior to clinic visit can help screen out patients who will require the additional time for discussions, and this may be achieved using a web-based questionnaire that patients fill well ahead of their visit [**Rogers & Lowe, 2016**]. Having this ability can preclude the need for additional room/space for patients to fill in their questionnaire, and reduce the likelihood of disrupting the clinic on the day of their visit. This information may also help determine if certain healthcare professionals could be present during the appointment to help address their concerns there and then. This may be a consideration in oncology clinics that are not set up to have multiple professionals in attendance. The increased referrals as part of the increased medical actions in the ENT subgroup, may have been related to this scenario.

A CNS-led clinic to address some of the specific concerns identified during doctor-led clinics [**de Leeuw et al, 2013**] is one service delivery model that could improve the efficacy of HN-PCI. A randomised controlled trial of nurse-led psychosocial interventions in HNC patients showed good HRQOL outcomes overall, particularly emotional functioning and fatigue, which persisted at 24 months FU [**van der Muellen et al, 2014**]. Another service delivery model that may help to address patients psychosocial concerns during cancer survivorship is a shared care model between the oncology doctor and the general practitioner, where both play roles in initiating and coordinating discussions about patients' psychological concerns. **MacKenzie et al [2015]** reports that the majority of cancer patients undergoing RT were willing to discuss emotional concerns with their oncology doctor and/or their general practitioners. On the other hand, **Mosher et al [2014]** notes that most lung cancer patients (75%) prefer to talk about their distress and emotional concerns with their general practitioners rather than the oncology doctor. Those who did not want to discuss their emotional concerns with the cancer doctor indicated that there were 'more important things to discuss about during their oncology visit' [**Mackenzie et al, 2015**]. Furthermore, there is evidence that patients and general practitioners would support such a model. **Adam et al [2011]** report that patients and primary care teams believe primary care has an important role to play in cancer care, where an active approach through specific review appointments would legitimise the raising of concerns. Indeed, this is an area that could be explored with the HN-PCI because patients surveyed about their views if the information on the HN-PCI would be useful to their general practitioners (after excluding not known, n=11 from 123), 59% reported that 'quite a bit' (27/109) or 'very much' (37/109) [**Rogers et al, 2009**]. In this current study, other than the surgeon and dentist, patients selected the family doctor (4-6%) on the HN-PCI among other professionals they would like to gain access/referred on to.

Education and training of oncology doctors may change their perception and approach towards a more holistic and patient-centred approach during post-treatment survivorship could break down some of the barriers towards routine use of PROs rather than the narrowed mindset where PROs are only in specific situations i.e. research/clinical trials in the oncology settings. Additional generic training in communication skills can help towards changing doctors' perception and beliefs while acquiring new skills. Specific training in HN-PCI should include how the tool is handled, how to manage situations when patients select large number of items, and how to manage certain types of concern e.g. FOR, regret of treatment, spirituality etc. Additionally, training in understanding the UWQOL measures and its interpretations could provide additional information to that furnished by HN-PCI data. Development of rehabilitative/supportive care pathways for managing various problems in the HN-PCI checklist based on existing local/regional services could help information-giving and strategies for active management. Auditing the HN-PCI usage should include patient feedback about their experience using the tool with specific questions relating to responder burden particularly with long-term use of the tool, relevance of the tool in general and/or the items on the checklist, satisfaction with the consultation, and also the efficacy of any HN-PCI-specified rehabilitation/clinical pathways received.

The feasibility of using the HN-PCI as a holistic assessment tool in routine clinical practice is suggested by the results obtained in this study and augmented by other HN-PCI studies. In the current format, HN-PCI can be completed regularly in routine FU clinics. It maintains a multidimensional, holistic content while retaining the HNC-specific items, ensuring that HNC patients are able to assess all aspects of the lives in context of their HNC. The HN-PCI also has the ability to screen for significant distress, while simultaneously indicating which unmet concerns are likely to be associated with this. The HN-PCI is simple in its structure, where there is only one question associated with a checklist, thereby, easy for patients to read and understand. The HN-PCI can be filled in using TST or the paper version, which may cater for a wider user-base with different levels of education and socioeconomic backgrounds. Overall, there is favourable acceptance by patients. All these fulfill the **National Cancer Action Team [2011]** criteria set out for PRO tools that are suitable for use during holistic assessments i.e. self-directed, thereby easy for patients to read and understand, considers all of the domains of assessment, and able to stimulate the assessment conversation. This current study has shown that having HN-PCI assisted discussions have resulted in formulation of an action plan to address concerns, which was measured by the increased number of medical actions compared to conventional consultations. Based on this, it may be concluded that the HN-PCI has the ability to personalise the care of HNC received through the engagement of both the patient and their doctor.

Future studies of the HN-PCI should include a qualitative investigation into how the HN-PCI is used by doctors and patients during the consultations, particularly on how it mediates the decision-making process that results in a shared action plan that is personalised to the patient. This may help future training of doctors in handling the HN-PCI in clinics. Future studies should also evaluate the longitudinal impact of HN-PCI to augment the positive results reported in the early stages. This may inform the long-term service planning and delivery. Other areas of research interest include exploring ways that the HN-PCI can help patients disclose their concerns ahead of their appointments and developing the HN-PCI further as a platform for self-management that they can access at anytime.

8.2. Closure

A patient-centred approach is key in personalising HNC survivorship. The HN-PCI is a PRO that can help personalise HNC patient survivorship by promoting patient-centredness during routine HNC visits. As a prompt sheet, the tool enables patients to disclose their concerns, and encourage discussions about a wider range of concerns, particularly in psychological/emotional areas. Critically, the HN-PCI intervention also resulted in higher number of medical outcomes, suggesting an influencing role in shared decision–making in patient care. There is good acceptance of the tool by patients, who report lower levels of distress and better satisfaction scores after HN-PCI mediated consultations. While the HN-PCI was able to indirectly identify patients with significant distress in clinic, its role in understanding the perceived need for additional help/supportive care through requests for referrals was not clearly defined in this study. Wider adoption of the HN-PCI will depend on reducing the barriers that impact upon the efficacy of its implementation. Future work should focus on deeper understanding of how the tool is used to influence clinical decision-making during routine visits, and obtaining longitudinal data that demonstrates its impact on shared clinical decision-making in the long-term.

REFERENCES

CHAPTER 1: INTRODUCTION

1. Abrahams E, Silver M. The case for personalized medicine. J Diabetes Sci Technol. 2009; 3(4):680-4.
2. Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, Rothman M; PRO Harmonization Group. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16, 2001. Value Health 2003; 6:522-31
3. Andersson-Segesten K, Erichsen M, Westerlund A, Ojerskog I. Patients' fears, worries, and concerns when visiting an out-patient clinic. Scand J Prim HealthCare. 1989; 7(4):197-201.
4. Arndt J, Cook A, Goldenberg JL, Cox CR. Cancer and the threat of death: The cognitive dynamics of death thought suppression and its impact on behavioral health intentions. J Pers Soc Psychol. 2007; 92:12–29.
5. Balfe M, O'Brien K, Timmons A, Butow P, O' Sullivan E, Gooberman-Hill R, Sharp L. The unmet supportive care needs of long-term head and neck cancer caregivers in the extended survivorship period. J Clin Nurs. 2016 Jun;25(11-12):1576-86.
6. Berthiller J, Lee YC, Boffetta P, Wei Q, Sturgis EM, Greenland S, Morgenstern H, Zhang ZF, Lazarus P, Muscat J, Chen C, Schwartz SM, Eluf Neto J, Wünsch Filho V, Koifman S, Curado MP, Matos E, Fernandez L, Menezes A, Daudt AW, Ferro G, Brennan P, Hashibe M. Marijuana smoking and the risk of head and neck cancer: pooled analysis in the INHANCE consortium. Cancer Epidemiol Biomarkers Prev. 2009; 18: 1544-51.
7. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002; 288(19):2469-75.
8. Bourhis J, Overgaard J, Audry H, Ang KK, Saunders M, Bernier J, Horiot JC, Le Maître A, Pajak TF, Poulsen MG, O'Sullivan B, Dobrowsky W, Hliniak A, Skladowski K, Hay JH, Pinto LH, Fallai C, Fu KK, Sylvester R, Pignon JP. Meta-Analysis of Radiotherapy in Carcinomas of Head and neck (MARCH) Collaborative Group. Hyperfractionated or accelerated radiotherapy in head and neck cancer: a meta-analysis. Lancet. 2006; 368:843-54.
9. Bourhis J, Sire C, Graff P, Grégoire V, Maingon P, Calais G, Gery B, Martin L, Alfonsi M, Desprez P, Pignon T, Bardet E, Rives M, Geoffrois L, Daly-Schveitzer N, Sen S, Tuchais C, Dupuis O, Guerif S, Lapeyre M, Favrel V, Hamoir M, Lusinchi A, Temam S, Pinna A, Tao YG, Blanchard P, Aupérin A. Concomitant chemoradiotherapy versus acceleration of radiotherapy with or without concomitant chemotherapy in locally advanced head and neck carcinoma (GORTEC 99-02): an open-label phase 3 randomised trial. Lancet Oncol. 2012; 13:145-53.
10. Bradshaw PT, Siega-Riz AM, Campbell M, Weissler MC, Funkhouser WK, Olshan AF. Associations between dietary patterns and head and neck cancer: the Carolina head and neck cancer epidemiology study. Am J Epidemiol. 2012; 175:1225-33.
11. Brown JS, Blackburn TK, Woolgar JA, Lowe D, Errington RD, Vaughan ED, Rogers SN. A comparison of outcomes for patients with oral squamous cell carcinoma at intermediate risk of recurrence treated by surgery alone or with post-operative radiotherapy. Oral Oncol. 2007 Sep;43(8):764-73. Epub 2006 Dec 14. PubMed PMID: 17174140.
12. Cadoni G, Boccia S, Petrelli L, Di Giannantonio P, Arzani D, Giorgio A, De Feo E, Pandolfini M, Gallì P, Paludetti G, Ricciardi G. A review of genetic epidemiology of head and neck cancer related to polymorphisms in metabolic genes, cell cycle control and alcohol metabolism. Acta Otorhinolaryngol Ital. 2012; 32:1-11.
13. Carlson LE, Waller A, Mitchell AJ. Screening for distress and unmet needs in patients with cancer: review and recommendations. J Clin Oncol. 2012; 30(11):1160-77.
14. Carvalho AL, Singh B, Spiro RH, Kowalski LP, Shah JP. Cancer of the oral cavity: a comparison between institutions in a developing and a developed nation. Head Neck. 2004 Jan;26(1):31-8.
15. Chandu A, Smith AC, Rogers SN. Health-related quality of life in oral cancer: a review. J Oral Maxillofac Surg 2006; 64:495-502.
16. Chang ET, Adami HO. The enigmatic epidemiology of nasopharyngeal carcinoma. Cancer Epidemiol Biomarkers Prev. 2006; 15: 1765-77.
17. Chen YJ, Chang JT, Liao CT, Wang HM, Yen TC, Chiu CC, Lu YC, Li HF, Cheng AJ. Head and neck cancer in the betel quid chewing area: recent advances in molecular carcinogenesis. Cancer Sci. 2008; 99:1507-14.

18. Chuang SC, Jenab M, Heck JE, Bosetti C, Talamini R, Matsuo K, Castellsague X, Franceschi S, Herrero R, Winn DM, La Vecchia C, Morgenstern H, Zhang ZF, Levi F, Dal Maso L, Kelsey K, McClean MD, Vaughan T, Lazarus P, Muscat J, Ramroth H, Chen C, Schwartz SM, Eluf-Neto J, Hayes RB, Purdue M, Boccia S, Cadoni G, Zaridze D, Koifman S, Curado MP, Ahrens W, Benhamou S, Matos E, Lagiou P, Szeszenia-Dabrowska N, Olshan AF, Fernandez L, Menezes A, Agudo A, Daudt AW, Merletti F, Macfarlane GJ, Kjaerheim K, Mates D, Holcatova I, Schantz S, Yu GP, Simonato L, Brenner H, Mueller H, Conway DI, Thomson P, Fabianova E, Znaor A, Rudnai P, Healy CM, Ferro G, Brennan P, Boffetta P, Hashibe M. Diet and the risk of head and neck cancer: a pooled analysis in the INHANCE consortium. Cancer Causes Control. 2012; 23:69-88.
19. Conley BA, Cumberlin R, Sandberg A, Solomon B, Van Waes C. NIH symposium summary: organ preservation therapies for squamous cancers of the head and neck. Clin Cancer Res. 2001; 7: 745-53.
20. Conway DI, McKinney PA, McMahon AD, Ahrens W, Schmeisser N, Benhamou S, Bouchardy C, Macfarlane GJ, Macfarlane TV, Lagiou P, Minaki P, Bencko V, Holcátová I, Merletti F, Richiardi L, Kjaerheim K, Agudo A, Castellsague X, Talamini R, Barzan L, Canova C, Simonato L, Lowry RJ, Znaor A, Healy CM, McCartan BE, Marron M, Hashibe M, Brennan P. Socioeconomic factors associated with risk of upper aerodigestive tract cancer in Europe. Eur J Cancer. 2010 Feb;46(3):588-98.
21. Conway DI, McMahon AD, Smith K, Black R, Robertson G, Devine J, McKinney PA. Components of socioeconomic risk associated with head and neck cancer: a population-based case-control study in Scotland. Br J Oral Maxillofac Surg. 2010;48(1):11-7.
22. da Silva SD, Hier M, Mlynarek A, Kowalski LP, Alaoui-Jamali MA. Recurrent oral cancer: current and emerging therapeutic approaches. Front Pharmacol. 2012 Jul 30;3:149.
23. DAHNO. National Clinical Audit Support Programme Head Neck Cancer DAHNO Second Annual Report - 2005-2006. 2007. Avaiable at: https://catalogue.ic.nhs.uk/publications/clinical/headneck/clin-audi-supp-prog-head-neck-dahn-2005-2006/clin-audi-supp-prog-head-neck-dahn-05-06-rep2.pdf. Accessed on 20 July 2017.
24. DAHNO. National Clinical Audit Support Programme Head Neck Cancer DAHNO Seventh Annual Report 2010-2011.2012. https://catalogue.ic.nhs.uk/publications/clinical/headneck/clin-audi-supp-prog-head-neck-dahn-2010-2011/clin-audi-supp-prog-head-neck-dahn-10-11-rep.pdf.
25. Davies NJ, Batehup L. Towards a personalised approach to aftercare: a review of cancer follow-up in the UK. J Cancer Surviv. 2011; 5(2):142-51.
26. de Bree R, Leemans CR. Recent advances in surgery for head and neck cancer. Curr Opin Oncol. 2010 May;22(3):186-93.
27. Delaney G, Barton M, Jacob S. Estimation of an optimal radiotherapy utilization rate for gastrointestinal carcinoma: a review of the evidence. Cancer. 2004; 101:657-70.
28. Denis F, Garaud P, Bardet E, et al. Late toxicity results of the GORTEC 94–01 randomized trial comparing radiotherapy with concomitant radio-chemoradiotherapy for advanced-stage oropharynx carcinoma: comparison of LENT/SOMA, RTOG/ EORTC, and NCI-CTC scoring systems. Int J Radiat Oncol Biol Phys 2003; 55: 93–98.
29. Department of Health (DOH). National Cancer Survivorship Initiative Vision. 2010. Availale at:http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111477.pdf. Accessed on 20 July 2017.
30. Epstein JB, Wong FL, Stevenson-Moore P. Osteoradionecrosis: clinical experience and a proposal for classification. J Oral Maxillofac Surg. 1987; 45(2):104-10.
31. Food and Drug Administration. Guidance for industry. Patient-reported outcome measures: Use in medical product development to support labeling claims. 2009. Available at:
32. Freedman ND, Park Y, Subar AF, Hollenbeck AR, Leitzmann MF, Schatzkin A, Abnet CC. Fruit and vegetable intake and head and neck cancer risk in a large United States prospective cohort study. Int J Cancer. 2008; 122:2330-6.
33. Ginsburg GS, Willard HF. Genomic and personalized medicine: foundations and applications. Transl Res. 2009; 154(6):277-87.
34. Giuliani M, McQuestion M, Jones J, Papadakos J, Le LW, Alkazaz N, Cheng T, Waldron J, Catton P, Ringash J. Prevalence and nature of survivorship needs in patients with head and neck cancer. Head Neck. 2016 Jul;38(7):1097-103.
35. Gold D. The psychosocial care needs of patients with HPV-related head and neck cancer. Otolaryngol Clin North Am. 2012 Aug;45(4):879-97.
36. Greenberg JS, El Naggar AK, Mo V, Roberts D, Myers JN. Disparity in pathologic and clinical lymph node staging in oral tongue carcinoma. Implication for therapeutic decision making. Cancer. 2003 Aug 1;98(3):508-15.

37. Guizard AV, Uhry Z, de Raucourt D, Mazzoleni G, Sánchez MJ, Ligier K; GRELL EUROCARE-5 Working Group. Trends in net survival from head and neck cancer in six European Latin countries: results from the SUDCAN population-based study. Eur J Cancer Prev. 2017 Jan;26 Trends in cancer net survival in six European Latin Countries: the SUDCAN study:S16-S23. doi: 10.1097/CEJ.0000000000000296.
38. Gutiontov SI, Shin EJ, Lok B, Lee NY, Cabanillas R. Intensity-modulated radiotherapy for head and neck surgeons. Head Neck. 2016 Apr;38 Suppl 1:E2368-73.
39. Hammarstedt L, Lindquist D, Dahlstrand H, Romanitan M, Dahlgren LO, Joneberg J, Creson N, Lindholm J, Ye W, Dalianis T, Munck-Wikland E. Human papillomavirus as a risk factor for the increase in incidence of tonsillar cancer. Int J Cancer 2006; 119: 2620–23.
40. Hammerlid E, Silander E, Hörnestam L, Sullivan M.Health-related quality of life three years after diagnosis of head and neck cancer--a longitudinal study. Head Neck. 2001 Feb;23(2):113-25
41. Hashibe M, Brennan P, Chuang SC, Boccia S, Castellsague X, Chen C, Curado MP, Dal Maso L, Daudt AW, Fabianova E, Fernandez L, Wünsch-Filho V, Franceschi S, Hayes RB, Herrero R, Kelsey K, Koifman S, La Vecchia C, Lazarus P, Levi F, Lence JJ, Mates D, Matos E, Menezes A, McClean MD, Muscat J, Eluf-Neto J, Olshan AF, Purdue M, Rudnai P, Schwartz SM, Smith E, Sturgis EM, Szeszenia-Dabrowska N, Talamini R, Wei Q, Winn DM, Shangina O, Pilarska A, Zhang ZF, Ferro G, Berthiller J, Boffetta P. Interaction between tobacco and alcohol use and the risk of head and neck cancer: pooled analysis in the International Head and Neck Cancer Epidemiology Consortium. Cancer Epidemiol Biomarkers Prev. 2009;18:541-50.
42. Heck JE, Berthiller J, Vaccarella S, Winn DM, Smith EM, Shan'gina O, Schwartz SM, Purdue MP, Pilarska A, Eluf-Neto J, Menezes A, McClean MD, Matos E, Koifman S, Kelsey KT, Herrero R, Hayes RB, Franceschi S, Wünsch-Filho V, Fernández L, Daudt AW, Curado MP, Chen C, Castellsagué X, Ferro G, Brennan P, Boffetta P, Hashibe M. Sexual behaviours and the risk of head and neck cancers: a pooled analysis in the International Head and Neck Cancer Epidemiology (INHANCE) consortium. Int J Epidemiol. 2010; 39:166-81.
43. Henry M, Habib LA, Morrison M, Yang JW, Li XJ, Lin S, Zeitouni A, Payne R, MacDonald C, Mlynarek A, Kost K, Black M, Hier M. Head and neck cancer patients want us to support them psychologically in the posttreatment period: Survey results. Palliat Support Care. 2014 Dec;12(6):481-93.
44. Her M, Kavanaugh A. Patient-reported outcomes in rheumatoid arthritis. Curr Opin Rheumatol. 2012; 24(3):327-34.
45. Heutte N, Plisson L, Lange M, Prevost V, Babin E. Quality of life tools in head and neck oncology. Eur Ann Otorhinolaryngol Head Neck Dis. 2014. Feb;131(1):33-47. http:// www.fda.gov/downloads/drugs/guidance/ucm193282.pdf. Accessed on 20 July 2017.
46. Huang DT, Johnson CR, Schmidt-Ullrich R, Grimes M. Postoperative radiotherapy in head and neck carcinoma with extracapsular lymph node extension and/or positive resection margins: a comparative study. Int J Radiat Oncol Biol Phys. 1992; 23:737–42.
47. Jackson RS, Schmalbach CE. New Frontiers in Surgical Innovation. Otolaryngol Clin North Am. 2017 Jun 7. pii: S0030-6665(17)30057-9. doi:10.1016/j.otc.2017.03.009. [Epub ahead of print] Review. PubMed PMID: 28601195.
48. Jefferies S, Eeles R, Goldgar D, A'Hern R, Henk JM, Gore M. The role of genetic factors in predisposition to squamous cell cancer of the head and neck. Br J Cancer. 1999; 79: 865-7.
49. Jemal A, Siegel R, Xu J, Ward E. Cancer statistics, 2010. CA Cancer J Clin. 2010; 60: 277-300.
50. Kachroo N, Gnanapragasam VJ. The role of treatment modality on the utility of predictive tissue biomarkers in clinical prostate cancer: a systematic review. J Cancer Res Clin Oncol. 2013 Jan;139(1):1-24.
51. Kowalski LP, Franco EL, Torloni H, Fava AS, de Andrade Sobrinho J, Ramos G, Oliveira BV, Curado MP. Lateness of diagnosis of oral and oropharyngeal carcinoma: factors related to the tumour, the patient and health professionals. Eur J Cancer B Oral Oncol. 1994; 30B: 167-173.
52. Kreimer AR, Clifford GM, Boyle P, Franceschi S. Human papillomavirus types in head and neck squamous cell carcinomas worldwide: a systematic review. Cancer Epidemiol Biomarkers Prev 2005; 14: 467–75.
53. Lawn S, Schoo A. Supporting self-management of chronic health conditions: common approaches. Patient Educ Couns. 2010 Aug;80(2):205-11.
54. Lefebvre J-L, Chevalier D, Luboinski B, Kirkpatrick A, Collette L, Sahmoud T. Larynx preservation in pyriform sinus cancer: preliminary results of a European Organization for Research and Treatment of Cancer Phase III Trial. J Natl Cancer Inst. 1996; 88: 890–899.
55. Li RJ, Richmon JD. Transoral endoscopic surgery: new surgical techniques for oropharyngeal cancer. Otolaryngol Clin North Am. 2012 Aug;45(4):823-44.

56. Lipscomb J, Gotay CC, Snyder CF. Patient-reported outcomes in cancer: a review of recent research and policy initiatives. CA Cancer J Clin. 2007; 57(5):278-300.
57. Maddams J, Møller H, Devane C. Cancer Prevalence in the UK. 2008. National Cancer Intelligence Network and Macmillan Cancer Support, London. Avaialable at: http://www.thames-cancer-reg.org.uk/news/uk_prevalence_14072008.pdf. Accessed 20 July 2017.
58. Mehanna H, Paleri V, West CML, Nutting C. Head and neck cancer—Part 1: Epidemiology, presentation, and prevention. BMJ 2010; 341:c4684.
59. Mehanna HM, Morton RP. Deterioration in quality-of-life of late (10-year) survivors of head and neck cancer. Clin Otolaryngol. 2006 Jun;31(3):204-11.
60. Mehta PS, Harrison LB. Function and organ preservation in adult cancers of the head and neck. Expert Rev Anticancer Ther. 2007; 7: 361-71.
61. Moore KA, Ford PJ, Farah CS. "I have quality of life…but…": Exploring support needs important to quality of life in head and neck cancer. Eur J Oncol Nurs.2014 Apr;18(2):192-200.
62. Moriya T, Kanomata N, Kozuka Y, Hirakawa H, Kimijima I, Kimura M, Watanabe M, Sasano H, Ishida T, Ohuchi N, Kurebayashi J, Sonoo H. Molecular morphological approach to the pathological study of development and advancement of human breast cancer. Med Mol Morphol. 2010 Jun;43(2):67-73.
63. Morton T, Morgan M. Examining how personalised care planning can help patients with long-term conditions. Nurs Times. 2009; 105(37):13-5.
64. Mourad M, Jetmore T, Jategaonkar AA, Moubayed S, Moshier E, Urken ML. Epidemiological Trends of Head and Neck Cancer in the United States: A SEER Population Study. J Oral Maxillofac Surg. 2017 May 22. pii: S0278-2391(17)30537-2. doi: 10.1016/j.joms.2017.05.008.
65. Mullan F. Seasons of survival: reflections of a physician with cancer. N Engl J Med. 1985; 313:270-273.
66. O 'Brien KM, Timmons A, Butow P, Gooberman-Hill R, O'Sullivan E, Balfe M, SharpL. Associations between neighbourhood support and financial burden with unmet needs of head and neck cancer survivors. Oral Oncol. 2017 Feb;65:57-64.
67. O'Hanlon S, Forster DP, Lowry RJ. Oral cancer in the North-East of England: incidence, mortality trends and the link with material deprivation. Community Dent Oral Epidemiol. 1997; 25: 371-6.
68. Office of National Statistics. Cancer incidence and mortality in the United Kingdom,2008-2010. 2012. Avaiable at: http://www.ons.gov.uk/ons/dcp171778_289890.pdf.. Accessed on 20 July 2017.
69. Oskam IM, Verdonck-de Leeuw IM, Aaronson NK, Witte BI, de Bree R, Doornaert P, Langendijk JA, Leemans CR. Prospective evaluation of health-related quality of life in long-term oral and oropharyngeal cancer survivors and the perceived need for supportive care. Oral Oncol. 2013 May;49(5):443-8.
70. Oxford Cancer Intelligence Unit. Profile of head and neck cancers in England. 2010. Available at: http://library.ncin.org.uk/docs/100504-OCIU-Head_and_Neck_Profiles.pdf.. Accessed on 20 July 2017.
71. Patel PR, Salama JK. Reirradiation for recurrent head and neck cancer. Expert Rev Anticancer Ther. 2012; 12:1177-89.
72. Perri F, Muto P, Aversa C, Daponte A, Della Vittoria G, Pepe S, Caponigro F. Integrated therapeutic approaches in head and neck cancer: the importance of multidisciplinary team management. Anticancer Agents Med Chem. 2013 Jul 1;13(6):834-43.
73. Pignon JP, Bourhis J, Domenge C, Designe, L. Chemotherapy added to locoregional treatment for head and neck squamous cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on head and neck cancer. Lancet. 2000; 355:949–955.
74. Pignon JP, le Maitre A, Maillard E, Bourhis J. Meta-analysis of chemotherapy in head and neck cancer (MACH-NC): an update on 93 randomised trials and 17,346 patients. Radiother Oncol 2009; 92: 4–14.
75. Pusic A, Liu JC, Chen CM, Cano S, Davidge K, Klassen A, Branski R, Patel S, Kraus D, Cordeiro PG. A systematic review of patient-reported outcome measures in head and neck cancer surgery. Otolaryngol Head Neck Surg. 2007 Apr;136(4):525-35. Review. PubMed PMID: 17418246.
76. Qin H, Luo J, Zhu YP, Xie HL, Yang WQ, Lei WB. Combination of taxanes, Cisplatin and Fluorouracil as induction chemotherapy for locally advanced head and neck cancer: a meta-analysis. PLoS One. 2012; 7(12):e51526.
77. Razak AR, Siu LL, Le Tourneau C. Molecular targeted therapies in all histologies of head and neck cancers: an update. Curr Opin Oncol. 2010; 22:212-20.

78. Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: a review of assessment tools. Support Care Cancer 2007; 15:1125-44.
79. Ringash J, Bezjak A. A structured review of quality of life instruments for head and neck cancer patients. Head Neck. 2001 Mar;23(3):201-13.
80. Robbins KT, Clayman G, Levine PA, Medina J, Sessions R, Shaha A, Som P, Wolf GT; American Head and Neck Society; American Academy of Otolaryngology--Head and Neck Surgery. Neck dissection classification update: revisions proposed by the American Head and Neck Society and the American Academy of Otolaryngology-Head and Neck Surgery. Arch Otolaryngol Head Neck Surg. 2002; 128:751-8.
81. Robbins KT, Shaha AR, Medina JE, Califano JA, Wolf GT, Ferlito A, Som PM, Day TA; Committee for Neck Dissection Classification, American Head and Neck Society.Consensus statement on the classification and terminology of neck dissection. Arch Otolaryngol Head Neck Surg. 2008; 134:536-8.
82. Rogers SN, Brown JS, Woolgar JA, Lowe D, Magennis P, Shaw RJ, Sutton D, Errington D, Vaughan D. Survival following primary surgery for oral cancer. Oral Oncol. 2009 Mar;45(3):201-11.
83. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009 Jul;45(7):555-61.
84. Seiwert TY, Cohen EE. State-of-the-art management of locally advanced head and neck cancer. Br J Cancer. 2005; 92:1341-8.
85. Shiboski CH, Schmidt BL, Jordan RC. Tongue and tonsil carcinoma: increasing trends in the U.S. population ages 20–44 years. Cancer 2005; 103:1843–49.
86. Siegel R, DeSantis C, Virgo K, Stein K, Mariotto A, Smith T, Cooper D, Gansler T, Lerro C, Fedewa S, Lin C, Leach C, Cannady RS, Cho H, Scoppa S, Hachey M, Kirch R, Jemal A, Ward E. Cancer treatment and survivorship statistics, 2012. CA Cancer J Clin. 2012; 62(4): 220-41.
87. Simcock R, Simo R. Follow-up and Survivorship in Head and Neck Cancer. Clin Oncol (R Coll Radiol). 2016 Jul;28(7):451-8.
88. Sturgis EM, Wei Q. Genetic susceptibility--molecular epidemiology of head and neck cancer. Curr Opin Oncol. 2002; 14:310-7.
89. Sutton DN, Brown JS, Rogers SN, Vaughan ED, Woolgar JA. The prognostic implications of the surgical margin in oral squamous cell carcinoma. Int J Oral Maxillofac Surg. 2003 Feb;32(1):30-4.
90. Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. Clin Med. 2002; 2(3):227-9.
91. The Department of Veterans Affairs Laryngeal Cancer Study Group. Induction chemotherapy plus radiation compared with surgery plus radiation in patients with advanced laryngeal cancer. N Engl J Med. 1991; 324: 1685–1690.
92. Trizna Z, Schantz SP. Hereditary and environmental factors associated with risk and progression of head and neck cancer. Otolaryngol Clin North Am. 1992; 25: 1089–1103.
93. Vartanian JG, Kowalski LP. Acceptance of major surgical procedures and quality of life among long-term survivors of advanced head and neck cancer. Arch Otolaryngol Head Neck Surg. 2009; 135: 376-9.
94. Verdonck-de Leeuw IM, van Nieuwenhuizen A, Leemans CR. The value of quality-of-life questionnaires in head and neck cancer. Curr Opin Otolaryngol Head Neck Surg. 2012 Apr;20(2):142-7.
95. Vermorken JB, Remenar E, van Herpen C, Gorlia T, Mesia R, Degardin M, Stewart JS, Jelic S, Betka J, Preiss JH, van den Weyngaert D, Awada A, Cupissol D, Kienzer HR, Rey A, Desaunois I, Bernier J, Lefebvre JL; EORTC 24971/TAX 323 Study Group. Cisplatin, fluorouracil, and docetaxel in unresectable head and neck cancer. N Engl J Med. 2007 Oct 25;357(17):1695-704.
96. Watson EK, Rose PW, Neal RD, Hulbert-Williams N, Donnelly P, Hubbard G, Elliott J, Campbell C, Weller D, Wilkinson C. Personalised cancer follow-up: risk stratification, needs assessment or both? Br J Cancer. 2012 Jan 3;106(1):1-5.
97. Wehage IC, Fansa H. Complex reconstructions in head and neck cancer surgery: decision making. Head Neck Oncol. 2011; 8;3:14.
98. Weinstein GS, O'Malley BW Jr, Magnuson JS, Carroll WR, Olsen KD, Daio L, Moore EJ, Holsinger FC. Transoral robotic surgery: a multicenter study to assess feasibility, safety, and surgical margins. Laryngoscope. 2012 Aug;122(8):1701-7.
99. Wells M, Cunningham M, Lang H, Swartzman S, Philp J, Taylor L, Thomson J. Distress, concerns and unmet needs in survivors of head and neck cancer: a cross-sectional survey. Eur J Cancer Care (Engl). 2015 Sep;24(5):748-60.

100. Woolgar JA. The topography of cervical lymph node metastases revisited: the histological findings in 526 sides of neck dissection from 439 previously untreated patients. Int J Oral Maxillofac Surg. 2007; 36:219-25.

CHAPTER 2: IDENTIFYING NEEDS AND CONCERNS

1. Acheson RM. The definition and identification of need for health care. Journal of Epidemiology and Community Health 1978; 32: 10-15.
2. Adams E, Boulton M, Rose P, Lund S, Richardson A, Wilson S, Watson E. Views of cancer care reviews in primary care: a qualitative study. Br J Gen Pract. 2011 Apr;61(585):173-82.
3. Aguilar ML, Sandow P, Werning JW, Brenneman L, Psoter WJ. The Head and Neck Cancer Patient Concern Inventory(©) : Patient Concerns' Prevalence, Dental Concerns' Impact, and Relationships of Concerns with Quality of Life Measures. J Prosthodont. 2017 Apr;26(3):186-195.
4. Ahmed AE, Lowe D, Kirton JA, O'Brien MR, Mediana A, Frankland H, Bruce H, Kennedy T, Rogers SN, Moots RJ. Development of a Rheumatology-specific Patient Concerns Inventory and Its Use in the Rheumatology Outpatient Clinic Setting. J Rheumatol. 2016 Apr;43(4):779-87.
5. Allen S, Lowe D, Harris RV, Brown S, Rogers SN. Is social inequality related to different patient concerns in routine oral cancer follow-up clinics? Eur Arch Otorhinolaryngol. 2017 Jan;274(1):451-459.
6. Aristotle. Nicomachean ethics. Ostwald M, trans. New York: Bobbs Merrill, 1962; 1:26-36.
7. Asadi-Lari M, Packham C, Gray D. Need for redefining needs. Health Qual Life Outcomes 2003; 1:34.
8. Baile WF, Aaron J. Patient-physician communication in oncology: past, present, and future. Curr Opin Oncol 2005; 17:331–335.
9. Baile WF, Palmer JL, Bruera E, Parker PA. Assessment of palliative care cancer patients' most important concerns. Support Care Cancer. 2011 Apr;19(4):475-81.
10. Balint M. The doctor, his patient and the illness. Lancet 1955; 1:318.
11. Barg FK, Cronholm PF, Straton JB, Keddem S, Knott K, Grater J, Houts P, Palmer SC. Unmet psychosocial needs of Pennsylvanians with cancer: 1986-2005. Cancer. 2007 Aug 1;110(3):631-9.
12. Best M, Butow P, Olver I. Spiritual support of cancer patients and the role of the doctor. Support Care Cancer. 2014 May; 22(5):1333-9.
13. Bradshaw J. A taxonomy of social need. In: MacLachlan G, editor. Problems and Progress in Medical Care, 7th Series. London: Oxford University Press, 1972.
14. Brandes K, Linn AJ, Butow PN, van Weert JC. The characteristics and effectiveness of Question Prompt List interventions in oncology: a systematic review of the literature. Psychooncology. 2015 Mar;24(3):245-52.
15. Carey M, Lambert S, Smits R, Paul C, Sanson-Fisher R, Clinton-McHarg T. The unfulfilled promise: a systematic review of interventions to reduce the unmet supportive care needs of cancer patients. Support Care Cancer. 2012 Feb;20(2):207-19.
16. Cegala DJ, Post DM.The impact of patients' participation on physicians' patient-centered communication. Patient Educ Couns. 2009 Nov;77(2):202-8.
17. Chatzimarkakis J. Why should patients be more empowered?. J Diabetes Sci Technol. 2010; 4(6):1570-3.
18. **(Chen 2009A)** Chen SC, Liao CT, Lin CC, Chang JT, Lai YH. Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. Oral Oncol. 2009 Sep;45(9):815-20.
19. **(Chen 2009B)** Chen SC, Tsai MC, Liu CL, Yu WP, Liao CT, Chang JT. Support needs of patients with oral cancer and burden to their family caregivers. Cancer Nurs. 2009 Nov-Dec;32(6):473-81.
20. **(Chen 2009C)** Chen AM, Jennelle RL, Grady V, Tovar A, Bowen K, Simonin P, Tracy J, McCrudden D, Stella JR, Vijayakumar S. Prospective study of psychosocial distress among patients undergoing radiotherapy for head and neck cancer. Int J Radiat Oncol Biol Phys. 2009 Jan 1;73(1):187-93.
21. Cianci R, Gambrel PA. Maslow's hierarchy of needs: Does it apply in a collectivist culture. Journal of Applied Management and Entrepreneurship 2003; 8: 143-161.
22. Clayton MF, Dudley WN. Patient-centered communication during oncology follow-up visits for breast cancer survivors: content and temporal structure. Oncol Nurs Forum. 2009

Mar;36(2):E68-79.

23. Committee on Quality of Health Care in America. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy Press: Washington, D.C., 2001.
24. Culyer AJ. Need and the National Health Service. Oxford: Martin Robertson, 1976.
25. DAHNO. National Clinical Audit Support Programme Head Neck Cancer Tenth Annual Report 2013-2014. 2015. Available at: http://content.digital.nhs.uk/catalogue/PUB18081/clin-audi-supp-prog-head-neck-dahn-13-14.pdf. Accessed on 20 July 2017.
26. Department of Health (DOH). Cancer Reforms Strategy. 2007. Available at: http://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf. Accessed on 20 July 2017.
27. Department of Health Supporting people with Long Term Condition: Commissioning Personalised Care Planning, A Guide for Commissioners, London: Department of Health, 2010.
28. Department of Health: The health of the nation: a strategy for health in England. London, Department of Health; 1992.
29. Department of Health. Cancer reform strategy. 2007. http://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf.
30. Department of Health. National Cancer Survivorship Initiative Vision. 2010. Available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111477.pdf. Accessed on 20 July 2017.
31. Department of Health. The NHS Cancer Plan and the new NHS. Providing a patient-centered service. 2004. Available at: www.wales.**nhs**.uk/technologymls/english/resources/pdf/**cancer**_nsf.pdf. Accessed on 10 May 2014.
32. Department of Health. The single assessment process. Key implications for older people. 2003. Available at: http://webarchive.nationalarchives.gov.uk/20031124094727/http://www.doh.gov.uk:80/scg/sap/olderpeople.pdf. Accessed 20 July 2017.
33. Detmar SB, Aaronson NK, Wever LD, Muller M, Schornagel JH. How are you feeling? Who wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life issues. J Clin Oncol. 2000 Sep 15;18(18):3295-301.
34. Detmar SB, Muller MJ, Wever LD et al. Patient–physician communication during outpatient palliative treatment visits: an observational study. JAMA 2001; 285:1,351–1,357.
35. Donabedian, A. Aspects of Medical Care Administration. Harvard University Press: Cambridge, Mass. 1974.
36. Dowsett SM, Saul JL, Butow PN, Dunn SM, Boyer MJ, Findlow R, Dunsmore J Communication styles in the cancer consultation: preferences for a patient-centred approach. Psychooncology. 2000 Mar-Apr;9(2):147-56
37. Doyal L, Gough I. The theory of human need. Critical Social Policy 1984; 4:6-38.
38. Drossman DA, Leserman J, Li ZM, Mitchell CM, Zagami EA, Patrick DL. The rating form of IBD patient concerns: a new measure of health status. Psychosom Med. 1991 Nov-Dec;53(6):701-12.
39. Epstein R, Street R, Jr. Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. National Cancer Institute: Bethesda, MD, 2007.
40. Fagerlind H, Lindblad AK, Bergström I et al. Patient–physician communication during oncology consultations. Psychooncology 2008; 17: 975–985.
41. FDA Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims (2009). https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf
42. Feldman-Stewart D, Brundage MD, Tishelman C; SCRN Communication Team. A conceptual framework for patient-professional communication: an application to the cancer context. Psychooncology. 2005 Oct;14(10):801-9; discussion 810-1.
43. Fetscher I. Karl Marx on human nature. Social Research 1973; 40: 443-67.
44. Fitzgerald R. Human Needs and Politics: The Ideas of Christian Bay and Herbert Marcuse. Political Psychology 1985; 6: 87-108.
45. Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. Qual Life Res. 2008; 17:1297–1302.
46. Ghazali N, Kanatas A, Langley D, Scott B, Lowe D, Rogers SN. Treatment Referral Before and After the Introduction of the Liverpool Patients Concerns Inventory (PCI) into Routine Head and Neck Oncology Outpatient Clinics. Support Care Cancer 2011 19:1879-86
47. Ghazali N, Rogers SN. The Head and Neck Cancer Patients Concerns Inventory (PCI): A practical holistic assessment tool in outpatients setting. Patient Reported Outcomes newsletter

2011; 45: 1-4.

48. Ghazali N, Kanatas A, Scott B, Lowe D, Zuydam A, Rogers SN. Use of the Patient Concerns Inventory to identify speech and swallowing concerns following treatment for oral and oropharyngeal cancer. J Laryngol Otol. 2012 Aug;126(8):800-8. doi: 10.1017/S0022215112001107.
49. **(Ghazali 2013A)** Ghazali N, Kanatas A, Bekiroglu F, Lowe D, Rogers SN. The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic. Bulletin of The Royal College of Surgeons of England 2013; 95(3): 1-6.
50. **(Ghazali 2013B)** Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN. Fear of recurrence among head and neck cancer survivors: longitudinal trends. Psychooncology. 2013 Apr;22(4):807-13.
51. Gysels M, Higginson IJ, Rajasekaran M, Davies E, Harding R. Improving supportive and palliative care for adults with cancer: Research Evidence. 2004. National Institute of Clinical Excellence & Kings College London, London.
52. Harrison JD, Young JM, Price MA, Butow PN, Solomon MJ. What are the unmet supportive care needs of people with cancer? A systematic review. Support Care Cancer. 2009; 17:1117-28.
53. Hatta JM, Doss JG, Rogers SN. The feasibility of using Patients Concerns Inventory (PCI) in managing Malaysian oral cancer patients. Int J Oral Maxillofac Surg. 2014 Feb;43(2):147-55.
54. Holland JC, Bultz BD. The NCCN guideline for distress management: A case for making distress the sixth vital sign. J Natl Compr Canc Netw. 2007; 5:3-7.
55. Huber M, Knottnerus JA, Green L, van der Horst H, Jadad AR, Kromhout D, Leonard B, Lorig K, Loureiro MI, van der Meer JW, Schnabel P, Smith R, van Weel C, Smid H. How should we define health? BMJ. 2011 Jul 26;343:d4163.
56. Hudon C, St-Cyr Tribble D, Légaré F, Bravo G, Fortin M, Almirall J. Assessing enablement in clinical practice: a systematic review of available instruments. Journal of Evaluation in Clinical Practice. 2010;16(6):1301-1308.
57. Hudon C, Fortin M, Haggerty J, Loignon C, Lambert M, Poitras ME. Patient-centered care in chronic disease management: a thematic analysis of the literature in family medicine. Patient Educ Couns. 2012; 88:170-6.
58. James M. Towards an integrated needs and outcome Framework. Health Policy 1999; 46: 165–177.
59. Jayadevappa R, Chhatre S. Patient Centered Care - A Conceptual Model and Review of the State of the Art. Open Health Services and Policy Journal 2011: 4: 15-25.
60. Jelsness-Jørgensen LP, Moum B, Bernklev T. Worries and Concerns among Inflammatory Bowel Disease Patients Followed Prospectively over One Year. Gastroenterol Res Pract. 2011;2011:492034.
61. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319.
62. Kanatas A, Ghazali N, Lowe D, Rogers SN. The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. Int J Oral Maxillofac Surg. 2012 Apr;41(4):429-36.
63. Kanatas A, Ghazali N, Lowe D, Udberg M, Heseltine J, O'Mahony E, Rogers SN. Issues patients would like to discuss at their review consultation: variation by early and late stage oral, oropharyngeal and laryngeal subsites. Eur Arch Otorhinolaryngol. 2013 Mar;270(3):1067-74.
64. Kanatas A, Humphris G, Lowe D, Rogers SN. Further analysis of the emotional consequences of head and neck cancer as reflected by the Patients' Concerns Inventory. Br J Oral Maxillofac Surg. 2015 Oct;53(8):711-8.
65. Kanatas A, Lowe D, Velikova G, Roe B, Horgan K, Shaw RJ, Rogers SN. Issues patients would like to discuss at their review consultation in breast cancer clinics--a cross-sectional survey. Tumori. 2014 Sep-Oct;100(5):568-79.
66. Laine C, Davido F. Patient-centered medicine: a professional evolution. Journal of the American Medical Association 1996; 275: 152-156.
67. Lawn S, Schoo A. Supporting self-management of chronic health conditions: common approaches. Patient Educ Couns. 2010 Aug;80(2):205-11.
68. Leventhal H, Cleary PD. The smoking problem: a review of the research and theory in behavioral risk modification. Psychol Bull. 1980 Sep;88(2):370-405.
69. Lightfoot J. Identifying needs and setting health care priorities: Issues of theory and practice. Health Social Care 1995; 3: 105-14
70. Llewellyn CD, McGurk M, Weinman J. Illness and treatment beliefs in head and neck cancer: is Leventhal's common sense model a useful framework for determining changes in outcomes over time? J Psychosom Res. 2007 Jul;63(1):17-26.

71. Llewellyn CD, Weinman J, McGurk M, Humphris G. Can we predict which head and neck cancer survivors develop fears of recurrence? J Psychosom Res 2008; **65**:525-32.
72. Low C, Fullarton M, Parkinson E, O'Brien K, Jackson SR, Lowe D, Rogers SN. Issues of intimacy and sexual dysfunction following major head and neck cancer treatment. Oral Oncol. 2009 Oct;45(10):898-903.
73. Low C, Fullarton M, Parkinson E, O'Brien K, Jackson SR, Lowe D, Rogers SN. Issues of intimacy and sexual dysfunction following major head and neck cancer treatment. Oral Oncol. 2009 Oct;45(10):898-903.
74. Lutz BJ, Bowers BJ. Patient-centered care: understanding its interpretation and implementation in health care. Sch Inq Nurs Pract. 2000; 14:165-83.
75. Mackenzie LJ, Carey ML, Sanson-Fisher RW, D'Este CA, Paul CL, Yoong SL. Agreement between HADS classifications and single-item screening questions for anxiety and depression: a cross-sectional survey of cancer patients. Ann Oncol. 2014 Apr;25(4):889-95. doi: 10.1093/annonc/mdu023. PubMed PMID: 24667721.
76. Macmillan Cancer Support. The Recovery Package. 2013. Avaiable at: https://www.macmillan.org.uk/_images/recovery-package-sharing-good-practice_tcm9-299778.pdf. Accessed on 20 February 2018.
77. Mahmood R, Butterworth C, Lowe D, Rogers SN. Characteristics and referral of head and neck cancer patients who report chewing and dental issues on the Patient Concerns Inventory. Br Dent J. 2014 Jun 13;216(11):E25.
78. Maslow AH. A Theory of Human Motivation. Psychological Review 1943: 50, 370-396.
79. Matthew GK. Measuring need and evaluating services. In Portfolio for Health: Problems and Progress in Medical Care, sixth series. Edited by G. McLachlan. 1971. Oxford University Press: London.
80. Mazor KM, Beard RL, Alexander GL, Arora NK, Firneno C, Gaglio B, Greene SM,Lemay CA, Robinson BE, Roblin DW, Walsh K, Street RL Jr, Gallagher TH. Patients' and family members' views on patient-centered communication during cancer care. Psychooncology. 2012; 22:2487-95.
81. McAllister M, Dunn G, Payne K, Davies L, Todd C. Patient empowerment: the needto consider it as a measurable patient-reported outcome for chronic conditions. BMC Health Serv Res. 2012 Jun 13;12:157.
82. McDowell ME, Occhipinti S, Ferguson M, Dunn J, Chambers SK. Predictors of change in unmet supportive care needs in cancer. Psychooncology. 2010 May;19(5):508-16. doi: 10.1002/pon.1604. PubMed PMID: 19598292.
83. McDowell ME, Occhipinti S, Ferguson M, et al. Predictors of change in unmet supportive care needs in cancer. Psychooncology 2010; 19: 508-16.
84. McWhinney I. The need for a transformed clinical method. In M. Stewart, & D. Roter, Communicating with medical patients. 1989. London: Sage.
85. Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. Soc Sci Med. 2000; 51:1087-110.
86. Miller N, Rogers SN. A review of question prompt lists used in the oncology setting with comparison to the Patient Concerns Inventory. Eur J Cancer Care (Engl). 2016 Mar 14. doi: 10.1111/ecc.12489. [Epub ahead of print].
87. Millsopp L, Frackleton S, Lowe D, Rogers SN. A feasibility study of computer-assisted health-related quality of life data collection in patients with oral and oropharyngeal cancer. Int J Oral Maxillofac Surg 2006; 35:761-4.
88. National Cancer Action Team (NCAT) 2011. http://webarchive.nationalarchives.gov.uk/20130612144851/http://; .nhs.uk/our-work/living-beyond-cancer/holistic-needs-assessment.
89. National Cancer Action Team (NCAT). Rehababilitation care pathways, Head and Neck. 2010. Available at: http://www.cancerni.net/files/file/AHP/NCAT_Rehab_HeadAndNeck.pdf. Accessed on 20 July 2017.
90. National Cancer Action Team (NCAT). Holistic Needs Assessment for people with cancer A practical guide for healthcare professionals. Available at http://webarchive.nationalarchives.gov.uk/20130612144851/http://ncat.nhs.uk/our-work/living-beyond-cancer/holistic-needs-assessment. Accessed on 20 July 2017.
91. National Comprehensive Cancer Network. Distress management clinical practice guidelines. J Natl Compr Cancer Netw 2008;1.
92. National Institute of Health Excellence. Improving Outcome in Head and Neck Cancer. Available at: https://www.nice.org.uk/guidance/csg6/resources/improving-outcomes-in-head-and-neck-cancers-update-pdf-773377597. Accessed on 20 July 2017.

93. National Institute of Health Excellence. Improving Supportive and Palliative Care for Adults with Cancer. 2004. Available at: https://www.nice.org.uk/guidance/csg4/resources/improving-supportive-and-palliative-care-for-adults-with-cancer-pdf-773375005. Accessed on 20 July 2017.
94. National Health Service (NHS) England. Five year forward view. 2014. Available at: https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf. Accessed on 20 February 2018.
95. National Health Service (NHS) England. New care models: Empowering patients and communities. 2015. Available at: https://www.england.nhs.uk/wp-content/uploads/2015/12/vanguards-support-directory.pdf. Accessed on 20th February 2018.
96. National Health Service (NHS) England. Achieving World Class Cancer Outcomes: Taking the strategy forward. Avaiable at: https://www.england.nhs.uk/wp-content/uploads/2016/05/cancer-strategy.pdf. Accessed on 20 February 2018.
97. Nordenfelt L. The concepts of health and illness revisited. Med Health Care Philos. 2007 Mar;10(1):5-10.
98. **(Oxford A)** Oxford University Press. Compact Oxford English dictionary. Oxford, 2008. Page 679.
99. **(Oxford B)** Oxford University Press. Compact Oxford English dictionary. Oxford, 2008. Page 201.
100. Parker PA, Davison BJ, Tishelman C, Brundage MD; SCRN Communication Team. What do we know about facilitating patient communication in the cancer care setting? Psychooncology. 2005 Oct;14(10):848-58
101. Penguin Books. Concise Thesaurus, London, 2002. Pages 139-140.
102. Perocchia RS, Hodorowski JK, Williams LA, Kornfeld J, Davis NL, Monroe M, Bright MA. Patient-centered communication in cancer care: the role of the NCI's Cancer Information Service. J Cancer Educ. 2011; 26:36-43.
103. **(Richardson et al, 2007A)** Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: a review of assessment tools. Support Care Cancer 2007; 15:1125-44.
104. **(Richardson et al, 2007B)** Richardson A, Plant H, Moore S, Medina J, Cornwall A, Ream E. Developing supportive care for family members of people with lung cancer: a feasibility study. Support Care Cancer. 2007 Nov;15(11):1259-69.
105. Rochford A. Patient empowerment for patient self-management. WONCA Europe 20th Anniversary project 2015. Available at: http://www.woncaeurope.org/sites/default/files/001%20–%20Patient%20Empowerment_0.pdf. Accessed on 20 February 2018.
106. Rodriguez KL, Bayliss N, Alexander SC, Jeffreys AS, Olsen MK, Pollak KI, Kennifer SL, Tulsky JA, Arnold RM. How oncologists and their patients with advanced cancer communicate about health-related quality of life. Psychooncology. 2010 May;19(5):490-9.
107. Rogers SN, McNally D, Mahmood M, et al. Psychologic response of the edentulous patient after primary surgery for oral cancer: a cross-sectional study. J Prosthet Dent 1999; 82:317-321.
108. Rogers SN, Gwanne S, Lowe D, Humphris G, Yueh B, Weymuller EA Jr. The addition of mood and anxiety domains to the University of Washington quality of life scale. Head Neck. 2002 Jun;24(6):521-9.
109. **(Rogers 2009A)** Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009 Jul;45(7):555-61.
110. **(Rogers 2009B)** Rogers SN, Lowe D. Screening for dysfunction to promote MDT intervention using the University of Washington Quality of Life questionnaire (UW-QOL). Arch Otolaryngol Head Neck Surg 2009;135:369–75
111. Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM. Fear of recurrence following head and neck cancer in the outpatient clinic. Eur Arch Otorhinolaryngol. 2010 Dec;267(12):1943-9.
112. **(Rogers 2011A)** Rogers SN, Clifford N, Lowe D. Patient and carer unmet needs: a survey of the British association of head and neck oncology nurses. Br J Oral Maxillofac Surg. 2011 Jul;49(5):343-8.
113. **(Rogers 2011B)** Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM. Fear of recurrence following head and neck cancer in the outpatient clinic. Eur Arch Otorhinolaryngol 2011; 267:1943-9.
114. Rogers SN, Cleator AJ, Lowe D, Ghazali N. Identifying pain-related concerns in routine follow-up clinics following oral and oropharyngeal cancer. World J Clin Oncol. 2012 Aug 10;3(8):116-25.
115. Rogers SN, Lowe D. An evaluation of the Head and Neck Cancer Patient Concerns Inventory across the Merseyside and Cheshire Network. Br J Oral Maxillofac Surg. 2014 Sep;52(7):615-

23.
116. **(Rogers 2015A)** Rogers SN, Hazeldine P, O'Brien K, Lowe D, Roe B. How often do head and neck cancer patients raise concerns related to intimacy and sexuality in routine follow-up clinics? Eur Arch Otorhinolaryngol. 2015 Jan;272(1):207-17.
117. **(Rogers 2015B)** Rogers SN, Audisio RA, Lowe D. Do the elderly raise different issues when using the Patient Concerns Inventory in routine head and neck cancer follow-up clinics? Eur J Cancer Care (Engl). 2015 Mar;24(2):189-97.
118. Rogers SN, Lowe D, Kanatas A. Suitability of the Patient Concerns Inventory as a holistic screening tool in routine head and neck cancer follow-up clinics. Br J Oral Maxillofac Surg. 2016 May;54(4):415-21.
119. Sanson-Fisher R, Girgis A, Boyes A, et al. The unmet supportive care needs of patients with cancer. Supportive Care Review Group. Cancer 2000; 88:226-37.
120. Schramme T. A qualified defence of a naturalist theory of health. Med Health Care Philos. 2007 Mar;10(1):11-7; discussion 29-32.
121. Scott B, Ghazali N, Lowe D, Bekiroglu F, Rogers SN. The Patients Concerns Inventory in head and neck cancer: comparison between self-completed paper and touch screen versions in the clinic setting. Eur J Oncol Nurs. 2013 Dec;17(6):863-9.
122. Snyder CF, Jensen RE, Geller G, Carducci MA, Wu AW. Relevant content for a patient-reported outcomes questionnaire for use in oncology clinical practice: Putting doctors and patients on the same page. Qual Life Res. 2010 Sep;19(7):1045-55.
123. Soothill K, Morris SM, Harman J, Francis B, Thomas C, McIllmurray MB. The significant unmet needs of cancer patients: probing psychosocial concerns. Support Care Cancer. 2001 Nov;9(8):597-605.
124. Stevens A, Gabbay J. Needs assessment needs assessment. Health Trends. 1991;23(1):20-3.
125. Stevens A, Gillam S. Needs assessment: from theory to practice. BMJ 1998, 316:1448-1452.
126. Street RL Jr, Makoul G, Arora NK, Epstein RM (2009) How does communication heal? Pathways linking clinician-patient communication to health outcomes. Patient Education and Counseling 74:295–301.
127. Takeuchi EE, Keding A, Awad N, Hofmann U, Campbell LJ, Selby PJ, Brown JM, Velikova G. Impact of patient-reported outcomes in oncology: a longitudinal analysis of patient-physician communication. J Clin Oncol. 2011 20;29(21):2910-7.
128. Taylor S, Harley C, Campbell LJ, Bingham L, Podmore EJ, Newsham AC, Selby PJ, Brown JM, Velikova G. Discussion of emotional and social impact of cancer during outpatient oncology consultations. Psychooncology. 2011 Mar;20(3):242-51.
129. The NHS Choice Framework: What choices are available to me in the NHS? Available at: https://www.gov.uk/government/publications/the-nhs-choice-framework/the-nhs-choice-framework-what-choices-are-available-to-me-in-the-nhs. (Accessed 23 June 2017).
130. Velikova G, Booth L, Smith AB et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. J Clin Oncol 2004;22:714–724.
131. Velikova G, Brown JM, Smith AB, Selby PJ. Computer-based quality of life questionnaires may contribute to doctor-patient interactions in oncology. Br J Cancer. 2002 Jan 7;86(1):51-9.
132. Vetter NJ. Needs, supply and demand for health care by elderly people in the NHS. Reviews in Clinical Gerontology 2002 12; 375–380.
133. Wahba MA, Bridwell WG. Maslow reconsidered: A review of research on the need hierarchy theory. Organizational Behavior and Human Performance 1976; 15: 212-40.
134. Wakefield DS, Cyphert ST, Murray JF, Uden-Holman T, Hendryx MS, Wakefield BJ, Helms CM. Understanding patient-centered care in the context of total quality management and continuous quality improvement. Jt Comm J Qual Improv. 1994; 20:152-61.
135. Weatherley P. Basic needs and social policy. Critical Social Policy 1996; 16: 45-65.
136. Wen KY, Gustafson DH. Needs assessment for cancer patients and their families. Health Qual Life Outcomes. 2004 Feb 26;2:11.
137. WHO. Constitution of the World Health Organization. 2006. www.who.int/governance/eb/who_constitution_en.pdf.
138. WHO. Constitution of the World Health Organization. 2006. www.who.int/governance/eb/who_constitution_en.pdf.
139. Wright J, Williams R, Wilkinson JR. Development and importance of health needs assessment. BMJ 1998**;** 316:1310-1313
140. Zucca A, Sanson-Fisher R, Waller A, Carey M. Patient-centred care: making cancer treatment centres accountable. Support Care Cancer. 2014 Apr 3. [Epub ahead of print].

CHAPTER 3: HEAD AND NECK CANCER SURVIVORSHIP

1. Aarstad AK, Aarstad HJ, Bru E, Olofsson J. Psychological coping style versus disease extent, tumour treatment and quality of life in successfully treated head and neck squamous cell carcinoma patients. Clin Otolaryngol. 2005 Dec;30(6):530-8
2. Aarstad AK, Aarstad HJ, Olofsson J. Personality and choice of coping predict quality of life in head and neck cancer patients during follow-up. Acta Oncol 2008; 47:879–890.
3. Aarstad AK, Lode K, Larsen JP, Bru E, Aarstad HJ. Choice of psychological coping in laryngectomized, head and neck squamous cell carcinoma patients versus multiple sclerosis patients. Eur Arch Otorhinolaryngol. 2011 Jun;268(6):907-15.
4. Ackerstaff AH, Rasch CR, Balm AJ, de Boer JP, Wiggenraad R, Rietveld DH, Gregor RT, Kröger R, Hauptmann M, Vincent A, Hilgers FJ. Five-year quality of life results of the randomized clinical phase III (RADPLAT) trial, comparing concomitant intra-arterial versus intravenous chemoradiotherapy in locally advanced head and neck cancer. Head Neck. 2012 Jul;34(7):974-80.
5. Agarwal J, Krishnatry R, Chaturvedi P, Ghosh-Laskar S, Gupta T, Budrukkar A,Murthy V, Deodhar J, Nair D, Nair S, Dikshit R, D'Cruz AK. Survey of return to work of head and neck cancer survivors: A report from a tertiary cancer center in India. Head Neck. 2017 May;39(5):893-899.
6. Agarwal M, Hamilton JB, Crandell JL, Moore CE. Coping strategies of African American head and neck cancer survivors. J Psychosoc Oncol. 2010;28(5):526-38.
7. Algtewi E, Owens J, Baker SR. Online support groups for head and neck cancer and health-related quality of life. Qual Life Res. 2017 Apr 17. doi: 10.1007/s11136-017-1575-8.
8. Almståhl A, Alstad T, Fagerberg-Mohlin B, Carlén A, Finizia C. Explorative study on quality of life in relation to salivary secretion rate in patients with head and neck cancer treated with radiotherapy. Head Neck. 2016 May;38(5):782-91.
9. Aynehchi BB, Obourn C, Sundaram K, Bentsianov BL, Rosenfeld RM. Validation of the Modified Brief Fatigue Inventory in head and neck cancer patients. Otolaryngol Head Neck Surg. 2013 Jan;148(1):69-74.
10. Badr H, Gupta V, Sikora A, Posner M. Psychological distress in patients and caregivers over the course of radiotherapy for head and neck cancer. Oral Oncol. 2014 Oct;50(10):1005-11.
11. Bailey JA 2nd. The foundation of self-esteem. J Natl Med Assoc. 2003 May;95(5):388-93.
12. Bajwa HK, Singareddy R, Alluri KR. High-dose-rate interstitial brachytherapy in oral cancer-Its impact on quality of life. Brachytherapy. 2016 May-Jun;15(3):381-6.
13. Bakhshaee M, Raziee HR, Afshari R, Amali A, Roopoosh M, Lotfizadeh A. Opium Addiction and Risk of Laryngeal and Esophageal Carcinoma. Iran J Otorhinolaryngol. 2017 Jan;29(90):19-22.
14. Balfe M, O'Brien K, Timmons A, Butow P, O' Sullivan E, Gooberman-Hill R, Sharp L. The unmet supportive care needs of long-term head and neck cancer caregivers in the extended survivorship period. J Clin Nurs. 2016 Jun;25(11-12):1576-86.
15. Barrios R, Tsakos G, García-Medina B, Martínez-Lara I, Bravo M. Oral health-related quality of life and malnutrition in patients treated for oral cancer. Support Care Cancer. 2014 Nov;22(11):2927-33.
16. Batıoğlu-Karaaltın A, Binbay Z, Yiğit Ö, Dönmez Z. Evaluation of life quality, self-confidence and sexual functions in patients with total and partial laryngectomy. Auris Nasus Larynx. 2017 Apr;44(2):188-194.
17. Baxi SS, Shuman AG, Corner GW, Shuk E, Sherman EJ, Elkin EB, Hay JL, Pfister DG. Sharing a diagnosis of HPV-related head and neck cancer: the emotions, the confusion, and what patients want to know. Head Neck. 2013 Nov;35(11):1534-41.
18. Bessell A, Moss TP. Evaluating the effectiveness of psychosocial interventions for individuals with visible differences: a systematic review of the empirical literature. Body Image 2007; 4:227-238.
19. Best J, Muzaffar J, Mitchell-Innes A. Quality of information available via theinternet for patients with head and neck cancer: are we improving? Eur ArchOtorhinolaryngol. 2015 Nov;272(11):3499-505.
20. Bilal S, Doss JG, Rogers SN. The use of the FACT-H&N (v4) in clinical settings within a developing country: a mixed method study. J Craniomaxillofac Surg. 2014 Dec;42(8):1590-7.
21. Bjordal K, Kaasa S. Psychological distress in head and neck cancer patients 7-11 years after curative treatment. Br J Cancer. 1995 Mar;71(3):592-7.
22. Björklund M, Sarvimäki A, Berg A. Health promoting contacts as encountered by individuals with head and neck cancer. J Nurs Healthcare Chronic Illness 2009;1:261–268.
23. Bloom EL, Oliver JA, Sutton SK, Brandon TH, Jacobsen PB, Simmons VN. Post-operative

smoking status in lung and head and neck cancer patients: association with depressive symptomatology, pain, and fatigue. Psycho-oncology. 2015; 24(9):1012-9.

24. Bøje CR, Dalton SO, Primdahl H, Kristensen CA, Andersen E, Johansen J, Andersen LJ, Overgaard J. Evaluation of comorbidity in 9388 head and neck cancer patients: a national cohort study from the DAHANCA database. Radiother Oncol. 2014 Jan;110(1):91-7.
25. Bornbaum CC, Day AM, Doyle PC. Examining the construct validity of the V-RQOL in speakers who use alaryngeal voice. Am J Speech Lang Pathol. 2014May;23(2):196-202.
26. Bozec A, Schultz P, Gal J, Chamorey E, Chateau Y, Dassonville O, Poissonnet G,Santini J, Peyrade F, Saada E, Guigay J, Benezery K, Leysalle A, Santini L,Giovanni A, Messaoudi L, Fakhry N. Evaluation of the information given to patients undergoing head and neck cancer surgery using the EORTC QLQ-INFO25questionnaire: A prospective multicentric study. Eur J Cancer. 2016 Nov;67:73-82.
27. Bressan V, Bagnasco A, Aleo G, Catania G, Zanini MP, Timmins F, Sasso L. Thelife experience of nutrition impact symptoms during treatment for head and neckcancer patients: a systematic review and meta-synthesis. Support Care Cancer.2017 May;25(5):1699-1712.
28. Campbell BH, Spinelli K, Marbella AM, Myers KB, Kuhn JC, Layde PM. Aspiration, weight loss, and quality of life in head and neck cancer survivors. Arch Otolaryngol Head Neck Surg. 2004 Sep;130(9):1100-3.
29. Cavell S, Broadbent E, Donkin L, Gear K, Morton RP. Observations of benefit finding in head and neck cancer patients. Eur Arch Otorhinolaryngol. 2016 Feb;273(2):479-85.
30. Ch'ng S, Oates J, Gao K, Foo K, Davies S, Brunner M, Clark JR. Prospective quality of life assessment between treatment groups for oral cavity squamous cell carcinoma. Head Neck. 2014 Jun;36(6):834-40.
31. Chambers MS, Garden AS, Kies MS, Martin JW. Radiation-induced xerostomia in patients with head and neck cancer: pathogenesis, impact on quality of life, and management. Head Neck. 2004 Sep;26(9):796-807.
32. Chaplin JM, Morton RP. A prospective, longitudinal study of pain in head and neck cancer patients. Head Neck. 1999 Sep;21(6):531-7.
33. **(Chen 2009A)** Chen SC, Liao CT, Lin CC, Chang JT, Lai YH. Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. Oral Oncol. 2009 Sep;45(9):815-20.
34. **(Chen 2009B)** Chen SC, Tsai MC, Liu CL, Yu WP, Liao CT, Chang JT. Support needs of patients with oral cancer and burden to their family caregivers. Cancer Nurs. 2009 Nov-Dec;32(6):473-81.
35. **(Chen 2009C)** Chen AM, Jennelle RL, Grady V, Tovar A, Bowen K, Simonin P, Tracy J, McCrudden D, Stella JR, Vijayakumar S. Prospective study of psychosocial distress among patients undergoing radiotherapy for head and neck cancer. Int J Radiat Oncol Biol Phys. 2009 Jan 1;73(1):187-93.
36. Chen SC, Yu WP, Chu TL, Hung HC, Tsai MC, Liao CT. Prevalence and correlates of supportive care needs in oral cancer patients with and without anxiety during the diagnostic period. Cancer Nurs. 2010 Jul-Aug;33(4):280-9
37. Chen SC, Liao CT, Chang JT. Orofacial pain and predictors in oral squamous cell carcinoma patients receiving treatment. Oral Oncol. 2011 Feb;47(2):131-5.
38. Chou HL, Liaw JJ, Yu LH, Tang WR. An exploration of life attitudes in patients with nasopharyngeal carcinoma. Cancer Nurs. 2007 Jul-Aug;30(4):317-23.
39. Christensen AJ, Moran PJ, Ehlers SL, Raichle K, Karnell L, Funk G. Smoking and drinking behavior in patients with head and neck cancer: effects of behavioral self-blame and perceived control. J Behav Med. 1999 Oct;22(5):407-18.
40. Chronopoulos A, Zarra T, Ehrenfeld M, Otto S. Osteoradionecrosis of the jaws: definition, epidemiology, staging and clinical and radiological findings. Aconcise review. Int Dent J. 2017 Jun 25. doi: 10.1111/idj.12318. [Epub ahead ofprint]
41. Chua KS, Reddy SK, Lee MC, Patt RB. Pain and loss of function in head and neck cancer survivors. J Pain Symptom Manage. 1999 Sep;18(3):193-202.
42. Cnossen IC, de Bree R, Rinkel RN, Eerenstein SE, Rietveld DH, Doornaert P, Buter J, Langendijk JA, Leemans CR, Verdonck-de Leeuw IM. Computerized monitoring of patient-reported speech and swallowing problems in head and neck cancer patients in clinical practice. Support Care Cancer. 2012 Nov;20(11):2925-31.
43. Cocks H, Ah-See K, Capel M, Taylor P. Palliative and supportive care in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S198-S207.
44. Cohen LM, Poppel DM, Cohn GM, Reiter GS. A very good death: measuring quality of dying in end-stage renal disease. J Palliat Med. 2001 Summer;4(2):167-72.
45. Crossley ML. ‘Let me explain’: narrative emplotment and one patient’s experience of oral

cancer. Soc Sci Med 2003;56:439–448.

46. Danker H, Keszte J, Singer S, Thomä J, Täschner R, Brähler E, Dietz A. Alcohol consumption after laryngectomy. Clin Otolaryngol. 2011 Aug;36(4):336-44.
47. Department of Health. National Cancer Survivorship Initiative Vision. 2010. Available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111477.pdf. Accessed on 20 July 2017.
48. Devins GM, Wong JC, Payne AY, Lebel S, Lee RN, Mah K, Irish J, Rodin G. Distancing, self-esteem, and subjective well-being in head and neck cancer. Psychooncology. 2015 Nov;24(11):1506-13.
49. Dewa CS, Trojanowski L, Tamminga SJ, Ringash J, McQuestion M, Hoch JS. Work-related experiences of head and neck cancer survivors: an exploratory and descriptive qualitative study. Disabil Rehabil. 2017 Feb 25:1-7.
50. Dholam KP, Bachher GK, Yadav PS, Quazi GA, Pusalkar HA. Assessment of quality of life after implant-retained prosthetically reconstructed maxillae and mandibles postcancer treatments. Implant Dent. 2011 Feb;20(1):85-94.
51. Djan R, Penington A. A systematic review of questionnaires to measure the impact of appearance on quality of life for head and neck cancer patients. J Plast Reconstr Aesthet Surg. 2013 May;66(5):647-59.
52. Dooks P, McQuestion M, Goldstein D, Molassiotis A. Experiences of patients wit laryngectomies as they reintegrate into their community. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2012; 20(3):489-98.
53. Dropkin MJ. Anxiety, Coping Strategies, and Coping Behaviors in Patients Undergoing Head and Neck Cancer Surgery. Canc Nurs 2001; 24: 143-8.
54. Dropkin MJ. Body image and quality of life after head and neck surgery. Canc Pract 1999; 7: 309-1.
55. Drost BH, van de Langenberg R, Manusama OR, Janssens AS, Sikorska K, Zuur CL, Klop WM, Lohuis PJ. Dermatography (Medical Tattooing) for Scars and Skin Grafts in Head and Neck Patients to Improve Appearance and Quality of Life. JAMA Facial Plast Surg. 2017 Jan 1;19(1):16-22.
56. Duke RL, Campbell BH, Indresano AT, Eaton DJ, Marbella AM, Myers KB, Layde PM. Dental status and quality of life in long-term head and neck cancer survivors. Laryngoscope. 2005 Apr;115(4):678-83.
57. Dunne S, Mooney O, Coffey L, Sharp L, Desmond D, Timon C, O'Sullivan E,Gallagher P. Psychological variables associated with quality of life following primary treatment for head and neck cancer: a systematic review of the literature from 2004 to 2015. Psychooncology. 2017 Feb;26(2):149-160.
58. Egestad H, Nieder C. Differences in quality of life in obese and normal weight head and neck cancer patients undergoing radiation therapy. Support Care Cancer. 2015 Apr;23(4):1081-90.
59. Egestad H, Nieder C. Undesirable financial effects of head and neck cancer radiotherapy during the initial treatment period. Int J Circumpolar Health. 2015 Jan;74(1):26686.
60. Ehrsson YT, Sundberg K, Laurell G, Langius-Eklöf A. Head and neck cancerpatients' perceptions of quality of life and how it is affected by the diseaseand enteral tube feeding during treatment. Ups J Med Sci. 2015;120(4):280-9.
61. Eickmeyer SM, Walczak CK, Myers KB, Lindstrom DR, Layde P, Campbell BH. Quality of life, shoulder range of motion, and spinal accessory nerve status in 5-year survivors of head and neck cancer. PM R. 2014 Dec;6(12):1073-80.
62. Eisbruch A, Schwartz M, Rasch C, Vineberg K, Damen E, Van As CJ, et al. Dysphagia and aspiration after chemoradiotherapy for head-and-neck cancer: which anatomic structures are affected and can they be spared by IMRT? Int J Radiat Oncol Biol Phys 2004;60(5Radiat):1425–39.
63. Elani HW, Allison PJ. Coping and psychological distress among head and neck cancer patients. Support Care Cancer. 2011 Nov;19(11):1735-41.
64. Epstein JB, Wilkie DJ, Fischer DJ, Kim YO, Villines D. Neuropathic and nociceptive pain in head and neck cancer patients receiving radiation therapy. Head Neck Oncol. 2009 Jul 14;1:26. doi: 10.1186/1758-3284-1-26.
65. Espie CA, Freedlander E, Campsie LM, Soutar DS, Robertson AG. Psychologicaldistress at follow-up after major surgery for intra-oral cancer. J Psychosom Res.1989;33(4):441-8.
66. Ethunandan M, Rennie A, Hoffman G, Morey PJ, Brennan PA. Quality of dying in head and neck cancer patients: a retrospective analysis of potential indicators of care. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2005 Aug;100(2):147-52.
67. Ezenwa MO, Fischer DJ, Epstein J, Johnson J, Yao Y, Wilkie DJ. Caregivers' perspectives on oral health problems of end-of-life cancer patients. Support Care Cancer. 2016

Nov;24(11):4769-77.

68. Fang CY, Heckman CJ. Informational and Support Needs of Patients with Head andNeck Cancer: Current Status and Emerging Issues. Cancers Head Neck. 2016;1. pii: 15.
69. Farhangfar A, Makarewicz M, Ghosh S, Jha N, Scrimger R, Gramlich L, Baracos V. Nutrition impact symptoms in a population cohort of head and neck cancer patients: multivariate regression analysis of symptoms on oral intake, weight loss and survival. Oral Oncol. 2014 Sep;50(9):877-83.
70. Flexen J, Ghazali N, Lowe D, Rogers SN. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral andoropharyngeal cancer. Br J Oral Maxillofac Surg. 2012 Jun;50(4):314-20.
71. Furness P, Garrud P, Faulder A, Swift J. Coming to terms—a grounded theory of adaptation to facial surgery in adulthood. J Health Psychol 2006;11:453–466.
72. Ganzer H, Rothpletz-Puglia P, Byham-Gray L, Murphy BA, Touger-Decker R. The eating experience in long-term survivors of head and neck cancer: a mixed-methods study. Support Care Cancer. 2015 Nov;23(11):3257-68.
73. Garzaro M, Riva G, Raimondo L, Aghemo L, Giordano C, Pecorari G. A study of neck and shoulder morbidity following neck dissection: The benefits of cervical plexus preservation. Ear Nose Throat J. 2015 Aug;94(8):330-44.
74. Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN. Fear of recurrence among head and neck cancer survivors: longitudinal trends. Psychooncology. 2013 Apr;22(4):807-13.
75. Ghazali N, Kanatas A, Langley D, Scott B, Lowe D, Rogers SN. Treatment Referral Before and After the Introduction of the Liverpool Patients Concerns Inventory (PCI) into Routine Head and Neck Oncology Outpatient Clinics. Support Care Cancer 2011 19:1879-86.
76. Goldstein NE, Genden E, Morrison RS. Palliative care for patients with head and neck cancer: "I would like a quick return to a normal lifestyle". JAMA. 2008 Apr 16;299(15):1818-25.
77. Göllnitz I, Inhestern J, Wendt TG, Buentzel J, Esser D, Böger D, Mueller AH, Piesold JU, Schultze-Mosgau S, Eigendorff E, Schlattmann P, Guntinas-Lichius O. Role of comorbidity on outcome of head and neck cancer: a population-based study in Thuringia, Germany. Cancer Med. 2016 Nov;5(11):3260-3271.
78. Handschel J, Naujoks C, Kübler NR, Krüskemper G. Fear of recurrencesignificantly influences quality of life in oral cancer patients. Oral Oncol.2012 Dec;48(12):1276-80.
79. Hanly P, Maguire R, Balfe M, Hyland P, Timmons A, O'Sullivan E, Butow P, SharpL. Burden and happiness in head and neck cancer carers: the role of supportivecare needs. Support Care Cancer. 2016 Oct;24(10):4283-91.
80. Harding S, Sanipour F, Moss T. Existence of benefit finding and posttraumatic growth in people treated for head and neck cancer: a systematic review. PeerJ.2014 Feb 11;2:e256.
81. Hassel AJ, Danner D, Freier K, Hofele C, Becker-Bikowski K, Engel M. Oral health-related quality of life and depression/anxiety in long-term recurrence-free patients after treatment for advanced oral squamous cell cancer. J Craniomaxillofac Surg. 2012 Jun;40(4):e99-102.
82. He Y, Chen L, Chen L, Hu W, Wang C, Tang L, Mai H, Li J, Wu L, Fan Y.Relationship Between the Comprehensive Nutritional Index and the EORTC QLQ-H&N35 in Nasopharyngeal Carcinoma Patients Treated with Intensity-Modulated RadiationTherapy. Nutr Cancer. 2017 Apr;69(3):436-443.
83. Henry M, Habib LA, Morrison M, Yang JW, Li XJ, Lin S, Zeitouni A, Payne R, MacDonald C, Mlynarek A, Kost K, Black M, Hier M. Head and neck cancer patients want us to support them psychologically in the posttreatment period: Survey results. Palliat Support Care. 2014 Dec;12(6):481-93.
84. Ho S, Rajandram RK, Chan N, Samman N, McGrath C, Zwahlen RA. The roles of hope and optimism on posttraumatic growth in oral cavity cancer patients. Oral Oncol. 2011 Feb;47(2):121-4.
85. Hodges LJ, Humphris GM. Fear of recurrence and psychological distress in head and neck cancer patients and their carers. Psychooncology. 2009 Aug;18(8):841-8.
86. Hong CH, Napeñas JJ, Hodgson BD, Stokman MA, Mathers-Stauffer V, Elting LS, Spijkervet FK, Brennan MT; Dental Disease Section, Oral Care Study Group, Multi-national Association of Supportive Care in Cancer (MASCC)/International Society of Oral Oncology (ISOO). A systematic review of dental disease in patients undergoing cancer therapy. Support Care Cancer. 2010 Aug;18(8):1007-21.
87. Hordern A. Intimacy and sexuality after cancer: a critical review of the literature. Cancer Nurs. 2008 Mar-Apr;31(2):E9-17.
88. Horiot JC, Bone MC, Ibrahim E, Castro JR. Systematic dental management in head and neck irradiation. Int J Radiat Oncol Biol Phys. 1981 Aug;7(8):1025-9.

89. Horney DJ, Smith HE, McGurk M, Weinman J, Herold J, Altman K, Llewellyn CD. Associations between quality of life, coping styles, optimism, and anxiety and depression in pretreatment patients with head and neck cancer. Head Neck. 2011 Jan;33(1):65-71.
90. Hoskin PJ, Robinson M, Slevin N, Morgan D, Harrington K, Gaffney C. Effect of epoetin alfa on survival and cancer treatment-related anemia and fatigue in patients receiving radical radiotherapy with curative intent for head and neck cancer. J Clin Oncol. 2009 Dec 1;27(34):5751-6.
91. Hu T, Cooke M, McCarthy A. A qualitative study of the experience of oral cancer among Taiwanese men. Int J Nurs Pract 2009;15:326–333.
92. Humphris GM, Rogers S, McNally D, Lee-Jones C, Brown J, Vaughan D. Fear ofrecurrence and possible cases of anxiety and depression in orofacial cancerpatients. Int J Oral Maxillofac Surg. 2003 Oct;32(5):486-91.
93. Humphris GM, Rogers SN. The association of cigarette smoking and anxiety,depression and fears of recurrence in patients following treatment of oral and oropharyngeal malignancy. Eur J Cancer Care (Engl). 2004 Sep;13(4):328-35.
94. Huyett P, Kim S, Johnson JT, Soose RJ. Obstructive sleep apnea in the irradiated head and neck cancer patient. Laryngoscope. 2017 May 23. doi:10.1002/lary.26674. [Epub ahead of print]
95. Ichikura K, Yamashita A, Sugimoto T, Kishimoto S, Matsushima E. Persistence ofpsychological distress and correlated factors among patients with head and neckcancer. Palliat Support Care. 2016 Feb;14(1):42-51.
96. Isaksson J, Wilms T, Laurell G, Fransson P, Ehrsson YT. Meaning of work and the process of returning after head and neck cancer. Support Care Cancer. 2016 Jan;24(1):205-13.
97. Jabbour J, Milross C, Sundaresan P, Ebrahimi A, Shepherd HL, Dhillon HM,Morgan G, Ashford B, Abdul-Razak M, Wong E, Veness M, Palme CE, Froggatt C, CohenR, Ekmejian R, Tay J, Roshan D, Clark JR. Education and support needs in patientswith head and neck cancer: A multi-institutional survey. Cancer. 2017 Jun1;123(11):1949-1957.
98. Jacobi I, van der Molen L, Huiskens H, van Rossum MA, HilgersFJ. Voice and speech outcomes of chemoradiation for advanced head and neck cancer: a systematic review. Eur Arch Otorhinolaryngol. 2010; 267(10):1495-505.
99. Jacobson AS, Buchbinder D, Hu K, Urken ML. Paradigm shifts in the managementof osteoradionecrosis of the mandible. Oral Oncol. 2010 Nov;46(11):795-801.
100. Jager-Wittenaar H, Dijkstra PU, Vissink A, van der Laan BF, van Oort RP, Roodenburg JL. Critical weight loss in head and neck cancer--prevalence and risk factors at diagnosis: an explorative study. Support Care Cancer. 2007 Sep;15(9):1045-50.
101. Jansen F, van Uden-Kraan CF, van Zwieten V, Witte BI, Verdonck-de Leeuw IM. Cancer survivors' perceived need for supportive care and their attitude towards self-management and eHealth. Support Care Cancer. 2015 Jun;23(6):1679-88.
102. Jellema AP, Slotman BJ, Doornaert P, Leemans CR, Langendijk JA. Impact of radiation-inducedxerostomia on quality of life after primary radiotherapy among patients with head and neck cancer. Int J Radiat Oncol Biol Phys. 2007; 69:751–760.
103. Jenewein J, Zwahlen RA, Zwahlen D, Drabe N, Moergeli H, Büchi S. Quality of life and dyadic adjustment in oral cancer patients and their female partners. European journal of cancer care. 2008; 17(2):127-35.
104. Jereczek-Fossa BA, Santoro L, Alterio D, et al. Fatigue during head-and-neck radiotherapy: prospective study on 117 consecutive patients. Int. J. Radiat. Oncol. Biol. Phys. 2007; 68(2):403– 415.
105. Jiang N, Zhao Y, Jansson H, Chen X, Mårtensson J. Experiences of xerostomia after radiotherapy in patients with head and neck cancer: A qualitative study. J Clin Nurs. 2017 May 17. doi: 10.1111/jocn.13879. [Epub ahead of print]
106. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319.
107. Kamisetty A, Mayland CR, Jack B, Lowe D, Rogers SN. Place and time of death in patients treated with palliative intent for oral cancer. Br J Oral Maxillofac Surg. 2014 May;52(5):458-60.
108. Kamstra JI, Jager-Wittenaar H, Dijkstra PU, Huisman PM, van Oort RP, van der Laan BF, Roodenburg JL. Oral symptoms and functional outcome related to oral and oropharyngeal cancer. Support Care Cancer. 2011 Sep;19(9):1327-33.
109. Kartin PT, Tasci S, Soyuer S, Elmali F. Effect of an oral mucositis protocol on quality of life of patients with head and neck cancer treated with radiation therapy. Clin J Oncol Nurs. 2014 Dec;18(6):E118-25.
110. Katre C, Johnson IA, Humphris GM, Lowe D, Rogers SN. Assessment of problems with appearance, following surgery for oral and oro-pharyngeal cancer using the University of

Washington appearance domain and the Derriford appearance scale. Oral Oncol. 2008 Oct;44(10):927-3.

111. Katz MR, Irish JC, Devins GM, Rodin GM, Gullane PJ. Psychosocial adjustment in head and neck cancer: the impact of disfigurement, gender and social support. Head Neck. 2003 Feb;25(2):103-12.
112. Katz MR, Irish JC, Devins GM, Rodin GM, Gullane PJ. Reliability and validity of an observer-rated disfigurement scale for head and neck cancer patients. Head Neck. 2000 Mar;22(2):132-41
113. Kobayashi M, Sugimoto T, Matsuda A, Matsushima E, Kishimoto S. Association between self-esteem and depression among patients with head and neck cancer: a pilot study. Head Neck. 2008 Oct;30(10):1303-9.
114. Koch R, Wittekindt C, Altendorf-Hofmann A, Singer S, Guntinas-Lichius O.Employment pathways and work-related issues in head and neck cancer survivors.Head Neck. 2015 Apr;37(4):585-93.
115. Korfage A, Schoen PJ, Raghoebar GM, et al. Five-year follow-up of oral functioning and quality of life in patients with oral cancer with implant-retained mandibular overdentures. Head Neck 2011; 33:831–839.
116. Kowalski LP, Carvalho AL. Natural history of untreated head and neck cancer. Eur J Cancer 2000; 36:1032–1037.
117. Kraaijenga SA, Oskam IM, van der Molen L, Hamming-Vrieze O, Hilgers FJ, van den Brekel MW. Evaluation of long term (10-years+) dysphagia and trismus in patients treated with concurrent chemo-radiotherapy for advanced head and neck cancer. Oral Oncol. 2015 Aug;51(8):787-94.
118. Krebber AM, Jansen F, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Screening for psychological distress in follow-up care to identify head and neck cancer patients with untreated distress. Support Care Cancer. 2016 Jun;24(6):2541-8.
119. Kumar VV, Jacob PC, Ebenezer S, Kuriakose MA, Kekatpure V, Baliarsing AS,Al-Nawas B, Wagner W. Implant supported dental rehabilitation following segmentalmandibular reconstruction- quality of life outcomes of a prospective randomizedtrial. J Craniomaxillofac Surg. 2016 Jul;44(7):800-10.
120. Kuo TL, Lin CH, Jiang RS, Yen TT, Wang CC, Liang KL. End-of-life care for head and neck cancer patients: a population-based study. Support Care Cancer. 2017 May;25(5):1529-1536.
121. Lam DK, Schmidt BL. Orofacial pain onset predicts transition to head and neck cancer. Pain. 2011 May;152(5):1206-9.
122. Lang H, France E, Williams B, Humphris G, Wells M. The psychological experience of living with head and neck cancer: a systematic review and meta-synthesis. Psychooncology. 2013 Dec;22(12):2648-63.
123. Langius JA, Zandbergen MC, Eerenstein SE, van Tulder MW, Leemans CR, Kramer MH, Weijs PJ. Effect of nutritional interventions on nutritional status, quality of life and mortality in patients with head and neck cancer receiving(chemo)radiotherapy: a systematic review. Clin Nutr. 2013 Oct;32(5):671-8.
124. Laraway DC, Rogers SN. A structured review of journal articles reporting outcomes using the University of Washington Quality of Life Scale. Br J Oral Maxillofac Surg 2012;50:122–31
125. Lee LY, Chen SC, Chen WC, Huang BS, Lin CY. Postradiation trismus and its impact on quality of life in patients with head and neck cancer. Oral Surg Oral Med Oral Pathol Oral Radiol. 2015 Feb;119(2):187-95.
126. Li N, Otomaru T, Taniguchi H. Sleep quality in long-term survivors of head and neck cancer: preliminary findings. Support Care Cancer. 2017 Jul 9.
127. Li, Q & Loke, AY. The positive aspects of caregiving for cancer patients: A critical review of the literature and directions for future research. Psycho-oncology 2013; 22: 2399–2407.
128. Lin CR, Chen SC, Chang JT, Fang YY, Lai YH. Fear of Cancer Recurrence and Its Impacts on Quality of Life in Family Caregivers of Patients With Head and Neck Cancers. J Nurs Res. 2016 Sep;24(3):240-8.
129. Lin YL, Lin IC, Liou JC. Symptom patterns of patients with head and neck cancer in a palliative care unit. J Palliat Med. 2011 May;14(5):556-9.
130. Linder JA, Singer DE, van den Ancker M, Atlas SJ. Measures of Health-related Quality of Life for Adults with Acute Sinusitis: A Systematic Review. Journal of General Internal Medicine. 2003;18(5):390-401.
131. List MA, Lee Rutherford J, Stracks J, Haraf D, Kies MS, Vokes EE (2002) An exploration of the pretreatment coping strategies of patients with carcinoma of the head and neck. Cancer 95:98–104.
132. Llewellyn CD, McGurk M, Weinman J. How satisfied are head and neck cancer(HNC) patients with the information they receive pre-treatment? Results from the satisfaction with cancer

information profile (SCIP). Oral Oncol. 2006 Aug;42(7):726-34.

133. Lobo LL, Tufik S. Effects of alcohol on sleep parameters of sleep-deprived healthy adults. Sleep. 1997; 20:52–59.
134. Longacre ML, Ridge JA, Burtness BA, Galloway TJ, Fang CY. Psychological functioning of caregivers for head and neck cancer patients. Oral Oncol. 2012 Jan;48(1):18-25. doi: 10.1016/j.oraloncology.2011.11.012Ross S, Mosher CE, Ronis-Tobin V, Hermele S, Ostroff JS. Psychosocial adjustment of family caregivers of head and neck cancer survivors. Support Care Cancer. 2010 Feb;18(2):171-8.
135. López-Jornet P, Camacho-Alonso F. The quality of internet sites providing information relating to oral cancer. Oral Oncol. 2009 Sep;45(9):e95-8.
136. Loth A, Michel J, Giorgi R, Santini L, Rey M, Elbaum JM, Roux N, Giovanni A,Dessi P, Fakhry N. Prevalence of obstructive sleep apnoea syndrome followingoropharyngeal cancer treatment: A prospective cohort study. Clin Otolaryngol.2017 Mar 23. doi: 10.1111/coa.12869. [Epub ahead of print] .
137. Low C, Fullarton M, Parkinson E, O'Brien K, Jackson SR, Lowe D, Rogers SN. Issues of intimacy and sexual dysfunction following major head and neck cancer treatment. Oral Oncol. 2009 Oct;45(10):898-903.
138. Ma L, Wu T, Pan J, Kong X, Guo Q, Yang L, Zhang Y, Lin S, Chen C, Huang C. The correlation between the comprehensive nutrition index and quality of life of patients with nasopharyngeal carcinoma treated by intensity-modulated radiotherapy. Nutrition and cancer. 2014; 66(1):152-8.
139. Macfarlane TV, Wirth T, Ranasinghe S, Ah-See KW, Renny N, Hurman D. Head and neck cancer pain: systematic review of prevalence and associated factors. Journal of oral & maxillofacial research. 2012; 3(1):e1.
140. Macgregor F. Facial disfigurement: Problems and management of social interaction and implications for mental health. Aesth Plast Surg 1990; 14: 249-57.
141. Maguire R, Hanly P, Balfe M, Timmons A, Hyland P, O'Sullivan E, Butow P, Sharp L. Worry in Head and Neck Cancer Caregivers: The Role of Survivor Factors, Care-Related Stressors, and Loneliness in Predicting Fear of Recurrence. Nurs Res. 2017 Jul/Aug;66(4):295-303.
142. Martins SP, Ferreira CL, Del Giglio A. Placebo-Controlled, Double-Blind, Randomized Study of a Dry Guarana Extract in Patients with Head and Neck Tumors Undergoing Chemoradiotherapy: Effects on Fatigue and Quality of Life. J Diet Suppl. 2016 Jun 20:1-10. [Epub ahead of print].
143. McCall VW, Reboussin BA, Cohen W. Subjective measurement of insomnia and quality of life in depressed inpatients. J Sleep Res. 2000; 9:43–48.
144. McMillan SC, Tofthagen C, Morgan MA. Relationships among pain, sleep disturbances, and depressive symptoms in outpatients from a comprehensive cancer center. Oncol Nurs Forum. 2008; 35:603–611.
145. Mertl J, Žáčková E, Řepová B. Quality of life of patients after total laryngectomy: the struggle against stigmatization and social exclusion using speech synthesis. Disabil Rehabil Assist Technol. 2017 Apr 27:1-11. doi: 10.1080/17483107.2017.1319428. [Epub ahead of print].
146. Meyer A, Keszte J, Wollbrück D, Dietz A, Oeken J, Vogel HJ, Koscielny S, Breitenstein K, Meister EF, Pabst F, Schock J, Bourkas S, Singer S. Psychological distress and need for psycho-oncological support in spouses of total laryngectomised cancer patients-results for the first 3 years after surgery. Support Care Cancer. 2015 May;23(5):1331-9.
147. Millsopp L, Brandom L, Humphris GM, Lowe D, Rogers SN. Facial appearance after operations for oral and oropharyngeal cancer: A comparison of case-notes and patient-completed questionnaire. British Journal of Oral and Maxillofacial Surgery 2006; 44: 358-363.
148. Molassiotis A, Rogers M. Symptom experience and regaining normality in the first year following a diagnosis of head and neck cancer: a qualitative longitudinal study. Palliat Support Care. 2012 Sep;10(3):197-204.
149. Moreno KF, Khabbaz E, Gaitonde K, Meinzen-Derr J, Wilson KM, Patil YJ. Sexuality after treatment of head and neck cancer: findings based on modification of sexual adjustment questionnaire. Laryngoscope. 2012;122(7): 1526Y1531.
150. Mortensen GL, Paaske PB. Patients perceive tonsil cancer as a strike at psycho-socially "vital organs". Dan Med J. 2012 Sep;59(9):A4504.
151. Moubayed SP, Sampalis JS, Ayad T, Guertin L, Bissada E, Gologan OE, Soulières D, Lambert L, Filion E, Nguyen-Tan PF, Christopoulos A. Predicting depression andquality of life among long-term head and neck cancer survivors. Otolaryngol Head Neck Surg. 2015 Jan;152(1):91-7.
152. Mücke T, Koschinski J, Wolff KD, Kanatas A, Mitchell DA, Loeffelbein DJ, DeppeH, Rau A. Quality of life after different oncologic interventions in head and neck cancer patients. J Craniomaxillofac Surg. 2015 Nov;43(9):1895-8.

153. National Cancer Action Team (NCAT). Living with & beyond cancer. Holistic needs assessment. 2011. Avaiable at: http://webarchive.nationalarchives.gov.uk/20130612144851/http://ncat.nhs.uk/our-work/living-beyond-cancer/holistic-needs-assessment. Accessed 20 July 2017.
154. Neilson K, Pollard A, Boonzaier A, Corry J, Castle D, Smith D, Trauer T, Couper J. A longitudinal study of distress (depression and anxiety) up to 18 months after radiotherapy for head and neck cancer. Psychooncology. 2013 Aug;22(8):1843-8.
155. Newell R, Ziegler L, Stafford N, Lewin RJ. The information needs of head andneck cancer patients prior to surgery. Ann R Coll Surg Engl. 2004 Nov;86(6):407-10.
156. Ni Riordain R, McCreary C. Head and neck cancer information on the internet:type, accuracy and content. Oral Oncol. 2009 Aug;45(8):675-7.
157. Nibu K, Ebihara Y, Ebihara M, Kawabata K, Onitsuka T, Fujii T, Saikawa M. Quality of life after neck dissection: a multicenter longitudinal study by the Japanese Clinical Study Group on Standardization of Treatment for Lymph Node Metastasis of Head and Neck Cancer. Int J Clin Oncol. 2010 Feb;15(1):33-8.
158. Nightingale CL, Sterba KR, Tooze JA, Milliron BJ, Tetrick LA, Paek MS, Weaver KE. Vulnerable characteristics and interest in wellness programs among head and neck cancer caregivers. Support Care Cancer. 2016 Aug;24(8):3437-45.
159. Ninu MB, Miccinesi G, Bulli F, De Massimi A, Muraca MG, FranchiG, Squadrelli Saraceno M. Psychological distress and health-related quality of life among head and neck cancer patients during the first year after treatment. Tumori. 2016 Jan-Feb;102(1):96-102.
160. Nund RL, Rumbach AF, Debattista BC, Goodrow MN, Johnson KA, Tupling LN, Scarinci NA, Cartmill B, Ward EC, Porceddu SV. Communication changes following non-glottic head and neck cancer management: The perspectives of survivors an carers. Int J Speech Lang Pathol. 2015 Jun;17(3):263-72.
161. O'Sullivan EM, Higginson IJ. 'I'll continue as long as I can, and die when I can't help it': a qualitative exploration of the views of end-of-life care by those affected by head and neck cancer (HNC). BMJ Support Palliat Care. 2016 Mar;6(1):43-51.
162. Oh HK, Chambers MS, Martin JW, Lim HJ, Park HJ. Osteoradionecrosis of themandible: treatment outcomes and factors influencing the progress ofosteoradionecrosis. J Oral Maxillofac Surg. 2009 Jul;67(7):1378-86.
163. Oozeer NB, Benbow J, Downs C, Kelly C, Welch A, Paleri V. The effect of comorbidity on quality of life during radiotherapy in head and neck cancer. Otolaryngol Head Neck Surg. 2008 Aug;139(2):268-72.
164. Østhus AA, Aarstad AK, Olofsson J, Aarstad HJ. Comorbidity is an independent predictor of health-related quality of life in a longitudinal cohort of head and neck cancer patients. Eur Arch Otorhinolaryngol. 2013 May;270(5):1721-8.
165. Pace-Balzan A, Butterworth C, Lowe D, Rogers SN. The responsiveness of the Liverpool Oral Rehabilitation Questionnaire (LORQ): a pilot study. Int J Prosthodont. 2009 Sep-Oct;22(5):456-8.
166. Pace-Balzan A, Rogers SN. Dental rehabilitation after surgery for oral cancer. Curr Opin Otolaryngol Head Neck Surg. 2012 Apr;20(2):109-13.
167. Paleri V, Wight RG, Silver CE, Haigentz M Jr, Takes RP, Bradley PJ, Rinaldo A, Sanabria A, Bień S, Ferlito A. Comorbidity in head and neck cancer: a critical appraisal and recommendations for practice. Oral Oncol. 2010 Oct;46(10):712-9.
168. Pan XB, Huang ST, Chen KH, Jiang YM, Ma JL, Qu S, Li L, Chen L, Zhu XD. Concurrent chemoradiotherapy degrades the quality of life of patients with stage II nasopharyngeal carcinoma as compared to radiotherapy. Oncotarget. 2017 Feb21;8(8):14029-14038.
169. Papadakos J, McQuestion M, Gokhale A, Damji A, Trang A, Abdelmutti N, Ringash J. Informational Needs of Head and Neck Cancer Patients. J Cancer Educ. 2017 Feb 2. doi: 10.1007/s13187-017-1176-9. [Epub ahead of print] .
170. Parker V, Bennett L, Bellamy D, Britton B, Lambert S. Study Protocol:Evaluation of a DVD intervention designed to meet the informaton needs ofpatients with head and neck cancer and their partner, carer and families. BMCHealth Serv Res. 2016 Nov 22;16(1):670.
171. Pattison N, Brown MR, Gubbay A, Peacock J, Ross JR, Chapman S, Sauzet O, Williams J. Towards a pain free hospital: an in-depth qualitative analysis of the pain experiences of head and neck cancer patients undergoing radiotherapy. Br J Pain. 2016 Feb;10(1):29-37.
172. Penner JL. Psychosocial care of patients with head and neck cancer. Semin in Oncol Nurs 2009; 25: 231-241.
173. Peteet JR, Balboni MJ. Spirituality and religion in oncology. CA Cancer J Clin. 2013 Jul-Aug;63(4):280-9.
174. Petrić D, Franciskoví T, Juretić M, Suković Z, Graovac M, Racki S, Ruzić T,Britvić D.

Defense mechanisms in alcohol dependent patients with oral andoropharinegal cancer. Coll Antropol. 2011 Sep;35(3):809-16.

175. Pinna R, Campus G, Cumbo E, Mura I, Milia E. Xerostomia induced by radiotherapy: an overview of the physiopathology, clinical evidence, and management of the oral damage. Ther Clin Risk Manag. 2015 Feb 4;11:171-88.
176. Potash AE, Karnell LH, Christensen AJ, Vander Weg MW, Funk GF. Continued alcohol use in patients with head and neck cancer. Head Neck. 2010 Jul;32(7):905-12.
177. Rana M, Kanatas A, Herzberg PY, Khoschdell M, Kokemueller H, Gellrich NC, Rana M. Prospective study of the influence of psychological and medical factors on quality of life and severity of symptoms among patients with oral squamous cell carcinoma. Br J Oral Maxillofac Surg. 2015 Apr;53(4):364-70.
178. Razmpa E, Saedi B, Motiee-langroudi M, Garajei A, Hoseinpor S, Motamedi MH.Opium usage as an etiologic factor of oral cavity cancer. J Craniofac Surg. 2014 Sep;25(5):e505-7.
179. Rhoten BA, Murphy B, Ridner SH. Body image in patients with head and neck cancer: a review of the literature. Oral Oncol. 2013 Aug;49(8):753-60.
180. Richardson AE, Morton RP, Broadbent EA. Changes over time in head and neck cancer patients' and caregivers' illness perceptions and relationships with quality of life. Psychol Health. 2016 Oct;31(10):1203-19.
181. Rigoni L, Bruhn RF, De Cicco R, Kanda JL, Matos LL. Quality of life impairmentin patients with head and neck cancer and their caregivers: a comparative study. Braz J Otorhinolaryngol. 2016 Nov - Dec;82(6):680-686.
182. Rinkel RN, Verdonck-de Leeuw IM, de Bree R, Aaronson NK, Leemans CR. Validity of patient-reported swallowing and speech outcomes in relation to objectively measured oral function among patients treated for oral or oropharyngeal cancer. Dysphagia. 2015 Apr;30(2):196-204.
183. Roe JW, Carding PN, Dwivedi RC, Kazi RA, Rhys-Evans PH, Harrington KJ, Nutting CM. Swallowing outcomes following Intensity Modulated Radiation Therapy (IMRT) for head & neck cancer - a systematic review. Oral Oncol. 2010 Oct;46(10):727-33.
184. Rogers SN, McNally D, Mahmoud M, et al. Psychologic response of the edentulous patient after primary surgery for oral cancer: a cross-sectional study. J Prosthet Dent 1999; 82:317–321.
185. **(Rogers 2007A)** Rogers SN, Ahad SA, Murphy AP. A structured review and theme analysis of papers published on 'quality of life' in head and neck cancer: 2000-2005. Oral Oncol. 2007 Oct;43(9):843-68.
186. **(Rogers 2007B)** Rogers SN, Thomson R, O'Toole P, Lowe D. Patients experience with long-term percutaneous endoscopic gastrostomy feeding following primary surgery for oral and oropharyngeal cancer. Oral Oncol. 2007 May;43(5):499-507.
187. Rogers SN, Scott J, Chakrabati A, Lowe D. The patients account of outcome following primary surgery for oral and oropharyngeal cancer using a ‘quality of life’ questionnaire. European Journal of Cancer Care 2008; 17: 182-188.
188. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009 Jul;45(7):555-61.
189. Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM. Fear of recurrence following head and neck cancer in the outpatient clinic. Eur ArchOtorhinolaryngol. 2010 Dec;267(12):1943-9.
190. **(Rogers 2012A)** Rogers SN, Cleator AJ, Lowe D, Ghazali N. Identifying pain-related concerns inroutine follow-up clinics following oral and oropharyngeal cancer. World J Clin Oncol. 2012 Aug 10;3(8):116-25.
191. **(Rogers 2012B)** Rogers SN, Harvey-Woodworth CN, Hare J, Leong P, Lowe D. Patients' perception of the financial impact of head and neck cancer and the relationship to health-related quality of life. Br J Oral Maxillofac Surg. 2012 Jul;50(5):410-6.
192. **(Rogers 2012C)** Rogers SN, Harvey-Woodworth CN, Lowe D. Patients' perspective of financial benefits following head and neck cancer in Merseyside and Cheshire. Br J OralMaxillofac Surg. 2012 Jul;50(5):404-9.
193. **(Rogers 2015A)** Rogers SN, D'Souza JJ, Lowe D, Kanatas A. Longitudinal evaluation of health-related quality of life after osteoradionecrosis of the mandible. Br J Oral Maxillofac Surg. 2015 Nov;53(9):854-7.
194. **(Rogers 2015B)** Rogers SN, Hazeldine P, O'Brien K, Lowe D, Roe B. How often do head and neck cancer patients raise concerns related to intimacy and sexuality in routine follow-up clinics? Eur Arch Otorhinolaryngol. 2015 Jan;272(1):207-17.
195. **(Rogers 2015C)** Rogers SN, Hogg ES, Cheung WK, Lai LK, Jassal P, Lowe D, Kanatas A. 'What will I be like' after my diagnosis of head and neck cancer? Eur Arch Otorhinolaryngol.2015 Sep;272(9):2463-72.

196. **(Rogers 2016A)** Rogers SN, Cross B, Talwar C, Lowe D, Humphris G. A single-item screening question for fear of recurrence in head and neck cancer. Eur ArchOtorhinolaryngol. 2016 May;273(5):1235-42.
197. **(Rogers 2016B)** Rogers SN, Heseltine N, Flexen J, Winstanley HR, Cole-Hawkins H, Kanatas A. Structured review of papers reporting specific functions in patients with cancer of the head and neck: 2006 - 2013. Br J Oral Maxillofac Surg. 2016 Jul;54(6):e45-51.
198. **(Rogers 2016C)** Rogers SN, Semple C, Babb M, Humphris G. Quality of life considerations in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S49-S52.
199. Röing M, Hirsch JM, Holmström I, Schuster M. Making new meanings of being in the world after treatment for oral cancer. Qual Health Res. 2009 Aug;19(8):1076-86.
200. Roland NJ, Bradley PJ. The role of surgery in the palliation of head and neck cancer. Curr Opin Otolaryngol Head Neck Surg. 2014 Apr;22(2):101-8.
201. Roussel LM, Micault E, Peyronnet D, Blanchard D, Guarnieri S, Choussy O, Géry B, Béquignon A, Joubert C, Parienti JJ, Babin E. Intensive nutritional care forpatients treated with radiotherapy in head and neck cancer: a randomized studyand meta-analysis. Eur Arch Otorhinolaryngol. 2017 Feb;274(2):977-987.
202. **(Rylands 2016A)** Rylands J, Lowe D, Rogers SN. Influence of deprivation on health-related quality of life of patients with cancer of the head and neck in Merseyside and Cheshire. Br J Oral Maxillofac Surg. 2016 Jul;54(6):669-76.
203. **(Rylands 2016B)** Rylands J, Lowe D, Rogers SN. Outcomes by area of residence deprivation in a cohort of oral cancer patients: Survival, health-related quality of life, and place of death. Oral Oncol. 2016 Jan;52:30-6.
204. Sato J, Yamazaki Y, Satoh A, Onodera-Kyan M, Abe T, Satoh T, Notani K, Kitagawa Y. Pain may predict poor prognosis in patients with oral squamous cell carcinoma. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2011 May;111(5):587-92. doi: 10.1016/j.tripleo.2010.11.033. PubMed PMID: 21497734.
205. Sawada NO, de Paula JM, Sonobe HM, Zago MM, Guerrero GP, Nicolussi AC.Depression, fatigue, and health-related quality of life in head and neck cancerpatients: a prospective pilot study. Support Care Cancer. 2012 Nov;20(11):2705-11.
206. Saxena S, Orley J; WHOQOL Group. Quality of life assessment: The world health organization perspective. Eur Psychiatry. 1997;12 Suppl 3:263s-6s.
207. Schaller A, Larsson B, Lindblad M, Liedberg GM. Experiences of pain: a longitudinal, qualitative study of patients with head and neck cancer recently treated with radiotherapy. Pain Manag Nurs. 2015 Jun;16(3):336-45.
208. Scharpf J, Karnell LH, Christensen AJ, Funk GF. The role of pain in head and neck cancer recurrence and survivorship. Arch Otolaryngol Head Neck Surg. 2009 Aug;135(8):789-94.
209. Sciubba JJ. End-of-life care in the head and neck cancer patient. Oral Dis. 2016 Nov;22(8):740-744.
210. Scott B, D'Souza J, Perinparajah N, Lowe D, Rogers SN. Longitudinal evaluation of restricted mouth opening (trismus) in patients following primary surgery for oral and oropharyngeal squamous cell carcinoma. Br J Oral Maxillofac Surg. 2011 Mar;49(2):106-11.
211. Semple CJ, McGowan B. Need for appropriate written information for patients, with particular reference to head and neck cancer. J Clin Nurs. 2002 Sep;11(5):585-93. Review. PubMed PMID: 12201885.
212. Sesterhenn AM, Folz BJ, Bieker M, Teymoortash A, Werner JA. End-of-life care for terminal head and neck cancer patients. Cancer Nurs. 2008 Mar-Apr;31(2):E40-6.
213. Sherman AC, Simonton S, Adams DC, Vural E, Hanna E. Coping with head and neck cancer during different phase treatment. Head Neck 2000; 22:787–793
214. Shiraz F, Rahtz E, Bhui K, Hutchison I, Korszun A. Quality of life,psychological wellbeing and treatment needs of trauma and head and neck cancerpatients. Br J Oral Maxillofac Surg. 2014 Jul;52(6):513-7.
215. Shuman AG, Duffy SA, Ronis DL, Garetz SL, McLean SA, Fowler KE, Terrell JE. Predictors of poor sleep quality among head and neck cancer patients. Laryngoscope. 2010 Jun;120(6):1166-72.
216. Silveira MH, Dedivitis RA, Queija DS, Nascimento PC. Quality of life in swallowing disorders after nonsurgical treatment for head and neck cancer. Int Arch Otorhinolaryngol. 2015 Jan;19(1):46-54.
217. Simmons VN, Litvin EB, Jacobsen PB, Patel RD, McCaffrey JC, Oliver JA, Sutton SK, Brandon TH. Predictors of smoking relapse in patients with thoracic cancer or head and neck cancer. Cancer. 2013 Apr 1;119(7):1420-7.
218. Singer S, Danker H, Dietz A, et al. Sexual problems after total or partial laryngectomy.

Laryngoscope. 2008;118(12):2218Y2224.

219. Singer S, Danker H, Guntinas-Lichius O, Oeken J, Pabst F, Schock J, Vogel HJ, Meister EF, Wulke C, Dietz A. Quality of life before and after total laryngectomy: results of a multicenter prospective cohort study. Head Neck. 2014 Mar;36(3):359-68.
220. Sist T, Wong C. Difficult problems and their solutions in patients with cancer pain of the head and neck areas. Curr Rev Pain. 2000;4(3):206-14.
221. Spalthoff S, Zimmerer R, Jehn P, Gellrich NC, Handschel J, Krüskemper G. Neck Dissection's Burden on the Patient: Functional and Psychosocial Aspects in 1,652 Patients With Oral Squamous CellCarcinomas. J Oral Maxillofac Surg. 2017 Apr;75(4):839-849.
222. Speksnijder CM, van der Bilt A, Abbink JH, et al. Mastication in patients treated for malignancies in tongue and/or floor of mouth: a 1-year prospective study. Head Neck 2011; 33:1013–1020.
223. **(Sterba 2017A)** Sterba KR, Zapka J, Armeson KE, Shirai K, Buchanan A, Day TA, Alberg AJ. Physical and emotional well-being and support in newly diagnosed head and neck cancer patient-caregiver dyads. J Psychosoc Oncol. 2017 May 1:1-20.
224. **(Sterba 2017B)** Sterba KR, Zapka J, LaPelle N, Garris TK, Buchanan A, Scallion M, Day T. Development of a survivorship needs assessment planning tool for head and neck cancer survivors and their caregivers: a preliminary study. J Cancer Surviv. 2017 Jun 21. doi: 10.1007/s11764-017-0621-4. [Epub ahead of print].
225. Swore Fletcher B, Cohen MZ, Schumacher K, Lydiatt W. A blessing and a curse: head and neck cancer survivors' experiences. Cancer Nurs. 2012 Mar-Apr;35(2):126-32.
226. Talwar B, Donnelly R, Skelly R, Donaldson M. Nutritional management in headand neck cancer: United Kingdom National Multidisciplinary Guidelines. J LaryngolOtol. 2016 May;130(S2):S32-S40.
227. Telfer MR, Shepherd JP. Psychological distress in patients attending anoncology clinic after definitive treatment for maxillofacial malignant neoplasia.Int J Oral Maxillofac Surg. 1993 Dec;22(6):347-9.
228. Terkawi AS, Tsang S, Alshehri AS, Mulafikh DS, Alghulikah AA, AlDhahri SF. Theburden of chronic pain after major head and neck tumor therapy. Saudi J Anaesth. 2017 May;11(Suppl 1):S71-S79. doi: 10.4103/sja.SJA_162_17. PubMed PMID: 28616006;PubMed Central PMCID: PMC5463569.
229. Terro W, Crean SJ. Prospective, longitudinal assessment of quality of life in patients with cancer of the head and neck and their primary carers. Br J Oral Maxillofac Surg. 2017 Jul;55(6):613-617. doi:10.1016/j.bjoms.2017.04.004. Epub 2017 Apr 26.
230. Thambyrajah C, Herold J, Altman K, Llewellyn C. “Cancer doesn’t mean curtains”: benefit finding in patients with head and neck cancer in remission. J Psychosoc Oncol 2010;28:666–682.
231. Trunzo JJ, Pinto BM, Chougule PB. Smoking related cancers: a brief report onproblem solving, distress, and risk behaviors in patients and caregivers. JPsychosoc Oncol. 2014;32(2):224-33.
232. Ullgren H, Kirkpatrick L, Kilpeläinen S, Sharp L. Working in silos? - Head &Neck cancer patients during and after treatment with or without early palliative care referral. Eur J Oncol Nurs. 2017 Feb;26:56-62.
233. Umeda M, Shigeta T, Takahashi H, Oguni A, Kataoka T, Minamikawa T, Shibuya Y, Komori T. Shoulder mobility after spinal accessory nerve-sparing modified radical neck dissection in oral cancer patients. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2010 Jun;109(6):820-4.
234. Vakharia KT, Ali MJ, Wang SJ. Quality-of-life impact of participation in a head and neck cancer support group. Otolaryngol Head Neck Surg. 2007 Mar;136(3):405-10.
235. Van Liew JR, Brock RL, Christensen AJ, Karnell LH, Pagedar NA, Funk GF. Weight loss after head and neck cancer: A dynamic relationship with depressive symptoms.Head Neck. 2017 Feb;39(2):370-379.
236. Veldhuis D, Probst G, Marek A, Noack V, Ural A, Adamietz I, Dazert S, Minovi A. Tumor site and disease stage as predictors of quality of life in head and neck cancer: a prospective study on patients treated with surgery or combined therapy with surgery and radiotherapy or radiochemotherapy. Eur Arch Otorhinolaryngol. 2016 Jan;273(1):215-24. doi: 10.1007/s00405-015-3496-x. Epub 2015 Jan 10. PubMed PMID: 25575842.
237. Verdonck-de Leeuw IM, van Bleek WJ, Leemans CR, de Bree R. Employment and return to work in head and neck cancer survivors. Oral Oncol. 2010Jan;46(1):56-60.
238. Vickery L, Latchford G, Hewison J, Bellew M, Feber T. The impact of head and neck cancer and facial disfigurement on the quality of life of patients and their partners. Head Neck. 2003; 25:289–96.
239. Wallace KL, Middleton S, Cook IJ. Development and validation of a self-report symptom inventory to assess the severity of oral–pharyngeal dysphagia. Gastroenterology

2000;118(4):678–87.

240. Wells M, Cunningham M, Lang H, Swartzman S, Philp J, Taylor L, Thomson J. Distress, concerns and unmet needs in survivors of head and neck cancer: across-sectional survey. Eur J Cancer Care (Engl). 2015 Sep;24(5):748-60.
241. Wells M, Cunningham M, Lang H, Swartzman S, Philp J, Taylor L, Thomson J. Distress, concerns and unmet needs in survivors of head and neck cancer: a cross-sectional survey. Eur J Cancer Care (Engl). 2015 Sep;24(5):748-60.
242. White C. Body dimensions and cancer: A heuristic cognitive behavioural model. Psyco-oncology 2000; 9: 183-92.
243. WHO. Constitution of the World Health Organization. 2006. Available at: www.who.int/governance/eb/ who_constitution_en.pdf. Accessed 20 July 2017.
244. Wijbenga JG, Schepers RH, Werker PM, Witjes MJ, Dijkstra PU. A systematic review of functional outcome and quality of life following reconstruction of maxillofacial defects using vascularized free fibula flaps and dental rehabilitation reveals poor data quality. J Plast Reconstr Aesthet Surg. 2016 Aug;69(8):1024-36.
245. Williams JE, Yen JT, Parker G, Chapman S, Kandikattu S, Barbachano Y. Prevalence of pain in head and neck cancer out-patients. J Laryngol Otol. 2010Jul;124(7):767-73.
246. Wilson IB, Cleary PD. Linking clinical variables with healthrelated quality of life. A conceptual model of patient outcomes. JAMA 1995;273:59–65.
247. Wooley OW, Wooley SC, Dunham RB. Deprivation, expectation and threat: effects on salivation in the obese and nonobese. Physiol Behav. 1976 Aug;17(2):187-93.
248. World Health Organisation. Sexual Health. WHO [http://www.who.int/reproductive-health/gender/sexual_health.html]. 2005.
249. World Health Organization (1993). WHOQoL Study Protocol. WHO (MNH7PSF/93.9). Available at: http://www.who.int/mental_health/media/68.pdf. Accessed on 20 July 2017.
250. Wu YS, Lin PY, Chien CY, Fang FM, Chiu NM, Hung CF, Lee Y, Chong MY. Anxietyand depression in patients with head and neck cancer: 6-month follow-up study. Neuropsychiatr Dis Treat. 2016 Apr 27;12:1029-36.
251. Xiao C, Beitler JJ, Higgins KA, Conneely K, Dwivedi B, Felger J, Wommack EC, Shin DM, Saba NF, Ong LY, Kowalski J, Bruner DW, Miller AH. Fatigue is associated with inflammation in patients with head and neck cancer before and after intensity-modulated radiation therapy. Brain Behav Immun. 2016 Feb;52:145-52.
252. Zhang L, Samet J, Caffo B, Punjabi NM. Cigarette smoking and nocturnal sleep architecture. Am J Epidemiol. 2006; 164:529–537.
253. Ziegler L, Newell R, Stafford N, Lewin R. A literature review of head and neckcancer patients information needs, experiences and views regardingdecision-making. Eur J Cancer Care (Engl). 2004 May;13(2):119-26.
254. Zwahlen RA, Dannemann C, Gratz KW, Studer G, Zwahlen D, Moergeli H, et al. Quality of life and psychiatric morbidity in patients successfully treated for oral cavity squamous cell cancer and their wives. Journal of Oral and Maxillofacial Surgery. 2008; 66:1125–32.

CHAPTER 4: OVERVIEW MD

1. Donovan KA, Grassi L, McGinty HL, Jacobsen PB. Validation of the distress thermometer worldwide: state of the science. Psychooncology. 2014 Mar;23(3):241-50.
2. Feldman-Stewart D, Brundage MD, Tishelman C; SCRN Communication Team. A conceptual framework for patient-professional communication: an application to the cancer context. Psychooncology. 2005 Oct;14(10):801-9; discussion 810-1.
3. Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. Qual Life Res. 2008 Dec;17(10):1297-302.
4. Ha JF, Longnecker N.Doctor-patient communication: a review. Ochsner J. 2010 Spring;10(1):38-43.
5. Hassan SJ, Weymuller EA Jr. Assessment of quality of life in head and neck cancer patients. Head Neck. 1993 Nov-Dec;15(6):485-96.
6. Heaven CM, Maguire P. The relationship between patients' concerns and psychological distress in a hospice setting. Psychooncology. 1998 Nov-Dec;7(6):502-7.
7. Hegel MT, Moore CP, Collins ED, Kearing S, Gillock KL et al. Distress, psychiatric syndromes, and impairment of function in women with newly diagnosed breast cancer. Cancer 2006;107:2924–2931.
8. Hegel MT, Collins ED, Kearing S, Gillock KL, Moore CP, Ahles TA. Sensitivityand specificity

of the Distress Thermometer for depression in newly diagnosed breast cancer patients. Psychooncology. 2008 Jun;17(6):556-60.

9. Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, Holland JC. Screening for psychologic distress in ambulatory cancer patients. Cancer. 2005; **103**: 1494-502.
10. Keir ST, Calhoun-Eagan RD, Swartz JJ, Saleh OA, Friedman HS: Screening for distress in patients with brain cancer using the NCCN's rapid screening measure. Psychooncology 2008, 17:621-625.
11. Loblaw DA, Bezjak A, Bunston T. Development and testing of a visit-specific patient satisfaction questionnaire: the Princess Margaret Hospital Satisfaction with Doctor Questionnaire (PMH/PSQ-MD). J Clin Oncol 1999; 17: 1931–1938.
12. Loblaw DA, Bezjak A, Singh PM, Gotowiec A, Joubert D, Mah K, Devins GM. Psychometric refinement of an outpatient, visit-specific satisfaction with doctor questionnaire. Psychooncology. 2004 Apr;13(4):223-34.
13. Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA Jr. The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Head Neck. 2002; 24: 521-29.
14. (Rogers 2009A) Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol 2009; 45:555-61.
15. (Rogers 2009B) Rogers SN, Lowe D. Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life questionnaire. Arch Otolaryngol Head Neck Surg. 2009; 135: 369-75.
16. Rogers SN, Lowe D, Yueh B, Weymuller EA Jr. The physical function and social-emotional function subscales of the University of Washington Quality of Life Questionnaire. Arch Otolaryngol Head Neck Surg. 2010; 136: 352-7.
17. Parker PA, Davison BJ, Tishelman C, Brundage MD; SCRN Communication Team. What do The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic we know about facilitating patient communication in the cancer care setting? Psychooncology. 2005 Oct;14(10):848-58
18. Ozalp E, Cankurtaran ES, Soygür H, Geyik PO, Jacobsen PB. Screening for psychological distress in Turkish cancer patients. Psychooncology. 2007 Apr;16(4):304-11.
19. Patrick-Miller LJ, Broccoli TL, Levine E, Much JK. Screening for psychosocial distress among ambulatory oncology patients: evaluation of the distress thermometer. Psycho-Oncology 2004;13:S64–S65.
20. Pusic A, Liu JC, Chen CM, Cano S, Davidge K, Klassen A, Branski R, Patel S, Kraus D, Cordeiro PG. A systematic review of patient-reported outcome measures in head and neck cancer surgery. Otolaryngol Head Neck Surg. 2007 Apr;136(4):525-35. Review. PubMed PMID: 17418246.
21. Roth AJ, Kornblith AB, Batel-Copel L, Peabody E, Scher HI, Holland JC. Rapid screening for psychologic distress in men with prostate carcinoma. Cancer 1998;82:1904–1908.
22. Shim EJ, Shin YW, Jeon HJ, Hahm BJ. Distress and its correlates in Korean cancer patients: pilot use of the distress thermometer and the problem list. Psycho-Oncology 2008;17:548–555.

CHAPTER 5: PILOT STUDY

1. Epstein RM, Franks P, Fiscella K, Shields CG, Meldrum SC, Kravitz RL, Duberstein PR. Measuring patient-centered communication in patient-physician consultations: theoretical and practical issues. Soc Sci Med 2005; 61:1516-28.
2. Epstein RM, Street RL. Patient-centered communication in cancer care: Promoting healing and reducing suffering (NIH Publication No. 07-6225). 2007. Bethesda, MD: National Cancer Institute.
3. Ereaut G, Whiting R. What do we mean by well being? And what might it matter? Department of Children, Schools and Family Research report number DCSF-RW073. 2008. Linguistic Landscapes. Available at http//www. dera.ioe.ac.uk/8572/1/dcsf-rw073%20v2.pdf. Accessed on 4 February 2012.
4. Flexen J, Ghazali N, Lowe D, Rogers SN. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral andoropharyngeal cancer. Br J Oral Maxillofac Surg. 2012 Jun;50(4):314-20.

5. Ghazali N, Kanatas A, Langley DJ, Scott B, Lowe D, Rogers SN. Treatment referral before and after the introduction of the Liverpool Patients Concerns Inventory (PCI) into routine head and neck oncology outpatient clinics. Support Care Cancer 2011; 19:1879-86.
6. Ghazali N, Kanatas A, Scott B, Lowe D, Zuydam A, Rogers SN. Use of the Patient Concerns Inventory to identify speech and swallowing concerns following treatment for oral and oropharyngeal cancer. J Laryngol Otol. 2012 Aug;126(8):800-8.
7. **(Ghazali 2013A)** Ghazali N, Roe B, Lowe D, Rogers SN. Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxillofac Surg. 2013 Jun;51(4):294-300.
8. **(Ghazali 2013B)** Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN. Fear of recurrence among head and neck cancer survivors: longitudinal trends. Psychooncology. 2013 Apr;22(4):807-13.
9. Loblaw DA, Bezjak A, Bunston T. Development and testing of a visit-specific patient satisfaction questionnaire: the Princess Margaret Hospital Satisfaction with Doctor Questionnaire (PMH/PSQ-MD). J Clin Oncol 1999; 17: 1931–1938.
10. Mays N, Pope C. Qualitative research: Rigour and qualitative research. BMJ 1995;311:109.
11. Miles MB, Huberman AM. Early steps in analysis. In: Miles MB, Huberman AM. Qualitative Data Analysis. 2nd ed. Thousand Oaks, California: SAGE, 1994: 55-72
12. Millsopp L, Frackleton S, Lowe D, Rogers SN. A feasibility study of computer-assisted health-related quality of life data collection in patients with oral and oropharyngeal cancer. Int J Oral Maxillofac Surg 2006; 35:761-4.
13. Ritchie J, Spencer E. Qualitative data analysis for applied policy research. In: Bryman A & Burgess RG, eds. Analysing Qualitative Data. London: Routledge, 1994: 173-94
14. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol 2009; 45:555-61.
15. Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA .The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Head Neck 2002; 24: 521-529.
16. Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM. Fear of recurrence following head and neck cancer in the outpatient clinic. Eur Arch Otorhinolaryngol 2011; 267:1943-9.
17. Srivastava A, Thomson SB. Framework Analysis: A Qualitative Methodology for Applied Policy Research. J Admins Governance 2009; 4: 72-9.
18. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision making in persons with cancer: a systematic review. Ann Oncol 2010; 21:1145-51.
19. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. J Clin Oncol 2004;22(4):714–724.

CHAPTER 6: DOMAIN GENERATION

1. Atkinson S, Abu el Haj M. Domain analysis for qualitative public health data. Health Policy Plan. 1996 Dec;11(4):438-42.
2. Flexen J, Ghazali N, Lowe D, Rogers SN. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral andoropharyngeal cancer. Br J Oral Maxillofac Surg. 2012 Jun;50(4):314-20.
3. Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. Am J Public Health. 1984 Sep;74(9):979-83
4. **(Ghazali 2013A)** Ghazali N, Roe B, Lowe D, Rogers SN. Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxillofac Surg. 2013 Jun;51(4):294-300.
5. **(Ghazali 2013B)** Ghazali N, Kanatas A, Bekiroglu F, Lowe D, Rogers SN. The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic. Bulletin of The Royal College of Surgeons of England 2013; 95(3): 1-6.
6. Ghazali N, Roe B, Lowe D, Rogers SN. Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life. Br J Oral Maxillofac Surg. 2015 Apr;53(4):371-9.
7. Ghazali N, Roe B, Lowe D, Tandon S, Jones T, Brown J, Shaw R, Risk J, Rogers SN. Screening for distress using the distress thermometer and the University of Washington Quality of Life in post-treatment head and neck cancer survivors. Eur Arch Otorhinolaryngol. 2017

May;274(5):2253-2260.
8. Green B., Jones M., Hughes D. & Willimas A. Applying the Delphi technique in a study of GP's information requirements. Health and Social Care in the Community 1999; 7(3):198-205.
9. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000 Oct;32(4):1008-15.
10. Hatta JM, Doss JG, Rogers SN. The feasibility of using Patients Concerns Inventory (PCI) in managing Malaysian oral cancer patients. Int J Oral Maxillofac Surg. 2014 Feb;43(2):147-55.
11. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319.
12. Kanatas A, Ghazali N, Lowe D, Udberg M, Heseltine J, O'Mahony E, et al. Issues patients would like to discuss at their review consultation: variation by early and late stage oral, oropharyngeal and laryngeal subsites. Eur Arch Oto-Rhino-Laryngol. 2013; 270:1067-74.
13. Linstone H. & Turoff M. (eds). The Delphi Method: Techniques and Applications. Addison-Wesley, Reading, MA. 1975.
14. Powell C. The Delphi technique: myths and realities. J Adv Nurs. 2003; 41(4):376-82.
15. Mourad M, Jetmore T, Jategaonkar AA, Moubayed S, Moshier E, Urken ML. Epidemiological Trends of Head and Neck Cancer in the United States: A SEER Population Study. J Oral Maxillofac Surg. 2017 May 22. pii: S0278-2391(17)30537-2. doi: 10.1016/j.joms.2017.05.008.
16. Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: a review of assessment tools. Support Care Cancer 2007; 15:1125-44.
17. Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA Jr. The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Head Neck. 2002; 24: 521-29.
18. **(Rogers 2009A)** Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009; 45: 555-61.
19. **(Rogers 2009B)** Rogers SN, Lowe D. Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life questionnaire. Arch Otolaryngol Head Neck Surg. 2009; 135: 369-75.
20. Rogers SN, Lowe D, Yueh B, Weymuller EA Jr. The physical function and social-emotional function subscales of the University of Washington Quality of Life Questionnaire. Arch Otolaryngol Head Neck Surg. 2010; 136: 352-7.
21. Rogers SN, Cleator AJ, Lowe D, Ghazali N. Identifying pain-related concerns inroutine follow-up clinics following oral and oropharyngeal cancer. World J Clin Oncol. 2012 Aug 10;3(8):116-25.
22. Scott B, Ghazali N, Lowe D, Bekiroglu F, Rogers SN. The Patients Concerns Inventory in Head and Neck Cancer: comparison between self-completed paper and touch screen versions in the clinic setting. Eur J Oncol Nurs 2013; 17: 863-869.
23. Sumsion T. The Delphi technique: an adaptive research tool. British Journal of Occupational Therapy 1998: 61(4): 153-156.

CHAPTER 7: MAIN STUDY

1. Abendstein H, Nordgren M, Boysen M, Jannert M, Silander E, Ahlner-Elmqvist M, Hammerlid E, Bjordal K. Quality of life and head and neck cancer: a 5 year prospective study. Laryngoscope. 2005 Dec;115(12):2183-92.
2. Al-Hayder S, Elberg JJ, Charabi B. Clinical outcome and health-related quality-of-life following microsurgical reconstruction in patients with oral and oropharyngeal cancer. Acta Otolaryngol. 2017 May;137(5):541-545
3. Barbera L, Zwaal C, Elterman D, McPherson K, Wolfman W, Katz A, Matthew A; Interventions to Address Sexual Problems in People with Cancer Guideline Development Group. Interventions to address sexual problems in people with cancer. Curr Oncol. 2017 Jun;24(3):192-200.
4. Becker G, Momm F, Xander C, Bartelt S, Zander-Heinz A, Budischewski K, Domin C, Henke M, Adamietz IA, Frommhold H. Religious belief as a coping strategy: an explorative trial in patients irradiated for head-and-neck cancer. Strahlenther Onkol. 2006 May;182(5):270-6.
5. Best M, Butow P, Olver I. Doctors discussing religion and spirituality: A systematic literature review. Palliat Med. 2016 Apr; 30(4):327-37.
6. Best M, Butow P, Olver I. Spiritual support of cancer patients and the role of the doctor. Support Care Cancer. 2014 May; 22(5):1333-9. doi:10.1007/s00520-013-2091-1. Bower JE. Cancer-

related fatigue-mechanisms, risk factors, and treatments. Nat Rev Clin Oncol. 2014; 11:597-609.

7. Brown LF, Kroenke K. Cancer-related fatigue and its associations with depression and anxiety: a systematic review. Psychosomatics. 2009; 50:440-7
8. Butt Z, Wagner LI, Beaumont JL, Paice JA, Straus JL, Peterman AH, Carro G, Von Roenn JH, Shevrin D, Cella D. Longitudinal screening and management of fatigue, pain, and emotional distress associated with cancer therapy. Support Care Cancer. 2008; 16:151-9.
9. Carlson LE, Angen M, Cullum J, Goodey E, Koopmans J, Lamont L, MacRae JH, Martin M, Pelletier G, Robinson J, Simpson JS, Speca M, Tillotson L, Bultz BD. High levels of untreated distress and fatigue in cancer patients. Br J Cancer. 2004; 90:2297-304
10. Cartmill B, Cornwell P, Ward E, Davidson W, Porceddu S. Long-term functional outcomes and patient perspective following altered fractionation radiotherapy with concomitant boost for oropharyngeal cancer. Dysphagia. 2012; 27:481-90.
11. Chaturvedi SK, Shenoy A, Prasad KM, Senthilnathan SM, Premlatha BS. Concerns, coping and quality of life in head and neck cancer patients. Support Care Cancer. 1996; 4:186–90.
12. Chen SC, Lai YH, Liao CT, Chang JT, Lin CY, Fan KH, Huang BS. Supportive care needs in newly diagnosed oral cavity cancer patients receiving radiation therapy. Psychooncology. 2013; 22:1220-8.
13. Chen SC, Liao CT, Lin CC, Chang JT, Lai YH. Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. Oral Oncol. 2009; 45:815-20.
14. Chu A, Genden E, Posner M, Sikora A. A patient-centered approach to counseling patients with head and neck cancer undergoing human papillomavirus testing: a clinician's guide. Oncologist. 2013;18(2):180-9.
15. Clayton MF, Dudley WN. Patient-centered communication during oncology follow-up visits for breast cancer survivors: content and temporal structure. Oncol Nurs Forum. 2009 Mar;36(2):E68-79
16. Connolly T, Reb J. Regret in cancer-related decisions. Health Psychol. 2005 Jul;24(4S):S29-34.
17. Costa JM, López M, García J, León X, Quer M. Impact of total laryngectomy on return to work. Acta Otorrinolaringol Esp. 2017 May 17. pii: S0001-6519(17)30089-4.
18. Delgado-Guay MO, Hui D, Parsons HA, Govan K, De la Cruz M, Thorney S, Bruera E. Spirituality, religiosity, and spiritual pain in advanced cancer patients. J Pain Symptom Manage. 2011 Jun;41(6):986-94.
19. Detmar SB, Aaronson NK, Wever LD, Muller M, Schornagel JH. How are you feeling? Who wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life issues. J Clin Oncol. 2000 Sep 15;18(18):3295-301.
20. Detmar SB, Muller MJ, Schornagel JH, Wever LD, Aaronson NK.Health-related quality-of-life assessments and patient-physician communication: a randomized controlled trial. JAMA. 2002 Dec 18;288(23):3027-34
21. Detmar SB, Muller MJ, Wever LD et al. Patient–physician communication during outpatient palliative treatment visits: an observational study. JAMA 2001; 285:1,351–1,357.
22. Donovan KA, Grassi L, McGinty HL, Jacobsen PB. Validation of the distress thermometer worldwide: state of the science. Psychooncology. 2014 Mar;23(3):241-50.
23. Donovan KA, Jacobsen P, Holland JC, Trask PC, Fleishman S, Zabora J, Baker F. Psychometric properties and correlates of distress thermometer scale. Psycho-Oncology 2004;13(S13):16.
24. Engelen V, Detmar S, Koopman H, Maurice-Stam H, Caron H, Hoogerbrugge P, Egeler RM, Kaspers G, Grootenhuis M. Reporting health-related quality of life scores to physicians during routine follow-up visits of pediatric oncology patients: is it effective? Pediatr Blood Cancer. 2012 May;58(5):766-74.
25. Epstein RM, Franks P, Fiscella K, Shields CG, Meldrum SC, Kravitz RL, Duberstein PR. Measuring patient-centered communication in patient-physician consultations: theoretical and practical issues. Soc Sci Med. 2005 Oct;61(7):1516-28
26. Fagerlind H, Lindblad AK, Bergström I et al. Patient–physician communication during oncology consultations. Psychooncology 2008; 17: 975–985.
27. Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. Qual Life Res. 2008 Dec;17(10):1297-302.
28. Flexen J, Ghazali N, Lowe D, Rogers SN. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral andoropharyngeal cancer. Br J Oral Maxillofac Surg. 2012 Jun;50(4):314-20.
29. Garland SN, Johnson JA, Savard J, Gehrman P, Perlis M, Carlson L, Campbell T. Sleeping well with cancer: a systematic review of cognitive behavioural therapy for insomnia in cancer patients. Neuropsychiatr Dis Treat. 2014; 10:1113-24.
30. Gessler S, Low J, Daniells E, Williams R, Brough V, Tookman A, Jones L.Screening for distress in cancer patients: is the distress thermometer a valid measure in the UK and does it measure

change over time? A prospective validation study. Psychooncology. 2008 Jun;17(6):538-47.

31. Ghazali N, Kanatas A, Scott B, Lowe D, Zuydam AC, Rogers SN. Use of the Patient Concerns Inventory to identify speech and swallowing concerns following treatment for oral and oropharyngeal cancer. J Laryngol Otol. 2012; 126:800-8.
32. **(Ghazali 2013A)** Ghazali N, Roe B, Lowe D, Rogers SN. Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxillofac Surg. 2013 Jun;51(4):294-300.
33. **(Ghazali 2013B)** Ghazali N, Kanatas A, Bekiroglu F, Scott B, Lowe D, Rogers SN. The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic. N Bulletin of The Royal College of Surgeons of England 2013; 95(3): 1-6.
34. **(Ghazali 2013C)** Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN. Fear of recurrence among head and neck cancer survivors: longitudinal trends. Psychooncology. 2013 Apr;22(4):807-13.
35. Ghazali N, Roe B, Lowe D, Rogers SN. Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life. Br J Oral Maxillofac Surg. 2015 Apr;53(4):371-9.
36. Gill SS, Frew J, Fry A, Adam J, Paleri V, Dobrowsky W, Chatterjee S, Kelly CG. Priorities for the head and neck cancer patient, their companion and members of the multidisciplinary team and decision regret. Clin Oncol (R Coll Radiol). 2011 Oct;23(8):518-24.
37. Grassi L, Johansen C, Annunziata MA, Capovilla E, Costantini A, Gritti P, Torta R, Bellani M; Italian Society of Psycho-Oncology Distress Thermometer Study Group. Screening for distress in cancer patients: a multicenter, nationwide study in Italy. Cancer. 2013; 119: 1714-21.
38. Greenhalgh J, Abhyankar P, McCluskey S, Takeuchi E, Velikova G.How do doctors refer to patient-reported outcome measures (PROMS) in oncology consultations? Qual Life Res. 2013 Jun;22(5):939-50.
39. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Soc Sci Med. 2005 Feb;60(4):833-43.
40. Gysels M, Higginson IJ, Rajasekaran M, Davies E, Harding R (2004) Improving supportive and palliative care for adults with cancer: Research Evidence. National Institute of Clinical Excellence & Kings College London, London
41. Halyard MY, Ferrans CE. Quality-of-Life assessment for routine oncology clinical practice. J Support Oncol. 2008 May-Jun;6(5):221-9, 233.
42. Hammerlid E, Silander E, Hörnestam L, Sullivan M.Health-related quality of life three years after diagnosis of head and neck cancer--a longitudinal study. Head Neck. 2001 Feb;23(2):113-25
43. Hassan SJ, Weymuller EA Jr. Assessment of quality of life in head and neck cancer patients. Head Neck. 1993 Nov-Dec;15(6):485-96.
44. Hatta JM, Doss JG, Rogers SN. The feasibility of using Patients Concerns Inventory (PCI) in managing Malaysian oral cancer patients. Int J Oral Maxillofac Surg. 2014 Feb;43(2):147-55.
45. Heaven CM, Maguire P. The relationship between patients' concerns and psychological distress in a hospice setting. Psychooncology. 1998 Nov-Dec;7(6):502-7.
46. Hegel MT, Collins ED, Kearing S, Gillock KL, Moore CP, Ahles TA. Sensitivityand specificity of the Distress Thermometer for depression in newly diagnosed breast cancer patients. Psychooncology. 2008 Jun;17(6):556-60.
47. Hegel MT, Moore CP, Collins ED, Kearing S, Gillock KL et al. Distress, psychiatric syndromes, and impairment of function in women with newly diagnosed breast cancer. Cancer 2006;107:2924–2931.
48. Hilarius DL, Kloeg PH, Gundy CM, Aaronson NK. Use of health-related quality-of-life assessments in daily clinical oncology nursing practice: a community hospital-based intervention study. Cancer. 2008 Aug 1;113(3):628-37.
49. Holland JC, Bultz BD. The NCCN guideline for distress management: A case for making distress the sixth vital sign. J Natl Compr Canc Netw. 2007; 5:3-7.
50. Hoole J, Kanatas AN, Mitchell DA. Psychosexual therapy and education in patients treated for cancer of the head and neck. Br J Oral Maxillofac Surg. 2015 Sep;53(7):601-6.
51. Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, Holland JC. Screening for psychologic distress in ambulatory cancer patients. Cancer. 2005; **103**: 1494-502.
52. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319.
53. Kanatas A, Ghazali N, Lowe D, Rogers SN. The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. Int. J. Oral Maxillofac. Surg. 2012; 41: 429–436.

54. Kandasamy A, Chaturvedi SK, Desai G. Spirituality, distress, depression, anxiety, and quality of life in patients with advanced cancer. Indian J Cancer. 2011 Jan-Mar;48(1):55-9. doi: 10.4103/0019-509X.75828. PubMed PMID: 21248445.
55. Keir ST, Calhoun-Eagan RD, Swartz JJ, Saleh OA, Friedman HS: Screening for distress in patients with brain cancer using the NCCN's rapid screening measure. Psychooncology 2008, 17:621-625.
6. Landwehr MS, Watson SE, Macpherson CF, Novak KA, Johnson RH. The cost of cancer: a retrospective analysis of the financial impact of cancer on young adults. Cancer Med. 2016 May;5(5):863-70.
7. Levinson W, Roter D.Physicians' psychosocial beliefs correlate with their patient communication skills. J Gen Intern Med. 1995 Jul;10(7):375-9.
8. Lewis S, Salins N, Kadam A, Rao R. Distress screening using distress thermometer in head and neck cancer patients undergoing radiotherapy and evaluation of causal factors predicting occurrence of distress. Indian J Palliat Care. 2013; 19:88-92.
9. Loblaw DA, Bezjak A, Bunston T. Development and testing of a visit-specific patient satisfaction questionnaire: the Princess Margaret Hospital Satisfaction with Doctor Questionnaire (PMH/PSQ-MD). J Clin Oncol 1999; 17: 1931–1938.
10. Loblaw DA, Bezjak A, Singh PM, Gotowiec A, Joubert D, Mah K, Devins GM. Psychometric refinement of an outpatient, visit-specific satisfaction with doctor questionnaire. Psychooncology. 2004 Apr;13(4):223-34.
11. Low C, Fullarton M, Parkinson E, O'Brien K, Jackson SR, Lowe D, Rogers SN. Issues of intimacy and sexual dysfunction following major head and neck cancer treatment. Oral Oncol. 2009 Oct;45(10):898-903.
12. Luckett T, Butow PN, King MT. Improving patient outcomes through the routine use of patient-reported data in cancer clinics: future directions. Psychooncology. 2009 Nov;18(11):1129-38.
13. Maguire P. Improving the recognition of concerns and affective disorders in cancer patients. Ann Oncol. 2002;13 Suppl 4:177-81.
14. Maher NG, Britton B, Hoffman GR. Early screening in patients with head and neck cancer identified high levels of pain and distress. J Oral Maxillofac Surg. 2013; 71:1458-64.
15. Manne S, Badr H. Intimacy processes and psychological distress among couples coping with head and neck or lung cancers. Psychooncology. 2010 Sep;19(9):941-54.
16. Mertl J, Žáčková E, Řepová B. Quality of life of patients after total laryngectomy: the struggle against stigmatization and social exclusion using speech synthesis. Disabil Rehabil Assist Technol. 2017 Apr 27:1-11.
17. Miles, M & Huberman, A. Qualitative data analysis : An expanded source book (2nd edition), Thousand Oakes: Sage. 1994.
18. Momeni A, Kim RY, Kattan A, Lee GK. Microsurgical head and neck reconstruction after oncologic ablation: a study analyzing health-related quality of life. Ann Plast Surg. 2013 Apr;70(4):462-9.
19. Moore CW, Rauch PK, Baer L, Pirl WF, Muriel AC. Parenting changes in adults with cancer. Cancer. 2015 Oct 1;121(19):3551-7.
20. Morgan PA(1), de Oliveira JS, Alexander SC, Pollak KI, Jeffreys AS, Olsen MK, Arnold RM, Abernethy AP, Rodriguez KL, Tulsky JA.Comparing oncologist, nurse, and physician assistant attitudes toward discussions of negative emotions with patients. J Physician Assist Educ. 2010;21(3):13-7.
21. National Comprehensive Cancer Network. Distress management clinical practice guidelines. J Natl Compr Cancer Netw 2008;1.
22. Ong LM, Visser MR, Lammes FB, de Haes JC Doctor-patient communication and cancer patients' quality of life and satisfaction. Patient Educ Couns. 2000 Sep;41(2):145-56.
23. Oskam IM, Verdonck-de Leeuw IM, Aaronson NK, Witte BI, de Bree R, Doornaert P, Langendijk JA, Leemans CR. Prospective evaluation of health-related quality of life in long-term oral and oropharyngeal cancer survivors and the perceived need for supportive care. Oral Oncol. 2013 May;49(5):443-8.
24. Oozeer NB, Corsar K, Glore RJ, Penney S, Patterson J, Paleri V. The impact of enteral feeding route on patient-reported long term swallowing outcome after chemoradiation for head and neck cancer. Oral Oncol. 2011; 47:980-3.
25. Oxford Handbook of medical statistics Peacock and Peacock. ISBN 978-0-19-955128-6 Page 356
26. Ozalp E, Cankurtaran ES, Soygür H, Geyik PO, Jacobsen PB. Screening for psychological distress in Turkish cancer patients. Psychooncology. 2007 Apr;16(4):304-11.
27. Pandey M, Srita GP, Devi N, Thomas BC, Hussain BM, Krishnan R. Distress anxiety and depression in cancer patients undergoing chemotherapy. World J Surg Oncol. 2006; 4:68.

28. Parker PA, Davison BJ, Tishelman C, Brundage MD; SCRN Communication Team. What do The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic we know about facilitating patient communication in the cancer care setting? Psychooncology. 2005 Oct;14(10):848-58
    patient concerns inventory: a tool to uncover unmet needs in a cancer outpatient clinic. Bulletin of the Royal College of Surgeons of England 95 (3), 1e6.
29. Patrick-Miller LJ, Broccoli TL, Levine E, Much JK. Screening for psychosocial distress among ambulatory oncology patients: evaluation of the distress thermometer. Psycho-Oncology 2004;13:S64–S65.
30. Peteet JR, Balboni MJ. Spirituality and religion in oncology. CA Cancer J Clin. 2013 Jul-Aug;63(4):280-9. doi: 10.3322/caac.21187. Epub 2013 Apr 26. Review. PubMed PMID: 23625473.
31. Pusic A, Liu JC, Chen CM, Cano S, Davidge K, Klassen A, Branski R, Patel S, Kraus D, Cordeiro PG. A systematic review of patient-reported outcome measures in head and neck cancer surgery. Otolaryngol Head Neck Surg. 2007 Apr;136(4):525-35.
32. Rissanen R, Arving C, Ahlgren J, Nordin K. Group versus individual stress management intervention in breast cancer patients for fatigue and emotional reactivity: A randomised intervention study. Acta Oncol. 2014; 53:1221-9.
33. Rodriguez KL, Bayliss N, Alexander SC, Jeffreys AS, Olsen MK, Pollak KI, Kennifer SL, Tulsky JA, Arnold RM. How oncologists and their patients with advanced cancer communicate about health-related quality of life. Psychooncology. 2010 May;19(5):490-9.
34. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009; 45: 555-61.
35. Rogers SN, Cleator AJ, Lowe D, Ghazali N. Identifying pain-related concerns inroutine follow-up clinics following oral and oropharyngeal cancer. World J Clin Oncol. 2012 Aug 10;3(8):116-25.
36. Rogers SN, Hazeldine P, O'Brien K, Lowe D, Roe B. How often do head and neck cancer patients raise concerns related to intimacy and sexuality in routine follow-up clinics? Eur Arch Otorhinolaryngol. 2015 Jan;272(1):207-17.
37. Rogers SN, Lowe D. Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life Questionnaire. Arch Otolaryngol Head Neck Surg. 2009 Apr;135(4):369-75.
38. Roth AJ, Kornblith AB, Batel-Copel L, Peabody E, Scher HI, Holland JC. Rapid screening for psychologic distress in men with prostate carcinoma. Cancer 1998;82:1904–1908.
39. Rosenbloom SK, Victorson DE, Hahn EA, Peterman AH, Cella D. Assessment is not enough: a randomized controlled trial of the effects of HRQL assessment on quality of life and satisfaction in oncology clinical practice. Psychooncology. 2007 Dec;16(12):1069-79.
40. Rzepakowska A, Sielska-Badurek E, Osuch-Wójcikiewicz E, Niemczyk K. Multiparametric Assessment of Voice Quality and Quality of Life in Patients Undergoing Microlaryngeal Surgery-Correlation Between Subjective and Objective Methods. J Voice. 2017 May 23. pii: S0892-1997(17)30034-6.
41. Scarpa M, Pinto E, Saadeh LM, Parotto M, Da Roit A, Pizzolato E, Alfieri R, Cagol M, Saraceni E, Baratto F, Castoro C. Sleep disturbances and quality of life in postoperative management after esophagectomy for esophageal cancer. World J Surg Oncol. 2014; 12:156.
42. Scott B, Ghazali N, Lowe D, Bekiroglu F, Rogers SN. The Patients Concerns Inventory in head and neck cancer: comparison between self-completed paper and touch screen versions in the clinic setting. Eur J Oncol Nurs. 2013 Dec;17(6):863-9.
43. Shim EJ, Shin YW, Jeon HJ, Hahm BJ. Distress and its correlates in Korean cancer patients: pilot use of the distress thermometer and the problem list. Psycho-Oncology 2008;17:548–555.
44. Siminoff LA, Graham GC, Gordon NH.Cancer communication patterns and the influence of patient characteristics: disparities in information-giving and affective behaviors. Patient Educ Couns. 2006 Sep;62(3):355-60.
45. Snyder CF, Dy SM, Hendricks DE, Brahmer JR, Carducci MA, Wolff AC, Wu AW.Asking the right questions: investigating needs assessments and health-related quality-of-life questionnaires for use in oncology clinical practice. Support Care Cancer. 2007 Sep;15(9):1075-85.
46. Sodergren SC, Husson O, Robinson J, Rohde GE, Tomaszewska IM, Vivat B, Dyar R, Darlington AS; EORTC Quality of Life Group. Systematic review of the health-related quality of life issues facing adolescents and young adults with cancer. Qual Life Res. 2017 Mar 1. doi: 10.1007/s11136-017-1520-x.
47. Stone DS, Ganz PA, Pavlish C, Robbins WA. Young adult cancer survivors and work: a systematic review. J Cancer Surviv. 2017 May 6. doi: 10.1007/s11764-017-0614-3

48. Street RL Jr, Gordon H, Haidet P. Physicians' communication and perceptions of patients: is it how they look, how they talk, or is it just the doctor? Soc Sci Med. 2007 Aug;65(3):586-98.
49. Taberna M, Inglehart RC, Pickard RK, Fakhry C, Agrawal A, Katz ML, Gillison ML. Significant changes in sexual behavior after a diagnosis of human papillomavirus-positive and human papillomavirus-negative oral cancer. Cancer. 2017 Apr 1;123(7):1156-1165.
50. Takayama T, Yamazaki Y, Katsumata N. Relationship between outpatients' perceptions of physicians' communication styles and patients' anxiety levels in a Japanese oncology setting. Soc Sci Med. 2001 Nov;53(10):1335-50.
51. Takeuchi EE, Keding A, Awad N, Hofmann U, Campbell LJ, Selby PJ, Brown JM, Velikova G. Impact of patient-reported outcomes in oncology: a longitudinal analysis of patient-physician communication. J Clin Oncol. 2011 Jul 20;29(21):2910-7.
52. Taylor S, Harley C, Campbell LJ, Bingham L, Podmore EJ, Newsham AC, Selby PJ, Brown JM, Velikova G. Discussion of emotional and social impact of cancer during outpatient oncology consultations. Psychooncology. 2011 Mar;20(3):242-51.
53. Velikova G, Awad N, Coles-Gale R, Wright EP, Brown JM, Selby PJ. The clinical value of quality of life assessment in oncology practice—a qualitative study of patient and physician views. Psychooncology 2008; 17:690–698.
54. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. J Clin Oncol 2004;22(4):714–724.
55. Velikova G, Brown JM, Smith AB, Selby PJ. Computer-based quality of life questionnaires may contribute to doctor-patient interactions in oncology. Br J Cancer. 2002 Jan 7;86(1):51-9.
56. Williams AL. Perspectives on spirituality at the end of life: a meta-summary. Palliat Support Care. 2006 Dec;4(4):407-17.
57. Zhou J, Jolly S. Obstructive sleep apnea and fatigue in head and neck cancer patients. Am J Clin Oncol. 2015 Aug;38(4):411-4.

CHAPTER 8: MD STUDY CONCLUSIONS

1. Adams E, Boulton M, Rose P, Lund S, Richardson A, Wilson S, Watson E. Views of cancer care reviews in primary care: a qualitative study. Br J Gen Pract. 2011 Apr;61(585):173-82.
2. de Leeuw J(1), Prins JB, Teerenstra S, Merkx MA, Marres HA, van Achterberg Nurse-led follow-up care for head and neck cancer patients: a quasi-experimental prospective trial. Support Care Cancer. 2013 Feb;21(2):537-47.
3. Hatta JM, Doss JG, Rogers SN. The feasibility of using Patients Concerns Inventory (PCI) in managing Malaysian oral cancer patients. Int J Oral Maxillofac Surg. 2014 Feb;43(2):147-55.
4. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319.
5. Mackenzie LJ, Carey ML, Sanson-Fisher RW, D'Este CA, Paul CL, Yoong SL. Agreement between HADS classifications and single-item screening questions for anxiety and depression: a cross-sectional survey of cancer patients. Ann Oncol. 2014 Apr;25(4):889-95.
6. Macmillan Cancer Support. The Recovery Package. 2013. Avaiable at: https://www.macmillan.org.uk/_images/recovery-package-sharing-good-practice_tcm9-299778.pdf. Accessed on 20 February 2018.
7. Mitchell AJ. Screening for cancer-related distress: when is implementation successful and when is it unsuccessful? Acta Oncol. 2013 Feb;52(2):216-24.
8. Mosher CE, Winger JG, Hanna N, Jalal SI, Fakiris AJ, Einhorn LH, Birdas TJ, Kesler KA, Champion VL. Barriers to mental health service use and preferences for addressing emotional concerns among lung cancer patients. Psychooncology. 2014 Jul;23(7):812-9.
9. National Health Service (NHS) England. Achieving World Class Cancer Outcomes: Taking the strategy forward. Avaiable at: https://www.england.nhs.uk/wp-content/uploads/2016/05/cancer-strategy.pdf. Accessed on 20 February 2018.
10. National Health Service (NHS) England. Five year forward view. 2014. Available at: https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf. Accessed on 20 February 2018.
11. Richardson A, Plant H, Moore S, Medina J, Cornwall A, Ream E. Developing supportive care for family members of people with lung cancer: a feasibility study. Support Care Cancer. 2007 Nov;15(11):1259-69.

12. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009 Jul;45(7):555-61.
13. Rogers SN, Lowe D. An evaluation of the Head and Neck Cancer Patient Concerns Inventory across the Merseyside and Cheshire Network. Br J Oral Maxillofac Surg. 2014 Sep;52(7):615-23.
14. van der Meulen IC, May AM, de Leeuw JR, Koole R, Oosterom M, Hordijk GJ, Ros WJ. Long-term effect of a nurse-led psychosocial intervention on health-related quality of life in patients with head and neck cancer: a randomised controlled trial. Br J Cancer. 2014 Feb 4;110(3):593-601.

References for Appendix Litrature Review

1. Aarstad HJ, Osthus AA, Olofsson J, Aarstad AK. Level of distress predicts subsequent survival in successfully treated head and neck cancer patients: a prospective cohort study. Acta Otolaryngol. 2014 Feb;134(2):211-9. doi: 10.3109/00016489.2013.841989. Epub 2013 Nov 21. PubMed PMID: 24256042.
2. Adnane C, Oubahmane T, Adouly T, Elhani L, Rouadi S, Abada RL, Roubal M, Mahtar M. Cross-cultural and Moroccan Validation of the University of Washington Quality of Life Questionnaire for Patients With Head and Neck Cancer. Ann Otol Rhinol Laryngol. 2016 Feb;125(2):151-9. doi: 10.1177/0003489415601687. Epub 2015 Aug 27. PubMed PMID: 26318159.
3. Agarwal SK, Gogia S, Agarwal A, Agarwal R, Mathur AS. Assessment of voice related quality of life and its correlation with socioeconomic status after total laryngectomy. Ann Palliat Med. 2015 Oct;4(4):169-75. doi: 10.3978/j.issn.2224-5820.2015.09.05. PubMed PMID: 26541395.
4. Agarwal SK, Munjal M, Koul R, Agarwal R. Prospective evaluation of the quality of life of oral tongue cancer patients before and after the treatment. Ann Palliat Med. 2014 Oct;3(4):238-43. doi: 10.3978/j.issn.2224-5820.2014.03.02. PubMed PMID: 25841903.
5. Algtewi E, Owens J, Baker SR. Online support groups for head and neck cancer and health-related quality of life. Qual Life Res. 2017 Apr 17. doi: 10.1007/s11136-017-1575-8. [Epub ahead of print] PubMed PMID: 28417218.
6. Almståhl A, Alstad T, Fagerberg-Mohlin B, Carlén A, Finizia C. Explorative study on quality of life in relation to salivary secretion rate in patients with head and neck cancer treated with radiotherapy. Head Neck. 2016 May;38(5):782-91. doi: 10.1002/hed.23964. Epub 2015 Jun 20. PubMed PMID: 25537660.
7. Alvarez-Camacho M, Gonella S, Ghosh S, Kubrak C, Scrimger RA, Chu KP, Wismer WV. The impact of taste and smell alterations on quality of life in head and neck cancer patients. Qual Life Res. 2016 Jun;25(6):1495-504. doi: 10.1007/s11136-015-1185-2. Epub 2015 Nov 20. PubMed PMID: 26589527.
8. Andrade MS, Gonçalves AN, Guedes RL, Barcelos CB, Slobodticov LD, Lopes SA, Francisco AL, Angelis EC. Correlation between swallowing-related quality of life and videofluoroscopy after head and neck cancer treatment. Codas. 2017 Mar 9;29(1):e20150175. doi: 10.1590/2317-1782/20172015175. Portuguese, English. PubMed PMID: 28300950.
9. Arias F, Arraras JI, Asin G, Uzcanga MI, Maraví E, Chicata V, Eito C, Zarandona U, Mora I, Vila M, Domínguez MA. Quality of life and voice assessment in patients with early-stage glottic cancer. Head Neck. 2015 Mar;37(3):340-6. doi: 10.1002/hed.23603. Epub 2014 Apr 10. PubMed PMID: 24415515.
10. Aro K, Bäck L, Loimu V, Saarilahti K, Rogers S, Sintonen H, Roine R, Mäkitie A. Trends in the 15D health-related quality of life over the first year following diagnosis of head and neck cancer. Eur Arch Otorhinolaryngol. 2016 Aug;273(8):2141-50. doi: 10.1007/s00405-015-3732-4. Epub 2015 Jul 28. PubMed PMID: 26216625.
11. Axelsson L, Silander E, Nyman J, Bove M, Johansson L, Hammerlid E. Effect of prophylactic percutaneous endoscopic gastrostomy tube on swallowing in advanced head and neck cancer: A randomized controlled study. Head Neck. 2017 May;39(5):908-915. doi: 10.1002/hed.24707. Epub 2017 Feb 2. PubMed PMID 28152219.
12. Bacorro WR, Sy Ortin TT, Suarez CG, Mendoza TR, Que JC. Validation of the MD Anderson Symptom Inventory-Head-and-Neck-Filipino (MDASI-HN-F): clinical utility of symptom screening among patients with head-and-neck cancer. BMJ Support Palliat Care. 2017 Jun;7(2):140-149. doi: 10.1136/bmjspcare-2014-000787. Epub 2015 May 3. PubMed PMID: 25941198.
13. Bajwa HK, Singareddy R, Alluri KR. High-dose-rate interstitial brachytherapy in oral cancer-Its

impact on quality of life. Brachytherapy. 2016 May-Jun;15(3):381-6. doi: 10.1016/j.brachy.2016.02.002. Epub 2016 Mar 3. PubMed PMID: 26947320

14. Barber B, Dergousoff J, Nesbitt M, Mitchell N, Harris J, O'Connell D, Côté D, Biron V, Seikaly H. Depression as a predictor of postoperative functional performance status (PFPS) and treatment adherence in head and neck cancer patients: a prospective study. J Otolaryngol Head Neck Surg. 2015 Sep 18;44:38. doi: 10.1186/s40463-015-0092-4. PubMed PMID: 26385356; PubMed Central PMCID: PMC4574730.
15. Barrios R, Bravo M, Gil-Montoya JA, Martínez-Lara I, García-Medina B, Tsakos G. Oral and general health-related quality of life in patients treated for oral cancer compared to control group. Health Qual Life Outcomes. 2015 Jan 23;13:9. doi: 10.1186/s12955-014-0201-5. PubMed PMID: 25613348; PubMed Central PMCID: PMC4311475.
16. Barrios R, Tsakos G, García-Medina B, Martínez-Lara I, Bravo M. Oral health-related quality of life and malnutrition in patients treated for oral cancer. Support Care Cancer. 2014 Nov;22(11):2927-33. doi: 10.1007/s00520-014-2281-5. Epub 2014 May 22. PubMed PMID: 24848576; PubMed Central PMCID: PMC4183889.
17. Barrios R, Tsakos G, Gil-Montoya JA, Montero J, Bravo M. Association between general and oral health-related quality of life in patients treated for oral cancer. Med Oral Patol Oral Cir Bucal. 2015 Nov 1;20(6):e678-84. PubMed PMID: 26449436; PubMed Central PMCID: PMC4670247.
18. Barroso EM, Carvalho AL, Paiva CE, Murphy BA, Paiva BS. The Vanderbilt Head and Neck Symptom Survey Brazilian Portuguese version 2.0 (VHNSS 2.0): psychometric properties for patients with head and neck cancer who have undergone radiotherapy. BMC Res Notes. 2015 Oct 1;8:522. doi: 10.1186/s13104-015-1470-8. PubMed PMID: 26428472; PubMed Central PMCID: PMC4589957.
19. Barroso EM, Carvalho AL, Paiva CE, Nunes JS, Paiva BS. Translation and cross-cultural adaptation into Brazilian Portuguese of the Vanderbilt Head and Neck Symptom Survey version 2.0 (VHNSS 2.0) for the assessment of oral symptoms in head and neck cancer patients submitted to radiotherapy. Braz J Otorhinolaryngol. 2015 Nov-Dec;81(6):622-9. doi: 10.1016/j.bjorl.2015.08.014. Epub 2015 Sep 8. PubMed PMID: 26480908.
20. Batıoğlu-Karaaltın A, Binbay Z, Yiğit Ö, Dönmez Z. Evaluation of life quality, self-confidence and sexual functions in patients with total and partial laryngectomy. Auris Nasus Larynx. 2017 Apr;44(2):188-194. doi: 10.1016/j.anl.2016.03.007. Epub 2016 Apr 16. PubMed PMID: 27095740.
21. Beck-Broichsitter BE, Huck J, Küchler T, Hauke D, Hedderich J, Wiltfang J, Becker ST. Self-perception versus professional assessment of functional outcome after ablative surgery in patients with oral cancer. J Cancer Res Clin Oncol. 2017 Feb;143(2):305-311. doi: 10.1007/s00432-016-2287-0. Epub 2016 Oct 18. PubMed PMID: 27757527.
22. Becker C, Becker AM, Dahlem KKK, Offergeld C, Pfeiffer J. Aesthetic and functional outcomes in patients with a nasal prosthesis. Int J Oral Maxillofac Surg. 2017 May 15. pii: S0901-5027(17)31446-7. doi: 10.1016/j.ijom.2017.04.024.[Epub ahead of print] PubMed PMID: 28521966.
23. Bian X, Song T, Wu S. Outcomes of xerostomia-related quality of life for nasopharyngeal carcinoma treated by IMRT: based on the EORTC QLQ-C30 and H&N35 questionnaires. Expert Rev Anticancer Ther. 2015 Jan;15(1):109-19. doi: 10.1586/14737140.2015.961427. Epub 2014 Sep 18. Review. PubMed PMID: 25231774.
24. Bilal S, Doss JG, Rogers SN. The use of the FACT-H&N (v4) in clinical settings within a developing country: a mixed method study. J Craniomaxillofac Surg. 2014 Dec;42(8):1590-7. doi: 10.1016/j.jcms.2014.04.015. Epub 2014 May 2. PubMed PMID: 25224886.
25. Binenbaum Y, Amit M, Billan S, Cohen JT, Gil Z. Minimal clinically important differences in quality of life scores of oral cavity and oropharynx cancer patients. Ann Surg Oncol. 2014 Aug;21(8):2773-81. doi: 10.1245/s10434-014-3656-z. Epub 2014 Apr 8. PubMed PMID: 24710774.
26. Bonner J, Giralt J, Harari P, Spencer S, Schulten J, Hossain A, Chang SC, Chin S, Baselga J. Cetuximab and Radiotherapy in Laryngeal Preservation for Cancers of the Larynx and Hypopharynx: A Secondary Analysis of a Randomized Clinical Trial. JAMA Otolaryngol Head Neck Surg. 2016 Sep 1;142(9):842-9. doi: 10.1001/jamaoto.2016.1228. PubMed PMID: 27389475; PubMed Central PMCID: PMC5025385.
27. Bornbaum CC, Day AM, Doyle PC. Examining the construct validity of the V-RQOL in speakers who use alaryngeal voice. Am J Speech Lang Pathol. 2014 May;23(2):196-202. doi: 10.1044/2013_AJSLP-13-0024. PubMed PMID: 24686439.
28. Bottomley A, Tridello G, Coens C, Rolland F, Tesselaar ME, Leemans CR, Hupperets P, Licitra L, Vermorken JB, Van Den Weyngaert D, Truc G, Barillot I, Lefebvre JL. An international

phase 3 trial in head and neck cancer: quality of life and symptom results: EORTC 24954 on behalf of the EORTC Head and Neck and the EORTC Radiation Oncology Group. Cancer. 2014 Feb 1;120(3):390-8. doi: 10.1002/cncr.28392. Epub 2013 Oct 25. PubMed PMID: 24452673.

29. Bozec A, Schultz P, Gal J, Chamorey E, Chateau Y, Dassonville O, Poissonnet G, Santini J, Peyrade F, Saada E, Guigay J, Benezery K, Leysalle A, Santini L, Giovanni A, Messaoudi L, Fakhry N. Evaluation of the information given to patients undergoing head and neck cancer surgery using the EORTC QLQ-INFO25 questionnaire: A prospective multicentric study. Eur J Cancer. 2016 Nov;67:73-82. doi: 10.1016/j.ejca.2016.08.005. Epub 2016 Sep 9. PubMed PMID: 27616438.
30. Bozec A, Schultz P, Gal J, Chamorey E, Chateau Y, Dassonville O, Poissonnet G, Santini J, Peyrade F, Saada E, Guigay J, Benezery K, Leysalle A, Santini L, Giovanni A, Messaoudi L, Fakhry N. Evaluation of the information given to patients undergoing head and neck cancer surgery using the EORTC QLQ-INFO25 questionnaire: A prospective multicentric study. Eur J Cancer. 2016 Nov;67:73-82. doi: 10.1016/j.ejca.2016.08.005. Epub 2016 Sep 9. PubMed PMID: 27616438.
31. Brandão TB, Vechiato Filho AJ, Batista VE, de Oliveira MC, Santos-Silva AR. Obturator prostheses versus free tissue transfers: A systematic review of the optimal approach to improving the quality of life for patients with maxillary defects. J Prosthet Dent. 2016 Feb;115(2):247-253.e4. doi: 10.1016/j.prosdent.2015.08.002. Epub 2015 Oct 21. Review. PubMed PMID: 26481066.
32. Brandão TB, Vechiato Filho AJ, Prado Ribeiro AC, Gebrim EM, Bodard AG, da Silva DP, Santos-Silva AR, Ishida LC, Dias RB. Evaluation of use of acrylic resin-based surgical guide in the function and quality of life provided by mandibular prostheses with microvascular free fibula flap: A four-year, randomized, controlled trial. J Prosthet Dent. 2016 Sep;116(3):457-463.e2. doi: 10.1016/j.prosdent.2016.02.012. Epub 2016 May 4. PubMed PMID: 27158033.
33. Burghartz M, Ginzkey C, Hackenberg S, Hagen R. Two-stage autotransplantation of the human submandibular gland: First long-term results. Laryngoscope. 2016 Jul;126(7):1551-5. doi: 10.1002/lary.25854. Epub 2016 Feb 4. PubMed PMID: 26845689.
34. Bussu F, Galli J, Valenza V, D'Alatri L, Pizzuto DA, Almadori G, Giordano A, Paludetti G. Evaluation of swallowing function after supracricoid laryngectomy as a primary or salvage procedure. Dysphagia. 2015 Dec;30(6):686-94. doi: 10.1007/s00455-015-9645-y. Epub 2015 Aug 13. PubMed PMID: 26267541.
35. Canis M, Weiss BG, Ihler F, Hummers-Pradier E, Matthias C, Wolff HA. Quality of life in patients after resection of pT3 lateral tongue carcinoma: Microvascular reconstruction versus primary closure. Head Neck. 2016 Jan;38(1):89-94. doi: 10.1002/hed.23862. Epub 2015 Jun 16. PubMed PMID: 25224592.
36. Capozzi LC, McNeely ML, Lau HY, Reimer RA, Giese-Davis J, Fung TS, Culos-Reed SN. Patient-reported outcomes, body composition, and nutrition status in patients with head and neck cancer: Results from an exploratory randomized controlled exercise trial. Cancer. 2016 Apr 15;122(8):1185-200. doi: 10.1002/cncr.29863. Epub 2016 Feb 1. PubMed PMID: 26828426.
37. Cardoso LR, Rizzo CC, de Oliveira CZ, dos Santos CR, Carvalho AL. Myofascial pain syndrome after head and neck cancer treatment: Prevalence, risk factors, and influence on quality of life. Head Neck. 2015 Dec;37(12):1733-7. doi: 10.1002/hed.23825. Epub 2014 Sep 25. PubMed PMID: 24986588.
38. Cavell S, Broadbent E, Donkin L, Gear K, Morton RP. Observations of benefit finding in head and neck cancer patients. Eur Arch Otorhinolaryngol. 2016 Feb;273(2):479-85. doi: 10.1007/s00405-015-3527-7. Epub 2015 Jan 30. PubMed PMID: 25634065.
39. Ch'ng S, Oates J, Gao K, Foo K, Davies S, Brunner M, Clark JR. Prospective quality of life assessment between treatment groups for oral cavity squamous cell carcinoma. Head Neck. 2014 Jun;36(6):834-40. doi: 10.1002/hed.23387. Epub 2013 Sep 2. PubMed PMID: 23720248.
40. Charalambous A, Lambrinou E, Katodritis N, Vomvas D, Raftopoulos V, Georgiou M, Paikousis L, Charalambous M. The effectiveness of thyme honey for the management of treatment-induced xerostomia in head and neck cancer patients: A feasibility randomized control trial. Eur J Oncol Nurs. 2017 Apr;27:1-8. doi: 10.1016/j.ejon.2017.01.001. Epub 2017 Jan 16. PubMed PMID: 28279391.
41. Chen AM, Daly ME, Farwell DG, Vazquez E, Courquin J, Lau DH, Purdy JA. Quality of life among long-term survivors of head and neck cancer treated by intensity-modulated radiotherapy. JAMA Otolaryngol Head Neck Surg. 2014 Feb;140(2):129-33. doi: 10.1001/jamaoto.2013.5988. PubMed PMID: 24337483.
42. Chen J, Liu P, Wang Q, Wu L, Zhang X. Influence of Intensity-Modulated Radiation Therapy on the Life Quality of Patients with Nasopharyngeal Carcinoma. Cell Biochem Biophys. 2015 Dec;73(3):731-6. doi: 10.1007/s12013-015-0638-0. PubMed PMID: 27259317.

43. Chen XL, Qiu ZW, Gu MF, Su Y, Liu LZ, Liu Y, Mo CW, Xu Q, Sun J, Li DH.Translation and validation of the Chinese version of the Quality OF Life Radiation Therapy Instrument and the Head & Neck Module (QOL-RTI/H&N). Health Qual Life Outcomes. 2014 Apr 14;12:51. doi: 10.1186/1477-7525-12-51. PubMed PMID: 24731442; PubMed Central PMCID: PMC4022371.
44. Chera BS, Eisbruch A, Murphy BA, Ridge JA, Gavin P, Reeve BB, Bruner DW, Movsas B. Recommended patient-reported core set of symptoms to measure in head and neck cancer treatment trials. J Natl Cancer Inst. 2014 Jul 8;106(7). pii: dju127. doi: 10.1093/jnci/dju127. Print 2014 Jul. Review. PubMed PMID: 25006189; PubMed Central PMCID: PMC4192043.
45. Choby GW, Kim J, Ling DC, Abberbock S, Mandal R, Kim S, Ferris RL, Duvvuri U. Transoral robotic surgery alone for oropharyngeal cancer: quality-of-life outcomes. JAMA Otolaryngol Head Neck Surg. 2015 Jun;141(6):499-504. doi: 10.1001/jamaoto.2015.0347. PubMed PMID: 25834991.
46. Chotigavanich C, Dowdall JR, Franco RA Jr. Acoustic Characteristics of Voice Before and After Endoscopic Partial Laryngectomy in Early Glottic Cancer. J Voice. 2016 May;30(3):371-6. doi: 10.1016/j.jvoice.2011.08.006. Epub 2016 Feb 2. PubMed PMID: 26846542.
47. Christopher KM, Osazuwa-Peters N, Dougherty R, Indergaard SA, Popp C, Walker R, Varvares MA. Impact of treatment modality on quality of life of head and neck cancer patients: Findings from an academic medical institution. Am J Otolaryngol. 2017 Mar - Apr;38(2):168-173. doi: 10.1016/j.amjoto.2016.12.003. Epub 2016 Dec 29. PubMed PMID: 28081981.
48. Ciocca L, Tarsitano A, Mazzoni S, Gatto MR, Marchetti C, Scotti R. Evaluation of Masticatory Efficiency and QoL Improvements After Prosthetic Rehabilitation of Mandibular Cancer Patients Reconstructed with a Fibula Free Flap. Int J Prosthodont. 2015 Jul-Aug;28(4):418-24. doi: 10.11607/ijp.4156. PubMed PMID: 26218029.
49. Cnossen IC, van Uden-Kraan CF, Eerenstein SE, Jansen F, Witte BI, Lacko M, Hardillo JA, Honings J, Halmos GB, Goedhart-Schwandt NL, de Bree R, Leemans CR, Verdonck-de Leeuw IM. An online self-care education program to support patients after total laryngectomy: feasibility and satisfaction. Support Care Cancer. 2016 Mar;24(3):1261-8. doi: 10.1007/s00520-015-2896-1. Epub 2015 Aug 26. PubMed PMID: 26306518; PubMed Central PMCID: PMC4729815.
50. Cohen WA, Albornoz CR, Cordeiro PG, Cracchiolo J, Encarnacion E, Lee M, Cavalli M, Patel S, Pusic AL, Matros E. Health-Related Quality of Life following Reconstruction for Common Head and Neck Surgical Defects. Plast Reconstr Surg. 2016 Dec;138(6):1312-1320. PubMed PMID: 27879602.
51. Côté M, Trudel M, Wang C, Fortin A. Improving Quality of Life With Nabilone During Radiotherapy Treatments for Head and Neck Cancers: A Randomized Double-Blind Placebo-Controlled Trial. Ann Otol Rhinol Laryngol. 2016 Apr;125(4):317-24. doi: 10.1177/0003489415612801. Epub 2015 Oct 25. PubMed PMID: 26503964.
52. Crombie AK, Farah CS, Batstone MD. Health-related quality of life of patients treated with primary chemoradiotherapy for oral cavity squamous cell carcinoma: a comparison with surgery. Br J Oral Maxillofac Surg. 2014 Feb;52(2):111-7. doi: 10.1016/j.bjoms.2013.09.014. Epub 2013 Oct 20. PubMed PMID: 24148700.
53. Dale OT, Han C, Burgess CA, Eves S, Harris CE, White PL, Shah RT, Howard A, Winter SC. Long-term functional outcomes in surgically treated patients withoropharyngeal cancer. Laryngoscope. 2015 Jul;125(7):1637-43. doi: 10.1002/lary.25226. Epub 2015 Mar 17. PubMed PMID: 25781307.
54. Daugaard R, Kjaer T, Johansen C, Christiansen J, Andersen E, Nielsen AL, Dalton SO. Association between late effects assessed by physicians and quality of life reported by head-and-neck cancer survivors. Acta Oncol. 2017 Feb;56(2):342-347. doi: 10.1080/0284186X.2016.1267873. Epub 2017 Jan 12. PubMed PMID: 28079429.
55. de Almeida JR, Park RC, Villanueva NL, Miles BA, Teng MS, Genden EM. Reconstructive algorithm and classification system for transoral oropharyngeal defects. Head Neck. 2014 Jul;36(7):934-41. doi: 10.1002/hed.23353. Epub 2014 May 19. PubMed PMID: 23606444.
56. de Oliveira RL, Dos Santos RF, de Carvalho SH, Agripino GG, Canto MM, de Vasconcelos Carvalho M, Marinho SA, Gallottini M, de Santana Sarmento DJ. Prospective evaluation of quality of life in patients with head and neck cancer. Oral Surg Oral Med Oral Pathol Oral Radiol. 2017 Mar;123(3):350-357. doi:10.1016/j.oooo.2016.11.021. Epub 2016 Dec 7. PubMed PMID: 28108141.
57. Dholam KP, Chouksey GC, Dugad J. Oral health-related quality of life afterprosthetic rehabilitation in patients with oral cancer: A longitudinal study with the Liverpool Oral Rehabilitation Questionnaire version 3 and Oral Health Impact Profile-14 questionnaire. Indian J Cancer. 2016 Apr-Jun;53(2):256-260. doi: 10.4103/0019-509X.197716. PubMed PMID: 28071622.

58. Dholam KP, Dugad JA, Sadashiva KM. Impact of oral rehabilitation on patients with head and neck cancer: A study using the Liverpool Oral Rehabilitation Questionnaire and the Oral Health Impact Profile-14. J Prosthet Dent. 2017 Apr;117(4):559-562. doi: 10.1016/j.prosdent.2016.06.019. Epub 2016 Oct 17. PubMed PMID: 27765395.
59. Dinescu FV, Ţiple C, Chirilă M, Mureşan R, Drugan T, Cosgarea M. Evaluation of health-related quality of life with EORTC QLQ-C30 and QLQ-H&N35 in Romanian laryngeal cancer patients. Eur Arch Otorhinolaryngol. 2016 Sep;273(9):2735-40. doi: 10.1007/s00405-015-3809-0. Epub 2015 Oct 28. PubMed PMID: 26511987.
60. Doğan MD, Can G, Meral R. Effectiveness of Black Mulberry Molasses in Prevention of Radiotherapy-Induced Oral Mucositis: A Randomized Controlled Study in Head and Neck Cancer Patients. J Altern Complement Med. 2017 Jul 5. doi:10.1089/acm.2016.0425. [Epub ahead of print] PubMed PMID: 28677999.
61. Drost BH, van de Langenberg R, Manusama OR, Janssens AS, Sikorska K, Zuur CL, Klop WM, Lohuis PJ. Dermatography (Medical Tattooing) for Scars and Skin Grafts in Head and Neck Patients to Improve Appearance and Quality of Life. JAMA Facial Plast Surg. 2017 Jan 1;19(1):16-22. doi: 10.1001/jamafacial.2016.1084. PubMed PMID: 27657879.
62. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, van der Velden LA, Lacko M, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Feasibility of an eHealth application "OncoKompas" to improve personalized survivorship cancer care. Support Care Cancer. 2016 May;24(5):2163-2171. doi: 10.1007/s00520-015-3004-2. Epub 2015 Nov 12. PubMed PMID: 26563178; PubMed Central PMCID: PMC4805720.
63. Dwivedi RC, St Rose S, Chisholm EJ, Clarke PM, Kerawala CJ, Nutting CM, Rhys-Evans PH, Kazi R, Harrington KJ. Acoustic parameters of speech: Lack of correlation with perceptual and questionnaire-based speech evaluation in patients with oral and oropharyngeal cancer treated with primary surgery. Head Neck. 2016 May;38(5):670-6. doi: 10.1002/hed.23956. Epub 2015 Jun 25. PubMed PMID: 25524696.
64. Dzebo S, Mahmutovic J, Erkocevic H. Quality of Life of Patients with Oral Cavity Cancer. Mater Sociomed. 2017 Mar;29(1):30-34. doi: 10.5455/msm.2017.29.30-34. PubMed PMID: 28484351; PubMed Central PMCID: PMC5402360.
65. Eadie TL, Lamvik K, Baylor CR, Yorkston KM, Kim J, Amtmann D. Communicative participation and quality of life in head and neck cancer. Ann Otol Rhinol Laryngol. 2014 Apr;123(4):257-64. doi: 10.1177/0003489414525020. PubMed PMID: 24671481; PubMed Central PMCID: PMC4374344.
66. Egestad H, Nieder C. Differences in quality of life in obese and normal weight head and neck cancer patients undergoing radiation therapy. Support Care Cancer. 2015 Apr;23(4):1081-90. doi: 10.1007/s00520-014-2463-1. Epub 2014 Oct 4. PubMed PMID: 25281231
67. Ehrsson YT, Sundberg K, Laurell G, Langius-Eklöf A. Head and neck cancer patients' perceptions of quality of life and how it is affected by the disease and enteral tube feeding during treatment. Ups J Med Sci. 2015;120(4):280-9. doi: 10.3109/03009734.2015.1075630. PubMed PMID: 26482657; PubMed Central PMCID: PMC4816889.
68. Eickmeyer SM, Walczak CK, Myers KB, Lindstrom DR, Layde P, Campbell BH. Quality of life, shoulder range of motion, and spinal accessory nerve status in 5-year survivors of head and neck cancer. PM R. 2014 Dec;6(12):1073-80. doi: 10.1016/j.pmrj.2014.05.015. Epub 2014 May 28. PubMed PMID: 24880060; PubMed Central PMCID: PMC4247358.
69. Elfring T, Boliek CA, Winget M, Paulsen C, Seikaly H, Rieger JM. The relationship between lingual and hypoglossal nerve function and quality of life in head and neck cancer. J Oral Rehabil. 2014 Feb;41(2):133-40. doi: 10.1111/joor.12116. Epub 2013 Nov 29. PubMed PMID: 24289234.
70. Elliott DA, Nabavizadeh N, Romer JL, Chen Y, Holland JM. Medical marijuana use in head and neck squamous cell carcinoma patients treated with radiotherapy. Support Care Cancer. 2016 Aug;24(8):3517-24. doi: 10.1007/s00520-016-3180-8. Epub 2016 Mar 23. PubMed PMID: 27005465.
71. Engelen M, Buurman DJM, Bronkhorst EM, van Heumen CCM. Translation, cross-cultural adaptation, and validation of the Liverpool Oral Rehabilitation Questionnaire (LORQ) into the Dutch language. J Prosthet Dent. 2017 May 26. pii: S0022-3913(17)30239-1. doi: 10.1016/j.prosdent.2017.03.023. [Epub ahead of print]PubMed PMID: 28552282.
72. Erkal EY, Canoğlu D, Kaya A, Aksu G, Sarper B, Akansel G, Meydancı T, Erkal HS. Assessment of early and late dysphagia using videofluoroscopy and quality of life questionnaires in patients with head and neck cancer treated with radiation therapy. Radiat Oncol. 2014 Jun 14;9:137. doi: 10.1186/1748-717X-9-137. PubMed PMID: 24928361; PubMed Central PMCID: PMC4073176.
73. Fang QG, Shi S, Li M, Zhang X, Liu FY, Sun CF. Free flap reconstruction versus non-free flap

reconstruction in treating elderly patients with advanced oral cancer. J Oral Maxillofac Surg. 2014 Jul;72(7):1420-4. doi: 10.1016/j.joms.2014.01.010. Epub 2014 Jan 23. PubMed PMID: 24613030.

74. Fang QG, Shi S, Zhang X, Li M, Liu FY, Sun CF. Long term quality of life in pediatric patients surviving parotid tumors. Int J Pediatr Otorhinolaryngol. 2014 Feb;78(2):235-7. doi: 10.1016/j.ijporl.2013.11.011. Epub 2013 Nov 22. PubMed PMID: 24332607.
75. Flach GB, Verdonck-de Leeuw IM, Witte BI, Klop WM, van Es RJ, Schepman KP, de Bree R. Patients' perspective on the impact of sentinel node biopsy in oral cancer treatment. Oral Surg Oral Med Oral Pathol Oral Radiol. 2016 Sep;122(3):279-86. doi: 10.1016/j.oooo.2016.03.014. Epub 2016 Mar 31. PubMed PMID: 27262509.
76. Florie M, Baijens L, Kremer B, Kross K, Lacko M, Verhees F, Winkens B. Relationship between swallow-specific quality of life and fiber-optic endoscopic evaluation of swallowing findings in patients with head and neck cancer. Head Neck. 2016 Apr;38 Suppl 1:E1848-56. doi: 10.1002/hed.24333. Epub 2015 Dec 23. PubMed PMID: 26695518.
77. Franco P, Martini S, Di Muzio J, Cavallin C, Arcadipane F, Rampino M,Ostellino O, Pecorari G, Garzino Demo P, Fasolis M, Airoldi M, Ricardi U.Prospective assessment of oral mucositis and its impact on quality of life and patient-reported outcomes during radiotherapy for head and neck cancer. MedOncol. 2017 May;34(5):81. doi: 10.1007/s12032-017-0950-1. Epub 2017 Apr 6. PubMed PMID: 28386836.
78. Galli J, Pandolfini M, Rigante M, Schinaia L, Guidi ML, Almadori G, Paludetti G. Sensory dysfunction and quality of life after great auricular nerve sacrifice during parotidectomy: our experience. J Laryngol Otol. 2015 Nov;129(11):1121-7. doi: 10.1017/S0022215115001863. Epub 2015 Aug 12. PubMed PMID: 26264365.
79. Gandhi AK, Roy S, Thakar A, Sharma A, Mohanti BK. Symptom Burden and Quality of Life in Advanced Head and Neck Cancer Patients: AIIMS Study of 100 Patients. Indian J Palliat Care. 2014 Sep;20(3):189-93. doi: 10.4103/0973-1075.138389. PubMed PMID: 25191005; PubMed Central PMCID: PMC4154165.
80. Ganzer H, Rothpletz-Puglia P, Byham-Gray L, Murphy BA, Touger-Decker R. The eating experience in long-term survivors of head and neck cancer: a mixed-methods study. Support Care Cancer. 2015 Nov;23(11):3257-68. doi: 10.1007/s00520-015-2730-9. Epub 2015 Apr 8. PubMed PMID: 25851804
81. Garzaro M, Riva G, Raimondo L, Aghemo L, Giordano C, Pecorari G. A study of neck and shoulder morbidity following neck dissection: The benefits of cervical plexus preservation. Ear Nose Throat J. 2015 Aug;94(8):330-44. PubMed PMID: 26322451.
82. Ghazali N, Roe B, Lowe D, Rogers SN. Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life. Br J Oral Maxillofac Surg. 2015 Apr;53(4):371-9. doi: 10.1016/j.bjoms.2015.01.022. Epub 2015 Feb 20. PubMed PMID: 25708200.
83. Ghazali N, Roe B, Lowe D, Tandon S, Jones T, Brown J, Shaw R, Risk J, Rogers SN. Screening for distress using the distress thermometer and the University of Washington Quality of Life in post-treatment head and neck cancer survivors. Eur Arch Otorhinolaryngol. 2017 May;274(5):2253-2260. doi: 10.1007/s00405-017-4474-2.Epub 2017 Feb 6. PubMed PMID: 28168421.
84. Gobbo M, Bullo F, Perinetti G, Gatto A, Ottaviani G, Biasotto M, Tirelli G. Diagnostic and therapeutic features associated with modification of quality-of-life's outcomes between one and six months after major surgery for head and neck cancer. Braz J Otorhinolaryngol. 2016 Sep-Oct;82(5):548-57. doi: 10.1016/j.bjorl.2015.10.013. Epub 2015 Dec 18. PubMed PMID: 26878840.
85. Goldstein DP, Ringash J, Bissada E, Jaquet Y, Irish J, Chepeha D, Davis AM. Evaluation of shoulder disability questionnaires used for the assessment of shoulder disability after neck dissection for head and neck cancer. Head Neck. 2014 Oct;36(10):1453-8. doi: 10.1002/hed.23490. Epub 2013 Dec 18. PubMed PMID: 23996914.
86. Govers TM, Schreuder WH, Klop WM, Grutters JP, Rovers MM, Merkx MA, Takes RP. Quality of life after different procedures for regional control in oral cancer patients: cross-sectional survey. Clin Otolaryngol. 2016 Jun;41(3):228-33.doi: 10.1111/coa.12502. Epub 2016 Feb 4. PubMed PMID: 26198548.
87. Greco A, Orlandi E, Mirabile A, Takanen S, Fallai C, Iacovelli NA, Rimedio A, Russi E, Sala M, Monzani D, Rosenthal DI, Gunn GB, Steca P, Licitra L, Bossi P. Italian version of the M.D. Anderson Symptom Inventory--Head and Neck Module: linguistic validation. Support Care Cancer. 2015 Dec;23(12):3465-72. doi: 10.1007/s00520-015-2701-1. Epub 2015 Mar 21. PubMed PMID: 25791393.
88. Gunn GB, Atalar B, Mendoza TR, Cleeland CS, Selek U, Özyar E, Rosenthal DI. Linguistic

Validation of the Turkish Version of the M.D. Anderson Symptom Inventory - Head and Neck Cancer Module. Balkan Med J. 2016 May;33(3):339-43. doi: 10.5152/balkanmedj.2015.150148. Epub 2016 May 1. PubMed PMID: 27308079; PubMed Central PMCID: PMC4898994.

89. Hagen R, Scheich M, Kleinsasser N, Burghartz M. Two-stage autotransplantation of human submandibular gland: a novel approach to treat postradiogenic xerostomia. Eur Arch Otorhinolaryngol. 2016 Aug;273(8):2217-22. doi: 10.1007/s00405-015-3752-0. Epub 2015 Aug 19. PubMed PMID: 26285780.
90. Hajdú SF, Plaschke CC, Johansen C, Dalton SO, Wessel I. Cross-Cultural Translation, Adaptation and Reliability of the Danish M. D. Andeson Dysphagia Inventory (MDADI) in Patients with Head and Neck Cancer. Dysphagia. 2017 Aug;32(4):472-479. doi: 10.1007/s00455-017-9785-3. Epub 2017 Mar 7. PubMed PMID: 28271296.
91. Hanly P, Maguire R, Balfe M, Hyland P, Timmons A, O'Sullivan E, Butow P, Sharp L. Burden and happiness in head and neck cancer carers: the role of supportive care needs. Support Care Cancer. 2016 Oct;24(10):4283-91. doi: 10.1007/s00520-016-3261-8. Epub 2016 May 16. PubMed PMID: 27185021.
92. Harrington KJ, Ferris RL, Blumenschein G Jr, Colevas AD, Fayette J, Licitra L, Kasper S, Even C, Vokes EE, Worden F, Saba NF, Kiyota N, Haddad R, Tahara M, Grünwald V, Shaw JW, Monga M, Lynch M, Taylor F, DeRosa M, Morrissey L, Cocks K, Gillison ML, Guigay J. Nivolumab versus standard, single-agent therapy of investigator's choice in recurrent or metastatic squamous cell carcinoma of the head and neck (CheckMate 141): health-related quality-of-life results from a randomised, phase 3 trial. Lancet Oncol. 2017 Jun 23. pii: S1470-2045(17)30421-7.doi: 10.1016/S1470-2045(17)30421-7. [Epub ahead of print] PubMed PMID: 28651929.
93. Hartford AC, Davis TH, Buckey JC, Foote RL, Sinesi MS, Williams BB, Fariss AK, Schaner PE, Claus PL, Okuno SH, Hussey JR, Clarke RE. Hyperbaric Oxygen as Radiation Sensitizer for Locally Advanced Squamous Cell Carcinoma of the Oropharynx: A Phase 1 Dose-Escalation Study. Int J Radiat Oncol Biol Phys. 2017 Mar 1;97(3):481-486. doi: 10.1016/j.ijrobp.2016.10.048. Epub 2016 Nov 15. PubMed PMID: 28126298.
94. He Y, Chen L, Chen L, Hu W, Wang C, Tang L, Mai H, Li J, Wu L, Fan Y.Relationship Between the Comprehensive Nutritional Index and the EORTC QLQ-H&N35 in Nasopharyngeal Carcinoma Patients Treated with Intensity-Modulated Radiation Therapy. Nutr Cancer. 2017 Apr;69(3):436-443. doi: 10.1080/01635581.2017.1283422. Epub 2017 Feb 22. PubMed PMID: 28287323.
95. Henry M, Habib LA, Morrison M, Yang JW, Li XJ, Lin S, Zeitouni A, Payne R, MacDonald C, Mlynarek A, Kost K, Black M, Hier M. Head and neck cancer patients want us to support them psychologically in the posttreatment period: Survey results. Palliat Support Care. 2014 Dec;12(6):481-93. doi: 10.1017/S1478951513000771. Epub 2013 Oct 24. PubMed PMID: 24153040.
96. Heydarirad G, Rezaeizadeh H, Choopani R, Mosavat SH, Ameri A. Efficacy of a traditional Persian medicine preparation for radiation-induced xerostomia: a randomized, open-label, active-controlled trial. J Integr Med. 2017 May;15(3):201-208. doi: 10.1016/S2095-4964(17)60333-9. PubMed PMID: 28494850.
97. Hoffman KE, Pugh SL, James JL, Scarantino C, Movsas B, Valicenti RK, Fortin A, Pollock J, Kim H, Brachman DG, Berk LB, Bruner DW, Kachnic LA. The impact of concurrent granulocyte-macrophage colony-stimulating factor on quality of life in head and neck cancer patients: results of the randomized, placebo-controlled Radiation Therapy Oncology Group 9901 trial. Qual Life Res. 2014 Aug;23(6):1841-58. doi: 10.1007/s11136-014-0628-5. Epub 2014 Feb 4. PubMed PMID: 24492945; PubMed Central PMCID: PMC4533105.
98. Holtmaat K, van der Spek N, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Posttraumatic growth among head and neck cancer survivors with psychological distress. Psychooncology. 2017 Jan;26(1):96-101. doi: 10.1002/pon.4106. Epub 2016 Feb 25. PubMed PMID: 26918531.
99. Hoole J, Kanatas A, Calvert A, Rogers SN, Smith AB, Mitchell DA. Validated questionnaires on intimacy in patients who have had cancer. Br J Oral Maxillofac Surg. 2015 Sep;53(7):584-93. doi: 10.1016/j.bjoms.2015.05.003. Epub 2015 May 30. Review. PubMed PMID: 26037739.
100. Høxbroe Michaelsen S, Grønhøj C, Høxbroe Michaelsen J, Friborg J, von Buchwald C. Quality of life in survivors of oropharyngeal cancer: A systematic review and meta-analysis of 1366 patients. Eur J Cancer. 2017 Jun;78:91-102. doi: 10.1016/j.ejca.2017.03.006. Epub 2017 Apr 18. Review. PubMed PMID: 28431302.
101. Hsin LJ, Lin WN, Fang TJ, Lee LA, Kang CJ, Huang BS, Lin CY, Fan KH, Tsang NM, Hsu CL, Chang JT, Liao CT, Yen TC, Chang KP, Chuang HF, Li HY. Life quality improvement in hoarse patients with early glottic cancer after transoral laser microsurgery. Head Neck. 2017 Jul 11. doi: 10.1002/hed.24873. [Epub ahead of print] PubMed PMID: 28695624.

102. Huang TL, Chien CY, Tsai WL, Liao KC, Chou SY, Lin HC, Dean Luo S, Lee TF, Lee CH, Fang FM. Long-term late toxicities and quality of life for survivors of nasopharyngeal carcinoma treated with intensity-modulated radiotherapy versus non-intensity-modulated radiotherapy. Head Neck. 2016 Apr;38 Suppl 1:E1026-32. doi: 10.1002/hed.24150. Epub 2015 Jul 18. PubMed PMID: 26041548.
103. Huyett P, Kim S, Johnson JT, Soose RJ. Obstructive sleep apnea in the irradiated head and neck cancer patient. Laryngoscope. 2017 May 23. doi: 10.1002/lary.26674. [Epub ahead of print] PubMed PMID: 28543072.
104. Ichikura K, Yamashita A, Sugimoto T, Kishimoto S, Matsushima E. Persistence of psychological distress and correlated factors among patients with head and neck cancer. Palliat Support Care. 2016 Feb;14(1):42-51. doi: 10.1017/S1478951515000711. Epub 2015 Jun 19. Erratum in: Palliat Support Care. 2016 Feb;14(1):86-8. PubMed PMID: 26089108.
105. Jang-Chun L, Jing-Min H, Yee-Min J, Dai-Wei L, Chang-Ming C, Chun-Shu L, Wen-Yen H, Yu-Fu S, Kuen-Tze L, Chao-Yueh F, Cheng-Hsiang L, Hsing-Lung C. Comparisons of quality of life for patients with nasopharyngeal carcinoma after treatment with different RT technologies. Acta Otorhinolaryngol Ital. 2014 Aug;34(4):241-6. PubMed PMID: 25210217; PubMed Central PMCID: PMC4157538.
106. Jansen F, Snyder CF, Leemans CR, Verdonck-de Leeuw IM. Identifying cutoff scores for the EORTC QLQ-C30 and the head and neck cancer-specific module EORTC QLQ-H&N35 representing unmet supportive care needs in patients with head and neck cancer. Head Neck. 2016 Apr;38 Suppl 1:E1493-500. doi: 10.1002/hed.24266. Epub 2015 Nov 13. PubMed PMID: 27111696.
107. Janssens GO, Langendijk JA, Terhaard CH, Doornaert PA, van den Ende P, de Jong MA, Takes RP, Span PN, Kaanders JH. Quality-of-life after radiotherapy for advanced laryngeal cancer: Results of a phase III trial of the Dutch Head and Neck Society. Radiother Oncol. 2016 May;119(2):213-20. doi: 10.1016/j.radonc.2016.02.023. Epub 2016 May 8. PubMed PMID: 27165613.
108. Johnson J, Johansson M, Rydén A, Houltz E, Finizia C. Impact of trismus on health-related quality of life and mental health. Head Neck. 2015 Nov;37(11):1672-9. doi: 10.1002/hed.23816. Epub 2015 Jan 27. PubMed PMID: 24985733.
109. Jungerman I, Toyota J, Montoni NP, Azevedo EHM, Guedes RLV, Damascena A, Lowe D, Vartanian JG, Rogers SN, Kowalski LP. Patient Concerns Inventory for head and neck cancer: Brazilian cultural adaptation. Rev Assoc Med Bras (1992). 2017 Apr;63(4):311-319. doi: 10.1590/1806-9282.63.04.311. PubMed PMID: 28614532.
110. Kanatas A, Humphris G, Lowe D, Rogers SN. Further analysis of the emotional consequences of head and neck cancer as reflected by the Patients' Concerns Inventory. Br J Oral Maxillofac Surg. 2015 Oct;53(8):711-8. doi: 10.1016/j.bjoms.2015.02.026. Epub 2015 Jun 6. PubMed PMID: 26055236.
111. Kanatas A, Singh P, Lowe D, Rogers SN. How will I be after my operation for oral cancer? Br J Oral Maxillofac Surg. 2015 Jul;53(6):538-45. doi: 10.1016/j.bjoms.2014.10.019. Epub 2015 Apr 30. PubMed PMID: 25936243.
112. Kannan P, Mukherji A, Saravanan K, Reddy KS, Vivekanandam S, Shamsudheen C, Santhosh V. Change in the Quality of Life in Oropharyngeal, Laryngeal and Hypopharyngeal Cancer Patients treated with Volumetric Modulated Arc-Based Concomitant Boost Radiotherapy. Gulf J Oncolog. 2016 May;1(21):36-45. PubMed PMID: 27250886.
113. Karlsson T, Bergström L, Ward E, Finizia C. A prospective longitudinal study of voice characteristics and health-related quality of life outcomes following laryngeal cancer treatment with radiotherapy. Acta Oncol. 2016 Jun;55(6):693-9. doi: 10.3109/0284186X.2016.1150604. Epub 2016 Apr 8. PubMed PMID: 27056401.
114. Keilmann A, Konerding U, Oberherr C, Nawka T. Articulation handicap index: an instrument for quantifying psychosocial consequences of impaired articulation. Eur Arch Otorhinolaryngol. 2016 Dec;273(12):4493-4500. Epub 2016 Jun 17. PubMed PMID: 27317563.
115. Kendall KA, Kosek SR, Tanner K. Quality-of-life scores compared to objective measures of swallowing after oropharyngeal chemoradiation. Laryngoscope. 2014 Mar;124(3):682-7. doi: 10.1002/lary.24344. Epub 2013 Oct 2. PubMed PMID: 23929736.
116. Kim SA, Roh JL, Lee SA, Lee SW, Kim SB, Choi SH, Nam SY, Kim SY. Pretreatment depression as a prognostic indicator of survival and nutritional status in patients with head and neck cancer. Cancer. 2016 Jan 1;122(1):131-40. doi: 10.1002/cncr.29693. Epub 2015 Sep 15. PubMed PMID: 26371775.
117. Kisser U, Adderson-Kisser C, Coenen M, Stier-Jarmer M, Becker S, Sabariego C, Harréus U. The development of an ICF-based clinical guideline and screening tool for the standardized assessment and evaluation of functioning after head and neck cancer treatment. Eur Arch

Otorhinolaryngol. 2017 Feb;274(2):1035-1043. doi: 10.1007/s00405-016-4317-6. Epub 2016 Sep 30. Review. PubMed PMID: 27695934.

118. Kjaer T, Dalton SO, Andersen E, Karlsen R, Nielsen AL, Hansen MK, Frederiksen K, Johansen C. A controlled study of use of patient-reported outcomes to improve assessment of late effects after treatment for head-and-neck cancer. Radiother Oncol. 2016 May;119(2):221-8. doi: 10.1016/j.radonc.2016.04.034. Epub 2016 May 10. PubMed PMID: 27178143.
119. Kjaer T, Johansen C, Andersen E, Karlsen R, Nielsen AL, Frederiksen K, Rørth M, Dalton SO. Do we reach the patients with the most problems? Baseline data from the WebCan study among survivors of head-and-neck cancer, Denmark. J Cancer Surviv. 2016 Apr;10(2):251-60. doi: 10.1007/s11764-015-0471-x. Epub 2015 Jul 31. PubMed PMID: 26227655.
120. Klein J, Livergant J, Ringash J. Health related quality of life in head and neck cancer treated with radiation therapy with or without chemotherapy: a systematic review. Oral Oncol. 2014 Apr;50(4):254-62. doi: 10.1016/j.oraloncology.2014.01.015. Epub 2014 Feb 18. Review. PubMed PMID: 24559650.
121. Kobayashi W, Kukobota K, Ito R, Sakaki H, Nakagawa H, Teh BG. Can Superselective Intra-Arterial Chemoradiotherapy Replace Surgery Followed by Radiation for Advanced Cancer of the Tongue and Floor of the Mouth? J Oral Maxillofac Surg. 2016 Jun;74(6):1248-54. doi: 10.1016/j.joms.2016.01.007. Epub 2016 Jan 8. PubMed PMID: 26851311.
122. Koch R, Wittekindt C, Altendorf-Hofmann A, Singer S, Guntinas-Lichius O. Employment pathways and work-related issues in head and neck cancer survivors. Head Neck. 2015 Apr;37(4):585-93. doi: 10.1002/hed.23640. Epub 2014 Apr 10. PubMed PMID: 24677561.
123. Kovács AF, Stefenelli U, Thorn G. Long-term quality of life after intensified multi-modality treatment of oral cancer including intra-arterial induction chemotherapy and adjuvant chemoradiation. Ann Maxillofac Surg. 2015 Jan-Jun;5(1):26-31. doi: 10.4103/2231-0746.161055. PubMed PMID: 26389030; PubMedCentral PMCID: PMC4555943.
124. Kraaijenga SA, Lapid O, van der Molen L, Hilgers FJ, Smeele LE, van den Brekel MW. Feasibility and potential value of lipofilling in post-treatment oropharyngeal dysfunction. Laryngoscope. 2016 Dec;126(12):2672-2678. doi: 10.1002/lary.26003. Epub 2016 Apr 14. PubMed PMID: 27076387.
125. Kraaijenga SA, Oskam IM, van der Molen L, Hamming-Vrieze O, Hilgers FJ, van den Brekel MW. Evaluation of long term (10-years+) dysphagia and trismus in patients treated with concurrent chemo-radiotherapy for advanced head and neck cancer. Oral Oncol. 2015 Aug;51(8):787-94. doi: 10.1016/j.oraloncology.2015.05.003. Epub 2015 May 28. PubMed PMID: 26027851.
126. Kraaijenga SA, Oskam IM, van Son RJ, Hamming-Vrieze O, Hilgers FJ, van den Brekel MW, van der Molen L. Assessment of voice, speech, and related quality of life in advanced head and neck cancer patients 10-years+ after chemoradiotherapy. Oral Oncol. 2016 Apr;55:24-30. doi: 10.1016/j.oraloncology.2016.02.001. Epub 2016 Feb 10. PubMed PMID: 26874554.
127. Kraaijenga SA, van der Molen L, Jacobi I, Hamming-Vrieze O, Hilgers FJ, van den Brekel MW. Prospective clinical study on long-term swallowing function and voice quality in advanced head and neck cancer patients treated with concurrent chemoradiotherapy and preventive swallowing exercises. Eur Arch Otorhinolaryngol. 2015 Nov;272(11):3521-31. doi: 10.1007/s00405-014-3379-6. Epub 2014 Nov 8. PubMed PMID: 25381096.
128. Krebber AM, Jansen F, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Screening for psychological distress in follow-up care to identify head and neck cancer patients with untreated distress. Support Care Cancer. 2016 Jun;24(6):2541-8. doi: 10.1007/s00520-015-3053-6. Epub 2015 Dec 23. PubMed PMID: 26694718; PubMed Central PMCID: PMC4846709.
129. Kucharska E, Głowacki R, Bereza K, Gładysz T, Walocha E, Golec J, Tomaszewska IM. Validation of the Polish version of the EORTC Head and Neck module (QLQ-H&N35). Przegl Lek. 2016;73(2):67-71. PubMed PMID: 27197425.
130. Kucuk H, Kurnaz SC, Kutlar G. Treatment expectations and quality of life outcomes of patients with laryngeal cancer based on different treatment methods. Eur Arch Otorhinolaryngol. 2015 May;272(5):1245-50. doi: 10.1007/s00405-014-3066-7. Epub 2014 May 1. PubMed PMID: 24789062.
131. Kumar A, Sharma A, Mohanti BK, Thakar A, Shukla NK, Thulkar SP, Sikka K, Bhasker S, Singh CA, Vishnubhatla S. A phase 2 randomized study to compare short course palliative radiotherapy with short course concurrent palliative chemotherapy plus radiotherapy in advanced and unresectable head and neck cancer. Radiother Oncol. 2015 Oct;117(1):145-51. doi: 10.1016/j.radonc.2015.07.026. Epub 2015 Aug 21. PubMed PMID: 26303014.
132. Kumar VV, Jacob PC, Ebenezer S, Kuriakose MA, Kekatpure V, Baliarsing AS, Al-Nawas B, Wagner W. Implant supported dental rehabilitation following segmental mandibular reconstruction- quality of life outcomes of a prospective randomized trial. J Craniomaxillofac

Surg. 2016 Jul;44(7):800-10. doi: 10.1016/j.jcms.2016.04.013. Epub 2016 Apr 16. PubMed PMID: 27193480

133. Lai CH, Chen MF, Fang FM, Chen WC. Estimation of life expectancy and quality-adjusted life expectancy in non-metastatic nasopharyngeal cancer patients treated by intensity-modulated radiotherapy with or without chemotherapy. Oral Oncol. 2014 Jul;50(7):646-50. doi: 10.1016/j.oraloncology.2014.03.011. Epub 2014 Apr 18. PubMed PMID: 24747031.
134. Landström FJ, Reizenstein J, Adamsson GB, Beckerath Mv, Möller C. Long-term follow-up in patients treated with curative electrochemotherapy for cancer in the oral cavity and oropharynx. Acta Otolaryngol. 2015;135(10):1070-8. doi: 10.3109/00016489.2015.1049663. Epub 2015 Jun 10. PubMed PMID: 26061895.
135. Lango MN, Egleston B, Fang C, Burtness B, Galloway T, Liu J, Mehra R, Ebersole B, Moran K, Ridge JA. Baseline health perceptions, dysphagia, and survival in patients with head and neck cancer. Cancer. 2014 Mar 15;120(6):840-7. doi: 10.1002/cncr.28482. Epub 2013 Dec 18. PubMed PMID: 24352973; PubMed Central PMCID: PMC3951722.
136. Laoufi S, Mirghani H, Janot F, Hartl DM. Voice quality after treatment of T1a glottic cancer. Laryngoscope. 2014 Jun;124(6):1398-401. doi: 10.1002/lary.24445. Epub 2013 Nov 13. PubMed PMID: 24115183.
137. Lastrucci L, Bertocci S, Bini V, Borghesi S, De Majo R, Rampini A, Pernici P, Gennari PG. Late toxicity, evolving radiotherapy techniques, and quality of life in nasopharyngeal carcinoma. Radiol Med. 2017 Apr;122(4):303-308. doi: 10.1007/s11547-016-0722-6. Epub 2017 Jan 9. PubMed PMID: 28070838.
138. Lazarus CL, Husaini H, Falciglia D, DeLacure M, Branski RC, Kraus D, Lee N, Ho M, Ganz C, Smith B, Sanfilippo N. Effects of exercise on swallowing and tongue strength in patients with oral and oropharyngeal cancer treated with primary radiotherapy with or without chemotherapy. Int J Oral Maxillofac Surg. 2014 May;43(5):523-30. doi: 10.1016/j.ijom.2013.10.023. Epub 2013 Dec 11. PubMed PMID: 24332586.
139. Lazarus CL, Husaini H, Hu K, Culliney B, Li Z, Urken M, Jacobson A, Persky M, Tran T, Concert C, Palacios D, Metcalfe-Klaw R, Kumar M, Bennett B, Harrison L. Functional outcomes and quality of life after chemoradiotherapy: baseline and 3 and 6 months post-treatment. Dysphagia. 2014 Jun;29(3):365-75. doi: 10.1007/s00455-014-9519-8. Epub 2014 Mar 8. PubMed PMID: 24609609.
140. Lechien JR, Khalife M, Huet K, Fourneau AF, Delvaux V, Piccaluga M, Harmegnies B, Saussez S. Impact of Chemoradiation After Supra- or Infrahyoid Cancer on Aerodynamic, Subjective, and Objective Voice Assessments: A Multicenter Prospective Study. J Voice. 2017 May 17. pii: S0892-1997(17)30064-4. doi: 10.1016/j.jvoice.2017.04.009. [Epub ahead of print] PubMed PMID: 28527541.
141. Lee LY, Chen SC, Chen WC, Huang BS, Lin CY. Postradiation trismus and its impact on quality of life in patients with head and neck cancer. Oral Surg Oral Med Oral Pathol Oral Radiol. 2015 Feb;119(2):187-95. doi: 10.1016/j.oooo.2014.10.003. Epub 2014 Oct 15. PubMed PMID: 25487985.
142. Lee MS, Nelson AM, Thompson LM, Donovan KA. Supportive care needs of oral cancer survivors: Prevalence and correlates. Oral Oncol. 2016 Feb;53:85-90. doi: 10.1016/j.oraloncology.2015.11.007. Epub 2015 Dec 9. PubMed PMID: 26684544.
143. Li N, Otomaru T, Taniguchi H. Sleep quality in long-term survivors of head and neck cancer: preliminary findings. Support Care Cancer. 2017 Jul 9. doi:10.1007/s00520-017-3804-7. [Epub ahead of print] PubMed PMID: 28691133.
144. Li P, Zhang X, Luo RH, Zhao M, Liu ST, Du W, Qi JX. Long-term quality of life in survivors of head and neck cancer who have had defects reconstructed with radial forearm free flaps. J Craniofac Surg. 2015 Mar;26(2):e75-8. doi: 10.1097/SCS.0000000000001280. PubMed PMID: 25675013.
145. Li T, Ma L, Mao C. The Validation and Reliability of the Chinese Version of the Speech Handicap Index for Patients With Oral and Oropharyngeal Cancer. J Voice. 2016 Mar;30(2):247.e23-31. doi: 10.1016/j.jvoice.2015.02.010. Epub 2015 Mar 26. PubMed PMID: 25817541.
146. Li X, Sun Q, Guo S. Functional Assessments in Patients Undergoing Radial Forearm Flap Following Hemiglossectomy. J Craniofac Surg. 2016 Mar;27(2):e172-5. doi: 10.1097/SCS.0000000000002261. PubMed PMID: 26845095.
147. Licitra L, Mesía R, Keilholz U. Individualised quality of life as a measure to guide treatment choices in squamous cell carcinoma of the head and neck. Oral Oncol. 2016 Jan;52:18-23. doi: 10.1016/j.oraloncology.2015.10.020. Epub 2015 Nov 11. Review. PubMed PMID: 26578389.
148. Lin CR, Chen SC, Chang JT, Fang YY, Lai YH. Fear of Cancer Recurrence and Its Impacts on Quality of Life in Family Caregivers of Patients With Head and Neck Cancers. J Nurs Res. 2016

Sep;24(3):240-8. doi: 10.1097/jnr.0000000000000169. PubMed PMID: 27509212.

149. Linardoutsos G, Rapidis AD, Lowe D, Bramis I, Rogers SN. Development of the Greek version of the University of Washington quality of life questionnaire for patients with head and neck cancer. J Craniomaxillofac Surg. 2014 Jul;42(5):601-7. doi: 10.1016/j.jcms.2013.08.001. Epub 2013 Sep 12. PubMed PMID: 24289872.
150. Liu SM, Wang HB, Sun Y, Shi Y, Zhang J, Huang MW, Zheng L, Lv XM, Zheng BM, Reilly KH, Yan XY, Ji P, Wu YF, Zhang JG. The efficacy of iodine-125 permanent brachytherapy versus intensity-modulated radiation for inoperable salivary gland malignancies: study protocol of a randomised controlled trial. BMC Cancer. 2016 Mar 7;16:193. doi: 10.1186/s12885-016-2248-7. PubMed PMID: 26951097; PubMed Central PMCID: PMC4782516.
151. Loh SY, Mcleod RWJ, Elhassan HA. Trismus following different treatment modalities for head and neck cancer: a systematic review of subjective measures. Eur Arch Otorhinolaryngol. 2017 Jul;274(7):2695-2707. doi: 10.1007/s00405-017-4519-6. Epub 2017 Mar 25. Review. PubMed PMID: 28343337; PubMed Central PMCID: PMC5486547.
152. Loimu V, Mäkitie AA, Bäck LJ, Sintonen H, Räsänen P, Roine R, Saarilahti K. Health-related quality of life of head and neck cancer patients with successful oncological treatment. Eur Arch Otorhinolaryngol. 2015 Sep;272(9):2415-23. doi: 10.1007/s00405-014-3169-1. Epub 2014 Jul 2. PubMed PMID: 24986429.
153. Loorents V, Rosell J, Salgado Willner H, Börjeson S. Health-related quality of life up to 1 year after radiotherapy in patients with head and neck cancer (HNC). Springerplus. 2016 May 20;5(1):669. doi: 10.1186/s40064-016-2295-1. eCollection 2016. PubMed PMID: 27347463; PubMed Central PMCID: PMC4899339.
154. Loth A, Michel J, Giorgi R, Santini L, Rey M, Elbaum JM, Roux N, Giovanni A, Dessi P, Fakhry N. Prevalence of obstructive sleep apnoea syndrome following oropharyngeal cancer treatment: A prospective cohort study. Clin Otolaryngol. 2017 Mar 23. doi: 10.1111/coa.12869. [Epub ahead of print] PubMed PMID: 28332763.
155. Ma L, Wu T, Pan J, Kong X, Guo Q, Yang L, Zhang Y, Lin S, Chen C, Huang C. The correlation between the comprehensive nutrition index and quality of life of patients with nasopharyngeal carcinoma treated by intensity-modulated radiotherapy. Nutr Cancer. 2014;66(1):152-8. doi: 10.1080/01635581.2014.853815. Epub 2013 Dec 13. PubMed PMID: 24328938.
156. Maguire R, Hanly P, Balfe M, Timmons A, Hyland P, O'Sullivan E, Butow P, Sharp L. Worry in Head and Neck Cancer Caregivers: The Role of Survivor Factors, Care-Related Stressors, and Loneliness in Predicting Fear of Recurrence. Nurs Res. 2017 Jul/Aug;66(4):295-303. doi: 10.1097/NNR.0000000000000223. PubMed PMID: 28654567.
157. Mahmood R, Butterworth C, Lowe D, Rogers SN. Characteristics and referral of head and neck cancer patients who report chewing and dental issues on the PatientConcerns Inventory. Br Dent J. 2014 Jun 13;216(11):E25. doi:10.1038/sj.bdj.2014.453. PubMed PMID: 24923963.
158. Majid A, Sayeed BZ, Khan M, Lakhani M, Saleem MM, Rajani H, Ramesh P, Hashmani N, Zia M, Abid H, Majid B, Jamali M, Murtaza K, Kamal A, Hussain M. Assessment and Improvement of Quality of Life in Patients Undergoing Treatment for Head and Neck Cancer. Cureus. 2017 May 2;9(5):e1215. doi: 10.7759/cureus.1215. PubMed PMID: 28589064; PubMed Central PMCID: PMC5453744.
159. Martín M, Marín A, López M, Liñán O, Alvarenga F, Büchser D, Cerezo L. Products based on olive oil, betaine, and xylitol in the post-radiotherapy xerostomia. Rep Pract Oncol Radiother. 2017 Jan-Feb;22(1):71-76. Epub 2016 Nov 25. PubMed PMID: 27920611; PubMed Central PMCID: PMC5126143.
160. Martins SP, Ferreira CL, Del Giglio A. Placebo-Controlled, Double-Blind, Randomized Study of a Dry Guarana Extract in Patients with Head and Neck Tumors Undergoing Chemoradiotherapy: Effects on Fatigue and Quality of Life. J Diet Suppl. 2016 Jun 20:1-10. [Epub ahead of print] PubMed PMID: 27322597.
161. Maxwell JH, Mehta V, Wang H, Cunningham D, Duvvuri U, Kim S, Johnson JT, Ferris RL. Quality of life in head and neck cancer patients: impact of HPV and primary treatment modality. Laryngoscope. 2014 Jul;124(7):1592-7. doi: 10.1002/lary.24508. Epub 2013 Dec 18. PubMed PMID: 24353066.
162. Mazzeo E, Antognoni P, Parmiggiani M, D'Ambrosio C, De Marco G, Marra L, Gottardi G, Bertoni F. IMRT-SIB with concurrent and neo-adjuvant platinum-based chemotherapy for locally advanced head and neck squamous cell cancer: analysis of clinical outcomes in a retrospective series of a single institution. Tumori. 2014 Nov-Dec;100(6):652-9. doi: 10.1700/1778.19272. PubMed PMID: 25688499.
163. McNeely ML, Parliament MB, Seikaly H, Jha N, Magee DJ, Haykowsky MJ, Courneya KS. Sustainability of outcomes after a randomized crossover trial of resistance exercise for shoulder

dysfunction in survivors of head and neck cancer. Physiother Can. 2015 Winter;67(1):85-93. doi: 10.3138/ptc.2014-13O. PubMed PMID: 25931658; PubMed Central PMCID: PMC4403331.

164. Memtsa PT, Tolia M, Tzitzikas I, Bizakis I, Pistevou-Gombaki K, Charalambidou M, Iliopoulou C, Kyrgias G. Validity and reliability of the Greek version of the xerostomia questionnaire in head and neck cancer patients. Support Care Cancer. 2017 Mar;25(3):847-853. doi: 10.1007/s00520-016-3471-0. Epub 2016 Oct 31. PubMed PMID: 27798747.
165. Memtsa PT, Tolia M, Tzitzikas I, Bizakis J, Pistevou-Gombaki K, Charalambidou M, Iliopoulou C, Kyrgias G. Assessment of xerostomia and its impact on quality of life in head and neck cancer patients undergoing radiation therapy. Mol Clin Oncol. 2017 May;6(5):789-793. doi: 10.3892/mco.2017.1200. Epub 2017 Mar 17. PubMed PMID: 28529753; PubMed Central PMCID: PMC5431738.
166. Mercadante S, Aielli F, Adile C, Ferrera P, Valle A, Fusco F, Caruselli A, Cartoni C, Massimo P, Masedu F, Valenti M, Porzio G. Prevalence of oral mucositis, dry mouth, and dysphagia in advanced cancer patients. Support Care Cancer. 2015 Nov;23(11):3249-55. doi: 10.1007/s00520-015-2720-y. Epub 2015 Apr 3. PubMed PMID: 25832897.
167. Metcalfe CW, Lowe D, Rogers SN. What patients consider important: temporal variations by early and late stage oral, oropharyngeal and laryngeal subsites. J Craniomaxillofac Surg. 2014 Jul;42(5):641-7. doi: 10.1016/j.jcms.2013.09.008. Epub 2013 Oct 8. PubMed PMID: 24238983.
168. Meyer A, Keszte J, Wollbrück D, Dietz A, Oeken J, Vogel HJ, Koscielny S, Breitenstein K, Meister EF, Pabst F, Schock J, Bourkas S, Singer S. Psychological distress and need for psycho-oncological support in spouses of total laryngectomised cancer patients-results for the first 3 years after surgery. Support Care Cancer. 2015 May;23(5):1331-9. doi: 10.1007/s00520-014-2485-8. Epub 2014 Oct 25. PubMed PMID: 25341549.
169. Miyoshi M, Fukuhara T, Kataoka H, Hagino H. Relationship between quality of life instruments and phonatory function in tracheoesophageal speech with voice prosthesis. Int J Clin Oncol. 2016 Apr;21(2):402-8. doi: 10.1007/s10147-015-0886-4. Epub 2015 Aug 13. PubMed PMID: 26266642.
170. Montalvo C, Finizia C, Pauli N, Fagerberg-Mohlin B, Andréll P. Impact of exercise with TheraBite device on trismus and health-related quality of life: A prospective study. Ear Nose Throat J. 2017 Jan;96(1):E1-E6. PubMed PMID: 28122104.
171. Morand GB, Madana J, Da Silva SD, Roskies M, Sultanem K, Black MJ, Mlynarek AM, Hier MP. Survival and quality of life in oropharyngeal cancer patients treated with primary chemoradiation after salivary gland transfer. J Laryngol Otol. 2016 Aug;130(8):755-62. doi: 10.1017/S0022215116008100. Epub 2016 Jun 24. PubMed PMID: 27339712.
172. Moubayed SP, Sampalis JS, Ayad T, Guertin L, Bissada E, Gologan OE, Soulières D, Lambert L, Filion E, Nguyen-Tan PF, Christopoulos A. Predicting depression and quality of life among long-term head and neck cancer survivors. Otolaryngol Head Neck Surg. 2015 Jan;152(1):91-7. doi: 10.1177/0194599814557772. Epub 2014 Nov 13. PubMed PMID: 25395572.
173. Mücke T, Koschinski J, Wolff KD, Kanatas A, Mitchell DA, Loeffelbein DJ, Deppe H, Rau A. Quality of life after different oncologic interventions in head and neck cancer patients. J Craniomaxillofac Surg. 2015 Nov;43(9):1895-8. doi: 10.1016/j.jcms.2015.08.005. Epub 2015 Aug 18. PubMed PMID: 26421469.
174. Nagy J, Braunitzer G, Antal M, Berkovits C, Novák P, Nagy K. Quality of life in head and neck cancer patients after tumor therapy and subsequent rehabilitation: an exploratory study. Qual Life Res. 2014 Feb;23(1):135-43. doi: 10.1007/s11136-013-0446-1. Epub 2013 Jun 4. PubMed PMID: 23733663.
175. Nemeth D, Zaleczna L, Huremovic A, Engelmann J, Poeschl PW, Strasz M, Holawe S, Kornek G, Laskus A, Sacher C, Erovic BM, Perisanidis C. Importance of chewing, saliva, and swallowing function in patients with advanced oral cancer undergoing preoperative chemoradiotherapy: a prospective study of quality of life. Int J Oral Maxillofac Surg. 2017 Jun 1. pii: S0901-5027(17)31466-2. doi:10.1016/j.ijom.2017.05.005. [Epub ahead of print] PubMed PMID: 28579265.
176. Nightingale CL, Curbow BA, Wingard JR, Pereira DB, Carnaby GD. Burden, quality of life, and social support in caregivers of patients undergoing radiotherapy for head and neck cancer: A pilot study. Chronic Illn. 2016 Sep;12(3):236-45. doi: 10.1177/1742395316644305. Epub 2016 Apr 10. PubMed PMID: 27068111; PubMed Central PMCID: PMC5515480.
177. Ninu MB, Miccinesi G, Bulli F, De Massimi A, Muraca MG, Franchi G, Squadrelli Saraceno M. Psychological distress and health-related quality of life among head and neck cancer patients during the first year after treatment. Tumori. 2016 Jan-Feb;102(1):96-102. doi: 10.5301/tj.5000448. Epub 2015 Oct 27. PubMed PMID: 26797934.
178. Noel CW, Lee DJ, Kong Q, Xu W, Simpson C, Brown D, Gilbert RW, Gullane PJ, Irish JC,

Huang SH, O'Sullivan B, Goldstein DP, de Almeida JR. Comparison of Health State Utility Measures in Patients With Head and Neck Cancer. JAMA Otolaryngol Head Neck Surg. 2015 Aug;141(8):696-703. doi:10.1001/jamaoto.2015.1314. PubMed PMID: 26204439.

179. Noronha V, Joshi A, Marfatia S, Patil V, Juvekar S, Arya S, Banavali S, Prabhash K. Health-related quality of life in patients with metastatic, relapsed, or inoperable squamous cell carcinoma of the head and neck in India. Support Care Cancer. 2016 Apr;24(4):1595-602. doi: 10.1007/s00520-015-2937-9. Epub 2015 Sep 19. PubMed PMID: 26386707.
180. Norquist J, Chirovsky D, Munshi T, Tolley C, Panter C, Gater A. Assessing the Comparability of Paper and Electronic Versions of the EORTC QOL Module for Head and Neck Cancer: A Qualitative Study. JMIR Cancer. 2017 May 12;3(1):e7. doi: 10.2196/cancer.7202. PubMed PMID: 28500019; PubMed Central PMCID: PMC5446668.
181. Oates J, Davies S, Roydhouse JK, Fethney J, White K. The effect of cancer stage and treatment modality on quality of life in oropharyngeal cancer. Laryngoscope. 2014 Jan;124(1):151-8. doi: 10.1002/lary.24136. Epub 2013 Aug 5. PubMed PMID: 23918289.
182. Offerman MP, Pruyn JF, de Boer MF, Busschbach JJ, Baatenburg de Jong RJ. Psychosocial consequences for partners of patients after total laryngectomy and for the relationship between patients and partners. Oral Oncol. 2015 Apr;51(4):389-98. doi: 10.1016/j.oraloncology.2014.12.008. Epub 2015 Jan 24.PubMed PMID: 25631352.
183. Oliveira KG, von Zeidler SV, Podestá JR, Sena A, Souza ED, Lenzi J, Bissoli NS, Gouvea SA. Influence of pain severity on the quality of life in patients with head and neck cancer before antineoplastic therapy. BMC Cancer. 2014 Jan 24;14:39. doi: 10.1186/1471-2407-14-39. PubMed PMID: 24460780; PubMed Central PMCID: PMC3904211.
184. Ouattassi N, Benmansour N, ElFakir S, Nejjari C, Alami MN. Translation and validation of EORTC QLQ-H&N 35 into Moroccan Arabic for ENT head and neck cancer patients in Morocco. Eur Arch Otorhinolaryngol. 2016 Sep;273(9):2727-34. doi: 10.1007/s00405-015-3808-1. Epub 2015 Oct 27. PubMed PMID: 26506999.
185. Palma LF, Gonnelli FAS, Marcucci M, Dias RS, Giordani AJ, Segreto RA, Segreto HRC. Impact of low-level laser therapy on hyposalivation, salivary pH, and quality of life in head and neck cancer patients post-radiotherapy. Lasers Med Sci. 2017 May;32(4):827-832. doi: 10.1007/s10103-017-2180-3. Epub 2017 Mar 3. PubMed PMID: 28258315.
186. Pan XB, Huang ST, Chen KH, Jiang YM, Ma JL, Qu S, Li L, Chen L, Zhu XD. Intensity-modulated radiotherapy provides better quality of life than two-dimensional conventional radiotherapy for patients with stage II nasopharyngeal carcinoma. Oncotarget. 2017 Jul 11;8(28):46211-46218. doi: 10.18632/oncotarget.17582. PubMed PMID: 28515352.
187. Pan XB, Huang ST, Chen KH, Jiang YM, Ma JL, Qu S, Li L, Chen L, Zhu XD. Concurrent chemoradiotherapy degrades the quality of life of patients with stage II nasopharyngeal carcinoma as compared to radiotherapy. Oncotarget. 2017 Feb 21;8(8):14029-14038. doi: 10.18632/oncotarget.14932. PubMed PMID: 28152511; PubMed Central PMCID: PMC5355159.
188. Parkar SM, Shah MN. A relationship between quality-of-life and head and neck cancer: A systemic review. South Asian J Cancer. 2015 Oct-Dec;4(4):179-82. doi:10.4103/2278-330X.175955. Review. PubMed PMID: 26981509; PubMed Central PMCID: PMC4772395.
189. Passchier E, Stuiver MM, van der Molen L, Kerkhof SI, van den Brekel MW, Hilgers FJ. Feasibility and impact of a dedicated multidisciplinary rehabilitation program on health-related quality of life in advanced head and neck cancer patients. Eur Arch Otorhinolaryngol. 2016 Jun;273(6):1577-87. doi: 10.1007/s00405-015-3648-z. Epub 2015 May 30. PubMed PMID: 26024692.
190. Pauli N, Andréll P, Johansson M, Fagerberg-Mohlin B, Finizia C. Treating trismus: A prospective study on effect and compliance to jaw exercise therapy in head and neck cancer. Head Neck. 2015 Dec;37(12):1738-44. doi: 10.1002/hed.23818. Epub 2014 Sep 25. PubMed PMID: 24986051.
191. Pauli N, Fagerberg-Mohlin B, Andréll P, Finizia C. Exercise intervention for the treatment of trismus in head and neck cancer. Acta Oncol. 2014 Apr;53(4):502-9. doi: 10.3109/0284186X.2013.837583. Epub 2013 Oct 31. PubMed PMID: 24175896.
192. Pauli N, Svensson U, Karlsson T, Finizia C. Exercise intervention for the treatment of trismus in head and neck cancer - a prospective two-year follow-up study. Acta Oncol. 2016 Jun;55(6):686-92. doi: 10.3109/0284186X.2015.1133928. Epub 2016 Feb 15. PubMed PMID: 26878553.
193. Pedersen A, Wilson J, McColl E, Carding P, Patterson J. Swallowing outcome measures in head and neck cancer--How do they compare? Oral Oncol. 2016 Jan;52:104-8. doi: 10.1016/j.oraloncology.2015.10.015. Epub 2015 Nov 10. PubMed PMID: 26564310.
194. Peker K, Ozdemir-Karatas M, Balık A, Kürklü E, Uysal O, Rogers SN. Validation of the

Turkish version of the Liverpool Oral Rehabilitation Questionnaire version 3 (LORQv3) in prosthetically rehabilitated patients with head and neck cancer. BMC Oral Health. 2014 Oct 22;14:129. doi: 10.1186/1472-6831-14-129. PubMed PMID: 25339520; PubMed Central PMCID: PMC4216844.

195. Pellegrino F, Groff E, Bastiani L, Fattori B, Sotti G. Assessment of radiation-induced xerostomia: validation of the Italian version of the xerostomia questionnaire in head and neck cancer patients. Support Care Cancer. 2015 Apr;23(4):925-32. doi: 10.1007/s00520-014-2438-2. Epub 2014 Sep 19. PubMed PMID: 25236164.
196. Pereira da Silva A, Feliciano T, Vaz Freitas S, Esteves S, Almeida E Sousa C. Quality of life in patients submitted to total laryngectomy. J Voice. 2015 May;29(3):382-8. doi: 10.1016/j.jvoice.2014.09.002. Epub 2015 Jan 22. PubMed PMID: 25619472.
197. Perry A, Casey E, Cotton S. Quality of life after total laryngectomy: functioning, psychological well-being and self-efficacy. Int J Lang Commun Disord. 2015 Jul;50(4):467-75. doi: 10.1111/1460-6984.12148. Epub 2015 Feb 19. PubMed PMID: 25703153.
198. Petrosyan V, Ball D, Harrison R, Ameerally P. Among Patients Undergoing Ablative Treatment for Oral Cancer, Does the Provision of Oral Rehabilitation Improve the Quality of Life? A Review of the Current Literature. J Oral Maxillofac Surg. 2016 May;74(5):1096.e1-1096.e12. doi: 10.1016/j.joms.2015.12.012. Epub 2016 Jan 7. Review. PubMed PMID: 26824305.
199. Pierre CS, Dassonville O, Chamorey E, Poissonnet G, Ettaiche M, Santini J, Peyrade F, Benezery K, Sudaka A, Bozec A. Long-term quality of life and its predictive factors after oncologic surgery and microvascular reconstruction in patients with oral or oropharyngeal cancer. Eur Arch Otorhinolaryngol. 2014 Apr;271(4):801-7. doi: 10.1007/s00405-013-2592-z. Epub 2013 Jun 16. PubMed PMID: 23771320.
200. Pierre CS, Dassonville O, Chamorey E, Poissonnet G, Riss JC, Ettaiche M, Peyrade F, Benezery K, Chand ME, Leyssalle A, Sudaka A, Haudebourg J, Santini J, Bozec A. Long-term functional outcomes and quality of life after oncologic surgery and microvascular reconstruction in patients with oral or oropharyngeal cancer. Acta Otolaryngol. 2014 Oct;134(10):1086-93. doi: 10.3109/00016489.2014.913809. Epub 2014 Aug 18. PubMed PMID: 25131390.
201. Pollom EL, Wang E, Bui TT, Ognibene G, von Eyben R, Divi V, Sunwoo J, Kaplan M, Dimitri Colevas A, Le QT, Hara WY. A prospective study of electronic quality of life assessment using tablet devices during and after treatment of head and neck cancers. Oral Oncol. 2015 Dec;51(12):1132-7. doi: 10.1016/j.oraloncology.2015.10.003. Epub 2015 Oct 23. PubMed PMID: 26475062.
202. Pottel L, Lycke M, Boterberg T, Pottel H, Goethals L, Duprez F, Rottey S, Lievens Y, Van Den Noortgate N, Geldhof K, Buyse V, Kargar-Samani K, Ghekiere V, Debruyne PR. G-8 indicates overall and quality-adjusted survival in older head and neck cancer patients treated with curative radiochemotherapy. BMC Cancer. 2015 Nov 9;15:875. doi: 10.1186/s12885-015-1800-1. PubMed PMID: 26553007; PubMed Central PMCID: PMC4640221.
203. Pottel L, Lycke M, Boterberg T, Pottel H, Goethals L, Duprez F, Van Den Noortgate N, De Neve W, Rottey S, Geldhof K, Buyse V, Kargar-Samani K, Ghekiere V, Debruyne PR. Serial comprehensive geriatric assessment in elderly head and neck cancer patients undergoing curative radiotherapy identifies evolution of multidimensional health problems and is indicative of quality of life. Eur J Cancer Care (Engl). 2014 May;23(3):401-12. doi: 10.1111/ecc.12179. Epub 2014 Jan 28. PubMed PMID: 24467393.
204. Pugh SL, Wyatt G, Wong RK, Sagar SM, Yueh B, Singh AK, Yao M, Nguyen-Tan PF, Yom SS, Cardinale FS, Sultanem K, Hodson DI, Krempl GA, Chavez A, Yeh AM, Bruner DW. Exploratory Factor Analysis of NRG Oncology's University of Washington Quality of Life Questionnaire-RTOG Modification. J Pain Symptom Manage. 2017 Jan;53(1):139-145.e2. doi: 10.1016/j.jpainsymman.2016.11.002. Epub 2016 Nov 27. PubMed PMID: 27899312; PubMed Central PMCID: PMC5191964.
205. Qiu SS, Cambeiro M, Hontanilla B. Comparison of quality of life in head and neck stage IV squamous cell cancer patients treated with surgery and reconstruction versus radical radiotherapy. Ann Plast Surg. 2014 Aug;73(2):205-9. doi: 10.1097/SAP.0b013e318270449e. PubMed PMID: 23403545.
206. Rana M, Gellrich NC, Czens F, Kanatas A, Rana M. Coping with oral cancer: the impact of health and disease-related personality traits. Support Care Cancer. 2014 Nov;22(11):2981-6. doi: 10.1007/s00520-014-2300-6. Epub 2014 Jun 5. PubMed PMID: 24897962.
207. Reeve BB, Cai J, Zhang H, Weissler MC, Wisniewski K, Gross H, Olshan AF. Factors that impact health-related quality of life over time for individuals with head and neck cancer. Laryngoscope. 2016 Dec;126(12):2718-2725. doi: 10.1002/lary.26073. Epub 2016 May 25. PubMed PMID: 27224024.
208. Richardson AE, Morton R, Broadbent E. Caregivers' Illness Perceptions Contribute to Quality of

Life in Head and Neck Cancer Patients at Diagnosis. J Psychosoc Oncol. 2015;33(4):414-32. doi: 10.1080/07347332.2015.1046011. PubMed PMID: 25996835.

209. Richardson AE, Morton RP, Broadbent EA. Changes over time in head and neck cancer patients' and caregivers' illness perceptions and relationships with quality of life. Psychol Health. 2016 Oct;31(10):1203-19. doi: 10.1080/08870446.2016.1203686. Epub 2016 Jul 8. PubMed PMID: 27315836.
210. Rigoni L, Bruhn RF, De Cicco R, Kanda JL, Matos LL. Quality of life impairment in patients with head and neck cancer and their caregivers: a comparative study. Braz J Otorhinolaryngol. 2016 Nov - Dec;82(6):680-686. doi: 10.1016/j.bjorl.2015.12.012. Epub 2016 Apr 11. PubMed PMID: 27133907.
211. Ringash J, Bernstein LJ, Cella D, Logemann J, Movsas B, Murphy B, Trotti A, Wells N, Yueh B, Ridge J. Outcomes toolbox for head and neck cancer research. Head Neck. 2015 Mar;37(3):425-39. doi: 10.1002/hed.23561. Epub 2015 Jan 22. Review. PubMed PMID: 24318166.Heutte N, Plisson L, Lange M, Prevost V, Babin E. Quality of life tools in head and neck oncology. Eur Ann Otorhinolaryngol Head Neck Dis. 2014 Feb;131(1):33-47. doi: 10.1016/j.anorl.2013.05.002. Epub 2013 Nov 28. Review. PubMed PMID: 24291153.
212. Ringash J, Fisher R, Peters L, Trotti A, O'Sullivan B, Corry J, Kenny L, Van Den Bogaert W, Wratten C, Rischin D. Effect of p16 Status on the Quality-of-Life Experience During Chemoradiation for Locally Advanced Oropharyngeal Cancer: A Substudy of Randomized Trial Trans-Tasman Radiation Oncology Group (TROG) 02.02 (HeadSTART). Int J Radiat Oncol Biol Phys. 2017 Mar 15;97(4):678-686. doi: 10.1016/j.ijrobp.2016.03.017. Epub 2016 Mar 23. PubMed PMID: 27209505.
213. Rinkel RN, Verdonck-de Leeuw IM, de Bree R, Aaronson NK, Leemans CR. Validity of patient-reported swallowing and speech outcomes in relation to objectively measured oral function among patients treated for oral or oropharyngeal cancer. Dysphagia. 2015 Apr;30(2):196-204. doi: 10.1007/s00455-014-9595-9. Epub 2015 Jan 28. PubMed PMID: 25622807.
214. Rinkel RN, Verdonck-de Leeuw IM, Doornaert P, Buter J, de Bree R, Langendijk JA, Aaronson NK, Leemans CR. Prevalence of swallowing and speech problems in daily life after chemoradiation for head and neck cancer based on cut-off scores of the patient-reported outcome measures SWAL-QOL and SHI. Eur Arch Otorhinolaryngol. 2016 Jul;273(7):1849-55. doi: 10.1007/s00405-015-3680-z. Epub 2015 Jun 14. PubMed PMID: 26071622; PubMed Central PMCID: PMC4899484.
215. Rinkel RN, Verdonck-de Leeuw IM, van den Brakel N, de Bree R, Eerenstein SE, Aaronson N, Leemans CR. Patient-reported symptom questionnaires in laryngeal cancer: voice, speech and swallowing. Oral Oncol. 2014 Aug;50(8):759-64. doi: 10.1016/j.oraloncology.2014.05.009. Epub 2014 Jun 20. PubMed PMID: 24954064.
216. Risberg-Berlin B, Karlsson TR, Tuomi L, Finizia C. Effectiveness of olfactory rehabilitation according to a structured protocol with potential of regaining pre-operative levels in laryngectomy patients using nasal airflow-inducing manoeuvre. Eur Arch Otorhinolaryngol. 2014 May;271(5):1113-9. PubMed PMID: 24077871.
217. Roe JW, Drinnan MJ, Carding PN, Harrington KJ, Nutting CM. Patient-reported outcomes following parotid-sparing intensity-modulated radiotherapy for head and neck cancer. How important is dysphagia? Oral Oncol. 2014 Dec;50(12):1182-7. doi: 10.1016/j.oraloncology.2014.09.009. Epub 2014 Oct 14. PubMed PMID: 25448227.
218. Rogers SN, Cross B, Talwar C, Lowe D, Humphris G. A single-item screening question for fear of recurrence in head and neck cancer. Eur Arch Otorhinolaryngol. 2016 May;273(5):1235-42. doi: 10.1007/s00405-015-3585-x. Epub 2015 Mar 7. PubMed PMID: 25749490.
219. Rogers SN, D'Souza JJ, Lowe D, Kanatas A. Longitudinal evaluation of health-related quality of life after osteoradionecrosis of the mandible. Br J Oral Maxillofac Surg. 2015 Nov;53(9):854-7. doi: 10.1016/j.bjoms.2015.07.008. Epub 2015 Aug 24. PubMed PMID: 26316016.
220. Rogers SN, Hazeldine P, O'Brien K, Lowe D, Roe B. How often do head and neck cancer patients raise concerns related to intimacy and sexuality in routine follow-up clinics? Eur Arch Otorhinolaryngol. 2015 Jan;272(1):207-17. doi: 10.1007/s00405-014-2971-0. Epub 2014 Mar 14. PubMed PMID: 24627075.
221. Rogers SN, Hogg ES, Cheung WK, Lai LK, Jassal P, Lowe D, Kanatas A. 'What will I be like' after my diagnosis of head and neck cancer? Eur Arch Otorhinolaryngol. 2015 Sep;272(9):2463-72. doi: 10.1007/s00405-014-3189-x. Epub 2014 Jul 22. PubMed PMID: 25047397.
222. Rogers SN, Hogg ES, Cheung WK, Lai LK, Jassal P, Lowe D. The use of health related quality of life data to produce information sheets for patients with head and neck cancer. Ann R Coll Surg Engl. 2015 Jul;97(5):359-63. doi: 10.1308/003588415X14181254789448. PubMed PMID: 26264087; PubMed Central PMCID: PMC5096582.

223. Rogers SN, Lowe D, Kanatas A. Suitability of the Patient Concerns Inventory as a holistic screening tool in routine head and neck cancer follow-up clinics. Br J Oral Maxillofac Surg. 2016 May;54(4):415-21. doi: 10.1016/j.bjoms.2016.01.018. Epub 2016 Feb 24. PubMed PMID: 26919767.
224. Rogers SN, Pinto RS, Lancaster J, Bekiroglu F, Lowe D, Tandon S, Jones TM. Health related quality of life following the treatment of oropharyngeal cancer by transoral laser. Eur Arch Otorhinolaryngol. 2016 Nov;273(11):3913-3920. Epub 2016 Apr 18. PubMed PMID: 27091336.
225. Rylands J, Lowe D, Rogers SN. Influence of deprivation on health-related quality of life of patients with cancer of the head and neck in Merseyside and Cheshire. Br J Oral Maxillofac Surg. 2016 Jul;54(6):669-76. doi: 10.1016/j.bjoms.2016.03.030. Epub 2016 Apr 27. PubMed PMID: 27130568.
226. Rylands J, Lowe D, Rogers SN. Outcomes by area of residence deprivation in a cohort of oral cancer patients: Survival, health-related quality of life, and place of death. Oral Oncol. 2016 Jan;52:30-6. doi: 10.1016/j.oraloncology.2015.10.017. Epub 2015 Nov 12. PubMed PMID: 26586367.
227. Ryzek DF, Mantsopoulos K, Künzel J, Grundtner P, Zenk J, Iro H, Psychogios G. Early stage oropharyngeal carcinomas: comparing quality of life for different treatment modalities. Biomed Res Int. 2014;2014:421964. doi: 10.1155/2014/421964. Epub 2014 Feb 25. PubMed PMID: 24719863; PubMed Central PMCID: PMC3955642.

S, Di Mauro P, Ausoni S, Tonoli G, Costantini G, Maiolino L, Spinato R, Da Mosto MC, Baboci L, Del Mistro A, Serra A, Tirelli G. Multicenter research into the quality of life of patients with advanced oropharyngeal carcinoma with long-term survival associated with human papilloma virus. Oncol Lett. 2017 Jul;14(1):185-193. doi: 10.3892/ol.2017.6152. Epub 2017 May 10. PubMed PMID:28693152; PubMed Central PMCID: PMC5494809.

228. Samuels SE, Tao Y, Lyden T, Haxer M, Spector M, Malloy KM, Prince ME, Bradford CR, Worden FP, Schipper M, Eisbruch A. Comparisons of dysphagia and quality of life (QOL) in comparable patients with HPV-positive oropharyngeal cancer receiving chemo-irradiation or cetuximab-irradiation. Oral Oncol. 2016 Mar;54:68-74. doi: 10.1016/j.oraloncology.2015.12.001. Epub 2016 Jan 6. PubMed PMID: 26776757; PubMed Central PMCID: PMC4754145.
229. Sánchez D, Chala A, Alvarez A, Payan C, Mendoza T, Cleeland C, Sanabria A. Psychometric Validation of the M. D. Anderson Symptom Inventory-Head and Neck Module in the Spanish Language. J Pain Symptom Manage. 2016 Jun;51(6):1055-61. doi: 10.1016/j.jpainsymman.2015.12.320. Epub 2016 Feb 17. PubMed PMID: 26899822.
230. Sapir E, Tao Y, Feng F, Samuels S, El Naqa I, Murdoch-Kinch CA, Feng M, Schipper M, Eisbruch A. Predictors of Dysgeusia in Patients With Oropharyngeal Cancer Treated With Chemotherapy and Intensity Modulated Radiation Therapy. Int J Radiat Oncol Biol Phys. 2016 Oct 1;96(2):354-61. doi: 10.1016/j.ijrobp.2016.05.011. Epub 2016 May 17. PubMed PMID: 27473816.
231. Schweyen R, Kuhnt T, Wienke A, Eckert A, Hey J. The impact of oral rehabilitation on oral health-related quality of life in patients receiving radiotherapy for the treatment of head and neck cancer. Clin Oral Investig. 2017 May;21(4):1123-1130. doi: 10.1007/s00784-016-1874-4. Epub 2016 Jun 8. PubMed PMID: 27277517.
232. Shavi GR, Thakur B, Bhambal A, Jain S, Singh V, Shukla A. Oral Health Related Quality of Life in Patients of Head and Neck Cancer Attending Cancer Hospital of Bhopal City, India. J Int Oral Health. 2015 Aug;7(8):21-7. PubMed PMID: 26464534; PubMed Central PMCID: PMC4588784.
233. Shinn EH, Basen-Engquist K, Baum G, Steen S, Bauman RF, Morrison W, Garden AS, Sheil C, Kilgore K, Hutcheson KA, Barringer D, Yuan Y, Lewin JS. Adherence to preventive exercises and self-reported swallowing outcomes in post-radiation head and neck cancer patients. Head Neck. 2013 Dec;35(12):1707-12. doi: 10.1002/hed.23255. Epub 2013 Oct 21. PubMed PMID: 24142523; PubMed Central PMCID: PMC3943468.
234. Shinn EH, Basen-Engquist K, Baum G, Steen S, Bauman RF, Morrison W, Garden AS, Sheil C, Kilgore K, Hutcheson KA, Barringer D, Yuan Y, Lewin JS. Adherence to preventive exercises and self-reported swallowing outcomes in post-radiation head and neck cancer patients. Head Neck. 2013 Dec;35(12):1707-12. doi: 10.1002/hed.23255. Epub 2013 Oct 21. PubMed PMID: 24142523; PubMed Central PMCID: PMC3943468.
235. Shiraz F, Rahtz E, Bhui K, Hutchison I, Korszun A. Quality of life, psychological wellbeing and treatment needs of trauma and head and neck cancer patients. Br J Oral Maxillofac Surg. 2014 Jul;52(6):513-7. doi: 10.1016/j.bjoms.2014.03.019. Epub 2014 Apr 29. PubMed PMID: 24787647.
236. Si YF, Lan GP, Deng ZX, Weng JJ, Si JY, Qin YD, Huang B, Wang YL, Yang Y, Qin Y, Zhang

BJ, Han X, Xiong WM. Influence of endoscopic sinus surgery on the quality of life of patients with early nasopharyngeal carcinoma and the analysis of prognosis-related factors. Tumour Biol. 2017 Jul;39(7):1010428317707435. doi: 10.1177/1010428317707435. PubMed PMID: 28714364.

237. Silveira MH, Dedivitis RA, Queija DS, Nascimento PC. Quality of life in swallowing disorders after nonsurgical treatment for head and neck cancer. Int Arch Otorhinolaryngol. 2015 Jan;19(1):46-54. doi: 10.1055/s-0034-1395790. Epub 2014 Dec 5. PubMed PMID: 25992151; PubMed Central PMCID: PMC4392544.
238. Singer S, Araújo C, Arraras JI, Baumann I, Boehm A, Brokstad Herlofson B,Castro Silva J, Chie WC, Fisher S, Guntinas-Lichius O, Hammerlid E, Irarrázava ME, Jensen Hjermstad M, Jensen K, Kiyota N, Licitra L, Nicolatou-Galitis O, Pinto M, Santos M, Schmalz C, Sherman AC, Tomaszewska IM, Verdonck de Leeuw I, Yarom N, Zotti P, Hofmeister D; EORTC Quality of Life and the EORTC Head and Neck Cancer Groups. Measuring quality of life in patients with head and neck cancer: Update of the EORTC QLQ-H&N Module, Phase III. Head Neck. 2015 Sep;37(9):1358-67. doi: 10.1002/hed.23762. Epub 2014 Jul 21. PubMed PMID: 24832623.
239. Singer S, Danker H, Guntinas-Lichius O, Oeken J, Pabst F, Schock J, Vogel HJ, Meister EF, Wulke C, Dietz A. Quality of life before and after total laryngectomy: results of a multicenter prospective cohort study. Head Neck. 2014 Mar;36(3):359-68. doi: 10.1002/hed.23305. Epub 2013 Jun 1. PubMed PMID: 23728844.
240. Singh AK, Kushwaha JK, Anand A, Sonkar AA, Husain N, Srivastava K, Singh S. Human Papilloma Virus in Oral Cavity Cancer and Relation to Change in Quality of Life Following Treatment-a Pilot Study from Northern India. Indian J Surg Oncol. 2016 Dec;7(4):386-391. Epub 2016 Sep 22. PubMed PMID: 27872524; PubMed Central PMCID: PMC5097773.
241. So WK, Choi KC, Chen JM, Chan CW, Chair SY, Fung OW, Wan RW, Mak SS, Ling WM, Ng WT, Yu BW. Quality of life in head and neck cancer survivors at 1 year after treatment: the mediating role of unmet supportive care needs. Support Care Cancer. 2014 Nov;22(11):2917-26. doi: 10.1007/s00520-014-2278-0. Epub 2014 May 20. PubMed PMID: 24839941.
242. Spalthoff S, Zimmerer R, Jehn P, Gellrich NC, Handschel J, Krüskemper G. Neck Dissection's Burden on the Patient: Functional and Psychosocial Aspects in 1,652 Patients With Oral Squamous Cell Carcinomas. J Oral Maxillofac Surg. 2017 Apr;75(4):839-849. doi: 10.1016/j.joms.2016.09.037. Epub 2016 Sep 28. PubMed PMID: 27776222.
243. Spinato G, Stellin M, Azzarello G, Bonazza D, Zanconati F, Politi D, Cocuzza
244. Stachler RJ, Schultz LR, Nerenz D, Yaremchuk KL. PROMIS evaluation for head and neck cancer patients: a comprehensive quality-of-life outcomes assessment tool. Laryngoscope. 2014 Jun;124(6):1368-76. doi: 10.1002/lary.23853. Epub 2014 Apr 9. PubMed PMID: 24719292.
245. Stenner M, Beenen F, Hahn M, Koopmann M, Weiss D, Hüttenbrink KB. Exploratory study of long-term health-related quality of life in patients with surgically treated primary parotid gland cancer. Head Neck. 2016 Jan;38(1):111-7. doi: 10.1002/hed.23858. Epub 2015 May 22. PubMed PMID: 25223976.
246. Stier-Jarmer M, Sabariego C, Cieza A, Harréus U, Tschiesner U. Assessment of functional outcomes in head and neck cancer. Eur Arch Otorhinolaryngol. 2014 Jul;271(7):2021-44. doi: 10.1007/s00405-013-2744-1. Epub 2013 Oct 10. PubMed PMID: 24114063.
247. Stuiver MM, ten Tusscher MR, van Opzeeland A, Brendeke W, Lindeboom R, Dijkstra PU, Aaronson NK. Psychometric properties of 3 patient-reported outcome measures for the assessment of shoulder disability after neck dissection. Head Neck. 2016 Jan;38(1):102-10. doi: 10.1002/hed.23859. Epub 2015 Jun 15. PubMed PMID: 25224150.
248. Su Y, Mo CW, Cheng WQ, Wang L, Xu Q, Wu ZC, Wu ZL, Liu LZ, Chen XL. Development and validation of quality of life scale of nasopharyngeal carcinoma patients: the QOL-NPC (version 2). Health Qual Life Outcomes. 2016 May 10;14:76. doi: 10.1186/s12955-016-0480-0. PubMed PMID: 27164979; PubMed Central PMCID: PMC4862168.
249. Sun Q, Guo S, Wang D, Xu N, Fang QG. Shoulder Dysfunction After Radiotherapy in Surgically and Nonsurgically Treated Necks: A Prospective Study. Medicine (Baltimore). 2015 Jul;94(30):e1229. doi: 10.1097/MD.0000000000001229. Erratum in: Medicine (Baltimore). 2016 Jan;95(1):1.Fang, Qi-gen [Added]. PubMed PMID: 26222857; PubMed Central PMCID: PMC4554123.
250. Taberna M, Rullan AJ, Hierro C, Navarro V, Vázquez S, Lozano A, Vilajosana E, Maños M, Marí A, Viñals J, Mesía R. Late toxicity after radical treatment for locally advanced head and neck cancer. Oral Oncol. 2015 Aug;51(8):795-9. doi: 10.1016/j.oraloncology.2015.05.002. Epub 2015 Jun 4. PubMed PMID: 26051499.
251. Terkawi AS, Tsang S, Alshehri AS, Mulafikh DS, Alghulikah AA, AlDhahri SF. The burden of chronic pain after major head and neck tumor therapy. Saudi J Anaesth. 2017 May;11(Suppl 1):S71-S79. doi: 10.4103/sja.SJA_162_17. PubMed PMID: 28616006;PubMed Central PMCID:

PMC5463569.

252. Terro W, Crean SJ. Prospective, longitudinal assessment of quality of life in patients with cancer of the head and neck and their primary carers. Br J Oral Maxillofac Surg. 2017 Jul;55(6):613-617. doi: 10.1016/j.bjoms.2017.04.004. Epub 2017 Apr 26. PubMed PMID: 28456448.
253. Thomas AA, Timmons A, Molcho M, Pearce A, Gallagher P, Butow P, O'Sullivan E, Gooberman-Hill R, O'Neill C, Sharp L. Quality of life in urban and rural settings: a study of head and neck cancer survivors. Oral Oncol. 2014 Jul;50(7):676-82. doi: 10.1016/j.oraloncology.2014.03.007. Epub 2014 Apr 14. PubMed PMID: 24731737.
254. Thor M, Olsson CE, Oh JH, Hedström J, Pauli N, Johansson M, Deasy JO, Finizia C. Temporal patterns of patient-reported trismus and associated mouth-opening distances in radiotherapy for head and neck cancer: A prospective cohort study.Clin Otolaryngol. 2017 Apr 30. doi: 10.1111/coa.12896. [Epub ahead of print]PubMed PMID: 28463432.
255. Tian L, An R, Zhang J, Sun Y, Zhao R, Liu M. Effect of the patient-to-patient communication model on dysphagia caused by total laryngectomy. J Laryngol Otol 2017 Mar;131(3):253-258. doi: 10.1017/S0022215116009968. Epub 2017 Jan 18. PubMed PMID: 28095938.
256. Trachootham D, Songkaew W, Hongsachum B, Wattana C, Changkluengdee N, Karapoch J, Thirdsuttironnapumi S, Meennuch E, Klaitong C, Sinthusek T, Lam-ubol A. Nutri-jelly may improve quality of life and decrease tube feeding demand in head and neck cancer patients. Support Care Cancer. 2015 May;23(5):1421-30. doi: 10.1007/s00520-014-2488-5. Epub 2014 Nov 5. PubMed PMID: 25370890; PubMed Central PMCID: PMC4376960.
257. Tribius S, Raguse M, Voigt C, Münscher A, Gröbe A, Petersen C, Krüll A, Bergelt C, Singer S. Residual deficits in quality of life one year after intensity-modulated radiotherapy for patients with locally advanced head and neck cancer: Results of a prospective study. Strahlenther Onkol. 2015 Jun;191(6):501-10. doi: 10.1007/s00066-015-0824-4. Epub 2015 Mar 8. PubMed PMID: 25747264.
258. Trivic SK, Trivic A, Singer S, Milovanovic J, Stankovic P, Mikic A, Vukasinovic M, Djordjevic V, Jotic A, Folic M, Stevanovic D. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Head and Neck Module, updated version: Preliminary psychometric data from Serbian laryngectomized patients. Head Neck. 2016 Apr;38 Suppl 1:E916-24. doi: 10.1002/hed.24127. Epub 2015 Jul 18. PubMed PMID: 26189891.
259. Tsai WL, Huang TL, Liao KC, Chuang HC, Lin YT, Lee TF, Huang HY, Fang FM. Impact of late toxicities on quality of life for survivors of nasopharyngeal carcinoma. BMC Cancer. 2014 Nov 21;14:856. doi: 10.1186/1471-2407-14-856. PubMed PMID: 25413127; PubMed Central PMCID: PMC4247772.
260. Tuomi L, Johansson M, Andréll P, Finizia C. Interpretation of the Swedish Self Evaluation of Communication Experiences after Laryngeal cancer: Cutoff levels and minimum clinically important differences. Head Neck. 2016 May;38(5):689-95. doi: 10.1002/hed.23955. Epub 2015 May 26. PubMed PMID: 25522220.
261. Tuomi L, Johansson M, Lindell E, Folkestad L, Malmerfors M, Finizia C. Voice Range Profile and Health-related Quality of Life Measurements Following Voice Rehabilitation After Radiotherapy; a Randomized Controlled Study. J Voice. 2017 Jan;31(1):115.e9-115.e16. doi: 10.1016/j.jvoice.2016.03.012. Epub 2016 Apr 15. PubMed PMID: 27091469.
262. Tuomi L, Karlsson T, Johansson M, Finizia C. Health-related quality of life and voice following radiotherapy for laryngeal cancer--a comparison between glottic and supraglottic tumours. Acta Oncol. 2015 Jan;54(1):73-9. doi: 10.3109/0284186X.2014.925576. Epub 2014 Jun 10. PubMed PMID: 24914482.
263. Ullgren H, Kirkpatrick L, Kilpeläinen S, Sharp L. Working in silos? - Head & Neck cancer patients during and after treatment with or without early palliative care referral. Eur J Oncol Nurs. 2017 Feb;26:56-62. doi: 10.1016/j.ejon.2016.12.003. Epub 2016 Dec 21. PubMed PMID: 28069153
264. Vainshtein JM, Moon DH, Feng FY, Chepeha DB, Eisbruch A, Stenmark MH. Long-term quality of life after swallowing and salivary-sparing chemo-intensity modulated radiation therapy in survivors of human papillomavirus-related oropharyngeal cancer. Int J Radiat Oncol Biol Phys. 2015 Apr 1;91(5):925-33. doi: 10.1016/j.ijrobp.2014.12.045. PubMed PMID: 25832685; PubMed Central PMCID: PMC4384167.
265. Valls-Mateus M, Ortega A, Blanch JL, Sabater F, Bernal-Sprekelsen M, Vilaseca I. Long-term quality of life after transoral laser microsurgery for laryngeal carcinoma. J Surg Oncol. 2016 Dec;114(7):789-795. doi: 10.1002/jso.24471. Epub 2016 Oct 6. PubMed PMID: 27709626.
266. van der Linden N, Flach GB, de Bree R, Uyl-de Groot CA. Cost-utility of sentinel lymph node biopsy in cT1-T2N0 oral cancer. Oral Oncol. 2016 Feb;53:20-6. doi: 10.1016/j.oraloncology.2015.11.011. Epub 2015 Nov 26. PubMed PMID: 26631953.

267. van der Meulen IC, May AM, de Leeuw JR, Koole R, Oosterom M, Hordijk GJ, Ros WJ. Long-term effect of a nurse-led psychosocial intervention on health-related quality of life in patients with head and neck cancer: a randomised controlled trial. Br J Cancer. 2014 Feb 4;110(3):593-601. doi: 10.1038/bjc.2013.733. Epub 2013 Nov 26. PubMed PMID: 24280999; PubMed Central PMCID: PMC3915114.
268. van Gemert J, Holtslag I, van der Bilt A, Merkx M, Koole R, Van Cann E. Health-related quality of life after segmental resection of the lateral mandible: Free fibula flap versus plate reconstruction. J Craniomaxillofac Surg. 2015 Jun;43(5):658-62. doi: 10.1016/j.jcms.2015.03.018. Epub 2015 Apr 2. PubMed PMID: 25939312.
269. van Loon JW, Smeele LE, Hilgers FJ, van den Brekel MW. Outcome of transoral robotic surgery for stage I-II oropharyngeal cancer. Eur Arch Otorhinolaryngol. 2015 Jan;272(1):175-83. doi: 10.1007/s00405-014-2939-0. Epub 2014 Mar 8. PubMed PMID: 24609641.
270. van Nieuwenhuizen AJ, Buffart LM, Brug J, Leemans CR, Verdonck-de Leeuw IM. The association between health related quality of life and survival in patients with head and neck cancer: a systematic review. Oral Oncol. 2015 Jan;51(1):1-11. doi: 10.1016/j.oraloncology.2014.09.002. Epub 2014 Sep 26. Review. PubMed PMID: 25262163.
271. Van Nuffelen G, Van den Steen L, Vanderveken O, Specenier P, Van Laer C, Van Rompaey D, Guns C, Mariën S, Peeters M, Van de Heyning P, Vanderwegen J, De Bodt M. Study protocol for a randomized controlled trial: tongue strengthening exercises in head and neck cancer patients, does exercise load matter? Trials. 2015 Sep 4;16:395. doi: 10.1186/s13063-015-0889-5. PubMed PMID: 26340887; PubMed Central PMCID: PMC4560920.
272. Veldhuis D, Probst G, Marek A, Noack V, Ural A, Adamietz I, Dazert S, Minovi A. Tumor site and disease stage as predictors of quality of life in head and neck cancer: a prospective study on patients treated with surgery or combined therapy with surgery and radiotherapy or radiochemotherapy. Eur Arch Otorhinolaryngol. 2016 Jan;273(1):215-24. doi: 10.1007/s00405-015-3496-x. Epub 2015 Jan 10. PubMed PMID: 25575842.
273. Verdonck-de Leeuw IM, Buffart LM, Heymans MW, Rietveld DH, Doornaert P, de Bree R, Buter J, Aaronson NK, Slotman BJ, Leemans CR, Langendijk JA. The course of health-related quality of life in head and neck cancer patients treated with chemoradiation: a prospective cohort study. Radiother Oncol. 2014 Mar;110(3):422-8. doi: 10.1016/j.radonc.2014.01.002. Epub 2014 Feb 25. PubMed PMID: 24582144.
274. Vilaseca I, Bernal-Sprekelsen M, Him R, Mandry A, Lehrer E, Blanch JL. Prognostic factors of quality of life after transoral laser microsurgery for laryngeal cancer. Eur Arch Otorhinolaryngol. 2015 May;272(5):1203-10. doi: 10.1007/s00405-014-3030-6. Epub 2014 Apr 12. PubMed PMID: 24728230.
275. Visacri MB, Ferrari GB, Dias P, Pimentel R, de Souza CM, Costa AP, de Carvalho Pincinato E, Lima CS, Mazzola PG, Moriel P. Quality of Life of Patients with Squamous Cell Carcinoma of the Head and Neck Receiving High-Dose Cisplatin Chemotherapy and Radiotherapy. South Med J. 2015 Jun;108(6):343-9. doi:10.14423/SMJ.0000000000000298. PubMed PMID: 26079459.
276. Visacri MB, Ferrari GB, Pimentel R, Ambrósio RD, Lima CS, Mazzola PG, Moriel P. Evaluation of the quality of life of patients before treatment of squamous cell carcinoma of the head and neck by means of chemoradiotherapy. Contemp Oncol (Pozn). 2015;19(2):148-53. doi: 10.5114/wo.2015.51420. Epub 2015 May 13. PubMed PMID: 26034394; PubMed Central PMCID: PMC4444448.
277. Wang K, Amdur RJ, Mendenhall WM, Green R, Aumer S, Hackman TG, Zanation AM, Zevallos JP, Patel SN, Weissler MC, Chera BS. Impact of post-chemoradiotherapy superselective/selective neck dissection on patient reported quality of life. Oral Oncol. 2016 Jul;58:21-6. doi: 10.1016/j.oraloncology.2016.04.015. Epub 2016 May 14. PubMed PMID: 27311398.
278. Wells M, Cunningham M, Lang H, Swartzman S, Philp J, Taylor L, Thomson J. Distress, concerns and unmet needs in survivors of head and neck cancer: a cross-sectional survey. Eur J Cancer Care (Engl). 2015 Sep;24(5):748-60. doi: 10.1111/ecc.12370. Epub 2015 Aug 7. PubMed PMID: 26250705.
279. Wells M, Swartzman S, Lang H, Cunningham M, Taylor L, Thomson J, Philp J, McCowan C. Predictors of quality of life in head and neck cancer survivors up to 5 years after end of treatment: a cross-sectional survey. Support Care Cancer. 2016 Jun;24(6):2463-72. doi: 10.1007/s00520-015-3045-6. Epub 2015 Dec 11. PubMed PMID: 26660345.
280. Wijbenga JG, Schepers RH, Werker PM, Witjes MJ, Dijkstra PU. A systematic review of functional outcome and quality of life following reconstruction of maxillofacial defects using vascularized free fibula flaps and dental rehabilitation reveals poor data quality. J Plast Reconstr Aesthet Surg. 2016 Aug;69(8):1024-36. doi: 10.1016/j.bjps.2016.05.003. Epub 2016 May 13. Review. PubMed PMID: 27292287.

281. Wu YS, Lin PY, Chien CY, Fang FM, Chiu NM, Hung CF, Lee Y, Chong MY. Anxiety and depression in patients with head and neck cancer: 6-month follow-up study. Neuropsychiatr Dis Treat. 2016 Apr 27;12:1029-36. doi: 10.2147/NDT.S103203. eCollection 2016. PubMed PMID: 27175080; PubMed Central PMCID: PMC4854266.
282. Xiao C, Zhang Q, Nguyen-Tân PF, List M, Weber RS, Ang KK, Rosenthal D, Filion EJ, Kim H, Silverman C, Raben A, Galloway T, Fortin A, Gore E, Winquist E, Jones CU, Robinson W, Raben D, Le QT, Bruner D. Quality of Life and Performance Status From a Substudy Conducted Within a Prospective Phase 3 Randomized Trial of Concurrent Standard Radiation Versus Accelerated Radiation Plus Cisplatin for Locally Advanced Head and Neck Carcinoma: NRG Oncology RTOG 0129. Int J Radiat Oncol Biol Phys. 2017 Mar 15;97(4):667-677. doi: 10.1016/j.ijrobp.2016.07.020. Epub 2016 Jul 25. PubMed PMID: 27727063; PubMed Central PMCID: PMC5266672.
283. Xiao W, Chan CWH, Fan Y, Leung DYP, Xia W, He Y, Tang L. Symptom clusters in patients with nasopharyngeal carcinoma during radiotherapy. Eur J Oncol Nurs. 2017 Jun;28:7-13. doi: 10.1016/j.ejon.2017.02.004. Epub 2017 Apr 11. PubMed PMID: 28478859.
284. Yadav K, Nair D, Agarwal J, Chakrabarti S, Joshi S, Ingole P, Mishra A, Tathe N, Chaturvedi P. Prevalence of Functional Problems After Oral Cavity Malignancy Treatment at a Tertiary Center: Utilizing PSS HN (Performance Status Scale for Head and Neck) Scale. J Maxillofac Oral Surg. 2016 Mar;15(1):38-44. doi: 10.1007/s12663-015-0805-2. Epub 2015 Jun 4. PubMed PMID: 26929551; PubMed Central PMCID: PMC4759033.
285. Yamashita A, Ichikura K, Sugimoto T, Kishimoto S, Shimozuma K, Matsushima E. Reliability and validity of the Head and Neck Cancer Inventory (HNCI) in Japanese patients. Palliat Support Care. 2015 Oct;13(5):1373-80. doi: 10.1017/S1478951514001345. Epub 2015 Jan 26. PubMed PMID: 25620032.
286. Yang CJ, Roh JL, Choi KH, Kim MJ, Choi SH, Nam SY, Kim SY. PretreatmentDysphagia Inventory and videofluorographic swallowing study as prognostic indicators of early survival outcomes in head and neck cancer. Cancer. 2015 May 15;121(10):1588-98. doi: 10.1002/cncr.29245. Epub 2015 Jan 13. PubMed PMID: 25639759.
287. Yang CJ, Roh JL, Kim MJ, Lee SW, Kim SB, Choi SH, Nam SY, Kim SY. Pretreatment quality of life as a prognostic factor for early survival and functional outcomes in patients with head and neck cancer. Qual Life Res. 2016 Jan;25(1):165-74. doi: 10.1007/s11136-015-1063-y. Epub 2015 Jul 9. PubMed PMID: 26156405.
288. Yang W, Zhao S, Liu F, Sun M. Health-related quality of life after mandibular resection for oral cancer: reconstruction with free fibula flap. Med Oral Patol Oral Cir Bucal. 2014 Jul 1;19(4):e414-8. PubMed PMID: 24608209; PubMed Central PMCID: PMC4119320
289. Yeh CF, Li WY, Chu PY, Kao SY, Chen YW, Lee TL, Hsu YB, Yang CC, Tai SK. Pretreatment pain predicts perineural invasion in oral squamous cell carcinoma: A prospective study. Oral Oncol. 2016 Oct;61:115-9. doi: 10.1016/j.oraloncology.2016.07.016. Epub 2016 Sep 9. PubMed PMID: 27688113.
290. Yekaninejad MS, Pakpour AH, Tadakamadla J, Kumar S, Mosavi SH, Fridlund B, Bottomley A, Aaronson NK. Oral-health-related quality of life in patients with cancer: cultural adaptation and the psychometric testing of the Persian version of EORTC QLQ-OH17. Support Care Cancer. 2015 May;23(5):1215-24. doi: 10.1007/s00520-014-2468-9. Epub 2014 Oct 15. PubMed PMID: 25312650.
291. Yuan Y, Zhang P, He W, Li W. Comparison of Oral Function: Free Anterolateral Thigh Perforator Flaps Versus Vascularized Free Forearm Flap for Reconstruction in Patients Undergoing Glossectomy. J Oral Maxillofac Surg. 2016 Jul;74(7):1500.e1-6. doi: 10.1016/j.joms.2016.03.039. Epub 2016 Apr 7. PubMed PMID: 27131032.
292. Yuce Sari S, Yazici G, Yuce D, Karabulut E, Cengiz M, Ozyigit G. The effect of glutamine and arginine-enriched nutritional support on quality of life in head and neck cancer patients treated with IMRT. Clin Nutr ESPEN. 2016 Dec;16:30-35. doi: 10.1016/j.clnesp.2016.08.003. Epub 2016 Sep 13. PubMed PMID: 28531452.
293. Zavalishina L, Karra N, Zaid WS, El-Hakim M. Quality of life assessment in patients after mandibular resection and free fibula flap reconstruction. J Oral Maxillofac Surg. 2014 Aug;72(8):1616-26. doi: 10.1016/j.joms.2014.02.018. Epub 2014 Feb 19. PubMed PMID: 24780606.
294. Zhang LJ, Jiang N, Li Z, Chen XW, Wang PG, Wang X, Zhao Y. Psychometric Properties of the Chinese Version of the M.D. Anderson Dysphagia Inventory for Head and Neck Cancer Patients. Cancer Nurs. 2017 May/Jun;40(3):E9-E16. doi: 10.1097/NCC.0000000000000397. PubMed PMID: 27244664.
295. Zhang X, Li MJ, Fang QG, Li ZN, Li WL, Sun CF. Free fibula flap: assessment of quality of life of patients with head and neck cancer who have had defects reconstructed. J Craniofac Surg.

2013 Nov;24(6):2010-3. doi: 10.1097/SCS.0b013e3182a3057d. PubMed PMID: 24220393.

296. Zhang X, Li MJ, Fang QG, Sun CF. A comparison between the pectoralis major myocutaneous flap and the free anterolateral thigh perforator flap for reconstruction in head and neck cancer patients: assessment of the quality of life. J Craniofac Surg. 2014 May;25(3):868-71. doi: 10.1097/SCS.0000000000000443. PubMed PMID: 24699104.
297. Zhao C, Chen J, Yu B, Chen X. Improvement in quality of life in patients with nasopharyngeal carcinoma treated with non-invasive extracorporeal radiofrequency in combination with chemoradiotherapy. Int J Radiat Biol. 2014 Oct;90(10):853-8. doi: 10.3109/09553002.2014.916579. Epub 2014 Jun 25. PubMed PMID: 24758521.
298. Zheng Y, Liu M, Li M, Zhang J, Ge J, Sun Y, Tian L. The influence of the 'patient-to-patient model' on swallowing problems in patients with supraglottic laryngeal cancer. ORL J Otorhinolaryngol Relat Spec. 2014;76(3):171-7. doi: 10.1159/000365092. Epub 2014 Jul 29. PubMed PMID: 25074851.
299. Żmijewska-Tomczak M, Milecki P, Olek-Hrab K, Hojan K, Golusiński W, Rucińska A, Adamska A. Factors influencing quality of life in patients during radiotherapy for head and neck cancer. Arch Med Sci. 2014 Dec 22;10(6):1153-9. doi: 10.5114/aoms.2013.34317. Epub 2013 Apr 19. PubMed PMID: 25624853; PubMed Central PMCID: PMC4296053.

Appendix 1: Literature review of HRQOL-themed publications

Method

The methodology presented is based on the method previously described by **Rogers et al [2007; 20].** A single author (NG) searched and scrutinized the literature. The ISI search engine with cross-referenced PubMed and OVID was searched using the search terms 'Quality of life', 'Head and neck cancer' and 'Questionnaires' for the period 2013 to present (20 July 2017). This time scale was chosen as the two previous detailed reviews have dealt with the period from 200-2005 [**Rogers et al, 2007**] and 2006-2013 [**Rogers et al, 2016].** Further cross-referencing used the keyword 'HRQOL'. Only studies published in the English language were selected.

The abstracts were searched for evidence of patient self-reported questionnaires/ patient-reported outcome measures and HRQOL outcome. Full text article was obtained to clear any ambiguous methodology in the abstract. During the abstract/literature review, the following HNC subsites were included: oral cavity, oropharynx, nasopharynx, parotid and larynx. The sites excluded from this review were oesophageal, gastric, thyroid, skin and base of skull. Other exclusion criteria were non-human subjects, repeat citation/study findings, studies that were not patient-reported and studies unrelated to QOL. A proforma was used to record key findings.

The type of article was classified into 5 categories by the researcher (NG) based on **Rogers et al [2007]:** (1) Predictors of HRQOL i.e. reported on factors influencing HRQOL outcomes; (2) "Functional" outcome i.e. reported physical functional outcomes e.g. swallowing, mouth opening, mucositis, and emotional functioning e.g. distress; (3) Questionnaire development/validation i.e. reports of psychometric testing, translation of questionnaire, comparative study of different types of questionnaire; (4) Clinical trials i.e. reports of HRQOL outcomes related to clinical trials; (4) Review/Editorial i.e. published literature reviews, systematic reviews, meta-analysis and reports of meeting.

Results

The search identified 538 articles. Based on the exclusion criteria, 239 abstract/papers were excluded. Thus, a total of 299 articles were reviewed. The results are summarised in Table A1-1. The papers included in this review are shown in Table A1-2.

Table A1-1: Summary of search findings and articles reviewed

TOTAL SEARCH OUTPUT	**538 papers**
EXCLUDED	**239**
Reasons for papers excluded	
Not head and neck cohort only	4
Not head and neck cancer	122
Thyroid/Skull base	27
Not PRO	50
Not QOL studies	20
Not English language	14
Repeat citation	1
Not human subjects	1
TOTAL PAPERS REVIEWED	**299**
Year published	
2017	59
2016	94
2015	75
2014	70
2013	1
Cohort	
Head and neck	204
Larynx	31
Oropharynx only	19
Oral cavity only	17
Oral cavity/oropharynx	7
Nasopharynx/ Nose	13
Others/ other combinations	8
Design	
Cross-sectional	236
Longitudinal	46
Reviews	17
Types of paper	
Predictor for HRQOL	161
Functional outcomes	61
Clinical trial	21
Questionnaire development	39
Review/Editorial	17

Discussion

The aim of this review was to provide the most recent evidence as a foundation for exploring the experience of patients and their carers of HNC based on self-reported HRQOL measures. This is to complement the narrative accounts of their living with HNC based on qualitative assessments [**Lang et al, 2013**]. Table A1-2 provides an overview of the areas evaluated by self-reported HRQOL measures, and demonstrates the holistic and global nature of (head and neck) cancer survivorship.

The limitation of this review lies in the methodology, which has been detailed previously [**Rogers et al, 2007**]. A potential problem relates to missing articles, which may be the result of an inadequate search strategy, and the exclusion of some articles, including non-English language articles. Rejection of some articles based only on the abstracts presented may result in potential loss of evidence if the abstract did not contain the pertinent information required. In addition, this review was carried out by only a single researcher, which can introduce selection bias. A single researchers' interpretation of the abstract is not tested against an expert opinion provided by other researchers.

Table A1-2: showing the papers selected from the literature search (Des: Study design; L: longitudinal; C: cross-sectional) (PRO: patient-reported outcome; abbreviations for PRO at the end of table)

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
1	2017	Si	NPC	C	Predictor of HRQOL	FACT-H&N EORTC QLQ-H&N35	Evaluate outcomes of surgery (endoscopic sinus surgery approach) vs CRT	Pain and dry mouth scores better in surgery group
2	2017	Hsin	Glottic	L	Functional outcome 'Speech/Voice'	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate impact of transoral laser microsurgery (TOLM) on speech outcomes	QLQ-H&N35 speech subscale improvement with time
3	2017	Dogan	HNC	L	Clinical trial	UWQOL CTCAE v4	Randomised trial comparing mulberry molasses intervention to prevent RT-induced mucositis	No difference in HRQOL status
4	2017	Maguire	HNC	C	Predictor of HRQOL 'Carers' FOR'	FACT-G Worry of Cancer Scale to measure FOR	To establish the role of care-related stressors-as distinct from survivor characteristics-in predicting FOR in HNC caregivers	Caregivers who reported more loneliness, spent more time caring, and had greater financial stress from caring had higher scores on Worry of Cancer. Female caregivers, those caring for younger survivors, and those with survivors who had undergone less extensive forms of surgery also reported higher FOR.
5	2017	Spinato	OPC	C	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate QOL outcomes in long-term survivors of HPV (+) vs HPV (–) treated with multimodality Tx	

6	2017	Li	HNC	C	Functional outcome ‘Sleep’	Pittsburgh Sleep Quality Index Epworth Sleepiness Scale OHIP-14 SF-36	To evaluate sleep quality in post-treatment HNC	Poor sleep quality associated with extensive ND, a lower SF-36 mental component score, and a higher OHIP-14 psychological disability score
7	2017	Harrington	HNC	L	Clinical trial	EORTC-QLQ-C30 EORTC-QLQ-H&N35 EQ-5D	Phase 3 RCT. Nivolumab versus standard, single-agent therapy of investigator's choice in recurrent or metastatic HN SCC (CheckMate141)	The intervention stabilised symptoms and functioning from baseline to 15 weeks compared with other therapy. QOL outcomes support its use in this subpopulation.
8	2017	Terkawi	HNC	C	Functional outcome ‘Symptom burden: Chronic Pain’	Brief Pain Inventory-Short Form Neuropathic Pain Questionnaire-Short Form Pain Catastrophizing Scale questionnaires	Evaluate prevalence of chronic pain and determine factors associated with it	There is high burden of chronic pain in posttreatment. Chronic pain related to poor HRQOL status manifested by its interference with general activity, mood, walking ability, normal work, and sleeping.
9	2017	Jungerman	HNC	C	Development of questionnaire/ Validation	HN-PCI UWQOL	Translate and validate in Portuguese language for Brazilians	FOR was the most common item of concern. Positive acceptance by patients.
10	2017	Majid	HNC	L	Predictor of HRQOL	EORTC QLQ-C30	Evaluate outcomes of treatment	No difference in HRQOL status between pre and post treatment. Worsening of diarrhoea,constipation, nausea/vomiting, and financial difficulty in posttreatment period.
11	2017	Nemeth	OC	C	Predictor of HRQOL	UW-QOL FACT-H&N	Evaluate outcomes of neoadjuvant chemo with surgery and immediate reconstruction	Most frequent complaints: Chewing difficulties, decreased salivary function, and swallowing dysfunction

12	2017	Engelen	HNC	C	Development of questionnaire/ validation	Liverpool Oral Rehabilitation Questionnaire (LORQ	Translate into Dutch language and validate	
13	2017	Huyett	HNC	C	Functional outcome ‘Breathing/Sleeping problems’	Epworth sleepiness scale UWQOL Functional Outcomes of Sleep Questionnaire	Evaluate prevalence of sleeping apnoea related to RT	Suggestion that prevalence of sleep apnoea is increased in HNC patients
14	2017	Memtsa	HNC	L	Predictor of HRQOL; Functional outcomes ‘xerostomia’	EORTC QLQ-C30 QLQ-H&N35 XQ (Greek)	Evaluate outcomes of RT	Subjective symptom of xerostomia parallelled salivary flow and QOL.
15	2017	Lechien	Larynx	C	Functional outcomes ‘Voice’	VHI EORTC QLQ-H&N35	Evaluate outcomes of CRT in supra- versus infrahyoid tumours	Patients with infrahyoid tumour had presented more severe VHI values, dysphonia, breathiness, asthenia, and some acoustic cues than suprahyoid tumour. The EORTC QLQ-H&N35 communication item was better in the suprahyoid patient group.
16	2017	Becker	Nasal	C	Predictor of HRQOL	UWQOL Patient satisfaction survey	Evaluate patient satisfaction with nasal prosthesis.	'Satisfaction with function' had the most influence on UWQOL domains.
17	2017	Pan	NPC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate treatment outcomes in IMRT versus other RT delivery system with/without chemotherapy	IMRT with or without concurrent chemotherapy had better outcomes in head and neck related symptoms and general aspects of QoL than those receiving 2D-CRT with or without concurrent chemotherapy

18	2017	Norquist	HNC	C	Questionnaire development / validation	EORTC QLQ-C30 EORTC QLQ-H&N35	To qualitatively assess the comparability of paper and electronic versions of the EORTC QLQ-H&N35	Electronic and paper verrsions were comparable
19	2017	Heydarirad	HNC	C	Clinical trial	EORTC QLQ-C30 EORTC QLQ-H&N35	RCT testing two natural products against artificial saliva (control) in reducing RT-induced xerostomia	Test intervention had better xerostomia scores than control. May be useful adjunct in management of xerostomia
20	2017	Dzebo	OC	C	Predictor of HRQOL	UWQOL	To evaluate outcomes of treatment , and determine cut off points for 'success'	
21	2017	Xiao	NPC	C	Functional outcomes 'Symptom burden'	FACT- H&N MDADI (chinese)	To identify symptom clusters following RT	Four system clusters identified, may guide intervention to manage ide effects of treatment
22	2017	Thor	HNC	C	Functional outcomes 'Trismus'	GTQ EORTC QLQ-H&N35	To identify trismus-related domains, its impact on QOL	Eating/Jaw/Pain/QoL were significant domains in trismus-related QOL
23	2017	Hoxbroe	OPC	-	Review/Editorial		Review and meta-analysis of 1366 patients relating to HRQOL outcomes	OPC survivors face clinically important deteriorations in QOL that most markedly centre on xerostomia, dysphagia and chewing.
24	2017	Algtewi	HNC	C	Predictors of HRQOL 'Support group'		Investigate the association between using online support groups (OSGs) and HRQOL	OSG participation is associated to better HRQoL either directly or indirectly through decreasing depression, anxiety and the negative adjustment behaviours and increasing self-efficacy and empowerment of the users.

25	2017	Yuce Sari	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35 QLQ-OES18	Evaluate outcomes in case-control intervention with glutamine and arginine-enriched solution (GAES) during RT	Control group showed poorer scores of social functions, and for individual items: Pain, appetite, dry mouth, sticky saliva. Control group also had trouble with taste, trouble with social eating and swallowing problems
26	2017	Terro	HNC	L	Predictor of HRQOL	UW-QOL 3 other PRO	Evaluate patient and carers HRQOL during survivorship	Patients reported serious deterioration in psychosocial and physical domains Carers showed deterioration of anxiety and depression
27	2017	Franco	HNC	L	Functional outcome 'Mucositis'	OMWQ-HN FACT-H&N	Evaluate the impact of oral mucositis during RT on QOL	Progressive increase in OM during treatment and a partial recovery after RT were correlated to PROs and QOL.
28	2017	Loh	HNC	-	Review/Editorial		Systematic review literature on trismus measurements	
29	2017	Loth	OPC	C	Functional outcome 'Sleep'	Epworth Sleepiness Scale EORTC QLQ-C30 EORTC QLQ-H&N35	Identify post-treatment OPC with sleep apnoea and evaluate impact on QOL	Global Health Status Scale and fatigue score was poorer in those with sleep apnoea
30	2017	He	NPC	C	Predictor of HRQOL	EORTC QLQ-H&N35	Evaluate nutritional status and HRQOL outcomes during IMRT	Nutritional status and QLQ-H&N35 scores in NPC patients decreased during IMRT
31	2017	Andrade	OC, OPC, HPC, Larynx	C	Functional outcome 'Dysphagia'	MDADI	Correlate PRO with objective measure in relation to post-treatment dysphagia	MDADI correlates with objective measure

32	2017	Charalambous	HNC	C	Clinical trial	XeQOL	Testing feasibility of a trial evaluating the effectiveness of thyme honey for the management of treatment-induced xerostomia	
33	2017	Hajdu	HNC	C	Questionnaire development/ validation	MDADI	Translate into Danish language and validate	
34	2017	Palma	HNC	C	Predictor of HRQOL; Functional outcomes ‘xerostomia’	UWQOL	Evaluate low-level laser therapy intervention to reduce RT-induced xerostomia	Low-level laser therapy mitigates salivary hypofunction and increase salivary pH, with HRQOL improvement
35	2017	Ghazali	HNC	C	Predictor of HRQOL ‘Distress’	UWQOL DT	Identify correlation between DT and HRQOL outcomes	DT screening identifies emotional distress which correlates with poorer HRQOL functioning/status
36	2017	Pan	NPC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate outcomes with different treatment modalities	RT had better outcomes than CCRT for global QoL, functional scales, symptom scales of fatigue and insomnia, financial problems, and weight gain.
37	2017	Axelsson	HNC	L	Functional outcomes ‘Swallowing’	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated the long-term swallowing function with prophylactic PEG tube placement	No long-term deterioration in swallowing outcomes with PEG tubes
38	2017	Hartford	HNC	L	Clinical trial	FACT-H&N PSS-H&N	Explore the feasibility of hyperbaric oxygen (HBO) treatments immediately before IMRT in conjunction with cisplatin	HRQOL in intervention group comparable to control group

39	2017	Montavlo	HNC	C	Functional outcomes ‘Trismus’			
40	2017	De Oliveira	HNC	L	Predictive for HRQOL	UWQOL	Evaluate HRQOL status post-treatment	HRQOL status changes at different time points after treatment completion
41	2017	Tian	Larynx	C	Predictive for HRQOL		Evaluate different types of communication model on dysphagia	QOL scores based on dysphagia questionnaires were significantly higher in the patient communication and physician communication groups than in the routine communication group.
42	2017	Christopher	HNC	L	Predictive of HRQOL	EORTC QLQ-H&N35	Evaluate outcomes of CRT	HNC survivors exhibit different QOL related symptoms depending on combined treatment modalities, and time post-treatment
43	2017	Daugaard	HNC	L	Functional outcome	EORTC QLQ-C30 EORTC QLQ-H&N35	Compare patient-reported and clinician assessed problem related to late effects of treatment	Dysphagia: patients and clinicans correlated well. Fibrosis and xerostomia not as well correlated.
44	2016	Dholam	OC	C	Predictor of HRQOL	OHIP LORQ	Evaluate long-term outcomes of prosthetic rehabilitation	Improvement in all domains of LORQv3 and OHIP-14 with rehabilitation
45	2017	Lastrucci	NPC	C	Predictor of HRQOL	FACT-G FACT-NP PSS-H&N XeQOLS EQ-5D-3L	Evaluate outcomes of NPC treated by RT and IMRT	FACT-G and PSS-H&N scores better in < 55 years; PS-H&N and XeQOL scores better in IMRT

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
46	2017	Ullgren	HNC	C	Predictor of HRQOL (Issue: Information)	QLQ C-30 INFO25	Evaluate outcomes and informational needs of palliative HNC managed by early referral to palliative care	Global health was the lowest reported functional scale; Fatigue was the highest reported symptom. Better satisfaction when given written care plan. Higher use of ED in those les satisfied with information given.
47	2017	Martín	HNC	C	Functional outcome 'xerostomia'	XeQOLS VAS	Evaluate the intervention of topical agents in the management of RT-induced xerostomia	Improved xerostomia-related QOL scores with intervention; 7/8 topical agents had good HRQOL scores.
48	2017	Pugh	HNC	C	Questionnaire development / validation	UWQOL-Radiation Therapy Oncology Group (RTOG) modification (UW-QOL-RTOG Modification)	Psychometric testing	
49	2016	Cohen	HNC	L	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate outcomes of surgical resection in different HNC subsites	Differences in HRQOL scores shown by different subsites
50	2017	Singh	OPC	L	Predictor of HRQOL	UWQOL	Evaluate HPV status in newly diagnosed HPV+ OPC	No differences seen in HRQOL in relation to HPV status
51	2017	Memtsa	HNC	C	Questionnaire development/ validation	XeQ	Translate into Greek, and validation	
52	2016	Valls-Mateus	Larynx	L	Predictor of HRQOL	UWQOL SF-12	Evaluate outcomes of laryngeal ca treates with transoral laser surgery (TOLR)	Very good long-term HRQOL outcomes, global QOL score equal at 1- and 5 years postTOLR. Reduction in activity scores at long-term.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
53	2017	Spalthoff	HNC	C	Predictor of HRQOL		Evaluate outcomes of types of ND	Significant differences seen in HRQOL between non-ND versus ND group, and also within ND subgroups. The problems include impairments in speech intelligibility, ingestion & swallowing, tongue mobility, mouth opening, lower jaw mobility, neck mobility, and shoulder / arm movement
54	2017	Dholam	OC	L	Predictor of HRQOL	OHIP LORQ	Evaluate outcomes of prosthetic rehabilitation	Oral rehab improved HRQOL in areas of oral function, orofacial appearance, and patient satisfaction with prosthesis
55	2017	Beck-Broichsitter	OC	C	Functional outcomes	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate/compare professionals and patient assessment of physical dysfunction	Speech: professionals scored better than self-assessment Swallowing better in local flaps as reported by patients
56	2017	Xiao	HNC	C	Clinical trial	PSS-H&N HNRQ SQLI	Evaluate outcomes between 2 different RT regime with chemotherapy	No HRQOL differences reported between arms
57	2017	Kisser	HNC	C	Questionnaire development	ICF	Development of ICF-based clinical guideline & screening tool	
58	2017	Yeh	OC	C	Predictor of HRQOL ‘Pain’	EORTC QLQ-H&N35 VAS for pain	Evaluate pretreatment parameters in predicting PNI	PNI predicted by higher VAS scores
59	2017	Drost	HNC	C	Functional outcome ‘Facial appearance’	Utrecht Questionnaire for Outcome Assessment in Aesthetic Rhinoplasty Patient Scar Assessment Questionnaire	Evaluate facial medical tattooing intervention in the management of facial disfigurement	Improved scores with intervention

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
60	2016	Bozec	HNC	C	Predictor of HRQOL (Issue: information)	EORTC QLQ-C30 EORTC QLQ-INFO25	Evaluate outcomes of treatment and of informational provision	Low correlation between HRQOL and informational provision
61	2016	Lin	HNC	C	Predictor of HRQOL (Issue: FOR)	FOR Inventory (Caregiver) MOSHS	Evaluate the experience of carers of HNC undergoing RT	Higher FOR scores in patients undergoing shortened vs longer RT courses
62	2016	Sapir	HNC	C	Functional outcome 'Taste'	UWQOL HNQOL XeQOL	Evaluate the outcomes of CRT	Dysguesis correlated with mean RT to OC. Patient-reported xerostomia correlated with severe dysgeusia.
65	2016	Morand	OPC	C	Functional outcome 'xerostomia'	EORTC QLQ-H&N35	Evaluate outcomes of salivary gland transfer before CRT	Low xerostomia scores after salivary gland transfer
66	2016	Martins	HNC	C	Clinical trial	FACT-HN EORTC-HN35 EORTC-Q30	Phase 2 RCT evaluating the 'guarana' intervention in the management of fatigue	Guarana is not beneficial. No difference in terms of HRQOL scores.
67	2016	Keillmann	HNC	C	Questionnaire development/ Validation	Articulation handicap index (AHI)		
68	2016	Richardson	HNC	C	Predictor of HRQOL (Issue: relationship; carers)	PSS-H&N Brief IPQ	Evaluating illness perception and relationship changes in HNC patients and their carers	Perceptions of emotional impact and illness concern reduced over time in patients and carers.
69	2016	Wang	OPC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC H&N-35 EAT-10 (swallowing) NDII	Evaluating outcomes of preplanned CRT followed by superselective ND	Intervention did not prevent recovery of most QOL metrics to near baseline. Early reduction in ND scores, more pronounced with more nodes dissected.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
70	2016	Gunn	HNC	C	Questionnaire development/ validation	MDADI	Translation into Turkish and validation	
71	2017	Schweyen	HNC	C	Predictor of HRQOL	OHIP-G14	Evaluate impact of oral rehabilitation	Prosthetic treatment in HNC patients do not lead to the same improvement in OHRQoL as found in the normal population
72	2015	Chen	NPC	L	Predictor of HRQOL	SF-36 EORTC H&N-35	Evaluate outcomes of different types of RT regime	Any RT regime reduces HRQOL
73	2016	Kannan	OPC, Larynx HPX	L	Predictor of HRQOL	EORTC-H&N35 EORTC-Q30	Evaluate outcomes of RT with concomitant boost radiotherapy by Volumetric Intensity Modulated Arc Therapy (VMAT) technique	Comparable results
74	2016	Wijbenga	HNC	-	Review		Reviews impact of oral rehabilitation with or without dental implants following reconstruction of such segmental maxillofacial defects with fibula flap.	
75	2017	Zhang	HNC	C	Questionnaire development/ validation	MDADI	Translate into chinese language and validate	
76	2016	Reeve	HNC	C	Predictor of HRQOL	FACT-H&N	Evaluate clinical and sociodemographic factors influencing outcomes	
77	2016	Ringash	OPC	C	Clinical trial	FACT-H&N	Phase 3 RCT (HEADSTART)	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
78	2016	Kucharska	HNC	C	Questionnaire development/ validation	QLQ-C30 EORTC QLQ-H&N35	Development of the Polish version	
79	2016	Hanly	HNC	C	Predictor of HRQOL	SCNS-P&C CarerQol (assesses burden and happiness)	Evaluate carers experience and unmet needs	Different aspects of carer characteristics and unmet needs are associated with carer burden and happiness, impact on HRQOL
80	2016	Flach	OC	L	Predictor of HRQOL	QLQ-C30 QLQ-H&N35 HADS IES SDQ	Evaluates outcomes of sentinel node biopsy (SNB)	Comparable outcomes for SNB-negative and SNB-positive patients in terms of HRQOL, psychological distress and shoulder function.
81	2016	Kumar	OC	L	Predictor of HRQOL 'Dental/teeth'	EORTC-QLQ c30, EORTC-QLQ H&N35 OHIP DSI	Evaluate outcomes of dental rehabilitation using implant-supported overdentures in segmental mandibulectomy defect reconstruction with fibula free flap	Implant-based reconstruction with fibula flap improves QOL outcomes.
82	2016	Kjaer	HNC	L	Predictor of HRQOL 'symptom burden'	EORTC QLQ C-30, EORTC QLQ H&N35 HADS	Evaluated impact of regular patient-reported feedback of side-effects of treatment to clinicians	Regular feedback of Patient-reported symptoms improves clinicians identification of late effects of treatment
83	2016	Wu	HNC	C	Predictor of HRQOL 'Psychological distress'	EORTC QLQ-H&N35	Evaluated the prevalence of psychological distress and HRQOL	Anxiety prevalent at early in journey; depression occurs later. Loss of sense, loss of speech, low libido, dry mouth, and weight loss were related to depression over time. Depressed patients were more likely to use more analgesia and nutritional supplements.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
84	2016	Janssens	Larynx	L	Clinical trial	EORTC QLQ-C30 EORTC QLQ-H&N35	Phase 3 RCT comparing accelerated radiotherapy with carbogen and nicotinamide (ARCON) against accelerated radiotherapy alone (AR).	
85	2016	Su	NPC	C	Questionnaire development/ validation	FACT-G FACT-H&N	Development/validation of the QOL-NPC	
86	2016	Brandao	HNC	C	Predictor of HRQOL	OHIP-14	Evaluate outcomes of using surgical guides in fibula flap reconstruction of the mandible	Good QOL scores obtained with use of guides which helps guide mandible and implant placement.
87	2016	Rigoni	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ H&N35 Coop/Wonca CSI	Evaluate outcomes in patients and their carers	QOL impairment is similar between patients and their carers.
88	2016	Rylands	HNC	C	Predictor of HRQOL	UWQOL	Evaluate the association between deprivation and HRQOL outcomes	Deprivation is associated with overall QOL, particularly socioemotional function
89	2016	Yuan	HNC	L	Predictor of HRQOL	EORTC QLQ- H&N35 UWQOL OHIP	Evaluated outcomes of postresection thigh and radial flap reconstruction	Both flaps showed good HRQOL score posttreatment
90	2016	Janssen	HNC	C	Questionnaire development/ validation	EORTC QLQ-H&N35 UWQOL	Evaluated relationship between 2 questionnaires and determine cut-off points	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
91	2017	Batıoğlu-Karaaltın	Larynx	C	Predictor of HRQOL ‘sexual function & self confidence’	EORTC QLQ-C30 EORTC QLQ-H&N35 ASEX BDI,BAI RSES)	Evaluated outcomes of total laryngectomy (TL) versus partial laryngectomy (PL)	TL patients had more problems regarding depression, anxiety, self-esteem and sexual functions
92	2016	Tuomi	Larynx	L	Functional outcomes	S-SECEL EORTC QLQ-H&N35	Evaluated outcomes of voice therapy in postRT	HRQL and self-perceived communication function showed improvement in study group and trends of impairment in control group
93	2016	Rogers	OPC	C	Predictor of HRQOL	UWQOL	Evaluated outcomes of TOLM	76% reported overall QOL as being good, very good or outstanding, and by domain 95% reported none or only minor problems, most notably for swallowing, chewing and speech.
94	2016	Kraaijenga	OPC	C	Functional outcome	Subjective Functional Oral Intake Scale scores Swallowing Quality of Life Questionnaire	Evaluate outcomes of lipofiller injections in posttreatment OPC	
95	2016	Nightingale	HNC	L	Predictors of HRQOL ‘Carers burden’		Evaluate burden and QOL in HNC carers during and after RT	Carers experience psychosocial impairments during and shortly after patient RT
96	2016	Karlsson	Larynx	L	Predictors of HRQOL	S-SECEL EORTC QLQ-H&N35	Longitudinal descriptive study of HRQOL postRT	Comparable results with other similar studies
97	2016	Elliot	HNC	C	Predictor of HRQOL		Evaluated outcomes of medical marijuana (MM) use in HNC treated with RT	MM provided benefit in altered sense, weight maintenance, depression, pain, appetite, dysphagia, xerostomia, muscle spasm, and sticky saliva.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
98	2015	Parkar	HNC	-	Review/Editorial	EORTC QLQ-C30 EORTC QLQ-H&N35	Review HNC papers using the EORTC questionnaire	
99	2016	Bajwa	OC	L	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes of brachytherapy	Pain, swallowing, sensory, speech, social contact, social eating worsened at 3mths but improved over 2ys. Sexuality & financial status showed delayed improvement. Dry mouth and sticky saliva were significant determinants of QOL with delayed improvement
100	2016	Liu	Salivary gland	L	Clinical trial	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate protocol in management of inoperable salivary gland malignancy	
101	2016	Yadav	HNC	C	Predictor of HRQOL	PSS-H&N	Evaluate physical morbidity post surgery	Type of resection and reconstruction impacted on physical morbidity
102	2016	Rogers	HNC	-	Review/editorial		Evaluated HRQOL-related papers from 2006 to 2013	
103	2016	Holtmaart	HNC	C	Predictor of HRQOL	PTGI HADS EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate prevalence of Posttraumatic growth in HNC, and its impact on HRQOL	Prevalence of PTG is low, occurred in relationship domain.
104	2016	Sanchez	HNC	C	Questionnaire development/ validation	MDASI-HN	Psychometric testing and validation	
105	2016	Gabbo	HNC	C	Predictor of HRQOL	UWQOL	Evaluated the degree of HRQOL improvement in patients treated by surgery over a time period	Significant HRQOL improvement in was at 6mths. More invasive treatment and bigger tumours had biggest QOL improvement between time-points

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
106	2016	Pauli	HNC	C	Functional outcome ‘Trismus’	GTQ EORTC-QLQ-C30 EORTC QLQ-H&N35	Evaluated long-term outcome of jaw opening exercises intervention	Positive persistent effect of exercises in objective and HRQOL-related outcomes
107	2016	Kraaijenga	HNC	C	Functional outcome ‘Voice/articulation’	VHI SHI	Evaluated outcomes of advanced HNC treated by chemoRT	Patient-reported voice problems (VHI>15) and speech (SHI>6) in daily life were present in 68% and 77% of patients, respectively
108	2016	Kobayashi	HNC	C	Clinical trail	UWQOL	Evaluated different chemoRT regimes	
109	2016	Chotigavanich	Glottic	C	Functional outcome ‘Voice/articulation’	V-RQOL survey	Evaluated outcomes of narrow-margin endoscopic PL intervention	Better voice-related QOL in subgroup who underwent superficial surgery
110	2016	Boughartz	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes of new surgical technique of submandibular gland preservation in RT	
111	2016	Li	HNC	C	Predictor of HRQOL	UWQOL	Evaluated outcomes following free flap reconstruction	Chewing, swallowing and speech outcomes favourable. PORT impacts negatively on function.
112	2016	Capozzi	HNC	L	Predictor of HRQOL		Evaluated the timings to initiate a lifestyle and progressive resistance exercise training intervention i.e. during or after RT	Improvements in HRQOL scores with exercise
113	2016	Petrosyan	OC	-	Review/Editorial		Systematic review of outcomes of oral rehabilitaton and impact on HRQOL	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
114	2016	Ninu	HNC	C	Functional outcomes ‘Distress’	DT EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes at 1 year post treatment	Distress higher in those with tracheostomy. Higher levels of suffering related to sensory problems, social eating, and dry mouth among patients treated with combined therapy
115	2016	Samuels	OPC	C	Predictor of HRQOL ‘Dysphagia’	HNQOL UWQOL	Evaluated RT versus CRT in HPV(+) patients	QOL Summary and domain scores for eating were good pretreatment, worse at 3mths, and then improved to near baseline at 12mths without differences between the groups in any QOL domains
116	2016	Florie	HNC	C	Functional outcome	MDADI	Evaluated MDADI and FEES outcomes	
117	2016	Krebber	HNC	C	Functional outcome ‘Distress’	HADS EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated use of touch-screen computer system OncoQuest in screening for distress in routine follow up care	OncoQuest distress screening is beneficial as 82% were identified with an increased level of distress. Higher HADS score was related to a worse emotional functioning, worse fatigue score, and problems with sexuality, oral pain and speech.
118	2016	Lee	OC	C	Predictor of HRQOL ‘Unmet needs’	SUNS	Evaluated the unmet support care needs of OC patients	Substantial unmet needs reported across all domains, with many of top unmet needs within the emotional domain. Poorer mental and physical health were associated with greater unmet needs.
119	2016	Wells	HNC	C	Predictor of HRQOL	QLACS	Evaluated predictors of HRQOL status in first 5 years posttreatment survivorship	Socio-economic factors and comorbidity are important predictors of QoL in HNC survivors.

120	2016	Van der Linden	HNC	C	Predictors of HRQOL	EQ5D	Evaluated economic impact of treatment approaches to neck	
121	2016	Alvarez-Camacho	HNC	L	Functional outcome ‘Taste & smell’	CCS UWQOLv3	Evaluated taste and smell outcomes in tube-fed versus oral fed patients	CCS was a significant predictor of overall QoL, social-emotional, physical and overall functions.
122	2016	Rylands	HNC	C	Predictors of HRQOL	UWQOL	Evaluated deprivation and its association with mortality and HRQOL	Patients residing in more deprived areas had worse QOL outcomes in regard to social-emotional functioning and overall QOL but not in regard to physical oral function.
123	2016	Licitra	HNC	-	Review/editorial		Reviewed HRQOL studies to evaluate the use of HRQOL in clinical care	
124	2016	Pedersen	HNC	C	Functional outcome ‘Dysphagia’	PSS: Normalcy of Diet MDADI	Evaluated the swallowing outcomes in posttreatment HNC patients and to assess relationship between clinical assessment and PRO-dysphagia	Clinical dysphagia, associated with significant morbidity, and patient reported dysphagia related to quality of life are not interchangeable and must be measured separately.
125	2016	Duman-Lubberding	HNC	C	Predictor of HRQOL ‘Self-management’	Patient satisfaction was measured with the Net Promotor Scale (NPS)	Evaluated the feasibility of using a web-based self-management application (OncoKompas)	OncoKompas was feasible with an adoption grade of 64%, an implementation grade of 75-91%, a mean satisfaction score of 7.3, and a positive NPS (1.9).

126	2015	Pottel	HNC	C	Predictor of HRQOL	Euroqol-5 dimensions (EQ-5D)	Evaluated the feasibility of using the Geriatric-8 (G-8) questionnaire and a comprehensive geriatric assessment (CGA) in ChemoRT treatment decision	G-8 is indicative of quality-adjusted survival
127	2015	Agrawal	Larynx	C	Functional outcome ‘Voice/articulation’	VHI V-RQOL	Evaluated the outcomes of TL	Comparatively better voice-related QOL scores due to cross-cultural differences.
128	2016	Dinescu	Larynx	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes of TL versus PL	TL group had low scores regarding functional scales: role, emotional and social; and high scores on insomnia and financial difficulties. PL group had a high score on functional scales: role, emotional and social.
129	2016	Ouattassi	HNC	C	Questionnaire development/ Validation	EORTC QLQ-C30 EORTC QLQ-H&N35	Translation into Moroccoan Arabic language	
130	2015	Cote	HNC	C	Clinical trial	EORTC QLQ-C30 EORTC QLQ-H&N35 Pain VAS questionnaire	Randomised trial in placebo-controlled of nabilone intervention in management of RT-related side effects	At the dosage used, nabilone was not potent enough to improve patients' QOL over placebo
131	2015	Ehrrson	HNC	C	Predictor of HRQOL ‘Tube feeding’	Schedule for the Evaluation of Individual Quality of Life (SEIQoL)	Evaluated which HRQOL areas are influenced by having a nasogastric feeding tube or a percutaneous endoscopic gastrostomy tube	Neither showed any advantage over the other
132	2016	Brandao	HNC	-	Review/Editorial		Systematic review of maxillary rehabilitation following surgery	

133	2015	Barosso	HNC	C	Questionnaire development/ validation	VHNSS 2.0	Translation of questionnaire into Brazilian Portuguese language	
134	2015	Pollum	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes and the feasibility of using electronic data capture	QOL assessment using tablet devices in HNC patients is feasible, but may be more challenging in elderly patients.
135	2015	Shavi	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate outcomes following treatment in Indian population	Main factors affecting QOL were loss of weight, use of painkillers, sticky saliva, reduced mouth opening and problems in social eating. Type of treatment impacted on specific areas of QOL.
136	2015	Barrios	OC / OPC	C	Predictor of HRQOL ‘oral health’	SF-12 OHIP-14 OIDP	Evaluated the relationship between oral-related QOL to overall HRQOL	Long-term oral-related QOL influenced HRQoL
137	2015	Barosso	HNC	C	Questionnaire development / validation	VHNSS 2.0	Validation study	
138	2015	Mucke	HNC	C	Predictor of HRQOL	UWQOL	Evaluated outcomes, comparison between different treatment modality	RT triggers functional limitations and emotional distress, impacts on HRQOL
139	2015	Kovac	OC/ OPC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated outcomes of multitreatment modalities	Complex reconstruction and adjuvant (chemo)RT were main reasons for significant QOL impairment
140	2015	Noronha	HNC	C	Clinical trial	EORTC QLQ-C30 EORTC QLQ-H&N35	Randomized trial metronomic (methotrexate and celecoxib) versus cisplatin	QOL not significantly different between 2 groups. Metronomic arm showed better pain improvement scores between time points.

141	2015	Barber	HNC	L	Predictor of HRQOL	QIDS FACT-H&N	Evaluated the relationship between preoperative depressive symptoms (PDS) and postoperative functional performance status (PFPS)	PDS affected PFPS and survival outcomes
142	2016	Kim	HNC	C	Predictor of HRQOL	BDI EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated the the presence of Pretreatment depression (PDS) and pretreatment QOL, nutritional status, and survival outcomes	PDS was predictive of 3-year Disease-Free Survival. Differences seen in HRQOL scores seen in PDS and non-PDS.
143	2015	Van Nuffelen	HNC	L	Clinical trial		Evaluate 3 different tongue strengthening exercise intervention	
144	2015	Garzaro	HNC	C	Functional outcome ‘Shoulder dysfunction’	UWQOL	Evaluate shoulder function after ND and cervical root preservation	Nerve preservation grouphad significantly less pain, fewer shoulder complaints, and fewer limitations on activities and recreation, as well as significantly better health-related and overall QoL
145	2016	Adnane	HNC	C	Questionnaire development/ Validation	UWQOL	Translation into Moroccan Arabic language	
146	2015	Rogers	HNC	C	Predictor of HRQOL ‘Osteoradionecrosis	UWQOL	Evaluate outcomes related to osteoradionecrosis (ORN) diagnosis/management	UWQOL scores for grade III ORN were particularly poor, even after mandibular resection/reconstruction.
147	2016	Cnossen	Larynx	C	Predictor of HRQOL ‘Self-management’	Net Promoter Score (NPS)	Evaluate the feasibility of using online self-care education programme supporting early rehabilitation of TL	The online self-care programme was feasible with high patient satisfaction and acceptance.

148	2015	Kumar	HNC	L	Clinical trial		Randomised palliative RT regime in unresectable HNC	
149	2016	Hagen	HNC	C	Functional outcome ‘xerostomia’	EORTC QLQ-H&N35	Evaluated the outcomes of submandibular gland autotransfer before and after RT	xerostomia was markedly reduced due to improved saliva production of the reimplanted gland
150	2015	Bussu	Larynx	C	Functional outcome	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluated the recovery of swallowing after supracricoid partial laryngectomy (SCL)	
151	2016	Miyoshi	Larynx	C	Functional outcome ‘Speech/voice’	SF-8 VHI-10 V-RQOL	Evaluate the outcomes using the transoeophageal voice prosthesis after laryngectomy	Voice intensity correlated with comprehensive QOL, including physical and mental health.
152	2015	Galli	Parotid	C	Predictor of HRQOL		Evaluate outcomes of parotidectomy and nerve preservation	Sacrifice of the great auricular nerve has only a small impact on QOL
153	2015	Rogers	HNC	C	Questionnaire development/ validation	UWQOL	Describes the development of patient information sheet based on HRQOL scores	
154	2015	Wells	HNC	C	Predictor of HRQOL ‘Unmet needs’	DT HN- PCI	Evaluated the unmet needs and distress in posttreatment HNC	One-third of the survivors had moderate or severe Distress. 74% had at least one unmet need.
155	2016	Kjaer	HNC	C	Predictor of HRQOL ‘Symptom burden’	EORTC QLQ C-30 EORTC QLQ H&N35 HADS	Evaluated the outcomes of treatment, and the feasibility of computerised data acquisition.	Late symptoms are common in HNC survivors
156	2015	Sun	HNC	C	Functional outcome ‘Shoulder function’	UWQOL	Evaluated should outcomes in neck dissection and/or RT	RT does not increase shoulder dysfunction in surgically treated necks.

157	2015	Ciocca	HNC	C	Predictor of HRQOL	Head and Neck (H&N30)	Evaluated the outcomes of implant-retained or removable prosthesis after mandibular reconstruction	Comparable QOL outcomes
158	2016	Aro	HNC	C	Predictor of HRQOL	15D HRQoL	Evaluated outcomes within 1 year following diagnosis	Comparable results with similar studies
159	2015	Noel	HNC	C	Predictor of HRQOL	SG TTO VAS exercises EQ-5D HUI3	Evaluated health utilities (HU) and HRQOL	Indirect HU measures may be more reflective of the health status of patients with head and neck cancer than direct measures
160	2016	Govers	OC	C	Functional outcomes 'Shoulder dysfunction'	EuroQol-5D-3L	Evaluated shoulder function outcomes and HU in various management options	More invasive procedures appear to result in lower health utility
161	2016	Trivic	Larynx	C	Questionnaire development / validation	EORTC-QLQ-H&N43	Translate into Serbian language and validate	
162	2016	Yang	HNC	L	Predictor of HRQOL	EORTC QLQ C-30 EORTC QLQ H&N35	Evaluated pretreatment HRQOL status with treatment outcomes	Significant relationships between certain pretreatment QOL measures and survival or functional outcomes
163	2016	Ichikura	HNC	C	Functional outcome 'distress'	FACT-H&N HADS	Evaluate persistence of psychological distress during hospitalization and physical outcomes	Impaired physical and emotional function is associated with persistent psychological distress
164	2016	Viscari	HNC	C	Predictor of HRQOL	UWQOL	Evaluate HRQOL outcomes in CRT	QOL scores reduced with start of treatment, then improves esp after 2nd chemo cycle and after 6 week RT. The

								abilities to taste, swallow, salivate, and participate in activities and recreation were affected significantly.
165	2016	Rinkel	HNC	C	Functional outcome ‘Speech and swallowing’	SWAL-QOL SHI	Evaluate swallowing and speech outcomes after ChemoRT	Swallowing -related QOL scores worse in those taking soft diet or using tube feeding. Less swallowing problems in larynx/hypopharynx compared to OC/OPC. IMRT related to less psychosocial speech problems. CRT related to higher daily swallowing and speech problems.
166	2015	Landstom	HNC	C	Predictor of HRQOL	EORTC QLQ H&N35	Evaluate outcomes using electrochemotherapy (ECT)	QOL outcome 1 year post-ECT showed a significant increase in problems with senses (taste, smell), speech, mouth opening and xerostomia.
167	2015	Kanatas	HNC	C	Functional outcome ‘Emotional problems’	UWQOL HN-PCI	Evaluate emotional problems reported by disease-free posttreatment patients attending routine clinics	
168	2015	Taberna	HNC	C	Predictor of HRQOL	RTOG toxicity questionnaire	Evaluate the prevalence of toxicity following CRT	
169	2016	Huang	HNC	C	Predictors of HRQOL	EORTC QLQ C-30 EORTC QLQH&N35	Evaluate long-term outcomes of C-IMRT	IMRT technique was associated with the improvement of QOL

170	2015	Hoole	HNC	-	Review/Editorial		Identification of validated questionnaire for assessment of intimacy in HNC	
171	2015	Visacri	HNC	L	Predictors of HRQOL	UWQOL	Evaluate outcomes of cisplatin-RT regime	
172	2015	Kraaijenga	HNC	C	Functional outcome 'Dysphagia and trismus'	FOIS SWAL-QOL	Evaluate swallowing and mouth opening outcomes following CRT	Swallowing and mouth opening problems are substantial in Long-term survivors after organ-preservation CRT.
173	2016	Passchier	HNC	C	Predictor of HRQOL 'Distress'	EORTC QLQ C-30 EORTC QLQ H&N35 DT	Evaluate feasibility and outcomes of a dedicated multidisciplinary (MDT)rehabilitation program	Dedicated MDT HNR program is feasible and has a positive impact on HRQoL
174	2016	Bozek	HNC	C	Predictor of HRQOL 'Information'		Evaluates the information given to HNC patients treated by surgery	Satisfaction with information given, correlates with HRQOL
175	2015	Richardson	HNC	C	Predictor of HRQOL		Evaluated HRQOL status in carers and patients	
176	2014	Silviera	HNC	C	Functional outcome 'Swallowing'	SWAL-QOL	Evaluated swallowing outcomes CRT versus RT only	Relationship between OC primary site and the fatigue domain; and also between advanced cancer stage and the impact of food selection,communication, and social function domains. CRT, feeding tubes and trachesotomy impacted negatively on QOL.
177	2017	Bacorro	HNC	C	Questionnaire development/ validation	MDASI-HN	Translation into Filipino language and validation	

178	2015	van Gemert	HNC	C	Predictor of HRQOL	EORTC QLQ C-30 EORTC QLQ H&N35	Evaluate outcomes between reconstruction plate and fibula flap in segmental defects mandible	comparable HRQoL
179	2015	Kanatas	HNC	C	Questionnaire development/ validation	UWQOL	Evaluate large database of UWQOL data to present patient information sheet about likely HRQOL outcomes with treatment	
180	2015	McNeely	HNC	L	Clinical trial; Functional outcome ‘Shoulder dysfunction’		Evaluate shoulder resistance exercise outcomes in randomised, cross-over trials	
181	2015	Ganzer	HNC	C	Functional outcome ‘Swallowing’	VHNSS 2.0	Evaluate the eating experience of posttretament patients	Psychological, functional, and social losses associated with eating were identified. Patients modify or avoid foods that are challenging yet report enjoyment with eating. Challenges with eating were downplayed.
182	2014	Agrawal	OC	C	Predictor of HRQOL	UWQOL	Evaluate treatment outcomes	Early stage had better HRQOL outcomes
183	2015	Choby	OPC	C	Predictor of HRQOL	UWQOL	Evaluate outcomes of transoral robotic surgery (TORS)	Very good short- and long-term HRQOL outcomes
184	2015	Vainshtein	OPC	C	Predictor of HRQOL	HNQOL UWQOL XQ	Evaluated outcomes of swallowing and salivary-sparing C-IMRT protocols in HPV(+) OPC	Stable or improved HRQOL in nearly all domains compared with pretreatment and 2y FU.

185	2015	Mecedante	HNC	C	Predictor of HRQOL	Karnofsky	Evaluated the prevalence and impact of oral symptoms in those with advanced cancer	A wide range of symptoms are experienced, early detection helpful esp in palliative setting
186	2016	Li	OC, OPC	C	Questionnaire development/ Validation	SHI UWQOL	Validation of translation into chinese language	
187	2015	Greco	HNC	C	Questionnaire development/ Validation	MDADI	Validation of translation into Italian language	
188	2015	Dale	OPC	C	Functional outcomes 'Dysphagia'	MDADI	Evaluated long-term swallowing outcomes in OPC	Comparable results obtained with other published studies.
189	2016	Rogers	OC/ OPC	C	Functional outcome 'FOR'	FOR questionnaire UWQOL	Evaluated the prevalence of FOR and impact on HRQOL status	FOR is prevalent and impact significantly on HRQOL
190	2015	Tribius	HNC	C	Predictor of HRQOL	EORTC QLQ C-30 EORTC QLQ H&N35	Evaluate the outcomes of IMRT	Patients experience long-term dry mouth and sticky saliva, esp post-definitive IMRT.
191	2015	Ghazali	HNC	C	Predictor of HRQOL 'Unmet needs'	UWQOL HN-PCI	Evaluate the prevalence of unmet needs/concerns of disease-free posttreatment patient attending routine clinics	Patients reporting poor HRQoL outcomes were significantly more likely to indicate more items of concern.

192	2015	Perry	Larynx	C	Predictor of HRQOL		Evaluate outcomes of TL	TL survivors demonstrated reduced physical health QOL and social relationship QOL and higher levels of depression and anxiety when compared with normative samples. Psychological well-being had a stronger association than functioning (speech, swallowing) for their psychological QOL.
193	2014	Mazzeo	HNC	C	Functional outcome	Xerostomia-related Q	Evaluate outcomes of IMRT with boost schedule with concurrent chemo and neoadjuvant platinum-based regime	
194	2015	Li	HNC	C	Predictor of HRQOL	UWQOL	Evaluated the outcomes of radial flap reconstruction	Good long-term HRQOL status with flap.
195	2015	Yang	HNC	C	Functional outcome	MDADI	Evaluated the relationship between objective measure, PRO and survival outcomes	PRO was able to pretreatment MDADI predicted survival
196	2016	Cavell	HNC	C	Predictor of HRQOL 'Benefit finding'		Evaluated unmet needs, coping and benefit finding in posttreatement cohort	Patients reported at least moderate benefit finding in the majority of areas. More benefit finding was predicted by the presence of more advanced disease, Maori/Pacific Island ethnicity, lower baseline QOL, and the use of active coping strategies.

197	2015	Offerman	Larynx	C	Predictor of HRQOL		Evaluate patient and carer experience following TL	
198	2014	Żmijewska-Tomczak	HNC	C	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate outcomes of CRT	
199	2015	Rinkel	OC / OPC	C	Questionnaire development/ validation	SWAL-QOL SHI FROG	Validate SWAL-QOL	
200	2016	Yamashita	HNC	C	Questionnaire development/ validation	Head and Neck Cancer Inventory (HNCI)	Validation of translation into Japanese language	
201	2015	Pereira da Silva	Larynx	C	Predictor of HRQOL	EORTC-QLQ-C30 HADS Self-Evaluation of Communication Experiences after Laryngeal Cancer Questionnaire	Evaluated treatment outcomes with TL	
202	2015	Barrios	OC/ OPC	C	Predictor of HRQOL	SF-12 OHIP OIDP	Evaluate oral health related HRQOL compared with normal control population	At least 6 months after treatment, oral cancer patients had worse OHRQoL, worse physical HRQoL and similar psychological HRQoL than the general population.
203	2016	Veldhuis	OPC Larynx	C	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluated treatment outcomes in two different HNC subsites	OPC patients described more problems with fatigue and oral health.

204	2016	Almståhl	HNC	L	Functional outcome ‘xerostomia’	EORTC-QLQ-C30 EORTC-QLQ-H&N35 HADS	Evaluated objective and patient-reported experience with salivary flow after RT	Poor salivary flow related to poor emotional functioning, sticky saliva, and dyspnea. Distress levels were higher with this group.
205	2016	Dwivedi	OC/OPC	C	Functional outcomes ‘Speech’	SHI London Speech Evaluation scale	Evaluated speech acoustic outcomes after treatment	
206	2016	Tuomi	Larynx	C	Questionnaire development/ Validation	S-SECEL	Evaluated cut-off points for questionnaire use	
207	2015	Lee	HNC	C	Functional outcome ‘mouth opening /trismus’	HADS EORTC-QLQ-H&N35	Evaluated outcomes i.e. objective measure and HRQOL in HNC with mouth opening problems	Moderate chewing dysfunction with regard to different types of food were noted. Patients with objective trismus had problems with social contact, sexuality, teeth, mouth opening, dry mouth, feeling ill, nutritional supplement, and weight loss.
208	2014	Roe	HNC	C	Predictor of HRQOL; functional outcome ‘swallowing’	MDADI UWQOL	Evaluate the outcomes of parotid-sparing protocol with RT	Swallowing dysfunction occurred with protocol, lasts beyond treatment completion but results suggest patients able to cope and overcome dysfunction
209	2014	Tsai	NPC	C	Predictor of HRQOL	EORTC QLC-C30 CTCAE v4	Evaluate the outcomes of treatment in NPC	survivors with more severe neuropathy, hearing loss or xerostomia had a worse outcome on global QoL, all five functional scales, and a variety of symptomatic scales.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
210	2015	Moubayed	HNC	C	Predictor of HRQOL	HADS EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate clinical factors that can predict posttreatment depression	Pretreatment predictors of depression were smoking at diagnosis, >14 alcoholic drinks per week, T3 or T4 status, and >3 medications.
211	2015	Kraaijenga	HNC	C	Predictor of HRQOL	FOIS VHI SWAL-QOL	Evaluate outcomes of preventative and posttreatment swallowing rehabilitation programme	
212	2015	Meyer	Larynx	C	Functional outcome	HADS	Evaluated psychological distress of spouses of total laryngectomised	57% reported a high level distress and 33% reported restlessness. 21% spouses reported wanting to learn relaxation methods and 5%) had received psychological treatment.
213	2015	Trachootham	HNC	C	Clinical trial		Evaluate Nutri-gel intervention to improve eating difficulties induced by RT	
214	2015	Peker	HNC	C	Questionnaire development/ validation	LORQv3	Validation of Turkish translation of questionnaire	
215	2015	Yekaninejad	HNC	C	Questionnaire development / validation	European Organization for Research and Treatment of Cancer Oral Health Questionnaire (QLQ-OH17)	Translation into Persian language and validation	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
216	2015	Egestad	HNC	C	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35 CTCAE	Evaluate impact of BMI on RT outcomes	BMI influences HRQOL and toxicity. Overweight patients experienced more dyspnea, and dry mouth postRT. Overweight patients also received less information about food/drink during treatment.
217	2015	van Nieuwenhuizen	HNC	-	Review/editorial		Review of the relationship between HRQOL and survival	Strong evidence for a positive association between pre-treatment physical functioning and survival and between change in global QoL from pre-treatment to 6mths after treatment and survival.
218	2015	Pellegrino	HNC	C	Questionnaire development/ validation	XeQOL	Validation of Italian translation of questionnaire	
219	2015	Bian	HNC	-	Review	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Review of papers using the outcomes of IMRT using the questionnaire	maximal deterioration of most QoL scales including global health status developed intra-treatment or at the end of treatment and then followed by a gradual recovery to 1 year, 1-2 years post-IMRT, compared with baseline level.
220	2014	Bilal	HNC	C	Questionnaire development/ validation	FACT-H&N	Validation of Urdu translation for Pakistani patients	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
221	2016	Canis	OC	L	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate outcomes of reconstruction of T3 tongue defects	After reconstruction, there were fewer problems with swallowing, speech, and social eating.
222	2016	Stuiver	HNC	C	Questionnaire development/ validation	Shoulder Disability Questionnaire (SDQ), Neck Dissection Impairment Index (NDII), and the Shoulder Pain and Disability Index (SPADI)	Evaluation of psychometric properties of questionnaires	
	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
223	2016	Stenner	Parotid	C	Predictor of HRQOL	EORTC-QLQ-C30 EORTC-QLQ-H&N35	Evaluate long-term HRQOL status in patients treated by parotid surgery	
224	2014	Jung-Chun	NPC	C	Predictor of HRQOL	SF-36 EORTC-QLQ-H&N35	Evaluate the HRQOL in patients treated by different RT modalities	Different RT modalities used was significantly associated with speech difficulties, Chewing problems and dysphagia, and dry throat sensation.
225	2014	Gandhi	HNC	C	Predictor of HRQOL 'Symptom burden'	EORTC QLQ-C15-PAL	Evaluate symptom burden and HRQOL	Advanced HNC has a significant burden of symptoms.
226	2014	Pierre	OPC	C	Predictor of HRQOL	DOSS VHI-10 EORTC-QLQ-C30 EORTC QLQ-H&N35	Evaluate long-term functional outcomes and HRQOL	Speech outcomes influenced by BOT involvement and T-size; swallowing outcomes influenced by age, gender and RT.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
227	2014	Zheng	Larynx	C	Functional outcome ‘swallowing’	EORTC-QLQ-C30 EORTC QLQ-H&N35 SWAL-QOL	Evaluated patient-to-patient model and swallowing problems in patients with supraglottic laryngeal cancer	
228	2015	Rogers	HNC	C	Predictor for HRQOL	UWQOL	Evaluated outcomes in a large database, and developed tabulated view	
229	2014	Chera	HNC	-	Review		Review of patient-reported core set of symptoms to measure clinical trials	
230	2015	Cardoso	HNC	C	Predictor for HRQOL ‘Symptom burden: myofacial pain’	UWQOL	Evaluated the prevalence of myofascial pain and impact on HRQOL status	Prevalence is 1/9 patients and they have poorer HRQOL status
231	2015	Loimu	Larynx, pharynx or nasal cavity	L	Predictor for HRQOL	15D-HRQOL	Evaluated outcomes of treatment	Comparable findings to similar studies
232	2015	Pauli	HNC	L	Predictor for HRQOL; Functional outcome ‘Mouth opening’	EORTC-QLQ-C30 EORTC QLQ-H&N35 GTQ	Evaluated exercise intervention to improve mouth opening	Exercise improved mouth opening
233	2015	Johnson	HNC	C	Functional outcome ‘Mouth opening’	GTQ SF-36 HADS	Evaluated impact of trismus on HRQOL	Trismus is associated with a significant impact on HRQOL, and is seen in those with depression

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
234	2014	Rinkel	Larynx	C	Predictor for HRQOL; Functional outcome 'Swallowing, Speech, Voice'	VHI SHI SWAL-QOL EORTC QLQ-C30, EORTC QLQ-HN35 HADS	Evaluate the prevalence of dysfunction and its impact on HRQOL	Prevalence of voice, speech, and swallowing problems is high, and clearly related to quality of life and distress
235	2014	Erkal	HNC	C	Functional outcome 'Dysphagia'	EORTC QLQ-C30, EORTC QLQ-HN35	Evaluated the relationship between multiple outcomes (PRO and objective) with radiation doses	Evaluation of multiple outcome measures compliment each other and help identify late effects of RT
236	2014	Mahmood	HNC	C	Predictor of HRQOL 'Oral health'	UWQOL HN-PCI	Evaluated patient concerns regarding oral health and impact on HRQOL	3 groups of patients are identified: patients with significant chewing problems, patients without significant chewing problems who wanted to discuss dental-related concerns and patients without significant chewing problems who did not want to discuss such concerns.
237	2015	Tuomi	Larynx	C	Predictor for HRQOL		Evaluated outcomes of RT in subgroups supraglottic and glottis	
238	2014	Eickmeyer	HNC	C	Predictor for HRQOL; Functional outcomes 'shoulder dysfunction'	UWQOL FACT-H&N PSS-H&N	Evaluating outcomes of treatment in particular shoulder dysfunction with neck dissection	QOL measures demonstrated the highest level of function in no dissection group, an intermediate level of functioning with nerve sparing, and poorest function when the nerve is sacrificed.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
239	2014	Rana	HNC	C	Predictor of HRQOL ‘Coping’	Freiburg Personality Inventory Freiburg Questionnaire of Coping with Illness	Evaluated the influence of personality on coping	Personality affects coping behaviour
240	2014	Barrios	HNC	C	Predictor for HRQOL ‘Oral health’	OHIP	Evaluated the impact of malnutrition on oral-HRQOL	Malnourished status is related to poorer oral HRQOL status
241	2014	So	HNC	C	Predictor for HRQOL ‘unmet needs’	SCNS-SF34 (Chinese) FACT-H&N	Evaluate the possible mediating effects of unmet need to HRQOL	Unmet needs accounted for majority of the variance seen in total HRQOL score. Optimism, educational level, comorbidity, number of somatic symptoms, household income, eating ability, support from others, whether the cancer is under control or not and travelling time from home to hospital have direct or indirect effects, or both, on the QOL of HNC survivors.
242	2015	Singer	HNC	C	Questionnaire development/ validation	EORTC-QLC-H&N60	Pilot testing the updated version of questionnaire	After pilot, refinement of questionnaire resulted in the production of the EORTC QLQ-H&N43
	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
243	2015	Kucuk	Larynx	C	Predictor of HRQOL	BDI EORTC QLQ-C30, EORTC QLQ-HN35		Advanced stage had poorer Emotional, cognitive, and social functions. Sense and speech problems were also significantly higher in this group.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
244	2014	Shiraz	HNC	C	Predictor for HRQOL	HADS ASD WHOQoL-BREF	Evaluate psychological distress, measure impact of QOL, explore preference for psychological support.	High HADS scores on reported poorer QOL. Some with distress declined help
245	2014	Zavalishina	HNC	C	Predictor for HRQOL		Evaluated outcomes of mandibular reconstruction	
246	2014	Zhao	NPC	C	Predictor for HRQOL	EORTC QLQ-C30 EORTC QLQ-HN35	Evaluated the intervention of non-invasive extracorporeal radiofrequency (ERF) with CRT	Combination CRT and ERF had better QOL scores
247	2014	Lai	HNC	C	Predictor for HRQOL	EORTC QLQ-C30 EORTC QLQ-HN35	Evaluate QALY in IMRT intervention in NPC	QALY for NPC were lower than reference population
248	2014	Thomas	HNC	C	Predictor for HRQOL	FACT-H&N	Evaluated the impact of place of residence (rural versus urban) on outcomes	There are significant differences in life experiences of cancers survivors in urban and rural settings. Patient in rural residences had better physical, emotional and H&N specific QOL than those living in urban areas.
249	2014	Chen	HNC	C	Questionnaire development / validation	QOL-RTI/H&N	Translate and validate the Chinese version of questionnaire	
250	2014	Vilaseca	Larynx	C	Predictors for HRQOL	SF-36 UWQOL	Evaluate outcomes of TOLM	RT and ND negatively impact QOL. Elderly patients cope better with their disabilities. Worse speech in larger tumours. Swallowing problems seen with age and PORT.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
251	2014	Ryzek	OPC	C	Predictors of HRQOL	EORTC QLQ-C30, EORTC QLQ-HN35	Evaluate treatment outcomes in early versus late stage OPC	Better QOL outcomes in early OPC treated by syurgery
252	2014	Stachler	HNC	C	Questionnaire development / validation	PROMIS VHI EORTC QLQ-C30, EORTC QLQ-HN35	Evaluate the correlations between different PROs	Significant correlations between the PROMIS instruments and EORTC functional scales were observed. The fatigue PROMIS scale correlated with VHI.
253	2014	Binenbaum	HNC	C	Questionnaire development/ validation	UWQOL EORTC QLQ-C30, EORTC QLQ-HN35	Determine the minimal important differences in the respective questionnaires	
254	2014	Zhang	HNC	C	Predictors of HRQOL	UWQOL	Evaluate outcomes of reconstruction using pectoralis major versus thigh flap	Patients reconstructed with thigh had better shoulder but worse speech functions compared with pectoralis major.
255	2014	Bornbaum	Larynx	C	Questionnaire development/ validation	V-RQOL	Testing content validity of questionnaire in patients who underwent TL	Some V-RQOL questions do not align with their proposed domains. An alternative scoring algorithm may be warranted for alaryngeal populations

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
256	2014	Koch	HNC	C	Predictors of HRQOL ‘Need for psychological support’	FACT; Miller Behavioral Style Scale General Perceived Self-Efficacy Scale Patient Health Questionnaire-9 (PHQ-9) Hornheider-Fragebogen short version (HFB)	Explored the issues of need for psychological support and employment in HNC survivorship	Many patients do not return to employment posttreatment. Current unemployment was associated with harder physical work before cancer diagnosis, surgical treatment, and current risky alcohol consumption. Unemployed survivors reported decreased FACT functional and social well-being and higher PHQ depression scores.
257	2014	Eadie	HNC	C	Questionnaire development/ validation	Communicative Participation Item Bank (CPIB),	Determine how a new self-report outcome measure of communicative participation related to validated HRQOL	A stronger correlation was found between the CPIB and the VHI-10 compared with the correlation with UWQOL.
258	2015	Rogers	HNC	C	Predictors for HRQOL; Functional outcome ‘Intimacy’	UWQOL HN-PCI	Determine the prevalence of intimacy related concern/unmet need in disease-free posttreatment patients attending routine clinics	15% reported problems of considerable /some concern or selected intimacy/sexuality on the PCI
259	2014	Fang	HNC	C	Predictors of HRQOL ‘Appearance’	UWQOL (appearance)	Evaluated outcomes of a local flap technique	
260	2015	Van Loon	OPC	C	Predictors of HRQOL			Patients who needed PORT had a worse outcome and patients treated with TORS only

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
261	2014	Lazarus	HNC	C	Predictors of HRQOL	EAT-10 MDADI SHI EORTC H&N35	Evaluate outcomes of CRT	Comparable results obtained with similar studies.
262	2014	Yang	HNC	C	Predictors of HRQOL	UWQOL OHIP-14	Evaluate outcomes of using fibula flap in mandibular reconstruction	With UWQOL, the best-scoring domain was mood, whereas the lowest scores were for chewing and saliva. With OHIP-14, the lowest-scoring domain was social disability, followed by handicap, and psychological disability.
263	2014	Verdonck-de Leeuw	HNC	L	Predictors of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate HRQOL status from diagnosis to 2 years follow-up in those treated with CRT	HRQOL of HNSCC patients during the first 2 years after CRT is different for survivors compared to control group.
264	2014	Klein	HNC	-	Review/Editorial		Review papers reporting HRQOL in those receiving CRT	HRQoL declines after treatment but recovers to baseline levels, generally within 12mths. Xerostomia-related HRQoL deficits may remain long-term. Combined CRT showed a trend toward worse HRQoL compared with RT alone. IMRT had better HRQOL compared with other RT modalities.
265	2014	Hoffman	HNC	L	Clinical trial		Randomized, placebo-controlled trial evaluating the efficacy of GM-CSF in reducing mucosal injury and symptom burden from curative RT	Concurrent GM-CSF administration during HN RT does not significantly improve patient-reported QoL symptom burden

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
266	2014	Pottel	HNC	C	Predictors of HRQOL	Vulnerable Elders Survey-13 (VES-13), G8 and the Combined Screening Tool	Evaluate screening tools for elderly in treatment planning and correlation with HRQOL	The G8 remains the best screening tool, which correlates with HRQOL
267	2014	Oliveira	HNC	C	Functional outcome ‘Pain’	BPI EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate the severity of pain and its impact on HRQOL in untreated HNC patients	Severity of pain is statistically related to the advanced stages of cancer and directly affects HRQOL
	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
268	2014	Bottomley	Larynx HPX	L	Clinical trial		RCT 2 arm of different CRT regimes	
269	2015	Arias	Larynx	C	Predictors of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35 VHI	Evaluate outcomes by comparing surgery versus RT for early glottis cancer	Voice quality, emotional functioning, and social contact were better in the RT group
270	2014	Maxwell	OPC	C	Predictors of HRQOL	UWQOL	Evaluate outcomes of OPC (HPV + versus HPV-) treated by surgery versus RT	HPV+ patients had better baseline and posttreatment overall QOL. The overall and category specific QOL scores for HPV+ patients were not affected by primary treatment modality.
271	2014	Lango	HNC	C	Functional outcome	SWAL-QOL EuroQOL-5D-3L	Evaluate baseline dysphagia and its impact on HRQOL, and survival	Baseline dysphagia affects multiple domains of QOL and predictive of disease recurrence and disease-related death.
272	2014	Chen	HNC	C	Predictors of HRQOL	UWQOL	Evaluate the long-term outcomes treated with IMRT	84% reported HRQOL was "much better" or"somewhat better" than at the time of cancer diagnosis. 82% rated their overall QOL as "outstanding" or "very good."

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
273	2014	Fang	Parotid	C	Predictors of HRQOL	UWQOL	Evaluate outcomes of surgery	Parotidectomy had limited impact on HRQOL
274	2014	Lazarus	OC	C	Predictors of HRQOL	Head and Neck Cancer Inventory	Evaluate outcomes of tongue exercise intervention in postCRT in tongue cancers	The experimental group demonstrated greater QOL impairment in the social disruption domain following treatment, whereas the control group demonstrated a slight improvement in functioning
	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
275	2014	Ma	NPC	C	Predictors of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate the correlation between comprehensive nutritional status and HRQOL in patients receiving IMRT	A positive correlation seen between comprehensive nutritional status with QoL scores of functional and global QoL scales. Patients with different nutritional status had different QoL.
276	2015	Ringash	HNC	-	Review/Editorial		Reports outcome of National Cancer Institute committee meeting regarding set of instruments suitable for widespread application in the conduct of clinical trials for HNC	
277	2014	Heutte	HNC	-	Review/Editorial		Review articles using Quality of life tools in head and neck oncology	

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
278	2014	Linardoutsos	HNC	C	Questionnaire development/ Validation	UWQOL	Translate and validate Greek version of UWQOL	
279	2014	Elfring	HNC	C	Predictor for HRQOL	EORTC QLQ-H&N35	Evaluate the impact of nerve transection on HRQOL	No significant differences between patient nerve status and HRQOL outcomes for speech, sticky saliva and use of feeding tubes
280	2014	van der Meulen	HNC	L	Clinical trial	CES-D EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate the nurse-led psychosocial intervention	Intervention improved several domains of HRQOL and depressive symptoms in HNC patients
281	2014	Aarstad	HNC	C	Predictors of HRQOL	GHQ EORTC QLQ-C30 EORTC QLQ-H&N35		The GHQ sum scores predicted survival, and even when adjusted for HRQOL status.
282	2014	Pauli	HNC	C	Functional outcome	EORTC QLQ-C30 GTQ	Evaluated trismus posttreatment	
283	2014	Metcalfe	HNC	C	Predictors of HRQOL	UWQOL	Evaluate domains selected as 'Most important' by patients according to stage and subsite	Swallowing, chewing, speech and saliva were selected more often by late stage OC. Swallowing and saliva were more important in OPC, and taste in late stage OPC.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
284	2013	Zhang	OC	C	Predictors of HRQOL	UWQOL SF-36	Evaluate outcome of immediate mandibular reconstruction with free fibula flap	With SF-36, the lowest-scoring domain was vitality, whereas the highest scores occurred in physical role. In UWQOL, the key domains affected by surgery are chewing, speech, and appearance. Pain scores were better.
285	2014	Henry	HNC	C	Predictors of HRQOL	SCNS-SF34 FACT-G FACT-H&N HADS	Evaluate the prevalence of unmet needs, and determine predictors of unmet needs	There is an overwhelming presence of unmet psychological needs. Patients who are divorced and present low levels of physical well-being were more likely to have more unmet needs.
286	2014	Crombie	HNC	C	Predictors of HRQOL	UWQOL EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate outcomes of OC treated vy CRT versus surgery with/out adjuvant tretment	With UWQOL, surgical group recorded higher scores than the CRT only group in all domains except shoulder and Anxiety. With EORTC, surgical group recorded lower scores in all scales and items.
287	2013	Shinn	HNC	C	Functional outcomes ‘dysphagia’	MDADI	To evaluate adherence to swallowing exercises	Adherence was associated with the Physical MDADI Subscale score. However, majority of HNC patients are non-adherent to swallowing exercise regime.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
288	2014	Laoufi	Larynx	C	Functional outcomes ‘Speech/ Voice’	VHI-30 EORTC QLQ-H&N35	To evaluate outcomes following treatment by RT versus transoral laser surgery (LS)	Long-term subjective voice-related quality of life was worse after LS, but no difference in other domains.
289	2014	Stier-Jarmer	HNC	-	Review/Editorial		Review literature regarding outcomes measured by clinical trials based on the ICF-HNC	
290	2014	Risberg-Berlin	Larynx	L	Functional outcome ‘Smell function’	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate the Nasal Airflow-Inducing Manoeuvre (NAIM) intervention for improving smell function	Itervention has potential to improve smell function to baseline values after treatment.
291	2014	Goldstein	HNC	-	Review/Editorial		Review papers relating to self-reported ‘Shoulder dysfunction’	Seven questionnaires available.
292	2014	Singer	Larynx	C	Predictors of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate HRQOL status at 1y post TL	QOL decreases initially after laryngectomy; some QOL areas recover slowly over the year after surgery, and some remain significantly worse than at baseline. Areas that did not recover to baseline were physical functioning, role functioning, social functioning, fatigue, dyspnea, appetite loss, financial difficulties, senses, speech, and social contact, whereas global health status, coughing, and weight improved.

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
293	2014	Kendall	OPC	C	Predictor of HRQOL; Functional outcome ‘dysphagia’	UWQOL MDADI	Evaluate outcome at 1 year following CRT treatment	Patient perception of the impact of swallowing function on quality of life does not correlate well with actual physiologic functioning.
294	2014	Oates	OPC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate outcomes	Comparable results to similar studies
295	2014	Pierre	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate long-term outcomes of microvascular reconstruction in OC/OPC	Dysphagia scores were predicted by RT, age and gender. Speech scores were predicted by BOT and T stage.
296	2014	Nagy	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35 UWQOL	Evaluate the impact of post-treatment intraoral and extraoral rehabilitation	HRQOL after rehabilitation was significantly enhanced as compared to the post-treatment status, in all domains of both questionnaires
297	2014	Ch’ng	HNC	C	Predictor of HRQOL	EORTC QLQ-C30 EORTC QLQ-H&N35	Evaluate the effect of PORT-associated morbidity	PORT is associated with reduced global health status, increased xerostomia, and marginally increased levels of fatigue at 6 months posttreatment for oral cavity cancer
	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
298	2014	de Almeida	OPC	C	Functional outcomes	MDADI modified Velopharyngeal Insufficiency Quality of Life (VPIQL)		adjuvant radiotherapy was a predictor of poor swallowing

	Year	Author	Cohort	Des	Type	PRO	Purpose	Outcome
299	2014	Qui	HNC	C	Predictor of HRQOL	UWQOL	Evaluate outcomes in advanced stage HNC treated by surgery + reconstruction versus radical RT	

Abbreviations for PRO:

ASEX: Arizona Sexual Experiences Scale; Acute Stress Disorder (ASD) Scale); Beck's Depression Inventory (BDI); Beck's Anxiety Inventory (BAI); Brief IQP: Brief Illness Perception Questionnaire; Brief ICF Core Set for head and neck cancer (ICF-HNC)Chemosensory Complaint Score (CCS); Caregiver Strain Index (CSI); Common Terminology Criteria for Adverse Events (CTCAE); Distress Thermometer (DT); Dysphagia Outcome and Severity Scale (DOSS); Euroqol-5 dimensions (EQ-5D); Eating assessment tool (EAT-10); Functional Assessment of Cancer Therapy-Head and Neck Cancer; (FACT-H&N;)Functional Oral Intake Scale (FOIS); Functional Rehabilitation Outcomes Grade(FROG); Gothenburg Trismus Questionnaire (GTQ); General health questionnaire (GHQ); Hospital Anxiety and Depression Scale (HADS); Head Neck Cancer Inventory (HNCI); Head and Neck Radiotherapy Questionnaire (HNRQ); Head and Neck QOL instrument (HNQOL); Health Utilities Index Mark 3 (HUI3); Liverpool Oral Rehabilitation Questionnaire (LORQ)

M. D. Anderson Dysphagia Inventory (MDADI); Medical Outcomes Short-Form Health Survey (MOSHS); M. D. Anderson Symptom Inventory-Head and Neck Module (MDASI-HN); Neck Dissection Impairment Index (NDII); Oral Health Impact Profile (OHIP); Oral Mucositis Weekly; Oral Impacts on Daily Performances (OIDP) ; Performance Status Scale (PSS): Normalcy of Diet; Performance Status Scale-Head and Neck Cancer (PSS-H&N); Posttraumatic Growth Inventory (PTGI) ; Patient-Reported Outcomes Measure Information System (PROMIS); Quality of Life in Adult Cancer Survivors (QLACS); Quick Inventory of Depressive Symptoms (QIDS); Quality OF Life Questionnaire-Head and Neck Cancer (QOL-H&S); Quality of life (WHOQoL-BREF); Radiation Therapy Instrument and the Head & Neck Module (QOL-RTI/H&N); Rosenberg Self-Esteem Scale (RSES); Speech Handicap Index (SHI); Survivors Unmet Needs Survey (SUNS); Short-Form Health Survey (SF-8); Short-Form Supportive Care Needs Questionnaire (SCNS-SF34); Spitzer Quality of Life Index (SQLI); Swedish Self-Evaluation of Communication Experiences after Laryngeal Cancer (S-SECEL)V-RQOL:; Voice-related quality of life; VHI: Voice Handicap Index; VHNSS 2.0: Vanderbilt Head and Neck Symptom Survey version 2.0; Voice Handicap Index-10 (VHI-10); Swallowing; Quality of Life Questionnaire (SWAL-QOL); Xerostomia Questionnaire (XQ)

Appendix 2. The Patient Concerns Inventory (version 1)

THE HEAD AND NECK PATIENT CONCERNS INVENTORY

Please choose from the list of issues you would specifically like to talk about in the consultation/whilst at clinic today. You can choose more than one option: (Tick the box ☑)

- ☐ Activity
- ☐ Anger
- ☐ Anxiety
- ☐ Appearance
- ☐ Appetite
- ☐ Bowel habit (diarrhoea or constipation)
- ☐ Breathing
- ☐ Carer
- ☐ Chewing/eating
- ☐ Dental health/teeth
- ☐ Depression
- ☐ Energy levels
- ☐ Fatigue/tiredness
- ☐ Fear of the cancer coming back
- ☐ Financial / benefits
- ☐ Hearing
- ☐ Home care/district nurse support
- ☐ Intimacy
- ☐ Lifestyle issues (smoking/alcohol)
- ☐ Memory
- ☐ Mobility
- ☐ Mood
- ☐ Mouth opening
- ☐ Nausea
- ☐ Pain in head and neck
- ☐ Pain elsewhere
- ☐ PEG tube
- ☐ Recreation
- ☐ Regret about treatment
- ☐ Relationships
- ☐ Salivation
- ☐ Sex
- ☐ Shoulder
- ☐ Sleeping
- ☐ Smell
- ☐ Speech/voice/being understood
- ☐ Spiritual /religious aspects
- ☐ Support for my family
- ☐ Swallowing
- ☐ Swelling
- ☐ Taste
- ☐ Temperament and personality
- ☐ Vomiting/sickness
- ☐ Weight
- ☐ Wound healing
- ☐ Anything else

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Tick the box ☑)

- ☐ Chaplain
- ☐ Clinical nurse specialist
- ☐ Dental hygienist
- ☐ Dentist
- ☐ Dietician
- ☐ Family doctor
- ☐ Nursing staff
- ☐ Occupational therapist
- ☐ Oral rehabilitation team
- ☐ Physiotherapist
- ☐ Radiotherapist/oncologist
- ☐ Social worker
- ☐ Speech and language therapist
- ☐ Surgeon
- ☐ Anyone else

Appendix 3. The Patient Concerns Inventory (version 2). Newly added items are in CAPITALS.

THE HEAD AND NECK PATIENT CONCERNS INVENTORY

Please choose from the list of issues you would specifically like to talk about in the consultation/whilst at clinic today. You can choose more than one option: (Tick the box ☑)

☐ Activity
☐ Angry
☐ Anxiety
☐ Appearance
☐ Appetite
☐ Bowel habit (diarrhoea or constipation)
☐ Breathing
☐ Carer
☐ CANCER TREATMENT
☐ Chewing/eating
☐ Dental health/teeth
☐ COPING
☐ COUGHING
☐ Depression
☐ DEPENDANTS / CHILDREN
☐ Energy levels
☐ Fatigue/tiredness
☐ FEAR OF ADVERSE EVENTS
☐ Fear of the cancer coming back
☐ Financial / benefits
☐ Hearing
☐ Home care/district nurse support
☐ INDIGESTION
☐ Intimacy
☐ Lifestyle issues (smoking/alcohol)
☐ Memory
☐ Mobility
☐ Mood
☐ Mouth opening
☐ MUCUS PRODUCTION
☐ Nausea
☐ Pain in head and neck
☐ Pain elsewhere
☐ PEG tube
☐ Recreation
☐ Regret about treatment
☐ REGURGITATION
☐ Relationships
☐ Salivation
☐ Sexuality
☐ SELF-ESTEEM
☐ Shoulder
☐ Sleeping
☐ Smell
☐ Speech/voice/being understood
☐ Spiritual /religious aspects
☐ Support for my family
☐ Swallowing
☐ Swelling
☐ Taste
☐ Temperament and personality
☐ Vomiting/sickness
☐ Weight
☐ Wound healing
☐ Anything else / Others

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Tick the box ☑)

☐ Chaplain
☐ Clinical nurse specialist
☐ Dental hygienist
☐ Dentist
☐ Dietician
☐ Family doctor
☐ Nursing staff
☐ Occupational therapist
☐ Oral rehabilitation team
☐ Physiotherapist
☐ Radiotherapist/oncologist
☐ Social worker
☐ Speech and language therapist
☐ Surgeon
☐ Anyone else

Appendix 4. The Patient Concerns Inventory (version 3). Newly added items are in CAPITALS.

THE HEAD AND NECK PATIENT CONCERNS INVENTORY

Please choose from the list of issues you would specifically like to talk about in the consultation/whilst at clinic today. You can choose more than one option: (Tick the box ☑)

☐ Activity
☐ Angry
☐ Anxiety
☐ Appearance
☐ Appetite
☐ Bowel habit (diarrhoea or constipation)
☐ Breathing
☐ Carer
☐ Cancer treatment
☐ Chewing/eating
☐ Dental health/teeth
☐ DIZZINESS
☐ Coping
☐ Coughing
☐ Depression
☐ Dependents / Children
☐ Energy levels
☐ Fatigue/tiredness
☐ Fear of adverse events
☐ Fear of the cancer coming back
☐ Financial / benefits
☐ Hearing
☐ Home care/district nurse support
☐ Indigestion
☐ Intimacy
☐ Lifestyle issues (smoking/alcohol)
☐ Memory
☐ Mobility
☐ Mood
☐ Mouth opening
☐ Mucus production
☐ Nausea
☐ Pain in head and neck
☐ Pain elsewhere
☐ PEG tube
☐ Recreation
☐ Regret about treatment
☐ Regurgitation
☐ Relationships
☐ Salivation
☐ Sexuality
☐ Self-esteem
☐ Shoulder
☐ SKIN RASH
☐ Sleeping
☐ Smell
☐ Speech/voice/being understood
☐ Spiritual /religious aspects
☐ Support for my family
☐ Swallowing
☐ Swelling
☐ Taste
☐ Temperament and personality
☐ Vomiting/sickness
☐ Weight
☐ Wound healing
☐ Anything else / Others

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Tick the box ☑)

☐ Chaplain
☐ Clinical nurse specialist
☐ Dental hygienist
☐ Dentist
☐ Dietician
☐ Family doctor
☐ Nursing staff
☐ Occupational therapist
☐ Oral rehabilitation team
☐ Physiotherapist
☐ Radiotherapist/oncologist
☐ Social worker
☐ Speech and language therapist
☐ Surgeon
☐ Anyone else

Appendix 5. Research Ethics Approval

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Liverpool East

HRA NRES Centre Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7827
Fax: 0161 625 7299

14 June 2012

Professor Simon Rogers
Consultant Maxillofacial Surgeon
University Hospital Aintree NHS Foundation Trust
Maxillofacial Unit
University Hospital Aintree
L9 7AT

Dear Professor Rogers,

Study title:	**Development and Evaluation of the Head and Neck Patient Concerns Inventory in Maxillofacial and Otorhinolaryngology Oncology Settings**
REC reference:	**11/H1002/7**

Thank you for sending the progress report for the above study dated 10 June 2012. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research as described in the application and protocol agreed by the REC, taking account of any substantial amendments.

11/H1002/7: **Please quote this number on all correspondence**

Yours sincerely

Ms Josephine Foxall Dant
Assistant Co-ordinator

E-mail: Jo.foxall-dant@northwest.nhs.uk

Appendix 6. Patient information sheet

Patient Concerns Inventory for Head & Neck Cancer Patients in Outpatients Clinics

Aintree University Hospitals NHS Foundation Trust

WELCOME

This 'Information Leaflet' has been designed to tell you about the Patients Concerns Inventory (PCI) and the study that we are conducting related to this.

What is the Patient Concerns Inventory?

The Patients Concerns Inventory (PCI) is used in the cancer (oncology) out-patients clinics. It is a list of 55 issues that patients and their carers might wish to mention in their consultation and a list of 15 team members they might specifically wish to see or be referred on to.

The PCI has been developed in partnership with patients in our regional unit and has been successfully trialled in head and neck cancer patients in the Maxillofacial Surgery unit.

Why do we need a PCI?

We have found out from patients and carers that there are many issues that they would like to bring up in their consultation. However during the consultation they may forget. The PCI acts as a prompt.

During a trial of the PCI patients have made the following comments:

- *'it made it a bit more personal'*
- *'reminds me of the points I want discuss'*
- *'allows consultation to get straight to the point'*
- *'encourages me to talk about things I would otherwise not discuss'*
- *'if it helps you its fine by me'*

Which patients use the PCI?

All patients treated for head and neck cancer attending the outpatient clinic during their follow-up at the Regional Cancer Centre are encouraged to use the PCI.

What does this study aim to do?

We would like to evaluate the application and usefulness of the PCI in head and neck cancer patients managed through the ENT and maxillofacial units.

When is the PCI completed?

The PCI is filled in before your consultation.

What is involved?

1. First you need to register in the normal way at the clinic reception desk.

2. At this point, you may be invited to complete the PCI by a researcher. This is voluntary; you do not have to do it. If you don't take part this will not affect the quality of care you receive.

3. Upon the invitation to participate, you will be taken by the researcher to a separate room in the clinic to do the PCI, which is completed in a paper form. It takes approximately 10 minutes to complete along with other questionnaires. The researcher is usually present to assist if required.

4. Depending on the study design, information from the PCI may or not be made available to your doctor. However, you may discuss the concerns that you have highlighted through the PCI as part of a routine clinic visit.

5. Your consultation will be sound recorded. Only one copy of the audiotaped consultation is made and is used only for the purpose of this study.

6. You will **NOT** lose your place in the clinic order. Once you have completed the PCI you will be seated back in the waiting area ready for your consultation.

7. Once you have completed your consultation, you will be asked to recall the items discussed during the consultation in a short checklist.

8. You will be given a satisfaction questionnaire with self-addressed envelope for you to complete and post back within 1 week of your consultation.

9. All information is confidential. No individuals name or other details are used. Identification is by NHS number only. Access to the information is password-protected and limited separate room in the clinic to do the PCI.

Ethical approval and your consent would be sought to use this information for educational purposes.

THANK YOU FOR YOUR INTEREST AND SUPPORT

Appendix 7. Patient consent form

Aintree University Hospitals NHS
NHS Foundation Trust

Regional Maxillofacial Unit
Aintree University Hospitals NHS Foundation Trust

Appointment date:	NHS number:	

CONSENT FORM

PATIENTS CONCERNS INVENTORY (PCI)
FOR HEAD AND NECK CANCER STUDY

Please read each statement carefully and complete the option that represents your choice.

I have read the information sheet on the use of PCI.	YES	NO
I understand that participation in this study is voluntary.	YES	NO
I confirm that I understand the purpose of this study.	YES	NO
I agree to use the PCI. I understand that the PCI information may or may not be passed on to my consultant on the day.	YES	NO
I agree to have my consultation audiotaped. I understand that any identifiable information in the recorded consultation will be erased to maintain patient-doctor confidentiality. The recorded consultation will be transcribed in written form for the purpose of this study. Only one recorded copy is retained and this will be stored in a secure facility for duration of 5 years to allow collaborative members of the research team to listen to the audiotaped consultation in the future.	YES	NO
I give permission for the researcher to contact me after the appointment for the purpose of conducting a satisfaction survey.	YES	NO
I give permission for my medical and related records to be examined and information taken for confidential use in this study.	YES	NO

Name of patient	Date	Signature
Consented by	Date	Signature

Appendix 8. University of Washington Quality of Life, version 4

Date: _____/_____/_____ Study Number: |__|__|__|__|__|__|__|__|

University of Washington Quality of Life Questionnaire (UW-QOL v4)

This questionnaire asks about your health and quality of life ***over the past seven days****. Please answer all of the questions by ticking one box for each question.*

---

1. **Pain**. (Tick one box: ☑)
   - ☐ I have no pain. (100)
   - ☐ There is mild pain not needing medication. (75)
   - ☐ I have moderate pain - requires regular medication (e.g. paracetamol). (50)
   - ☐ I have severe pain controlled only by prescription medicine (e.g. morphine). (25)
   - ☐ I have severe pain, not controlled by medication. (0)

2. **Appearance**. (Tick one box: ☑)
   - ☐ There is no change in my appearance. (100)
   - ☐ The change in my appearance is minor. (75)
   - ☐ My appearance bothers me but I remain active. (50)
   - ☐ I feel significantly disfigured and limit my activities due to my appearance. (25)
   - ☐ I cannot be with people due to my appearance. (0)

3. **Activity**. (Tick one box: ☑)
   - ☐ I am as active as I have ever been. (100)
   - ☐ There are times when I can't keep up my old pace, but not often. (75)
   - ☐ I am often tired and have slowed down my activities although I still get out. (50)
   - ☐ I don't go out because I don't have the strength. (25)
   - ☐ I am usually in bed or chair and don't leave home. (0)

4. **Recreation**. (Tick one box: ☑)
   - ☐ There are no limitations to recreation at home or away from home. (100)
   - ☐ There are a few things I can't do but I still get out and enjoy life. (75)
   - ☐ There are many times when I wish I could get out more, but I'm not up to it. (50)
   - ☐ There are severe limitations to what I can do, mostly I stay at home and watch TV. (25)
   - ☐ I can't do anything enjoyable. (0)

5. **Swallowing**. (Tick one box: ☑)
   - ☐ I can swallow as well as ever. (100)
   - ☐ I cannot swallow certain solid foods. (70)
   - ☐ I can only swallow liquid food. (30)
   - ☐ I cannot swallow because it "goes down the wrong way" and chokes me. (0)

6. **Chewing**. (Tick one box: ☑)
   - ☐ I can chew as well as ever. (100)
   - ☐ I can eat soft solids but cannot chew some foods. (50)
   - ☐ I cannot even chew soft solids. (0)

7. **Speech**. (Tick one box: ☑)
    - ☐ My speech is the same as always. (100)
    - ☐ I have difficulty saying some words but I can be understood over the phone. (70)
    - ☐ Only my family and friends can understand me. (30)
    - ☐ I cannot be understood. (0)

8. **Shoulder**. (Tick one box: ☑)
    - ☐ I have no problem with my shoulder. (100)
    - ☐ My shoulder is stiff but it has not affected my activity or strength. (70)
    - ☐ Pain or weakness in my shoulder has caused me to change my work / hobbies. (30)
    - ☐ I cannot work or do my hobbies due to problems with my shoulder. (0)

9. **Taste**. (Tick one box: ☑)
    - ☐ I can taste food normally. (100)
    - ☐ I can taste most foods normally. (70)
    - ☐ I can taste some foods. (30)
    - ☐ I cannot taste any foods. (0)

10. **Saliva**. (Tick one box: ☑)
    - ☐ My saliva is of normal consistency. (100)
    - ☐ I have less saliva than normal, but it is enough. (70)
    - ☐ I have too little saliva. (30)
    - ☐ I have no saliva. (0)

11. **Mood**. (Tick one box: ☑)
    - ☐ My mood is excellent and unaffected by my cancer. (100)
    - ☐ My mood is generally good and only occasionally affected by my cancer. (75)
    - ☐ I am neither in a good mood nor depressed about my cancer. (50)
    - ☐ I am somewhat depressed about my cancer. (25)
    - ☐ I am extremely depressed about my cancer. (0)

12. **Anxiety**. (Tick one box: ☑)
    - ☐ I am not anxious about my cancer. (100)
    - ☐ I am a little anxious about my cancer. (70)
    - ☐ I am anxious about my cancer. (30)
    - ☐ I am very anxious about my cancer. (0)

Which issues have been the most important to you during the past 7 days?
Tick ☑ **up to 3 boxes.**

☐ Pain
☐ Appearance
☐ Activity
☐ Recreation
☐ Swallowing
☐ Chewing
☐ Speech
☐ Shoulder
☐ Taste
☐ Saliva
☐ Mood
☐ Anxiety

GENERAL QUESTIONS

Compared to the month before you developed cancer, how would you rate your health-related quality of life? (Tick one box: ☑)

☐ Much better	(100)
☐ Somewhat better	(75)
☐ About the same	(50)
☐ Somewhat worse	(25)
☐ Much worse	(0)

In general, would you say your **health-related quality of life** <u>during the past 7 days</u> has been: (Tick one box: ☑)

☐ Outstanding	(100)
☐ Very good	(80)
☐ Good	(60)
☐ Fair	(40)
☐ Poor	(20)
☐ Very poor	(0)

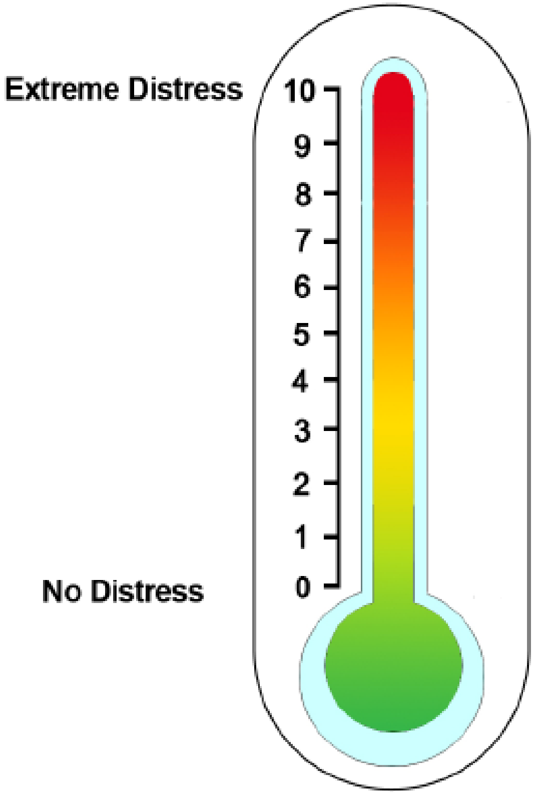
Overall quality of life includes not only physical and mental health, but also many other factors, such as family, friends, spirituality, or personal leisure activities that are important to your enjoyment of life. Considering everything in your life that contributes to your personal well-being, rate your **overall quality of life** <u>during the past 7 days</u>. (Tick one box: ☑)

☐ Outstanding	(100)
☐ Very good	(80)
☐ Good	(60)
☐ Fair	(40)
☐ Poor	(20)
☐ Very poor	(0)

Please describe any other issues (medical or nonmedical) that are important to your quality of life and have not been adequately addressed by our questions (you may attach additional sheets if needed).

Appendix 9. Distress thermometer

First please circle the number (0-10) that best describes how much distress you have been experiencing in the past week including today.



Appendix 10. Princess Margaret Princess Margaret Hospital Patient Satisfaction with Physician Questionnaire (PSQ-MD)

NHS number																

Princess Margaret Hospital Patient Satisfaction with Physician Questionnaire (PSQ-MD)

This form contains a list of questions about your views on the last visit you made to the doctor. Please answer all of them. Your answers are anonymous and are kept entirely confidential, so feel free to say whatever you wish. For each question please **circle** the answer that is nearest your opinion.

For example:

1 *This doctor listened carefully.*
Strongly agree / Agree / Disagree / Strongly disagree / [✓ Does not apply]

1 ***I will follow the doctor's advice because I think s/he is absolutely right.***
Strongly agree Agree Disagree Strongly disagree Does not apply

2 ***The doctor did not take my problems very seriously.***
Strongly agree Agree Disagree Strongly disagree Does not apply

3 ***The doctor considered my individual needs when treating my condition.***
Strongly agree Agree Disagree Strongly disagree Does not apply

4 ***The doctor did not give me all the information I thought I should have been given.***
Strongly agree Agree Disagree Strongly disagree Does not apply

5 ***The doctor went straight to my medical problem without greeting me first.***
Strongly agree Agree Disagree Strongly disagree Does not apply

6 ***The doctor used words I did not understand.***
Strongly agree Agree Disagree Strongly disagree Does not apply

7 ***There was not enough time to tell the doctor everything I wanted.***
Strongly agree Agree Disagree Strongly disagree Does not apply

8 ***I feel the doctor did not spend enough time with me.***
Strongly agree Agree Disagree Strongly disagree Does not apply

9 ***It seemed to me that the doctor was not really interested in my emotional well-being.***
Strongly agree Agree Disagree Strongly disagree Does not apply

10 ***I really felt understood by my doctor.***
Strongly agree Agree Disagree Strongly disagree Does not apply

11 ***After my last visit with my doctor, I feel much better about my concerns.***
Strongly agree Agree Disagree Strongly disagree Does not apply

12 ***The doctor was not friendly to me.***
Strongly agree Agree Disagree Strongly disagree Does not apply

13 ***I understand my illness much better after seeing this doctor.***
Strongly agree Agree Disagree Strongly disagree Does not apply

14 ***This doctor was interested in me as a person and not just my illness.***
Strongly agree Agree Disagree Strongly disagree Does not apply

15 ***I feel I understand pretty well the doctor’s plan for helping me.***
Strongly agree Agree Disagree Strongly disagree Does not apply

16 ***I would not recommend this doctor to a friend.***
Strongly agree Agree Disagree Strongly disagree Does not apply

17 ***The doctor seemed to brush off my questions.***
Strongly agree Agree Disagree Strongly disagree Does not apply

18 ***The doctor should have told me more about how to care for my condition.***
Strongly agree Agree Disagree Strongly disagree Does not apply

19 ***After talking with the doctor, I have a good idea of what changes to expect in my health over the next few weeks and months.***
Strongly agree Agree Disagree Strongly disagree Does not apply

20 ***The doctor told me to call back if I had any questions or problems.***
Strongly agree Agree Disagree Strongly disagree Does not apply

21 ***I felt the doctor was being honest with me.***
Strongly agree Agree Disagree Strongly disagree Does not apply

22 ***The doctor explained the reason why the treatment was recommended for me.***
Strongly agree Agree Disagree Strongly disagree Does not apply

23 ***It seemed to me that the doctor was not really interested in my physical well-being.***
Strongly agree Agree Disagree Strongly disagree Does not apply

24 ***The doctor should have shown more interest.***
Strongly agree Agree Disagree Strongly disagree Does not apply

Appendix 11. Non-validated patient-reported outcomes of consultation

Date		NHS number	

POST-CONSULTATION QUESTIONNAIRE

Thank you for taking part in this short follow up survey regarding your most recent outpatient clinic consultation. This questionnaire is aimed at understanding your perspectives on your perceived views of the consultation. Please read carefully and answer the most representative response for the relevant question. Thank you for your participation.

1. From your perspectives, what were the items of your concern that you had wanted to discuss with your doctor during the most recent consultation? Please write in the space allocated below:

2. How would you rate the extent to which these concerns were addressed?

   Strongly agree　Agree　Disagree　Strongly disagree　Does not apply

3. Were you able to see or be referred to the healthcare professional or individual you had hoped to see during your most recent the consultation?

   YES　NO

4. To what degree would you agree to the statement: My expectations of the consultation were fulfilled in the most recent outpatient clinic visit.

   Strongly agree　Agree　Disagree　Strongly disagree　Does not apply

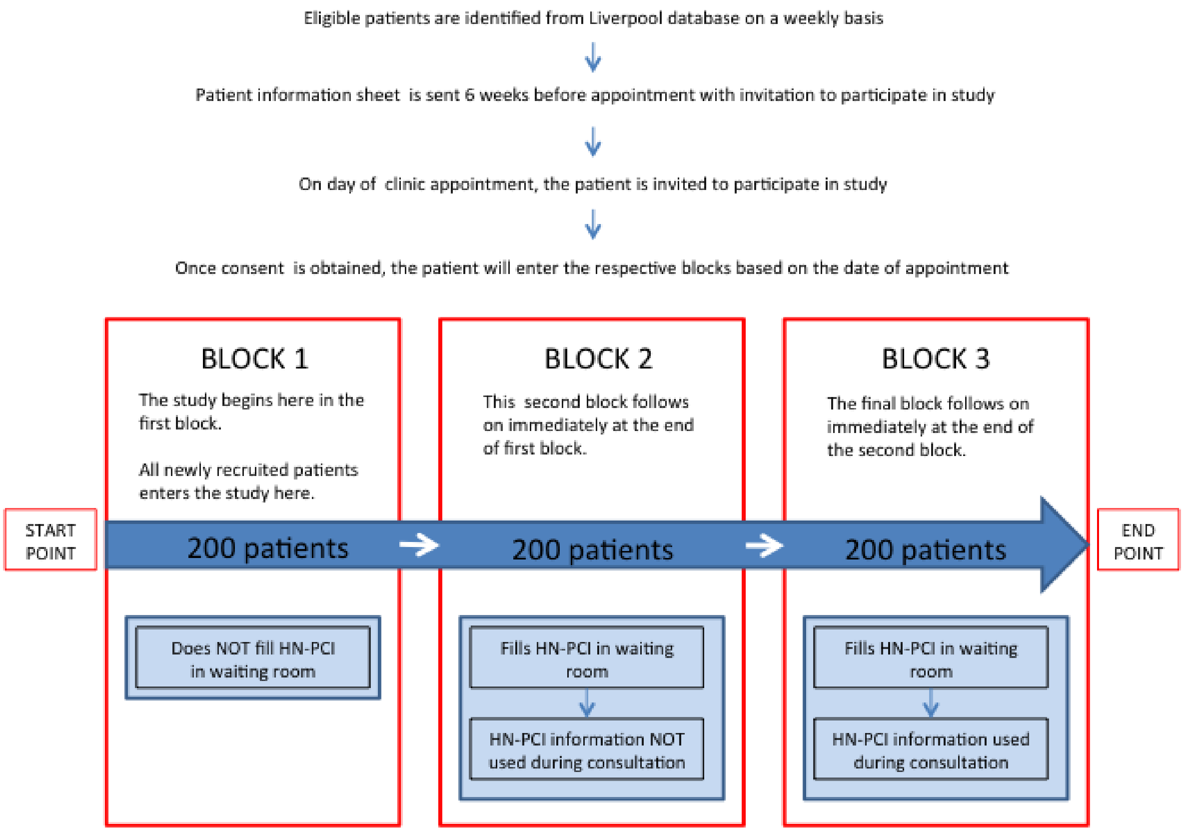
5 To what degree would you agree to the statement: I felt the PCI was intrusive.

Strongly agree　Agree　Disagree　Strongly disagree　Does not apply

6 To what degree would you agree to the statement: I felt the PCI was unhelpful.

Strongly agree　Agree　Disagree　Strongly disagree　Does not apply

Appendix 12. Study design



Eligible patients are identified from Liverpool database on a weekly basis

Patient information sheet is sent 6 weeks before appointment with invitation to participate in study

On day of clinic appointment, the patient is invited to participate in study

Once consent is obtained, the patient will enter the respective blocks based on the date of appointment

The study begins here in the first block.

All newly recruited patients enters the study here.

This second block follows on immediately at the end of first block.

The final block follows on immediately at the end of the second block.

Appendix 13: Published pilot study

Ghazali N, Roe B, Lowe D, Rogers SN. Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxillofac Surg. 2013 Jun;51(4):294-300. doi: 10.1016/j.bjoms.2012.08.002.

Available online at www.sciencedirect.com

SciVerse ScienceDirect

British Journal of Oral and Maxillofacial Surgery 51 (2013) 294–300

BRITISH
Journal of
Oral and
Maxillofacial
Surgery

www.bjoms.com

Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study

N. Ghazali[a,*], B. Roe[b], D. Lowe[b], S.N. Rogers[b]

[a] *Regional Maxillofacial Unit, University Hospital Aintree, Longmoor Lane, Liverpool L9 1AE, UK*
[b] *Evidence-Based Practice Research Centre (EPRC), Faculty of Health, Edge Hill University, St Helens Road, Ormskirk L39 4QP, UK*

Accepted 8 August 2012
Available online 24 August 2012

Abstract

The Patient Concerns Inventory (PCI) is a tool that enables patients to highlight issues they wish to discuss, and helps to uncover concerns that might otherwise be missed. Previous PCI studies have involved direct observation of a consultation by one assessor using a coding method based rigidly on items listed on the inventory. This pilot study explores the feasibility of developing a standardised method of scoring which can be used to evaluate it. We prospectively recruited 40 disease-free patients attending 42 routine outpatient consultations after treatment for head and neck cancer. Before the consultation they completed the University of Washington quality of life questionnaire and the PCI. Nineteen consultations were audio-recorded and transcribed, and 2 assessors used a thematic framework to analyse the content of the consultation to find the number and types of concerns, the professionals involved, and the clinical outcomes. The assessors were in agreement about 80% (65/81) of the audio-recordings. The mean number of items of concern highlighted on the PCI before consultation was 5.95, median (IQR) 4(3–8) in contrast to 6.47, median (IQR) 6(4–9) for those discussed; for involvement of professionals it was 0.74, median (IQR) 0(0–1) in contrast to 2.63, median (IQR) 3(1–4), respectively. We identified 4 new themes for the working thematic framework, which provided a dynamic, standardised, and comprehensive approach based on the observation and responses of those studied. This approach gave an insight into the way the PCI mediates consultations, and how patients do not always understand the support that specific professionals can provide. Overall, patients were satisfied with the consultations.

Keywords: Unmet needs; Patient Concerns Inventory; Head & Neck Cancer; Patient–doctor communication; Cancer

Introduction

Patients with cancer and their carers wish to be involved in making decisions about their care,[1] but it requires them to communicate their needs, concerns, and perspectives effectively,[2] and the process can be improved. The Patient Concerns Inventory (PCI) is a self-reported tool that focuses on patient-centred consultation and promotes multidisciplinary care.[3–8] Its raison d'être is to assist patients to highlight issues they wish to discuss; it enables them to voice their concerns in consultations, and encourages them to share in the decisions made about the type of support they would like. It is a multi-item checklist of issues that fall under the broad categories of "General function", "Specific head and neck function", "Emotional-psychological" concerns, and "Others", which include finances, matters related to treatment, and supportive care. It also allows patients to choose the people they wish to see or to be referred to from a range of professionals including multidisciplinary clinicians and non-medical professionals such as financial advisors and chaplains. It can easily be completed on a touch-screen computer,[9] and is practical for routine use in outpatient settings.

---

[*] Corresponding author. Tel.: +44 0151 529 5287; fax: +44 0151 529 5288.
E-mail addresses: naseemghazali@doctors.org.uk (N. Ghazali), Brenda.Roe@edgehill.ac.uk (B. Roe), astraglobeltd@btconnect.com (D. Lowe), snrogers@doctors.org.uk (S.N. Rogers).

0266-4356/$ – see front matter © 2012 The British Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.bjoms.2012.08.002

Early PCI studies conducted in a single practitioner's clinical practice have suggested that the inventory helps to uncover concerns that might otherwise be missed.[3–8] However, data were analysed from direct observation of the consultation by one assessor using an itemised checklist that focused on specific words that corresponded directly to items on the PCI. They did not consider items not on the list and may have missed some that were included if the patients or doctors used different words than those listed.

The primary aim of this study was to pilot a thematic framework to score items discussed in a PCI-mediated consultation for agreement and standardisation, and to evaluate its suitability for use in a multiclinic, rollout study. Other secondary aims were to compare the number and category of items highlighted on the PCI with those discussed, and to report the clinical outcomes and satisfaction reported by patients.

Method

Subjects

We prospectively recruited disease-free patients who had been treated for head and neck cancer and were attending routine clinics of one maxillofacial surgeon from February to May 2011. Those awaiting treatment, having palliative treatment, or who were attending the clinic for reasons other than routine follow up, were excluded. Information sheets about the study were posted to all eligible patients 2 weeks before their appointments. On the day of appointment while they were waiting, the researcher asked them whether they were willing to participate. Formal informed consent was subsequently obtained from those recruited.

Data collection

Patients completed the University of Washington quality of life questionnaire[10] (UW-QoL) then the PCI. The UW-QoL is a health-related quality of life (HRQoL) questionnaire specific to head and neck cancer that consists of 12 domains scaled from 0 (worst) to 100 (best) according to the hierarchy of response. Other questions relate to the previous week and ask patients to choose up to three domains most important to them, to rate their HRQoL, and to rate their overall quality of life. The PCI questionnaire lists 55 issues (including "Anything else") and 15 professionals (including "Anyone else") for patients to choose.[3] Both questionnaires were written as Microsoft Access-based software application packages and were filled in using a touch-screen computer linked to the hospital mainframe. After completion, the clinician retrieved a summarised report.[9] On one occasion when the touch-screen computer had broken down, 6 paper versions of the questionnaires were used.

Audio-recording equipment

To ensure uniformity, audio-recordings were made only in consultations that involved one maxillofacial surgeon, as other clinicians were not familiar with the PCI. A Tascam DR-100 (TEAC UK Ltd., Watford, UK) recorder was used to record the whole of the consultation, and it was saved in MP3 format. All identifiable information was removed to maintain confidentiality. Only recordings of complete consultations were used and transcribed.

Data analysis

Evaluation of the consultation involved identifying the number and type of concerns, involvement by healthcare or supportive professionals, and the clinical actions that resulted from the consultation. The framework, which involves 5 steps, was used to analyse the transcribed recordings.[11,12] The proposed framework (Table 1) is based on themes derived from previous knowledge (the PCI, which was distilled from various HRQoL questionnaires specific to head and neck cancer, and involvement by the Merseyside head and neck cancer focus group).[3] The themes were then coded into discrete categories that related to the items of concern, healthcare professionals, and type of clinical action or decision made during the consultation – for example, words or phrases such as "lethargy", "exhausted", or "run down" were categorised under the theme of "Fatigue or tiredness". Outcomes were classified as medical or non-medical actions. Medical actions comprised being placed on the waiting list for operations to aid rehabilitation, symptomatic or supportive medical treatment, investigations, and referrals. Non-medical actions included provision of information, advice on lifestyle, strategies for coping, and reassurance. The system was developed to standardise the classification of spoken phrases or terms used by patients and clinicians for the purpose of evaluation.

Rigour

To improve the reliability of qualitative data analysis (rigour), a second independent skilled qualitative researcher assessed the transcripts, and their decisions were compared.[14] Both assessors evaluated every one of 4 transcripts selected randomly. This also enabled formation of the thematic framework, which was used by one assessor to evaluate the remaining transcripts. When an item was identified by one and missed by the other it was discussed until resolved. This involved building a holistic picture of the patient or clinician, or both, on which to base analysis of the words used, and to identify key ideas and themes that were ultimately agreed by both assessors. This was particularly relevant when items were missed because they were not in the framework as they were carefully considered as potential new codings. However, for the purpose of this pilot study, they were considered under "Others". The overall level of agreement for each consultation assessed was derived as a percentage from the

Table 1
The framework approach.[11]

	Step	Definition	Process
1	Familiarisation	The process through which the researcher becomes familiarised with the data	Listened to audio-recordings Read through transcripts
2	Identification of thematic framework	Identification of issues, themes and concepts from the data. They can also be based on previous knowledge At this stage the framework can be tentative and open to further changes for refinement based on logical and intuitive thinking	Previous knowledge of the themes was gained from the PCI[a] (items of concern and professionals), and through the conventional approach to clinical management (for clinic outcomes) Themes were structured according to a collection of words, terms, and expressions considered to be of the same type (thematic coding).[13] This provided a standardised list for reference during evaluation
3	Indexing	Identification of portions or sections of data that correspond to a particular theme	Transcripts were analysed by 2 assessors using thematic coding Portions of data that represented a theme were highlighted in the text, and the corresponding theme annotated in the margin for the purpose of indexing
4	Charting	Organisation of indexed data into charts (portions of highlighted text were organised systematically to identify the best way to report the findings).	Both assessors met to agree the codes. For each transcript assessed by both, the items were considered as "item agreed" or "missed". Those missed were discussed and ultimately resolved. Some items were missed because they had been overlooked, misclassified, or the theme was not included on the thematic framework. They were carefully considered to potentially create new themes to refine the existing framework for future studies
5	Mapping and interpretation	Analysis of key characteristics as set out in the tables	The indexed themes from the transcript were tabled according to type This was contrasted against another table consisting of the items identified by patients on the PCI before consultation

[a] Patient Concerns Inventory.

formula: number of items agreed/total number of items identified.

Evaluation by patients after consultation

Patients were given 2 questionnaires to complete after the consultation: the Princess Margaret Hospital patient satisfaction with doctor questionnaire[15] (PSQ-MD), which includes 24 items, and is validated and specific to visits in an oncology setting; and a non-validated questionnaire consisting of 4 questions to gauge patients' perceptions of their concerns (free text response), the extent to which their concerns were addressed (Likert-type scale), whether they were able to see or be referred to the professional they had wanted to see (yes/no), and their views about the PCI (Likert-type scale).

The study was done with approval from the North West – Liverpool East Research Ethics Committee (11/H1002/7).

Results

A total of 63 consultations (56 patients) from 6 clinics were eligible for inclusion in the study; 67% (42 consultations) were included and 33% (21) were missed. The losses resulted from a lack of opportunity to recruit during a busy clinic (14/21) and refusal to participate (7/21). Those enrolled were on average 5 years younger (mean 61.6 compared with 66.4 years) at clinic than those missed, and in regard to primary diagnosis, had more advanced T-stage (T3-4) tumours (38% compared with 15%), but fewer operations that involved flaps (29% compared with 61%); otherwise there were no notable differences in the demographic and clinicopathological data (results not shown).

Of the 42 enrolled consultations (40 patients), 69% (29) of the patients were men, mean (SD) age 61.6 (11.3) years. In 37 the primary diagnosis was squamous cell carcinoma. Sites of primary tumours were the oral cavity ($n = 28$), pharynx ($n = 11$), salivary glands ($n = 2$), and skin ($n = 1$). Fourteen were pathological stage 1, 12 were stage 2, 8 were stage 3, and 8 were stage 4. Primary treatment was operation ($n = 34$), primary radiation or chemoradiotherapy, or both ($n = 7$), flap surgery ($n = 12$), and adjuvant postoperative radiotherapy ($n = 14$). The median (IQR) time from first diagnosis to study consultation was 22 (10–53) months.

Items reported by patients on the PCI

PCI data were available from 42 consultations (touch-screen 36; paper 6). The mean number of items of concern highlighted was 5.52, median (IQR) 4(2–8), and of professionals was 0.50, median (IQR) 0(0–1). On almost all the questionnaires, patients had selected at least one item on the PCI (88%, 37/42) and on a minority (38%, 16/42) at least one healthcare professional had been selected. Items chosen by at least 20% were fear of recurrence (33%, 14), dental health (31%, 13), swallowing (29%, 12), chewing (26%, 11), speech (21%, 9),

Table 2
Content analysis and level of agreement between the 2 assessors. Data are number.

	Consultations					Total
	1	2	3	4	5	
Total number of items	17	15	14	15	20	81
Items missed	2	4	2	4	1	13
Definition of coding changed	1	1	1	0	0	3
Number of items agreed	14	10	11	11	19	65
Percentage agreement	82	67	79	73	95	80

pain in the head and neck (21%, 9), and pain elsewhere (21%, 9). Dentists were the only healthcare professionals selected by at least 10% (21%, 9).

Audio-recordings

There were 19 complete audio-recordings. The reasons for a recording being incomplete or for it not being done at all were lack of consent ($n = 12$), seeing a different surgeon ($n = 5$), forgetting to record ($n = 3$), and failure of the equipment ($n = 3$). Patients with audio-recordings were 5 years younger on average (mean 59 compared with 64 years) and were closer to the time of treatment (median 16 months compared with 45 months), also fewer had had adjuvant postoperative radiotherapy or radical neck dissection (16% compared with 52%). There were no notable differences in the number of items selected on the PCI before consultation (median (IQR) 4(3–8) compared with 4(1–8)) or in the number of healthcare professionals selected.

Content analysis

The main assessor reviewed all 19 transcripts. From these 5 were randomly selected for evaluation by both assessors (Table 2). Potential new themes for coding identified by content analysis included “wellbeing”, “dizziness”, “skin rash”, and “further surveillance”.

The 19 consultations that were recorded lasted for a median (IQR) duration of 8.4 (5.6–10.3) min. For these the mean number of items of concern highlighted on the inventory was 5.95, median (IQR) 4(3–8), and the mean number of professionals highlighted was 0.74, median (IQR) 0(0–1). In contrast, content analysis of the audio-recordings gave a mean of 6.47, median (IQR) 6(4–9) for items of concern, and 2.63, median 3(1–4) for professionals.

The contrast between the items selected on the PCI and the content of the discussions is shown in Table 3. More items were discussed than were raised on the PCI particularly in regard to healthcare professionals. Of the items on the PCI, fear of recurrence stands out as it was selected on the inventory by 8/19 patients and was discussed by 9/19.

Clinical outcomes

The median number of clinical decisions or actions taken during consultations was 2.8 (range 2–5). The predominant decision made was for no intervention and the most common actions were appointments for further surveillance, provision of information, and giving reassurance. Two consultations resulted in onward referrals.

Outcomes reported by patients after consultation

During the latter part of this pilot, questionnaires were distributed after 22 consultations (15 patients), of which 11 had been audio-recorded. Questionnaire response was therefore 68% (15/22), and returns were completed within a median of 1 day (range 0–12) from the consultation. Fourteen patients felt that they had been able to see the person they had hoped to see on that day. Most responses described satisfactory experiences (Table 4).

Discussion

This study explored the feasibility of introducing a thematic framework approach to content analysis for future use in evaluating outcomes of PCI-mediated consultations. We found that the approach enabled us to explore the personal and dynamic nature of patients’ needs in the period after they had completed treatment because it is based on the observation of the subjects involved. Other valuable features include its dynamic approach (allows the framework to be amended during analysis), the system used (standardises the approach to handling data), and its comprehensive nature (allows a full review of the data). The study also showed the feasibility of prospective recruitment in a busy clinic, and the varied attitudes of patients to having consultations audio-recorded. It also gave an insight into the use of a visit-specific questionnaire about patients’ satisfaction, which has never been used before in head and neck cancer.

The study also highlighted the potential problem of loss of recruitment. Lack of familiarity with the study by patients, staff, and researchers, and the nature of a dynamic, busy clinic may account for the logistical reasons for losses. Another problem is the multilayered process of obtaining consent where patients give consent (or otherwise) to individual sections of the study. Many patients were happy to provide PCI, UW-QoL, and clinical data, but about half were not happy about the consultations being audio-recorded. This may have a greater potential for systematic error than losses for logistical reasons. However, these problems could be overcome in future prospective studies.

When the thematic framework was used for content analysis, more items were discussed than had been highlighted originally. This was because new themes had been introduced, which may or may not have been related to some of the items highlighted. The new themes identified as items

Table 3
Number of items of concern or health professionals selected by 19 patients on the Patient Concerns Inventory (PCI) and noted from the audio-recordings of their consultations. Items of concern were selected by 4 or more of the 19 patients, whereas the health professionals selected are all those noted on the PCI or mentioned in the consultation.

	On PCI	Discussed	On PCI and not discussed	On PCI and discussed	Not on PCI but discussed
Items of concern					
Fear of recurrence	8	9	2	6	3
Other[a]	0	12	0	0	12
Chewing	5	7	1	4	3
Dental health	4	6	1	3	3
Swallowing	6	5	1	5	0
Saliva	4	6	1	3	3
Pain in head and neck	4	5	4	0	5
Anxiety	4	6	1	3	3
PEG	3	5	0	3	2
Speech	4	5	1	3	2
Activity	3	4	1	2	2
Sleeping	4	3	1	3	0
Mood	5	2	4	1	1
Swelling	2	4	1	1	3
Appearance	2	4	0	2	2
Depression	5	1	4	1	0
Weight	1	4	1	0	4
Lifestyle	1	5	0	1	4
Mucus	4	1	3	1	0
Mobility	4	1	4	0	1
Total of these 20 items	73	95	31	42	53
Total of other 35 items	40	28	28	12	16
Total of all 55 items	113	123	59	54	69
Health professionals					
General practitioner	2	11	0	2	9
Dentist	5	7	3	2	5
Other[b]	1	8	1	0	8
Oncologist	2	6	1	1	5
Speech and language therapist	0	5	0	0	5
Emotional support therapist	0	4	0	0	4
Oral rehabilitation	0	3	0	0	3
Social worker	2	1	1	1	0
Dietician	0	2	0	0	2
Psychologist	0	2	0	0	2
Physiotherapist	1	0	1	0	0
Clinical nurse specialist	0	1	0	0	1
Surgeon	1	0	1	0	0
Total of all the health professionals	14	50	8	6	44

[a] Wellbeing (7), wellbeing and dizziness (1), new cancer (1), deformed jaw (1), altered sensation (1), skin rash (1).

[b] Psychiatrist (1), dermatologist (1), financial advisor (2), alcohol nurse (1), ENT consultant (1), medical specialty doctor (1), respiratory consultant (1).

of concern include “Dizziness” and “Skin rash”. “Dizziness” includes terms such as “light-headedness”, “giddy”, “woozy”, and “vertigo”. “Skin rash” includes descriptions of skin symptoms such as “rash”, “eczema”, and “dry, flaky skin”. These, along with the theme “Further surveillance” in relation to clinical outcome, have been incorporated into the existing theoretical framework for use in further studies.

Another new theme identified was “Wellbeing”, which was most commonly discussed during the consultations. We recognise that the linguistic implications of the term are complex, and we considered it as a fluid social construct that is subject to primary cultural judgement.[16] As an operational definition to form the basis for coding, we considered “wellbeing” to be the subjective notion of how well a person’s life is going, and it includes descriptions such as “doing well”, “feeling great in myself”, and “super”. The frequency with which the theme was discussed may be a reflection that some patients feel they have coped well and do not have any concerns, but in others, it could simply be an automatic response to enquiries about their condition because further exploratory PCI-led discussions have identified various concerns.

Thematic mapping of individual transcripts showed that more items were discussed than were highlighted, and it may relate to the way the PCI is used in a consultation. One of these is by the association of themes – for example, the clinician was able to discuss fear of recurrence when “anxiety” had

Table 4
Results of questionnaires filled in after consultation by 15 patients, comprising the Princess Margaret Hospital patient satisfaction with doctor questionnaire (PSQ-MD)[14] and non-validated questionnaires specific to the study.

	Strongly agree	Agree	Disagree	Strongly disagree	Does not apply	Positive response[a]
Princess Margaret Hospital patient satisfaction with doctor questionnaire (PSQ-MD)						
I will follow the doctor's advice because I think s/he is absolutely right	11	3	–	–	1	14/14
The doctor did not take my problems very seriously	–	–	4	10	1	14/14
The doctor considered my individual needs when treating my condition	10	3	–	1	1	13/14
The doctor did not give me all the information I thought I should have been given	–	–	4	10	1	14/14
The doctor went straight to my medical problem without greeting me first	–	–	3	12	–	15/15
The doctor used words I did not understand	1	–	5	9	–	14/15
There was not enough time to tell the doctor everything I wanted	1	–	5	8	1	13/14
I feel the doctor did not spend enough time with me	–	–	3	12	–	15/15
It seemed to me that the doctor was not really interested in my emotional wellbeing	–	–	3	12	–	15/15
I really felt understood by my doctor	11	4	–	–	–	15/15
After my last visit with my doctor, I feel much better about my concerns	5	8	1	–	1	13/14
The doctor was not friendly to me	–	–	2	13	–	15/15
I understand my illness much better after seeing this doctor	5	6	1	–	3	11/12
This doctor was interested in me as a person and not just my illness	10	4	–	1	–	14/15
I feel I understand pretty well the doctor's plan for helping me	8	4	–	2	1	12/14
I would not recommend this doctor to a friend	1	–	–	14	–	14/15
The doctor seemed to brush off my questions	–	–	1	14	–	15/15
The doctor should have told me more about how to care for my condition	2	–	2	10	1	12/14
After talking with the doctor, I have a good idea of what changes to expect in my health over the next few weeks and months	6	6	–	–	3	12/12
The doctor told me to call back if I had any questions or problems	9	4	1	–	1	13/14
I felt the doctor was being honest with me	11	4	–	–	–	15/15
The doctor explained the reason why the treatment was recommended for me	7	5	–	–	3	12/12
It seemed to me that the doctor was not really interested in my physical wellbeing	–	–	1	14	–	15/15
The doctor should have shown more interest	–	–	2	13	–	15/15
Non-validated questions specific to this study						
How would you rate the extent to which these concerns were addressed?	8	7	–	–	–	15/15
To what degree would you agree to the statement: my expectations of the consultation were fulfilled in the most recent outpatient visit?	10	4	–	1	–	14/15
To what degree would you agree to this statement: I felt the PCI was intrusive?	2	–	8	5	–	13/15
To what degree would you agree to the statement: I felt the PCI was unhelpful?	–	1	8	6	–	14/15

[a] Strongly agree/agree, or strongly disagree/disagree, as appropriate and applicable.

been selected on the PCI because of the known association between them,[6,7] which gave the patient an opportunity to disclose concerns if he or she so wished (Supplementary Figure). Other known thematic associations are between swallowing and use of a percutaneous endoscopic gastrostomy tube; saliva, chewing, and swallowing; and fear of recurrence and depression. Another way is based on the permission-giving impact of the PCI – for example, a patient did not indicate fear of recurrence on the PCI during the current visit but had done so in the past, which allowed it to be brought up again for discussion during the current visit.

Some items that were rarely indicated on the PCI were often touched upon during consultations – for example, relationships, but others indicated on the PCI were not discussed. This was because there was not enough time in the consultation to discuss all the items chosen. The PCI could be used to indicate patients who need more time, and clinical nurse specialists could provide this after the consultation with the doctor. We also found that more professionals were discussed during the consultation than were indicated on the PCI. In some instances this reflects some patients' lack of understanding about the role of each professional, and about the services that are available. Another reason why more professionals were discussed during consultations is because of the multidisciplinary team approach and also the importance of the general practitioner (GP) in the community, and was evident by the frequency with which the GP and oncologist were mentioned. However, it has not resulted in an increase in the number of referrals (2/19 patients) compared with a previous study (21/100 patients).[5]

Results obtained from a small subgroup of patients suggest that most were satisfied with their consultations. While surveys on the satisfaction of patients are thought to favour the clinician, scales that are specific to a visit are thought to measure different aspects than those that cover the duration of the relationship between the patient and physician.[17] However, the PSQ-MD questionnaire has never been used in head and neck oncology and precludes any potential comparisons with other groups. Our early data provide a measure of its feasibility and an understanding of how it could translate into a true measure of satisfaction.

Acknowledgement

This work was supported by the British Association of Oral & Maxillofacial Surgeons Endowment Grant.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.bjoms.2012.08.002.

References

1. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision making in persons with cancer: a systematic review. *Ann Oncol* 2010;**21**:1145–51.
2. Epstein RM, Street Jr RL. *Patient-centered communication in cancer care: Promoting healing and reducing suffering (NIH Publication No. 07-6225)*. Bethesda: National Cancer Institute; 2007.
3. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. *Oral Oncol* 2009;**45**:555–61.
4. Flexen J, Ghazali N, Lowe D, Rogers SN. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral and oropharyngeal cancer. *Br J Oral Maxillofac Surg* 2012;**50**:314–20.
5. Ghazali N, Kanatas A, Langley DJ, Scott B, Lowe D, Rogers SN. Treatment referral before and after the introduction of the Liverpool Patients Concerns Inventory (PCI) into routine head and neck oncology outpatient clinics. *Support Care Cancer* 2011;**19**:1879–86.
6. Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM. Fear of recurrence following head and neck cancer in the outpatient clinic. *Eur Arch Otorhinolaryngol* 2010;**267**:1943–9.
7. Ghazali N, Swann H, Humphris G, Ozakinci G, Lowe D, Rogers SN. Longitudinal trends relating to fear of recurrence amongst head and neck cancer survivors. *Psycho-Oncology* 2012, http://dx.doi.org/10.1002/pon.3069.
8. Ghazali N, Kanatas A, Scott B, Lowe D, Zuydam A, Rogers SN. The use of the Patient Concerns Inventory to identify speech and swallowingconcerns following treatment for oral and oropharyngeal cancer. *J Laryngol Otol* 2012;**126**:800–8.
9. Millsopp L, Frackleton S, Lowe D, Rogers SN. A feasibility study of computer-assisted health-related quality of life data collection in patients with oral and oropharyngeal cancer. *Int J Oral Maxillofac Surg* 2006;**35**:761–4.
10. Rogers SN, Gwanne S, Lowe D, Humphris G, Yush B, Weymuller Jr EA. The addition of mood and anxiety domains to the University of Washington quality of life scale. *Head Neck* 2002;**24**:521–9.
11. Ritchie J, Spencer E. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. *Analysing qualitative, data*. Abingdon: Routledge; 1994. p. 173–94.
12. Srivastava A, Thomson SB. Framework analysis: a qualitative methodology for applied policy research. *J Adm Governance* 2009;**4**:72–9.
13. Miles MB, Huberman AM. Early steps in analysis. In: Miles MB, Huberman AM, editors. *Qualitative data analysis*. 2nd ed. Thousand Oaks: SAGE; 1994. p. 55–72.
14. Mays N, Pope C. Rigour and qualitative research. *BMJ* 1995;**311**:109–12.
15. Loblaw DA, Bezjak A, Bunston T. Development and testing of a visit-specific patient satisfaction questionnaire: the Princess Margaret Hospital Satisfaction with Doctor Questionnaire. *J Clin Oncol* 1999;**17**:1931–8.
16. Ereaut G, Whiting R. Linguistic landscapes. What do we mean by wellbeing? And why might it matter? (Research report number DCSF-RW073). Department for Children, Schools and Families, London; 2008.
17. Epstein RM, Franks P, Fiscella K, Shields CG, Meldrum SC, Kravitz RL, et al. Measuring patient-centered communication in patient–physician consultations: theoretical and practical issues. *Soc Sci Med* 2005;**61**:1516–28.

Appendix 14: Published paper on HN-PCI domain generation

Ghazali N, Roe B, Lowe D, Rogers SN. Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life. Br J Oral Maxillofac Surg. 2015 Apr;53(4):371-9. doi: 10.1016/j.bjoms.2015.01.022.

Available online at www.sciencedirect.com

SciVerse ScienceDirect

British Journal of Oral and Maxillofacial Surgery 53 (2015) 371–379

BRITISH
Journal of
Oral and
Maxillofacial
Surgery
www.bjoms.com

Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life

N. Ghazali [a,*], B. Roe [b], D. Lowe [b], S.N. Rogers [b,a]

[a] *Regional Maxillofacial Unit, University Hospital Aintree, Liverpool L9 1AE, UK*
[b] *Evidence-Based Practice Research Centre (EPRC), Faculty of Health, Edge Hill University, St Helens Road, Ormskirk L39 4QP, UK*

Accepted 28 January 2015
Available online 20 February 2015

Abstract

Currently, the head and neck cancer Patients' Concerns Inventory (HNC-PCI), a holistic, self-reported tool to help patients disclose needs and concerns during consultations, is not organised into domains. We used a Delphi approach to generate domains and applied them to an existing HNC-PCI database to assess association with health-related quality of life (HRQoL). The expert panel comprised 10 experts in head and neck cancer who were selected ad hoc. The HNC-PCI checklist was analysed and fed back to the panel for 3 rounds until consensus was achieved. Five domains were generated (A = Physical and functional; B = Psychological and emotional or spiritual well-being; C = Social care and well-being; D = Treatment-related; and E = Other) and were applied to a database compiled from 674 patients who had completed the PCI on 1276 occasions. On first completing the inventory (median 32 months after treatment) 81% selected items under domain A and 58% under domain B. Fewer items were selected/domain thereafter. Younger patients were more likely to select from domains B and C. Those treated by radiotherapy and adjuvant radiotherapy were more likely to select from domains A and C, respectively. Patients with laryngeal cancer tended to select from domain C, and those with poor HRQoL outcomes were significantly more likely to indicate more items of concern. The items selected under the HNC-PCI domains showed that certain clinical, pathological, and HRQoL factors were associated with specific patterns of needs or concerns.

Keywords: Patients Concerns Inventory; Head neck cancer; Holistic assessments; Unmet needs; Health-related quality of life

Introduction

Holistic assessment in cancer[1] involves an evaluation of a patient's perceived needs in various areas of health so that healthcare providers can understand and address them, and provide care that is tailored and supportive. The Patients' Concerns Inventory (PCI), a holistic, patient-reported tool that helps to disclose items of concern,[2] has already been successfully rolled out across a head and neck cancer (HNC) network.[3] HNC-PCI data are included in the national dataset audit for head and neck cancer (DAHNO) and efforts are continuing to incorporate them into the electronic holistic needs assessment of the National Cancer Survivorship Initiative.

The HNC-PCI checklist covers a spectrum of issues that affect patients[2,4–8] and comprises 57 items[9] that are not organised into domains. Grouping them into domains has practical advantages as it can ease completion by patients, guide discussion during holistic assessment,[1] and help to identify the services required.[1,2]

---

* Corresponding author. Tel.: +44 0151 529 5287; fax: +44 0151 529 5288.
E-mail addresses: naseemghazali@doctors.org.uk (N. Ghazali), Brenda.Roe@edgehill.ac.uk (B. Roe), astraglobeltd@btconnect.com (D. Lowe), snrogers@doctors.org.uk (S.N. Rogers).

http://dx.doi.org/10.1016/j.bjoms.2015.01.022
0266-4356/© 2015 Published by Elsevier Ltd. on behalf of The British Association of Oral and Maxillofacial Surgeons.

Previously, reports of patients' expressed needs and concerns through a HNC-PCI were summarised as an extensive bar chart or a list of the topmost ranked items.[3,5–9] Fear of recurrence, dental health and teeth, and chewing, eating, and swallowing, were most commonly highlighted.[3,5–9] Conversely, religious aspects, regret about treatment, and dependents and children, were rarely chosen.[2,9] Grouping by domain can enable findings to be summarised more systematically and allows comparative evaluation.

We aimed to generate domains for the HNC-PCI using a systematic methodology and to apply them to a growing HNC-PCI database for the purpose of describing emerging trends.

Method

Selection of domains

The Delphi technique, an established tool used to reach consensus in a group of experts, involves a series of sequential questionnaires or "rounds" interspersed by controlled feedback in which individual judgements are tapped and combined to address a lack of agreement or incomplete knowledge.[10] We used it to generate the HNC-PCI domains as it is a recognised method of solving problems in healthcare settings,[10,11] and can help to structure and organise communication in a group.

We selected on an ad hoc basis a panel of 10 healthcare experts with a wide range of expertise in head and neck cancer. This fulfilled the requirement of the Delphi method that the panel is representative and is measured by the qualities of those involved rather than by their number, as there is little empirical evidence that the number has an impact on the reliability or validity of the stages used to reach consensus.[10] Diverse viewpoints that span respectable controversy can help to generate interest and involvement, particularly when experts reflect current knowledge and perceptions.[10]

We used a 3-step approach (Fig. 1). To establish consensus on each item, 70% of panelists had to agree in rounds 2 and 3. When they did not, the checklist with the related items was distributed again until the expected level was achieved.

Application of HNC-PCI domains

Ethics approval was not required as the study met the local clinical governance department criteria for service evaluation. HNC-PCI data were collected from 2 main groups: 317 patients with head and neck cancer who attended 829 clinics between 1 August 2007 and 31 December 2011, and 447 patients treated for primary squamous cell carcinoma (SCC) of the head and neck between 1998 and 2009 (surveyed in March 2011).[12] A total of 90 patients were included in both groups, and once this was accounted for, 674 patients completed the inventory on 1276 occasions.

Table 1
Categories suggested by participants and researcher.

Thematic category and items	Frequency ($n = 10$)	Suggested categories after collation by researcher
A		
Fitness	2	Physical and functional well-being
Rehabilitation	2	
Physical	7	
B		
Social care/support	4	Social care and well-being
Practical	1	
Lifestyle	1	
Support	6	
Social life	3	
C		
Spiritual	5	Psychological and emotional well-being/spirituality
Emotional	8	
Feelings	6	
D		
Treatment	4	Treatment-related
Treatment-related	4	
Side-effects	8	
E		
Body image	1	Others
Personal	2	
Symptoms	1	
Illness	1	
Others	7	

Although it can be used as a stand-alone questionnaire, we use the HNC-PCI with the University of Washington Quality of Life questionnaire, version 4 (UWQoL),[13] which is a validated HNC-specific health-related QoL (HRQoL) tool that contains 12 domains scaled from 0 (worst) to 100 (best) according to the hierarchy of response. There are 2 subscale composite scores[14]: Physical function and Social-emotional function, and a single 6-point overall measure of QoL. Physical function is the simple mean score of the swallowing, chewing, speech, saliva, taste, and appearance domains. Social-emotional function is the simple mean of the activity, recreation, pain, mood, anxiety, and shoulder domains. For the single-item overall QoL scale, patients are asked to consider not only their physical and mental health, but also other factors such as family, friends, spirituality, or personal leisure activities that help them to enjoy life.

The HNC-PCI and UWQoL were self-administered using a touch-screen computer[2] and paper versions,[15] which were used in the surveys and in some outpatient clinics when the touch-screen computer was not available.

We investigated associations between the domains selected on the HNC-PCI and the characteristics of 674 patients who had completed the inventory for the first time. Statistical significance was assessed using Fisher's exact test or the chi square test as appropriate. Because of the large number of tests, probabilities of less than 0.01 were regarded as significant.

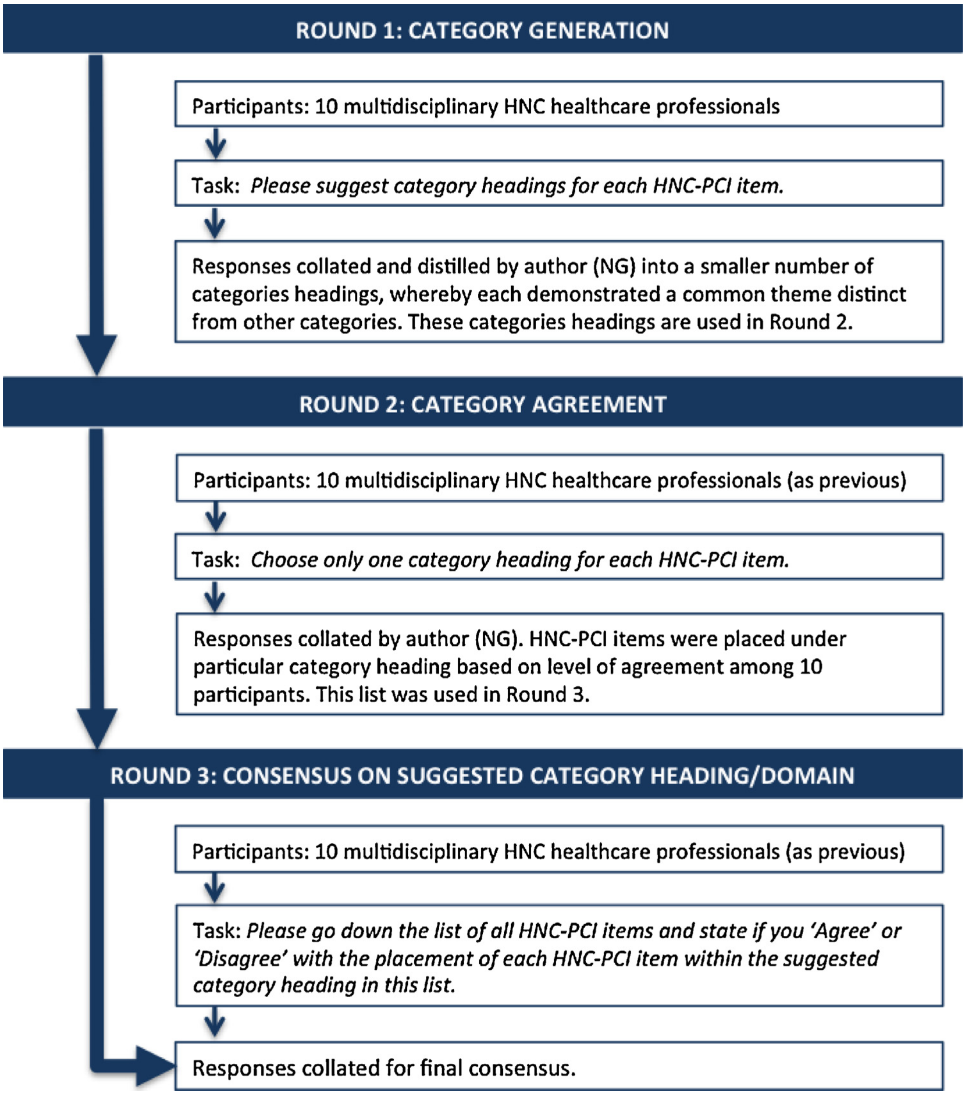


Fig. 1. Step-wise process used to generate domains.

Results

Selection of domains

The panel consisted of 2 doctors, 2 clinical nurse specialists, one speech and language therapist, 3 outpatient clinic nurses, one research nurse, and one PCI hospital volunteer. Table 1 shows the headings they suggested in Round 1. They were analysed and distilled into 5 groups based on thematic considerations: (A) Physical and functional well-being; (B) Social care and well-being; (C) Psychological and emotional well-being, and spirituality; (D) Treatment-related; and (E) Others, and were subsequently used as the domain headings in the inventory.

In Round 2 there was agreement of 70% and over on most items (89%, 51/57) (not shown). The 6 that remained (appearance; dependents and children; PEG tube; speech, voice, and being understood; and sexuality and relationships) were eventually resolved at the second stage of Round 2. At the first stage of Round 3, 100% agreement was achieved in almost all the items (93%, 53/57); in the second stage 70% or more was achieved in those that remained. The final consensus is shown in Table 2.

Application of domains

The 674 patients analysed had a mean (SD) age of 64 (11) years; 67% (449/674) were male. Primary diagnosis was made between 1 August 2007 and 31 December 2011, median (IQR) May 2007 (October 2004 to December 2008). In 616 (91%) it was SCC. Tumour site was the oral cavity in 340 (50%), pharynx in 170 (25%), larynx in 115 (17%), other sites in the head and neck in 40 (6%), and was unknown in 9 (1%). Tumour stage was advanced (T3-4) in 164/647 (25%) and in 180/652 (28%) nodes were invaded. Primary treatment was operation alone ($n = 335$,

Table 2
Suggested groupings and consensus.

	Item on patient concerns inventory
A: Physical and functional well-being	
1	Activity
5	Appetite
6	Bowel habit
7	Breathing
10	Chewing/eating
12	Coughing
13	Dental health/teeth
16	Dry mouth
17	Energy levels
18	Fatigue/tiredness
22	Hearing
24	Indigestion
28	Mobility
30	Mouth opening
31	Mucus
32	Nausea
33	Pain in head and neck
34	Pain elsewhere
39	Regurgitation
40	Salivation
43	Shoulder
44	Sleeping
45	Smell
46	Sore mouth
50	Swallowing
51	Swelling
52	Taste
54	Vomiting/sickness
55	Weight
B: Social care and well-being	
9	Carer
14	Dependents/children
21	Financial/benefits
23	Home care/district nurse
26	Lifestyle issues
36	Recreation
38	Relationships
47	Speech/voice/being understood
49	Support for my family
C: Psychological/emotional/spiritual well-being	
4	Appearance
2	Angry
3	Anxiety
11	Coping
15	Depression
19	Fear of the cancer coming back
20	Fear of adverse events
25	Intimacy
27	Memory
29	Mood
41	Self-esteem
42	Sexuality
48	Spiritual/religious aspects
53	Temperament and personality
D: Treatment-related	
8	Cancer treatment
37	Regret about treatment
35	PEG tube
56	Wound healing
E: Others	
57	Anything else

50%), operation with adjuvant radiotherapy ($n = 225$, 33%), chemoradiotherapy alone ($n = 96$, 14%), and in 18 (3%) was unknown. Of those operated on, 237/560 (42%) had free-flaps (179 soft tissue, 58 composite). The median (IQR) time from primary operation (or from primary diagnosis if no operation) to first completion of the inventory was 32 (14–58) months ($n = 660$). Most ($n = 472$, 70%) completed it only once at a median of 39 months (range 20–69). Just under one-third ($n = 202$, 30%) completed it more than once.

Of those who completed it for the first time ($n = 674$), 81% selected items in the physical and functional well-being domain, 30% in the social care and well-being domain, 58% in the psychological and emotional well-being and spirituality domain, and 15% in the treatment-related domain (Table 3). "Other" items were rarely chosen (4%). Fewer items were selected on subsequent forms; on the first inventory 11% selected none, and on later forms this had doubled to 23%.

We investigated associations between the selection of domains and the clinical characteristics of the patients who completed the inventory for the first time (Table 4). Younger patients (under 65 years) were more likely to select items from the psychological and emotional well-being and spirituality domain (66% compared with 48% for those 65 and over), and items in the social care and well-being domain (36% compared with 24% for those 65 and over). More women than men (64% compared with 55%) chose items in the psychological and emotional well-being and spirituality domain. Patients who had operation alone as the primary treatment were less likely to select from the physical and functional well-being domain (74%) than those who had operation and radiotherapy (89%) or chemoradiotherapy alone (86%). Those who had operation and radiotherapy were also more likely (39%) to select from the social care and well-being domain than other patients. More patients with laryngeal tumours chose items in the social care and well-being domain. There were no notable patterns of association between the domains and other clinicopathological variables.

We found clear associations between the domains selected and subscale scores on the UWQoL, and also with the single item UWQoL. Regarding overall QoL, patients with a serious condition were more likely to select items from each domain on the inventory. Those with particular problems[16] (see footnote to Table 4) were generally more likely to select from each domain than those not identified as having a problem.

Discussion

The domains generated from this exercise fulfilled the national recommendations for holistic assessment tools[1] as they included items that assessed physical, social and occupational, and psychological and spiritual well-being.

Physical and functional well-being consisted of items covering activities of daily living, physical symptoms (including pain), and functional impairment. Social care and well-being

Table 3
Items chosen on head and neck cancer Patient Concerns Inventory (PNC-PCI) by domain. Data are number (%).

Domain and items chosen	First PCI (674 patients)	Subsequent PCI (602 PCI from 202 patients)
Domain A: Physical and functional well-being		
0	128 (19)	181 (30)
1	122 (18)	104 (17)
2	92 (14)	88 (15)
3-4	139 (21)	105 (17)
5-9	153 (23)	106 (18)
10 or more	40 (6)	18 (3)
Domain B: Social care/social well-being		
0	470 (70)	480 (80)
1	156 (23)	92 (15)
2 or more	48 (7)	30 (5)
Domain C: Psychological/emotional/spiritual well-being		
0	286 (42)	343 (57)
1	197 (29)	133 (22)
2-3	132 (20)	81 (13)
4 or more	59 (9)	45 (7)
Domain D: Treatment-related		
0	573 (85)	557 (93)
1	85 (13)	40 (7)
2 or more	16 (2)	5 (<1)
Number of domains selected		
0	76 (11)	140 (23)
1	177 (26)	191 (32)
2	236 (35)	170 (28)
3	150 (22)	88 (15)
All 4	35 (5)	13 (2)
Main combinations of domains selected		
None	76 (11)	140 (23)
A only	137 (20)	155 (26)
A & C only	172 (26)	125 (21)
A, B, & C only	115 (17)	68 (11)
Other combinations	174 (26)	114 (19)

involved areas in which practical support may be needed, access to medical support and care, financial security (including occupation), involvement of family and friends, lifestyle choices, and interactions in social settings (recreational or social groups). The psychological and emotional well-being and spirituality domain assessed issues relating to psychological adjustments, feelings toward diagnosis and treatment, their effects on personality and sexual relationships, and religious and spiritual fulfilment. We created 2 additional domains to account for items that were treatment-related, and a single item domain of “Others” to account for any that had not been considered, such as the need for information.

The domains may reflect the experts’ opinion on how the concerns of individual patients can be addressed using available services. The panel found it difficult to achieve consensus on disease and treatment-related changes as they are often multidimensional in nature – for example, “appearance” can relate to physical and functional concerns and to psychological distress, and could also have an impact on social well-being or reflect a patient’s interest in further treatment.

Several studies have been done on the need for supportive care[12] in patients with cancer of the head and neck[17–23] but direct comparisons with our findings were impossible because there were fundamental differences in the populations studied. In our study, most patients chose items from the physical and functional well-being (81%), psychological, emotional and spiritual well-being (53%), and social care and well-being (30%) domains. Longitudinally, there was an overall reduction in the number of items selected across all domains.

The method of treatment is associated with concerns from the physical and functional domain. Recognised complications of radiotherapy may account for the reason why patients who had operation only were less likely to highlight concerns in this area. The fact that younger patients (under 65 years) are more likely to voice concerns in the psychological, emotional, and spiritual well-being, and social care and well-being domains, may have important implications for the planning of supportive care when the rising incidence of oropharngeal cancer in younger populations is taken into consideration.[24] The direct impact of laryngeal disease and treatment on verbal communication, and swallowing and breathing may explain why more concerns were expressed under the social care and well-being domain.

The association between need, HRQoL, and quality of care remains unclear.[25] We found a clear association between poor

Table 4
Domains selected on first use of head and neck cancer Patient Concerns Inventory (HNC-PCI) by patients' characteristics ($n = 674$). Data are number (%).

	Patients	Domain A: Physical and functional well-being	*p* value	Domain B: Social care and well-being	*p* value	Domain C: Psychological/emotional/spiritual well-being	*p* value	Domain D: Treatment-related	*p* value
Total no. of patients	674	546 (81)		204 (30)		388 (58)		101 (15)	
Sex									
Male	449	370 (82)	0.21	139 (31)	0.60	245 (55)	0.03	71 (16)	0.43
Female	225	176 (78)		65 (29)		143 (64)		30 (13)	
Age (years)									
<55	129	106 (82)	0.40	45 (35)	0.007	78 (60)	<0.001	23 (18)	0.06
55–64	242	203 (84)		87 (36)		166 (69)		45 (19)	
65–74	209	163(78)		46(22)		103(49)		22(11)	
75+	94	74(79)		26(28)		41(44)		11(12)	
Primary treatment									
Operation & radiotherapy	225	201(89)	<0.001	87(39)	0.005	130(58)	0.83	34(15)	0.52
Operation alone	335	249(74)		87 (26)		188(56)		47(14)	
Chemotherapy and radiotherapy alone	96	83(86)		27(28)		57(59)		18(19)	
Free-flap									
None	312	245(79)	0.27	94(30)	0.65	183(593)	0.69	44(14)	0.60
Soft	179	151(84		57(32)		98(55)		30(17)	
Composite	58	48(83)		21(36)		34(59)		7(12)	
Months from operation (or diagnosis if no operation)									
Within 12	149	121(81)	0.83	48(32)	0.57	88(59)	0.02	31(21)	0.13
12–23	124	103(83)		42(34)		85(69)		19(15)	
24–59	230	182(79)		68(30)		124(54)		29(13)	
60+	157	128(82)		42(27)		80(51)		20(13)	
Diagnosis									
SCC	616	502(81)	0.35	190(31)	0.53	351(57)	0.55	97(16)	0.22
Other	50	38(76)		13(26)		31(62)		4(8)	
T stage									
Tis, T1	256	200(78)	0.06	77(30)	0.35	147(57)	0.20	39(15)	0.97
T2	227	183(81)		62(27)		122(54)		34(15)	
T3, T4	164	143(87)		56(34)		103(63)		26(16)	
N stage									
N0	472	375(79)	0.19	145(31)	0.67	269(57)	0.97	65(14)	0.04
N1	70	59(84)		21(30)		40(57)		8(11)	
N2-3	110	95(86)		29(26)		64(58)		25(23)	
Tumour site									
Oral	340	268(79)	0.20	109(32)	0.002	187(55)	0.43	47(14)	0.73
Pharyngeal	170	147(86)		36(21)		101(59)		30(18)	
Laryngeal	115	91(79)		48(42)		66(57)		17(15)	
Other head and neck	40	33(83)		10(25)		27(68)		6(15)	

Table 4 (*Continued*)

	Patients	Domain A: Physical and functional well-being	*p* value	Domain B: Social care and well-being	*p* value	Domain C: Psychological/emotional/spiritual well-being	*p* value	Domain D: Treatment-related	*p* value
UWQoL physical function subscale score									
<50	78	74(95)	<0.001	35(45)	<0.001	52(67)	0.006	25(32)	<0.001
50–74	230	205(89)		81(35)		143(62)		31(13)	
75–89	141	121(86)		38(27)		84(60)		18(13)	
90–100	204	132(65)		43(21)		98(48)		23(11)	
UWQoL social-emotional subscale score									
<50	68	66(97)	<0.001	34(50)	<0.001	55(81)	<0.001	20(29)	0.001
50–74	205	190(93)		79(39)		137(67)		35(17)	
75–89	199	165(83)		52(26)		114(57)		25(13)	
90–100	182	112(62)		32(18)		71(39)		17(9)	
UWQoL overall score									
Outstanding/very good	243	173(71)	<0.001	52(21)	<0.001	107(44)	<0.001	28(12)	0.001
Good	224	186(83		65(29)		133(59)		33(15)	
Fair	131	124(95)		52(40)		95(73)		19(15)	
Poor/very poor	47	45(96)		24(51)		36(77)		16(34)	
UWQoL' problem as identified from UWQoL algorithm*									
Pain	115	111(97)	<0.001	45(39)	0.03	86(75)	<0.001	27(23)	0.006
Appearance	65	60(92)	0.02	31(48)	0.002	55(85)	<0.001	18(28)	0.005
Activity	87	81(93)	0.003	41(47)	<0.001	56(64)	0.20	25(29)	<0.001
Recreation	49	46(94)	0.02	24(49)	0.005	37(76)	0.01	12(24)	0.06
Swallowing	88	81(92)	0.005	36(41)	0.02	51(58)	0.99	25(28)	<0.001
Chewing	55	50(91)	0.07	22(40)	0.13	34(62)	0.57	22(40)	<0.001
Speech	41	39(95)	0.02	26(63)	<0.001	30(73)	0.05	13(32)	0.005
Shoulder	65	63(97)	<0.001	26(40)	0.09	45(69)	0.05	18(28)	0.005
Taste	74	69(93)	0.004	25(34)	0.50	46(62)	0.45	19(26)	0.009
Saliva	138	129(93)	<0.001	36(26)	0.34	89(64)	0.07	28(20)	0.06
Mood	87	84(97)	<0.001	46(53)	<0.001	76(87)	<0.001	17(20)	0.20
Anxiety	88	82(93)	0.002	39(44)	0.003	71(81)	<0.001	19(22)	0.07

* Significant problem trigger criteria[10]:- pain, appearance, activity, recreation, mood: (scores of 0 or 25 or 50 & important); swallowing, speech, anxiety: (scores of 0 or 30); shoulder, taste, saliva: (scores or 0 or 30 & important); chewing: (score of 0)

Results for those not triggered by the algorithm are not shown in the table.

outcomes for HRQoL and perceived needs of long-term survivors of head and neck cancer whose disease is in remission. When we related HRQoL outcomes to HNC-PCI data, we found that those who reported poor overall QoL (including those with poor outcomes for physical and socioemotional function, and those who were shown to have serious problems on the UWQoL) were more likely to select items for discussion. The clustering pattern of certain needs and their association with HRQoL can help healthcare professionals to identify patients at risk who would benefit in the long term from tailored and supportive care.

There are limitations in this study. We did not measure agreement between patients and professionals on the terminology used for the items. This is a subject for future work on the provision of additional information to help patients understand what each item refers to, and may overcome any potential individual variation in interpretation or meaning. Without a standard definition for guidance patients may find some items ambiguous. However, any vagueness could be cleared up during the consultation as the inventory itself can facilitate communication between the patient and doctor.

Although all our patients had cancer of the head and neck, the design was cross-sectional and restricted to patients who had been treated. A baseline level of perceived need at diagnosis or immediately after treatment was unavailable for comparison, and although we had a glimpse of a possible change in needs over time, most (70%) completed the inventory only once. Future prospective studies may consider other reported factors that can influence need, including comorbidity, psychological state, level of education, and socioeconomic status.

Conclusion

The categorisation of items into domains helps to show trends of perceived need and will potentially aid in the planning of supportive care. Emergent trends suggest that certain clinicopathological factors are associated with specific needs or concerns, and further work may help to clarify some of them. There were close associations between domains on the inventory and outcomes for HRQoL.

Conflict of interest

We have no conflicts of interest.

Acknowledgement

This work was funded by British Association of Oral & Maxillofacial Surgery Endowment fund.

References

1. Cancer Action Team. *Holistic common assessment of supportive and palliative care needs for adults with cancer: assessment guidance*. London: Cancer Action Team; 2007.
2. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. *Oral Oncol* 2009;**45**:555–61.
3. Rogers SN, Lowe D. An evaluation of the head and neck cancer patient concerns inventory across the Merseyside and Cheshire Network. *Br J Oral Maxillofac Surg* 2014;**52**:615–23.
4. Ghazali N, Kanatas A, Langley DJ, et al. Treatment referral before and after the introduction of the Liverpool Patients Concerns Inventory (PCI) into routine head and neck oncology outpatient clinics. *Support Care Cancer* 2011;**19**:1879–86.
5. Flexen J, Ghazali N, Lowe D, et al. Identifying appearance-related concerns in routine follow-up clinics following treatment for oral and oropharyngeal cancer. *Br J Oral Maxillofac Surg* 2012;**50**:314–20.
6. Zuydam AC, Ghazali N, Lowe D, et al. Evaluation of the limitations of using the University of Washington Quality of Life swallowing domain alone to screen patients in the routine clinical setting. *Br J Oral Maxillofac Surg* 2013;**51**:e148–54.
7. Rogers SN, Scott B, Lowe D, et al. Fear of recurrence following head and neck cancer in the outpatient clinic. *Eur Arch Otorhinolaryngol* 2010;**267**:1943–9.
8. Kanatas A, Ghazali N, Lowe D, et al. The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. *Int J Oral Maxillofac Surg* 2012;**41**:429–36.
9. Ghazali N, Roe B, Lowe D, et al. Uncovering patients' concerns in routine head and neck oncology follow up clinics: an exploratory study. *Br J Oral Maxillofac Surg* 2012;**51**:294–300.
10. Powell C. The Delphi technique: myths and realities. *J Adv Nurs* 2003;**41**:376–82.
11. Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. *PLoS Med* 2011;**8**:e1000393.
12. Kanatas A, Ghazali N, Lowe D, et al. Issues patients would like to discuss at their review consultation: variation by early and late stage oral, oropharyngeal and laryngeal subsites. *Eur Arch Otorhinolaryngol* 2013;**270**:1067–74.
13. Rogers SN, Gwanne S, Lowe D, et al. The addition of mood and anxiety domains to the University of Washington quality of life scale. *Head Neck* 2002;**24**:521–9.
14. Rogers SN, Lowe D. Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life Questionnaire. *Arch Otolaryngol Head Neck Surg* 2009;**135**:369–75.
15. Millsopp L, Frackleton S, Lowe D, et al. A feasibility study of computer-assisted health-related quality of life data collection in patients with oral and oropharyngeal cancer. *Int J Oral Maxillofac Surg* 2006;**35**:761–4.
16. Scott B, Ghazali N, Lowe D, et al. The Patients Concerns Inventory in head and neck cancer: comparison between self-completed paper and touch screen versions in the clinic setting. *Eur J Oncol Nurs* 2013;**17**:863–9.
17. Rogers SN, Lowe D, Yueh B, et al. The physical function and social-emotional function subscales of the University of Washington Quality of Life Questionnaire. *Arch Otolaryngol Head Neck Surg* 2010;**136**:352–7.
18. Chen SC, Lai YH, Liao CT, et al. Supportive care needs in newly diagnosed oral cavity cancer patients receiving radiation therapy. *Psychooncology* 2013;**22**:1220–8.
19. Chen SC, Yu WP, Chu TL, et al. Prevalence and correlates of supportive care needs in oral cancer patients with and without anxiety during the diagnostic period. *Cancer Nurs* 2010;**33**:280–9.
20. Chen SC, Lai YH, Liao CT, et al. Unmet information needs and preferences in newly diagnosed and surgically treated oral cavity cancer patients. *Oral Oncol* 2009;**45**:946–52.

21. Chen SC, Liao CT, Lin CC, et al. Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. *Oral Oncol* 2009;**45**:815–20.
22. Chen SC, Tsai MC, Liu CL, et al. Support needs of patients with oral cancer and burden to their family caregivers. *Cancer Nurs* 2009;**32**:473–81.
23. Oskam IM, Verdonck-de Leeuw IM, Aaronson NK, et al. Prospective evaluation of health-related quality of life in long-term oral and oropharyngeal cancer survivors and the perceived need for supportive care. *Oral Oncol* 2013;**49**:443–8.
24. Simard EP, Torre LA, Jemal A. International trends in head and neck cancer incidence rates: differences by country, sex and anatomic site. *Oral Oncol* 2014;**50**:387–403.
25. Carlson LE, Waller A, Mitchell AJ. Screening for distress and unmet needs in patients with cancer: review and recommendations. *J Clin Oncol* 2012;**30**:1160–77.

Appendix 15: Published paper of UWQOL and distress

Ghazali N, Roe B, Lowe D, Tandon S, Jones T, Brown J, Shaw R, Risk J, Rogers SN. Screening for distress using the distress thermometer and the University of Washington Quality of Life in post-treatment head and neck cancer survivors. Eur Arch Otorhinolaryngol. 2017 May;274(5):2253-2260.

Eur Arch Otorhinolaryngol (2017) 274:2253–2260
DOI 10.1007/s00405-017-4474-2

HEAD AND NECK

Screening for distress using the distress thermometer and the University of Washington Quality of Life in post-treatment head and neck cancer survivors

Naseem Ghazali[1,2] · Brenda Roe[3] · Derek Lowe[2,3] · Sank Tandon[4] · Terry Jones[1,4] · James Brown[2] · Richard Shaw[1,2] · Janet Risk[1] · Simon N. Rogers[2,3]

Received: 4 November 2016 / Accepted: 18 January 2017 / Published online: 6 February 2017

Abstract The primary aim was to determine the efficacy of the Distress Thermometer (DT) in screening for anxiety and mood problems against the University of Washington Quality of Life, version 4 (UWQOL). Secondary aims were to evaluate the association between demographic, clinical and health-related QOL variables with significant distress. Two hundred and sixty one disease-free HNC ambulatory patients attending routine follow-up clinics were prospectively recruited. Both DT and UWQOL were completed pre-consultation. Receiver operating characteristic (ROC) curve analyses of DT score for anxiety dysfunction yielded an area under the curve (AUC) of 0.877, with a sensitivity of 84% (43/51) and specificity of 76% (159/210) for a DT cut-off of ≥4; with a corresponding AUC of 0.825 for mood with sensitivity 78% (28/36) and specificity 71% (159/225). Treatment with radiotherapy and a longer consultation time were associated with significant distress (DT ≥4). Significant distress was also reported in two third of those reporting less than "Good" overall QOL. Distress levels were particularly associated with poor Social–Emotional function, more so than the association seen with poor physical function. DT is a reasonable screening tool for distress in the HNC population. The DT cut-off score ≥4 was effective in identifying those with significant distress. Significant distress is associated in survivors with poor health-related quality of life, those who received radiotherapy and patients who have longer consultation times in clinic.

Keywords Distress · Head and neck cancer · University of Washington Quality of Life · Distress thermometer · Screening

Background

Cancer-related distress is 'a multifactorial, unpleasant experience of a psychological, social or spiritual nature that interferes with the ability to cope with cancer treatment, its physical symptoms and its treatment. Distress extends along a continuum from common normal feelings of vulnerability, sadness and fear, to disabling problems, such as true depression, anxiety, panic and feeling isolated or in a spiritual crisis' [1]. Cancer-related distress is common [2]. It is reported that 35–70% of cancer patients experience distress at some time during their cancer journey [2]. Between 20 and 44% head and neck cancer (HNC) survivors will experience clinically significant depressive or anxiety symptoms at least once during the course of their illness [3, 4].

Longitudinal studies report cancer survivors may experience the trajectory of distress differently, and different factors, including demographic, clinical and social parameters, can influence the severity and consequential effects of distress [5]. Head and neck cancer (HNC) patients are prone to psychological problems because social interactions and emotional expression depends largely upon the structural and functional integrity of

✉ Naseem Ghazali
naseemghazali@doctors.org.uk

[1] Department of Molecular and Clinical Cancer Medicine, Institute of Translational Medicine, University of Liverpool, Liverpool, UK

[2] Regional Maxillofacial Unit, Aintree University Hospitals NHS Trust, Lower Lane, Liverpool L9 7AL, UK

[3] Faculty of Health and Social Care, Evidence-Based Practice Research Centre, Edge Hill University, Ormskirk, UK

[4] ENT Unit, Aintree University Hospitals NHS Trust, Liverpool, UK

the HN region [6]. Those with preexisting psychological morbidity, serious comorbidity, or social isolation, are particularly at risk of psychological distress [6]. This population demonstrates a high incidence of anxiety immediately post-diagnosis while depression peaks approximately 3 months post-completion of treatment, and levels for both constructs tend to return to pre-treatment levels by 12 months post-treatment completion [7, 8]. In addition, fear of cancer recurrence (FoR) is the most common concern of disease-free HNC survivors [9, 10] and can cause severe psychological morbidity [11]. Longitudinal follow-up suggests that screening for mood and anxiety may help identify those with persistent significant FoR due to its close association [12].

Distress impacts negatively on cancer care and outcomes, namely, quality of life (QOL) [13, 14], treatment adherence [15], satisfaction with care [16], and survival [17]. Distress levels in HNC patients have also been shown to relate negatively with QOL [18] and predicts survival in HNC patients [19]. Screening for distress is the first vital step in identifying patients who may be vulnerable to the damaging impact of chronic and/or significant distress [2, 5]. This sign-posting exercise may also aid professionals in developing with HNC survivors an individualized supportive care plan, incorporating various services including physical rehabilitation [20] social support [6] and psychosocial interventions [21], because cancer-related distress is explicitly tied to a number of common practical, physical, and psychological problems/concerns [5].

The Distress thermometer (DT) was introduced in 1998 as a rapid screening instrument for cancer-related distress [22] and has been validated for various cancer types worldwide [23] including the United Kingdom [24]. However, the DT has never been used to determine distress in a HNC cohort. Screening for psychological distress in HNC has been carried out using various tools, include the General Health Questionnaire [18, 19] and in particular, the Hospital Anxiety Depression Scale (HADS) [7, 8, 25–28]. Mood and Anxiety constructs were incorporated into the University of Washington Quality of Life (UWQOL), a widely used HNC-specific, validated health-related QOL measure [29]. The UWQOL is highly correlated with HADS [27] and thus, UWQOL has been used in routine clinical practice as a tool to help screen for a significant problem in these two areas [30].

The primary objective of this study was to screen for distress in post-treatment HNC patients using the DT and to determine an effective DT cut off score for this cohort. The secondary aims were to examine the relationship between significant distress with clinicopathological factors and quality of life.

Materials and methods

This work is part of a wider prospective roll out study on the Patients Concerns Inventory [31] and obtained research ethics approval from the North West Research ethics committee (study reference: 11/H1002/7).

Subjects and recruitment

Potential patients were derived from the outpatient clinic patient list of four participating HNC surgery consultants. These were two oral and maxillofacial/HNC surgeons (RJ, JB) and two otolaryngology/HNC surgeons (ST, TJ). The inclusion criteria for patient recruitment were disease-free HNC survivors who had completed primary treatment of at least 6 weeks. The exclusion criteria included HNC patients who had active/recurrent disease, those at the pre-treatment or palliative stage of survivorship, and those unable to speak or read English.

All eligible patients were sent the study patient information sheet together with their clinic appointment letter 6 weeks before their appointment date. On the day of appointment, eligible patients were approached in the waiting area for recruitment. Informed consent was sought and formalised. Recruitment opened on 15 June 2011 and patients were prospectively recruited consecutively according to the date and time of their clinic attendance. Recruitment closed on 9 January 2013.

Study design

Recruited patients completed the DT and UWQOL before their consultation. The consultation was audio-recorded as part of the wider Patient Concerns Inventory study. The digital audio-recording encompassed the entire consultation [31].

Measures

University of Washington Quality of Life, version 4 (UWQOL)

The UWQOL comprises 12 domains, scaled from 0 (worst) to 100 (best) according to the hierarchy of response [29]. The UWQOL has two subscale composite scores, i.e. ‘Physical function’ and ‘Social–Emotional function’ and a single six-point ‘overall’ QOL measure. ‘Physical function’ is the simple average of the swallowing, chewing, speech, saliva, taste and appearance domain scores whilst ‘Social–Emotional function’ is the simple average of the activity, recreation, pain, mood, anxiety and shoulder domains. In regard to the single item overall QOL scale, respondents were asked to consider not only physical

Table 1 Clinicopathological characteristics of 261 patients at first study clinic

	All patients ($n = 261$)
Sex	
Male	68% (175)
Female	32% (83)
Not known	1% (3)
Age	
Mean (SD)	63.0 (12.4)
Median (IQR)	63 (57–71)
<55	20% (53)
55–64	34% (89)
65–74	30% (77)
75+	14% (37)
Not known	2% (5)
Specialty	
MFU	52% (136)
ENT	48% (124)
Not known	0.4% (1)
Tumour site	
Oral	34% (90)
Oro-pharyngeal	21% (55)
Laryngeal	20% (52)
Other	25% (64)
Histology	
SCC	83% (217)
Not SCC	16% (43)
Not known	0.4% (1)
Overall pTNM stage	
1	28% (73)
2	25% (66)
3	11% (29)
4	20% (52)
Not known	16% (41)
Primary treatment	
Surgery only	44% (114)
Surgery + RT/CRT	38% (100)
RT/CRT only	15% (39)
Not known	3% (8)
Free-flap (214 surgery)	
Surgery without FF	70% (149)
Surgery with FF	29% (63)
Not known	1% (2)

and mental health, but also other factors, such as family, friends, spirituality or personal leisure activities important to their enjoyment of life.

To allow incorporation of UWQOL into routine clinical practice, i.e screening for dysfunction, a ‘significant problem’ was considered present in a particular UWQOL domain when it fulfilled one of the following criteria: (1) scores beyond a cut-off point specified in a domain, (2) (for some domains only) a score adjacent to the cut-off and respondents indicating the particular domain as being important during the previous week [30]. For example, a significant problem with Mood is triggered when the UWQOL Mood score was 0 or 25; or selection of Mood as being important in the past 7 days with a Mood score of 50. Furthermore, a significant problem with Anxiety is triggered when UWQOL Anxiety score was 0 or 30.

Distress thermometer (DT)

The DT is a single item self-report measure of distress. This instrument has been used to screen for distress in various types of cancer diagnoses [22–24, 32, 33]. It is scaled from 0 (no distress) to 10 (severe distress) in a thermometer layout to rate the level of distress experienced. A DT score of ≥ 5 was originally recommended as denoting significant distress necessitating psychosocial referral [34]. However, a DT score of ≥ 4 has been shown to correlate with optimal sensitivity and specificity to the HADS in various cross-cultural studies [13, 14, 23, 32].

Data analysis

To examine the relationship between distress and other variables, the Fisher’s exact test, Pearson’s chi-squared test or Kruskal–Wallis analysis were applied as appropriate. Statistical significance was regarded as $p < 0.01$. Receiver operating characteristic (ROC) curve analyses were performed to identify a DT cut-off score that effectively detects cases of significant distress defined by the UWQOL screening for dysfunction in anxiety and mood from the UWQOL [30]. All statistical analysis was performed using the SPSS version 19.0 (SPSS Inc.).

Results

There were 261 patients recruited at 325 clinics and data were analysed for the first clinic. Clinicopathological characteristics of the patients recruited to this study are shown in Table 1. Overall, the median (IQR) time from primary surgery (or from primary diagnosis if no surgery) to clinic attendance was 2.2 (0.9–3.8) years, $n = 256$. The median

Table 2 Level of reported distress at first study clinic prior to consultation

DT score	All clinics ($n=261$)
0 No distress	32% (84)
1	10% (27)
2	12% (31)
3	10% (25)
4	5% (14)
5	9% (23)
6	5% (14)
7	8% (20)
8	5% (12)
9	1% (2)
10 Extreme distress	3% (9)
Mean	2.9
Median (IQR)	2 (0–5)

(IQR) length of consultation was 4.9 (3.2–7.4) minutes, $n=213$.

Distress levels and identification of the DT cutoff

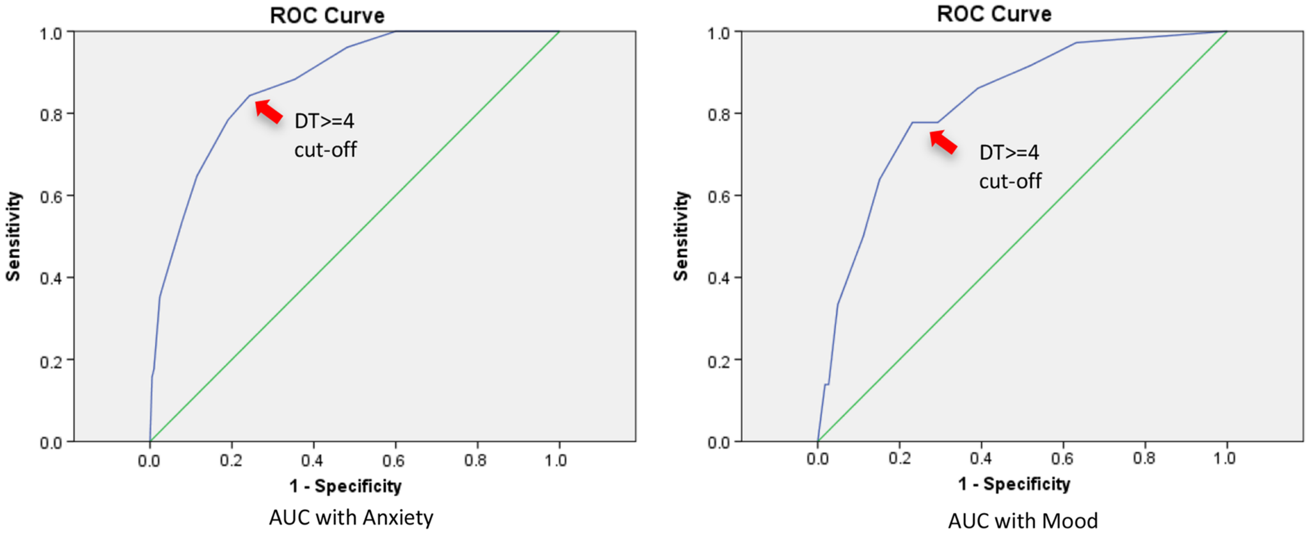
The mean DT score overall was 2.9 and the median (IQR) was 2 (0–5) (Table 2). The overall rate of significant distress (defined by a DT cut-off score of ≥4) was 36% (94/261). Thus, by this definition about two third of this cohort at clinic did not report significant distress.

ROCS analysis was performed to identify suitable DT cut-off points for emotional distress as defined as a 'significant problem' in the UWQOL mood (14%, 36/261) and anxiety (20%, 51/261) domains. Areas under the ROC curve (AUC) estimate the discriminative accuracy of cut-off scores in relation to a binary criterion, with a range from 1 (perfect discriminative accuracy) to 0.5 (poor discriminative accuracy) [13]. The ROC analyses showing the AUC using the DT as a predictor of UWQOL dysfunction are summarised in Table 3 and higher areas under the curve are

Table 3 Area under the Receiver Operative Curve (AUC) for DT score predicting a significant problem (dysfunction) in UWQOL domains

Domains in the physical function subscale of the UWQOL	Area under curve	Domains in the Social-Emotional subscale of the UWQOL	Area under curve
Appearance	0.628	Pain	0.763
Swallowing	0.668	Activity	0.755
Chewing	0.618	Recreation	0.795
Speech	0.691	Shoulder	0.674
Taste	0.626	Mood	0.825
Saliva	0.662	Anxiety	0.877

The AUC can be used as a summary measure of how well the DT predicts a binary outcome, i.e. having a significant problem as derived from the UWQOL algorithm



AUC with Anxiety

AUC with Mood

Fig. 1 ROC comparing DT score with UWQOL anxiety and mood dysfunction

Table 4 Sensitivity and specificity values for binary cut-offs within the distribution of DT scores in regard to UWQOL anxiety and mood dysfunction

Cut-off DT score	Anxiety		Mood	
	%Sensitivity	%Specificity	%Sensitivity	%Specificity
≥1	100	40	97	37
≥2	96	52	92	48
≥3	88	65	86	61
≥4	84	76	78	71
≥5	78	81	78	77
≥6	65	89	64	85
≥7	53	92	50	89
≥8	35	98	33	95
≥9	18	99	14	97

apparent towards dysfunction in domains within the Social-Emotional subscale of the UWQOL than for domains within the physical functioning subscale. The highest areas were for anxiety and mood dysfunction (Fig. 1), and for these Table 4 shows sensitivity and specificity values for binary cut-offs within the distribution of DT scores.

The ROC analyses offered support for cut-offs at ≥4 or ≥5. DT score yielded an AUC of 0.877 for anxiety dysfunction with a cut-off of ≥4 giving a sensitivity of 84% (43/51), specificity of 76% (159/210), positive predictive value of 46% (43/94) and negative predictive value of 95% (159/167); with a corresponding AUC of 0.825 for mood with sensitivity 78% (28/36), specificity 71% (159/225) positive predictive value of 30% (28/94) and negative predictive value of 95% (159/167).

Defining significant distress by a DT score cut-off of ≥5 gave a distress rate slightly lower at 31% (80/261). In predicting anxiety dysfunction it gave a sensitivity of 78% (40/51), specificity of 81% (170/210), positive predictive value of 50% (40/80) and negative predictive value of 94% (170/181); whilst in predicting mood dysfunction gave a sensitivity of 78% (28/36), specificity 77% (173/225), positive predictive value of 35% (28/80) and negative predictive value of 96% (173/181).

From a purely practical screening perspective of wanting to be inclusive and confident of capturing cases of dysfunction, the clinical choice would be to use ≥4 rather than ≥5, and further analysis continued using ≥4 to signify significant distress.

Relationship between DT score and clinicopathological variables

The relationship between significant distress (DT score ≥4) and age at consultation, gender, surgical specialty, histology, primary site, tumour stage, treatment, length of consultation and length of follow-up were evaluated. Only two variables showed a statistically significant association with significant distress, namely, length of consultation (Mann–Whitney test, $p < 0.001$) and treatment (Chi square, $p = 0.01$). For consultations lasting under 4 min the distress rate was 26% (22/85), between 4 and 8 min it was 34% (27/79) and for more than 8 min it was 57% (28/49). For patients having had primary surgery alone the rate was 30% (34/114), for surgery with adjuvant RT it was 37% (37/100), and for RT/CT without surgery it was 56% (22/39).

Other variables failed to demonstrate a statistically significant association with significant distress at $p < 0.01$, but age ($p = 0.04$, Mann–Whitney) and overall P-stage ($p = 0.04$, Chi-squared) were borderline associations, with higher distress rates noted for those aged under 55 years (51%, 27/53) and for those with advanced P-stage 4 tumours (48%, 33/77).

Distress and quality of life

The DT scores correlated moderately ($r_s = -0.44$) to UWQOL Physical subscale scores but more strongly ($r_s = -0.65$) with the Social–Emotional subscale score. Those scoring under 50 on the Social–Emotional scale were notably distressed (85% 22/26), with the rate decreasing as the score increased—61% (37/61) for 50–69 scores, 38% (20/52) for 70–79 scores and 12% (15/122) for 80–100 scores. For physical subscale scores under 50 the distress rate was 57% (13/23), with 47% (34/73) for scores 50–69, 53% (21/40) for scores 70–79 and 21% (26/125) for scores 80–100. Spearman correlation was $r_s = -0.52$ with overall QOL and 95% (20/21) of those with 'very poor' or 'poor' QOL had significant DT distress, 60% (27/45) of those with 'fair' QOL, 34% (33/96) of those with 'good' QOL and 14% (14/99) of those with 'very good' or 'outstanding' QOL.

Using the UWQOL dysfunction algorithm, significant dysfunction in anxiety OR mood was reported in 24%, 63/261. In addition, patients with significant problems in areas of pain, activity, recreation, mood and anxiety were more likely to report significant distress (Fisher's exact test, $p \leq 0.001$ in all). The reported importance of pain, mood and anxiety in the past week was also associated with significant distress ($p \leq 0.001$).

Discussion

This study evaluated the efficaciousness of DT in screening for significant distress in disease-free, post-treatment HNC survivors attending a routine outpatient clinic. According to NCCN guidelines [34], those with a score of ≥5 would require a referral for psychosocial care team, based on the recommendation that this cut off represents the threshold for those who will benefit from psychiatric referral [32]. Our study uses the UWQOL algorithm attempts to provide empirical evidence for this type of clinical judgment in relation to the HNC cohort.

Receiver operating characteristic analysis revealed that both DT cut-off scores ≥4 and ≥5 yielded AUC estimates indicating good overall accuracy relative to UWQOL dysfunction scores for Mood and Anxiety. However, the DT cut-off score ≥4 was found to be more effective in discriminating those with significant emotional distress compared with a ≥5 cut off score. In terms of predicting anxiety dysfunction, in choosing the ≥4 over ≥5 cut-off score, there is a trade off, i.e. there is better sensitivity with ≥4 (84 versus 78%) but worse specificity (76 versus 81%). In terms of predicting mood dysfunction, the ≥5 is only slightly more effective as the sensitivity rate is equal to the ≥4 cut off (i.e. 78%) but shows better specificity (77 versus 71%). Table 4 suggests that having a cut-off other than ≥4 or ≥5 reduces sensitivity or specificity quite considerably, and hence, the most optimal cut-off probably lies between 4 and 5. From a purely practical screening perspective of wanting to be inclusive and confident of capturing cases of dysfunction, the clinical choice would be to use ≥4 rather than ≥5. This may be the reason why both cut-offs have been suggested in the literature. While HADS was not used in this study, our results echo the findings of other studies that have evaluated a DT cut-off score ≥4 relative to HADS in cohorts at a similar plane on the cancer trajectory, i.e. post-treatment cancer patients attending outpatient clinics [23, 32]. Our finding may be related to the strong correlation between UWQOL with HADS [27–30].

Significant distress as determined by DT (cut-off score ≥4) was 36% in this cohort. When using the UWQOL algorithm, the significant mood and/or anxiety dysfunction rate was 24% (63/261), which is similar to that seen in our previous work in a different group of post-treatment disease-free HNC, where the reported rate was 26% (116/454) [4]. When UWQOL was combined with the Patients Concerns Inventory, a patient-reported tool that aids patients in highlighting their concerns, the proportion of patients with significant mood and anxiety problems/concerns was higher, i.e. 44% (89/204). In addition, those with significant mood and anxiety problems identified by UWQOL alone and the UWQOL-PCI combination showed a higher onward referral rate for psychological support [4]. The pick up rate using the UWQOL-PCI combination is nearer to the rate reported with DT with cut-off score ≥4. Based on this observation, we extrapolate that the DT cut-off score ≥4 may be able to identify most of HNC patients with significant distress.

In this study, only two clinical-pathological variables, namely, treatment received and length of consultation, were associated with significant distress. In this cohort, RT as a single modality or within a multimodality approach is associated with significant distress. It is known that HNC patients experience increasing symptoms of depression during RT [27]. Depressive symptoms persist post-radiation [3, 8] and while there is slight improvement with time, depression levels remain worse than at pre-treatment [35]. This is also reported by those irradiated post-surgery [3, 36]. In contrast, anxiety is less pronounced in HNC patients during RT, which improves after completion of RT [8]. RT-related distress is purportedly related to symptoms burden from side-effects of RT [8] particularly pain and fatigue in the acute stage, and xerostomia, trismus and osteoradionecrosis in the long-term. This could account for the higher referral rates for psychological support in irradiated HNC patients compared with other cancer types receiving RT [37]. It is surprising that overall advanced tumour stage 4 did not demonstrate more than borderline significance association with distress as tumours with larger dimensions tend to cause more dysfunction due to the extent and combination of treatment rendered. Perhaps this may be attributed to the influence of coping, although this was not evaluated in this study.

A longer consultation time was associated with significant distress in this study. Consultation comprises proportional time dedicated to HN examination, inspection of surgical wounds/dressing and patient–doctor discussions on a range of topics that may be related or otherwise to HNC. Any concerning issue(s) could result in an increase in the overall consultation time, e.g. through having extensive physical examinations and/or longer discussions. This may be relevant as the number and severity of cancer patients' concerns are associated with the development of distress [38]. Distress during routine oncology consultations is frequently associated with FoR [11], which is the most common concern in HNC clinic visits [9, 10, 12]. Patients find physical examination and direct reference to issues surrounding cancer recurrence during clinic appointment discussions reassuring [39] and this may account for longer consultations. Our previous work did not reveal any relationship between the number and type of patient concerns/issues with significant mood and/or anxiety problems [4], but this is the subject of further data analysis in this current cohort (in press). In a study of adjuncts in facilitating oncology consultations, e.g. prompt sheet for patients, higher levels of distress were related to longer consultation times and this was attributed to the contents of the prompt sheet, which include prompts to difficult questions, e.g. prognosis [40]. Associations between younger age, gender, performance status, and tumour characteristics with significant distress in HNC patients evident elsewhere [7, 25, 26] were not noted in our study.

The association between health-related quality of life (HRQOL) with significant distress was evaluated. In our cohort, significant distress was experienced in two third reporting less than "Good" overall QOL, suggesting an association between significant distress and poorer HRQOL, which is not unexpected, and in accordance to previous work [7, 8, 25]. Distress levels were particularly associated with poor Social–Emotional function, more so than the association seen with poor physical function. This may be related to the additional finding of patients with significant problems in the individual areas of pain, activity, recreation, mood and anxiety (i.e. components of the Social–Emotional function subscale) were more likely to report significant distress. Physical functioning showed moderate correlation to significant distress. There is an existing body of literature that supports the notion that both psychosocial and physical correlates contribute towards psychological distress and impacts upon HRQOL [20].

This study may be limited by not including a validated screening tool for anxiety and depression, such as the HADS. The addition of a psychological screening tool may speculatively enhance the overall accuracy, including the sensitivity and specificity of the DT cut-off score identified for a HNC cohort. Another limitation relates to the sample lacking diversity, where patients outside the defined cancer trajectory were excluded, i.e. pre-treatment, active treatment and palliative stages, and this may influence generalizability of the DT cut-off score identified. Furthermore, the DT cut off score of ≥4 was not cross-validated in a second sample, which may provide additional assurances particularly as a validated psychological screening tool was not used. This study did not evaluate other recognised factors related to distress, including performance status, comorbidity and other sociodemographic data, e.g. education and employment. This current paper is unable to comment on the beneficial outcomes of distress screening, which is a subject of another publication (in press).

Conclusions

DT is a reasonable screening tool for distress in the HNC population. The DT cut-off score ≥ 4 was effective in identifying those with significant distress. Significant distress is associated in survivors with poor HRQOL, those who received radiotherapy and patients who have longer consultation times in clinic.

Compliance with ethical standards

Conflict of interest The authors have no conflict of interest to declare.

References

1. Holland JC, Bultz BD (2007) The NCCN guideline for distress management: A case for making distress the sixth vital sign. J Natl Compr Canc Netw 5:3–7
2. Bultz B, Johansen C (2011) Screening for distress, the 6th vital sign: where are we, and where are we going? Psychooncology 20:569–571
3. Katz MR, Kopek N, Waldron J, Devins GM, Tomlinson G (2004) Screening for depression in head and neck cancer. Psychooncology 13:269–280
4. Kanatas A, Ghazali N, Lowe D, Rogers SN (2012) The identification of mood and anxiety concerns using the Patients Concerns Inventory following head and neck cancer. Int J Oral Maxillofac Surg 41:429–436
5. Carlson LE, Waller A, Mitchell AJ (2012) Screening for distress and unmet needs in patients with cancer: review and recommendations. J Clin Oncol 30:1160–1177
6. de Leeuw JR, de Graeff A, Ros WJ, Blijham GH, Hordijk GJ, Winnubst JA (2000) Prediction of depressive symptomatology after treatment of head and neck cancer: the influence of pre-treatment physical and depressive symptoms, coping, and social support. Head Neck 22:799–807
7. Hammerlid E, Ahlner-Elmqvist M, Bjordal K, Biojrklund A, Evensen J, Boysen M et al (1999) A prospective multicentre study in Sweden and Norway of mental distress and psychiatric morbidity in head and neck cancer patients. Br J Cancer 80:766–774
8. Kohda T, Otsubo K, Kuwakado Y, Tanaka K, Kitahara T, Yoshimura K et al (2005) Prospective studies on mental status and quality of life in patients with head and neck cancer treated by radiation. Psychooncology 14:331–336
9. Rogers SN, El-Sheikha J, Lowe D (2009) The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol 45:555–561
10. Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM (2011) Fear of recurrence following head and neck cancer in the outpatient clinic. Eur Arch Otorhinolaryngol 267:1943–1949
11. Hodges LJ, Humphris GM (2009) Fear of recurrence and psychological distress in head and neck cancer patients and their carers. Psychooncology 18:841–848
12. Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN (2013) Fear of recurrence amongst head and neck cancer survivors: longitudinal trends. Psychooncology 22:807–813
13. Shim EJ, Mehnert A, Koyama A et al (2006) Health-related quality of life in breast cancer: cross-cultural survey of German, Japanese, and South Korean patients. Breast Cancer Res Treat 99:341–350
14. Ozalp E, Cankurtaran ES, Soygur H, Ozdemir Geyik P, Jacobsen PB (2007) Screening for psychological distress in Turkish cancer patients. Psychooncology 16:304–311
15. DiMatteo MR, Lepper HS, Croghan TW (2000) Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. Arch Int Med. 160:2101–2107
16. Han WT, Collie K, Koopman C, Azarow J, Classen C et al (2005) Breast cancer and problems with medical interactions:

relationships with traumatic stress, emotional self-efficacy, and social support. Psychooncology 14:318–330

17. Hamer M, Chida Y, Molloy GJ (2009) Psychological distress and cancer mortality. J Psychosom Res 66:255–258
18. Aarstad AK, Beisland E, Osthus AA, Aarstad HJ (2011) Distress, quality of life, neuroticism and psychological coping are related in head and neck cancer patients during follow-up. Acta Oncol 50:390–398
19. Aarstad HJ, Osthus AA, Olofsson J, Aarstad AK (2014) Level of distress predicts subsequent survival in successfully treated head and neck cancer patients: a prospective cohort study. Acta Otolaryngol 134:211–219
20. De Boer MF, McCormick LK, Pruyn JF, Ryckman RM, van den Borne BW (1999) Physical and psychosocial correlates of head and neck cancer: a review of the literature. Otolaryngol Head Neck Surg 120:427–436
21. Reich M, Leemans CR, Vermorken JB, Bernier J, Licitra L, Parmar S, Golusinski W, Lefebvre JL (2014) Best practices in the management of the psycho-oncologic aspects of head and neck cancer patients: recommendations from the European Head and Neck Cancer Society Make Sense Campaign. Ann Oncol 25(11):2115–2124. doi:10.1093/annonc/mdu105
22. Roth AJ, Kornblith AB, Batel-Copel L, Peabody E, Scher HI, Holland JC (1998) Rapid screening for psychologic distress in men with prostate carcinoma. Cancer 82:1904–1908
23. Grassi L, Johansen C, Annunziata MA, Capovilla E, Costantini A, Gritti P, Torta R, Bellani M, Italian Society of Psycho-Oncology Distress Thermometer Study Group (2013) Screening for distress in cancer patients: a multicenter, nationwide study in Italy. Cancer. 119:1714–21
24. Gessler S, Low J, Daniells E, Williams R, Brough V, Tookman A, Jones L (2008) Screening for distress in cancer patients: is the distress thermometer a valid measure in the UK and does it measure change over time? A prospective validation study. Psychooncology 17:538–547
25. Chen SC, Liao CT, Lin CC, Chang JT, Lai YH (2009) Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. Oral Oncol 45:815–820
26. Verdonck-de Leeuw IM, de Bree R, Keizer AL, Houffelaar T, Cuijpers P, van der Linden MH, Leemans CR (2009) Computerized prospective screening for high levels of emotional distress in head and neck cancer patients and referral rate to psychosocial care. Oral Oncol 45:e129–e133
27. Kelly C, Paleri V, Downs C, Shah R (2007) Deterioration in quality of life and depressive symptoms during radiation therapy for head and neck cancer. Otolaryngol Head Neck Surg 136:108–111
28. Pandey M, Devi N, Thomas BC, Kumar SV, Krishnan R, Ramdas K (2007) Distress overlaps with anxiety and depression in patients with head and neck cancer. Psychooncology 16:582–586
29. Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA Jr (2002) The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Head Neck 24:521–529
30. Rogers SN, Lowe D (2009) Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life questionnaire. Arch Otolaryngol Head Neck Surg 135:369–375
31. Ghazali N, Roe B, Lowe D, Rogers SN (2012) Uncovering patient agendas in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxfac Surg 51:294–300
32. Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, Holland JC (2005) Screening for psychologic distress in ambulatory cancer patients. Cancer 103:1494–1502
33. Patrick-Miller LJ, Broccoli TL, Levine E, Much JK (2004) Screening for psychosocial distress among ambulatory oncology patients: evaluation of the distress thermometer. Psychooncology 13:S64–S65
34. National Comprehensive Cancer Network. Clinical practice guidelines in oncology-v.1.2005. Distress management: version1.2005.
35. Chawla S, Mohanti BK, Rakshak M, Saxena S, Rath GK, Bahadur S (1999) Temporal assessment of quality of life of head and neck cancer patients receiving radical radiotherapy. Qual Life Res 8:73–78
36. de Graeff A, de Leeuw JR, Ros WJ, Hordijk GJ, Blijham GH, Winnubst JA (1999) A prospective study on quality of life of patients with cancer of the oral cavity or oropharynx treated with surgery with or without radiotherapy. Oral Oncol 35:27–32
37. Chiu NM, Sun TF, Wu CK, Leung SW, Wang CJ, Wen JK (2001) Clinical characteristics of outpatients at a psycho-oncology clinic in a radiation oncology department. Chang Gung Med J 24:181–187
38. Chaturvedi SK, Shenoy A, Prasad KM, Senthilnathan SM, Premlatha BS (1996) Concerns, coping and quality of life in head and neck cancer patients. Support Care Cancer 4:186–190
39. Ghazali N, Kanatas A, Bekiroglu F, Scott B, Lowe D, Rogers SN (2013) The Patient Concerns Inventory: a tool to uncover unmet needs in a cancer outpatient clinic. Bul RCS Eng 95:1–6
40. Brown RF, Butow PN, Dunn SM, Tattersall MHN (2001) Promoting patient participation and shortening cancer consultations: a randomised trial. Br J Cancer 85:1273–1279

Appendix 16: Published paper on HN-PCI and distress

Ghazali N, Roe B, Lowe D, Tandon S, Jones T, Shaw R, Risk J, Rogers SN. Using the patients concerns inventory for distress screening in post-treatment head and neck cancer survivors. J Craniomaxillofac Surg. 2017 Oct;45(10):1743-1748. doi: 10.1016/j.jcms.2017.07.009.

Journal of Cranio-Maxillo-Facial Surgery 45 (2017) 1743–1748

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Using the patients concerns inventory for distress screening in post-treatment head and neck cancer survivors

Naseem Ghazali [a, b, *], Brenda Roe [c], Derek Lowe [b, c], Sank Tandon [d], Terry Jones [a, d], Richard Shaw [a, b], Janet Risk [a], Simon N. Rogers [b, c]

[a] *Department of Molecular & Clinical Cancer Medicine, Institute of Translational Medicine, University of Liverpool, Liverpool, UK*
[b] *Regional Maxillofacial Unit, Aintree University Hospitals NHS Trust, Liverpool, UK*
[c] *Evidence-Based Practice Research Centre, Faculty of Health & Social Care, Edge Hill University, Ormskirk, UK*
[d] *ENT Unit, Aintree University Hospitals NHS Trust, Liverpool, UK*

ARTICLE INFO

Article history:
Paper received 22 January 2017
Accepted 18 July 2017
Available online 27 July 2017

Keywords:
Distress
Head and neck
Cancer
Patient Concerns Inventory

ABSTRACT

Purpose: Cancer patients can experience significant distress during their cancer trajectory, which impacts upon clinical outcomes and quality of life. Screening for distress using holistic assessments can help identify and address unmet concerns/needs. The purpose of this study was to evaluate the relationship between concerns and distress, and the impact of distress on clinic outcomes in post-treatment head and neck cancer patients.

Methods: 170 patients attending routine follow-up clinics were prospectively recruited. All patients completed the Patient Concerns Inventory (PCI) and the Distress thermometer (DT) at preconsultation.

Results: The rate of significant distress (i.e. DT cut-off score ≥ 4) was 36% (62/170). Significantly distressed patients selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2–8) vs 2.61, 2 (0–4), $p < 0.001$). Significant distress was most strongly associated with Physical and Functional well-being ($p < 0.001$) and Psychological and Emotional well-being domains ($p = 0.001$). On balance, very little difference was noted between cut-off points of either ≥ 4 or ≥ 5 PCI items of concern selected. Both cut-off points demonstrated an acceptable level of sensitivity, specificity and predictive values for significant distress. Consultations were longer with increasing numbers of concerns.

Conclusions: Just over one-third of patients are significantly distressed. They were more likely to express a higher number of concerns. A cutoff score ≥ 4 or ≥ 5 PCI items selected can identify those at risk of significant distress. Concerns causing significant distress were related to emotional/psychological issues and physical function.

1. Introduction

Distress is commonly experienced during the cancer trajectory and significantly impacts upon cancer care and its outcomes, justifying calls for its screening (Carlson et al., 2012). Screening for distress is regarded as the primary step in managing cancer-related distress. This process involves identifying contributing causes, ranging from common practical, physical, and psychological problems/concerns by way of holistic assessments (Carlson et al., 2012; Richardson et al., 2007), and developing individualized supportive care plan to meet these issues. It is suggested that the number and severity of cancer patients' concerns is associated with development of distress (Maguire, 2002; Chaturvedi et al., 1996).

There is an accumulating body of work surrounding patient's concerns in the head and neck cancer (HNC) population based on the Patients Concerns Inventory (PCI). The PCI is a holistic tool that helps HNC patients disclose items of concern during routine clinical consultations, and also assists patients in indicating professionals with whom they wish to see or be referred to (Rogers et al., 2009) The PCI has been successfully rolled out as a sign-posting tool for supportive care across a regional HNC network in the United Kingdom.

---

[*] Corresponding author. Regional Maxillofacial Unit, University Hospital Aintree, Lower Lane, Liverpool, L9 7AL, UK. Fax: +44 151 529 5288.
E-mail address: naseemghazali@doctors.org.uk (N. Ghazali).

http://dx.doi.org/10.1016/j.jcms.2017.07.009

There is a wide range of reported HNC patient concerns (Rogers et al., 2010). Preliminary analysis of this dataset identified the most common patient concerns were fear of recurrence (FoR, 37%), dental health/teeth (27%), chewing (24%), pain in head/neck (20%), fatigue/tiredness (19%), saliva (18%) and swallowing (18%) (Rogers et al., 2009). When the PCI is used in conjunction with other measures, it is possible to identify individuals with significant problems i.e. requiring attention/support in specific areas. For example, those with significant problems from FoR can be identified when the PCI is used in conjunction with the FoR questionnaire (Rogers et al., 2010; Ghazali et al., 2013). Also, patients with significant problems in areas of mood and anxiety (Kanatas et al., 2012), pain (Rogers et al., 2012), appearance (Flexen et al., 2012), and speech and swallowing (Ghazali et al., 2012a) can be identified when the PCI is used in conjunction with the University of Washington Quality of Life version 4 (UWQOL).

Different factors have been related to the expression of specific concerns. For example, predictors of those experiencing significant FoR concerns over time (35%) were related to patient-related characteristics (i.e. female gender, those experiencing anxiety and mood disorders) rather than clinicopathological characteristics (Ghazali et al., 2013). On the other hand, clinicopathological factors were important predictors for those citing pain concerns with significant problems (i.e. received radiotherapy (RT), age < 65 years) (Rogers et al., 2012) and in those citing appearance concerns with significant appearance issues (i.e. oropharyngeal tumours, large primary tumours, and age <65 years) (Flexen et al., 2012). However, the relationship between patient concerns and distress in HNC has not been explored.

The Distress thermometer (DT) is a rapid, validated screening instrument for cancer-related distress for patients with various cancer types in America (National Comprehensive Cancer Network, 2005) and the United Kingdom (Gessler et al., 2008). However, there was paucity in the literature regarding patient concerns related to distress and the use of DT in distress screening in HNC population. A DT score of ≥5 was originally recommended as denoting significant distress necessitating psychosocial referral (National Comprehensive Cancer Network, 2005) but a DT score of ≥4 has been shown to correlate with optimal sensitivity and specificity to the Hospital Anxiety Depression Scale (HADS) in various cross cultural studies in identifying significant distress (Jacobsen et al., 2005; Ozalp et al., 2007; Shim et al., 2006; Grassi et al., 2013). Recently, we found that a DT cut-off score of ≥4 was effective in screening for significant anxiety and mood problems against the UWQOL in disease-free, post-treatment HNC survivors attending out-patient clinics (Ghazali et al., 2017), where just over one-third of HNC patients (36%, 94/261) reported significant distress.

The primary objective of this study was to determine the relationship between distress and patient concerns in a cohort of disease-free, post-treatment HNC patients attending routine follow-up. A specific objective was to evaluate the relationship between the numbers of concerns with significant distress, so as to identify suitable cut-off point based on the number of items selected on the PCI that could be used as a simple indicator for clinicians in risk assessing significant distress in clinic. The secondary aims were to determine the significance of distress on outcomes of clinic consultations in relation to patient's concerns.

2. Methods

This study obtained research ethics approval from the North West Research ethics committee (study reference: 11/H1002/7). The study was conducted in two HNC outpatient clinics within the Merseyside region.

2.1. Subjects

Study participants comprised surgeons and patients. Four consultant surgeons comprising two Oral & Maxillofacial surgeons and two Otolaryngology, Head and Neck surgeons, without prior experience of using the PCI were invited to participate in this study and formed a convenience sample. The inclusion criteria for patient recruitment were disease-free HNC survivors who had completed primary treatment of at least 6 weeks and had not used the PCI before. The exclusion criteria included HNC patients who were at pre-treatment or palliative stage of survivorship. In addition, patients who were unable to speak or read English were excluded.

2.2. Measures

2.2.1. Distress thermometer (DT)

The DT is a single item self-report measure of distress. This instrument is scaled from 0 (no distress) to 10 (severe distress) in a thermometer layout to rate the level of distress experienced. A DT cut-off score of ≥4 correlates with optimal sensitivity and specificity to the HADS in various cross cultural studies (Jacobsen et al., 2005; Ozalp et al., 2007; Shim et al., 2006; Grassi et al., 2013), and is effective in identifying significant anxiety and mood problems with good sensitivity and specificity to the UWQOL in HNC (Ghazali et al., 2017).

2.2.2. Patient Concerns Inventory (PCI)

The PCI is a checklist comprising 57 items of patient concern and 18 professionals tiled alphabetically (Ghazali et al., 2015). These items have been grouped into 5 domains: (A) Physical and Functional well-being (29 items); (B) Psychological and Emotional well-being/Spiritual (14 items); (C) Social care/Social well-being (9 items); (D) Treatment-related (4 items) and (E) Other (1 items). The PCI asks respondents to indicate items from the checklist they were concerned about and wanted to discuss with the doctor during their consultation. Patients were also asked to indicate professionals from the checklist they would like to speak or be referred to.

2.3. Study design

This work is part of a wider prospective project evaluating the PCI intervention set up into three study blocks organized sequentially. In Block 1, patients did not complete the PCI before their consultation, representing usual practice and the control group. In Block 2, patients completed the PCI at the pre-consultation stage but the PCI was withheld from clinicians during consultation, representing the ‘control in attention’ group. In Block 3, patients completed the PCI at the pre-consultation stage; the completed PCI was passed on to the clinicians and was available for use during the consultation, representing the intervention group. For the purpose of this study only patients from Blocks 2 and 3 were selected, and the PCI data acquired was derived from the clinic they had first experienced using the PCI.

All recruited patients also completed the DT at pre-consultation. Questionnaires were administered in a paper format. The length of consultation was determined from the start to the end of consultation, which was audio-recorded and subsequently transcribed. Thematic content analyses of the audio-recorded transcriptions were carried out by two assessors (NG, BR) based on a thematic framework approach (Ghazali et al., 2012b). Clinic outcomes were classified as medical (e.g. placement on surgical waiting list to aid rehabilitation, institution of symptomatic or supportive medical treatment, request for investigations, and onward referrals) or non-medical actions (e.g. provide information, advice on lifestyle, strategies for coping, and reassurance).

2.4. Data analysis

To examine the relationship between distress and other variables, Fishers Exact test, Pearson's chi-squared test or Mann–Whitney analysis were applied as appropriate. Statistical significance was regarded as $p \leq 0.01$. All statistical analysis was performed using SPSS version 19.0 (SPSS Inc.).

3. Results

One hundred and seventy patients ($n = 170$) were recruited at first attendance at clinics within study Blocks 2 and 3 during which they first used the PCI. Clinicopathological characteristics of these patients are shown in Table 1. Overall the median (IQR) time from primary surgery (or from primary diagnosis if no surgery) to clinic attendance was 2.2 (1.2–3.9) years, $n = 167$. The median (IQR) length of consultation was 5.2 (3.2–7.9) minutes, $n = 141$.

3.1. Distress and patient concerns

The mean DT score overall was 2.9 and the median (IQR) was 2 (0–5). The overall rate of significant distress (i.e. DT cut-off score of ≥4) was 36% (62/170). Thus, about two-thirds (64%, 108/170) of this cohort at clinic did not report significant distress.

Overall, the number of PCI items selected ranged from 0 to 18, mean 3.63, median (IQR) 2 (1–5). Patients with significant distress selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2–8) versus 2.61, 2 (0–4), Mann–Whitney test $p < 0.001$). More specifically, they selected more items from within the Physical and Functional well-being domain (mean 3.87 versus 1.96) and the Psychological and Emotional well-being domain (1.16 versus 0.46) than from the Social care/Social well-being domain (0.21 versus 0.10) and Treatment-related domain (0.16 versus 0.08). The association between PCI items and significant distress is also summarised in Table 2. There were trends within each domain for the likelihood of significant distress to increase with the number of items selected and for this to be compounded within the total score. In stepwise logistic regression to predict significant distress using the category variables within Table 2, the total number of items was the only variable selected (at $p < 0.001$) in regression modelling with $p < 0.01$ inclusion criteria. Three distinct predictive groups were apparent: 21% of patients selecting zero items – 9% (3/35) distressed, 47% selecting 1–4 items – 30% (24/80) distressed, and 32% selecting 5 or more items – 64% (35/55) distressed. Possible cut-offs in the number of PCI items selected in relation to significant distress are explored in Table 3. Specific PCI items associated with significant distress are shown in Table 4.

Table 1
Clinicopathological characteristics of the study sample.

		All patients ($n = 170$)
Gender	Male	66% (113)
	Female	33% (56)
	Not known	0.6% (1)
Age	Mean (SD)	64.2 (11.4)
	Median (IQR)	64 (58–73)
	<55	16% (27)
	55–64	36% (62)
	65–74	30% (51)
	75+	15% (26)
	Not known	2% (4)
Specialty	MFU	53% (90)
	ENT	46% (79)
	Not known	0.6% (1)
Tumour site	Oral	37% (63)
	Oro-pharyngeal	21% (35)
	Laryngeal	21% (36)
	Other	21% (36)
Histology	SCC	84% (143)
	Not SCC	15% (26)
	Not known	0.6% (1)
Overall P stage	1	29% (50)
	2	18% (31)
	3	11% (18)
	4	29% (50)
	Not known	12% (21)
Primary treatment	Surgery only	46% (78)
	Surgery + RT/CRT	38% (64)
	RT/CRT only	14% (23)
	Not known	3% (5)
Free-flap (142 with surgery)	Surgery without FF	72% (102)
	Surgery with FF	27% (38)
	Not known	1% (2)

MFU, maxillofacial unit; ENT, otorhinolaryngology; SCC, squamous cell carcinoma; RT, radiotherapy; CRT, chemoradiotherapy; FF, free flap.

3.2. Distress and patient concerns and length of consultation

The median (IQR) number of items actually discussed in the audio recorded consultations was 3 (2–5) items, $n = 141$. When patients were distressed and three or fewer items were discussed (19 patients), the median (IQR) length of consultation was 4.2 (3.1–6.0) minutes; when four or more items were discussed (33 patients), the median (IQR) consultation length was 8.4 (5.5–12.1) minutes (Mann–Whitney test, $p < 0.001$). In the absence of distress and three or fewer items were discussed (63 patients), the median (IQR) length of consultation was 3.3 (2.6–6.2) minutes; when four or more items were discussed (26 patients) the median (IQR) consultation length was 6.4 (4.3–8.9) minutes (Mann–Whitney test, $p < 0.001$).

3.3. Distress and perceived need for services

Overall, the number of professionals selected ranged from 0 to 4, mean 0.38, median (IQR) 0 (0–1), $n = 170$, with a mean 0.53 selected in those with significant distress and a mean 0.30 without significant distress. No strong associations were found with type of professional selected, though it was noted that 52% (11/21) of those

Table 2
Number of PCI items selected and significant distress (DT ≥ 4).

	Significant distress (DT ≥ 4)		
	%	n	p value[a]
Physical & functional well-being			
0	20%	11/56	
1–2	32%	16/50	
3–4	42%	13/31	<0.001
5–9	71%	17/24	
≥10 (range 10–15)	56%	5/9	
Treatment related			
0	35%	53/152	0.30
≥1 (range 1–2)	50%	9/18	
Social care & social well-being			
0	33%	50/150	0.03
≥1 (range 1–3)	60%	12/20	
Psychological, emotional & spiritual wellbeing			
0	28%	28/100	
1–2	42%	24/57	0.001
≥3 (range 3–6)	77%	10/13	
Total number of items			
0	9%	3/35	
1–2	30%	17/56	
3–4	29%	7/24	<0.001
5–9	61%	25/41	
≥10 (range 10–18)	71%	10/14	
Health professionals			
0	31%	37/121	0.01
≥1 (range 1–4)	51%	25/49	

[a] Chi-square test (physical & functional, psychological emotional & spiritual well-being, total number), otherwise Fisher's exact test.

Table 3
Possible cut-offs in the number of PCI items in relation to significant distress.

Number of total PCI items as cut-off	Sensitivity	Specificity	Positive predictive value	Negative predictive value
≥1	95% (59/62)	30% (32/108)	44% (59/135)	91% (32/35)
≥2	82% (51/62)	49% (53/108)	48% (51/106)	83% (53/64)
≥3	68% (42/62)	66% (71/108)	53% (42/79)	78% (71/91)
≥4	61% (38/62)	72% (78/108)	56% (38/68)	76% (78/102)
≥5	56% (35/62)	81% (88/108)	64% (35/55)	77% (88/115)
≥6	42% (26/62)	88% (95/108)	67% (26/39)	73% (95/131)
≥7	34% (21/62)	90% (97/108)	66% (21/32)	70% (97/138)

Table 4
Specific PCI items associated with significant DT distress (DT score ≥ 4).

PCI item	If PCI item selected, what % had a DT score ≥ 4		If PCI item NOT selected, what % had a DT score ≥ 4		p value[a]
Anxiety	77	10/13	33	52/157	0.005
Bowel	78	7/9	34	55/161	0.01
Depression	88	7/8	34	55/162	0.004
Fatigue	62	21/34	30	41/136	0.001
Mood	78	7/9	34	55/161	0.01
Pain in head/neck	65	17/26	31	45/144	0.002
Sleeping	65	13/20	33	49/150	0.007
Swallowing	67	20/30	30	42/140	<0.001

[a] Fishers exact test.

wanting to see the surgeon were distressed, 83% (5/6) of those wanting to see the physiotherapist, and all those wanting to see either a psychologist (2/2) or Emotional Support therapist (2/2).

The number of medical actions taken based on audiotaped consultations (n = 141) ranged from 1 to 4, and the percentage with 2 or more actions was 52% (27/52) for those with significant distress and 29% (26/89) without distress (Fishers exact test, p = 0.01). In regard to non-medical actions (range 2–4), the percentage with 3 or more actions was 37% (19/52) for those with significant distress and 21% (19/89) without distress (Fishers exact test, p = 0.18).

4. Discussion

This seminal work evaluated the relationship between patient concerns and distress in post-treatment HNC survivors using PCI. We found a very strong association between level of distress and number of reported concerns. Distress levels was associated with the number of items of concerns selected, suggesting that the number of PCI items selected could potentially be a surrogate marker of significant distress. Concerns relating to the Psychological and Emotional well-being and the Physical and Functional well-being domains were related to significant distress. The study also demonstrated that experiencing significant distress and having numerous concerns impacts upon the length of consultations and the outcomes of these consultations. Furthermore, the study findings also suggest that when the PCI is used as a single tool, it can potentially undertake multiple tasks simultaneously i.e. enable patients to voice their concerns, identify those at risk of significant distress, sign-post supportive services required by patients and may facilitate the running of outpatient clinics by indicating which patients may require longer appointments based on their profile of concerns.

The study design allowed a prospective, multicenter recruitment of a cohort representing the breadth of HNC subsites attending routine follow-up clinics run by multiple clinicians of different specialities. The data acquired was cross-sectional and this must be considered in relation to the nature of distress, which can be experienced at anytime during the cancer journey. Furthermore, patient concerns also vary at different time-points along the cancer journey (Richardson et al., 2007). The degree of concern expressed may fluctuate and could contribute differently toward the overall experience of cancer-related distress. We have not specifically attempted to quantify the degree of concern per item selected other than establishing the presence of a significant problem for the item of concern as described previously (Rogers et al., 2009, 2010; Ghazali et al., 2013; Kanatas et al., 2012; Rogers et al., 2012; Flexen et al., 2012; Ghazali et al., 2012a).

The majority of patients in this cohort did not experience significant distress (64%, 108/170). Patients with significant distress selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2–8) versus 2.61, 2 (0–4); Mann–Whitney test, p < 0.001). This corresponds to other studies (Maguire, 2002; Chaturvedi et al., 1996) where patient concerns were related with the development of distress. The potential relationship between the numbers of concerns with the likelihood of experiencing significant distress was further evaluated, where it was possible to suggest a cut-off point indicating significant distress with a reasonable degree of sensitivity and specificity. On balance, cut-off points of either ≥4 or ≥5 items of concern selected on the PCI demonstrated an acceptable level of sensitivity, specificity and predictive values (Table 3) for likelihood of experiencing significant distress. From a clinical perspective, using either ≥4 or ≥5 cut-off score can help guide clinicians in risk assessing patients for significant distress, who may benefit from more in depth evaluation and intervention, at pre-consultation.

Those experiencing significant distress were more likely to select items from the Physical and Functional well-being domain (p < 0.001) and the Psychological and Emotional well-being domain (p = 0.001). This finding demonstrates that emotional distress is not the only significant contributing factor in cancer-related distress in a HNC population predominantly treated with surgery (84%, 142/170). Severe distress, in particular physical distress related to oral cavity dysfunction, has been reported in another HNC cohort treated by ablative surgery and immediate reconstruction (Chen et al., 2009). Furthermore, the use of RT (Ghazali et al., 2017; Lewis et al., 2013) and chemoRT (Chen et al., 2013) are also strongly associated with significant distress in this population. HNC survivors struggling to cope with the after-effects of HNC treatment are likely to express significant distress and require physical support more than any other cancer types (Chen et al., 2009, 2013). Addressing significant distress related to physical concerns can be initiated in clinic. This includes both non-medical (e.g. education, advice, reassurances) and medical actions (e.g. investigations, surgery, medications, referrals). Treatment-related domain was not associated with significant distress (p = 0.3). It is possible that disease-free, post-treatment HNC patients were less likely to be significantly distressed about these issues following treatment completion. Comparisons with other studies are not possible due to methodological differences in assessing concerns (Jacobsen et al., 2005; Grassi et al., 2013).

When individual PCI items of concern were evaluated, Anxiety (p = 0.005), Depression (p = 0.004), Mood (p = 0.01), Pain in head/neck (p = 0.002), Sleeping (p = 0.007), Fatigue (p = 0.001), Swallowing (p < 0.001) and Bowel habit (p = 0.01) were related to significant distress. Apart from bowel habit, the other concerns associated with significant distress in this study have been consistently been reported by HNC patients previously (Rogers et al., 2009; Kanatas et al., 2012; Ghazali et al., 2012a). It is recognised that Anxiety, Mood and Depression are essential components of, and possible overlapping elements of emotional distress in cancer (Holland and Bultz, 2007; Pandey et al., 2006). Post-treatment dysphagia is related to weight loss, progressive reduction in swallowing function, narrowing range of oral dietary intake and reliance on gastrostomy tube feeding (Oozeer et al., 2011), and these confer a global impact on the long-term day-to-day functioning and QOL (Cartmill et al., 2012). Altered bowel function is related to distress in colorectal, urological and gynaecological cancer survivors but this has never been reported previously in HNC cohorts. This finding may be related to complications of opiate analgesia use, alterations to bowel function due to full reliance on enteral feeding and also secondary to hormonal imbalances in a subgroup of thyroid cancers included within this study cohort. Pain is highly correlated to significant distress in HNC patients throughout the survivorship trajectory (Lewis et al., 2013; Maher et al., 2013). Cancer-related fatigue is a common problem in cancer survivors (Carlson et al., 2004; Brown and Kroenke, 2009) and is linked to emotional reactivity (Rissanen et al., 2014; Bower, 2014). Like pain, sleep disturbances and insomnia can occur throughout the survivorship trajectory in HNC survivors (Scarpa et al., 2014; Zhou and Jolly, 2014). While individual symptom/concern was related to significant distress in its own right, there is increasing interest in the prevalence of symptoms that frequently co-occur in symptom clusters with distress. For example, sleep disturbances and insomnia occur commonly with other frequently reported side effects of cancer and/or its treatment, namely pain, fatigue, depression and distress (Butt et al., 2008; Garland et al., 2014). It is postulated that the clustering of co-occurring symptoms might be related to underlying inflammatory processes common to these concerns (Garland et al., 2014).

Overall, the number of professionals selected ranged from 0 to 4, mean 0.38, median (IQR) 0 (0–1), n = 170. From the patent's perspectives, the attending doctor in clinic is often seen as the main clinician managing their cancer care. Thus, it is unsurprising that patients have indicated this professional as the one they would like to see or meet during their appointment, particularly those experiencing significant distress (52%, 11/21). Furthermore, those who were significantly distressed were more likely to select other professionals compared with those not experiencing significant distress (mean 0.53 vs. 0.30). In this scenario, perhaps the attending clinician needs to be more proactive in suggesting onward referral or having direct access to the other professionals' support in clinic. However, it remains unclear why so few additional HNC multidisciplinary personnel are ticked generally on the PCI and this is a subject of future research.

Those significantly distressed with larger numbers of concerns were more likely to have had longer consultations compared with patients not reporting significant distress with fewer concerns. Apart from increasing the length of consultation, significant distress impacts upon the individual management of these patients. Overall, those with significant distress were more likely to receive both medical and non-medical actions related to their consultation compared to those without distress. While this finding is unsurprising, it places huge demand upon resources and outpatient clinic management. A different approach may be required to meet the concerns of significantly distressed patients in clinics where the PCI is used. Suggestions include asking patients to prioritize their list of concerns for discussion during clinic, referral to the most appropriate professional who may be present at the clinic or at another appointment and self-referral through a web-based PCI application. Future work should focus on the impact of PCI-directed pathways in managing distress.

5. Conclusions

Significant distress is experienced in just over one-third of post-treatment HNC patients attending clinic. The PCI has the potential to be a risk assessment tool for significant distress. Using the PCI with a cut-off point ≥ 4 or ≥ 5 of items selected, it was possible to identify those at risk of significant distress. The concerns of patients with significant distress were related to Psychological and Emotional/Spiritual well-being, and to Physical and Functional well-being. Treatment that maximizes functional outcomes without compromising cure should be considered at the outset to address this upfront. A shift of emphasis toward supportive rehabilitation is paramount in the post-treatment period, where managing physical and psychological concerns with close involvement of other personnel within a multidisciplinary team is required. Addressing concerns and distress can result in longer consultations and a higher number of both medical and non-medical actions. Further work is required in understanding the impact of distress screening and PCI-directed pathways in the management of patient concerns.

Acknowledgement

The authors would like to acknowledge Professor James Brown, FDSRCS, FRCS (OMFS) for his contributions toward data collection. This study was funded by the British Association of Oral & Maxillofacial Surgeons' Endowment funds.

References

Bower JE: Cancer-related fatigue-mechanisms, risk factors, and treatments. Nat Rev Clin Oncol 11: 597, 2014

Brown LF, Kroenke K: Cancer-related fatigue and its associations with depression and anxiety: a systematic review. Psychosomatics 50: 440, 2009

Butt Z, Wagner LI, Beaumont JL, Paice JA, Straus JL, Peterman AH, et al: Longitudinal screening and management of fatigue, pain, and emotional distress associated with cancer therapy. Support Care Cancer 16: 151, 2008

Carlson LE, Angen M, Cullum J, Goodey E, Koopmans J, Lamont L, et al: High levels of untreated distress and fatigue in cancer patients. Br J Cancer 90: 2297, 2004

Carlson LE, Waller A, Mitchell AJ: Screening for distress and unmet needs in patients with cancer: review and recommendations. J Clin Oncol 30: 1160, 2012

Cartmill B, Cornwell P, Ward E, Davidson W, Porceddu S: Long-term functional outcomes and patient perspective following altered fractionation radiotherapy with concomitant boost for oropharyngeal cancer. Dysphagia 27: 481, 2012

Chaturvedi SK, Shenoy A, Prasad KM, Senthilnathan SM, Premlatha BS: Concerns, coping and quality of life in head and neck cancer patients. Support Care Cancer 4: 186, 1996

Chen SC, Liao CT, Lin CC, Chang JT, Lai YH: Distress and care needs in newly diagnosed oral cavity cancer patients receiving surgery. Oral Oncol 45: 815, 2009

Chen SC, Lai YH, Liao CT, Chang JT, Lin CY, Fan KH, et al: Supportive care needs in newly diagnosed oral cavity cancer patients receiving radiation therapy. Psychooncology 22: 1220, 2013

Flexen J, Ghazali N, Lowe D, Rogers SN: Identifying appearance-related concerns in routine follow-up clinics following treatment for oral and oropharyngeal cancer. Br J Oral Maxfac Surg 50: 314, 2012

Garland SN, Johnson JA, Savard J, Gehrman P, Perlis M, Carlson L, et al: Sleeping well with cancer: a systematic review of cognitive behavioural therapy for insomnia in cancer patients. Neuropsychiatr Dis Treat 10: 1113, 2014

Gessler S, Low J, Daniells E, Williams R, Brough V, Tookman A, et al: Screening for distress in cancer patients: is the distress thermometer a valid measure in the UK and does it measure change over time? A prospective validation study. Psychooncology 17: 538, 2008

Ghazali N, Kanatas A, Scott B, Lowe D, Zuydam AC, Rogers SN: Use of the patient concerns inventory to identify speech and swallowing concerns following treatment for oral and oropharyngeal cancer. J Laryngol Otol 126: 800, 2012a

Ghazali N, Roe B, Lowe D, Rogers SN: Uncovering patient agendas in routine head and neck oncology follow up clinics: an exploratory study. Br J Oral Maxfac Surg 51: 294, 2012b

Ghazali N, Cadwallader E, Lowe D, Humphris G, Ozakinci G, Rogers SN: Fear of recurrence among head and neck cancer survivors: longitudinal trends. Psychooncology 22: 807, 2013

Ghazali N, Roe B, Lowe D, Rogers SN: Patients concerns inventory highlights perceived needs and concerns in head and neck cancer survivors and its impact on health-related quality of life. Br J Oral Maxfac Surg 53: 371, 2015

Ghazali N, Roe B, Lowe D, Tandon S, Jones T, Brown J, et al: Screening for distress using the distress thermometer and the University of Washington Quality of Life in post-treatment head and neck cancer survivors. Eur Arch Otorhinolaryngol 274: 2253, 2017

Grassi L, Johansen C, Annunziata MA, Capovilla E, Costantini A, Gritti P, et al: Italian Society of Psycho-Oncology Distress Thermometer Study Group: Screening for distress in cancer patients: a multicenter, nationwide study in Italy. Cancer 119: 1714, 2013

Holland JC, Bultz BD: The NCCN guideline for distress management: a case for making distress the sixth vital sign. J Natl Compr Canc Netw 5: 3, 2007

Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, et al: Screening for psychologic distress in ambulatory cancer patients. Cancer 103: 1494, 2005

Kanatas A, Ghazali N, Lowe D, Rogers SN: The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. Int J Oral Maxillofac Surg 41: 429, 2012

Lewis S, Salins N, Kadam A, Rao R: Distress screening using distress thermometer in head and neck cancer patients undergoing radiotherapy and evaluation of causal factors predicting occurrence of distress. Indian J Palliat Care 19: 88, 2013

Maguire P: Improving the recognition of concerns and affective disorders in cancer patients. Ann Oncol 13(Suppl. 4): 177, 2002

Maher NG, Britton B, Hoffman GR: Early screening in patients with head and neck cancer identified high levels of pain and distress. J Oral Maxillofac Surg 71: 1458, 2013

National Comprehensive Cancer Network: Clinical practice guidelines in oncology-v.1.2005. Distress Management, version 1; 2005

Ozalp E, Cankurtaran ES, Soygür H, Geyik PO, Jacobsen PB: Screening for psychological distress in Turkish cancer patients. Psychooncology 16: 304, 2007

Oozeer NB, Corsar K, Glore RJ, Penney S, Patterson J, Paleri V: The impact of enteral feeding route on patient-reported long term swallowing outcome after chemoradiation for head and neck cancer. Oral Oncol 47: 980, 2011

Pandey M, Srita GP, Devi N, Thomas BC, Hussain BM, Krishnan R: Distress anxiety and depression in cancer patients undergoing chemotherapy. World J Surg Oncol 4: 68, 2006

Richardson A, Medina J, Brown V, Sitzia J: Patients' needs assessment in cancer care: a review of assessment tools. Support Care Cancer 15: 1125, 2007

Rissanen R, Arving C, Ahlgren J, Nordin K: Group versus individual stress management intervention in breast cancer patients for fatigue and emotional reactivity: a randomised intervention study. Acta Oncol 53: 1221, 2014

Rogers SN, El-Sheikha J, Lowe D: The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol 45: 555, 2009

Rogers SN, Scott B, Lowe D, Ozakinci G, Humphris GM: Fear of recurrence following head and neck cancer in the outpatient clinic. Eur Arch Otorhinolaryngol 267: 1943, 2010

Rogers SN, Cleator AJ, Lowe D, Ghazali N: Identifying pain-related concerns in routine follow-up clinics following oral and oropharyngeal cancer. World J Clin Oncol 3: 116, 2012

Scarpa M, Pinto E, Saadeh LM, Parotto M, Da Roit A, Pizzolato E, et al: Sleep disturbances and quality of life in postoperative management after esophagectomy for esophageal cancer. World J Surg Oncol 12: 156, 2014

Shim EJ, Mehnert A, Koyama A, Cho SJ, Inui H, Paik NS, et al: Health-related quality of life in breast cancer: A cross-cultural survey of German, Japanese, and South Korean patients. Breast Cancer Res Treat 99: 341, 2006

Zhou J, Jolly S: Obstructive sleep apnea and fatigue in head and neck cancer patients. Am J Clin Oncol 38: 411, 2015

Appendix 17: Published paper using data derived from MD study

Zhou Y, Humphris G, Ghazali N, Friderichs S, Grosset D, Rogers SN. How head and neck consultants manage patients' emotional distress during cancer follow-up consultations: a multilevel study. Eur Arch Otorhinolaryngol. 2015 Sep;272(9):2473-81. doi: 10.1007/s00405-014-3209-x.

Eur Arch Otorhinolaryngol (2015) 272:2473–2481
DOI 10.1007/s00405-014-3209-x

How head and neck consultants manage patients' emotional distress during cancer follow-up consultations: a multilevel study

Yuefang Zhou · Gerry Humphris · Naseem Ghazali · Simon Friderichs · David Grosset · Simon N. Rogers

Received: 13 June 2014 / Accepted: 24 July 2014 / Published online: 31 July 2014

Abstract Head and neck cancer (HNC) patients suffer substantial emotional problems. This study aimed to explore how utterance-level variables (source, type and timing of emotional cues) and patient-level variables (e.g. age, gender and emotional well-being) relate to consultants' responses (i.e. reducing or providing space) to patient expressions of emotional distress. Forty-three HNC outpatient follow-up consultations were audio recorded and coded, for patients' expressions of emotional distress and consultants' responses, using the Verona Coding Definitions of Emotional Sequence. Multilevel logistic regression modelled the probability of the occurrence of consultant-reduced space response as a function of patient distress cue expression, controlling for consultation and patient-related variables. An average of 3.5 cues/concerns (range 1–20) was identified per consultation where 84 out of 152 total cues/concerns were responded by reducing space. Cue type did not impact on response; likewise for the quality of patient emotional well-being. However, consultants were more likely to reduce space to cues elicited by patients, as opposed to those initiated by themselves. This reduced space response was more pronounced as the consultation continued. However, about 6 min into the consultation, this effect (i.e. tendency to block patients) started to weaken. Head and neck consultants' responses to negative emotions depended on source and timing of patient emotional expressions. The findings are useful for training programme development to encourage consultants to be more flexible and open in the early stages of the consultation.

Keywords Head and neck cancer · Emotional distress · The VR-CoDES · Multilevel

Abbreviations

HNC	Head and neck cancer
NICE	National Institute for Clinical Excellence
OSCE	Objective and structured clinical examination
VR-CoDES	Verona Coding Definitions of Emotional Sequence
QoL	Quality of life
PCI	Patient concerns inventory

Introduction

Head and neck cancer (HNC) patients suffer substantial psychological distress [1–3]. Appropriate attendance to patient emotional needs, a key feature of patient-centred

Y. Zhou (✉) · G. Humphris · S. Friderichs · D. Grosset
School of Medicine, University of St Andrews, St Andrews, Fife, KY16 9TF St Andrews, Scotland, UK
e-mail: yz10@st-andrews.ac.uk

S. Friderichs
e-mail: saf3@st-andrews.ac.uk

D. Grosset
e-mail: dg54@st-andrews.ac.uk

G. Humphris
Edinburgh Cancer Centre, The Western General Hospital, Edinburgh EH4 2XU, UK
e-mail: gmh4@st-andrews.ac.uk

N. Ghazali · S. N. Rogers
Oral and Maxillofacial Surgery, Aintree University Hospital, Liverpool L9 7AL, UK
e-mail: naseemghazali@doctors.org.uk

S. N. Rogers
Evidence-Based Practice Research Centre (EPRC), Faculty of Health, Edge Hill University, Ormskirk L39 4QP, UK
e-mail: snrogers.aintree@gmail.com

care, has been found to be associated consistently with many improved patient outcomes in both general medicine [4] and oncology [5, 6]. In the United Kingdom, the National Institute for Clinical Excellence (NICE) guidelines recommended that the psychosocial issues are routinely assessed and discussed in oncology practice [7]. Despite recognised patient benefits, national efforts and many communication-training programmes [8, 9], research evidence suggests a continued prevalence of unaddressed psychological issues among cancer patients [10–14]. It is, therefore, important to intricately investigate the factors influencing oncologists' positive responses to patients' negative emotions in routine oncology practice.

Previous studies suggested that a number of variables, at different levels of the consultation, impact on a clinician's response to patient emotional expressions. At the conversation (i.e. utterance) level, source [15–17], type [18, 19] and timing [17, 19] of emotional expression were found to be important predictors for clinicians' responses. Regarding source of emotion (i.e. cues elicited by patients versus clinicians), Pollak et al. [15] found that, when patients initiated negative emotions, oncologists responded with a terminator statement 73 % of the time, to discourage further disclosure of emotions. Similar findings were reported in more recent studies, where a multilevel approach was adopted to respect the clustered nature of the data contained within the consultation [16, 17]. Del Piccolo et al. [16] found that psychiatrists provided space for further disclosure of a concern more frequently when the concern had been initiated by the psychiatrist in the first place. Finset et al. [17] supported this finding in a cancer care setting that oncologists were more likely to give room for further disclosure of cues/concerns that were initiated by themselves. However, no published evidence is available so far to support this relationship in HNC consultations. With regard to the type of emotion, Kennifer et al. [18] reported that oncologists responded most empathically to intense emotions. A recent multilevel study confirmed that certain cue types influenced the way that medical students responded to the simulated patients in the Objective Structured Clinical Examinations (OSCE) [19]. In this study, the cue types and responses were coded according the Verona Coding Definitions of Emotional Sequence (VR-CoDES) [20, 21]. The importance of studying timing of cue expression in medical consultations has been highlighted in a ground-breaking review [22]. A number of recent multilevel sequential studies have subsequently confirmed the significance of timing in relation to provider responses. For example, medical students were more likely to reduce space to emotional cues expressed by simulated patients nearer the end of the 5-min OSCE consultations [19]. In a similar direction, oncologists were found to give more space for emotional disclosure to the first cue/concern in real consultations of more than 10 min [17]. Again, little is known about how the cue type and the timing of cue expression might impact on oncologists' responses to emotions expressed by HNC patients.

At the patient-level (i.e. consultation), female patients with female oncologists were more likely to encourage empathic responses from clinicians [17]. Emotion-related quality of life of cancer patients has also been indicated as a predictor influencing the discussion around emotion during consultations [14]. There is little evidence showing how HNC patients' emotional well-being might relate to the dynamics of emotional discussion with their clinicians.

In the light of the studies discussed above, this study aims to explore how utterance-level variables (source, type and timing of emotional cues) and patient-level variables (age, gender and emotional well-being) relate to oncologists' responses to HNC patients' emotional distress.

Methods and materials

Participants and procedures

Patient participants were 58 HNC survivors attending follow-up outpatient consultations at Aintree University hospital, Liverpool, UK. Those consultations without emotional distress cues ($n = 14$) and those with unusually frequent emotional cues ($n = 1$) were excluded, resulting in 43 consultations included in the study. Generally speaking, the cohort was a heterogeneous group having had different treatment combinations. In addition, these patients were all on longitudinal follow-up appointments (up to 5 years post-treatment). However, none of the patients received any specific intervention (e.g. psychological therapy) for emotional issues before the consultation. Staff participants were four head and neck consultations (all male) with at least 3 years of working experience. Each consultant had a minimum of ten consultations. All patients completed a quality of life (QoL) survey (84 % also completed a Patient Concerns Inventory (PCI) [23]) prior to the consultation being audio recorded. Informed written consent was obtained from both patient and consultants. The study was part of a larger study aiming to investigate patients' concerns in head and neck oncology settings, which was given a favourable ethical opinion on 21st February 2011, by the North West 3 Research Ethics Committee—Liverpool East (approval number: 11/H1002/7). Therefore, this study has been performed in accordance with the ethical standards laid down in an appropriate version of the 1964 Declaration of Helsinki.

Table 1 Definitions of cues and concerns and examples from the HNC consultations

Definitions	Typical examples from the H&N cancer consultations
CONCERN: a clear and unambiguous expression of an unpleasant current or recent emotion where the emotion is explicitly verbalised with or without a stated issue of importance	Are you sure it's nothing else though? That's what I am concerned about I am now feeling quite anxious I am concerned that it might be like a…something there
CUE: a verbal or non-verbal hint suggests an underlying unpleasant emotion and would need a clarification from the health provider Instances included	
Cue A: vague or unspecified words or phrases in which the patient uses to describe his/her emotions	Well, I am really nervous now I am so stressed out at the moment Just tightness sometimes isn't it You know sometimes I go ouch you know
Cue B: verbal hints to hidden concerns (emphasising, unusual words, unusual description of symptoms, profanities, exclamations, metaphors, ambiguous words, double negations, expressions of uncertainties and hope)	What the hell is wrong with me? It wiped me out completely And I've got this funny sensation…creeping feeling
Cue C: words or phrases that emphasises (verbally or non-verbally) physiological or cognitive correlates (regarding sleep, appetite, physical energy, excitement or motor slowing down, sexual desire, concentration) of unpleasant emotional states	I've gone off my appetite; I am not eating properly at all I am still feeling a bit tired I cannot seem to open my mouth as wide as I used to
Cue D: neutral expressions that mention issues of potential emotional importance which stand out from the narrative background and refer to stressful life events and conditions	I've been made redundant, busy suing my employer I'm bad tempered all the time I'm seeing a counsellor If I'm having my tea, and something gets stuck, then that's it. I can't eat anymore And that's about it now
Cue E: a patient-elicited repetition of a previous neutral expression (repetitions, reverberations or echo of neutral expression within a same turn are not included)	Turn 1. It just feels tight Turn 2. It just feels tight when I swallow
Cue F: non-verbal cues including clear expressions of negative or unpleasant emotions (crying) or hint to hidden emotions (sighing, silence after provider question, frowning etc.)	Not available with audio data
Cue G: a clear and unambiguous expression of an unpleasant emotion which occurred in the past (more than 1 month ago) or is without time frame	I was really worried at the time I had a bit of a panic when I came here last time…that little lump I really had a rough time

HNC head and neck cancer

Measures

The VR-CoDES, previously applied in the oncology setting [17], was employed to code both patient expression of emotional distress [20] and consultants' responses [21]. It is a well-validated scheme developed over 10 years by an international expert group of researchers and practitioners. According to the manual, an emotional cue is defined as a hint suggesting an underlying negative emotion, whereas a concern is an explicitly verbalised expression of negative emotion. Examples of coded cues/concerns and responses were presented in Table 1. In coding responses to emotional cues/concerns, the dimension of providing space versus reducing space (i.e. providing or reducing room for further disclosure of emotion) has been considered in our analysis. Two medical students, trained on the VR-CoDES, coded the transcripts while listening to the tape to preserve the voice tone. Coding was overseen by an experienced coder (YZ) and a member of the VR-CoDES developer (GH). Both inter- and intra-coder reliabilities were considered satisfactory according to Altman's criteria [24] (Table 2). The subscale of mood and anxiety from the University of Washington Head and Neck Cancer Questionnaire (UW-QoL, V4 [25]) was used to indicate the quality of patient emotional well-being.

Data analysis

A two-level logistic regression was conducted to acknowledge the nested data structure, where utterances (level 1) were nested within consultations (level 2). The outcome variable was reduced space response. Explanatory variables at level 1 were: specific type of cue and concern (1 presence, 0 absence), time location when a cue/concern was expressed relative to the first utterance start time, patient elicitation (1 patient elicited, 0 consultant elicited). Predictive variables at level 2 were: QoL scores on mood and anxiety (0–200, with a higher score indicating a better quality), patient age, gender (1 male, 0 female), cancer stage (1–4, with a higher score describing increased disease severity) and consultation duration (in seconds). Analysis

Table 2 Results of inter- and intra-coder reliability ($n = 44$)

Type	Occasion of check	No. of transcripts	Cohen's Kappa (95 % CI)		
			Cues/concerns	Elicitation (patient/clinician)	Response (provide/reduce space)
Inter-coder	Beginning	2	0.71 (0.64, 0.81)	0.82 (0.69, 0.97)	0.74 (0.54, 0.80)
	Closer to the end	3	0.75 (0.48, 0.80)	0.78 (0.58, 0.88)	0.86 (0.69, 0.92)
Intra-coder	Coder 1	2	0.79 (0.76, 0.85)	0.93 (0.81, 0.99)	0.79 (0.66, 0.84)
	Coder 2	2	0.92 (0.81, 0.98)	0.86 (0.79, 0.98)	0.84 (0.67, 0.91)

Table 3 Patient characteristics ($n = 43$)

Clinical/demographic information	Descriptive statistics
Age (year)	Mean 62.86 (SD 15.10), (range 21–91)
Gender	
Male	24 (55.81 %)
Female	19 (44.19 %)
Smoking	
Never smoked	26 (60.47 %)
Currently smoking	11 (25.58 %)
Previous smoked	6 (13.95 %)
Alcohol	
Yes (including rarely)	17 (39.53 %)
No (never)	24 (55.81 %)
Previous alcoholic	2 (4.65 %)
Cancer stage	Mean 2.19 (SD 1.20), (range 1–4)
Tumour site	
Oral cavity	13 (30.23 %)
Larynx	10 (23.26 %)
Oro-pharynx	11 (25.58 %)
Other (thyroid, nose, salivary gland, unknown)	9 (20.93 %)
Treatment	
Surgery alone	17 (39.53 %)
Radiotherapy alone (RT)	4 (9.30 %)
Chemo-radiotherapy (CRT)	3 (6.98 %)
Surgery + RT	16 (37.21 %)
Surgery + CRT	3 (6.98 %)
Follow-up appointment duration (minutes)	Mean 5.50 (SD 2.84), (range 1.5–13.18)
Time interval between treatment completion and video consultation (months)	Mean 25.44 (SD 14.43), (range 1–55)

Categorical variables are presented with percentages with absolute values, while continuous variables are presented with means, standard deviations, minimum and maximum values

followed three steps: (1) a null model with random intercept, explored the variance composition at each level; (2) predictive variables were entered at level 1 followed by level 2, with variables with a significant effect at $p < 0.05$ were retained for the next model; and (3) patient demographics and the consultation duration was controlled for in the final model. Analyses were conducted in STATA/IC^{TM} 10.0 for Windows using the *xtmelogit* procedure.

Results

Patient characteristics

Table 3 presents descriptive statistics of relevant clinical and demographic information of the 43 participating patients. The majority of patients were over 60 years of age, with about 56 % males, and over half of the patients never smoked or drank alcohol. Overall, these patients had an average severity of cancer and about 30 % of them had oral cavity cancer. Broadly speaking, 48.83 % received a single modality treatment (i.e. surgery alone or radiotherapy alone) and 51.17 % received a multimodality treatment (i.e. chemo-radiotherapy, surgery plus radiotherapy, surgery plus chemo-radiotherapy). The average consultation duration was 5.5 min, ranging from 1.5 to 13.18 min. On average, the time interval between completion of treatment and inclusion into the study (i.e. date consultation took place) was 25.44 months, ranging from 1 to 55 months.

Frequency of cues/concerns and responses

As shown in Table 4, a total number of 152 cues/concerns were identified among 43 consultations, resulting in an average number of 3.53 cues/concerns per consultation. Cue B (verbal hints) was most frequently observed, followed by Cue D (stressful life events); whereas Cue E, F and G were rarely or never observed. Subsequent Chi-square tests confirmed no significant difference between provided versus reduced space response to specific cue types. Within the reduced space response, patient- versus clinician-elicited cue/concern, however, showed an initial difference [$\chi^2(1) = 8.067$, $p < 0.01$], which warrants further investigation when controlling for clustered effects of the consultation.

Table 4 Frequency of cues of concerns and responses (consultation $n = 43$)

Cue type/elicitation	Response			Cue/concern mean	Chi square		
	Providing space	Reducing space	Total	Per consultation	Value	*df*	*P*
Concern	4 (26.67 %)	11 (73.33 %)	15	0.35	2.198	1	0.138
Cue A	5 (38.46 %)	8 (61.54 %)	13	0.30	0.226	1	0.634
Cue B	33 (43.42 %)	43 (56.58 %)	76	1.77	0.106	1	0.744
Cue C	10 (52.63 %)	9 (47.37 %)	19	0.44	0.547	1	0.459
Cue D	14 (58.33 %)	10 (41.67 %)	24	0.56	2.131	1	0.144
Cue E	0 (0 %)	1 (100 %)	1	0.02		N/A	
Cue G	2 (50 %)	2 (50 %)	4	0.09	0.046	1	0.830
Total	68 (44.74 %)	84 (55.26 %)	152	3.53	1.684	1	0.194
Patient-elicited	19 (30.16 %)	44 (69.84 %)	63	1.47	8.067	1	0.005*
Clinician-elicited	49 (55.06 %)	40 (44.94 %)	89	2.07	0.910	1	0.340

No instance of Cue F was observed

* $p < 0.01$

Table 5 Description of variables included in the study

Outcome variable at level 1 ($n = 152$)		Min–Max
Reduced space response[a]	84 (55.26 %)	
Explanatory variable		
Level 1 (utterance, $n = 152$)		
Cue time[b](s)	164.59 (SD 148.95)	(2–702)
Patient elicitation[a]	63 (41.45 %)	
Level 2 (consultation, $n = 43$)		
UW-QoL mood + anxiety[b]	148.26 (SD 43.64)	(30–200)
Consultation duration[b](s)	329.77 (SD 170.20)	(90–791)
Patient age[b]	62.86 (SD 15.10)	(21–91)
Patient gender(male)[a]	24 (55.81 %)	
Cancer stage[b]	2.19 (SD 1.20)	(1–4)

QoL quality of life [25]

[a] Dichotomous variables are presented with percentages with absolute values

[b] Continuous variables are presented with means, standard deviations, minimum and maximum values

Consultants' responses to cues/concerns

Table 5 shows the descriptive statistics of the variables included in the multilevel analyses, except for those reported in Table 4. The frequency of the outcome variable (reduced space response) accounted for about 55 % of the entire utterances in level 1. As for the explanatory variables at level 1(utterance), approximately 40 % of the cues/concerns were initiated by patients; and on average they occurred at about 3 min after the first utterance in the consultation. Regarding predictors at level 2 (consultation), a mean score of 148.26 on QoL mood and anxiety indicated an overall satisfactory quality of emotional well-being.

A number of findings emerged from the multilevel logistic regress analyses (Table 6). (1) Overall, little variance (7.32 % in null model) was explained by the between-consultation difference. (2) Cue type did not make any impact on the occurrence possibility of the reduced space response (Model 1 and 2). (3) A positive linear relationship was found between cue time (in seconds) and the reduced space response (OR 1.00, $p < 0.01$ in Model 2, effect being preserved at Model 4 with $p < 0.05$). The model was significantly improved when the cue time-squared term was included [$\chi^2(1) = 4.44$, $p < 0.05$], suggesting that a curvilinear relationship existed between the timing of cue expression and the reduced space response (OR 0.99, $p < 0.05$). (4) Consultants reduced space to cues elicited by patients (OR 2.25, $p < 0.05$ in Model 4 with effects being consistent in all models). (5) Patient emotional QoL did not influence reduced space response (OR 0.99, $p > 0.05$).

Timing of cue expression and responses

Figure 1 shows the curvilinear relationship between the timing of cue/concern expression and probability of reduced space response occurrence. *X*-axis is the time location of a cue/concern expressed by a patient in a typical consultation up to 500 s (approximately 8.3 min, only six consultations out of our sample of 43 had a duration of over 500 s). *Y*-axis is the predicted probability of a consultant's reduced space response (log odds). As can be seen from the Fig. 1, the largest log odds occur when a cue/concern is expressed at about 360 s (6 min). This figure suggested that consultants were more likely to reduce space to emotional distress expressed closer to the end of the consultation until about 6 min into the consultation. Further into the consultation, this relationship appeared to weaken.

Table 6 Multilevel logistic regression models for the outcome variable reduced space response

Fixed effects	Null model	Model 1			Model 2			Model 3			Model 4		
		OR	95 % CI	*P*	OR	95 % CI	*P*	OR	95 % CI	*P*	OR	95 % CI	*P*
Level 1 ($n = 152$)													
Concern		3.05	0.34, 27.53	>0.05	2.46	0.23, 26.10	>0.05						
Cue A		3.11	0.32, 30.33	>0.05	3.03	0.27, 33.85	>0.05						
Cue B		2.33	0.32, 16.66	>0.05	1.77	0.21, 15.14	>0.05						
Cue C		1.72	0.20, 14.48	>0.05	1.29	0.13, 12.85	>0.05						
Cue D		1.00	0.13, 7.80	>0.05	0.73	0.08, 6.79	>0.05						
Cue time[a]		1.00	0.99, 1.01	0.067	1.00	1.00, 1.01	0.006**	1.01	1.00, 1.01	0.018*	1.01	1.00, 1.01	0.013*
Cue time squared[b]					0.99	0.99, 0.99	0.036*	0.99	0.99, 1.00	0.056	0.99	0.99, 0.99	0.047*
Patient elicitation		2.96	1.37, 6.38	0.006**	3.10	1.42, 6.79	0.005**	2.35	1.11, 5.00	0.026*	2.25	1.01, 4.79	0.036*
Level 2 ($n = 43$)													
QoL mood + anxiety								0.99	0.98, 1.00	>0.05			
Consultation duration											1.00	0.99, 1.00	>0.05
Patient age											0.71	0.32, 1.55	>0.05
Patient gender (ref: female)											0.98	0.95, 1.00	>0.05
Cancer stage											1.05	0.78, 1.40	>0.05
Random effect (intercept)													
Level 2 variance (95 % CI)	0.26 (0.02, 3.34)	0			0			0			0		
Level 2 ICC[c]	7.32 %	0			0			0			0		
Log likelihood	−103.96	−95.99			−93.77			−94.81			−94.42		
LR[1] test	$\chi^2(1) = 1.11, p > 0.05$	$\chi^2(1) = 0, p > 0.05$			$\chi^2(1) = 0, p > 0.05$			$\chi^2(1) = 0, p > 0.05$			$\chi^2(1) = 0, p > 0.05$		
LR[2] test	n/a	$\chi^2(7) = 15.94, p = 0.026$* Better than null model			$\chi^2(1) = 4.44, p = 0.035$* Better than model 1			n/a			n/a		

LR[1] test likelihood ratio test comparing the mixed effects logistic model to a standard logistic model, *LR[2] test* likelihood ratio test for model improvement

* $p < 0.05$, ** $p < 0.01$

[a] Cue time is entered grant mean centred

[b] Computed via cue time stamp × cue time stamp, based on the grand mean centred term

[c] Intra-class correlation indicates the proportion of total variance due to between-group difference

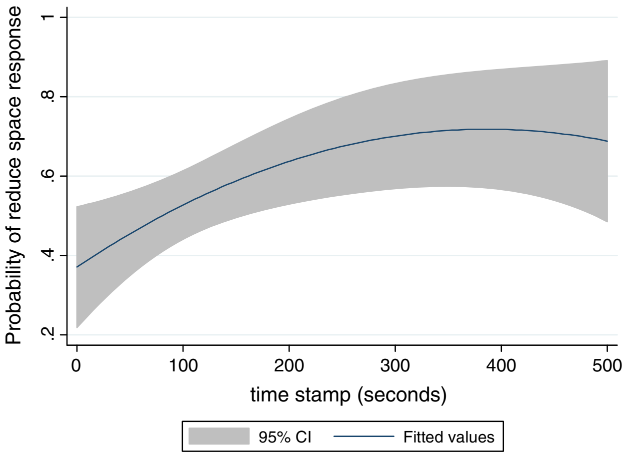


Fig. 1 Predicted probability of reduced space response as a function of the timing of emotional distress cue/concern expression

Discussion

This is the first time a multilevel modelling approach has been adopted in a head and neck cancer setting to study oncologists' responses to patients' emotional distress. The main finding regarding the curvilinear relationship between the timing of cue expression and the reduced space response is generally consistent with the findings in the literature that, oncologists were less likely to give space for disclosure of emotions that occurred later in the consultation [17]. Our contribution lies in the fact that these findings help to explain the complexity of consultants' strategies in dealing with subtle emotional issues expressed by HNC patients, by highlighting a time point when consultants started to open up for emotional disclosure. Most consultants in our study are experienced oncologists, good at working effectively in their provision of cancer care. It is likely that discussion of emotions occurs, after symptoms and technical issues have been dealt with in the initial section of the consultation. It might be argued that this is the most effective practice with HNC outpatients. It will be beneficial for future researchers to collect outcome measures to test this hypothesis. It is also important, however, not to take for granted that providing space for disclosure of emotions is always appropriate during consultations. As highlighted by Smith et al. [26], it is important that doctors focus on both instrumental tasks, such as sharing decisions, and emotion management in consultations. This is the first time an evidence has been provided to support that timing, that is, 'when to do what' rather than 'what should be done', has become crucial to clinical practice, which has the potential to influence patient outcomes.

It was not a surprise to find that consultants were more likely to reduce space for disclosure of emotions initiated by patients, compared to those raised by themselves, considering what have already been reported in the literature in other oncology setting [17] and psychiatry consultations [16]. Giving the majority of the HNC patients completed a Patient Concerns Inventory, an instrument to help identify and raise needs/concerns, it was, however, a surprise to see that consultants, who were fully aware of the expectation to address those issues, were actually less active in acknowledging emotional issues when raised by patients. A number of possibilities might help explain why this happened. First, previous studies indicated that clinicians tended to focus more on controlling symptoms and side effects and less on dealing with psychosocial issues [10, 11]. Second, handling emotional concerns at an appropriate time in a busy outpatient clinic might be more effective than responding to emotional issues whenever patients raise them, as indicated by our finding. Third, there might be too many emotional issues raised by patients that it may be more efficient for consultants to direct them to a specialist, rather than addressing them at the consultation. Unfortunately, due to unbalanced sample size in our patient groups (adoption of PCI $n = 36$, non-adoption of PCI $n = 7$), it was impossible to conduct meaningful statistical analysis to test the usefulness of the PCI. Future researchers are encouraged to explore further, with rigorous design, possible impact of instruments, designed to help identify patient concerns such as PCI, on the dynamics of discussions around emotional issues during medical consultations.

An average of 3.5 cues/concerns per consultations found in our study is consistent with the mean frequency (between three and four) of cue/concern occurrence in oncology, where the same VR-CoDES was used [17, 28]. It is important to note that a higher number of cue/concern expressions does not suggest an effective consultation [28]. Our study failed to support the previous finding by Zhou et al. [19] that responses differed according to cue types. Medical students provided room for the disclosure of emotional cues expressed in vague and unspecified words, but reduced space to cues emphasising physiological/cognitive correlates in the OSCE setting was not replicated in our HNC setting, although a similar multilevel analysis approach and the same coding scheme were adopted. On the other hand, oncologists do appear to respond differently to different types of emotions, as suggested by both correlational [18] and experimental [29] studies that patient expressions of sadness (compared to anger and fear) were more likely to receive empathic responses from oncologists. It is worth noting that the VR-CoDES only captures the manner in which the emotion is expressed (e.g. explicitly or verbal hints using metaphors), rather than the content of emotion (e.g. sadness or anger). It will be useful for future research to investigate the impact of both variables of how and what emotion is expressed on clinician responses. Patient self-reported quality of emotional well-being was, unsurprisingly, not found to be significantly correlated with a consultant's reduced space response. Emotional functioning of patients prior to consultation is commonly studied, as indicator of psychological distress, to correlate with patient expressions of emotional distress at consultations [28], through complex pathways from preferences of discussing emotional issues to initiation of emotional topics [14]. How patient-level variables, beyond the common demographics, contributing to our understanding of emotional discussion, in particular clinician responses, are still largely unexplored. Future researchers are encouraged to explore further the role these important variables (i.e. patient individual differences and other social, economic and educational status factors) play in the dynamics of consultation through rigorous research design and theoretical grounding.

The reported findings should be interpreted in the light of the following limitations. Firstly, due to a limited sample size and thus low statistical power, type II errors are likely. Future researchers are encouraged to replicate these promising findings using a larger sample and with different cancer patient groups, or even in other medical settings. Secondly, the quality of non-verbal behaviours (both emotional distress and responses) is limited due to the nature of the audio data, despite the fact that the intonations in speech have been preserved while coding. Thirdly, some clinician level variables, such as gender [17] and quality of rapport with patients [27], previously indicated as important predictors for clinicians' responses, were not included in the multilevel models in our study. A much larger sample size is required to conduct a three-level analysis incorporating the clinician variables (at the level 3). Finally, all findings are drawn in a correlational, rather than causal, direction. Experimental studies, a relatively new development in healthcare communication research, are needed to establish causal relationships, for example, manipulating the timing of cue expression and the type of emotional cue provision [29] to study clinician responses.

Despite these limitations, this is the first time an evidence was found to support a complex relationship between the timing of patient emotional expressions and clinicians' responses. Moreover, this is the first study that oncology consultants were found to close down emotional disclosure when initiated by patient using a multilevel approach in a clinical setting of head and neck cancer.

The implications of these findings may be stated tentatively. Consultants in their outpatient follow-up appointments should be encouraged to allow patients to express their emotional concerns when they arise and at an appropriate timing. The current body of knowledge from healthcare communication studies supports this more flexible and engaged structure of clinician–patient interaction. The positive outcomes of this approach within the HNC field of healthcare that are expected should be an important focus for future investigation.

Acknowledgments The authors would like to thank all patients and consultants who participated in the study.

Conflict of interest We do not have financial disclosure or any conflict of interest.

References

1. Hutton JM, Williams M (2001) An investigation of psychological distress in patients who have been treated for head and neck cancer. Br J Oral Maxillofac Surg 39:333–339
2. Frampton M (2001) Psychological distress in patients with head and neck cancer: review. Br J Oral Maxillofac Surg 39:67–70
3. Katz MR, Kopek N, Waldron J, Devins GM, Tomlinson G (2004) Screening for depression in head and neck cancer. Psychooncology 13:269–280
4. Stewart M, Brown JB, Donner A et al (2000) The impact of patient-centered care on outcomes. J Fam Pract 49:796–804
5. Ford S, Fallowfield L, Lewis S (1994) Can oncologists detect distress in their outpatients and how satisfied are they with their performance during bad news consultations? Br J Cancer 70:767–770
6. Epstein RM, Street RL Jr (2007) Patient-centered communication in cancer care: promoting healing and reducing Suffering. National Cancer Institute, Bethesda, NIH Publication No. 07–6225
7. NICE (2001) Improving Supportive and Palliative Care for Adults with Cancer: The Manual, National Institute for Clinical Excellence, Editor
8. Roter DL, Hall JA, Kern DE, Barker LR, Cole KA, Roca RP (1995) Improving physicians' interviewing skills and reducing patients' emotional distress. A randomized clinical trial. Arch Intern Med 155:1877–1884
9. Fallowfield L, Jenkins V, Farewell V, Saul J, Duffy A, Eves R (2002) Efficacy of a cancer research UK communication skills training model for oncologists: a randomised controlled trial. Lancet 359:650–656
10. Ford S, Fallowfield L, Lewis S (1996) Doctor-patient interactions in oncology. Soc Sci Med 42:1511–1519
11. Detmar SB, Muller MJ, Wever LD, Schornagel JH, Aaronson NK (2001) The patient–physician relationship. Patient-physician communication during outpatient palliative treatment visits: an observational study. J Am Med Assoc 285:1351–1357
12. Pruyn JFA, Heule-Dieleman HAG, Knegt PP et al (2004) On the enhancement of efficiency in care for cancer patients in outpatient clinics: an instrument to accelerate psychosocial screening and referral. Patient Educ Couns 53:135–140
13. Strong V, Waters R, Hibberd C et al (2007) Emotional distress in cancer patients: the Edinburgh cancer centre symptom study. Br J Cancer 96:868–874
14. Taylor S et al (2011) Discussion of emotional and social impact of cancer during outpatient oncology consultations. Psychooncology 20:242–251
15. Pollak KI, Arnold RM, Jeffreys AS et al (2007) Oncologist communication about emotion during visits with patients with advanced cancer. J Clin Oncol 25:5748–5752
16. Del Piccolo L, Mazzi MA, Goss C, Rimondini M, Zimmermann C (2012) How emotions emerge and are dealt with in first diagnostic consultations in psychiatry. Patient Educ Couns 88:29–35

17. Finset A, Heyn L, Ruland C (2013) Patterns in clinicians' responses to patient emotion in cancer care. Patient Educ Couns 93:80–85
18. Kennifer SL, Alexander SC, Pollak KI et al (2008) Negative emotions in cancer care: do oncologists' responses depend on severity and type of emotion? Patient Educ Couns 76:51–56
19. Zhou Y, Collinson A, Laidlaw A, Humphris G (2013) How do medical students respond to emotional cues and concerns expressed by simulated patients during OSCE consultations? A multilevel study. PLoS One 8(10):e79166. doi:10.1371/journal.pone.0079166
20. Zimmermann C, Del Piccolo L, Bensing J, Bergvik S, De Haes H et al (2011) Coding patient emotional cues and concerns in medical consultations: the Verona Coding Definitions of Emotional Sequences (VR-CoDES). Patient Educ Couns 82:141–148
21. Del Piccolo L, de Haes H, Heaven C, Jansen J, Verheul W et al (2011) Development of the Verona Coding Definitions of Emotional Sequences to code health providers' responses (VR-CoDES-P) to patient cues and concerns. Patient Educ Couns 82:149–155
22. Zimmermann C, Del Piccolo L, Finset A (2007) Cues and concerns by patients in medical consultations: a literature review. Psychol Bull 133:438–463
23. Rogers SN, El-Sheikha J, Lowe D (2009) The development of a Patient Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol 45:555–561
24. Altman DG (1991) Practical statistics for medical research. Chapman and Hall, London, p 611
25. Rogers SN, Gwanne S, Lowe D et al (2002) The addition of mood and anxiety domains to the University of Washington Quality of Life scale. Head Neck 24:520–529
26. Smith A, Juraskova I, Butow P, Miguel C, Lopez AJ, Chang S (2011) Sharing versus caring. The relative impact of sharing decisions versus managing on patient outcomes. Patient Educ Couns 82:233–239
27. Lelorain S, Brédart A, Dolbeault S, Cano A, Bonnaud-Antignac A, Cousson-Gélie F, Sultan S (2014) How can we explain physician accuracy in assessing patient distress? A multilevel analysis in patients with advanced cancer. Patient Educ Couns 94:322–327
28. Oguchi M, Jansen J, Butow P, Colagiuri B, Divine R, Dhillon H (2011) Measuring the impact of nurse cue-response behaviour on cancer patients' emotional cues. Patient Educ Couns 82:163–168
29. Sheldon LK, Ellington L, Barrett R, Dudley WN, Clayton MF, Rinaldi K (2009) Nurse responsiveness to cancer patient expressions of emotion. Patient Educ Couns 76:63–70