Assessment of Quality of Life in Individual Patients with Head and Neck Cancer:

Opinions and Preferences of Patients and Clinicians

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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

Head and neck cancer patients face considerable challenges as a result of their diagnosis and therapy. Psychosocial aspects are accepted as critically important in their care. Our hypothesis was that **'carefully designed and structured questionnaires can be used to improve the quality of life of head and neck cancer patients'.** This thesis reports the development of and findings from a series of studies considering the opinions and preferences of patients and clinicians about questionnaires and the process of care, supported by interviews and analysis of taped consultations. This work provided a detailed insight into aspects of head and neck cancer care from all perspectives.

In summary, my main conclusions were:

- The current practice of relying on consultations alone to manage the care of cancer patients does not ensure that all concerns are identified. This is particularly true for emotional and psychosocial issues.
- There are substantial differences in patient characteristics, therapeutic burden and status between thyroid patients and other H&N cancer patients. A specific QoL module should be developed to meet the needs of thyroid patients.
- Patients were not able to choose a questionnaire with any consistency.
- Patients and clinicians had clear and cogent views about the process of care, consultations and questionnaires which provided invaluable insight into the needs of this patient population.
- No current questionnaire is ideal for individual assessment but, from this study a combination of the EORTC QLQ C30 and H&N modules and HADS is recommended.
- The main area of omission from current assessments is 'fear of recurrence'. This is common and needs to be addressed in care for H&N and also Thyroid cancer patients.

The results have provided an evidence base for future work in this field building towards a model of care which encompasses all aspects of patient needs.

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Preface

This study developed through my practice as a NHS Maxillofacial Surgeon. My main areas of clinical care, during higher training in the 1980s and Consultant practice in the 1990s, have been oncology, trauma and reconstructive surgery with an emphasis on free-tissue transfer. These areas bring doctors into close contact with patients who have suffered severe and sometimes devastating disturbance of key functions and who have to come to terms with a much altered life, in terms of personal goals, family life and life in a wider social context. Many studies report the impact of facial disfigurement and this continues to have negative effects on social interactions and work, people with such problems being consistently reported as less employable and less socially acceptable than the general population.

During my NHS years the way that patients and their families adjusted or failed to adjust to their new life after surgery or other cancer treatment became an increasing interest. This period coincided with the early permeation of health related quality of life (QoL) assessment into clinical practice, very much at that time as a measurement tool for clinical trials. Some patients would adapt well and remain cheerful and composed despite radical and disabling treatment; others would withdraw from family and friends despite relatively minor physical impairments. Some relationships became stronger, with family engagement with the patient and their condition both in and beyond the clinical environment, others lost their family support with new partners emerging and coming with them to clinic sometimes years after therapy. One patient committed suicide shortly after he had learned that his disease was not fully controlled and his family felt that, for him, this was the only way out of an intolerable situation with which he could not come to terms.

I had always wished to undertake clinical research into the area of patient experience, quality of life and ways to evaluate these aspects of experience in a way which meets their needs, given the key place of these factors in the management of and support for our patients, their carers and their families. The first study in which I played an active role was undertaken in Liverpool during my training years in the early 1990s and looked at the support patients needed and where they perceived it was offered. The result showed a high dependence on the hospital team. Support and where it is best based remains a core theme, highlighted again in the Cancer Reform Strategy, published in 2007.

At that time publications on QoL were appearing in the literature and Chapter 1 brings the patient narrative into the philosophy which has underpinned the development and progress of this thesis. It then focuses on the strategies underpinning provision of cancer care in the National Health Service and the theory and development of generic and site specific questionnaires for use in clinical trials.

The study has evolved through a changing environment of care, with increasing centralisation of care. Chapter 2 provides an overview of specific items relating to H&N and thyroid cancers and of QoL measurement in this patient population. It was the change in practice and centralisation of clinics, together with the introduction to multi-disciplinary assessment prior to therapy which led to the pilot study. We had become accustomed to all team members, including the Clinical Nurse Specialist (CNS) and Allied Health Professionals (AHPs) being present at the consultation. Although this arrangement was sometimes described as intimidating it did have good points in that all present heard the same information and acted appropriately to provide information and support. Bringing a larger team of oncologists and surgeons together made this impossible and there was a fear that issues may not be communicated fully between team members.The pilot work looked to determine whether use of a questionnaire might be an acceptable way of assisting communication between patients and their doctors and other health professionals. The pilot study is reported in chapter 3.

This pilot study indicated that patients found questionnaire assessments helpful but doctors gave a much lower level of support. The area appeared to be worthy of further exploration as a potential clinical tool and we commenced our planning for the main study with the hypothesis that: ***'carefully designed and structured questionnaires can be used to improve the quality of life of head and neck cancer patients'.***

The design of this study required a careful review of recent work towards introduction of QoL measures into routine clinical practice, with an emphasis on questionnaire choice and technology for assessment. Consideration of the special site specific requirements of head and neck patients was integral to that process. This preparatory phase is covered in Chapter 4.

This work led to consideration as to which measure patients would find best reflected their status and what should form part of a consultation. As the consultation lies at the heart of communication I needed a measure which would

allow assessment of what patients would wish to see in a consultation and whether what they considered was actually included. To achieve this I adapted a questionnaire from that of Detmar et al (2000). For QoL questionnaire assessment although there were numerous well validated measures, at that time no-one had undertaken a study of patient preference as to which to use in a routine clinical setting. This became a core goal of the study. Discussions centred on what a question consisted of with awareness from the pilot study that an item could be well phrased but fail to address a core concern or alternatively address a core concern but be written badly and thus be difficult for the patient to interpret and score. These issues are considered and the study design is presented in Chapter 5. For a measure to be effective, I needed to understand the views of my colleagues and a group from all MDT disciplines completed the same QoL measure as the patients and also gave detailed interviews, which were formally transcribed, about their thoughts on the way we might use questionnaires in clinical care and how that care might be guided by the results.

Chapter 6 describes the study on views and preferences for the content of consultations, analysis of the content of recorded consultations, the results and specific discussion on this aspect of the work. Chapter 7 considers patient aspects of the questionnaire choice study, again with discussion specific to this aspect of the thesis.

As indicated above, taking the patient opinions and preferences into account is only half of the work required to bring a questionnaire towards acceptability in the clinical setting. The less positive response of the doctors during the pilot study has already been reported so a parallel study was undertaken, firstly to gain MDT members' views on questionnaire assessments and secondly to determine which team member might best act on a response. The methodology and design of the clinician study is presented in Chapter 8 with results and specific discussion.

Chapter 9 brings the findings together looking at similarities and differences in the views of the patients and health professionals. It aims to gain a consensus as to whether our hypothesis has or might be achieved. Chapter 10 provides a critique of the study and the way in which the work might progress in the context of QoL measurements and the evolution towards more sophisticated methods and tools for data collection and the modern focus on Patient Related Outcomes (PROs). It places the study in context in relation to the current standard of care for Head and Neck (H&N) cancer patients and the way in which the questionnaire

assessment may contribute to care. A critique of the study in the overall context of QoL and clinical care is presented which informs the need for future work in this field.

In Chapter 11 we look to the future, placing this work in context with other current and developing work both by the research team and in the field of H&N QoL research. The Cancer Reform Strategy has brought ‘survivorship’, patient experience and support into the forefront of discussion. As more patients live with their cancer as a ‘chronic disease’ the care they need and the service delivery and organisational issues which support that care are a matter of priority. How we might further develop the work presented to meet those needs is discussed.

I close with supplementary material outlining my training and personal development and also outputs to date from the study.

In summary this thesis presents a journey for me from NHS practice to clinical research and, in a wider sense, the study has evolved alongside developments in all aspects of the work; assessment of QoL, the environment of clinical care, technology for data collection and a commitment by healthcare professionals to a more ‘holistic’ model of patient management and support.

Glossary and Abbreviations

AHP	Allied Health Professional
Ca	Carcinoma
CNS	Clinical Nurse Specialist
DH	Department of Health
EL	Early Larynx – study sub-group
ENT	Ear, Nose and Throat – study sub-group
EO	Early Oral – study sub-group
EORTC	European Organisation for Research and Treatment of Cancer
FACT	Functional Adaptation to Cancer Therapy
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health Related Quality of Life (abbreviated to QoL in this thesis)
LL	Late Larynx - study sub-group
LO	Late Oral – study sub-group
MDT	Multidisciplinary Team
MHI-5	Mental Health Inventory 5
POG	Psychosocial Oncology and Clinical Practice Research Group
PPM	Patient Pathway Manager (electronic patient record)
QoL	Quality of Life (abbreviated from HRQoL in this thesis)
RA	Research Assistant
SALT	Speech and Language Therapist
SCCa	Squamous Cell Carcinoma
SF-36	Short Form 36
Thy	Thyroid – study sub-group
TNM	Tumour, Nodes, Metastasis, the basis of cancer staging
UWQoL	University of Washington Quality of Life Questionnaire

Chapter 1 - Introduction

1.1 Overview and Patient Narratives

This chapter introduces the concepts which underpin this thesis and which are subsequently explored in later chapters. The first of these is the study of health related quality of life (QoL) and the second is the way in which cancer care is provided. The focus throughout is on the opinions of patients about how they talk to their doctors and other health professionals and published narratives will be considered in this opening section as the views expressed lie at the core of the research..

QoL is a multidimensional concept which looks at the way which patients feel about themselves in the context of a medical condition. Aspects such as physical status, emotional status, social factors and the way that patients consider that they are able to function in all aspects of their lives outside medical care are usually assessed. Methods of assessment include questionnaires; which may be validated or non-validated, interviews which may be structured, semi-structured and open interviews and case series or case studies. The measures which can be used are considered in outline in this chapter and the choices for this research are covered in more detail in Chapter 5. This study uses questionnaires and interviews as core methodology and tracks the content through to consultation and subsequent annotation.

For patients with head and neck (H&N) cancer, where key functions are affected by both the disease and its therapy, the potential for an adverse effect on QoL is arguably greater than that for other cancers. It is this impact of the condition on the patient's status which has led to a considerable body of research in this area. The challenge has been to bring the findings from QoL assessments into the routine clinic in a way that can have a practical impact on their care. At the core of this is reliable measurement of status and communication between health professionals and the patient and their family.

Patients have written comprehensively and movingly about their cancer and their relationship with health professionals. These narratives allow some important themes to be established which are considered in the experimental work that forms the core of this thesis, especially in Chapters 6, 7 and 9 where key elements of the patients' experience and wishes are considered. Patient

narratives provide an ideal background to illustrate why I chose to undertake a study which links patient wishes, doctor/patient communication and QoL tools in the setting of everyday practice.

Mitzi Blennerhassett's book (Blennerhassett 2008), eloquently describes the experience of being a cancer patient, the indignity of multiple intimate examinations and disturbance of basic bodily functions whilst attempting to continue to support her children at a time when her marriage was deteriorating through the pressures of her illness and her husband's redundancy. Even more worrying than facing those aspects of the disease and its treatment which could not be avoided, the problems with communication are apparent throughout. In her book she deals with this by the use of pictures and poetry and each chapter ends with a commentary on how care might be better. The poem at the start of Chapter 6 sums up her feelings on communication and the experience of moving from one health care professional to another; professionals who do not say the same thing, undermining her confidence, and who often seem unwilling to answer her questions:

'Smiles are not enough

And now I'm passed from one to another

And find there is even more to discover

You don't seem to value the thing I most need

But without it, I bleed

I so much want to believe in your smile

But it's clicked on and off (to cover the guile?)

Why can't you see that, by shutting me out

You leave me in doubt.'

As this chapter unfolds, Mitzi describes the time when her treatment was discussed. 'There are two options for treatment, 'removing the lump is not possible since it has invaded the muscle''. This is not what Mitzi has previously been led to believe as she had been told that there was a third option, simple removal of her lump. In the conversation it becomes apparent that her status had not changed but the information she was being given had changed substantially. Her anger shines through: 'the first doctor has known this all along and had lied, this was like a sledge hammer; bad news combined with deceit as shocking as

my reduced options and as devastating as the diagnosis itself.' Those of us who are health professionals know we face consultations where additional evidence has come to light but hearing the impact of this for an individual is chastening. Throughout the book the issues of honesty, clear communication between health professionals and each other as well as with the patient so that all know what has been said, are core to the narrative. Whilst it can be argued that Mitzi's first cancer was treated some years ago and she has since had a more positive experience, one wonders how, without a core document to inform the whole team, clarity and consistency in communication can be achieved.

The H&N cancer journey can be particularly harrowing and individual experience relates to what is important in everyday life. The broadcaster John Diamond depended on his voice and his ability to communicate well and describes the loss of specific functions in his narrative. He substituted a column in 'The Times' for his radio programme, writing an impressive diary about his experience after diagnosis of a cancer of the base of the tongue. These columns were later expanded into a book about his cancer, his experience and, ultimately acceptance that he could not be cured (Diamond, 1999). He describes the effects of the cancer undermining his whole personality, having founded his career on a witty, satirical and highly articulate form of verbal communication. Losing this left him 'moping ….. and behaving like a crotchety invalid'. In terms of meeting friends in a highly social life-style he describes retching, feeling that the tongue is a lump of unresponsive tissue, sitting at the dinner table with friends unable to articulate words or to share their social meal. This personal account combines his experience with thoughts on the impact on his family, his wife and their young children, and seeking a way forwards. After one time of bad news the family carefully chooses a puppy 'because a dog is about hope and the future'.

My final patient narrative, to which interest is further added by the contribution from his wife and primary carer, is taken from 'Our story'; published by the Speak Easy Club for Layngectomees, based in Cornwall (Salter, 2008). This book brings together a number of peoples' experience of living after laryngectomy. That of Alan and Rosemary Cummins is particularly frank and makes the point that patients and their carers face an unending adaptation and an enduring loss: 'There's the loss of my job. I was a business advisor working with an enterprise team and spent my days chatting……. It was a huge blow to me when I was dropped by my work without any offer of support'. Rosemary adds 'That hit Alan

very hard. His self-esteem plummeted. His personality was taken away. He became very depressed which was so unlike him. Even your friends don't understand the problems of being a neck breather. You can't unless you live with it on a daily basis.'

They talk through the loss of their future plans for retirement and then move onto an area missing from other narratives:

'There is the loss of intimacy between us as partners. I no longer feel attractive. I don't like me. ……..Even speaking is very tricky when you're lying on a bed', Rosemary says 'I think we have become more detached from each other post operation. ……. We expressed our love spontaneously and enjoyed it. We walked a lot and talked a lot, sharing almost everything. Now I feel I am walking on eggshells. 'Dare I say this?' Should I do that? 'Will this help or make matters worse?' I have spent many a night crying alone down here on the sofa. I find it is a lonely place to be, living alongside a laryngectomee'

Even 5 years down the line from surgery, the hospital remained a place of support: 'There was even the loss of the cancer checks after five years of attending regular clinics. At the last one I was told I was alright and there would be no need for further attendance, Rose and I were shocked. ……I am very pleased and thankful to be told I am free from cancer - *but I am not alright!* It is the other secondary issues, losses, that both of us have difficulty coming to accept. 'Alright' for me now is a very different state to how I was before March 2001.'

They continue with a narrative on some specific problems; breathlessness, fatigue, coughing at the slightest stimulus, running nose, lack of concentration, many of the things raised in a QoL assessment. Their final comment is:

Rosemary: 'I don't think life as a laryngectomee or with a laryngectomee gets easier as time passes by.' Alan agrees 'I have lost everything and gained nothing. I am thankful I am alive but perhaps someone needs to come up with a definition of what a 'full recovery' is. It should not stop people from having a life saving operation but perhaps a clear explanation of the bad side (we were really told more about the good) would prepare people better.'

This narrative brings into the open the cost of 'survivorship' and the ongoing struggle to regain QoL in its wider dimensions. The limitations affect every area of life, physical, emotional, family life, social, financial. Alan and Rosemary were grateful to the staff but felt there was a lack of understanding of what they faced. Whether the complexity of their experience and needs can be captured through a

questionnaire is uncertain but perhaps a suitably worded measure could act as a prompt.

The impact of cancer on families is something which makes this disease such a dreaded burden. Carer narratives are less frequent but Ted Walker described his perspective of his wife's cancer journey after her diagnosis of cancer of the maxillary antrum (upper jaw and related air sinus), to her death and how he coped afterwards (Walker, 1992). Her therapy involved radical combined therapy (surgery and radiotherapy) and the fitting of an obturator, a specially constructed prosthesis to fill the defect in her upper jaw and allow speech and eating. Ted found his wife, Lorna's, journey distressing throughout and it seemed that she was the one who could cope. One wonders, looking at his experience retrospectively, what her needs might have been and how much of her courage was innate and how much an attempt to protect him, He is open about his deep shame because he felt disgust at what she had to go through and what she became after her mutilating surgery and finally, what she faced when her disease recurred.

These accounts place a very personal perspective on cancer care. There is much that we, as health professionals, can only achieve through support. We cannot take away the burden of therapy nor can we always predict what the future or, indeed the functional consequences of therapy, might be. We can look to place the patient and his/her family at the core of a holistic cancer service and it is to that aspiration that I look in this thesis. It is my **hypothesis** that a measure, in this case **a carefully designed questionnaire which can identify need, can act as a focus for communication and facilitate patient centred care, thus leading to improved QoL**.

These narratives provide a unique insight into the impact of cancer in general and H&N cancer specifically and the need for the best possible communication, the meeting of specific information needs and for appropriate support from the member of the multidisciplinary team (MDT) best placed to provide it. It is essential that any new initiative has the support and is of value to health professionals as well as patients and so, in this thesis, a detailed series of interviews are presented with a sample of health professionals from different disciplines who work in our MDT. The play 'Cancer Tales' (Dunn, 2007) focuses on the experience of five women, of life and death, of withdrawing care and survivorship. In its final chapter it suddenly changes emphasis to looking at the

role of health professionals carrying the burden of coping with patients who can often be demanding, are seriously ill and who may be dying. The surgeon, who is seen earlier as assured and confident, admits to the stresses of a life where 'you're battling with death and often not winning'. Blennerhasset (2008) and Diamond (1999) also acknowledge the skill and care of doctors and cancer nurses and particularly value information given simply. In 'Cancer Tales', likewise, the 'patients' praise doctors and nurses who give clear advice with compassion, even when this is bad news such as consideration of cessation of active therapy. Our health-care system has focussed on improving care for the patients; yet ever more aspirational targets can place significant pressures on staff and on infrastructure and resources. For this reason, the professional narratives in this thesis complement those of the patients. Should a person gifted with exceptional technical skills be required to become an advanced communicator? Might being faced with the emotional consequences of the attempt to cure the patient be one burden too many? How can teams support each other as well as those for whom they care? Who should do what? These questions lie at the core of providing a first-class but sustainable service for our cancer patients. The personalities and the insight of the health professionals but also the areas of uncertainty, come across strongly in Chapter 8.

To set the patient, family and health professional experience in context, it is important to understand the way in which cancer care is provided in the UK. The principles which underpinned the development of our cancer care are considered below. This process continues to be developed and refined and the study is set within an evolving clinical service, the pilot work having been done soon after the first major changes to team structure and the later and main study being set in a MDT which had developed to the point where discussions and treatment planning were well established and working relationships had matured. The specific environment of care in which this study is set and a synopsis of H&N cancer research related to QoL and function is described in Chapter 2. Subsequent chapters cover the exploration of questionnaire use in routine clinical practice through the pilot study (Chapter 3), the design of the definitive study (4), detailed methodology (5), and findings, discussion and critique in subsequent chapters. These offer a narrative of the progress of the work from concept to conclusion and the thesis ends with a consideration of future work.

1.2 Cancer care in the National Health Service

1.2.1 Cancer Strategy and Development of Specialist Care

The past twenty.years have seen profound changes in the way that cancer care is offered. In the past it was common to have individual teams, led by a single consultant surgeon or oncologist, working in small centres offering cancer surgery and/or radiotherapy with little support from allied health professionals and little co-location of surgical and radiotherapy clinics. For oral cancer the need for an integrated approach to diagnosis and therapy was raised as early as 1980 (Rapidis et al). They suggested an approach whereby two teams cared for patients, the curative team and the supportive team, who would help with the issues we might now term survivorship. They took a very forward looking approach and the main criticism looking back at their work is that they consider the medical (curative) team as the major team and the allied health professional team (supportive) as the minor team. Similar concerns were raised in numerous fora and at some cancer sites (H&N being one of these) it was suggested that treatment options were too often reliant on which discipline first assessed the patient. Concern was heightened by the EUROCARE study (EUROCARE 2, 1999) which attempted to compare outcomes using registry based ‘like for like’ data. The 30 registries held details on 800,000 patients diagnosed with cancer in the period 1978-1985. The survival of patients in the UK was lower than that in most European countries and it was considered that access to and quality of clinical care might be one of the factors. In parallel, initiatives to include patient views in influencing the way care was provided were gaining momentum. The Patients’ Charter (Department of Health,1991) and the setting up of hospital league tables increased consumerism as part of an attempt to develop a market system with the aim of improving choice and thereby services. However, in practice, choice remains limited by geography, service availability and the knowledge of the consumer. As the cost of providing cancer services and unease about variations in practice continued the Expert Advisory Group on Cancer (1995) recommended a substantial change to cancer services in England and Wales. Core principles included:

- care should be patient centred.

- the impact and psychosocial aspects of cancer on patients, families and carers should be recognised.
- information should be clear and accessible.
- good communication should occur between sectors.
- patient, family and carer and professional views should be taken into account in the development of services.

It is interesting to note how closely these recommendations reflect the wishes of the patients whose narratives were described in the earlier part of this chapter. The model of care produced from this report focussed on primary care with specialist care for common cancers being provided at District General Hospital (DGH) level and for rarer cancers at Cancer Centre level, with an expectation that the number of professionals offering treatment for this group would reduce and cancer therapy become the core of their workload. The care would be provided by integrated multidisciplinary cancer teams (MDTs) rather than by specialists working alone. H&N cancer falls into the 'less common cancers' group and was one of the sites for which care would be provided by Cancer Centres. However, there remained many issues, especially the support needs of patients after completion of radical therapy with curative intent. Selby et al (1996) reviewed the benefits from specialised cancer care, considering the evidence which underpinned the report. Registry data and hospital statistics showed large variations in the way that individual treatments were used and in the caseload for particular cancers amongst doctors offering therapies. Evidence was strongest for breast cancer that higher caseloads and experience conferred benefit. The risk ratio of death was 0.85 (95% CI 0.79 - 0.94) for patients managed by surgeons who had an annual caseload of more than 30 patients per year, compared to those treating less than 30 patients per year. For haematological cancer, where care was delivered to an agreed protocol, outcomes were the same across hospitals and similar results were seen in colorectal cancer. However, in both these instances, the number of patients treated was sufficient to maintain training and expertise. When rarer cancers were considered, good evidence was available for testicular cancer, with improved survival linked to high caseload and adherence to protocol driven management and for sarcoma where patients in Sweden treated outside specialist centres had twice as many recurrences. Although no evidence was available for some cancers (including H&N) the authors considered that significant survival benefits could be attained

and that all patients must have access to equally high standards of specialised care. A key recommendation was for continued assessment of results and attention to development of cancer care in the face of technical and demographic challenges.

This work led to the NHS Cancer Plan (2000) which set out the first comprehensive national cancer programme for England, having four main aims:

- to save more lives
- to ensure people with cancer get the right professional support and care as well as the best treatments.
- to tackle the inequalities in health that mean unskilled workers are twice as likely to die from cancer as professionals.
- to build for the future through investment in the cancer workforce, through strong research and through preparation for the genetics revolution, so that the NHS never falls behind in cancer care again.

These aims are very pertinent to H&N in that, as a less common cancer, services tended to be fragmented and delivered at local level with limited co-ordination between specialists and, even more critically, with the Allied Health Professionals (AHPs) who can make such an impact on recovery and help patients return to as near as possible a normal life. The population traditionally affected by this cancer is a deprived one, contributing to poor outcomes. The plan aimed to bring together prevention, diagnosis, treatment and care for cancer together with the investment needed to deliver the services required to meet its aims. Key commitments included preventive measures such as reducing smoking, goals and targets for referrals and treatment times and investment in palliative care.

The National Institute for Health and Clinical Excellence (NICE) was commissioned to produce recommendations on improving outcomes at site specific level and I was a member of the H&N group which brought together recommendations for improving outcomes (Improving Outcomes Guidance, IOG, 2004) which, in turn, informed the process for peer review of services. Key recommendations were that services should be commissioned at Cancer Network level and be delivered by MDTs managing at least 100 new cases of upper aerodigestive tract cancers per annum. Specialist teams would deal with thyroid cancers and rarer H&N cancers such as salivary and base of skull cancers. These teams would have all necessary support services; Clinical Nurse

Specialists (CNS), Speech & Language Therapists (SALTs), dietitians and dentists. Co-ordinated local teams would be configured to provide long term support. At site specific level, I will look further at the service which the patients in this study experienced in Chapter 2.

The next and most recent consideration of cancer services was the Cancer Reform Strategy (Department of Health, 2007). Again I was a member of the H&N group and our recommendations were published as an annex to the main report (Department of Health, 2007, Annex F) In the main report there was an emphasis on rehabilitation and support and provision in the best locality for patient need. In the H&N appendix we acknowedged the increasing incidence of cancer at this site and the need to continue to work to the aspirations of the IOG so that care is provided in the best centres but also that supportive care including living with the impact of this cancer, is provided locally.

Although the cancer service now relies on MDTs, it is only very recently that a formal report was published, considering health professionals' views on their structure, functions and effectiveness. Taylor and Ramirez (2009), on behalf of the National Cancer Action Team, carried out a major survey, with responses from 2054 MDT members, of whom 53% were doctors, 26% were nurses and 15% MDT co-ordinators. The review covered domains considered important for effective MDT functioning. These were structure, clinical decision making which included a section on patient-centred care/co-ordination of service, team governance and professional development and education of team members. Most tumour sites were represented, H&N being the fifth most frequent site with 109 responders (8%). In terms of overall response, at least 90% of MDT members agreed that effective MDT working results in:

- improved clinical decision making
- more co-ordinated patient care
- improvement to overall quality of care
- evidence based treatment decisions
- improved treatment.

These findings suggest that, in the opinion of those currently providing the service, MDTs have been and are effective in meeting the aspirations of the

Expert Advisory Group and the Department of Health Cancer Strategy. In terms of patient centred care at least 90% of respondents agreed that:

- patients should be made aware that an MDT will be advising on their treatment/ care.
- patient demography and co-morbidities should always be considered.
- patient psychosocial, supportive and palliative care issues should always be considered.
- patient's views should always inform the decision-making process.
- patient views/preferences should be presented to the MDT meeting by someone who has met the patient.

Aspects of the interaction with the patient were explored by cancer site. On identification of a keyworker to provide support, 82% of respondents overall, i.e. including responses from all MDTs, agreed, compared to 92% of H&N MDT members who felt this action was addressed. The highly positive responses of H&N team members continued.with 82% supporting the principle that a patient's care should only be discussed when someone is present who has been involved in assessing that individual (compared to 63% overall) and 28% endorsing the principle that patients should have the opportunity to attend the MDT discussion of their case (compared to 14% overall).

This survey did not ask for reasons for the responses given. In the context of this thesis I believe that these results confirm the complexity and multidimensionality of the management of physical, emotional, psychosocial, co-morbidity and other aspects of H&N cancer and that those who choose to specialise in this field are aware that they must communicate effectively with each other and with their patients if effective care is to be provided.

This section has provided a summary of the evolution and current status of UK cancer care. The specifics of H&N cancer and the practice in the centre in which my studies have been based will be considered further in Chapter 2.

1.3 Health Related Quality of Life in Cancer

1.3.1 Principles and Theory of Health Related Quality of Life Assessment

QoL is not a new concept having originally been described by Aristotle (BC 384-322) who understood that 'being well' and 'being happy' may not be the same thing as what constitutes happiness is a matter of dispute. It resumed its place in medical and social circles comparatively recently. Shaw (1990), as a celebrated writer, indicated that 'happiness is not the object of life,…..courage consists in the readiness to sacrifice happiness for an intense quality of life'.

In terms of moving this concept towards scientific and hypothesis driven evaluation, the World Health Organisation (1948) defined health as 'a state of complete physical, mental and social well-being and not merely the absence of disease.' This definition picks up the additional dimension which constitutes well-being and, presumably, a state of excellent QoL. These main areas continue to form the basis of the key elements of QoL measurements.

Numerous theories have been proposed but one which has gained acceptance in clinical practice as a practical definition is that of Calman (1984), often referred to as the 'gap' theory of QoL. Exploring the difference between aspiration and perception of current status, this theory allows assessment of QoL at individual level in a way that can be easily interpreted in clinical practice.

1.3.2 Tools for Health Related Quality of Life Assessment: principles underpinning the use of questionnaires

To allow comparison between populations, largely in relation to clinical trial research, a number of measures have been developed. These vary from questionnaires designed to consider general health across the population, irrespective of the presence or absence of a specific disease state, such as the Short Form-36, (SF-36) to those designed to explore specific issues in considerable detail according to patient prioritisation. An example of this latter approach is the Schedule for the Evaluation of Individual Quality of Life (SEIQOL) which is intended for the assessment of individuals (Wettergren, 2009). Questionnaires which have been developed for general assessment can be used in the cancer setting but through the late 1980s and early 1990s a series of generic cancer questionnaires were developed and validated. In Europe much of

this work was led by the European Organisation for Research and Treatment of Cancer (EORTC) and in the USA by the Functional Assessment of Cancer Therapy (FACIT) research teams.

Further developmental work led to modules being added to the generic questionnaires and also to the development of stand-alone measures. The main research groups have subjected their measures to carefully designed international psychometric validation studies; however some measures in clinical practice have been accepted by clinicians and by speciality organisations despite much lower levels of formal validation. In H&N, a good example of this approach is the University of Washington Quality of Life questionnaire (UWQoLv4). In developing the methodology which underpins this research consideration was given to the quality of psychometric validation, the 'track record' of the questionnaires as assessed through a review of the literature, the current place of measures within the clinical setting and the views of the multidisciplinary cancer team (MDT). This process is considered further in Chapter 4, together with a description of questionnaire based research and the reasons for the choices of instruments made in my study.

In addition to the generic and site specific assessments of cancer patients, it is acknowledged that mood plays an important part in patient assessment and measures have been developed to assess this aspect of QoL as a specific item. Measures in widespread use include the Hospital Anxiety and Depression Scale (HADS) and the Mental Health Inventory (MHI-5).

Finally, social status is an integral part of assessment. For H&N cancer it is accepted that the patient profile reflects a higher level of deprivation than that at many other sites (National Cancer Intelligence Network, 2008a). Measures which consider this as a stand-alone item have been developed more recently, an example being the Social Difficulties Inventory (SDI) (Wright et al, 2005). Publications on this aspect of QoL have appeared after we developed the methodology for this study and so are not included.

To set the scene for the thesis it is important to understand the tension between the use of a measure for population assessment and for individual assessment. The scientific processes for validation set clear parameters for the inclusion and exclusion of questionnaire items. Thus, a question which is critically important for a subset of patients may be removed. This process improves validity at population level yet inevitably blunts the sensitivity to individual needs. There is

evidence for the use of validated questionnaires to assist in doctor/patient communication, particularly the randomised controlled trial (RCT) reported by Velikova et al (2004). The choice for investigators working in this field lies between accepting the limitations of a validated measure or developing an individualised measure and undertaking the substantial task of validating an ever changing and evolving reflection of patient needs.

Undertaking research in this area is complicated by the number and different focus of the measures in clinical research. One aspect of choice must be the patients' own views as to whether any measure chosen truly allows them to communicate their status to the clinical team. It is this aspect of questionnaire choice which is examined in this thesis.

1.3.3 Technology in QoL Research

Questionnaires are delivered either in paper form, which was the main method until recent years, or data is collected by electronic means, including desk-top or laptop computers and portable digital handsets. In the first years of this century the provision of touch-screen computers has developed and is in active use in many centres, Touch-screen technology offers the ability to analyse the data in 'real time' and to feed results back to both patients and clinicians. It therefore adds a key element to using QoL questionnaire data in the routine clinic environment (Velikova et al, 1999a).

In this study we were looking to capture a substantial amount of data from a planned sample of 150 H&N cancer patients, using multiple questionnaires. The availability of a system capable of facilitating this endeavour was critically important. Touch-screens were, therefore, the method of capturing questionnaire scores in the main study, although paper based clinical report forms were used for convenience in the initial pilot study.

An additional feature of touch-screen technology is that it can capture change in status, a theme which has emerged as highly important for the routine use of QoL data in the study of clinician opinions and preferences (Chapter 8). This provision of patient focused data to clinicians for use in consultations can be powerful in driving the general acceptance of day to day use of QoL measurement in oncology clinics. As I am describing a simple single intervention cross sectional

study in this thesis, the longitudinal element of QoL assessment is not captured here.

1.4 Summary

This chapter has introduced the main general concepts which underpin the study and which will be further developed in subsequent chapters. The specific setting of H&N cancer will now be considered in terms of care for patients and QoL assessment.

CHAPTER 2 - Head and Neck and Thyroid Cancers, Clinical Overview, Environment of Care and Quality of Life Assessment

2.1 Introduction

In this thesis the patient groups studied are those with oral, laryngeal and thyroid cancer. This choice was made on the grounds of achieving sufficent coherence within participant groups to allow comparison; with subdivisions of 'early' and 'late' on therapeutic grounds to represent the treatment burden and very different long term outcomes in terms of physical function and side effects related to disease. H&N has much heterogeneity so, to allow comparisons, in the main part of this study I have looked at the experiences and opinions of patients with oral/oropharyngeal and laryngeal cancers, which constitute the most common cancers at this cancer site.

Thyroid cancer is frequently managed in the same clinical service yet has received little attention in the QoL literature. The population and disease profiles are different to those for H&N and it was felt important to include this group of patients, to give an understanding of their concerns and to ensure their inclusion in further work arising from the studies reported in this thesis.

This chapter will give a summary of the epidemiological and clinical factors which underpin the research, considering H&N and Thyroid cancer in turn and consider the way in which QoL has been approached in contributing to the management of these patients.

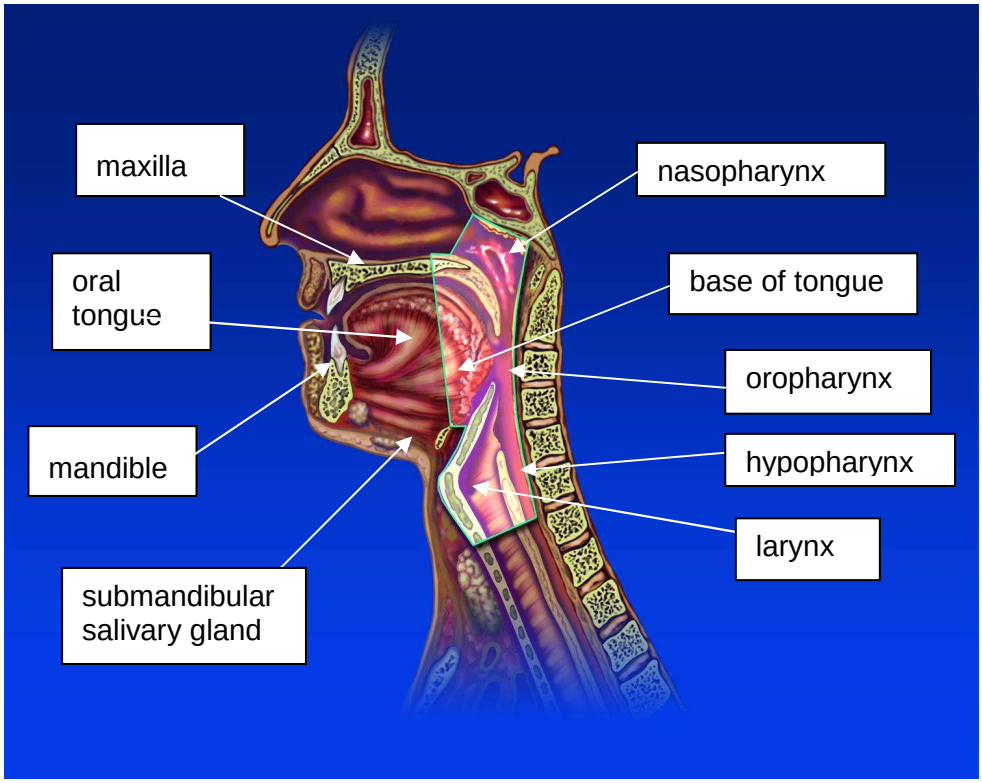
2.2 Head and Neck (H&N) Cancer

2.2.1 Normal Anatomy and Descriptive Terms

The term head and neck (H&N) cancer describes those cancers arising from the mucosal lining of the upper aerodigestive tract and major specific structures within this anatomical area, especially the four major salivary glands and the thyroid gland. The area covered by this descriptive term is shown in Figure 1. There are over 30 specific sites indicated in the International Classification of Disease v 10 (ICD 10) codes and, even at site level, the descriptors are complex. The oral cavity sites described include lips, buccal mucosa, alveolus and gingivae

(the tooth bearing segment of bone and the mucosa immediately surrounding the teeth), the tongue, hard and soft palate and floor of mouth. The anatomy of the larynx is similarly complex but is generally separated into 3 key areas; supraglottis, above the vocal cords; glottis, at the level of the vocal cords; and subglottic below the level of the vocal cords. The pharynx is divided into the nasopharynx, the oropharynx and the hypopharynx. In addition, the air sinuses, frontal, maxillary, ethmoid and sphenoid are considered as part of H&N as are the thyroid, parathyroid and salivary glands.

Figure 2 1. Anatomy of the upper areodigestive tract



Modified from illustration designed by Sanofi-Aventis (with permission)

It is important for this complexity to be recognised in this thesis as the population varies by site, for example, nasopharyngeal cancer tends to be diagnosed in a younger population than other H&N sites. This disparity is reflected in therapy and, in terms of this study, provides challenges in terms of achieving a representative sample of patients from whom to draw conclusions, hence the decision to include oral/oropharyngeal, laryngeal and thyroid cancers rather than a sample addressing all sites in this thesis.

2.2.2 Major Aspects of H&NCancer

The main cancer to be considered in terms of therapeutic impact and experience from the point of view of the patients is termed squamous cell carcinoma (SCCa). Carcinoma describes a malignant tumour which arises from epithelial elements. Over 90% of head and neck cancers are SCCa. Other specialist tissues, such as the thyroid and salivary glands have specific cancers. These behave differently and, as thyroid patients have been included in this study, a description of this group of cancers is provided below.

The main documented risk factors for head and neck SCCa are smoking and heavy alcohol consumption which have an independent but also a synergistic effect. Substantial evidence indicates that these habits can cause important differences in both the population of patients affected by the disease and its biology. Much interest currently focuses on the place of human papillovirus (HPV) in the development of oropharyngeal cancers in the young and this is likely to have an impact on future therapy for this group (Hennessey PT et al, 2009). This will not be considered in more detail as this work gained momentum after completion of recruitment to this study and the </=40 years of age H&N cancer group is not represented in our study.

2.2.3 Epidemiology

Head and neck cancer is a global disease. Oral cancer alone accounts for nearly 220,000 cases in males and 90,000 cases in females each year, constituting 5% and 2% respectively of new cancer diagnoses globally (Ferlay et al, 2004). It is particularly prevalent in the developing economies, especially India and South-East Asia but subject to considerable regional variation. For example, in India the incidence ranges from 7.2/100,000 population in Bhopal to 2.4/100,000 in Barshi (Roden and Wu, 2006). In the USA, in 2008, 47,500 new cases of H&N cancer were diagnosed and 11,260 died from their disease (Jemal, 2008). In the UK, 7.948 new cases were registered in 2000, 5504 males and 2444 females, making it the 8th most common cancer (3% of total cancer diagnoses) (Bosch et al, 2002). This level of variation shows the importance of racial origin, risk factors, environment, and also the need to understand underlying genetic susceptibilities.

In terms of sex distribution, more males than females are affected and it is generally believed that this relates to habits, particularly smoking and alcohol consumption. In recent years, reports are emerging of increased incidence in younger patients, considered to be related to human papillomavirus.

UK figures and service detail are captured in the National Head and Neck Cancer Audit (DAHNO, 2008). DAHNO data is derived from direct submissions by NHS Trusts in England and Wales according to a standard data submission format. It attempts to capture incidence, stage, site, waiting times, therapy and outcome data. Figures need to be interpreted with some caution as there are limitations in data entry, however, it remains the only attempt to capture national data. During the period of the current audit, figures were collected for oral and laryngeal cancers alone, relating directly to the groups described in this study and the two most common sites for H&N cancer.

A total number of 2,130 cases were submitted, 1049 larynx and 986 oral. Basic demographics indicate that, in the index period, defined as the opening of the audit in January 2004 to the census date of October 2007, 82% of laryngeal cancer patients were male compared to 58% of oral cancer patients. For both cancers the peak incidence lay in the seventh decade, with a median age of 67 for males and 64 for females with laryngeal cancer and 62 for males and 68 for females with oral cancer.

Young patients were unusual, only 17 laryngeal cancer patients and 41 oral cancer patients presenting at less than 40 years of age. In contrast 135 laryngeal cancer patients were aged 80 or above, with 331 of oral cancer patients falling into this age range. For H&N cancer, a significant concern is the development of second primary cancers; either synchronous or metachronous. Eckardt et al (1993), in a retrospective study found that 20 (5.2%) of patients from a population sample of 379 developed a second upper aerodigestive tract primary malignant tumour, the average delay between primary therapy and diagnosis of the second cancer being 49.2 months. Crosher and McIlory (1998) considered this risk using the resources of the Scottish Cancer Registry to study 1891 patients. Of these 228 (12%) developed a second primary cancer at a mean follow up time of 38 months. Fourteen patients had three cancers and two patients had four separate malignancies. The overall risk of a second cancer was 2.03 (95% CI 1.77-2.39) greater than expected in the general population; the relative risk for male patients

was 1.95 (95% CI 1.65 – 2.24) and for females 2.29 (95% CI 1.7-2.9). Reasons for this have been postulated as mucosal initiation and promotion by exogenous factors, with an emphasis on smoking and alcohol over the years but very recently increasing interest in human papilloma virus (HPV), or field cancerisation (Batsakis 1984, Slaughter 1953). The practical impact of these findings are continued surveillance and a shift with time in surveillance priorities from checking the site of the index cancer to diagnosis of new primary cancers.

There is a need to ensure that symptoms which might 'flag' a new cancer, such as pain, hoarseness of change in swallow are included in any future QoL questionnaire.

Characteristics of the cancer population can also be considered in socio-demographic context and this would be expected to have an impact on the results of my study, It is acknowledged that H&N patients represent a deprived group Woolley et al (2006) considered a group of 278 consecutive oral and oropharyngeal cancer patients, linking social deprivation to QoL, as measured by the UWQoLv4. She concluded that patients with the worst QoL outcome were single, under 65 years of age and were those who smoked and consumed alcohol heavily. There was a trend for these factors and low QoL to be linked to indices of deprivation at follow up but not at presentation. The most recent figures (NCIN, 2008b) indicate that H&N cancers, defined as ICD C00-C14 & C30-C32 (lip, oral cavity, pharynx and larynx) and measured by the Income Domain of Multiple Deprivation (IMD) (2007) show a particularly strong level of social deprivation. For H&N the most deprived quintile had a ratio of 2.1 to 1 comparing the incidence rates in the most deprived with the most affluent. This supports the aims of the EAGR in ensuring that all patients have access to the best of services, confirming the sociodemographic based inequalities in cancer experience. In terms of this study, it may well indicate a greater need for assistance in communication and needs for support.

2.2.4 Management of H&N Cancer

To set the experiences of patients enrolled in this study in context, the consensus cancer and therapeutic pathways for H&N patients are outlined below according to disease site. Treatment choices depend on the cancer stage. Staging depends on three major factors; the size of the primary tumour (T-stage), the involvement

of the lymph nodes in region of the cancer (N-stage) and the presence or absence of metastatic disease (M-stage). There are two main systems in standard clinical and clinical research practice, the TNM system of the Union International Contre le Cancer (Sobin and Wittekind, 2002) and the Stage I-IV system favoured by the AJCC (American Joint Committee on Cancer, 2002).

Table 2.1 UICC Staging for H&N Cancer

TNM	Descriptor	Definition
T Status	T0	Primary tumour cannot be detected
	Tis	Cancer 'in situ', the histological appearance is that of a tumour but invasion cannot be detected
	T1	Tumour less than 2cm in its greatest measurable dimension
	T2	Tumour between 2 and 4 cm in its greatest measurable dimension
	T3	Tumour more than 4 cm in its greatest measurable dimension
	T4	Tumour invades adjacent structures: e.g. cortical bone, extrinsic muscles of tongue, external skin
	TX	Primary tumour cannot be assessed
N Status	N0	No evidence of regional lymph node metastasis
	N1	Metastasis in a single ipsilateral lymph node, 3cm or less in greatest dimension
	N2a	Metastasis in a single ipsilateral lymph node, more than 3cm but less than 6cm in greatest dimension
	N2b	Metastasis in a multiple ipsilateral lymph nodes, none more than 6cm in greatest dimension
	N2c	Metastasis in bilateral or contralateral lymph nodes, none more than 6cm in greatest dimension
	N3	Metastasis in a lymph node more than 6cm in greatest dimension
M Status	M0	No evidence of distant metastasis
	M1	Distant metastasis
	MX	Distant metastasis cannot be assessed

T= the primary tumour, N = the lymph nodes of the neck, M = the presence of distant metastasis. For any these, the suffix 'x' means that aspect of staging cannot be accurately assessed.

Both of these staging systems describe cancers according to a numerical system where high numbers indicate more advanced disease and are described below. Staging using these systems does correlate with outcome in terms of overall survival and they represent a common language for researchers.

Table 2.2 AJCC Staging of H&N Cancer

Stage	TNM items		
Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T1, T2	N1	M0
	T3	N0, N1	M0
Stage IV	T1, T2, T3	N2	M0
	T4	Any N	M0
	Any T	Any N	M1

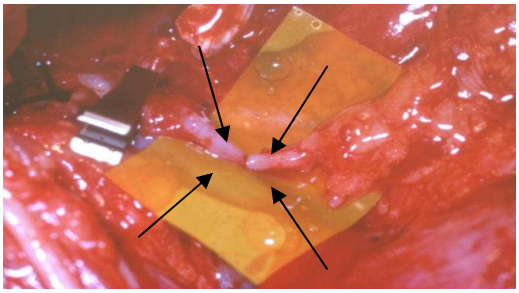
This correlation allows the TNM staging to be reported as a single figure, bringing groups of patients with a similar outcome into a single category.

Reporting through the AJCC system is clearly simple although some sensitivity in terms of understanding the specific characteristics of primary and nodal status is lost. In the study I have chosen to use a measure of therapeutic burden to assess patient views, however to show the results in comparison with a validated staging system, an analysis using the AJCC stage will be presented in chapters 6 and 7. It is customary, both in the literature and day to day clinical practice to use the staging systems as a guide to therapy. A T1 or T2 cancer without evidence of nodal involvement will often be amenable to single modality therapy, whereas a larger cancer or one with nodal involvement will need a more complex multimodal approach if a radical curative option is to be attempted.

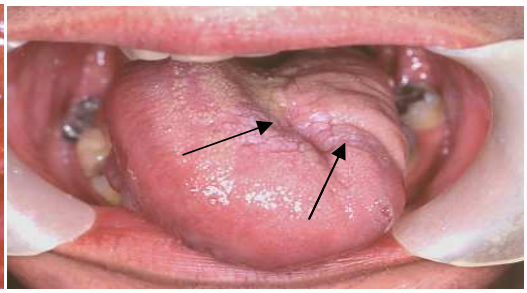
Modalities of therapy available to the cancer team include surgery, with or without reconstruction; radiotherapy, external beam or brachytherapy and systemic therapy by means of chemotherapeutic agents. Surgery aims to remove bulk disease at the primary cancer site with a margin of non-cancer tissue to achieve clearance of the invasive tumour cells. For early disease, surgery or radiotherapy may be used alone. By clinical consensus small primary cancers of the oral cavity are treated by surgery and occasionally brachytherapy (very localised high dose radiotherapy delivered using hollow needles loaded with iridium and left in place for 6 days). These techniques spare the jaws and teeth from radiation related damage. For larynx the approach has traditionally been to offer external beam radiotherapy, although endoscopic surgery is effective for T1 and T2A cancers. Where the primary cancer is larger, where the proximity to important anatomical structures may limit the margin and where the volume of primary cancer is large

or the margins are close or involved ; external beam radiotherapy is advised. It is accepted that the outcome for patients who have close or involved surgical margins is less good than for those with clear margins (Sutton et al, 2003). Where a large volume of tissue is removed, careful consideration must be given to the way the defect is reconstructed; local flaps (tissue moved from one site to another), pedicled flaps (tissue moved together with its blood supply) and, most ambitiously and routinely in modern surgical practice, free flaps (where a piece of tissue is harvested from a distant site, detached from its blood supply and revascularised using microvascular techniques to an artery or a vein situated in the neck). By these means even large and complex defects can be reconstructed, although at a lower level of function than the native tissue. Figure 2.3 shows a soft tissue and a bony reconstruction. For surgically treated patients, morbidity at the donor site is an important issue, as illustrated in 2.3.c, yet this is not addressed in current QoL questionnaires.

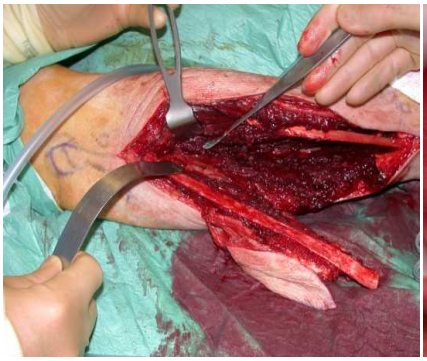
Figure 2.3: Methods of advanced surgical reconstruction.



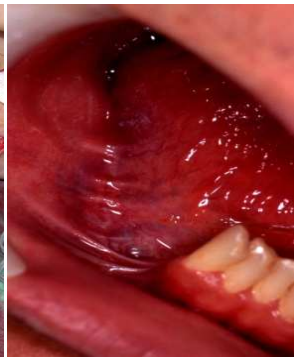
2.3.a. A microvascular anastamosis radial forearm free flap



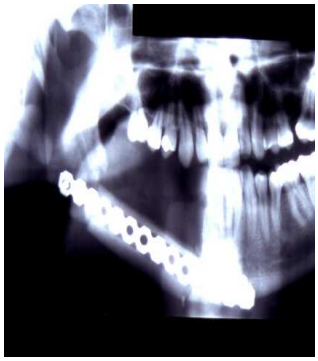
2.3.b. Tongue reconstruction using a forearm free flap.



2.3.c Harvesting a fibular flap



2 .3.d: Flap in situ



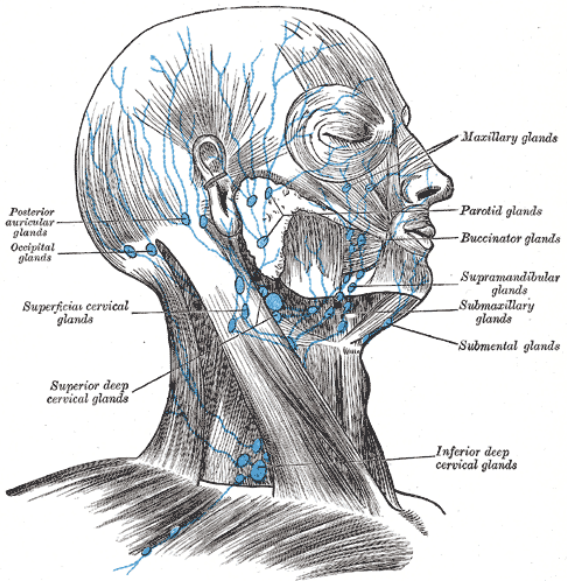
2.3.e: Radiological view.

Oral cavity cancer has consistently failed to respond to radiotherapy or, more recently, chemoradiotherapy in the way that other H&N sites have done. The reason for this site specific difference is, as yet, not understood.

The approach to advanced laryngeal cancer is rather different in that, unless bone and cartilage has been invaded by the cancer, every attempt is made to conserve the larynx, offering chemoradiotherapy wherever possible and radical external beam radiotherapy to those unfit for chemotherapy and its systemic effects. If non-surgical therapy fails, laryngectomy becomes the only option, accepting the functional and social consequences. Voice rehabilitation can be attempted using valves, oesophageal voice or electronic external larynx devices but is always inferior to the natural voice in strength and quality.

Consideration of the best therapy includes assessing the neck, as the site of the regional lymphatics; the structures which, in health drain tissue fluid and, in cancer, act as the first defence against systemic dissemination. As indicated above, the neck may be electively accessed for microvascular anastomosis in which case the nodes are cleared as a matter of convenience. The lymphatic drainage of the neck is shown in Figure 2.4.

Figure 2.4. Lymphatic Drainage of the Neck (from Gray's Anatomy)



If there is evidence of lymphatic involvement and surgery is planned for the primary disease, then an operation known as ‘neck dissection’ is carried out. The most significant predictors are depth of invasion and tumour thickness (Spiro RH et al, 1986, Woolgar, 1999) and nodal metastases are most often seen in tongue and floor of mouth primary cancers. For other sites, the likelihood of regional metastasis increases with the size of the primary cancer (Byers et al, 1988). The lowest incidence of neck metastasis is seen in lower alveolar ridge cancers (Byers et al, 1981). Treatment planning in the MDT has to take account of these factors.

The aim of a ND is to clear any cancerous lymph nodes. The operation causes specific morbidity by dissecting close to the accessory nerve, the nerve which plays a major role in shoulder function. It also results in stiffness and scarring of the neck and can impact on the lower branches of the facial nerve, resulting in a asymmetrical smile. Its place in H&N surgical therapy is well established and well supported by evidence from many prospective studies (Ferlito et al, 2009).

Where the regional lymphatics contain cancer external beam therapy is used as a adjunct to surgery. From this discussion it can be seen that external beam radiotherapy can be given to the primary cancer site and/or the neck, usually commencing about six weeks after surgery. This is known as ‘adjuvant’ therapy. It is delivered in treatment ‘fractions’, i.e. a small dose daily, destroying the cancer by incremental damage, the principle being that normal tissue has more capacity to resist and recover from radiotherapy induced damage.

The two principal modalities of therapy carry a very different side effect profile from the patient and carer perspective. Surgery leads to the worst functional status over the immediate post-operative period, followed by rapid progress over a few days/weeks and then a comparatively steady state. Radiotherapy continues to have therapeutic efficacy after the final fraction. It is usually administered as a 28 day course with a small dose given each day, producing a cumulative effect. Normal tissues which have a high cellular turnover suffer the greatest side effects; hence the oral mucosa, mucosa of the gastrointestinal tract and the haematopoietic tissues are at risk. It is usual to suffer mucositis (inflammation of the oral mucosa), gastro-intestinal symptoms and fatigue. These peak at around two or three weeks after therapy, with gradual recovery. Because of the anatomical site and the need to protect key structures such as the brain, eyes and spinal cord from too high a dose of radiotherapy, it is usually impossible to

spare the salivary glands from a dose of radiotherapy higher than their tolerance. As a result dry mouth and altered saliva are very frequently seen after therapy for H&N cancer.

Treatment has been stable for many years, the most recent therapeutic revolution being the addition of free flaps to the surgical reconstruction repertoire in the late 1980s and early 1990s. The major change affecting all patients has been the increase in chemo-therapy in recent years after a major meta-analysis reported an 8% gain in overall survival (Pignon et al, 2000) and this has gained further momentum with a further confirmatory update analysis (Bourhis et al, 2004) and the advent of targeted therapies. For some sites, especially in the context of this study for oro-pharyngeal and laryngeal cancers, chemo-radiotherapy is often the first treatment, reserving surgery for treatment failures. In common with most cancer sites, the genomic revolution is beginning to provide therapies which are having an impact on clinical practice. The most advanced of these is cetuximab, a monoclonal antibody. binding to the Epidermal Growth Factor Receptor (EGFR) sites. EGF is over-expressed in up to 90% of SCCas and the seminal paper by Bonner (2006) showed improved survival in a late stage (Stage III-IV) cohort of patients. Treatment for patients in this study was completed before Cetuximab became available, however, awareness of these new agents and their mode of action and different toxicity profiles is an area which must be taken into account in considering tools to facilitate communication,

This shift in therapies can be expected to continue as advances in molecular techniques identify ever more specific targets, allowing effective agents, potentially with lower morbidity to be introduced into clinical practice, adding to an ever changing and evolving experience of the patients and their carers who face this diagnosis.

2.2.5 The Environment of Care and Clinical Pathway

The clinical setting is the H&N multidisciplinary cancer network, based in the St. James's Institute of Oncology on the St. James's University Hospital site of the Leeds Teaching Hospitals NHS Trust. It brings together patients and clinicians from the Leeds Hospitals and also from the Mid-Yorkshire MHS Trust, delivering a service to a population base of over 1 million people in compliance with IOG. The MDT is one of the largest in the UK, in terms of both its size and complexity

and in terms of the number of patients managed through the service, seeing and assessing approximately 250 new patients per year, with a network of follow up clinics to which patients are returned once their acute care and early follow up is complete, separated both by speciality and geographical base. H&N represents one of the most complex clinical models as care is given by a number of specialities: clinical and medical oncology, maxillofacial, ENT and plastic surgeons and requires close integration with specialist pathology and radiology services.

The core MDT is shown in Table 2.3. Out-patients in Leeds and Mid Yorkshire are currently managed in six clinics for H&N and two clinics for thyroid cancer, situated at six separate hospital sites. This arrangement complies with the guidance (DH, 2000) that major surgery and chemoradiotherapy should be delivered in Cancer Centres but follow up and support provided locally. Each clinician who delivers a local service attends and brings all of his/her patients to the weekly MDT meeting and clinic. Out-patient follow up is provided at the Institute of Oncology during the acute non-surgical therapy phase. Major in-patient surgery is currently performed at the two main hospital sites in Leeds and diagnosis and surgery which does not require free tissue transfer is carried out at the Mid Yorkshire NHS Trust. Longer term follow up and support is provided in clinics at LTHT (Leeds General Infirmary and Leeds Dental Institute) and the Mid-Yorkshire Trust (Wakefield, Dewsbury and Pontefract). Paper records are kept separately at each site. An electronic single record for every patient would have significant advantages. Such a system, Patient Pathway Manager (PPM), is in the process of being rolled out to all sites, allowing integration of records and access by all teams members, doctors, nurses and AHPs. The extended MDT, involving specialist nurses, speech and language therapists, dieticians and occupational therapists is particularly important at this site as treatment routinely impacts on key functions such as eating, speech and swallowing as well as having an aesthetic impact. These areas of care also very much rely on their own, paper based, record. H&N is accepted as being the most demanding site in terms of the impact of the disease on patients and the need for integrated care pathways is well understood.

Table 2.3 The structure of the H&N MDT

HEAD AND NECK MEETING-ATTENDANCE FORM

NAME	TITLE	SIGNATURE
CONSULTANTS		
	CONS-RADIOLOGY	
	CONS-DENTAL RADIOLOGY	
	CONS MED ONCOLOGY	
	CONS ENT PINDERFIELDS	
	CONS-ONCOLOGY	
	CONS MAX FACIAL LGI	
	CONS PLASTIC SURG SJUH	
	CONS ENT LGI	
	CONS MAXILLO FACIAL	
	CONS MAX FACIAL PINDERS	
	CONS RESTORATIVE DENTIST	
	CONS MAX FACIAL LDI/LGI	
	CONS-ONCOLOGY	
	CONS RADIOLOGY-PINDERS	
	CONS ENT LGI	
PATHOLOGY		
	PATHOLOGY	
	PATHOLOGY	
	SPR PATHOLOGY	
REGISTRARS		
	SPR ENT	
	SPR MAX FACIAL	
	SPR PLASTIC SURGERY	
	SPR ONCOLOGY	
	SPR MAX FACIAL	
	SPR ENT	
	SPEECH & LANGUAGE THERAPIST	
	DIETITIAN	
	CNS PINDERFIELDS	
	CNS	
	H & N CO-ORDINATOR	
	CNS LEEDS	
	SENIOR RESEARCH NURSE	
	RESEARCH NURSE	
	SPEECH & LANGUAGE THERAPIST	
	DIETITIAN	

2.2.5.1 The Patient Pathway

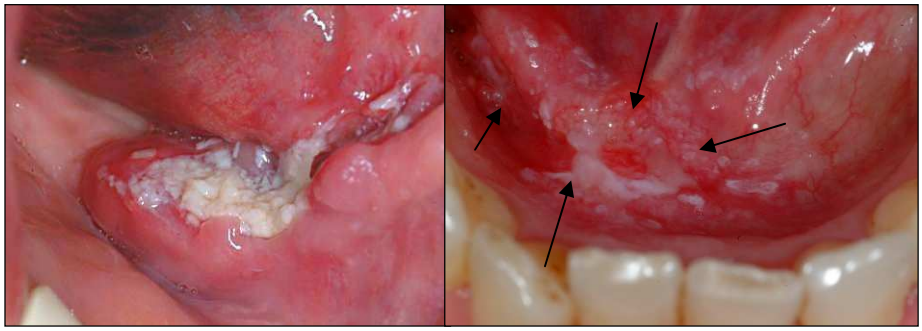
Patients are referred to the H&N team via their General Medical Practitioners (GPs) or General Dental Practitioners (GDPs). Most GDP referrals are for oral lesions, of which approximately 50% are referred by doctors and 50% by dentists. Referral guidelines have been issued by the DH to assist the referral pathway, indicating areas of concern which should prompt a 'fast-track' referral. This system allows completion of a standard fax which, on receipt prompts an urgent appointment to be generated within the DH target time of 14 days. At each Trust, patients are seen by the appropriate specialist, an ENT or a Maxillofacial surgeon. The full patient pathway is shown in Appendix 2.1.

At this visit, in addition to a full medical history, a detailed H&N assessment is carried out including examination of the neck for lymphadenopathy (enlargement of the lymph nodes) and careful inspection of the oral cavity, oropharynx and larynx. For the areas which are not immediately visible a flexible fine fibre optic tube (nasendoscope) is introduced through the nose and allows inspection of, although not biopsy of, the larynx. This also allows assessment of vocal cord mobility, an important feature in determining the extent of a laryngeal cancer. Careful palpation of all accessible areas is performed as some cancers, especially in the base of tongue, manifest only by subtle tissue thickening and firmness, rather than by visible features

At this stage, some suspicious areas are amenable to biopsy (sampling of a small piece of tissue to reach a diagnosis through examination of a stained section by a Histopathologist) in the clinic under local anaesthesia. More posterior areas, such as oropharynx, base of tongue, larynx and pharynx will require examination and biopsy under general anaesthesia.

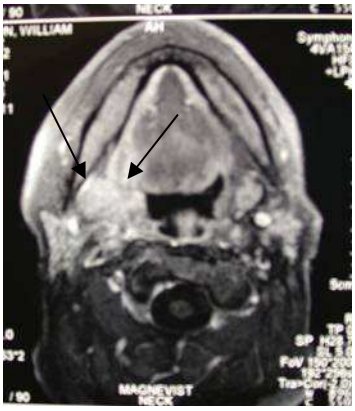
Once the biopsy has been examined and a report issued by the Pathologist, the patient and his/her carer or family return to clinic. The diagnosis is given and the main therapeutic options are briefly outlined. All patients are advised that their care will be discussed and recommendations will be made by a MDT, in line with the core recommendations of the Cancer Plan, to enable a decision regarding therapy and whether or not treatment with curative intent is possible Figure 2.5 shows the steps, from clinical inspection, through scanning to histopathological report.

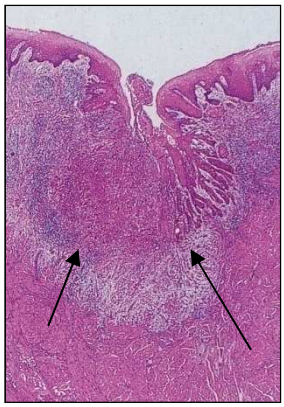
Figure 2.5. A: Clinical presentation of Cancer



a) Ulcerated SCCa **b) SCCa arising in an area of premalignancy indicated by arrows.**

B. Magnetic Resonance (MRI scan) **C. Histopathology section**





The white area is the cancer **The arrows show the cancer**

At the MDT the patient is presented by a member of the team who has been actively involved in the diagnostic pathway. An initial recommendation is made and key members of the MDT, usually a surgeon and an oncologist, together with AHPs, are identified who will meet and discuss options with the patient. Comorbidity and psychosocial issues are covered and, in an observational informal audit of 50 decisions which I carried out during the time I was recruiting patients to this study, 30 recommendations were influenced by these factors. The extent of the cancer as indicated by clinical examination and imaging (as in Figure 2.5.B) and the pathological characteristics (Figure 2.5.C) all have a core place in reaching a recommendation.

At consultation a full discussion is held with the patient and carers and the options for therapy outlined as already described in section 2.2.4. A frequent

complicating factor at this stage is the need for dental treatment to remove teeth which lie in potential radiotherapy fields and which place the patient at risk of osteoradionecrosis, an highly unpleasant condition where the jaw bone becomes necrotic, non-healing and which is difficult to treat. A further consideration is management of nutrition and either nasogastric or PEG/RIG (percutaneous endoscopic gastrostomy / radiologically inserted gastrostomy) tube feeding has to be arranged and completed prior to definitive therapy. All of these interventions are known to be effective but they add to the patient burden at a time when they are coming to terms with the cancer diagnosis and its implications. Cancer targets require that the first definitive treatment is commenced within 30 days of definitive diagnosis, hence, for the patient this 'waiting time' can be a period of intense activity, dominated by hastily arranged hospital visits.

Definitive treatment may be surgery or (chemo) radiotherapy alone in early disease as outlined above. Late stage presentation requires multimodality therapy. The therapeutic pathway for multimodality therapy may be as long as 12 weeks, giving a significant physical, emotional and financial burden to both patient and families.

At conclusion of the acute phase of management the patient enters an intense period of monitoring, to assist the management of specific side-effects, to be supported in coming to terms with life after cancer and to have surveillance for recurrent disease or the development of new H&N primary cancers. It was people in this surveillance phase who were invited to enter our study.

2.3 Thyroid Cancer

2.3.1 Epidemiology

There are four main types of thyroid cancer: papillary, follicular, medullary and anaplastic. Of these, the most common type, accounting for around 60% of diagnoses, is papillary cancer which is more common in women and in younger people. It is usually slow growing and presents as a lump in the neck. Follicular cancer, about 15% of cases, affects young or middle aged people and is more likely than papillary to undergo metastatic spread, usually to the lung or bones, Medullary cancer is quite rare (5-10% of thyroid cancers) and about 25% of

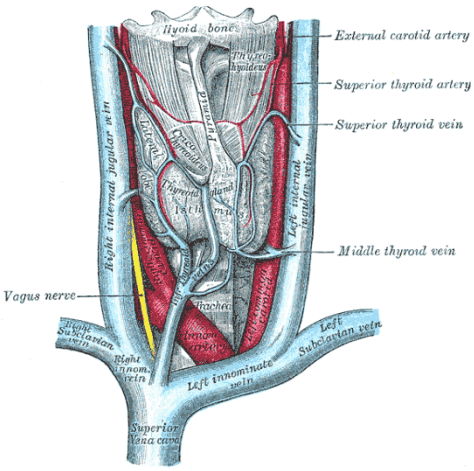
such cancers have a genetic basis as part of the MEN (Multiple Endocrine Neoplasia) syndromes. The remainder, about 15%, are anaplastic, meaning they no longer carry the morphology of thyroid tissue These cancers arise in older people (75% over 60 years of age) and carry a poorer prognosis (Cancer Research UK, 2009).

2.3.2 Management of Thyroid Cancer

The pathway is broadly similar to H&N cancers however the key difference is that lumps in the thyroid gland are common and often the diagnosis of cancer is made after the surgical removal of part of the thyroid gland (lobectomy). Depending on the characteristics of the cancer, further treatment can include removal of the residual thyroid gland, the giving of radio-iodine (the gland takes up iodine so delivering targeted radiotherapy in this way is highly effective) and/or external beam radiotherapy.

The anatomy of the thyroid gland and related structures is shown in Figure 2. The gland lies anteriorly in the neck, close to the great vessels. The vagus nerve, which has a branch passing immediately behind and to the side of the gland is responsible for moving the vocal cords and thus allowing the airway to function. The parathyroid glands lie immediately behind the thyroid gland and are responsible for calcium homeostasis. Lymphatic drainage is to the neck as for head and neck but to the lower levels of nodes.

Figure 2.6. Anatomy of the Thyroid Gland (from Gray's Anatomy)



The parathyroid glands which control calcium metabolism are situated just behind the thyroid gland and often buried in its substance so removal of one or more parathyroids is a risk in extensive surgery. The recurrent laryngeal branch of the vagus nerve (noted above) is also in close proximity For these reasons thyroidectomy is usually done at subtotal level.

Papillary and follicular cancers retain the ability of the parent thyroid tissue to take up iodine. This is used as the basis for radio-iodine therapy, often after thyroidectomy, to ablate any residual cancer. Medullary and anaplastic cancers do not respond to radio-iodine and external beam radiotherapy is given for extensive or recurrent disease. The result is that the morbidity for the most common cancers relates to the removal of the functioning thyroid gland and, potentially, parathyroid tissue with symptoms of fatigue, lethargy, weight gain, constipation and dry skin consistent with a state of hypothyroidism. For this reason, thyroxine replacement is a core part of management, monitoring thyroid hormonal and calcium status and correcting accordingly to maintain good status and, hence, QoL.

2.3.3 The Clinical Pathway

Core strategy documents for thyroid cancer are the same as for H&N as management is often undertaken by the same MDT. This is not the case in Leeds /Mid-Yorkshire although some members of the H&N MDT are also members of the thyroid MDT. The thyroid MDT meets fortnightly and differs from the H&N team in that it manages patients from the whole of Yorkshire. The main clinical input is from Clinical Oncologists who manage radio-iodine ablation and external beam radiotherapy and from specialist surgeons who carry out cancer thyroid surgery. As for H&N, centralisation of services is being driven by the recommendations of the IOG, with a smaller number of clinicians managing more patients.

The follow-up pathway is less intense than that for H&N reflecting the nature of the cancer. Care is often shared with the GP in terms of assessing thyroxine and calcium levels and managing prescribing.

In summary, the outcomes, especially for papillary and follicular cancers, tend to be good with most patients entering long term remission. The population tends to be a younger one than seen for H&N cancer and one would predict that the QoL outcomes are likely to be different.

2.4 Health Related Quality of Life in Cancer and in Head and Neck and Thyroid Cancer.

Health related quality of life [QoL] in cancer is an expanding field of interest. Over the past twenty years the clinical care of H&N cancer patients has developed significantly. The pace of change in medical technology is such that new interventional procedures and treatments will continually require evaluation. These developments give impetus to initiatives to understand the patient's experience and the impact of the disease and its therapy on the patient and his/her family. Decisions involve not only the greatest probability of cure but also judgements about the morbidity associated with treatment options. To ensure that treatments are used in the best way there is a need to focus not only on local disease control and survival but on the experience for the patient in terms of the effects both of the treatment and potential longer term morbidity. QoL studies aim to evaluate this aspect of patient care. In H&N cancer, patients and their clinicians face considerable variation both in the disease and in the therapy given. To facilitate best care, any investigation of QoL should reflect the experience of the patient group as a whole but also be sensitive to the needs of individuals. Although there is a substantial literature of H&N cancer, thyroid cancer is a disease which has seldom been addressed. In this section I will consider H&N cancer and then thyroid cancer with an emphasis on evidence which relates to the impact of the conditions and how this changes with time from diagnosis. The sources of information used in this section are:

- personal library derived from a long term interest in this area.
- conference abstracts and communications.
- literature searches carried out at intervals during this study, using Medline and search terms: 'quality of life;, 'head and neck cancer', 'oral cancer', 'larynx cancer'. These yielded a large number of studies, often of small numbers and often a mix of clinical factors and QoL.

The search strategy is shown in Table 2.5.

I have, therefore, been selective in the papers quoted here, limiting inclusion to those which I considered were related to the aims of my study, after manually reviewing those papers identified by the search

Table 2.5 Search Strategy for Literature Review, QoL H&N and Thyroid Cancers

Searches	Results	
1	Quality of Life.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	117908
2	Quality of Life.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	117908
3	limit 2 to (english language and humans)	97824
4	(Head and Neck Cancer).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	9459
5	4 and 3	694
6	Laryngeal Cancer.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	3375
7	limit 6 to (english language and humans)	1788
8	3 and 7	104
9	oral cancer.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	4713
10	limit 9 to (english language and humans)	3839
11	3 and 10	99
12	Thyroid Cancer.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	8293
13	limit 12 to (english language and humans)	6399
14	3 and 13	98
15	from 8 keep 2, 8-9, 18, 22, 25-27, 32-33...	33
16	from 14 keep 1, 6, 8, 11, 21, 30...	11
17	from 11 keep 19, 23, 39-40, 42-43, 66, 68...	14
18	from 17 keep 1-10	10

I will commence this section with an appraisal of the one comprehensive study which looks at the views of patients and health professionals in detail, that of Edwards (1997).

2.4.1 QoL and Patient and Health Professional Opinions, the Edwards' study

The most detailed consideration of patients' views in the field of H&N cancer care remains that of Edwards (1997). As this study is unique in its exploration of the views of patients, their carers and of health professionals I will cover its findings in some detail The author considered a number of issues which were part of my study and prioritised some common issues, some which fall outside the remit of my work, emphasising the importance of a continuing dialogue with patients and their carers.

The main findings were summarised as:

- inpatient accommodation was often inappropriate. The main need was to be on a ward with privacy and where others faced the same treatments and nurses experienced in their care.
- internal communication and co-ordination of care.
- information on what to expect and on the side-effects. People wanted to be involved in treatment options. Choice was a contentious issue.
- a need for someone to listen and advise. Psychosocial needs to be acknowledged and support made available and accessible to patients, relatives and professionals.
- teamwork was valued.
- the proposed changes to cancer care (Expert Advisory Group Report [EAGR]) were welcomed.

This report matches the narratives of the patients in terms of the need for good internal communication and for information on what to expect. It adds weight to the EAGR emphasis on the importance of psychosocial issues and on teamwork and appropriate facilities with care by staff experienced in meeting their needs.

Considering the aims of Edwards' seminal study, these were:

- to document patient experiences of UAT (Upper Aerodigestive Tract) cancer and cancer care.
- to explore patient and carer views of UAT cancer services.

- to explore professional views of UAT cancer services.
- to suggest ways in which these services could be made more patient focussed.

The study used focus groups with patients and carers and separately, with professionals. There are similarities with my study here but I allowed, for convenience, carers to be present at interviews and to contribute to the opinions expressed and undertook in depth interviews with individual professionals.

In the narrative of patient experience it is noted that most people were given their diagnosis in the presence and with the support of a family member. This is in accord with the practice of our MDT members. This approach had the support of participants in Edwards's study as did the breaking of bad news 'honestly, openly and sensitively'. The treatment itself was the least controversial and some who had surgery were surprised at how little the scars showed. The areas of concern were about insufficient information or choice about treatment and side effects or the giving of conflicting information. Again, here, the concerns raised in the patient narratives from Chapter 1 are echoed.

The next area of concern was unexpected adverse effects or complications of treatment. These were often blamed on the condition rather than the clinician. However, several people had post-operative complications which were not detected early enough. The worst of these was that one woman lost her leg. Considering the tension between questionnaires designed for population use and individual experience, this episode emphasises the difficulties. In a psychometrically valid instrument, it is unlikely that donor site morbidity would be included. This has certainly not been the case to date.

Patients judged success of treatment not only on whether their cancer was gone but how they could live and their quality of life. One woman had a first reconstruction which would have resulted in little morbidity but the graft did not take. The second operation allowed healing but left her unable to eat and disfigured, again an experience difficult to capture and including donor and recipient site morbidity. These facets of individual experience, specifically surgical matters, need to be considered in recording QoL at individual level.

The period around discharge was felt by patients to be challenging as the routine and support of the ward or radiotherapy team was put behind them. After

discharge the frequency of review was initially welcomed as a chance to keep in touch with hospital based support but later as a burden with participants reporting that they spent almost all their lives at the hospital. The consideration is whether new technologies, if they allow communication, could ease this burden.

From the professionals' viewpoint, team working was felt to be important and communication and organisation of services. Challenges to this were the urgency of treatment and managerial separation of services which needed to work together. They welcomed the EAGR proposal of services in a setting with specialist expertise. However there remained a tension between centralisation and accessibility, a tension which persists today.

They considered that the principles of 'gold standard' therapy were:

- to treat the person with cancer as an individual respecting their needs and wishes.
- give the best possible clinical care.
- involve patients in their care.
- have an open and caring attitude.
- work as a team.
- have good communication skills.
- provide information on what to expect and on the side effects of treatment.

Again familiar themes are emerging and these were taken into account in designing the questionnaire relating to the wishes for and perceived content of consultations which are the main part of Chapter 6.

The main physical impacts were pain, in the acute phase, often associated with radiotherapy rather than surgery, eating, often related to dry mouth and the pain associated with mucositis and weight loss. Other physical problems reported were fatigue, difficulty in speaking, hearing and tinnitus. In this study people were open about the everyday things they could not do including licking their lips for lubrication or licking stamps, kissing, opening their mouths, moving limbs from which flaps had been harvested and, in the one case already mentioned, losing a limb. In terms of the emotional journey embarrassment, shock, anxiety and

depression and the social impact were all reported as major aspects of life with and after H&N cancer.

This study gives a unique insight into H&N cancer from the point of view of both patients and carers and health professionals, a plan for research which I have attempted to emulate in my work.

2.4.2 Health Related Quality of Life Studies in Head and Neck Cancer

In this section I have considered the literature in the context of what we learn about the QoL of patients with head and neck cancer throughout their cancer journey. In the context of the study I was interested in use of the established questionnaires, identification of common or specific problems and the pattern of QoL findings with progression from the acute into the follow up phase.

As my study has concentrated on two H&N sites, oral/oropharyngeal (Oral) and laryngeal (Larynx) I searched for papers which also related to these specific H&N sites as well as more general papers, with an emphasis on determining the QoL measures used in the literature and also the longer term concerns of patients.

Hammerlid, Bjordal et al undertook a series of prospective studies which followed the self-reported QoL status of a cohort of H&N from diagnosis to 5 years post therapy using the European Organisation for Research and Treatment in Cancer core (EORTC QLQ C30) and H&N modules, QoL was assessed at 1,2,3,6 and 12 months after therapy. In the first report (Hammerlid et al, 2001a) findings from 357 patients (mean age 63, 72% males) were presented and site specific differences at diagnosis related to communication for laryngeal patients and pain for oral cancer patients. Those presenting with late stage disease reported significantly worse QoL over a range of domains. At 12 months (Bjordal et al, 2001), 68% of the surviving patients (218/280) completed questionnaires. QoL deteriorated significantly during treatment, followed by a slow recovery up to 12 months, except for senses, dry mouth and sexuality. Stage remained an important factor. Hammerlid et al (2001b) reported outcomes at 3 years, adding HADS to the EORTC measures. By this time QoL scores had returned to pre-treatment levels, with few exceptions. The greatest improvements were for mental health but significant deteriorations were recorded for dry mouth, senses, teeth and mouth opening. The difference between early and late stage responses gradually increased over time with stage remaining the most significant predictor of longer term QoL. Age and gender had little effect. Findings remained similar at

the end of five years (Abendstein et al, 2005). The cancer patients were compared with a general population, using SF-36 (Hammerlid et al, 2001c) and scores did not differ much from age/sex matched controls. Fang et al (2004) also compared SF-36 scores for oral cancer patients with population norms (Taiwan) but found that scores for the cancer patients remained lower, especially for older patients, those with lower incomes, the unemployed and, again, those presenting at a later stage. Rogers et al (1998a and b) used SF-36 and the University of Washington QoL questionnaire (UWQoLv4) and found, in a group of 50 consecutive patients who had had primary surgery for oral cancer, that status as reported by almost all domains fell by three months post-therapy but improved up to one year. This combination of SF-36 as a general measure with UWQoLv4 was considered suitable for comparative studies. They also looked at site specifc differences using the same questionnaires plus the EORTC QLQC30 in a consecutive population of 130 patients, finding that there were site specific differences in QoL (Rogers et al, 2000).

For oral cavity cancers there has been an emphasis on outcomes after radical surgery, given the major role of such surgery in management and also on shoulder function as these patients have a neck dissection as part of their operation. There has been interest in the use of QoL measures to predict outcome We looked at a series of oral cancer patients treated by primary surgery (Rogers, Fisher et al, 2002) finding that the main predictor of QoL was the size of the resection, which correlates to stage. Markkanen et al (2006) reported similar findings. Rogers et al (1999) considered the UWQoL as a predictor of outcome and again related poor scores to stage and also to poor outcome, which also correlates to stage. Wilgen et al (2004) and Rogers et al (2004) reported that shoulder and neck morbidity are important determinants of QoL for patients who have had neck dissection. Long term survival remains linked to reduction in QoL domains assessed by EORTC, Functional Adaptation to Cancer Therapy General and H&N measures (FACT-G and H&N) and UWQoLv4 questionnares, especially for dry mouth, mouth opening, shoulder function, chewing, speech and teeth. The results at one year predicted the long-term areas which would continue to score poorly (Nordgren et al, 2003, Rogers et al, 1999c, Smith et al, 2005).

For laryngeal cancer there is an emphasis on voice preservation strategies versus laryngectomy. Trivedi et al (2008) used FACT-G and FACT-H&N in a group of 40 patients and found comparable scores in both groups, although ‘dry mouth’ was slightly worse in the non-surgical group and ‘ability to communicate

with others' was worse for the laryngectomy group. Boscola-Rizzo et al (2008) used the EORTC questionnaires for long term QoL evaluation and found significant results in favour of non-surgical therapy for physical function, role function and global QoL. Surgical patients reported problems with senses, social contact and speech whereas the chemoradiotherapy group reported greater problems with dry mouth and saliva. Singer et al (2009), in a larger study (323 patients) to validate the EORTC QLQ C30 and H&N modules for post-surgical laryngeal cancer patients found that the questionnaire was able to differentiate groups.

Psychological issues are acknowledged to be important for this patient group because of the impact of the cancer on social function and integration as well as the challenges common to all cancer patients and their carers. We found that the adjustment begins at the beginning of the cancer journey (Shepherd and Fisher, 2004) with realisation of the impact but also concern about longer term survival and return of the cancer. Hodges and Humphris (2008) recently reported concerns about fear of recurrence (FoR) in H&N patients and their carers with carers reporting higher levels than patients. The literature on this aspect of cancer management has gained prominence in recent years and I will return to this in more detail in later chapters when considering the patient priorities which have emerged from the interviews (Chapter 7). In this section I am considering the use of questionnaires to measure distress and Rose and Yates (2002), Jenewein et al (2008), Llewellyn et al (2008) and Singer et al (2009) used the HADS questionnaire amongst other measures. Rose and Yates reported levels of 'caseness' for depression of 41.3% by the final week of non-surgical treatment, reducing to 29.9% by three months after therapy. Jenewein et al (2008)found better scores and less distress in patients who were in strong marital relationships. Llewellyn et al (2008), comparing oral (n=115) and throat cancer (n=47) patients and a group with benign H&N pathology (N=33) against an age matched normative sample did not find any effect on cognitive or emotional adaptation. Singer et al (2009), however, placed the relative frequency of mental disorders at 19.8%. The HADS gave the best sensitivity and specificity for the measures compared in their study. Aarstad et al (2005) looked in detail at mood, anxiety and sense of humour comparing their cancer population (n=78) with patients suffering benign H&N disease (n=61). They found more anxiety and depression in patients with more advanced disease and scores at diagnosis predicted outcome.

From these papers, Hodges & Humphris (2008) and Singer (2009) have emphasised the need for screening for mental disorder and managing this early in the cancer journey. Humphris (2008) has brought the evidence together to make a case for inclusion of a psychologist in the H&N MDT.

2.4.3 Health Related Quality of Life Studies in Thyroid Cancer

In this section I have considered the literature in the context of what we learn about the QoL of patients with thyroid cancer, throughout their cancer journey. Although the number of studies was limited, precedents were found for my intended use of questionnaires to explore the QoL status at this cancer site. Tan et al (2007) used the SF-36 to compare thyroid cancer patients (n=152) with a non-cancer population finding a reduction in physical functioning in patients aged over 50 and that being employed had a positive influence on role physical and role emotional scores. They recommend active recommendation of return to work. Almeida et al (2009) used the UWQoLv4 to assess a population of 154 patients. Patients who had had neck dissection reported worse chewing and shoulder scores and those who had more than 150mCi of radiotherapy reported significantly worse pain, swallowing, chewing, speech, taste, anxiety and composite scores.

Other papers looked at the effects of therapy. Dagan et al (2004) also used the UWQoL with similar findings to those above but also related the results to thyroid status and found that distress increased significantly during periods of hormone withdrawal during periodical imaging, which could have a physiological basis but could also be related to concern about the need for and possible result of the scan. Global low (good) scores were found in those patients who were in work and for those on effective thyroxine replacement therapy. Tagay et al (2006) also related short term hypothyroidism to poor Qol scores using the SF-36 and Taieb et al (2009) reported similar results using the FACT-G modules and FACIT-F, which measures fatigue. Schultz et al (2003) related QoL responses to somatic symptoms reporting musculoskeletal and psychological problems as the most prevalent and troubling. On psychological impact, Larisch et al (2004) related hormonal imbalance to critical mood deterioraton.

2.4.4 Summary of QoL Literature

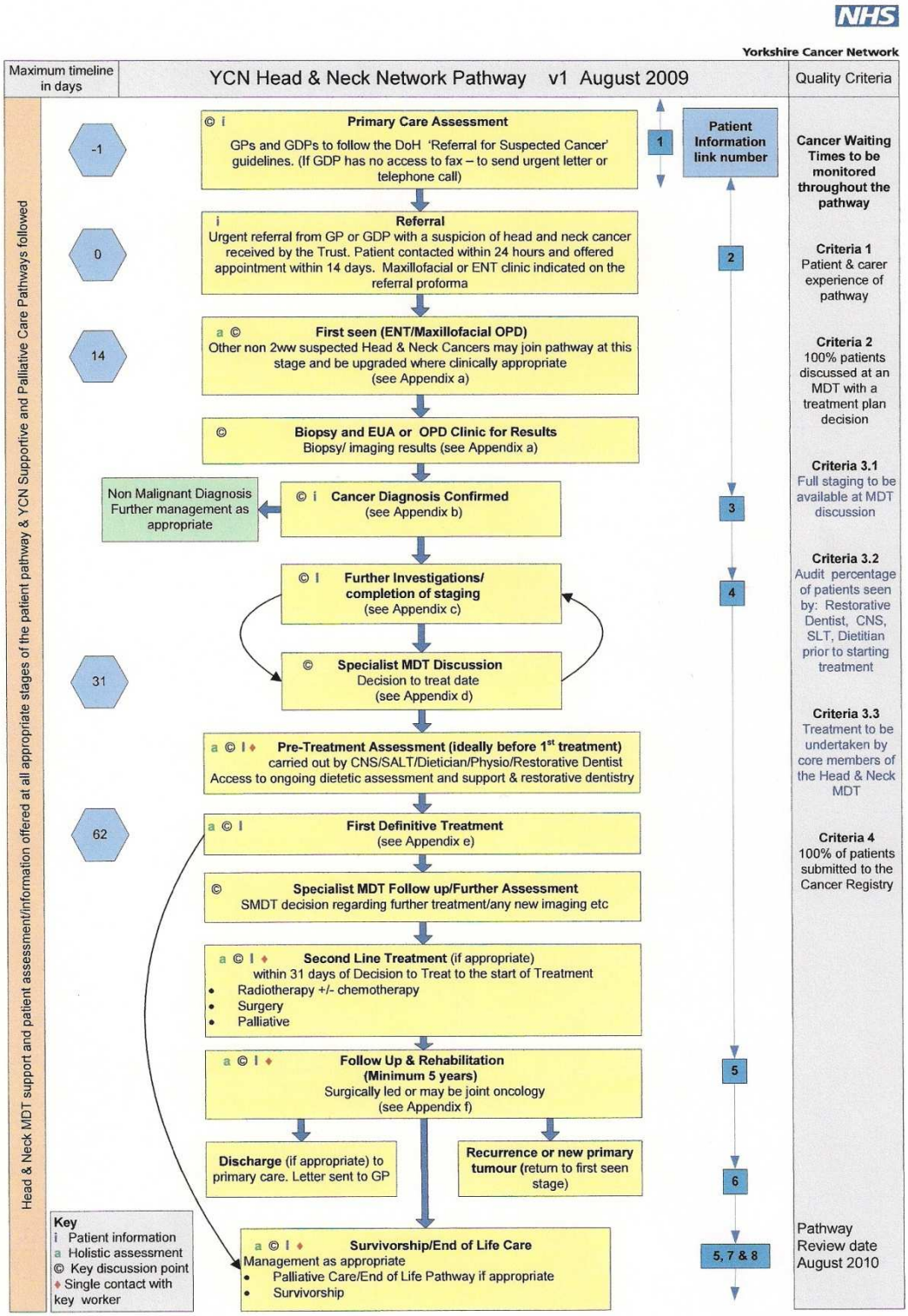
For the H&N groups there was a consensus that H&N patients report a decrease in QoL as measured by validated questionnaires from therapy to three months with a return towards pre treatment levels by one year, although some deficits remain and patients presenting at a late stage report worse status and continue to do so. Despite increasing use of non-surgical treatments, the evidence suggests long term reduction in QoL due to specific side effects of therapy for all patients. The psychological impact of H&N cancer is important.

For thyroid patients the establishment of a euthyroid state has been shown to be important for both physical and psychological well being.

Both cancer sites showed diminished QoL scores in some aspect of assessment over a range of measures. I did not find any study which included thyroid patients as part of the broader category of H&N.

In designing my definitive study, I took note of these findings and of the measures used in the studies reported and will develop this aspect of the study further in Chapter 4.

APPENDIX 2.1


NHS
Yorkshire Cancer Network
Maximum timeline in days
YCN Head & Neck Network Pathway v1 August 2009
Quality Criteria
Head & Neck MDT support and patient assessment/information offered at all appropriate stages of the patient pathway & YCN Supportive and Palliative Care Pathways followed
-1
© i Primary Care Assessment
GPs and GDPs to follow the DoH 'Referral for Suspected Cancer' guidelines. (If GDP has no access to fax – to send urgent letter or telephone call)
1
Patient Information link number
Cancer Waiting Times to be monitored throughout the pathway
0
i Referral
Urgent referral from GP or GDP with a suspicion of head and neck cancer received by the Trust. Patient contacted within 24 hours and offered appointment within 14 days. Maxillofacial or ENT clinic indicated on the referral proforma
2
Criteria 1
Patient & carer experience of pathway
14
a © First seen (ENT/Maxillofacial OPD)
Other non 2ww suspected Head & Neck Cancers may join pathway at this stage and be upgraded where clinically appropriate (see Appendix a)
Criteria 2
100% patients discussed at an MDT with a treatment plan decision
© Biopsy and EUA or OPD Clinic for Results
Biopsy/ imaging results (see Appendix a)
Criteria 3.1
Full staging to be available at MDT discussion
Non Malignant Diagnosis Further management as appropriate
© i Cancer Diagnosis Confirmed
(see Appendix b)
3
© I Further Investigations/ completion of staging
(see Appendix c)
4
Criteria 3.2
Audit percentage of patients seen by: Restorative Dentist, CNS, SLT, Dietitian prior to starting treatment
31
© Specialist MDT Discussion
Decision to treat date
(see Appendix d)
Criteria 3.3
Treatment to be undertaken by core members of the Head & Neck MDT
a © I ♦ Pre-Treatment Assessment (ideally before 1st treatment)
carried out by CNS/SALT/Dietician/Physio/Restorative Dentist
Access to ongoing dietetic assessment and support & restorative dentistry
62
a © I First Definitive Treatment
(see Appendix e)
Criteria 4
100% of patients submitted to the Cancer Registry
© Specialist MDT Follow up/Further Assessment
SMDT decision regarding further treatment/any new imaging etc
a © I ♦ Second Line Treatment (if appropriate)
within 31 days of Decision to Treat to the start of Treatment
• Radiotherapy +/- chemotherapy
• Surgery
• Palliative
a © I ♦ Follow Up & Rehabilitation
(Minimum 5 years)
Surgically led or may be joint oncology
(see Appendix f)
5
Discharge (if appropriate) to primary care. Letter sent to GP
Recurrence or new primary tumour (return to first seen stage)
6
Key
i Patient information
a Holistic assessment
© Key discussion point
♦ Single contact with key worker
a © I ♦ Survivorship/End of Life Care
Management as appropriate
• Palliative Care/End of Life Pathway if appropriate
• Survivorship
5, 7 & 8
Pathway Review date August 2010

Appendix

YCN Head & Neck Network Pathway

Pathway Details/Supporting Information

The Head & Neck pathway incorporates the supportive and palliative care pathways. Key discussion points, key information, key worker contacts and holistic assessments are identified by symbols along the Head & Neck pathway. The **holistic assessment** element of the pathway includes supportive care for the physical, psychological, social/financial, emotional, and spiritual well being of the patient and significant other.

The Head & Neck pathway will be supported by a tumour specific Patient Information Pathway. The Patient Information Pathway supports the steps in the Head & Neck pathway such as referral, diagnostic procedures and tests, diagnosis, treatments and side effects and support services. Each stage will be numbered from 1 to 8 indicating when the information might be offered. Additional national resources to meet assessed or expressed patient/carer information needs may be offered at any stage along the pathway.

a) First seen (Maxillofacial OPD or ENT OPD)

- Patient attends the Maxillofacial OPD or ENT OPD clinic
- Assessment carried out and FNA/ biopsy may be taken same day if appropriate (Access to specialist neck lump clinic at agreed centres with on-site cytology and ultrasound).
- Routine bloods and chest x-ray/OPT at time of first appointment if required
- Patient is given fully booked appt for Maxillofacial dept or ENT within 3-7 days or fully booked appt for theatre if GA required
- CT or MRI requested urgently if required (performed within 10 working days)
- MRI performed before biopsy if under GA. Biopsy date to be indicated on the MRI request form
- Patient may be given date for admission to ward (if appropriate)

b) Cancer Diagnosis confirmed

- Patient added to Centre H&N MDT list
- Patient receives appt for the next Maxillofacial or ENT OPD clinic
- GP faxed within 24 hours
- H&N CNS contact details and patient information offered
- Clinician inform patient about CNS service which may include home visits
- If the patient is diagnosed with Head & Neck cancer and is of appropriate age, refer patient to Teenager and Young Adult Service (TYAS) at Leeds, as per YCN TYAS pathway.
- If non malignant diagnosis further management as appropriate
- Any stage onwards patient entry into an ethically approved clinical trial considered.

c) Further investigations/completion of staging

- Patient attends for CT or MRI (if not already done).
- Patient given a fully booked appointment for the Maxillofacial or ENT OPD clinic, following imaging.
- Patient diagnosis and pre-planning for MDT

d) Specialist MDT Discussion

- Patient discussed at the Specialist Head & Neck Cancer MDT
- Key worker identified
- Outcome of MDT faxed to GP within 48 hours
- Unit team to contact centre team regarding transfer of care of patient
- Unit team to be informed of decision to treat date, first treatment date, type of treatment and outcome of MDT meeting in a timely manner

Decision to Treat/Best Supportive Care

- Patient seen in Centre H&N OPD clinic to discuss their care.
- Surgery date given
- Key worker, a permanent record of consultation and appropriate written information offered to the patient.
- Radiotherapy/chemotherapy planning starts

- Nutritional screening and access to designated dietetic resource for assessment/support (NICE IOG, 2004[1])
- Referral to Specialist Palliative team as appropriate (palliative care representative at the MDT meeting)
- Continued holistic assessment
- Best supportive and rehabilitative care including SALT and Dietetics as appropriate
- Pre-treatment assessment CNS/ restorative dentistry if appropriate (urgent dental treatment/extractions, implant planning etc) /gastroenterology/anaesthetic/ Dietetic/SALT/Physio/HDU/ITU bed availability etc organised as appropriate.

Note: criteria 3.2: Not all patients require restorative assessment so audit would not measure 100% of patients seen

e) First definitive treatment

- Patient admitted for surgery within 62 days.
- Radiotherapy +/-chemotherapy started within 62 days including dental treatment and gastrostomy if required.

<u>During First Definitive Treatment</u>

- Nutritional screening and access to designated dietetic resource for assessment/support during treatment (NICE IOG, 2004[1], Nutrition Support in Adults NICE 2006[2])
- Best supportive and rehabilitative care including CNS/ SALT/ Physio/ OT/dietetic as appropriate.

- Centre to let referring unit and GP team know that patient is discharged from the Ward when discharge from hospital is planned.

Before second line treatment patients who have had surgery and are going on to have (chemo-) radiotherapy may need further restorative assessment if appropriate

f) Follow up

- Ongoing dedicated Dietetic support within the Local Support Team (NICE IOG 2004)
- Best supportive care to enable rehabilitation of function and appearance including CNS/SALT/ PT / /psychology/OT/dietetic/ ongoing Restorative Dentistry services reviews for implants/dentures/prosthetic rehabilitation etc (locally where possible)
- Close liaison with Primary Care regarding ongoing follow-up/ rehabilitation
- Secondary care follow-up monthly.

Future Service Improvement Aspiration

To implement ultrasound and cytology at first seen clinic.

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[1] Improving Outcomes in Head and Neck Cancer, NICE 2004
[2] NICE Guidance; Nutrition Support in Adults, 2006

CHAPTER 3 - The Pilot Study

3.1 Aims and Objectives

The aim of the pilot study was to determine whether use of a H&N QoL questionnaire might assist in the care of patients in a H&N clinic. Objectives included an exploration as to whether and, if so how, the questionnaire had an effect on consultation, whether it was used by doctors and whether they found it helpful and whether issues raised were or were not already addressed in the standard consultation.

3.2 The Clinical Setting

The MDT, at the time of the pilot study, was based in the H&N Oncology Out-Patient Department of Cookridge Hospital, a specialist Cancer Hospital situated in the outskirts of Leeds. The patient population and team structure was as already described in Chapter 2. This study took place at a time of transition. Historically the team had been divided into an oral cancer team with maxillofacial surgeons and a specific oncologist and a laryngeal service with ENT surgeons and a specific oncologist and each consultation was attended by all AHPs who might have a place in treatment or patient support. With increasing centralisation of care, the MDT had increased in both size and complexity. In a satisfaction survey, led by our CNS, patients reported that they found the presence of an ever growing team of health professionals at their consultation intimidating and that they preferred to be seen by a limited number of people whose expertise was core to their immediate management. After this change some members of the team felt referrals for specialist help and support may not be directed efficiently and consistently. If they were excluded from consultations, they worried that they may miss some patients who might benefit from their expertise.

One possible answer appeared to be the use of a questionnaire to provide an assessment of patients' needs and a simple study was designed to explore the place and acceptability of such an approach.

3.3 Method

A number of prospective questionnaires were identified through a review of QoL instruments for use in oral cancer (Rogers, Fisher & Woolgar, 1999) In this review a Medline search identified 21 studies of QoL in H&N cancer and 9 in oral cancer. These could be grouped into four main groups: global and broader dimensions, general cancer, H&N cancer specific and H&N performance (specific physical functions). Candidate questionnaires identified by this classification were:

- Global measures: General Health Questionnaire (GHQ), Global Assessment of Recent Stress, Health Index, Hospital Anxiety & Depression Scale (HAD), Karnofsky Performance Index, Life Satisfaction (LS), Medical Outcomes Study Short-Form 36 Item Health Survey (SF-36), Memorial Symptom Assessment Score, Sickness Impact Profile (SIP), Spitzer Quality of Life Index (QL-Index).
- General cancer measures: EORTC Quality of Life Questionnaire (EORTC QLQ C30), Functional Assessment of Cancer Therapy Scale (FACT-G), Functional Living Index (FLIC), Rotterdam Symptom Checklist (RSCL), Quality of Life Index.
- H&N specific: EORTC Quality of Life H&N module (H&N 35), Functional Assessment of Cancer Therapy- H&N subscale (FACT-H&N), Functional Status in H&N Cancer (FSH&N-SR), H&N Specific Quality of Life (H&NCSQL), H&N Survey (H&NS), McMaster University Head & Neck Radiotherapy Questionnaire, Quality of Life Questionnaire, University of Washington Quality of Life Scale (UWQoL).
- Performance measures: Functional Intra-roal Glasgow Scale, Obturator Function Scale.

A further literature search did not identify further available instruments in common use in H&N practice. To decide a short-list we, as a MDT development group, decided that the global measures were too general and that the performance measures were too specific. The remaining measures were photocopied and distributed to MDT members and comments requested. A pilot group of 20 patients with H&N cancer were approached by the CNS as part of a separate qualitative research study and asked for their opinions on important issues to

address in clinic. Following completion of these preparatory tasks a MDT meeting was held to which all members were invited and at which all specialist groups were represented.

The group was asked to comment on available questionnaires and following discussion selected, by a well supported consensus, the University of Washington v4 (UWQoLv4) as the preferred questionnaire, considering that this instrument covered the issues most commonly raised by patients, was simple in both structure and wording and capable of completion without assistance. This questionnaire combines a series of questions relating to common problems for H&N patients, followed by a choice of concerns from which patients are asked to select the three most relevant to their experience. The questionnaire closes with a self-assessment of current and past QoL.

However, certain important issues were noted to be absent or included with insufficient clarity. For example, the questionnaire contains a question about eating whereas patients might be tube fed, use a mixture of tube and oral feeding or oral feeding alone and it was considered that this question was confusing. A decision was taken to add a box to indicate whether or not tube feeding was employed. Other issues patients had stated were important included social eating, sticky saliva, lymphoedema and nausea. Questions related to these areas were phrased in the style of the questionnaire and added. The questionnaire in its adapted form is appended [Appendix 3.1].

We wished to explore at what level of response we should pursue individual concerns with patients. At the time of this study there was no literature on the use of ‘cut-off’ scores. We used the MDT members as an expert group and reached an ‘a priori’ consensus on ‘cut-off’ scores. Scores at a level which were agreed to indicate concern are shown in red in Appendix 3.1.

Approval for the study as described below was granted by the Chairman of the Leeds West Research Ethics Committee (Leeds Research Committee ref 074aw/jl),

A cross sectional study was undertaken over a 12 week period in early 2002, inviting patients attending the MDT clinic to complete a single questionnaire assessment. We aimed to obtain a sample of convenience on which a definitive study could be based. On arrival, all follow up patients were handed a letter of information and a paper version of the questionnaire to complete prior to their

medical consultation. No assistance was offered in completing the questionnaire, to test its suitability for use in a routine setting.

Patients gave the clinician their completed questionnaire at consultation. Afterwards, patients and clinicians were asked to complete a simple form rating its usefulness and acceptability [Appendix 3.2]

I collected, collated and scored all questionnaires. Patients with low overall scores, with a low score in a specific domain or who asked for help in a specific area were contacted by the CNS, who reported back on the outcome of the intervention.

Data was analysed using SPSS v11; using descriptive methods to determine the main issues in the patient population and the frequency with which responses fell below the ‘a priori’ cut off level. Items of missing data were corrected to the group mean.

The CNS reported the concerns raised by the subset of patients who had specifically requested contact.

3.4 Results

3.4.1 UoWQoLv4 Questionnaire

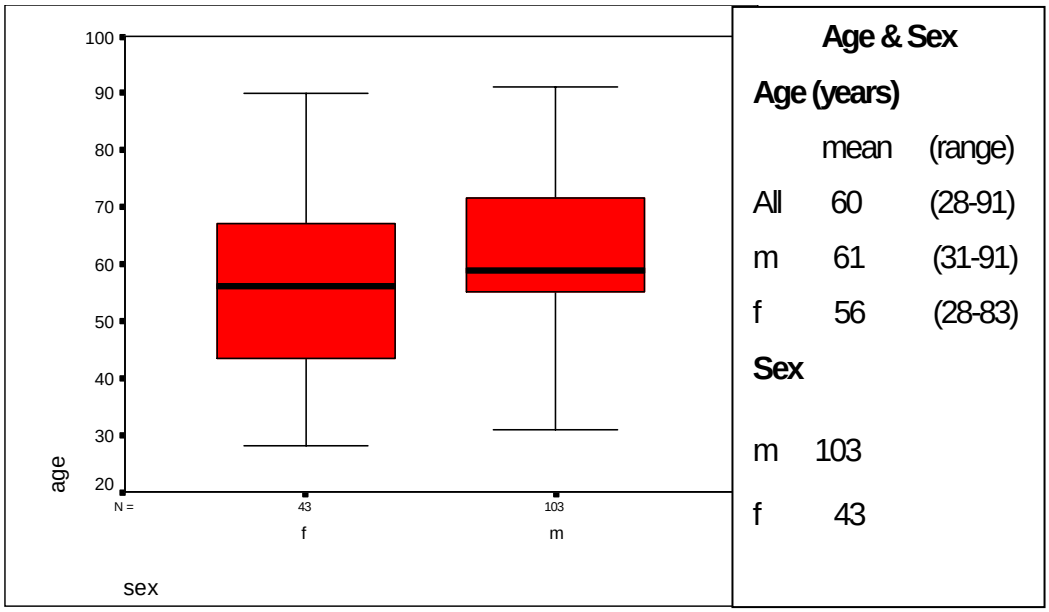
171 eligible patients were identified from clinic lists. 152 agreed to enter the study; reasons for refusals were not formally documented. After exclusions for errors in completion, 146 questionnaires were suitable for full analysis, giving an 81% response rate.

The demographic data [Figure 1] indicated that this population was comparable with other similar studies.

Site was recorded in all cases. These were classified as oral [58], ENT [61], salivary gland [12], thyroid [8] and other [7]. Within these groups the two most common sites were tongue [23 cases], and larynx [43 cases]. ‘Other’ describes patients presenting with a neck lump; in whom, despite examination under anaesthesia, surveillance biopsies and full scanning, a primary tumour was never found.

Therapy was most commonly combined; i.e. surgery followed by radiotherapy [66 cases], radiotherapy alone in 48 cases, surgery alone in 21, brachytherapy in 8, followed by surgery in 1 case; 2 patients did not have details of their therapy recorded. Time from completion of treatment varied from 1 to 144 months, with a median of 7 months.

Figure 3.1 Patient Demographics

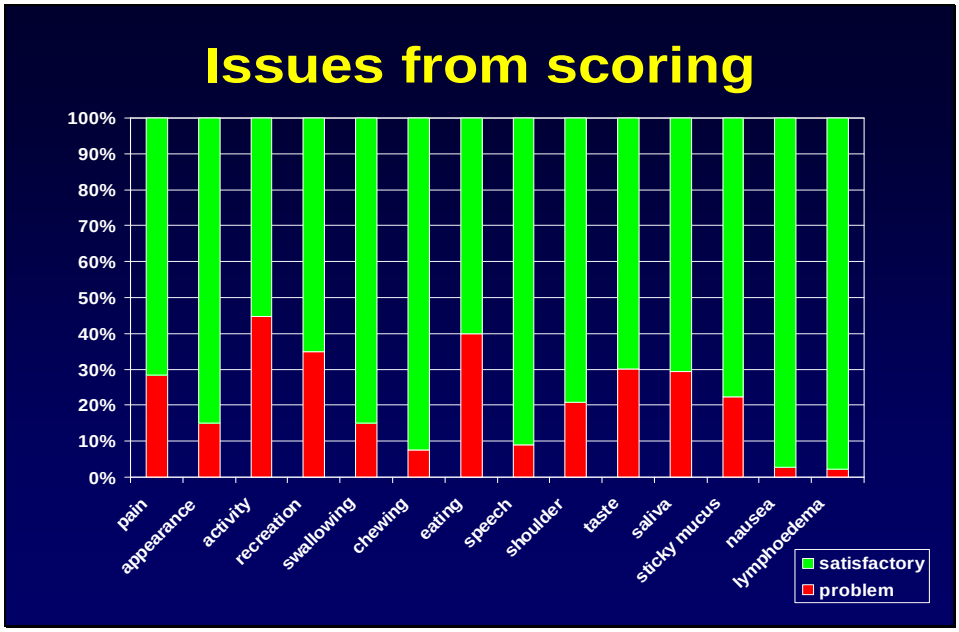


The scoring was interesting in that there was considerable variation amongst categories. Patients would often score highly in some, then dip below the 'problem' line in others or in a single domain. The relationship between scores and the 'cut off' values is shown in Figure 3.2.

117 patients [80%] fell below the previously agreed cut off point in at least one area. 29 patients [20%] scored above the cut off in all areas. Patients were most likely to state activity and recreation [44 patients] as problem areas, followed by social eating, taste, quality of saliva and pain. Later in the questionnaire they could indicate which areas were most important for them. 97 patients commented; identifying taste [32], social eating [32], sticky mucus/secretions [29], swallowing [26] and speech [23]. Two of these, social eating and sticky mucus had been added by members of the MDT during the development phase.

Anxiety was reported by 29% and depression by 35%. The final part of the questionnaire asked patients to rate their overall QoL. This was rated as good by 49% and fair to poor by 41%.

Figure 3.2. Issues from scoring

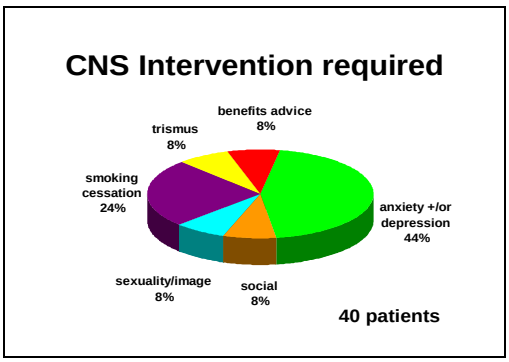


40 patients were identified by direct request for help, for contact by the CNS. Figure 3.3 shows the areas reported as being of concern to those patients.

As in other studies in this area, the most common problem was psychological distress. However, in contrast to those studies, in this one we are looking at unmet rather than population need. The CNS reviewed the records and contacted the patients identified as requiring help in the same way as she would have done had the issue been identified during the consultation.

10 patients, including the 8 citing sexuality/body image as areas of concern, were already having the issues identified addressed. For the remaining 30, interventions as a result of the study were new; these included referral to GPs, benefits agencies, charitable funds, physiotherapy and follow up by the CNS.

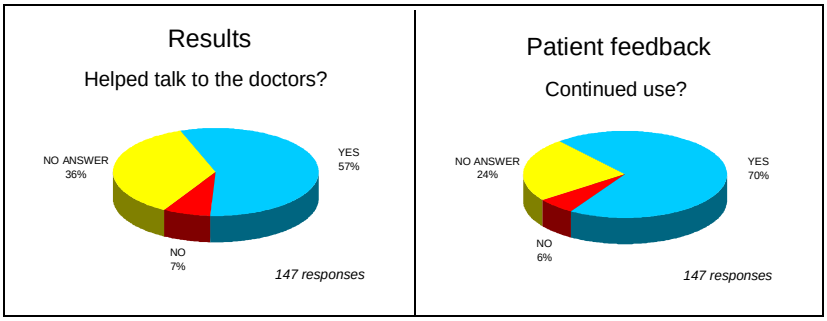
Figure 3.3. CNS Feedback on Patient Interventions



3.4.2 Patient and Clinician Feedback

147 full responses were received from patients. Feedback was positive. 57% considered the questionnaire helped them talk to their doctor whereas only 7% felt it hindered the consultation. 70% wished us to continue using the questionnaire and the 6% who gave a negative response had all reported depression. Informal feedback indicated that patients felt that a more individual view was being taken of their status and that the questionnaire reminded them of issues that they may otherwise not have raised.

Figure 3.4. Patient Feedback on Questionnaire Use



Feedback from clinicians was disappointing, with returns relating to only 39 consultations being received. Returns varied between members of the team. All returned at least one feedback form and returns were evenly divided between specialist areas, except for Plastic Surgery which had the lowest return (1), however this did result in a new intervention, the only one recorded by a clinician. Of these returns, in 18 consultations use of the questionnaire was rated as ‘helpful’ or ‘very helpful’, in 8 it had interfered with priorities and the one noted above recorded an additional intervention (referral of one of the patients who had responded negatively to use of the questionnaire and indicated depression for psychiatric assessment). Informal feedback, from all clinicians, was that the process of using the questionnaire was too time consuming and that, for most patients, there was no effect on management.

3.5 Discussion

This study showed:

- The majority of patients scored below our ‘a-priori’ cut off level in at least one area.
- Despite a coherent MDT, patient needs were not always met, 30 out of 146 patients [21%] gaining an additional intervention as a result of the use of the questionnaire.
- Patients often had isolated areas of concern and need. At individual level it is important to look at each question and domain rather than the total score. Resource implications limited CNS contact to those who scored below our predetermined cut off level in more than one area or who had a baseline [lowest possible] score in a specific question and confirmed a wish for further contact..
- Patients welcome a questionnaire assessment.
- Clinicians did not integrate the questionnaire into their patient assessment at a useful level for analysis.

Our choice of questionnaire was pragmatic, by team (investigator) preference. Whilst this is in accord with many recommendations we did not follow the established practice of combining a general cancer measure with a H&N specific measure and we may have failed to identify a number of concerns as a result. However, given the number of previously unidentified problems found in this study, this limitation did not influence the conclusion that the questionnaire might assist in helping patients identify their needs.

Because of the cross-sectional nature, it was not possible to assess whether some issues considered important by patients remained constant or were transient. There was a clustering towards the early period after therapy as the MDT policy is to return patients to their local clinic as soon as their condition is stable. This would have the effect of bias towards the most dependent population and it is accepted that patients’ QoL scores are lowest at 6 months, returning towards pre-treatment levels by 1 year (de Graeff et al, 2000, Rogers et al, 2002). Despite this bias, the level of problems reported was much higher than that anticipated in the team discussions during the preparation phase. We were limited by resource in the level to which we could explore those concerns but had anticipated that the questionnaire findings would reinforce our information on

those patients we knew to be struggling. The emergence of new, unmet need was a matter of concern. Although new initiatives were undertaken by the CNS according to her normal practice, i.e. taking the action she would have done had the issue been reported through a consultation rather than identified via the questionnaire, it is not possible to determine how effective the interventions were in meeting the patients' needs, however we would expect the areas addressed would form part of normal patient care.

Clinician returns were disappointing, especially in an environment in which support for the research and for QoL assessment was considerable. At the time of the study, there were vacancies in key posts and staff members were hard pressed. They reported insufficient time and that the questionnaire was unlikely to directly affect medical decisions. This mirrors the findings of Mehanna and Morton (2004) who reported that only 34% of H&N cancer clinicians had ever used a QoL measure, because use was too time consuming and there was no proven benefit for patient care. Our limited return from clinicians indicates the need for MDT members to perceive gains from the provision of information provided by the questionnaire. Mehanna and Morton reported that 88% of their clinical colleagues would favour the use of a 'core' questionnaire, with a clear structure and a limited number of questions.

Despite these shortcomings, the study indicated that the use of a carefully designed QoL questionnaire has potential to improve the care of patients attending a H&N clinic.

As a result of these findings, a definitive study was planned in an attempt to identify the best questionnaire; from the patients' and clinicians' point of view. The principles underpinning the design of this study are considered in Chapter 4 and the detailed methodology and conduct of the study in Chapter 5.

Appendix 3.1

Name _____
Date _____

University of Washington Quality of Life Questionnaire (UW-QOL v4) (modified for pilot study)

Cut-off values: **red**= a problem, below cut-off score, **green**= above cut-off score.

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.
   There is mild pain not needing medication.
   I have moderate pain - requires regular medication (e.g. paracetamol).
   I have severe pain controlled only by prescription medicine (e.g. morphine).
   I have severe pain, not controlled by medication.

2. **Appearance**. (Tick one box: ☑)

   There is no change in my appearance.
   The change in my appearance is minor.
   My appearance bothers me but I remain active.
   I feel significantly disfigured and limit my activities due to my appearance.
   I cannot be with people due to my appearance.

3. **Activity**. (Tick one box: ☑)

   I am as active as I have ever been.
   There are times when I can't keep up my old pace, but not often.
   I am often tired and have slowed down my activities although I still get out.
   I don't go out because I don't have the strength.
   I am usually in bed or chair and don't leave home.

4. **Recreation**. (Tick one box: ☑)

   There are no limitations to recreation at home or away from home.
   There are a few things I can't do but I still get out and enjoy life.
   There are many times when I wish I could get out more, but I'm not up to it.
   There are severe limitations to what I can do, mostly I stay at home and watch TV.
   I can't do anything enjoyable.

5. **Swallowing**. (Tick one box: ☑) Are you receiving feed via a feeding tube, if so, please tick □

I can swallow as well as ever.
I cannot swallow certain solid foods.
I can only swallow liquid food.
I cannot swallow because it "goes down the wrong way" and chokes me.

6. **Chewing**. (Tick one box: ☑)

I can chew as well as ever.
I can eat soft solids but cannot chew some foods.
I cannot even chew soft solids.

7. **Eating** (Tick one box: ✓) Additional Question for Pilot Study.

I enjoy eating out and have no problems
I eat out whenever possible, but order foods that are not messy to eat
I eat only with certain persons at selected places
I eat at home and only with certain people
I always prefer to eat alone.

8. **Speech**. (Tick one box: ☑)

My speech is the same as always.
I have difficulty saying some words but I can be understood over the phone.
Only my family and friends can understand me.
I cannot be understood.

9. **Shoulder**. (Tick one box: ☑)

I have no problem with my shoulder.
My shoulder is stiff but it has not affected my activity or strength.
Pain or weakness in my shoulder has caused me to change my work / hobbies.
I cannot work or do my hobbies due to problems with my shoulder.

10. **Taste**. (Tick one box: ☑)

I can taste food normally.
I can taste most foods normally.
I can taste some foods.
I cannot taste any foods.

11. **Saliva**. (Tick one box: ☑)

My saliva is of normal consistency.
I have less saliva than normal, but it is enough.
I have too little saliva.

I have no saliva.

12. **Sticky secretions** (Tick one box: ☑) Additional Question for Pilot Study

I do not have any problems with sticky mucus/secretions
I have some sticky mucus/secretions, but it isn't too bad
I am bothered by sticky mucus/secretions in my mouth/throat which are difficult to clear
I have trouble eating and breathing due to awful sticky mucus/secretions in my mouth/throat

13. **Nausea** (Tick one box: ☑) Additional Question for Pilot Study

I do not have any nausea
I experience nausea once or twice a week
I have nausea every day and need to take anti-nausea medication
I have awful nausea and medication does not help

15. Lymphoedema (swelling) (Tick one box: ✓) Additional Question for Pilot Study

I do not have any swelling at all
I have some swelling under my chin and jaw, but not in my face
I have swelling under my chin and jaw, and also a small amount in my face
There is a lot of swelling in my face as well as under my chin and jaw

11. **Mood**. (Tick one box: ☑)

My mood is excellent and unaffected by my cancer.
My mood is generally good and only occasionally affected by my cancer.
I am neither in a good mood nor depressed about my cancer.
I am somewhat depressed about my cancer.
I am extremely depressed about my cancer.

12. **Anxiety**. (Tick one box: ☑)

I am not anxious about my cancer.
I am a little anxious about my cancer.
I am anxious about my cancer.
I am very anxious about my cancer.

Which issues have been the most important to you during the past 7 days?

Tick ☑ **up to 3 boxes.**

Pain	Swallowing	Taste
Appearance	Chewing	Saliva
Activity	Speech	Mood
Recreation	Shoulder	Anxiety

Appendix 3.2

Quality of Life Questionnaire
Multidisciplinary Head & Neck Clinic

Leeds Teaching Hospitals.

Patient Feedback Sheet

Please give this sheet to the doctor who sees you in clinic.

Today's date:

About you: Your name: Your date of birth:

(or please ask the Receptionist to put one of your sticky labels from your notes here)

Where is/was your cancer?: mouth / throat / voicebox / other

(please ring the correct answer)

How long ago did you finish your treatment?:

Did you choose to use the questionnaire: yes / no

If yes, did you find that it:

Helped you talk to the doctors about what concerns you: yes /no

Made it more difficult to talk in clinic: yes / no

Helped you to find help or advice from new members of the Team? yes /no

Should we continue to use it? yes /no

Please add any extra comments over the page.

Thank you very much for your help.

Quality of Life Questionnaire

Multidisciplinary Head & Neck Clinic

Leeds Teaching Hospitals

Clinician Feedback Sheet

Today's date:
Clinician(s) seeing patient……..

Patients details: *(affix sticker from notes)*

Site of primary:

Did you use the questionnaire? yes no

If yes, did you find that it useful in your consultation?

Please score from 1 to 5 by circling the appropriate number,

1= unhelpful / no, 5 = very helpful / yes

Helped you talk to the patient about what concerns them	1	2	3	4	5
Interfered with your priorities for the consultation	1	2	3	4	5
Altered your perception of the patient's problems	1	2	3	4	5
Rating of the availability of the questionnaire to you in assisting with your care of this patient	1	2	3	4	5

Did the questionnaire prompt you to seek advice from additional team members?

yes no

If so, whom?…….

CHAPTER 4 - Designing the Questionnaire Assessment Study

4.1 Aims and Objectives

The main outcomes from the pilot study were:

- Patients supported use of a questionnaire in clinic.
- They considered it helped them to raise issues of concern with their doctors.

However doctors were much less supportive of the initiative.

The pilot study allowed the generation of a hypothesis for exploration in a definitive piece of work. Our working hypothesis was ***'that the use of a carefully designed QoL questionnaire has potential to improve the care of patients attending a H&N clinic.'***

The **aim** was to prove or disprove this hypothesis by means of a definitive study of patients' and clinicians' opinions and to formulate a strategy for continuing to develop this area of study in the future with the ultimate aim of introducing a suitable measure to use in routine clinical practice.

Key **objectives** of the study were:

- To gain patients' opinions on preference and content of a questionnaire for individual assessment.
- To ascertain whether the issues patients wished to raise could be effectively communicated by the use of an existing validated questionnaire.
- To determine which issues were considered important in a medical consultation.
- To ascertain if the questionnaire offered 'added value' or simply identified matters already addressed in the current MDT model of care.
- To determine the views of clinicians of all disciplines practising in the MDT about questionnaire assessment in general and choice of questionnaire as a specific item.

The structure of the study is shown in Figure 4.1

Figure 4.1 Overview of design

Part 1: Planning the study

: review of questionnaires
: consideration of information to be gathered
: consideration of technology
: definitive project plan
: external peer review

ETHICS and R&D APPROVAL

FUNDING

NCRI and NIHR CRN adoption

Part 2: Carrying out the study

: completion of questionnaires and interviews
: data validation and analysis
: generation of results
: critique

Part 3: Clinician study

: questionnaire and interviews
: data validation and results
: critique

Part 4: Bringing the findings together

: consideration of consensus or divisions between patients and clinicians
: conclusions
: defining the next stage
: further work

4.2 Overview of Methodology

To come to a decision as to whether to accept or reject our hypothesis it was essential to determine a way to allow the patients to state their opinion on questions and on questionnaires. We also wished to gain insight into their views beyond simply capturing questionnaire data. For consistency and comparison with other population groups the preferred method is to use a well developed and robustly psychometrically validated questionnaire. However, to gain the best assessment of an individual in routine clinical practice there is a need for an approach which allows them to prioritise issues of importance for discussion but which avoids 'questionnaire fatigue' by offering items which are related to their needs and care. This is particularly true for the specific items in H&N cancer questionnaires, where an item may relate to some patients' experience but not that of others.

Core items in design included how to rate questions and questionnaires, the choice of candidate questionnaires, the choice of study population, how to capture the experience and views of patients more fully and management of data burden.

Once the basic elements of design had been decided, the next phase involved the practical aspects of running the study and how to incorporate this into the clinic without either disrupting the way that the clinic functioned and also without causing inconvenience to participants. Finally we needed to bring the various strands together to reach a cogent conclusion.

4.3 Factors to Consider in Questionnaire Choice

In considering potential measures there were simple requirements to be met. If the questionnaire is to come into routine use throughout the cancer journey it must be short enough for completion not to be a burden and suitable for self-completion, yet responsive enough to allow needs to be communicated to members of the MDT.

A further issue was that any chosen questionnaire must be acceptable to the clinicians; easy to use and offering information of relevance. For this reason we considered it important to include a parallel study which gained knowledge of

clinician opinion and also explored how the MDT might manage information generated by questionnaires and who might take responsibility for specific areas of patient concern.

We determined that our preferred option would be to use a validated questionnaire as the basis for a future assessment, given the number of questionnaires already in the literature, providing patients and clinicians endorsed one of the measures to be tested. The next decision was the choice of questionnaire.

In general, the choice of measures depends on the target population and the areas which are to be studied. H&N cancer holds issues in terms of the patients' general health and also site specific and treatment specific issues. The cancer questionnaires in extensive use have often been developed as core (i.e. general) and site specific modules, designed to be used together. In deciding the suitability of a questionnaire, Fayers and Machin (2007) provide a simple and effective checklist for researchers, which I have summarised below:

Documentation:

- Is there formal written documentation about the instrument?
- Are there peer-reviewed publications which support the claims of the developers?
- Is there a user manual?

Development:

- Are the aims and intended usage clearly defined?
- Is there a clear conceptual basis for the dimensions assessed?
- Was the instrument developed using rigorous procedures, supported by published peer-reviewed evidence?

Validation:

- Comprehensiveness and sample sizes for validation studies.
- Correspondence of validated dimensions to the study proposed.
- Reliability and reproducibility of results.
- Sensitivity and responsiveness.

Target population:

- Previous use in intended population

- If the population differs, is it reasonable to expect the instrument to be applicable?

Feasibility:

- Is the method of administration feasible?
- How long does it take to complete (patient burden)
- Is help necessary?
- Are there difficult or potentially embarrassing items?
- Is processing easy or is coding required?
- Are they compatible? In which order should they be delivered?

Scoring:

- Is the scoring procedure defined?
- Are there global questions about QoL?

Interpretation:

- Are there guidelines for interpreting the scale scores?

All instruments have common properties in terms of performance. The level to which they meet these is variable and all the factors indicated in this section must be considered in choosing a measure for a study.

Validity is the process of deciding whether an instrument measures what it is intended to measure and is based on *content or face validity* (the extent to which items are sensible and reflect the intended domain of interest) and *criterion validity* (whether the scale has empirical association with external criteria, such as other established instruments). All instruments considered for this study carry support from the literature, although the strength of the validation studies varies as indicated in the section for each chosen measure. Reliability addresses the random variability associated with measurements. If patients' QoL status has not changed, then their responses should remain similar. My main study is cross-sectional in nature but this aspect is addressed by an attempt to achieve *test/retest* reproducibility. Sensitivity is the ability to detect differences. A main part of my study is to determine whether there are differences between sub-groups and, if so, whether specific measures or questions allow these to be identified.

All instruments considered have peer-reviewed validity studies in the H&N cancer population. They have not been validated for the thyroid population, however,

well validated thyroid measures are not available and, in respect of this cancer group, the use of the questionnaires used in this study must be considered exploratory.

4.3.1 Choice of Questionnaire

A review of QoL questionnaires in H&N cancer did not support claims of superiority for any of the current commonly used instruments and concluded that the choice depended primarily on the research question (Rogers, Fisher & Woolgar 1999a, Ringash & Bezjak 2001). A search of appropriate databases and a detailed group discussion at the 6th International Workshop on H&N Cancer, held under the auspices of the Sixth Workshop on the Biology, Prevention and Treatment of H&N Cancer in July 2002 identified a small number of questionnaires which have gained acceptance in H&N oncology. The general questionnaires are the European Organisation for Research and Treatment in Cancer Core Questionnaire [EORTC QLQ C-30], the Functional Analysis of Cancer Therapy General questionnaire [FACT G] and the Short Form 36 [SF-36]. H&N specific questionnaires include the EORTC H&N, FACT H&N and University of Washington Quality of Life Questionnaire [UWQoLv4]. The latter has been adopted by the British Association of Oral and Maxillofacial Surgeons [BAOMS] and the British Association of Head and Neck Oncologists [BAHNO] for the monitoring of patients. On these grounds I decided that three general questionnaires: SF-36, EORTC QLQC30 and FACT-G and three head and neck specific questionnaires: EORTC H&N module, FACT H&N and the UWQoLv4 had enough support both in the literature and in UK clinical practice to justify their inclusion in the study.

Scoring of psychological status is important in this group of patients and the Hospital Anxiety and Depression [HAD] scale has been most extensively used in H&N studies with the Mental Health Inventory [MHI 5 UK] scale also having support as a short and useful measure for assessing psychological status. Evidence suggests that a combination of the MHI 5 UK with the HAD provides the most sensitive and specific short way of detecting anxiety and depression in the assessment of cancer patients (Cull et al, 2001); and although not yet applied to H&N cancer, this combination was used in our study.

Examples of the questionnaires are appended (Appendix 4.1-4.8) to this chapter to allow comparison of their content and the number of items included in each measure. The general and H&N questionnaires show variation in questions asked, i.e. variation in *face validity,* variations in method of scoring and interpretation. The language has a format to suit the structure of the questionnaire and the practices of the organisation responsible for development, for example, the EORTC phrases questions in the third person whereas the FACT questionnaires are phrased in the first person. I accepted that a direct comparison of questionnaire scores would not be possible but interpretation of scores, especially at domain level may yield evidence about interpretation of that instrument. I will explore this further in chapter 6, where we look at the areas most likely to be raised in consultations and chapter 7, where I explore the findings from patient assessment of the selected questionnaires. The characteristics of each of the selected QoL measures are described below:

4.3.2 The Short Form-36 in Healthcare Research (SF-36v2)

The SF-36 is a well established questionnaire for use in the evaluation of patient groups and has the advantage that it can be used to compare study groups with normalised data (Rogers et al, 1998). It was first developed and reported by Ware (Ware & Sherbourne, 1992, Ware et al 1993). It has been extensively validated and is one of the most common tools in use for patient self-reporting in QoL research and is now available in more than 120 languages. It is a general measure designed to capture the QoL rating of patients across a range of medical areas unlike the other measures considered for the study which are cancer specific. In terms of the desired qualities of a questionnaire above, its validation is extensive, it has been reported in thousands of peer-reviewed papers, is simple to complete, contains an overall rating of QoL and covers the domains important for patient reported outcomes. Its only weakness from the point of view of this study is that, unlike the other measures selected, it was not designed to be specific for cancer but rather to allow comparison between disease states. Scoring options are the simple score model which was used in the early developmental phases giving an overall rating out of 100 across the domains, In later versions norm based scores for each domain: Physical functioning (PF), Role functioning (RF), Bodily pain (BP), General health (GH),

Vitality (V), Social functioning (SF), Role emotional (RF) and Mental health (MH) (Quality metric 2009) have been developed allowing comparison between populations. For simplicity and because we are not attempting comparisons, in this study I shall report the simple scoring model, relying on the face validity of individual and groups of questions to explore similar phrasing and reporting across the general measures. In terms of simple description the 36 questions are as follows:

- 2 general questions on self-perception of health now and compared to one year ago.
- 4 on limitations on work and everyday living as a result of physical health
- 3 on limitation on work or daily activities as a result of emotional health.
- 10 which constitute a de-escalating scale of physical status, commencing with vigorous activities and ending with bathing and dressing.
- 1 question on interference with social activities.
- 1 question on bodily pain.
- 1 question on limitation of everyday activities due to pain.
- 9 on various aspects of feeling of energy and vigour and mood.
- 1 general enquiry about impact of physical or emotional problems on social activities.
- 4 true or false statements about self-perception of health.

From this list it can be seen that the questionnaire offers a multidimensional assessment of health. Its complexity lies in the use of single questions to explore more than a single item.

4.3.3 The European Organisation for Research and Treatment of Cancer: General and Head and Neck Specific Measures (EORTC QLQ-C30 and H&N module)

The EORTC has developed an integrated system for assessing the QoL of cancer patients participating in clinical trials. It was founded in 1962 as an international not for profit organisation. In 1980 the QoL study group was founded which in 1986 initiated a programme to develop a modular integrated approach for evaluating QoL in patients participating in clinical trials (Fayers et al, 1997).

The core questionnaire was first developed on 1987 and subsequently refined. Its aims were to be:

- cancer specific.
- multidimensional in structure
- appropriate for self-administration
- applicable across a range of cultural settings.

The first report of international field testing was that of Aaronson et al (1991), the QLQ C30, the current format, was reported in 1993 (Aaronson et al 1993).The current core questionnaire (EORTC QLQ C30 v3) incorporates nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social), three symptom scales (fatigue, pain and nausea and vomiting) and a global health and quality of life scale. It ends with a number of single-item symptom measures. To return to the suggested list of attributes above: this questionnaire is cancer specific and thus designed for the study group I am exploring, it has been subject to rigorous validation and translated into many languages, it is suitable for self-reporting, and widely used and accepted in the field of cancer research.

It is designed to be used as a combination of core and H&N modules and this combination represents the most commonly used instruments in H&N cancer QoL research in Europe and has been well validated (Bjordal and Kaasa, 1992; Aaronson et al, 1993; Aaronson et al, 1996; Bjordal et al, 1999).This is complemented by a H&N module which is designed to capture items which relate specifically to the experience of patients with head and neck cancer. Each site specific module is developed according to a well defined methodology from exploration of items with professionals and patients, through to item selection and wording and rigorous field testing as reported in the studies noted above. The EORTC H&N module has 35 questions assessing symptoms and side-effects of treatment, social function and body image/sexuality. When a combination of the QLQ C30 and H&N module is used the total QoL assessment contains sixty five questions.

Scoring is as described in the manual (Fayers et al 1995, revised 1997). All of the scales and single item measures range in score from 0-100. A high scale score represents a higher response level, hence whether a high score represents good function or not depends on the wording of that domain. Thus a high score for a functional scale represents a high/healthy level of functioning, a high score for global health status/ QoL represents a high QoL, however a high score for the

symptom scales/items represent a high level of problems. The scores need to be considered as to whether they represent positive (function/QoL) or negative (symptom) items. The scoring system in the manual takes account of these items and is used in the scoring in this study.

4.3.4 The Functional Assessment of Cancer Therapy General and Head and Neck Specific Measures (FACT-G and H&N)

The FACIT Measurement System is a collection of QoL questionnaires targeted to the management of chronic illness which began with the development of the FACT-G in 1987. The FACT-G has been gradually refined through field testing and reports and, in version 4, the current version, consists of 27 items made up of general questions divided into four primary QoL domains. (Cella, 1987). These are:

- physical well-being (7 items)
- social/family well being (7 items)
- emotional well being (6 items)
- functional well-being.(7 items)

The model for development has been reported as being broadly similar to that already reported for the EORTC measures; the generation of items using an expert group of professionals and patients and subsequent sequential field testing (Webster et al, 2003). FACT G and H&N questionnaires have been validated and are more extensively used in the USA than in Europe (Cella et al, 1993; List et al, 1996). The design was formulated specifically for ease of administration and the FACT-G is reported to take 5 -10 minutes to complete, and the FACT-H&N, which consists of a series of 12 supplementary items is reported to take 2-3 minutes to complete. The FACT-H&N represents a list of common experiences for H&N patients which are described as ‘additional concerns’. The scales are designed to be used together. Both scales hold positive statements; e.g. ‘I am able to eat the foods that I like’ and negative statements, e.g. ‘I am unhappy with how my face and neck look’. Scoring is on a Likert scale of 0-4 to be scored positively in the case of a question where a high score represents good function and negatively where a high score equates to a poor status/symptom. As a rating on the lowest point scores 0, the highest possible score for the FACT-G is, therefore 108 and for the H&N module 40 (10

items are scored and two are simply noted). In this study, scoring was done according to the Users' Manual (Cella, 1987).

This measure is cancer specific, supported by the literature and easy to complete. The literature supporting its use in cancer research made it a suitable measure to include in the study as a potential measure to explore QoL at individual level.

4.3.5 The University of Washington Quality of Life version 4 Questionnaire (UWQoLv4)

The UWQoL questionnaire was first described by Hassan and Weymuller (1993) The advantages claimed for the instrument were:

- it is brief and self-administered.
- it is multifactorial, allowing sufficient detail to identify subtle change.
- it provides questions specific to H&N cancer.

The first version contained 9 domains: pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, and employment. It was compared to two standard instruments, the Karnofsky scale and Sickness Impact Profile (SIP). Using the SIP as a gold standard the UWQoL demonstrated an average criterion validity of 0.849 and a slightly lower level (0.826) for the Karnofsky scale. The UWQoL questionnaire scored >0.90 on reliability coefficients versus 0.80 for the Karnofsky and 0.87 for the SIP scale. Over subsequent years a body of literature has been published supporting the use of the UWQoL, however it has to be accepted that, as it was designed as a stand-alone instrument (Weymuller et al, 2000) for use at a less common cancer site, its psychometric validation has inevitably been less robust than that of the other main tools and, for this reason, I have reported the development of this questionnaire in some detail. It has gained considerable popularity amongst investigators working in H&N surgery, particularly in oral cancer (Rogers, 1999b). A study indicated that 65% of maxillofacial surgeons in the UK who assess QoL use this tool (Kanatas and Rogers, 2004).

The content has gradually evolved. In version 2 each of the 9 domains was followed by an importance rating scale and three new single item QoL questions were added (Deleyiannis et al, 1997). Version 3 added two new domains (taste,

saliva) and removed employment (Weymuller et al, 2000). The main change was to replace the ranking of importance for each domain, patients were asked to choose the three most important. The current version (v4) added a simple emotional assessment, adding anxiety and mood. Version 4 was first published in 2001 (Weymuller et al, 2001, Rogers et al, 2002).

Scoring is on a scale from 0-100, the scores for intermediate answers between the highest and lowest possible answers depending on the number of options. So, a question with 5 options has scores of 100, 75, 50, 25 and 0; those with 4 options can score 100, 70, 30 or 0 and the one question with three options (chewing) has scores of 100, 50 and 0. In each case a high score reflects better quality of life. A similar scheme is applied to the QoL questions.

4.3.6 The Hospital Anxiety and Depression Scale (HADS)

The HAD scale (Zigmond and Snaith, 1983) was developed as a result of the need to assess the contribution of mood disorder, especially anxiety and depression, to understand the contribution of these factors to suffering in the setting of medical practice. It is a general, not a cancer specific, measure. It has been extensively used in health science research to screen anxiety and depression across a wide range of conditions. The interaction between physical and mental disorders has been explored. Pain which was previously tolerable may become intolerable if a depressive state supervenes (Bradley, 1963). Of specific interest to my study, in maxillofacial cancer patients who had undergone therapy with curative intent it was found that one in three had significant anxiety and somatic symptoms which were reduced by discussing the nature of anxiety and its ability to manifest as somatic distress (Telfer & Shepherd 1993).

The measure was developed as a response to recognition of need and the fact that previous questionnaires were lengthy and represented a significant burden to patients who may already be distressed. During development much thought was given to the term ‘depression’. Its use varies from major states considered by specialist psychiatric practice, to matters of general states of distress including: demoralisation from prolonged suffering, reaction to loss (grief), tendency to undervalue self (loss of self-esteem) and pessimistic outlook on life. In developing the HADS it was decided to concentrate on the loss of pleasure response (anhedonia) as the best guide of to the type of disorder which might be

amenable to therapy (Snaith, 2003). It can be used either with predetermined 'cut off' scores for 'probable' and 'cases' of anxiety and depression or as a continuous scale. Controversy has been reported about using the 'cut offs' derived from studies of psychological distress in cancer patients. Studies in breast cancer (Hall et al, 1999) and lymphoma (Razavi et al, 1992) reported equivocal results. Ibbotson (1994) recommended different 'cut off' scores for patients with cancer. However the H&N studies reviewed in Chapter 2, section 2.4, used the standard 'cut-off' so this approach has been adopted for this study.

4.3.7 Mental Health Inventory 5 (MHI-5)

The MHI-5 is derived from the SF-36 and is well validated within the parent measure and accepted in clinical practice. One disadvantage is that, unlike the HADS, the MHI-5 does not have accepted cut-off scores (Kelly et al, 2008). It consists of five questions, with rating scales which increase or decrease depending on the wording of the question. In this study scores will simply be summed to allow comparisons between groups and sub-groups.

4.3.8 Summary

In this section we have looked at the measures to be used and justified their selection on the basis of merit in terms of psychometric validation or of use in the scientific and clinical setting in which my study is based. I have focussed on including a general measure, a site specific measure and an assessment of anxiety and depression in any future recommendations,

A challenge for questionnaire assessment in H&N cancer is the variation in the disease at different sites, its treatment and the impact of therapy. QoL varies not only because of basic personality factors which link to patients' perception of their QoL (Calman, 1984) but also aspects of family and social support and the morbidity resulting from treatment. The challenges of attempting to derive an instrument that allows patients to record their status and concerns and presents them in a useful way to clinicians are considerable. The instruments accepted for current use provide the most robust baseline from which to work towards acceptance of an already existing measure into clinical practice or to develop any future assessment tool. Other authors, for example Ringash and Bejak (2001),

emphasise the challenge and extensive validation requirement for new measures and advise that research should focus on learning as much as we can about the questionnaires already available to us. I have adopted that philosophy in my study, looking to use, or perhaps adapt our current measures to best reflect the issues patients wish to communicate to MDTs rather than to look or develop a new questionnaire.

4.4 Studies Comparing the Chosen Measures

Interpreting the meaning of scores can be difficult at individual level. Work in this area directly considering the needs of H&N cancer patients is limited. A study comparing the EORTC QLQ C30 and the FACT-G indicated that scores achieved in each area by the same patient may differ considerably (Kemmler et al, 1999). Comparison of the three general QoL indicators has been attempted in oral cancer reporting some correlations (Rogers et al, 1998), but the numbers of patients recruited was very small. Comparison studies have not been carried out in the wider context of H&N cancer or with consideration of patient preference. Despite the burden of data collection, usable responses were achieved in these studies. Comparison of the available and accepted tools is required before a single measure can be proposed and these studies would indicate that participants would be capable of completing a complex dataset to allow this comparison.

The key features of a proposed questionnaire are that it must be acceptable to and easily interpreted by patients, both in terms of the content and the wording of questions. In determining a design, the patients' views are imperative. Clinicians and MDT members must have a clear understanding of the relevance of the data supplied and the action required to meet the patient's need. Other important factors are the inclusion of issues which arise as part of consultations or which may indicate a change in disease status.

4.5 Quality of Life Assessment: technology for data collection

The utility of QoL assessments using standard questionnaires in the oncology clinic has gained support (Velikova et al, 1999a). Information technology allows

data to be collected rapidly and scored automatically (Velikova et al, 1999b) allowing the doctor information about present and cumulative QoL. In H&N cancer, using the UoWQoLv4 questionnaire, the acceptability of touch screen technology in a group of patients with oral cancer, including those who had never previously used a computer, has been confirmed (Millsopp, 2004). Detmar et al (2002) and Velikova et al (2004) reported randomised controlled trials showing the benefits of making available a QoL record at consultation in a routine clinic setting in terms of identification of issues and patient satisfaction. The potential benefit of quality of life data in individual patients to help prioritise problems, identify preferences and monitor changes was highlighted by Higginson (2001).

4.5.1 Technology for Data Capture

The Cancer Research UK Centre in Leeds has undertaken substantial research into the use of touch-screen computers in health related quality of life (HRQoL) research, successfully capturing data from patients in an acceptable and reliable way (Velikova et al, 1999b). The use of touch-screen technology has proved very successful in previous studies investigating HRQoL in patient populations. The ability to rapidly collect and automatically score data allows the doctor easy access to information about present and cumulative HRQoL (Detmar et al, 2002). This intervention resulted in an increase in the number of issues discussed at consultation and patients considered questionnaires a useful tool to inform their doctors about their problems. The benefit of making QoL scores readily available at clinic through availability of touch-screen data, in terms of identification of issues and patient satisfaction, has been demonstrated by randomised control trials (Velikova et al, 2002, Velikova et al, 2004). This work opened the path to the development of an integrated clinical/ research electronic database combining, the clinical pathway, clinical trials management and direct entry of patient generated data.

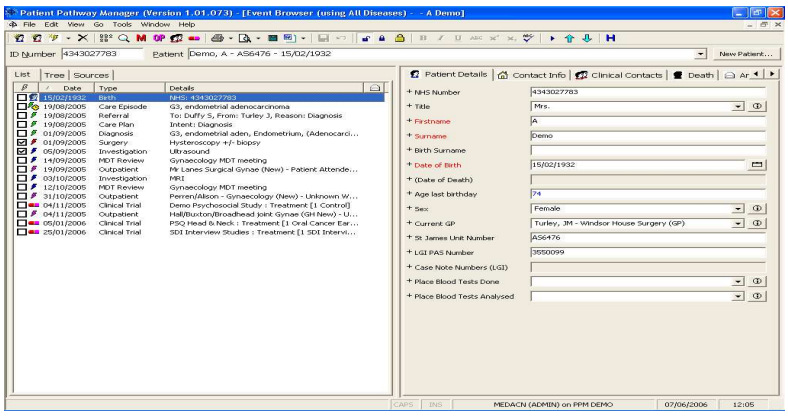
4.5.2 The Technology System Used in this Study

I was fortunate as the work led in terms of the electronic patient record, Patient Pathway Manager (PPM) by Mr Colin Johnston and Drs Geoff Hall and Michael Leahy, and in terms of the clinical trials database, led by Mr Alexander Newsham and Dr Adam Smith had reached the stage where the integrated system was

ready for use at the time I was finalising development of this study. My study was the first to use this technology which I have described briefly below.
The basis of the integrated system is the ability to use new generation on-line touchscreens to identify eligible patients and 'flag' them so that their research record, should they choose to join the study, can be linked to their clinical status. Should they choose not to participate, the system ensures that they are not approached twice. Data entered onto the touch-screen is automatically uploaded into the Trust's secure server, meeting the best possible standards for data security. If the system is used 'off-line'; as was the case for our clinics which, at the time the study was conducted, had not yet linked to PPM, synchronisation of the data took place as soon as the clinic had finished and the RA had returned to the Cancer Centre.

PPM is an integrated oncology information and data management system, built around a Microsoft SQL Server 2000 database and can be viewed and administered via a user interface application developed using Visual Basic 6. The system employs both remote desktop technology and thin client applications to deliver the application to a variety of user desktops, using a combination of MS Windows and SQL Server security technologies to manage user authentication on a secure NHS Trust network of servers. PPM integrates all the information relating to the care, treatment and management of oncology patients seen within the Trust and the user interface presents this information through a series of browsers, including a patient pathway browser, a search browser, a trial browser, clinics browser, MDT meeting browser, the combination of which allows a variety of activities to be managed and integrated through PPM. The information is presented as a 'pathway' of patient specific events which appears in a 'patient folder'; as shown in Figure 4.2.

Figure 4.2 PPM Pathway of Patient Events



Through this interface, files can be opened to view and manage consultation records, MDT decisions, therapy given, and current status. One option relates to entry into clinical trials and this links through to a trial specific database, using unique identifiers to protect anonymity so that the study related data can be exported to the University server and managed as a ‘stand alone’ Access database.

4.5.3 Capturing Patient Opinion on the Content of Questionnaires

The traditional way of using QoL measures has involved completion and scoring of a questionnaire, with a comparison to status represented by demographic factors such as age, sex or disease factors such as stage at diagnosis and therapy.

In this study we wished to gain opinions on the questionnaires. At the time the study was devised no published work was available to aid design. Scientific literature on asking questions suggests that questions should be direct and should not be biased towards a positive or a negative response.

Questions include two main dimensions, the first being that they may ask about something which has had an impact on the patient and thus is an important issue. The second relates to the way the question is written and whether the language clearly expresses the subject area and can easily be understood and answered. After discussion within our research and clinical teams, my decision was to explore these two areas individually to gain an insight into these aspects of questionnaire choice.

As already noted, we had three general, three H&N and two psychological measures in the study. A strategy needed to be considered to engage participants to answer the questions and give opinions but to maintain the data burden at an acceptable level. For the general questionnaires, it was decided to ask patients to complete the whole measure and then to grade the entire questionnaire with regard to ‘importance’ and ‘well written’. A rating scale ranging from 1= ‘not at all’ to 4= ‘very’ was used throughout the study whenever an opinion was sought. A second question was designed to allow them to express a clear preference between the three measures.

My wish was to focus on the specific domains and questions which are core to the experience of patients treated for H&N cancer and these are contained in the

H&N modules. Despite the data burden I felt that it was important to record a rating of 'importance' and 'well written' for each question.

The psychological measures were included in accord with data suggesting that this allowed the best assessment of an important dimension of patient welfare (Cull, et al, 2001). I did not include a formal rating but patients had the chance to comment as outlined in section 4.4.2.

This simple arrangement was incorporated into the touch-screen. The format of the questionnaire ratings was as shown in Figure 4.3. and as presented on the touch-screen in Figure 4.4.

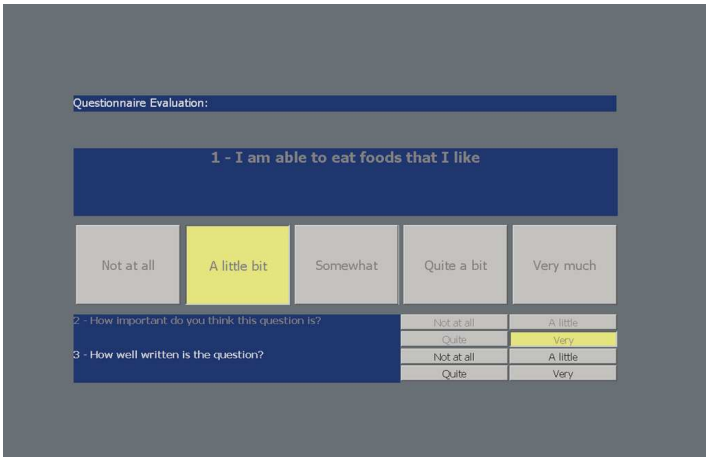
Figure 4.3 Rating a question in the H&N modules

	Not at all	**A little**	**Quite a bit**	**Very much**
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4

	Not at all	**A little**	**Quite a lot**	**Very**
26 (1) How important do you think this question is?	1	2	3	4

	Very poorly	**Poorly**	**Well**	**Very well**
26 (2) How well written is this question?	1	2	3	4

Figure 4.4 Rating a question on the touch-screen



For the study involving clinicians (reported in Chapter 8), an identical data collection was performed.

4.5.4.Interviews

Whilst direct data capture using questionnaires and the touch-screen would produce quantitative data, the core of this work lies in attempting to understand patients' and clinicians' opinions about data collection and its relevance in the clinical setting. Building on informal comments from patients and carers in the pilot study, a proforma to guide a semi-structured interview was devised (Appendix 4.9). This was designed to be administered on a one to one basis by a trained Research Assistant (RA). As I was a clinician working within the H&N MDT in Leeds, it was important that data be gathered by someone who would not be seen as directly involved in patient care and independent of the clinical team. For interviews with clinicians, I felt that the day to day working relationship would ease, rather than confound, the interaction so I personally performed all interviews with clinicians.

4.5.5 Capturing the Environment of Care

Recommendations to include QoL assessment as part of routine care can only be justified if there is gain for the patient, and ideally also the health professionals, as a result of the data made available. Consultation is the standard method of doctor/patient communication and depends on a historical model of enquiry which has evolved over the years. UK practice relies on an open dialogue model with the items raised depending on the interaction between the participants

I wished to explore both patients' and clinicians' views on the ideal and actual content of consultations. To do this, I used the questionnaire reported by Detmar et al (Detmar et al 2000) but adapted this to include issues which, from the literature, have been reported as important for H&N patients (such as 'appearance') The first set of questions covered what patients would wish to see included in consultations, recorded on a scale of 0= 'not discuss', 1= 'would discuss if the doctor raises this' and 2= 'I would wish to discuss this item'. The second set related to perceptions as to what was discussed in consultations on a Likert rating from 0= 'never' to 4= 'almost always'. The full list of questions and scoring scheme is given in Appendix 4.10.

To gain an understanding of the patient/doctor interaction, each consultation was tape recorded, with permission, and analysed thematically according to a simple

scheme (rating frequency and importance of items raised). This could then be compared with the data from questionnaires and interviews to determine how fully the issues of importance were being covered in the discussion. The interview included comments about the system of care and inevitably communication between health professionals allowing consideration as to whether more issues might have been addressed to the benefit of patients had the questionnaire data been available at consultation.

4.6 Recruitment and Patient Population

The consensus view from the literature is that, irrespective of measure used, QoL in H&N patients decreases from baseline to reach its lowest level at 3-6 months after completion of radical curative therapy and then improves back to baseline levels at about 1 year. It is reasonable to assume that the periods of greatest need and, thus the most useful time to employ a QoL assessment would be at the critical periods in the cancer journey, the acute phase (usually defined as the first 100 days), the time of relapse and the time of end of life care. We have studied the first of these in detail (Shepherd, 2002, Shepherd and Fisher, 2004) confirming the needs of patients in the acute phase. The pilot study, as a cross-sectional study, recruited patients mainly from the period shortly after treatment, with a median of 7 months, simply because it is in this period that patients have frequent appointments. However, for this definitive study, we were asking patients to complete a much more demanding and intense data collection. Discussion with the MDT and research group confirmed my belief that this level of data collection represented an inappropriate burden to a patient group recovering from therapy. A compromise was necessary in either the data-set or the patient population. I considered that the primary question was to determine whether patients endorsed a specific measure and that their experience would be sufficient to allow them to record their views and choices even if the demanding part of the cancer journey was behind them. I therefore set entry criteria of ‘at least one year after completion of primary therapy and currently disease free’.

The next patient related question was management of sub-sites, the profile of treatment related morbidity and side effects varying according to site and therapy. To attempt to obtain consensus views on the important issues, I decided to limit the study to the two most common sites ‘oral and oropharyngeal’ and ‘laryngeal’

cancer. In addition I wished to explore the opinions and preferences of patients with thyroid cancer.

In terms of stratification for presentation of results it is usual to present patient groups by disease stage; the higher the stage, the more advanced the disease at presentation. I wished to capture experience and particularly the impact of therapy. The staging system may not reflect therapeutic burden. The concept of therapeutic burden as a category for outcome analysis is new and differs from the classical analysis by stage because stage does not necessarily represent the complexity of therapy required for the cancer. A number of early stage patients fail to respond to single modality therapy and undergo the therapeutic burden of someone presenting at a later stage and others are deemed either unfit or refuse to accept multimodality management yet, despite limitation in therapy achieve a complete response. To capture this aspect of their status, I divided the population into 'early' and 'late' cancer, the decision being made on treatment modality(ies) as shown in Figure 4.5.

Figure 4.5 Defining the Study Population

	Early (single modality)	***Late (Multimodality)***
Oral	EO	LO
Larynx	EL	LL
Thyroid	Thy	

The result of this reasoning was that we had five study sub-groups: 'early oral' (EO), 'late oral' (LO), 'early larynx' (EL), 'late larynx' (LL) and thyroid. To determine sample size we made a number of assumptions, using the experience of previous work in this field by the research group.

Measurement of preference as a primary end-point is a new field. The most pertinent work to consider in devising a statistical method is that of Velikova et al (1999b) who compared preferences with regard to paper or touch screen completion of questionnaires. They used 'a priori' agreed criteria for acceptable levels of acceptance and preference. In this study we have chosen a method using a four point Likert scale in order to be able to assess the preference scale as ordinal data, in the same way as the QoL scores.

To assess choice of questionnaire, we planned to consider the stated preference for a given questionnaire over the others using a confidence level analysis. It was

considered that a questionnaire would be defined as the preferred one if it had been given the highest score by 40% of patients who expressed a preference. Given, this ‘a priori’ level we could determine a sample size for the total group. To detect a proportion of at least 61% with a 95% confidence interval [CI] of 10%, a sample size of 100 patients would be required. If such a response was not achieved, it was decided that a decision of ‘no preference’ would be taken. To assess the clinicians’ ratings frequency analysis of results was planned, accepting a majority opinion but taking account of all areas identified as important in the whole group (core response) and for sub-groups (site specific response).

If we consider the comparison of scores to calculate sample size, then an accepted level of difference between the group scores gives us the basis for the calculation. Each questionnaire was scored by the standard method and by rating, giving us sets of ordinal data for comparison at whole group and subgroup level. As the primary endpoint is the patient preference and rating of importance, assuming a difference of between two groups, such as ‘early’ and ‘late’ of 0.5 points on the rating of a questions within a questionnaire or domain (such as the EORTC-QLQ C30) and that the standard deviation of the means is (approximately) 20. Then the standardised difference (d) between the means of the two groups is 0.75 (mean1- mean2/ st. dev. 15/20).

Sample size can be calculated from this equation:

delta = d * sqrt(N/2)

In order to achieve a power of .80 and an alpha of 0.05, we need a delta of 2.7 (Howell, 1999).

Rearranging the equation, we can derive N (Sample size for each group) i.e.

N = 2 * (delta/d)squared, which in this case gives us around 26 for each group. To allow for incomplete completion we decided to attempt to recruit 30 patients to each subgroup.

We planned to assess patients’ and clinicians’ preferences by calculating the proportion stating a preference for a single instrument in each category, core, H&N and psychological and the proportion in each of the preference categories, as well as those stating no preference. Comparison to determine whether particular questionnaires were preferred by a definable subgroup of patients, used a one way analysis of variance ANOVA for analysis of multiple factors (sub-groups) and the independent t-test, with equal variances not assumed, for

comparisons between two groups using categoric variables (H&N vThy, Early v Late, Oral v Larynx, Stage I&II v III&IV, Gender) (Bland, 1986).

Patients' ratings were assessed using the scales indicated, treating them as ordinal data, in the same way as the QoL scores. At individual question level, the 'a priori' setting was the inclusion of any question rated as 'very important' by at least 5% of patients or 'quite important' by 30%. The phrasing was considered secondarily, the preferred style being used in the wording of the question for any proposed tool. All questions rated as 'very' or 'quite' important by clinicians would be analysed to determine whether they form part of a 'core' assessment across H&N cancer sites or whether they relate to assessment of a subgroup of patients. Their place in any candidate measure was to be decided by consensus clinical opinion.

Agreement between ratings at test and retest can be determined by determining the proportions of exact and global agreement and weighted kappa coefficients. Exact agreement refers to the number of patients giving the same response, considered in terms of each option; status, importance and phrasing. Global agreement is defined as one category either side of the original choice. The percentage agreement depends on the number of response categories. Although for 'importance' and 'phrasing', this number is consistent, for questionnaire scores it is not. Kappa is a coefficient of agreement that is corrected for chance agreement (Fleiss,1986; Armitage and Berry, 1995). For ordinal data, questionnaire and 'importance' and 'phrasing' scores, weighted kappa is calculated by giving different weights to disagreements according to the discrepancy. Values of kappa range from 0-1, with 0 indicating an agreement consistent with chance alone and 1 indicating perfect agreement. Interpretation of variables between 0 and 1, will follow the guidelines set out by Landis and Koch (1977): ≤0.2, poor agreement; 0.21 to 0.40, fair agreement; 0.41 to 0.60 moderate agreement and 0.81 to 1.00 very good agreement. The kappa coefficient was calculated for the QoL scores, the 'importance' scores and the 'phrasing' scores.

To ensure test/retest reproducibility, we aimed to gain two responses from a sample of 10% of the participant population.

Given the exploratory nature of this study and the complexity of the data-set, I accepted that we may well achieve 'soft' rather than 'hard' and statistically proven results and that we may well not reach the levels of difference in patient or

clinician opinions to justify the level of analysis described. Should this prove to be the case, simple measures such as frequency analysis, were considered to be valid in gaining understanding of patient and clinician opinions in a new field of scientific exploration.

4.7 Data Handling and Verification

From the design above, I designed a series of clinical report forms to gain information on the demographics of potential and actual participants (Appendix 4.11). The questionnaires were offered using the touch-screen, beginning with the modified consultation questionnaires, leading on to the three general questionnaires which were delivered in random order, then the three head and neck specific questionnaires and finally the psychological measures. Each question was manually typed onto the system together with the relevant scores.

The electronic system automatically uploaded responses to a central server. This included the allocation of a unique identifier to allow us to link the clinical trials database to the clinical records. As a member of the clinical team, I was able to confirm the details through PPM so that we could link technical data, such as staging, to the responses, maintaining the study base as a ‘stand alone’, anonymised dataset.

To attempt to gain an understanding of the reproducibility of responses, we attempted to link test/retest data on the subset of patients who underwent two interventions.

4.8 Data Analysis

Data analysis was planned to answer the primary questions and to allow understanding of the study population. depending on the level of differences seen in the responses and whether we met our ‘a priori’ requirements.

4.8.1 Demographic Analysis

This included the gender, age, site and stage of disease, therapy given and time from completion of therapy. The aim was to allow reporting by sub-group; i.e.

therapeutic burden but to also allow other potentially significant areas to be explored. The demographics of the sample are reported in Chapter 5.

4.8.2 Preferences and Perception of Consultation Content

This was analysed according to the scoring scheme as below and is reported in Chapter 6. Comparisons were made between groups and sub-groups as to what patients would wish to have covered in a consultation and what they felt was less important. A second set of questions explored what they considered actually took place in a consultation..

To set the findings in context, a simple analysis of the consultations was done, considering the number of issues raised and, across the groups, the frequency with which each was raised and how problematic that area seemed to be We also recorded the **consultation**, allowing direct comparison between interview data and the content of the consultation, to determine whether patient priorities were identified and addressed and where there might be omissions which the use of a standardised questionnaire might help address. To determine the characteristics of the doctor/patient interaction, a note was made of who introduced that item for discussion.

To determine severity, we rated responses on a simple scheme:

1 = mentioned

2 = mentioned as a problem

3 = mentioned as a priority requiring advice or action.

4.8.3 Questionnaire Analysis

Questionnaire analysis included the quality of life scores and preference rating for each questionnaire. Although direct comparisons across questionnaires is not possible, comparison between patient groups could be performed, looking at the areas highlighted for each sub-group in each questionnaire. Scoring for the questionnaires was done in accordance with User manuals. as described in section 4.3.1. Scoring for ‘importance’ and ‘well written’ was common to each questionnaire and so allowed comparisons both within study sub-groups and between measures. For this to take place a mean score was derived for each

general questionnaire and for each individual item in the H&N measures. These were compared by total study group and sub-groups.

This was supplemented by analysis of the **semi-structured interview** by the number of items raised and the priority which each item was accorded on a simple scale following the method used for the analysis of content of consultations. Patients were invited to comment on questionnaires, individual questions which were considered particularly good or poor and on issues which were particularly important to them :These results are reported in Chapter 6.

I analysed the recording of each interview and consultation. To check inter-rater reliability a subset (10% of the sample) was analysed by two researchers, myself and one of the research assistants (RAs) who administered the questionnaires and the results were compared. To check test/retest reliability, I re-analysed and re-scored the same subset of interviews, leaving a minimum period of 1 month between assessments.

A similar approach was taken to the **clinician** responses, however, this was extended to allow a more detailed analysis and all interviews were transcribed. These interviews were analysed by myself, again considering items and their importance, extending the scheme above.

4.9 Governance and Peer-Review

The study design was discussed within the research team and the multi-disciplinary cancer team. All suggestions were considered and the design refined to that presented above. All clinicians agreed that they were happy for their patients to participate.

For external peer review, the study was submitted to the National Cancer Research Institute Local Studies Group and was approved for entry into the national portfolio in the Head & Neck Cancer site section, in August 2005.

Ethics approval was granted by the Leeds West Research Ethics Committee on 29th April 2005 (Ref: Leeds West REC 05/1205/26*).*

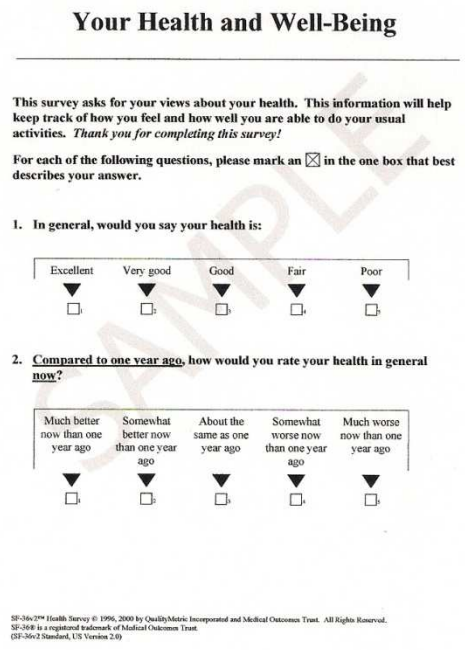
Funding was required to provide salaries for Research Assistants (RAs). This was initially funded by the Head and Neck Oncology Research Fund of the Leeds Teaching Hospitals NHS Trust. Funding to cover purchase of touch-screen computers and digital recorders was granted by the British Association of Oral &

Maxillofacial Surgeons. Completion of recruitment was made possible by two successful peer-reviewed applications for research support; the first to the Charitable Trustees of the Leeds Teaching Hospitals NHS Trust and the second to the British Association of Oral & Maxillofacial Surgeons.

Once the first funding had been confirmed, arrangements to conduct the study within the multi-disciplinary and specialist clinics based in the Leeds Teaching Hospital NHS Trust could be made. Practical aspects of conducting the study and the basic demographics which underpin the descriptions of the individual studies will be reported in the next chapter.

Appendices: Questionnaires

4.1: SF-36 v2



Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

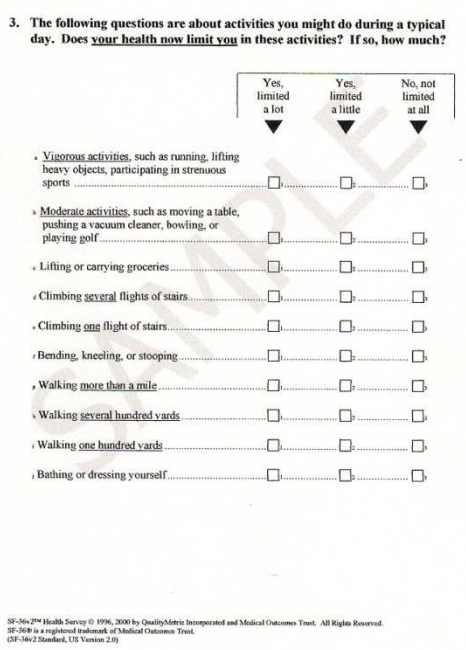
For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

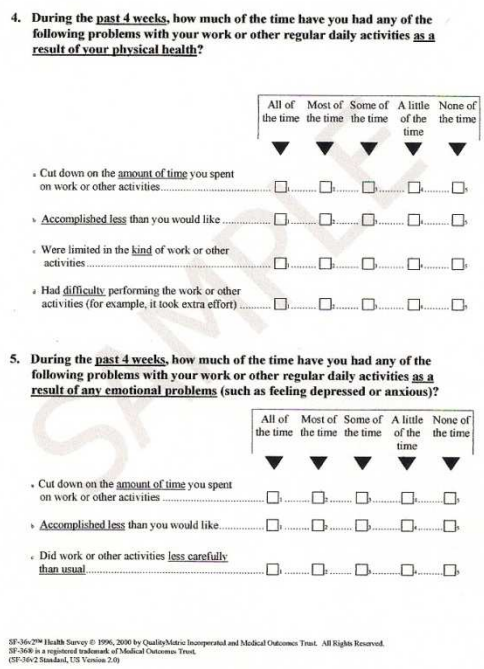
2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐1	☐2	☐3	☐4	☐5



3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing several flights of stairs	☐1	☐2	☐3
e. Climbing one flight of stairs	☐1	☐2	☐3
f. Bending, kneeling, or stooping	☐1	☐2	☐3
g. Walking more than a mile	☐1	☐2	☐3
h. Walking several hundred yards	☐1	☐2	☐3
i. Walking one hundred yards	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

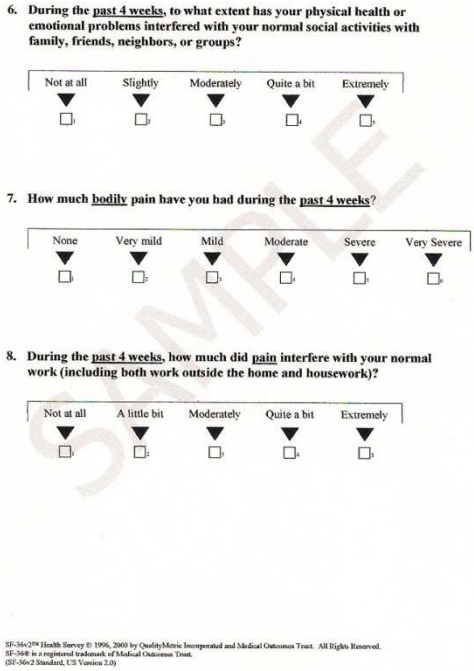


4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the kind of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	☐1	☐2	☐3	☐4	☐5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities less carefully than usual	☐1	☐2	☐3	☐4	☐5



6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

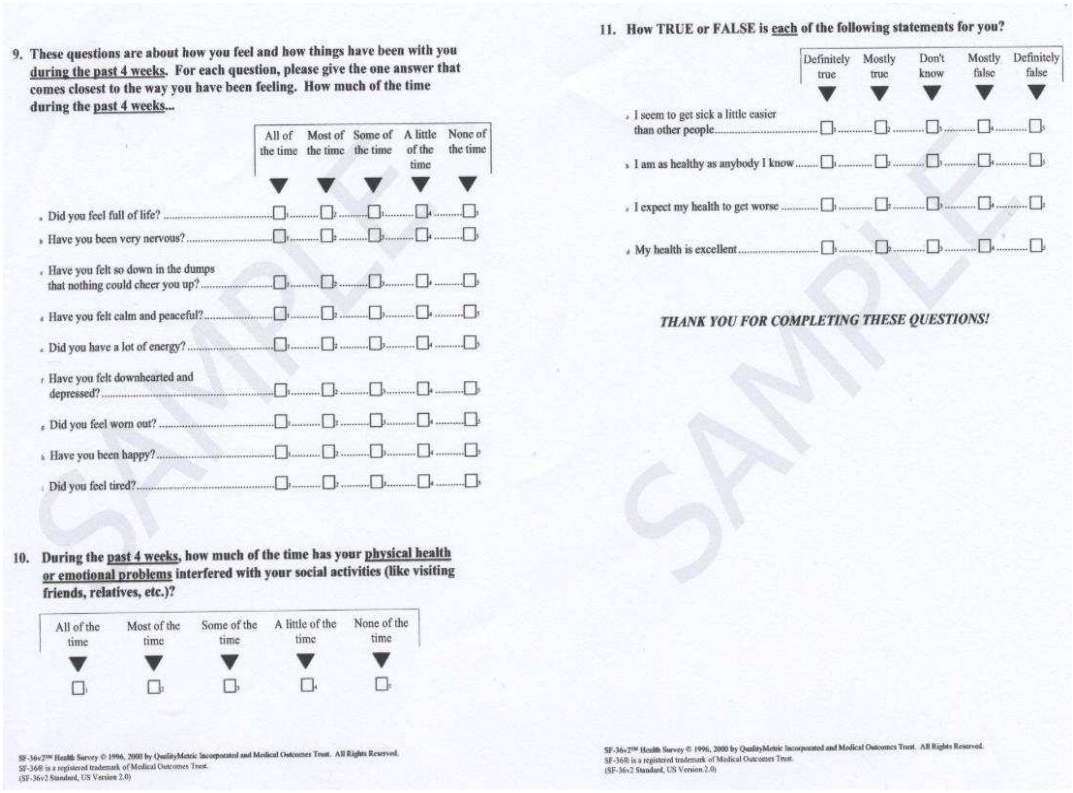
Not at all	Slightly	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very Severe
☐1	☐2	☐3	☐4	☐5	☐6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5



9. **These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt downhearted and depressed?	1	2	3	4	5
g. Did you feel worn out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

10. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

11. **How TRUE or FALSE is each of the following statements for you?**

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

THANK YOU FOR COMPLETING THESE QUESTIONS!

4.2: EORTC QLQ C30

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:
Your birthdate (Day, Month, Year):
Today's date (Day, Month, Year):

	Not at all	A little	Quite a bit	Very much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing,washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A little	Quite a bit	Very much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past	Not at all	A little	Quite a bit	Very much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on like reading a newspaper or watching	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering	1	2	3	4
26. Has your physical condition or medical interfered with your family life?	1	2	3	4
27. Has your physical condition or medical interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 best applies to

29. How would you rate your overall health during the past

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past

1	2	3	4	5	6	7
Very poor						Excellent

4.3 FACT-G

FACT-H&N (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-G (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

4.4: EORTC H&N 35

EORTC QLQ-H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	Not at all	A little	Quite a bit	Very much
1. Have you had pain in your mouth?	1	2	3	4
2. Have you had pain in your jaw?	1	2	3	4
3. Have you had soreness in your mouth?	1	2	3	4
4. Have you had a painful throat?	1	2	3	4
5. Have you had problems swallowing liquids?	1	2	3	4
6. Have you had problems swallowing pureed food?	1	2	3	4
7. Have you had problems swallowing solid food?	1	2	3	4
8. Have you choked when swallowing?	1	2	3	4
9. Have you had problems with your teeth?	1	2	3	4
10. Have you had problems opening your mouth wide?	1	2	3	4
11. Have you had a dry mouth?	1	2	3	4
12. Have you had sticky saliva?	1	2	3	4
13. Have you had problems with your sense of smell?	1	2	3	4
14. Have you had problems with your sense of taste?	1	2	3	4
15. Have you coughed?	1	2	3	4
16. Have you been hoarse?	1	2	3	4
17. Have you felt ill?	1	2	3	4
18. Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:	Not at all	A little	Quite a bit	Very much
19. Have you had trouble eating?	1	2	3	4
20. Have you had trouble eating in front of your family?	1	2	3	4
21. Have you had trouble eating in front of other people?	1	2	3	4
22. Have you had trouble enjoying your meals?	1	2	3	4
23. Have you had trouble talking to other people?	1	2	3	4
24. Have you had trouble talking on the telephone?	1	2	3	4
25. Have you had trouble having social contact with your family?	1	2	3	4
26. Have you had trouble having social contact with friends?	1	2	3	4
27. Have you had trouble going out in public?	1	2	3	4
28. Have you had trouble having physical contact with family or friends?	1	2	3	4
29. Have you felt less interest in sex?	1	2	3	4
30. Have you felt less sexual enjoyment?	1	2	3	4

During the past week:	No	Yes
31. Have you used pain-killers?	1	2
32. Have you taken any nutritional supplements (excluding vitamins)?	1	2
33. Have you used a feeding tube?	1	2
34. Have you lost weight?	1	2
35. Have you gained weight?	1	2

4.5: FACT H&N

FACT-H&N (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
H&N 1	I am able to eat the foods that I like	0	1	2	3	4
H&N 2	My mouth is dry	0	1	2	3	4
H&N 3	I have trouble breathing	0	1	2	3	4
H&N 4	My voice has its usual quality and strength	0	1	2	3	4
H&N 5	I am able to eat as much food as I want	0	1	2	3	4
H&N 6	I am unhappy with how my face and neck look	0	1	2	3	4
H&N 7	I can swallow naturally and easily	0	1	2	3	4
H&N 8	I smoke cigarettes or other tobacco products	0	1	2	3	4
H&N 9	I drink alcohol (e.g. beer, wine, etc.)	0	1	2	3	4
H&N 10	I am able to communicate with others	0	1	2	3	4
H&N 11	I can eat solid foods	0	1	2	3	4
H&N 12	I have pain in my mouth, throat or neck	0	1	2	3	4

4.6: UWQoLv4

Name: _____
Date: _____

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.
- ☐ There is mild pain not needing medication.
- ☐ I have moderate pain - requires regular medication (e.g. paracetamol).
- ☐ I have severe pain controlled only by prescription medicine (e.g. morphine).
- ☐ I have severe pain, not controlled by medication.

2. **Appearance**. (Tick one box: ☑)

- ☐ There is no change in my appearance.
- ☐ The change in my appearance is minor.
- ☐ My appearance bothers me but I remain active.
- ☐ I feel significantly disfigured and limit my activities due to my appearance.
- ☐ I cannot be with people due to my appearance.

3. **Activity**. (Tick one box: ☑)

- ☐ I am as active as I have ever been.
- ☐ There are times when I can't keep up my old pace, but not often.
- ☐ I am often tired and have slowed down my activities although I still get out.
- ☐ I don't go out because I don't have the strength.
- ☐ I am usually in bed or chair and don't leave home.

4. **Recreation**. (Tick one box: ☑)

- ☐ There are no limitations to recreation at home or away from home.
- ☐ There are a few things I can't do but I still get out and enjoy life.
- ☐ There are many times when I wish I could get out more, but I'm not up to it.
- ☐ There are severe limitations to what I can do, mostly I stay at home and watch TV.
- ☐ I can't do anything enjoyable.

5. **Swallowing**. (Tick one box: ☑)

- ☐ I can swallow as well as ever.
- ☐ I cannot swallow certain solid foods.
- ☐ I can only swallow liquid food.
- ☐ I cannot swallow because it "goes down the wrong way" and chokes me.

6. **Chewing**. (Tick one box: ☑)

- ☐ I can chew as well as ever.
- ☐ I can eat soft solids but cannot chew some foods.
- ☐ I cannot even chew soft solids.

 v. 4

7. **Speech**. (Check one box: ☑)

My speech is the same as always.
I have difficulty saying some words but I can be understood over the phone.
Only my family and friends can understand me.
I cannot be understood.

8. **Shoulder**. (Check one box: ☑)

I have no problem with my shoulder.
My shoulder is stiff but it has not affected my activity or strength.
Pain or weakness in my shoulder has caused me to change my work / hobbies.
I cannot work or do my hobbies due to problems with my shoulder.

9. **Taste**. (Check one box: ☑)

I can taste food normally.
I can taste most foods normally.
I can taste some foods.
I cannot taste any foods.

10. **Saliva**. (Check one box: ☑)

My saliva is of normal consistency.
I have less saliva than normal, but it is enough.
I have too little saliva.
I have no saliva.

11. **Mood**. (Check one box: ☑)

My mood is excellent and unaffected by my cancer.
My mood is generally good and only occasionally affected by my cancer.
I am neither in a good mood nor depressed about my cancer.
I am somewhat depressed about my cancer.
I am extremely depressed about my cancer.

12. **Anxiety**. (Check one box: ☑)

I am not anxious about my cancer.
I am a little anxious about my cancer.
I am anxious about my cancer.
I am very anxious about my cancer.

Which issues have been the most important to you during the past 7 days?
Check ☑ up to 3 boxes.

Pain	Swallowing	Taste
Appearance	Chewing	Saliva
Activity	Speech	Mood
Recreation	Shoulder	Anxiety

Other (please describe what it is).....

GENERAL QUESTIONS

Compared to the month before you developed cancer, how would you rate your health-related quality of life? (check one box: ☑)

Much better
Somewhat better
About the same
Somewhat worse
Much worse

In general, would you say your **health-related quality of life** during the past 7 days has been: (check one box: ☑)

Outstanding
Very good
Good
Fair
Poor
Very poor

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** during the past 7 days. (check one box: ☑)

Outstanding
Very good
Good
Fair
Poor
Very poor

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).

4.7: HADS HAD Scale

Name:

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

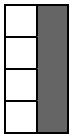
This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

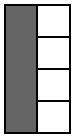
I feel tense or 'wound up':

Most of the time……
A lot of the time……
Time to time, Occasionally……
Not at all……..



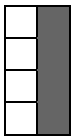
I still enjoy the things I used to enjoy:

Definitely as much……
Not quite so much…….
Only a little……
Hardly at all……



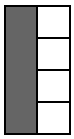
I get a sort of frightened feeling as if Something awful is about to happen:

Very definitely and quite badly…….
Yes, but not too badly……
A little, but it doesn't worry me……
Not at all……



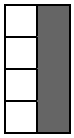
I can laugh and see the funny side of things:

As much as I always could……
Not quite so much now……
Definitely not so much now…….
Not at all……



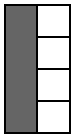
Worrying thought go through my mind:

A great deal of the time…….
A lot of the time……
From time to time but not too often..
Only occasionally……..



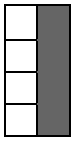
I feel cheerful:

Not at all……
Not often……
Not often……
Most of the time……



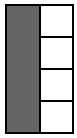
I can sit and feel relaxed:

Definitely……
Usually……..
Not often……
Not at all……



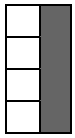
I feel as if I am slowed down:

Nearly all the time……
Very often……
Sometimes……
Not at all…….



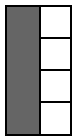
I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all…….
Occasionally……
Quite often……..
Very often……



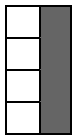
I have lost interest in my appearance:

Definitely……
I don't take as much care as I should.
I may not take quite as much care…..
I take just as much care as ever……..



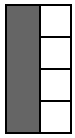
I feel restless as if I have to be on the move:

Very much indeed……..
Quite a lot……
Not very much……
Hardly at all……



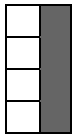
I look forward with enjoyment to things:

As much as I ever did…….
Rather less than I used to……
Definitely less than I used to……..
Hardly at all……



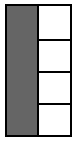
I get sudden feelings of panic:

Very often indeed……
Quite often……..
Not very often……
Not at all……..



I can enjoy a good book or radio or TV programme:

Often……
Sometimes……
Not often…….
Very seldom……..



4.8: MHI 5

MHI-5 UK Version

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Have you felt downhearted and low?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6

4.9 Interview Schedule

Recruitment structured interview

Note identification details on tape, then proceed through items as listed:

General Questionnaires: EORTC QLQ 30, FACT-G, SF36

1. Did you have a clear preference for one or particular questionnaires?

Yes/No

If yes: explore reasons: the way the questions were phrased, the holistic approach to the patients' experience of cancer, the way a particular question related to their current state, (go to 2) other.

2. Where there any particular questions you felt were particularly important for you? Yes/No

If yes, explore and note which ones and why.

Head & Neck Questionnaires: EORTC H&N, FACT-H&N, UWQoL

1. Did you have a clear preference for one or particular questionnaires? Yes/No
If yes: explore reasons: the way the questions were phrased, the holistic approach to the patients' experience of cancer, the way a particular question related to their current state, (go to 2) other.

2. Where there any particular questions you felt were particularly important for you? Yes/No
If yes, explore and note which ones and why.

Psychological Questionnaires: HAD, MHI 5

Did you consider that these questions helped you indicate how you are feeling?
Yes/No.
If yes, did you prefer one questionnaire? HADS/ MHI 5 / no preference

General points:

Is there anything which was not covered by the questionnaire that you think we should know to help the doctors/other team members to help you? :

Note any issues raised:

Are there any comments you would like to make about this study?

Date of appointment for follow up questionnaire:

Follow up structured interview

Before questionnaire:

Has anything changed since your last questionnaire in terms of problems related to your cancer, or your life in general?
Yes/No

If yes, note change and willingness to continue, if no, check willingness to continue.

After completion:

1. Did you have a clear preference for one or particular questionnaires?
Yes/No

If yes: explore reasons: the way the questions were phrased, the holistic approach to the patients' experience of cancer, the way a particular question related to their current state (go to 2), other.

2. Where there any particular questions you felt were particularly important for you? Yes/No

If yes, explore and note which ones and why and note.

Recheck answers at first interview and note and explore any changes in preference.

Is there anything which was not covered by the questionnaire that you think we should know to help the doctors/other team members to help you?

Note any issues raised:

Are there any comments you would like to make about this study?

Appendix 4.10

Quality of Life Assessment in Individual Head & Neck Patients

Baseline patients' preferences for communication and attitude to QOL issues

Doctor-patient communication is at the centre of good clinical practice and is receiving increasing attention in clinical training. We are interested in which topics you feel you should discuss with your patient during outpatient appointments.

Please tick the appropriate box below.

Would you discuss with your doctor during the clinic appointments:

	Rather not	***Yes, provided the doctor mentions it first***	***Yes, I would like to discuss this topic***
Physical symptoms of illness or side effects of treatment (e.g. pain, sickness, cough, tiredness)?	☐	☐	☐
Limitations in physical activities (walking, climbing stairs, general fitness)	☐	☐	☐
Limitations in physical activities specific to their disease (eating, speech, swallow, shoulder function)	☐	☐	☐
How they feel emotionally (nervous, anxious, depressed) as a consequence of their illness or treatment	☐	☐	☐
The impact of illness or treatment on their work, housework, leisure activities?	☐	☐	☐
The impact on their social activities (visiting friends, neighbours, clubs)?	☐	☐	☐
The impact of illness and treatment on relationships with their partner or family?	☐	☐	☐
The impact of illness or treatment on their appearance?	☐	☐	☐

Generally, how often do you discuss these issues with your doctor during clinic consultations?

	Never	Rarely	Sometimes	Often	Almost always
Overall health	☐	☐	☐	☐	☐
Symptoms of disease or side effects of treatment	☐	☐	☐	☐	☐
Limitations in physical activities as a results of disease / treatment (walking, climbing stairs)	☐	☐	☐	☐	☐
Limitations in physical activities specific to their disease (eating, speech, swallow, shoulder function)	☐	☐	☐	☐	☐
Limitation in doing work / housework or leisure activities	☐	☐	☐	☐	☐
Emotional distress	☐	☐	☐	☐	☐
Impact of disease on relationships with family/partner	☐	☐	☐	☐	☐
Impact of disease on social activities (visiting friends, neighbours)	☐	☐	☐	☐	☐
The impact of disease on appearance?	☐	☐	☐	☐	☐

Appendix 4.11

Recruitment to Study

Clinic: **Date:**

Hospital number (or identifier):

Sex: **Date of Birth:**

Consultant(s): **Speciality(ies):**

Ethnic Origin: British (white)/ British (other)/ European / Asian (Indian)/ Asian (Chinese)/ Afrocaribbean/ Other.

Marital status: married; living with partner/ other close family / living alone

Occupation: employed: yes / no. If yes: manual / non-manual.
change since diagnosis: yes /no.

Study group for which eligible:
early larynx / late larynx / early oral / late oral / thyroid

TNM: clinical:……./ na. **pathological:**……./ na. (na=not applicable)

Treatment: surgery / radiotherapy / combined [surgery + RT] / chemotherapy / brachytherapy (note all that apply)
Date treatment completed:

Agreed to take part: yes / no

If **no**, please note reason given

If **yes**: all questionnaires completed yes/no

interview completed yes/no

consultation taped yes/no

annotation requested yes/no

copy of letter requested yes/no

Date of second study (if possible note contact details in case date changes)

CHAPTER 5 - Practical Aspects of Study Management and Recruitment

5.1 Managing the Study

5.1.1 Appointment, Training and Governance of Staff

The need for the patient interviews to be performed by someone independent of the clinical team required appointment of suitably trained research assistants. I prepared a job description which was duly approved by Human Resources, the key elements being:

- Experience of working with patients, ideally with vulnerable patients.
- Experience of data collection and management.
- Experience of working with Microsoft Office and basic IT skills.

During the study, we had the services of two Research Assistants (RAs); the first held a Master's Degree in Psychology and she supported the study for the first period of recruitment (November 2005 – November 2006). The second had experience in clinical Oral & Maxillofacial Surgery and some research experience. He was Asian by ethnicity. One of our aims was to try to include ethnic minorities, an aim we hoped he might facilitate. In fact, the pattern of recruitment and characteristics of participants who entered remained constant between the two periods.

On appointment, given the direct contact with patients, a full CRB check had to be completed and, as well as a contract with the University, evidence supplied to support the granting of a Hon Contract as a Clinical Research Assistant by the Trust. Training was given to the staff according to the Standard Operating Procedures of the Cancer Research UK Psychosocial Oncology and Clinical Practice Research Group (POGCPRG), based at the University of Leeds. I undertook Induction to the study, data collection and entry together with practice in 'dummy' study entries to ensure compliance with the Clinical Report Forms and consistency in data collection. Practical experience in recruiting patients to studies was kindly provided by members of the POGCPRG, by allowing the RAs to observe their studies. During the second period of recruitment, the Good Clinical Practice guidelines (GCP) had been introduced. Both I and the second RA completed GCP training.

5.1.2 The Clinical Environment:

The study was based in the Head and Neck (H&N) Oncology team. This allowed recruitment through a number of clinics: the multidisciplinary head and neck clinic (MDC), based initially at the Cookridge Hospital and latterly at the Institute of Oncology, St James's University Hospital, the Maxillofacial Out-Patient Clinics based at the Leeds Dental Institute, the Ear, Nose and Throat (ENT) Clinics, based at the Leeds General Infirmary and the Thyroid Clinic which had some presence in the ENT clinic and also a medical oncology clinic based initially at the Cookridge Hospital and latterly at the Institute of Oncology. Recruitment opportunities were available for much of the working week.

Figure 5.1: Clinics from which participants could be recruited.

Day/Time	Monday	Tuesday	Wednesday	Thursday	Friday
Morning	MDC St. James's		Max-fac LDI	ENT 'valve' clinic	Max-fac LDI
Afternoon	Thyroid St. James's	ENT LGI		Max-fac LDI	

Key to recruitment by study group:
MDC: All H&N groups (EO, LO, EL & LL),Thyroid: Thyroid patients only.ENT: EL & LL and occasional thyroid. Max-fac: EO & LO
Note: Access to the 'valve' clinic was only possible in the second study period.

5.1.3 The Process of Recruitment

Information sheets (Appendix 5.1) were placed in all clinics and renewed as necessary. Clinic staff from all disciplines were briefed about the study.

On a weekly basis I opened and searched the clinical database to pre-screen for potentially eligible participants by disease site and stage. PPM allows a 'watch' system which can flag individuals and generate a trial episode.. For patients attending clinics where the records were still paper based we created a small number of 'slots' which allowed details to be entered manually and later synchronised with the main server. In practice this worked well for most cases, although the system was not able to be activated for 7 potential entrants (from 159). Ours was the first study to use the PPM clinical trials system and these failures occurred in the early period, each problem being rectified as the system was refined.

In clinic, the RA sought an introduction and provided the participant with an information sheet. Basic details (Appendix 5.2) were collected from those who agreed and further discussion or study entry arranged according to the wishes and convenience of the participant. In practice, people were keen to enter the study. In accord with our ethics approval, we were not allowed to formally record reasons for refusal to enter or withdrawal but the main reasons offered informally were lack of time and use of hospital transport requiring a return to the central waiting area.

Once a patient had agreed to enter, the consent form (Appendix 5.3) was completed and arrangements made for the interview and questionnaire completion. Much discussion had been held on whether the intervention should take place before or after the consultation. In practice, we needed to accommodate the participants, most of whom were keen to use the ‘waiting time; for the study. The clinics were relatively flexible in timing and usually running late, so participants simply completed the study and then had their consultation. When more practical, the consultation took place before the intervention.

The interview was conducted in a quiet room to provide privacy and a lack of distractions. Data was entered directly into the touch-screen computer.

Figure 5.2: Collection of data in the ‘quiet room’

Participants could break off the intervention at any stage. In practice, this was very unusual and of 144 datasets, 138 held a complete set of General and H&N questionnaire responses (reduced to 135 when psychological questionnaires were also considered, however these were not formally analysed in terms of opinion and preferences). The usual reason for interruption was the arrival of

hospital transport, although in one case, a participant's young child became restless so the intervention was terminated.

The touch-screen was configured to guide the participant through the intervention offering the questionnaires in random order automatically as shown in the following figures.

Figure 5.3 Using the Touch-screen: the welcome screen

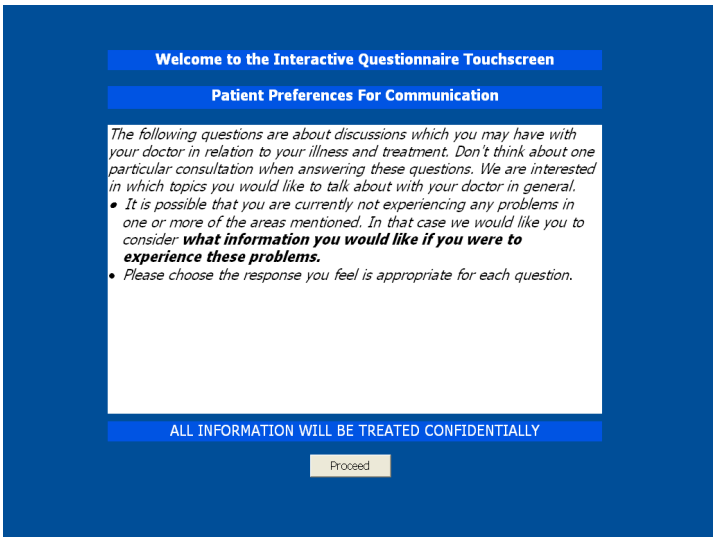


Figure 5.4 Using the Touch-screen: answering a question

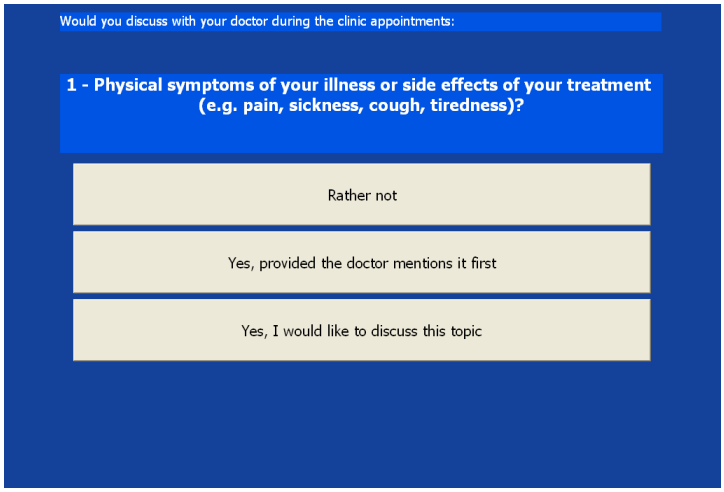
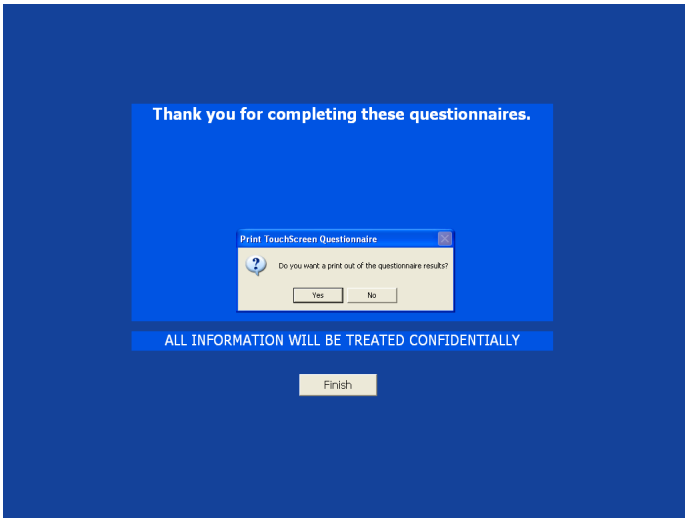


Figure 5.5 Using the Touch-screen: completion of intervention



At the conclusion of the interview data could either be saved to the touch-screen computer or, if a link to the Trust server was available, immediately uploaded into the central server. This approach was used whenever possible and was carried out for all participants who held a PPM clinical record and hence an electronic 'identity'; the only exceptions being the 'new' patients whose study identity had been created manually and offline. For these, synchronisation with the server was undertaken as quickly as was practically possible, The advantage of this approach was that sensitive data was not held on the laptop computer.

5.1.4 Day to Day Governance

Recruitment was monitored by means of an 'Excel' spreadsheet which linked to a graph showing target and actual figures. In the early stages, recruitment was rapid in line with target. After around six months, the number began to reduce. The reasons for this were explored. The usual follow up pattern for H&N cancer is of frequent appointments in the first three years after definitive therapy and less frequent ones thereafter. The ratio of eligible to already recruited patients was gradually decreasing, and we had increasingly to ensure that we identified patients returning for a longer term review and those reaching their first anniversary of their therapy and becoming eligible to join the study.

Recruitment was also monitored against sub-group and we perceived that two groups, early larynx (EL) and late larynx (LL) were progressing very slowly. I

explored the reasons for this with clinical colleagues. One problem was that in the ENT clinics there was a concentration of oncology surgical review patients on the third Tuesday of each month. Given the time required for the study intervention, recruitment of two patients per clinic was the maximum likely to be achieved. This was in contrast to the Maxillofacial clinics where oncology reviews were held in every clinic and the available population was therefore much greater. Although there was only one thyroid clinic per week, patients appeared very keen to join the study and this group achieved the highest recruitment figures but also had the highest refusal rate, usually due to time constraints..

We attempted to address the imbalance by preferentially approaching ENT patients at the MDC. During the second period of recruitment a new 'valve' clinic opened on Thursday mornings and arrangements were made to attend this clinic. Despite these measures, recruitment of ENT patients remained a challenge throughout the study

5.1.5 Test/Retest

The plan was to achieve this in 10% of the population. Practical limitations included the frequency of follow up appointments. H&N patients had frequent appointments but thyroid patients often attended only once per year and arranging two interventions proved extremely difficult in this group.

5.1.6 Closure of Intervention

Participants were thanked at the end of their intervention and permission sought to approach them again. In practice this was done opportunistically, when new patients (especially ENT patients), were not available for approach.

5.2 Recruitment

Recruitment took place over two periods, November 2005 – November 2006 and December 2007 – September 2008. The reason for the gap was the need firstly, to obtain external funding for a Research Assistant to conduct the interviews and secondly the period required to gain the necessary contracts (academic and

honorary), permissions (CRB check) and to ensure that the Research Assistant had been given full training to undertake the task.

Over the period of recruitment, 243 patient records were entered into the clinical trials management system (PPM Clinical Trials Database). Of these, 220 were approached at their clinic appointment and considered study entry. At completion of the study all hard copy consent and demographic forms were checked to ensure reconciliation with the questionnaire data. 152 patients consented to undertake the intervention and 'hard copy' clinical report forms, were completed. This represents a lower level of recruitment than is usually achieved in interview studies and I believe this was due to fully informing all eligible people about the length of the intervention. The high level of completion once entry had been agreed would support that view. Full 'hard copy' and electronic study records were retrieved for 144 patients. For 8 participants questionnaire data was not available via the server although hard copy records indicated that it had been collected (2 LO, 2 EL and 4 Thy).

We planned follow up interventions on 10% of the total sample and these were carried out for 22 participants. 10 full electronic records for test/retest could be retrieved automatically from the database but all patients were identified by manual checking. PPM had assigned new entry 'slots' to the remainder, although the unique identifiers were repeated and allowed manual linking of the anonymised records.

Data handling was made manageable through the ability to export study data directly as an 'Access' database to a University desk top computer and eliminating any need for manual data entry. PPM had applied its automatically generated identifiers using a binary numerical system so, to analyse by group and sub-groups, I simply needed to add our own study identifiers which were by study group and sequential entry study numbers. I exported the data into an 'Excel' spreadsheet and added a column to allow analysis according to study group, using our own identifiers by sub-group. Data was sorted by study group, basic demographics by questionnaire and by intervention. Once data had been fully verified it was entered into a SPSS v15 database for analysis.

5.2.1 Demographics of Study Population:

5.2.1.1 Comparison of Participants v Non-Participants:

The entry status is as shown in Tables 5.1-5.3. Slightly more males were approached than females (52.9% compared to 46.6%).

Table 5.1 Entry to study by number and percentage (all groups)

	Frequency	Valid Percent	Cumulative Percent
Refused	61	27.7	27.7
Entered	159	72.3	100.0
Total	220	100.0	

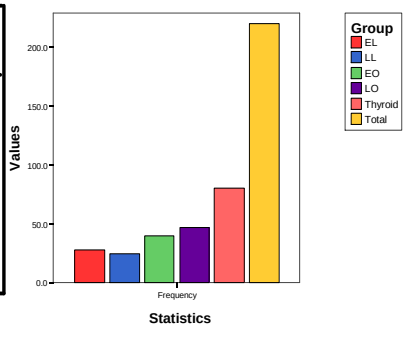
Table 5.2 Entry to study by gender (all groups)

	Frequency	Valid Percent	Cumulative Percent
Males	117	53.2	53.2
Females	103	46.8	100.0
Total	220	100.0	

In terms of eligible subjects per group, the highest availability was for oral cancer representing 39.3% of the study population and divided into late oral (21.3%) and early oral (18.1%). Thyroid patients represented 36.2% of the population approached. It proved more difficult to approach laryngeal patients who represented 24% of the population approached, divided into early (12.7%) and late (11.3%) subgroups.

Table 5.3 Entry to study by Sub-Group

	Frequency	Valid Percent	Cumulative Percent
EL	28	12.7	12.7
LL	25	11.4	24.1
EO	40	18.2	42.3
LO	47	21.4	63.6
Thyroid	80	36.4	100.0
Total	220	100.0	



Translating those who were approached and who spoke to the RAs about the study to actual entrants the figures are 144 from 220 (65.5%) for the whole study

group and 101 out of 140 (72.1%) for the H&N sites. Figures for each sub-group were EL 17 out of 28 (60.7%), LL 15 out of 25 (60.0%), EO 33 out of 40 (82.5%), LO 36 out of 47 (76.6%) and Thy (53.8%).

Table 5.4 Entry to study by sub-group, age and gender

Age

Group	Gender	Mean Age	N	Std. Deviation	Minimum	Maximum
EL	Males	67.00	21	10.488	50	89
	Females	58.43	7	11.872	34	69
	Total	64.86	28	11.273	34	89
LL	Males	66.67	18	8.616	49	79
	Females	65.86	7	9.599	54	76
	Total	66.44	25	8.704	49	79
EO	Males	67.09	23	13.853	42	96
	Females	66.53	17	13.766	40	85
	Total	66.85	40	13.641	40	96
LO	Males	57.50	36	9.776	40	81
	Females	73.91	11	7.803	62	86
	Total	61.34	47	11.631	40	86
Thy	Males	58.11	19	13.068	28	73
	Females	47.67	61	14.348	20	79
	Total	50.15	80	14.670	20	79
Total	Males	62.60	117	11.959	28	96
	Females	55.55	103	16.490	20	86
	Total	59.30	220	14.657	20	96

Comparisons between those who chose to enter and those who did not were similar for gender, age and stage of disease by total group and by sub-groups. Considering the eligible study population by age, this was as expected for the H&N population with values lying mainly in the 6th and 7th decade. Age is shown in Figure 5.4, by mean, standard deviation and range, for the whole group and also by gender. It is worthy of note that the youngest H&N patients to be considered for entry to the study were 40 years of age and the oldest 96 years of age, compared to 20 and 79 for thyroid. Considering the data in terms of the population over 80 entered into the DAHNO database (Chapter 2) representation of older patients was welcome, as this group is often excluded from studies. Data was further explored using an ANOVA, showing that thyroid patients were significantly younger than the H&N groups. This difference is apparent for all H&N groups and Table 5.5 also confirms that there were no significant differences between the different H&N subgroups with respect to age.

Table 5.5 Comparison of thyroid v H&N subgroups by age.

Dependent Variable: Age
Bonferroni

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
EL	LL	-1.58	3.370	1.000	-11.14	7.98
	EO	-1.99	3.018	1.000	-10.55	6.57
	LO	3.52	2.924	1.000	-4.78	11.81
	Thy	14.71*	2.689	<0.0001	7.08	22.34
LL	EL	1.58	3.370	1.000	-7.98	11.14
	EO	-.41	3.122	1.000	-9.27	8.45
	LO	5.10	3.031	.940	-3.50	13.70
	Thy	16.29*	2.806	<0.0001	8.33	24.25
EO	EL	1.99	3.018	1.000	-6.57	10.55
	LL	.41	3.122	1.000	-8.45	9.27
	LO	5.51	2.634	.377	-1.96	12.98
	Thy	16.70*	2.371	<0.0001	9.97	23.43
LO	EL	-3.52	2.924	1.000	-11.81	4.78
	LL	-5.10	3.031	.940	-13.70	3.50
	EO	-5.51	2.634	.377	-12.98	1.96
	Thy	11.19*	2.251	<0.0001	4.81	17.58
Thy	EL	-14.71*	2.689	<0.0001	-22.34	-7.08
	LL	-16.29*	2.806	<0.0001	-24.25	-8.33
	EO	-16.70*	2.371	<0.0001	-23.43	-9.97
	LO	-11.19*	2.251	<0.0001	-17.58	-4.81

Based on observed means.

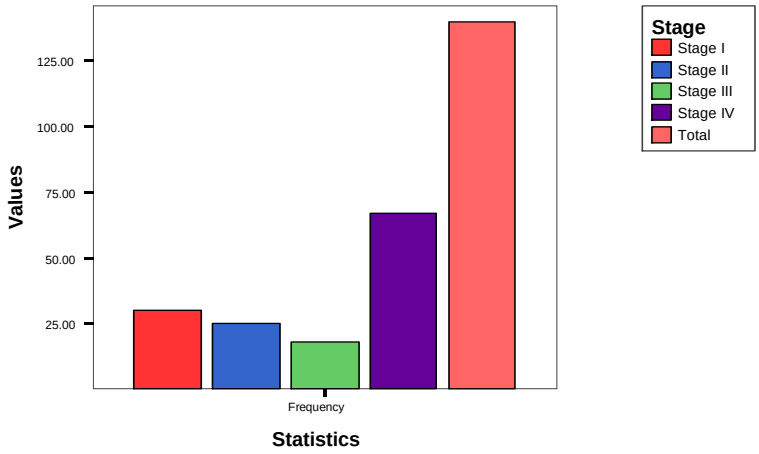
*. The mean difference is significant at the .05 level.

My final exploration of data in relation to entry relates to my use of ‘early’ and ‘late’ based on therapeutic burden rather than the conventional comparator of stage. Stage at presentation is shown in 5.6a, numerically and in 5.6b, graphically, confirming that the highest frequency was presentation with Stage IV disease (47.9%) a figure which corresponds to the literature for this cancer, where the frequency of late presentation is well recognised.

Table 5.6.a. Numerical table of entry by Stage

	Frequency	Percent	Valid Percent	Cumulative Percent
Stage I	30	13.6	21.4	21.4
Stage II	25	11.4	17.9	39.3
Stage III	18	8.2	12.9	52.1
Stage IV	67	30.5	47.9	100.0
Total	140	63.6	100.0	

Table 5.6.b. Stage by recruitment presented graphically.



The key question was whether I was looking at the same population using the 'early' 'late' burden of therapy rating as would have been the case had I used stage. To explore this we compared the two groups by category. Figures 5.7a and 5.7b show the comparisons for the whole H&N study population and by sub-group. To aid the comparison, we grouped Stages I and II as early, and Stages III and IV as late. This approach is commonly used in the H&N cancer literature.

Table 5.7 Comparing 'early'/'late' by therapeutic burden to stage I/II and III/IV.

5.7 a All H&N Patients.

	'Early'	'Late'	Total
Stage I/II	37	4	41
Stage III/IV	13	47	60
Total	50	51	101

5.7b Sub-group comparison.

	Stage I/II	Stage III/IV
EL	14	3
LL	2	13
EO	23	10
LO	2	34

It has to be accepted that the concept of therapeutic burden is new and in practice represents a continuum ranging from narrow field radiotherapy to the larynx, through radical radiotherapy to larynx and neck to addition of chemotherapy. As the 'cut off' for 'late' in the larynx group was laryngectomy it must be accepted that there is heterogeneity in the 'early' group. Nevertheless, given the number of patients who were assigned to different categories using 'therapeutic burden' rather than stage, it was considered appropriate to continue to explore therapeutic burden for comparison to the more traditional analysis by stage. The use of this parameter is supported by the fact that the largest number of transitions from 'early' to 'late' occurred in the oral group where, because the radiotherapy fields are much more standardised and chemotherapy is less often used, the 'cut offs' between the 'early' and 'late' categories are more clearly defined.

In the analysis of the definitive study the therapeutic burden was represented by 'early' v 'late' and stage by comparing Stage I&II with Stage III&IV.

5.2.1.2 Lifestyle and Return to Work in Head and Neck Cancer Patients

To gain an understanding of the impact of cancer on participants' lives and to give some background and context to later comments on issues and concerns, we asked for basic information on work (Appendix 5.2). Interest in this area is growing as more people survive cancer therapy and the financial challenge of both therapy and life beyond a cancer diagnosis becomes clear (Macmillan Cancer Support 2007). Peteet (2000) describes return to work as an important transition in the pathway from patient to survivor at individual level and at population level Cancer Research UK (CRUK, 2007) figures predict an increase in the prevalence of cancer amongst the working population. Although these

studies do not relate to H&N or thyroid cancer as distinct entities, it can be expected that the advances in therapy which have had an impact on other sites will become effective at this cancer site in coming years.

Data collected included whether the patient had been in work at the time of diagnosis, whether they were still in work and whether their working status had changed as a result of their cancer. Given the age profile of this population, it is not surprising that the majority of entrants (79 from a total of 140 H&N records) described themselves as beyond working age

61 patients were working at diagnosis and 43 remained in work at the time of the study, however 18 had or had chosen to change employment. A summary of working status for the H&N cancer patients is provided in Table 5.8 and the experience of return to work by subgroup, which proved to be very varied depending on whether the patient had 'early' or 'late' status and is therefore described in detail below.

Table 5.8 Return to work by subgroup, H&N cancer patients

Total group=61 responses

Group	Gender	Employment Status			
		Diagnosis	Working	Same	Changed
EL	Male	9	4	3	1
	Female	1	0	0	0
LL	Male	8	5	1	4
	Female	3	0	0	0
EO	Male	11	10	7	3
	Female	5	4	4	0
LO	Male	23	19	10	9
	Female	1	1	0	1
Total		**61**	**43**	**25**	**18**

Key: EL= 'early' larynx, LL= 'late' larynx, EO= 'early' oral, LO= 'late' oral

Early larynx (EL): 10 patients (9 males, 1 female)

Of the **9 males,** 4 were in paid work at diagnosis. A HGV driver, builder and salesman reported no change in occupation, however a car restorer did report a

change in occupation but did not indicate whether this was related to his cancer. Of those who had been in work, 1 patient was unemployed (unchanged) and 2 on incapacity benefits (unchanged), for the 2 remaining patients, no occupation had been entered. For the one female, no occupation was noted.

Late larynx (LL): 11 patients (8 males, 3 females).

Of the **8 males,** 5 were in paid work at diagnosis. Only one, a successful local politician, is known to have remained in his previous employment. One patient reported the change to highways inspector was due to his previous business entering receivership, an event he did not associate with his cancer. A bakery worker took early retirement as he could not cope with the dust and the current working status of a courier driver is uncertain. The final patient in this group reported a positive outcome from his cancer. He has come out of retirement in his 70s to teach skills in communication with cancer patients to medical students and Allied Health Professionals (AHPs). I patient was unemployed (status unchanged). For 2 male patients no details were entered; however, one of these had had multiple primary cancers and the other reported with a second primary cancer shortly after completing the study and died a few months later. It would seem unlikely that either of these patients were able to undertake work.

None of the **3 females** were in paid employment at diagnosis. One was and remained a housewife, the other two were and remained unemployed. One noted that she felt very discriminated against when she applied for work and that her laryngectomy prevented her applying for posts which met her previous skills in telemarketing.

Early oral (EO): 16 patients (11 males, 5 females)

Of the **11 males:** 10 were in paid employment at the time of diagnosis, and of these 7 reported continued employment in the same job. Work ranged from self-employed businessmen (2), civil service, TV presenter and broadcaster to haulier, engineering fitter and warehouseman. The remaining three whose current status is uncertain included a printer, warehouseman and a washing machine repairer. Only in one instance is a cancer related loss of job with subsequent continued unemployment noted.

Of the **5 females:** 4 were in paid employment, as a manager (2 patients), a property developer and a dental nurse. All continued in their previous work. The remaining patient was and remained a housewife.

Late oral (LO): 24 patients (23 males, 1 female).

Of the **23 males:** 19 were in paid employment at diagnosis.10 of whom continued in their previous employment (an accountant, engineers [4 patients], a manager, a postman a lorry driver, a welder and one man who did not state his occupation). One patient chose to train as a teacher and, although his previous employment is not noted, this may well represent choice; a further patient notes a change to agency work but not a reason for this. Outcomes are not noted for 2 patients, a gardener and a security officer. Of the remainder a Carer in a Residential Home had to cease work because of PEG feeding and continued severe morbidity; a medical physics technician struggled to return to work and achieved this transiently after prolonged absence but then developed paroxysmal atrial fibrillation and had to stop. Three patients reported losing their jobs (one manual worker and the other two occupation unknown) specifically as a result of their cancer and its treatment. The four who were not in paid employment at diagnosis were unemployed (2) or on incapacity benefit (2).

There was only **1 female** who reported work at diagnosis although she did not enter its nature. She changed her occupation to carer as a result of her cancer.

5.2.1.3 Lifestyle and Return to Work in Thyroid Patients

The thyroid patients present a different profile and experience of work. From 80 participants, only 18 described themselves as retired. In this group, there is a higher proportion of females patients to males. Table 5.9 summarises their responses.

Table 5.9 Working status of thyroid cancer patients

Gender	**Work Status**				
	Diagnosis	Working	Same	Changed	Unknown
Male	12	9	7	1	1
Female	50	28	17	6	5
Total	62	37	26	7	6

Total group=62 responses

62 (50 female, 12 male) described themselves as 'working age'. Of the female patients, 28 were working. 17 in their previous employment, 6 had changed roles and for 5 the outcome was not noted. 14 patients were housewives, 4 were students. 1 was incapacitated, I unemployed and 2 had missing data. Of the 12 males, 7 remained in their previous role, 1 had changed jobs and for 1 no outcome was noted. 1 was a family carer and 2 unemployed. When their experience of living with cancer was explored in a semi-structured interview, the value of work was acknowledged and the main limiting factors were reported to be fatigue. This was worst after radio-iodine and often delayed return to work.

5.3 Discussion

The practical elements of identifying, approaching and recruiting patients, on the whole, worked well and the availability of the electronic record was critically important in terms of the number of subjects who were approached and the number who entered the study. Attempting to complete this task using manual records would have proved impossible, emphasising the value of modern IT for comparative studies of patient experience and opinion using multiple measures. Inevitably we experienced some problems and in this first part of the discussion I will consider the technical aspects of data entry.

There was a mismatch between the number of hard copy records and the electronic records. A number of electronic records were identified by study number and anonymised unique PPM number only. I manually cross checked against the date of recruitment to the study and was able to reconcile the data in all but 8 cases. This study was the first to use the PPM database which evolved throughout our period of recruitment. It was designed to work seamlessly with the oncology records, however, most patients were accrued through the surgical clinics which were not using the electronic database. The most likely explanation for the loss of data would appear to be errors during uploading and synchronising remotely acquired data with the central server.

The allocation of a unique automatically generated identifier, rather than one generated through the study, meant that study numbers which had meaning in terms of group and sub-group analysis had to be manually entered. This feature has now been added to PPM. Participant numbers were allocated in binary system numbering; i.e. 1, 10, 101, rather than by consecutive numerals and again, this required manual cross checking and validation as our numbering was

by ordinal progression, included entry number and sub-group and included participants only rather than all people approached. As the first patient recorded and numbered using PPM declined to enter, this was a considerable task, requiring new study related identifiers being manually applied to the whole dataset.

Given the size of the study and the complexity of the database, the PPM clinical trials system was critically important to study management. However the need to carefully validate, check and cross-check the data rather than relying on PPM Access queries alone became apparent as the analysis progressed. This was an important learning point as we move towards automated collection and presentation of data in clinical practice. Where a patient's NHS record lies within the PPM system on a day to day basis, it is almost certain that the system will capture and link a second study entry. We knew from our hard copy, that 22 participants had completed test /retest, however PPM only identified 10 directly. It is likely that the duplicate records arose with uploads from locations remote from the PPM system, entered as new patients at the source of data collection and subsequently processed as such. Manual cross checking using recruitment date, gender and date of birth allowed me to identify the test/retest subjects.

Although this represented a substantial workload, at completion the data had been fully validated and was offered through the 'Access' database and the 'Excel' database to which I copied it for ease of editing, in a way which facilitated the analysis of each further episode.

In terms of the practical conduct of the study, a core requirement for successful recruitment was that participation would not cause inconvenience to either the participants or the clinical teams. We, therefore, had to take a pragmatic attitude to the timing of the interview and consultation. In practice most interviews took place prior to consultation, the potential bias associated with this approach being that patients may well be prompted to raise items for discussion which might otherwise have been omitted. The result of this would be that consultations might appear more effective at capturing issues than would otherwise be the case. This aspect of the study is addressed in detail in Chapter 6, page 128.

We had been concerned about the burden of data collection, and indeed this was the only substantial issue raised by peer-reviewers and the ethics committee. The choice of questionnaires had been carefully addressed and, to 'anchor' the study to a medical event, the consultation, I considered that a baseline measure of

opinion and perceived content of consultations was essential information. The added value of the psychological measures has already been discussed. I reduced the 'importance' and 'well written' questions to inclusion only in the H&N questionnaires, where specific questions reflected different issues. I also compromised on patient status. It would have been most interesting to interview those at active stages in their cancer journey but I elected to ask people who had reached a stable stage to enter the study as my priority was to achieve as full a dataset as possible and to make informed choices about the value of questionnaire assessment. To ensure the dataset was acceptable, we carefully monitored the first ten and then the next ten subjects for completion and whether they considered the intervention unduly burdensome. This aspect continued to be monitored monthly as the study progressed and did not prove to be a problem, as indicated by the high rate of completion of the full dataset. Factors which contributed to this success are most likely to be the availability and support of a trained RA throughout the intervention, the use of the touch-screen which was simple and quick to complete and the enthusiasm and support of the clinical team and the participants themselves.

The imbalance between the number of entrants to each study group remained a challenge throughout the period of the study. ENT patients (EL, LL) proved very difficult to accrue. Entry figures (EL 60.7% and LL 60%) are lower than for the oral sites (EO 82.5% and LO 76.8%). As we were not able to request reasons for non-participation, I can only suggest explanations. The availability of clinics did reduce the chances to make contact with this group but sufficient contact was achieved to achieve higher figures than those seen. I briefed colleagues from all clinics and the ENT Consultants and Nurses did all possible to ensure the study was introduced and patients given a chance to enter. This study is not alone in facing challenges with this group and likely explanations are problems in communication and perhaps low self-esteem and problems in adjustment. This would be supported by the results of the return to work data where LL patients fared especially badly. A further challenge to recruitment which is also recognised more widely in the literature is participation by ethnic minorities. We only achieved two entries from this group, one Asian male and one Philippino woman. One hope had been that the appointment of an Asian male as a RA might have facilitated ethnic inclusiveness but this was not the case.

The group achieving the lowest translation through from approach to entry (53.8%) was thyroid cancer. Again the data on age and work status may provide an explanation as well as the follow up practice for this cancer site. For the H&N sites, hospital appointments take place at frequent intervals and, if entry was inconvenient at one visit, rescheduling was comparatively easy and, at the next visit, participants were prepared for the time required for the study and could plan accordingly. Thyroid patients attend at infrequent intervals, often 6 to 12 monthly, so recruitment had to more 'opportunistic' accepting those patients who were willing to spend additional time at the hospital on that day. Consultations in the thyroid clinic tended to be briefer and more straightforward and delays were unusual. Many potential entrants were accustomed to this and also often had work or family duties to return to, making recruitment least successful in percentage terms through this group, although a level of entry beyond the target was easily achieved.

The one significant finding in relation to demographics was that thyroid patients were significantly younger than each of the other H&N groups. Given this, and their different disease experience, I shall consider them separately in each of the following sections, although I will relate their scores to those of the H&N groups to allow understanding of where their views are similar and where they differ.

The most controversial area in this section is my use of 'early' and 'late' based on therapeutic burden, not on stage at presentation. I have been sceptical of the use of stage at presentation for some time, knowing that some Stage I/II patients undergo extensive therapy after relapse whilst others with Stage III/IV disease respond unexpectedly well to single modality management. In QoL studies, I believe it to be essential to capture therapeutic burden and my study gives the chance to explore this concept further.

My final comments relate to the data on return to work. I wished to gain some insight into the status of the participants in terms of their day to day lives. Strategies to achieve this have included measurement of educational status, postcode and social deprivation and questionnaire assessments. Given the data burden of the whole study, I wished to use a measure which could be quickly and simply completed for as many potential participants as possible. Return to important aspects of 'normal' life has been a frequent discussion in my years of clinical practice and return to work has been many patient's measure of their success. It has limitations in terms of the age profile of the population and also

incomplete data as completion of this item was entirely voluntary, however, it has provided a useful insight in an area where there has been no previous published work specific to this cancer site. In a more general cancer population Amir et al (2008) have examined UK cancer survivors' views of work three years post diagnosis, looking at a sample of 225 patients, resulting in interviews with 41 participants. The reasons for attrition of the sample were the same as those in my small sample, the need to confine the interview to those who were of working age, had been working at the time of diagnosis and willing to offer details about their employment status. The importance of work was emphasised in the interviews and pre-treatment 35 of the 41 participants continued to work until treatment commenced and 33 returned to work at varying times after completion of therapy. Important aspects were finance and the therapeutic benefit of keeping busy, social support from colleagues and resuming their pre-cancer life. The attitudes of and relationships with work colleagues and managers were important and return was often easier for those who had been in the same employment for some years; i.e. return to the same or a similar post. Sadly the study identified a lack of information or advice from healthcare professionals on this aspect of survivorship, an area which I will consider further as I report the experience of patients in consultations in Chapter 6.

My small study reports very different experiences by stage and site of H&N cancer and for those patients with thyroid cancer. For the H&N groups the results indicated that patients diagnosed with early stage disease and requiring single modality therapy had a good chance of returning to their previous employment, this being the case for 3 out of 4 early larynx patients and 11 out of 14 early oral patients who were in paid employment at diagnosis. In these groups only one patient reported loss of employment which he thought was related to his cancer diagnosis. There is a marked contrast between early and late stage disease. The work experience of late larynx patients is particularly poor with two notable exceptions. Approximately 50% of the late oral patients in this study returned to work in their previous post. Although the figures represent a small number of patients and therefore limit the conclusions which can be drawn, the difficulties faced by 'late', i.e. multimodality therapy patients, are striking and indicate that exploration of work and finance is an important aspect of any future assessment.

5.4 Summary

In this chapter we have considered the practical conduct of the study and the characteristics of the study population has been described. The concept of ‘early’ and ‘late’ based on therapeutic burden has been considered. Subsequent chapters will consider specific aspects, commencing with a consideration of consultations as the core of the interaction between patients and the health professionals who provide their cancer care.

Appendices:

5.1: Information Sheet

Development of a Patient Specific Questionnaire for Use in a Head & Neck Clinic

You are being invited to take part in a research study to help us determine whether or not a questionnaire can be developed to help in the care of patients in a head & neck clinic. Before you decide it is important for you to understand why the research is being done and what it will involve. Ask if you are uncertain about anything or if you feel uncertain. There is a leaflet called 'Medical Research and You' and we shall be happy to provide a copy if you wish to have one.

The study we are doing follows on from the one we did recently in this clinic. In that first study we used a single questionnaire to see if it either helped patients in consultations or raised new issues that might be helped by a member of the multi-disciplinary team. In that study, 30 out of 147 patients had new issues explored and a considerable majority of patients supported the continued use of a questionnaire in the clinic. The problem was that the doctors and other clinicians had to look through the full questionnaire and, in a busy clinic setting, that is difficult to achieve. We wish to explore whether we can adjust the way the questionnaire is completed to see if we can make it specific to the needs of individuals.

Our next stage is to ask people attending the clinic for follow up to help us look at the main questionnaires used in the assessment of people attending head & neck clinics and to tell us their opinion of them. This involves answering questions on a touch screen and having a short interview. The investigation will take about 30 minutes and to check that we get similar responses, we need you to repeat the study in 3 to 4 months. We record your clinic consultation to see whether the same areas are covered and study a copy of the letter the clinic doctor sends to your own doctor for the same reason.

If you wish to take part, please let either myself or the nurse researcher know. If you prefer not to, we understand and your treatment will not be affected in any way.

This study forms part of a development programme for a patient specific questionnaire and results will form part of my doctoral thesis.

If you have any questions, please do not hesitate to ask us.

Yours faithfully,

Sheila E. Fisher, MSc, FDS, FRCS.
Senior Lecturer in Oral & Maxillofacial Surgery,
University of Leeds

Aine M. Donnelly MSc,
Research Assistant, Psychosocial Oncology and Clinical Practice Research Group,
University of Leeds.

Chapter 6 - Preferences and Perceptions of the Content of Consultations

The medical consultation lies at the core of the patient / professional interaction and, for the purposes of this study, an understanding of how both participants in this interaction, patients and clinicians, perceive it provides core material. The components of a consultation can be considered according to the WHO definition (1948) as physical, mental and social well-being and one could define a 'gold standard' consultation as one in which each of these is considered.

The **aims** of this chapter are to capture the opinions of patients in terms of what they would wish to have included in a consultation, to determine what they consider is discussed in consultations and to follow this through using a series of examples from routine consultations which were taped as part of this study and comments made by patients to the RAs about their main areas of concern in terms of their current status.

The literature indicates that physicians tend to focus in discussing medical and technical issues and emotional issues were usually raised by patients (Dimoska et al, 2008, Fagerlind H et al, 2008). When patients initiated such discussions, this was often terminated without further exploration (Pollak et al, 2007). These descriptions of modern cancer practice do not accord with the aspirations of the Cancer Plan or the more recent Cancer Reform Strategy (Chapter 1, Section 1.2) or the needs of the patients as captured in the narratives (Chapter 1, Section 1.1). There have been no studies of communication in the highly complex H&N environment of care and this lack of evidence led to including an analysis of consultation as part of this thesis. To consider my primary hypothesis that **'carefully designed and structured questionnaires can be used to improve the quality of life of H&N cancer patients'** it is essential to first understand patients' aspirations and their perception of reality and to measure the reality of H&N medical consultations.

This chapter reports the views of patients on what they would wish to see as part of a medical consultation and what they believe is included in a consultation together with comments made during their interviews. These aspects of the study are covered in the consultation content analysis derived from Detmar et al (2000) (see Chapter 4. Section 4.5.5). We followed the delivery of care through the

content of consultations by exploring the level of communication through the number of items raised, who raised them and how important they appeared to be. To gain an understanding of the dynamics of consultation and the place a future questionnaire might play, a note was made of whether patients or doctors initiated discussion of specific areas.

6.1 The Questionnaire Study: patient responses

To determine patients' views on medical consultations a questionnaire was adapted from Detmar et al (2000) (Appendix 6.1). The first group of questions related to wishes with regard to the content of consultations and the second covered a similar range of areas but considered whether patients felt that these were included in consultations. The question lists each began with a general question then items relating to physical matters both general and disease specific and symptoms and side effects arising from therapy. The next area to be addressed was emotional impact and emotional distress followed by social impacts on relationships and activities which form part of normal life. To this list, I added an item on appearance in view of its relevance to H&N cancer.

For the first set of questions the responses were:

0 = 'I would not wish to discuss this item'

1= 'I would like to discuss this item if the doctor raises it'

2= 'I would like to discuss this item'

For the second set of questions the patients used a Likert scale to rate how frequently they considered the area was discussed in consultations in a range from 0= 'never' through to 5= 'almost always'. The questionnaires were presented using the touch-screen system which automatically uploaded responses to a central server for analysis. This part of the study preceded the standard quality of life questionnaires. A parallel initiative, reporting clinicians' views, was carried out and is reported in Chapter 8.

To ensure that the range of experience and treatment related effects were included in the sample, I divided the participants into treatment groups as described in Chapter 4, Section 4.6 (Early Larynx [EL], Late Larynx [LL], Early Oral [EO], Late Oral [LO] and Thyroid [Thy]. To explore test /retest reliability a subgroup of patients completed the intervention twice.

6.1.1 Results

Full records were achieved for 144 participants (33 EO, 36 LO, 17 EL, 15 LL and 43 Thy). 22 patients achieved 2 interventions (7 EO, 9 LO, 3 EL, 2 LL and 1 Thy). The results for the whole group were as presented in Table 6.1.

Figure 6.1: Patients' wishes for consultations
Total group= 144 responses

Item	0	1	2
Physical symptoms & side effects of illness	5 (3.5%)	32 (22.2%)	107 (74.3%)
General physical activities	9 (6.3%)	38 (26.4%)	97 (67.4%)
Physical activities specific to illness (e.g. speech)	8 (5.6%)	21 (14.6%)	115 (79.9%)
How you feel emotionally	17 (11.8%)	38 (26.4%)	89 (61.8%)
Impact of illness or treatment on work & leisure	18 (12.5%)	44 (30.6%)	82 (56.9%)
Impact of illness or treatment on social activities	29 (20.1%)	51 (35.4%)	64 (44.4%)
Impact of illness or treatment on relationships	25 (17.4%)	45 (31.3%)	74 (51.4%)
Impact of illness or treatment on appearance	24 (16.7%)	34 (23.6%)	86 (59.7%)

Key 0= I would not wish to discuss this item: 1 = I would like to discuss this item if the doctor wishes it: 2 = I would like to discuss this item.

In general, patients most wanted to discuss 'physical activities affected by treatment', a category which includes key areas such as speech, swallowing and eating, with their doctors. This was closely followed by 'symptoms and side effects of treatment'.

Figure 6.2: Patients' perceived content of a medical consultation
Total group= 144 responses

Item	0	1	2	3	4
Overall health	12 (8.3%)	17 (11.8%)	45 (31.0%)	31 (21.4%)	39 (26.9%)
Symptoms of disease or treatment (e.g. pain, sickness, fatigue)	14 (9.7%)	19 (13.2%)	35 (24.3%)	38 (26.4%)	38 (26.4%)
General physical limitations as a result of disease or treatment	49 (34.0%)	26 (18.1%)	27 (18.8%)	15 (10.4%)	27 (18.8%)
Physical limitations specific to disease and treatment (e.g. speech)	21 (14.6%)	20 (13.9%)	35 (24.3%)	34 (23.6%)	34 (23.6%)
Emotional distress	49 (34.0%)	41 (28.5%)	28 (19.4%)	12 (8.3%)	14 (9.7%)
Impact of illness or treatment on work & leisure	65 (45.1%)	36 (25.0%)	27 (18.8%)	7 (4.9%)	9 (6.3%)
Impact of illness or treatment on relationships	60 (41.7%)	39 (27.1%)	30 (20.8%)	6 (4.2%)	9 (6.3%)
Impact of illness or treatment on appearance	60 (41.7%)	38 (26.2%)	24 (16.6%)	9 (6.3%)	9 (6.3%)

Key 0 = Never; 1 = Seldom; 2 = Sometimes; 3 = Often; 4 = Almost always

These matched the patients' views on what was perceived most likely to be discussed (Table 6.2), although 24% of patients indicated that symptoms and side effects were 'never' or 'rarely' mentioned and 29% considered this was also true for physical limitations due to the disease or its treatment.

Once the questions moved beyond 'hard' clinical evaluations, the gap between aspiration and reality became more marked. Although 61.8% of patients indicated a wish to discuss how they felt emotionally, this was perceived to be addressed 'almost always' or 'often' in only 11.2% of consultations. Patients endorsed a wish to discuss the impact of their disease on aspects of their daily living at a lower level and these aspects of living with a cancer diagnosis were unlikely to be raised in the consultation.

Patients rated a discussion about the impact of their disease on their appearance highly with 59.7% wishing to raise it, yet in only 12.6% of consultations was this issue 'almost always' or 'often' addressed.

Sub-group responses were explored using an ANOVA to analyse the results from the five sub-groups. Because the sub-groups represent small populations with numbers ranging from 15 to 43, the potential for spurious significant results was addressed by using the Bonferroni adjustment, thus setting a more stringent alpha level for each comparison. To ensure that the results were robust, the level for statistical significance was set at $p=0.01$, rather than the $p=0.05$ level usually adopted for population studies. To explore the data we looked at aspects of patient status which might impact on their experience of cancer and thus, their results. The sub-groups represent two aspects of H&N cancer, site and therapeutic burden. The latter was defined as the requirement for single modality therapy (early) or the requirement for multimodality therapy (late). To avoid omitting findings of importance because this classification derives from two aspects of disease I explored the data looking specifically at site (oral v larynx) and therapeutic burden (early v late) separately. In my study there were sufficient such patients to achieve statistical significance between these two groups, justifying considering them as separate categories in the analysis (Chapter 5, Section 5.2.1).

To explore the likelihood that thyroid patients would represent a different population with different experiences and priorities an analysis was performed of Thyroid v H&N cancer patients. Gender is another factor which might be expected to influence the outcome. Exploratory analyses indicated a difference in

results when all groups were included compared to analysis of H&N cancer patients alone. This appeared to be due to the presence of a large enough number of thyroid patients of relatively high status in terms of QoL to skew the analysis. For this reason, all group gender analysis and H&N patient gender analysis was performed. The final category which we felt might impact on the results was age. On exploring the data, this did not emerge as a factor and was not considered further.

The descriptive statistics for the whole study group and sub-groups are shown in Table 6.3 A and Table 6.3 B.

Table 6.3 A. Preferences for Content of Consultations by Group and Sub-group

Study Group	Number of subjects	Physical Sympt-oms Side Effects	Limitation in physical activity	Limitation in physical activity specific to disease	How you feel emotio-nally	Impact on work, house, leisure	Impact on family, partner & social	Impact on appear-ance
All Mean (SD)	144	1.79 (0.53)	1.60 (0.61)	1.75 (0.55)	1.50 (0.70)	1.44 (0.72)	1.24 (0.766)	1.33 (0.77)
EL Mean (SD)	17	1.47 (0.62)	1.47 (0.80)	!.71 (0.69)	1.47 (0.80)	1.29 (0.85)	0.94 (0.90)	1.24 (0.83)
LL Mean (SD)	15	1.67 (0.62)	1.87 (0.35)	1.93 (0.26)	1.47 (0.74)	1.40 (0.74)	1.47 (0.64)	1.47 (0.74)
EO Mean (SD)	33	1.79 (0.49)	1.67 (0.54)	1.73 (0.57)	1.36 (0.78)	1.33 (0.65)	1.12 (0.70)	1.30 (0.73)
LO Mean (SD)	36	1.69 (0.53)	1.58 (0.55)	1.72 (0.57)	1.58 (0.65)	1.47 (0.77)	1.36 (0.76)	1.28 (0.82)
Thyroid Mean (SD)	43	1.74 (0.49)	1.53 (0.67)	1.74 (0.54)	1.56 (0.63)	1.56 (0.67)	1.26 (0.79)	1.37 (0.76)

Key: Mean based on the score 0= would not discuss, 1= discuss if doctor raises 2= would wish to discuss.

Sub-group scores (EO, EL, LO, LL and Thy) followed the pattern of the study group as a whole across the range of issues addressed in this study in that symptoms and side effects of disease scored most highly followed by the other physical items with a gradual reduction as the ‘softer’ and social aspects were considered. A notable finding was the higher scores, mainly for LL but, to a lesser extent, for LO across a range of questions. This would indicate that these patients consider that clinicians discuss a wider range of issues. Whether this is perception or whether there may be variations in the content of consultation depending on status cannot be determined from this table alone but it is a finding worth further exploration.

Table 6.3 B Perceptions of the Content of Consultations by Group and Sub-group

SG	NS	OH	S&SE	PG	PS	LWH	ED	ImpFP	ImpSoc	Imp App
All mean (SD)	144	1.69 (1.14)	2.50 (1.23)	2.48 (1.28)	1.60 (1.51)	2.30 (1.36)	1.31 (1.29)	1.02 (1.19)	1.09 (1.89)	1.03 (1.20)
EL mean (SD)	17	1.82 (1.29)	2.24 (1.30)	1.88 (1.45)	1.00 (1.41)	1.82 (1.59)	0.82 (0.95)	0.53 (0.72)	1.00 (1.17)	1.06 (1.44)
LL mean (SD)	15	1.80 (1.37)	**2.93 (1.34)**	**2.87 (1.25)**	**2.07 (1.67)**	**2.53 (1.36)**	**1.87 (1.51)**	**1.20 (1.47)**	**1.73 (1.58)**	**1.53 (1.69)**
EO mean (SD)	33	1.55 (1.18)	2.00 (1.32)	2.03 (1.33)	1.15 (1.37)	2.06 (1.34)	0.82 (1.01)	0.73 (1.01)	0.61 (0.83)	0.67 (0.92)
LO mean (SD)	36	1.72 (1.03)	**2.72 (1.03)**	**2.72 (1.11)**	**1.97 (1.44)**	**2.97 (0.97)**	**1.72 (1.34)**	**1.22 (1.15)**	**1.36 (1.20)**	1.14 (1.07)
Thyroid mean (SD)	43	1.67 (1.09)	2.65 (1.15)	2.72 (1.20)	1.72 (1.55)	2.02 (1.39)	1.35 (1.31)	1.21 (1.32)	1.05 (1.15)	1.05 (1.15)

Key: SG=Study Group, NS=Number of Subjects, OH=Overall Health, S&SE= Symptoms and Side Effects of Disease or Therapy, PG=Limitation in Physical Activities, PS=Limitation in Physical Activities Specific to Disease or Treatment, LWH=Limitation in Work or Housework, ED=Emotional Distress, ImpFP=Impact of Disease on Relationships with Family or Partner, ImpSoc=Impact of Disease on Social Activities, ImpApp=Impact on Appearance. Mean score is shown as main result, Standard Deviation in brackets. Score: 0-4 Likert where 0= never to 5=almost always.

The ANOVA exploring the relationship between preferences for the content of a consultation and sub-group was remarkable for the similarity between all sub-groups, with most of the results yielding a significance result of p=1.000 and the remainder showing a very minor trend. This indicates a consistency in terms of what our patients would wish to see included in a consultation. The results for perceived content were rather different, although given the relatively stringent definition of a statistically significant difference, this was not achieved. However trends were seen in ‘symptoms and side effects of disease or treatment’ between EO and LL and LO and similarly for ‘limitations in physical activity’, both general and specific to disease, work and housework and social activities. Despite the lack of a significant result, these trends are of interest as evidence that the content of consultation might, or at least be perceived to be, different depending on therapeutic burden has not been considered before. The results of the independent t-tests which achieved statistical significance were as shown in Table 6.4.

Table 6.4 Independent t-test results: Patients' Perceptions of Consultation Content

Parameter	Question	T	df	Sig	StdError	95% CI	
						Lower	Upper
Early v Late	S&SE	-2.91	96.11	p=0.005	0.24	-1.19	-0.22
	PS	-3.15	98.58	p=0.002	0.29	-1.47	-0.33
	LWH	-3.41	92.35	p=0.001	0.25	-1.37	-0.36
	ED	-3.97	90.46	p<0.0001	0.24	-1.42	-0.47
Stage I/II v III/IV	ED	-3.78	99.00	p<0.0001	0.23	-1.33	-0.41
	ImpFP	-3.42	97.44	p=0.001	0.20	-1.08	-0.29
	ImpApp	-2.89	95.48	p=0.005	0.23	-1.12	-0.21

Key: S&SE=Symptoms & Side Effects of Disease or Therapy, PS=Limitation in Physical Activities Specific to Disease or Treatment, LWH=Limitation in Work or Housework, ED=Emotional Distress, ImpFP=Impact of Disease on Relationships with Family or Partner, ImpApp=Impact of Disease on Appearance.

These results emphasised the difference in patient experienced depending on the burden of disease and therapy. For the early v late therapeutic burden based parameter the significant differences were seen for 'symptoms and side effects related to the disease and its therapy' (S&SE) and 'physical limitations specific to the disease and its therapy' (PS), capturing the difference in therapeutic burden and the consequences in terms of long term status. The other significant finding was for emotional distress, a finding which was also present when Stage I&II disease at presentation was compared with Stage III &IV. For Stage the impact on relationships with family or partner (ImpFP) and impact on appearance (ImpApp) were also statistically significant. This may reflect the attitudes imparted at the beginning of the cancer journey when a more cautious prognosis and also likelihood of returning to normal function would be offered to these patients. Although no firm conclusions can be drawn from the quantitative data alone, it provides a basis for exploration of the consultations.

6.1.2 Test/retest

22 participants completed the intervention twice (EL3, LL2, EO7, LO9 and Thy1).

Dr Adam Smith and I explored the data and carried out a weighted *kappa* analysis for measure of agreement as described in the proposed statistical method (Chapter 4) (Pallant, 2007) For preferences for communication we used the 0, 1, 2 scoring but for 'perceived' content we combined the two lower responses to give an overall 'infrequent' (i.e. negative) rating and the two upper responses to give a 'frequent' (i.e. positive) rating. The small numbers limited

this approach. For the most highly endorsed response in the first section, 'limitation in physical activities specific to disease' the *kappa* was 0.52, but overall it was 0.3, signifying a modest association.

When we looked at patterns from the results, responses of 1 or 2 were usual in the 'preferences' section and it was variation between these two responses which were being assessed. The availability of 5 responses for the 'perceptions' category made a statistically valid result very unlikely.

I, therefore limited further analysis to descriptive considerations of the data. Table 6.5 a and b compared the means between the first and second interventions for 'preferences' and 'perceptions'.

Table 6.5 a Comparison of Means, Test/Retest, Preferences

Question	***Scores Mean (SD)***	
	Intervention 1	**Intervention 2**
Physical symptoms & side effects of treatment	1.55 (0.67)	1.55 (0.60)
(Limitations in physical activities (general)	1.64 (0.58)	1.64 (0.66)
Limitations in physical activities (specific)	1.64 (0.66)	1.77 (0.53)
Emotional impact	1.41 (0.85)	1.59 (0.67)
Impact on work, housework, leisure	1.41 (0.73)	1.45 (0.80)
Impact on social activities, family & friends,	1.27 (0.83)	1.32 (0.78)
Impact on appearance	1.27 (0.83)	1.18 (0.85)

I carried out an independent t-test comparing the means for each individual question confirming the impression from the tables that there was no statistical difference between the mean scores comparing the first and second interventions.

Table 6.5 b Comparison of Means, Test/Retest, Perceptions

Question	*Scores Mean (SD)*	
	Intervention 1	**Intervention 2**
Overall health	1.22 (1.19)	1.31 (0.78)
Symptoms of disease and side effects of treatment	2.59 (1.18)	2.31 (1.36)
Limitations in physical activities (general)	2.18 (1.22)	2.27 (1.16)
Limitations in physical activities (specific)	1.64 (1.43)	1.77 (1.27)
Impact on work, housework, leisure	2.45 (1.22)	2.27 (1.08)
Emotional impact	1.23 (1.02)	1.45 (1.22)
Impact on relationships with family/partner	0.95 (1.17)	1.09 (1.15)
Impact on social activities, friends/neighbours,	1.22 (1.02)	1.14 (1.25)
Impact on appearance	0.95 (1.13)	0.82 (0.91)

6.2 Consultation priorities derived from interview

The interview schedule asked participants to identify areas which were important to them, either from those included in the questionnaire or additional items. For the purpose of this thesis I reviewed the responses from a subset of patients. Twenty interviews were selected from the whole sample, looking to identify at least 5 from the longest recorded tapes, 10 from medium length tapes and 5 from the shortest tapes. The sub-groups represented in this sample were: EL (n=2), LL (n=2), EO (n=5), LO (n=5), Thy (n=6).

The patients had been asked firstly which were the important issues and secondly what they considered was important but not included in questionnaires.

They could also comment on their interactions with the clinical team and these findings were combined with those from the consultation in the next section.

Material from this part of the study was highly varied and inevitably subjective. To allow analysis we devised a scheme whereby the answer was coded into a main

areas: physical, emotional, social and/or financial and then by name, e.g. physical /:chewing, emotional / family distress. To grade severity a simple scheme was applied where:

1= item mentioned
2= item mentioned as a problem
3= item mentioned as a priority.

A score of 0 indicated that one rater has scored an item but the second had not included it. I scored all responses; a subset of 5 was scored together as a 'training set' by myself and one of the RAs who had accrued patients to the study. We then independently rated a further subset of interviews to determine inter-rater reliability and I rescored the same set of interviews at a time at least one month apart from the initial score.

The results of the inter-rater analysis are shown in Table 6.6.

The categories of response were developed through listening to the tape, making a summary of material and then identifying the key words, as one would code a medical intervention. There were no predetermined limits to the number of categories, in practice they were well defined and relatively easy to fit into the coding scheme as shown in Table 6.6.

From this table it can be seen that patients were much more likely than doctors to initiate discussion of significant problems. For H&N Rater 1 scored 42 items as initiated by patients compared to 43 for Rater 2. Both identified 18 issues raised initially by doctors. The majority were physical for both issues raised by patients and issues raised by doctors with both Rater 1 placing 30 (from 42) and Rater 2 placing 32 (out of 43) responses in this category for patient initiated discussions and 15 (from 18) for doctor led items. However a wider range of problems was captured, including responses at a level indicating a priority. The most common issues raised in consultations were site specific in keeping with the 'preferences' and 'perceptions' ratings already discussed. Eating was most common but, where swallowing was raised, it was likely to be scored at the highest level by both raters. Considering issues not included in questionnaires, fear of recurrence was the most prevalent issue.

Table 6.6 Rating Consultations: Results from Inter-rater Analysis

H&N Patients					
Issue-General	**Issue Specific**	**Rater 1**		**Rater 2**	
		Patient	**Doctor**	**Patient**	**Doctor**
Physical	Weight	1, 0,1,	1, 1, 1, 2, 2,	1, 2, 1,	1, 1, 1, 2, 3,
Physical H&N	Mouth Opening	2, 2, 3,		2, 2, 3,	
	Dry Mouth/Saliva	1, 3, 3,		1, 3, 3,	
	Tongue Mobility	1, 2		2, 3	
	Numbness	2, 2,		1, 2,	
	Eating	2, 1, 2, 3, 3, 2,	2, 1, 1, 2,	2, 2, 2, 3, 3, 3,	2, 1, 1, 3,
	Teeth/Chewing	0, 3,		2, 3,	
	Swallowing	3, 3, 3,	1,	3, 3, 3,	1,
	Oral Hygiene	1,	1,	2,	1,
	Voice/Comm	2, 1, 2,	1,1, 2,	2, 1, 2,	1, 1, 2,
	Sore Throat	1,		2,	
	Neck Pain/Stiff	1, 2,		2, 3,	
	Appearance	1		1	
	Medication		1,		1,
Emotional	Fear Recurrence	1, 2, 2, 2,		0, 3, 2, 3,	
	Anxiety	2, 3,		3, 0,	
	Bereavement	3,		3,	
Social	Eating		3,		3,
	Family	3,		2,	
	Work	1, 2,	2,	1, 2,	2,
	Activities	2,	1,	2,	1,
Other	Smoking	1, 2,		3, 3,	
	Sun Protection	1,		0,	
Thyroid Patients					
Issue-General	**Issue Specific**	**Rater 1**		**Rater 2**	
		Patient	**Doctor**	**Patient**	**Doctor**
Physical	Fatigue	1,		0	
	Weight	1		0	
	Medication	1, 1, 1,	1,	2, 1, 1,	1,
Physical H&N	Mouth Opening	1		0	
	Dry Mouth/Saliva	2, 3		3, 3,	
	Numbness				
	Eating	2		2	
	Sore Throat	2,		3,	
	Swallowing	2,		2,	
	Neck Pain/Stiff	2	1,	3	1,
	Parotid Swelling	3, 3		3, 3	
	Scar		2,		2,
Emotional	Fear Recurrence	2,		2,	
	Anxiety	2,		2,	

Thyroid patients had some common issues with H&N but of note was the importance of medication related issues and also that for 2 out of the 6 patients an episode of parotid swelling had occurred at a level which caused both raters to give a score of 3, representing a significant concern. Rater 1 identified 16 issues raised by patients and Rater 2 identified 13. In the thyroid patients selected no

social issues were identified. Anxiety, which may relate to thyroid status and fear of recurrence were the two emotional factors identified.

The scoring system showed, on face validity, a good degree of consensus. Rater 2 tended to score a little higher than Rater 1. On checking the data together, discrepancies in scores were explained by difficulties in hearing the tape, where one Rater had missed a short comment. Apart from those occasional problems, all scores were within one point of each other. The main area for debate was whether an issue was mentioned as a problem (score 2) or mentioned as a priority (score 3). Within the limits for this type of analysis it was concluded that the scheme was acceptable.

On retesting, my scores were very similar to the first occasion, indicating that such differences as were found were due rather to individual variation in scoring than subtleties in the language in the consultation which would have led to variation during repeated scoring by one person. I also scored ten further records but no further issues were identified, indicating that the majority of pertinent issues had been identified in the first series of results.

This indicated that specific problems were the focus of consultations but that fear of recurrence was raised in a number of consultations.

6.2.1 The Medical Consultation

As described in Chapter 5, these were taped with the permission of both patient and doctor. All patients were in the follow up stage and were familiar with the clinical teams. Although my emphasis was on issues raised, the way in which the consultation was conducted was of interest and I observed three styles of consultation. The first, which represented the majority of episodes, commenced with a broad opening question from which emerging themes were then explored. The second, often employed when a new doctor was meeting a patient for the first time, commenced with a brief summary of presentation, past therapy and current status and a check with the patient that this was accurate, then moving on to an open question about current status and problems. The final style, encountered least frequently, was at a recall visit for the results of specific tests when the immediate focus of the discussion was that element of care and the wider aspects of the patient's status were omitted. Examples of all three styles have been reported.

We recorded the time of consultation in an attempt to link this to the number of issues explored and to who raised them. Considering the results above, I had hoped that this information might allow exploration of the length of consultation by therapeutic burden. However, for H&N cancer, the process of clinical examination is a core part of the consultation and the interaction usually moved seamlessly between the two with comments being made by patients and their doctors throughout. At the time of clinical examination, comments were made on areas checked or matters of advice but sporadically. To determine the actual verbal period of interaction with any accuracy proved impossible.

6.2.2 Examples of Consultations and Comments on Consultation Content

The effectiveness of a consultation is a consideration in whether the use of a questionnaire might add new and useful information or whether it might help in priority setting. To set this in context it is important to understand the dynamics of the patient/doctor interaction. In this section I have given examples from the consultation styles noted above and also two examples of where there were problems in communication.

The first example is an **open consultation** in which the priority for the patient was the impact of his cancer and its treatment on his daughter. He also had concerns of his own about specific aspects and also there was a strong sense of psychological concerns.

Doctor (D): Maxillofacial Surgery Registrar (higher surgical trainee). Patient (P): LO35, Male, Aged 46. 2 years post surgery and postoperative RT. Duration: 12mins 45secs.

D: ‘How are you doing?’

P: ‘Terrible’.

D: ‘Why?’

P: ‘My daughter has been playing up for the last 18 months, going out, staying out. Police are involved and she has been taken into care. She’s only 12 and out all night, must be about 100 times this year. Playing truant, acting up and I’ve been told I mustn’t let her in if she tries to come home but let the Police know, I could be in trouble if I do anything.’

D: ‘Is this giving you a hard time?’

P: ‘I’ve got another 4 years’ (note presumably of planned follow-up). If I’ve got cancer in my mouth now I won’t have an operation. I don’t care. I’m not having it cut out.’.

D: ‘I hope it will be alright.’

P: ‘I don’t care.’

D: ‘OK if I take a look?’

P: ‘I’ll take teeth out……..daughter…she is well brought up, went to Church, seemed to have nice friends…..I’m getting an awful lot of thrush (oral candidiasis), phoned doctor, got cream stuff to put on it.’

D: ‘It doesn’t look too bad.’

P: ‘I can’t touch anything with this side of my tongue. It stings all the time. Feels like nerves in it jingling all the time.’

D: ‘The nerves do get damaged.’

P: ‘My mouth is always dry. I have to carry water all the time. I’ve not had a sweet, I mean a desert, for about 2 years.’

D: ‘Did you get RT to your mouth?’ (note: the Consultation was held at another Trust site, remote from the Cancer Centre, with access to specific records only at the time of the study. Now all have access to PPM and the full pathway record).’

P: ‘There was a wee lump in my mouth.’

D: Looks good, nice and healthy.’

P: ‘I’m still smoking.’

D: ’We could talk about risks but you probably have too much going on in your life to stop right now.’

P:‘I stopped for 6 months. Doctor couldn’t give me more tablets. I take paracetamol for my pain. If I take anything stronger I might get addicted. How much does that matter?’

D: ‘All seems healthy today’

P: ‘Has thrush gone?’

D: ‘It looks fine but we do need to keep you under review’

P: 'Social Services are messing things up. Once things are sorted I want to get away from here and go back to Pontefract.'

D: 'We need to give you an appointment.'

P: 'I'll send you my new address.'

In this example, the doctor was quick to acknowledge and not to dismiss the patient's concern although there was little, as a health professional, that she could do to assist his social problems. She showed empathy then used the strategy of asking to check the local disease site to bring the consultation back to the cancer and current medical status. At this point, more specific concerns begen to emerge. She sounded throughout in control. Considering this interaction in the context of whether a questionnaire might have helped, it may have alerted her to the likelihood of a difficult and intense conversation about personal psychological and family concerns and perhaps a provided a prompt to suggest that she might explore psychological support for her patient, an element of this interaction which was not addressed, In the end the patient had been reassured about his physical status and the broader issues were acknowledged but not proactively addressed.

Psychiatric help had emerged as an issue in the interview where, again, much emphasis had been on the family's problems with the comment that 'my daughter went haywire when my cancer was found, totally off the rails.' The patient had a clear view of the function of the clinic. 'The clinic is only here to do the physical. It does not look at the mental, that is as much a wound. It would be so good to have someone care about that part of it…..a Psychiatrist. someone who can help with this part'. It is worthy of note that this participant scored at 'caseness' level using HADS (score of 16 for the Anxiety Scale and 19 for Depression [caseness defined as a score of 11 or above]).

On questionnaires, the patient preferred the EORTC – 'this is the one which gives some insight into how I feel about things' and also expressed support for the inclusion of psychological questionnaires in a patient assessment.

This information indicates that a chance to offer psychological support which could have been identified using a questionnaire assessment and which would have been welcome was missed at this consultation and probably on an ongoing basis.

The second type of consultation differed from the first only in the entry and scene setting, so I have quoted only the opening statement here:

Doctor (D): Clinical Oncology Registrar (higher oncology trainee)

D: 'Hello, Mr xxxxx. We have not met before so I would like to go through what I understand from your notes before we talk about how you are now. I understand that you had a cancer of the voice box and this was treated by radiotherapy and you finished treatment in April last year. Is that correct?'

The patient acknowledged the summary and the consultation then followed the pattern of the open model as above, although, in this case, the patient was doing well with no significant physical or apparent emotional or social concerns.

The next example is of a **focussed consultation** where a patient had been referred back to clinic for a common problem, concerns about teeth some years after completion of therapy.

Doctor (D): Maxillofacial Senior House Officer (doctor with basic surgical training. This individual had gained her postgraduate diploma and was experienced in the care of post-therapy oncology patients).
Patient (P): Male, LO17, Male, Aged 80. 5 years + after surgery with reconstruction and postoperative RT.
Duration: 14mins 30 secs.

D: 'We have a letter from your dentist saying that your teeth are causing you trouble and I understand that you have had an operation to remove part of your tongue and also radtiotherapy a few years ago.'

P: 'I had come to the clinic for a few years but my Consultant discharged me last summer. I had an op on the floor of my mouth. This tooth, its affecting the teeth at the back of my mouth – they've been trying to save them. Getting quite loose and sore, really tender.'

D: 'Did your problems start after your radiotherapy?'

P: 'Only the last 2-3 years. Teeth have got worse. Really tender. Had to have false teeth at the top. Keep rubbing against side of mouth and gums, makes my mouth very sore. I had my op in the February and waited 11 months for things to heal before I got my first false teeth. I did so well for the first three years. My speech improved. After that I just haven't got any better. Worried about teeth, I've heard of osteoradionecrosis (note: an uncommon but serious condition where the

irradiated jaw bone necroses often after dental infection or extractions and which is difficult to control and manage). My whole jaw can feel quite tender. Sometimes the tooth is almost untouchable. People have told me how wonderful I am, doing things again with my arm. I know a lot of people are worse off than me.'

D: 'Are your flap and mouth OK?'

P: 'I want treatment here. I am struggling with my denture, have to use fixative, teeth can drop out, it gets very embarrassing.'

D: 'Is it affecting your eating?'

P: 'I can't eat lost of things – meat. I can manage fish. Adjust to that, avoid hard food, lots of veg. I make own soup, am sick to death of soup. I wish my mouth was just more comfortable, that's the main thing.'

D examines mouth

D: 'Would you like to have all these teeth out?'

P: 'I know they are in a terrible state.'

D: 'Your main problem is trying to keep them clean when you have so little saliva. It may be that they can be made more comfortable and I suggest we start with removing the worst tooth only then see how you go. I've checked the area where you had radiotherapy and the tooth is not in that area so you are not at risk of osteoradionecrosis.'

Patient accepts treatment plan and appointments are arranged.

This consultation was well focussed but illustrated the long term cost of successful therapy for oral cancer. It also indicated that patients are happy to raise issues providing they are in the presence of an empathetic doctor.

The examples above were typical of the range of consultations, from simple interactions with people who appeared to be coping well to those with profound physical, emotional and social concerns. Despite their training, doctors have to manage the consultation with no prior knowledge of what may emerge during the conversation and there is thus a risk that important prompts may be lost. Detmar et al (2000) and more recently Fagerlind et al (2008) reported that oncologists are more likely to address physical rather than psychosocial concerns.

The risk of undertaking a complex interaction such as a consultation without any prior briefing is that immediate responses are required which will occasionally be unhelpful, and at worst can lead to problems. This challenge to the core element of the way care is delivered takes us back to the patient narratives in Chapter 1 and the two examples quoted below both relate to communication, one within the clinic and the other relating to exchange of information and mutual trust between health professionals.

Doctors: Consultant Clinical Oncologist (D1) and Consultant ENT Surgeon (D2).
Patient: Male, aged 50, approximately 12 months after radical chemoradiotherapy.
Duration: 12 minutes.

D: 'it is good to see you gaining weight. You have put on 2 kg since your last visit.'

P: 'I am feeling better and have more energy now'.

D: 'We should think about removing your PEG' (feeding tube inserted directly into the stomach).

P: 'I really wouldn't want to do that.'

D: 'but your weight is so good, It is time to make progress.'

P: 'I would not want to have the tube out.'

This narrative continued for over two minutes without any significant advance. At this time a second Consultant intervened

D2: 'How much of your daily intake of nutrition do you still use your tube for?'

P: 'Virtually all of it.'

From this point the consultation became focussed on nutritional aspects. It is difficult to know how the misunderstanding arose. The first doctor was pleased at the improvement in an element of the patient's status which had clearly been causing concern but made an assumption about the route for nutrition. This distressed the patient who simply repeated a wish to keep the tube. This was the one occasion where communication broke down and a second professional had to intervene before mutual understanding was re-established. Given the pressures on medical staff, it was remarkable that this kind of event happened rarely. There would seem to be a role for collecting information via a

questionnaire to establish priorities and status so that doctors are as well briefed as possible.

The second example of a problematic consultation came from a patient and partner narrative as part of the interview.

Patient: 'My main problem is I can't eat, I just cannot eat at all.'

Partner: 'The one thing I didn't like – 'do a swallow test.' The dietitian had done one before and told him he would never swallow again. After Christmas this young doctor decided he needed another test. I said 'don't get your hopes up.' The dietitian, a smashing young woman, had told us straight. Doctor then got his hopes up. He (patient) said 'what if everybody's wrong?' That put him back further than anything else because it got his hopes up when he had learned to cope. Young doctor (with emphasis in tape on 'young') gave false hope. If I could have got my hands on him, I would have slapped him. It was so unfair.'

It was clear that the consultations did focus on physical issues and a few patients commented on what they would expect from the clinical team, reinforcing this perception of the way the clinics were structured and the roles of their doctors. Although this is anecdotal, the views were consistent and no participant mentioned experience of their doctor taking a wider role.

LO31, male, aged 63 said: 'We've got this wonderful doctor who saved my life. He does his job. He is a brilliant surgeon. We need to be able to talk to someone else about other things but who and when? The only doctors in the clinic are surgeons and at home there is my GP. My surgeon knows about surgery. The GP hasn't a clue about what is going on and there is nobody in the middle.' His partner concurred 'We need someone with common sense in the middle who understands. We get 'support', there have been times when we have been inundated with highly trained expensive people. The specialist should do his job but we do need someone else with a general approach who can give help and support with the non-medical bits.'

6.3 Summary

This chapter has raised a number of important and interesting issues. The concept that consultations might be tailored to the perceived needs of the patient with a concentration on a wider range of issues for those with more advanced

disease has not been raised in the literature but is of interest in a field where the literature suggests that stage is the most prominent predictor of QoL. The findings confirmed the literature in terms of the emphasis in the physical and arguably the ‘medical’ aspects of the cancer journey. The issues identified in the analysis of consultations are in accord with the literature, however, the level of concern about fear of recurrence is something which lay beyond the remit of questionnaire assessments at the time this study was developed.

Chapter 7 - Patient Opinions on Health Related Quality of Life Questionnaires (QoL) in Head & Neck(H&N) Clinical Practice

This chapter reports on the findings from the questionnaire rating study in which the series of general and H&N specific questionnaires was presented to patients in random order, followed by the psychological questionnaires.

The **aims** of this chapter are to explore the opinions and preferences of the study population for the questionnaires, to explore their self-reported QoL and to determine which items assisted in understanding the needs of the study group and sub-groups. To supplement this data and to allow consideration the views on questions expressed by individuals and also to determine what was important but excluded from the questionnaires, material arising from the interviews is discussed in the latter part of the chapter.

The core part of this work considers patient opinions and preferences and, in terms of the primary outcomes from this chapter these are reflected in:

- self-reported status
- questionnaire preference
- ratings for ‘importance’ and ‘well written’.
- opinions of the content of questionnaires and areas which should be incorporated to reflect patient status.

This was supported by analysis, according to scoring manuals for each questionnaire, of the actual scores arising from completion of the questionnaires. Differences between participant groups were an important part of this analysis. The experience of therapy, demographic profile (Chapter 5.2.1) and the symptom profile of the thyroid group was very different to that for the H&N sites (EL, LL, EO & LO) (Chapter 5), so the findings are presented by whole group, H&N patients compared to thyroid and by each H&N sub-group separately to attain the best possible understanding of the way status relates to questionnaires. My hypothesis was that significant differences between thyroid and H&N patients would emerge from the analysis. Having divided the H&N population into sub-groups this hypothesis extended to likely differences between sub-groups. Sub-groups were defined by two factors: therapeutic burden (early or late) and site

(larynx v oral) so these were explored independently. To compare the findings from this study with the traditional descriptions of early and late presentations by stage, the findings from early stage (Stage I&II) and late stage (III&IV). Staging of cancer was described in Chapter 2, section 2.2.4.

In the first section I have considered the way in which the questionnaires were scored and the data analysed for each measure, ending with a brief comment relating to findings from that analysis alone. In this part of the study three general questionnaires: the SF-36, EORTC QLQ C30 and FACT-G were delivered by touch-screen computer in random order. Participants were asked to answer each question and then, once the questionnaire had been completed, to score the whole questionnaire on 'importance' and how 'well written' the instrument was considered to be. The three H&N measures were then delivered, also in random order but, on this occasion an 'importance' and 'well written'; rating was attached to each individual question, rather than asking for a rating of the whole questionnaire. The two psychological questionnaires were simply completed without comment or rating, although opinions were requested during the interview. This section provided a valuable insight into the way that the questionnaires allowed self-reporting of status. Attempting in any way to compare the findings from different questionnaires is challenging. Their structures and scoring systems are very different, and even though I adapted some methods to facilitate understanding relationships between questions direct comparison is not possible using statistical methods alone. On analysing the data, there were common features, allowing some comparisons at descriptive level and also items unique to a single instrument where it is of interest to consider how well these were endorsed and by which populations of patients. This section on scoring has allowed the ratings of questionnaires and opinions about questionnaires to be placed in context. At the end of this section I have brought together comments relating to the findings from the whole range of questionnaires.

The second part of the chapter describes the opinion ratings and preferences in regard to questionnaires. For the general measures this was done through a single question but for the H&N questionnaires, as each question often functioned as a 'stand-alone' rating of a matter of specific function or experience, an opinion was given for each question individually. The development of the scoring system was described in Chapter 4 and considered the views expressed on questionnaires, on actual choices for whole measures and why some

questions were supported and where concerns were voiced. The final interview question was ‘Is there anything which was not included which you would wish to see in a future questionnaire?’ The range and frequency of requests were noted as this may be important in assembling any future measure or updates of current measures from a patient centred point of view.

7.1 H&N Patient responses to questionnaires

!44 participants entered the study. Although participants almost always completed the full set of questions and there was a little attrition as the study progressed, with the lowest number of participants (135) completing the psychological questionnaires. There were small differences in numbers between the measures due to the random allocation of the questionnaires and occasional inability to fully complete the intervention. The main reason for interruption of the study intervention was the arrival of hospital transport. The maximum number of responses possible was 144 (33 EO, 36 LO, 17 EL, 15 LL and 43 Thy). Results for each questionnaire indicate the number of responses by total and by each sub-group.

Scoring was done according to manual for each measure and statistical analysis performed to compare H&N v Thy, Early v Late, Stage I&II v III&IV. Age was explored but did not show significant results and was not considered further.

7.1.1 SF-36

As data was entered, scores on an ascending scale were recorded as shown in the example of the questionnaire (Appendix 4.1). Corrections to the recorded scores were required for ‘negative’ items as, on this questionnaire, a **high score** indicates a **better status**. Once this had been completed a mathematical transformation was carried out to express all scores on a scale of 0-100. The domains which emerge from grouping individual questions as indicated in the scoring manual are physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality, social function (SF), role function (RF) and mental health (MH). The mental health score includes all elements of the MHI-5. The raw data scores are shown in Table 7.1.1.1.1 – 7.1.1.1.5. Particularly poorly scoring participants’ records are shown in red (most scores <=50 across the range of items).

Table 7.1.1.1 SF-36 Scores by Sub-groups

Table 7.1.1.1.1 Early Larynx (EL): 17 Responses

Study number	PF	RP	BP	GH	Vitality	SF	RF	MH
EL1	100	100	100	95	88	100	100	95
EL10	15	50	19	40	31	25	50	30
EL11	40	31	11	35	31	68	0	55
EL12	30	25	23	35	56	38	33	40
EL13	85	88	100	70	69	100	75	65
EL14	100	93	100	75	75	50	92	70
EL15	70	50	78	40	75	75	50	65
EL16	40	50	100	35	38	88	50	45
EL18	100	88	100	75	100	50	100	95
EL19	95	81	89	75	56	75	83	75
EL2	100	100	100	80	88	100	100	80
EL3	65	31	45	30	25	38	42	30
EL4	20	38	56	45	56	50	17	55
EL5	10	25	11	20	31	25	17	50
EL6	0	0	100	45	69	0	8	40
EL7	80	50	78	85	69	68	67	50
EL8	70	93	78	50	63	88	83	45
EL Average	**60**	**58.41**	**69.88**	**54.71**	**60**	**61.06**	**56.88**	**57.94**

Table 7.1.1.1.2. Late Larynx (LL): 15 Responses

Study number	PF	RP	BP	GH	Vitality	SF	RF	MH
LL1	100	100	78	90	81	75	92	75
LL10	40	63	45	65	81	75	75	65
LL11	95	100	78	75	88	100	100	70
LL12	70	63	78	50	63	100	83	70
LL13	80	100	100	60	93	50	100	85
LL14	90	100	100	70	63	50	92	75
LL15	20	69	89	70	81	88	58	65
LL2	40	31	67	90	50	50	50	50
LL3	85	93	100	55	88	100	92	80
LL4	100	100	100	95	100	100	100	95
LL5	85	63	100	90	88	100	92	95
LL6	40	31	45	60	75	88	33	60
LL7	70	81	100	60	81	88	92	80
LL8	100	100	100	85	88	50	100	95
LL9	80	100	100	50	88	100	100	80
LL Average	**73**	**79.6**	**85.33**	**71**	**80.53**	**80.93**	**83.93**	**76**

Table 7.1.1.1.3. Early Oral (EO): 32 Responses

Study number	PF	RP	BP	GH	Vitality	SF	RF	MH
EO1	70	81	100	60	69	100	75	60
EO10	55	88	67	60	75	100	100	75
EO11	95	100	89	95	100	100	100	85
EO12	30	38	45	40	69	88	25	45
EO13	80	66	100	90	81	100	50	75
EO14	100	100	100	90	88	100	100	90
EO15	75	100	100	100	88	50	100	85
EO16	45	88	89	75	63	38	83	50
EO17	55	81	100	65	63	88	75	55
EO18	100	100	78	50	44	38	100	35
EO19	100	100	78	80	63	100	100	75
EO2	100	100	100	90	88	100	100	95
EO20	40	50	45	55	75	75	67	70
EO21	80	75	67	55	81	100	92	85
EO22	50	50	78	40	50	50	83	50
EO23	5	25	45	45	50	38	33	55
EO24	5	19	89	55	69	88	33	50
EO25	100	100	100	95	88	100	100	95
EO26	30	38	100	85	81	100	75	80
EO27	100	100	100	75	88	100	100	85
EO28	90	100	89	90	100	100	100	100
EO29	75	75	56	60	69	100	75	70
EO3	96	100	100	80	81	100	100	90
EO30	80	81	100	65	81	100	58	75
EO32	25	13	78	40	56	68	17	55
EO33	65	19	100	75	81	100	83	65
EO34	100	100	89	95	93	100	100	95
EO4	95	88	78	90	81	100	92	75
EO5	100	100	89	75	81	100	100	90
EO6	95	100	100	80	88	100	100	75
EO7	95	93	100	70	75	100	92	75
EO9	100	100	89	80	75	100	100	85
EO Average	**72.84**	**77.13**	**85.56**	**71.88**	**76.06**	**88.16**	**81.5**	**73.28**

7.1.1.1.4. Late Oral (LO): 35 Responses

Study number	PF	RP	BP	GH	Vitality	SF	RF	MH
LO1	5	100	100	55	81	100	100	90
LO10	**10**	**0**	**45**	**25**	**0**	**13**	**0**	**0**
LO11	**30**	**44**	**45**	**10**	**31**	**25**	**42**	**40**
LO12	**25**	**25**	**11**	**15**	**13**	**0**	**25**	**10**
LO13	70	63	34	35	56	68	75	65
LO14	**25**	**25**	**34**	**40**	**38**	**38**	**25**	**30**
LO15	**5**	**0**	**100**	**50**	**56**	**13**	**0**	**35**
LO16	**50**	**25**	**0**	**40**	**69**	**50**	**0**	**40**
LO17	100	100	100	85	93	100	92	100
LO18	**25**	**25**	**34**	**25**	**38**	**0**	**25**	**45**
LO19	**80**	**25**	**11**	**45**	**25**	**25**	**25**	**25**
LO2	65	44	45	45	38	68	67	30
LO20	35	93	100	80	81	88	92	70
LO21	90	75	89	70	56	100	58	60
LO22	100	100	100	80	93	100	100	90
LO24	100	100	89	80	88	88	100	75
LO25	95	75	67	85	81	75	50	70
LO26	95	88	100	90	93	100	83	90
LO27	100	100	89	95	100	100	100	90
LO28	90	100	100	50	88	100	100	85
LO3	**10**	**6**	**78**	**0**	**31**	**38**	**42**	**30**
LO30	100	100	100	65	100	100	100	95
LO31	50	50	67	50	75	25	75	50
LO32	**15**	**0**	**45**	**25**	**44**	**25**	**17**	**35**
LO34	95	56	89	65	56	100	67	35
LO35	**5**	**25**	**0**	**10**	**0**	**0**	**0**	**0**
LO36	80	69	100	50	69	100	67	60
LO37	40	63	45	30	50	68	42	55
LO38	0	50	11	65	88	75	92	70
LO39	65	56	78	75	88	100	58	65
LO5	10	100	56	80	75	100	100	55
LO6	**20**	**31**	**23**	**55**	**81**	**25**	**33**	**65**
LO7	**20**	**13**	**23**	**15**	**50**	**88**	**8**	**25**
LO8	**45**	**50**	**34**	**35**	**56**	**50**	**58**	**50**
LO9	100	93	89	40	88	100	100	85
LO Average	**52.86**	**56.26**	**60.89**	**50.29**	**61.97**	**64.14**	**57.66**	**54.71**

7.1.1.1.5. Thyroid (Thy): 43 Responses

Study number	PF	RP	BP	GH	Vitality	SF	RF	MH
Thy1	95	100	100	100	100	100	100	90
Thy11	55	81	100	60	88	88	50	75
Thy12	70	81	78	85	63	50	75	55
Thy13	70	44	78	30	44	68	50	40
Thy14	100	100	100	75	93	100	100	95
Thy15	85	100	100	85	88	100	100	80
Thy16	80	100	100	70	93	100	100	75
Thy17	75	63	78	75	56	88	67	60
Thy18	85	100	100	70	88	100	100	95
Thy2	100	100	67	90	75	100	100	85
Thy20	100	100	100	70	75	75	100	75
Thy21	65	100	78	70	88	100	92	80
Thy22	40	56	56	75	81	25	50	65
Thy23	100	100	100	60	63	100	100	80
Thy24	95	93	100	90	75	88	100	50
Thy25	100	93	100	45	75	100	58	75
Thy26	95	88	67	75	75	88	83	70
Thy27	90	100	100	40	63	100	100	55
Thy29	60	81	78	45	69	75	75	55
Thy3	95	81	100	90	93	100	100	90
Thy30	80	56	89	65	75	68	58	40
Thy31	50	50	34	15	50	13	42	50
Thy32	65	50	67	20	50	88	75	35
Thy33	90	93	100	90	81	100	100	75
Thy34	100	100	100	90	75	100	100	75
Thy36	55	56	78	40	69	75	50	55
Thy37	95	100	100	50	81	100	92	80
Thy38	85	81	78	60	44	88	83	35
Thy39	100	100	100	50	75	100	100	85
Thy4	90	100	100	95	63	100	92	95
Thy40	70	93	100	80	88	100	92	90
Thy41	100	100	100	80	88	100	100	80
Thy42	90	56	78	55	31	68	50	30
Thy43	50	19	0	30	13	0	33	10
Thy44	100	93	89	80	88	100	92	85
Thy45	95	100	78	80	93	100	100	95
Thy46	85	100	100	50	44	100	100	40
Thy47	90	100	89	80	69	100	100	85
Thy48	100	100	100	90	81	100	100	95
Thy5	55	63	67	55	44	88	67	55
Thy6	100	81	100	85	88	50	100	90
Thy7	100	100	100	90	81	100	100	85
Thy9	100	100	100	55	81	100	100	75
Thyroid Average	**83.72**	**84.93**	**86.67**	**67.09**	**72.02**	**85.65**	**84.33**	**69.42**

The raw data allowed the range of scores and the variation between individuals to be appreciated. This was reflected in the standard deviations in the sub-group tables. The sub-group tables allowed a visual comparison of the data and an understanding of where the main differences lay.

The scores for EL appeared low compared to those of the other groups, especially in comparison to LL, whereas the scores for EO were consistently higher than for LO. This is reflected in the number of participants considered to be scoring poorly, defined as scores <=50 across the item range. 6 out of 17 EL patients fell into this category, 4 from 15 LL, 4 from 32 EO and 14 from 35 LO. No thyroid patient scored at a low enough level to be included in this group. All sub-groups, including thyroid entered their lowest score for GH. For EL the next lowest ratings were for RF and RP. LL, in contrast scored at a low level on PF, with MH also comparatively low. This pattern was mirrored by the EO and LO groups. Thyroid patients had the highest scores and thus reported better quality of life, although three areas: GH, MH and Vitality were scored at a lower level than the other items. Bringing these scores together allowed an easier comparison between sub-groups and the aggregated scores were as presented in Table 7.1.1.2.

Table 7.1.1.2. Descriptive Statistics for SF-36

Study group	PF Mean (SD)	RP Mean (SD)	BP Mean (SD)	GH Mean (SD)	Vitality Mean (SD)	SF Mean (SD)	RE Mean (SD)	MH Mean (SD)
All n=142 mean (SD)	69.69 (31.14)	72.37 (30.41)	77.92 (30.41	62.96 (23.02)	69.92 (21.55)	77.47 (29.55)	73.79 (29.99)	65.96 (22.56)
EL n=17 mean (SD)	60.00 (35.62)	58.41 (31.58)	69.88 (34.86)	54.71 (22.74)	60.00 (22.57)	61.06 (29.84)	56.88 (33.86)	57.94 (20.08)
LL n=15 mean (SD)	73.00 (25.97)	79.60 (25.01)	85.33 (19.79)	71.00 (15.61)	80.53 (13.07)	80.93 (21.09)	83.93 (20.90)	76.00 (13.26)
EO n=32 mean (SD	72.84 (29.97)	77.12 (29.09)	85.56 (17.77)	71.88 (18.08)	76.06 (13.90)	88.16 (21.34)	81.50 (25.05)	73.28 (16.93)
LO=35 mean (SD)	52.86 (36.65)	56.26 (34.633)	60.89 (34.4.3)	50.29 (25.81)	61.97 (28.14)	64.14 (36.66)	57.66 (35.34)	54.26 (27.56)
Thy=4 mean (SD)	83.72 (17.60)	84.93 (20.68)	86.67 (20.55)	67.09 (21.39)	72.02 (18.92)	85.65 (20.55)	84.33 (20.86)	69.42 (21.22)

Key: PF=Physical Function, RP=Role Physical, BP= Bodily Pain, GH= General Health, SF= Social Function, RF= Role Function and MH= Mental Health.

To allow statistical comparison between sub-groups but also between factors which might influence the overall score, the data was entered into SPSS v 15. In common with the previous chapter, I applied the Bonferroni adjustment and the level for statistical significance was set at p<=0.01. Factors included in the analysis included: H&N v Thyroid, Early v Late, Oral v Larynx, and Gender. An

ANOVA was used to test significance between sub-groups, an independent T-test was used for the direct comparisons between two groups.

Table 7.1.1.3 ANOVA SF-36 by Sub-group

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Sig (2 tailed)	95% Confidence Interval	
						Lower Bound	Upper Bound
PF	**Thy**	**LO**	30.86	6.63	**p<0.0001**	11.94	49.79
RP	**Thy**	**LO**	28.67	6.44	**p<0.0001**	10.29	47.05
BP	**EO**	**LO**	24.67	6.36	**p=0.002**	6.52	42.84
	Thy	**LO**	25.79	5.92	**p<0.0001**	8.89	42.69
GH	**EL**	**LO**	21.59	5.27	**p=0.001**	6.54	36.63
	Thy	**LO**	16,81	4.91	**p=0.008**	2.80	30.81
SF	**EO**	**LO**	24.01	6.79	**p=0.006**	4.64	43.39
	Thy	**LO**	21.51	6.32	**p=0.009**	3.47	39.54
RF	**EO**	**LO**	23.84	6.76	**p=0.006**	4.56	43.13
	Thy	**EL**	27.44	7.92	**p=0.007**	4.85	50.04
	Thy	**LO**	26.67	6.29	**p<0.0001**	8.72	44.62
MH	**EO**	**LO**	19.02	5.259	**p=0.004**	4.04	33.99

The ANOVA indicated significant differences between sub-groups. For **PF** and **RF** thyroid patients scored significantly higher than LO. For **BP** thyroid patients again scored significantly higher than LO but LO patients also scored at a significantly lower than EO, for the first time in this analysis suggesting a difference related to therapeutic burden. The trend for LO patients to score at a lower level than the other sub-groups continued and for **GH** they again scored significantly lower than thyroid but also than another H&N sub-group, this time EL. For **SF** thyroid and EO patients scored significantly better than LO. **RF** showed similar results, again with thyroid scoring significantly higher than LO and EL, and LO, in turn had a significantly lower score than thyroid as noted above but also than EO. For the final item, **MH**, the one result reaching significance according to our criteria was for EO patients compared to the LO sub-group.

This first group analysis brought together some interesting findings. Despite the reported problems in returning to normal life after cancer as illustrated by the patient and carer narrative in chapter 1 and the figures on return to work (Chapter 5, section 5.2) LL patients scored consistently higher than not only LO but EL although this did not reach significance. Trends emerging from this data were that EO patients scored generally well, followed by EL and LL with LO consistently entering the lowest scores. Thyroid patients appeared to be scoring significantly

higher than the H&N groups, explored using an independent samples t-test, with equal variances not assumed, as shown in the table below.

Table 7.1.1.4 H&N v Thyroid, Independent Samples t-test

Item	T	df	Sig	Mean diff	Std error	95% CI	
						Lower	Upper
PF	-4.65	135.33	**p<0.0001**	-20.13	4.32	-28.68	-11.57
RP	-3.98	120.46	**p<0.0001**	-18.02	4.53	-26.99	-9.05
BP	-2.89	113.56	**p=0.005**	-12.56	4.34	-21.16	-3.96
RF	-3.3	119.28	**p=0.001**	-15.11	4.54	-24.1	-6.13

Equal variances not assumed. df=degrees of freedom, sig=significance (2 tailed), mean diff=mean difference, std error= standard error difference, 95%CI= 95%Confidence Interval of the difference.

This indicates a significant difference for BP and RF highly significant differences for PF and RP. Vitality and MH showed a trend towards higher scores for thyroid patients but this did not reach significance. This would support the hypothesis that thyroid patients report QoL in a different way to H&N and that they should be considered as a separate entity in QoL studies.

The relationship between early (i.e. single modality therapy) and late (i.e. multimodality therapy) was analysed in the same way, but no significant differences were seen, although there was a trend for early patients to report better QoL. For oral v larynx no significant differences were seen. Stage I&II patients tended to score higher than late Stage III&IV patients and this reached significance for BP. (Table 7.1.1.5).

Table 7.1.1.5 Stage I-II v Stage III-IV. Independent Samples t-test

Item	T	df	Sig	Mean diff	Std error	95%CI	
						Lower	Upper
BP	2.83	92.52	**p=0.006**	16.11	5.69	4.8	27.41

Gender proved interesting in that the results varied depending on whether the whole study group was selected or H&N patients alone. When the whole group was selected (81 males and 61 females) the female scores were consistently higher, although this only reached significance for GH (t=-2.81, df=138.26, sig [2 tailed] p=0.006, std error=3.72, 95%CI= -17.84 to -3.117). However, when the thyroid patients were removed from the analysis, this tendency to higher scores for females was reversed although statistical significance was not reached.

7.1.1.1 SF-36 Summary

The results from the SF-36 indicated that thyroid patients have higher scores than the H&N groups and, for a number of items, this was a statistically significant difference. The surprising result was the low level of scores recorded by the EL sub-group and the relatively high scores recorded by LL. When the effect of the thyroid patients was removed, multiple significant differences within the H&N sub-groups remained, mainly between LO and EO. Early patients tended to score more highly than late and Stage I&II compared to Stage III&IV, which would be expected if QoL reflects the impact of diagnosis and therapy. The effect of analysing the thyroid patients and H&N separately when gender was considered was shown to influence results and this practice was followed when considering the remaining questionnaires.

7.1.2 EORTC QLQ C30 and Head & Neck Modules

7.1.2.1 Scoring

The QLQ C-30, as already described (Chapter 4, Appendix 4.2), has a score derived from the sum of individual items. The way in which these items contribute to the overall score is shown in Table 7.1.2.1.

Table 7.1.2.1 Scoring and Scales for EORTCQLQ C30

	Abbreviation	Number of items	Items (question numbers)	Item range
Functional Scales				
Physical functioning	PF	5	1 – 5	3
Role functioning	RF	2	6,7	3
Emotional functioning	EF	4	21 – 24	3
Cognitive functioning	CF	2	20,25	3
Social functioning	SF	2	26,27	3
Global health status/QoL				
Global health status/QoL	QL	2	29,30	6
Symptom scales/items				
Fatigue	FA	3	10,12,18	3
Nausea & vomiting	NV	2	14, 15	3
Pain	PA	2	9, 19	3
Dyspnoea	DY	1	8	3
Insomnia	IN	1	11	3
Appetite loss	AP	1	13	3
Constipation	CO	1	16	3
Diarrhoea	DI	1	17	3
Financial difficulties	FI	1	28	3

Item range is the difference between the highest possible and the lowest possible score for an individual question.

The raw score (RS) is the sum of the scores for each domain or item, divided by the number of questions answered in that domain. The score for the functional

domains is derived from the raw score using the equation: *Score = {1-(RS-1)/range} x100.*

For the symptom domains the equation is: *Score = {(RS-10/range) x100.*
The health and quality of life ratings are combined and scored as for the symptom scores.

The responses from a study group are considered valid if more than 50% of items have been scored. The usual convention is that the missing scores are corrected to the mean, that the missing scores are corrected to the pattern of inter-relations calculated using multivariate analysis or that the scores are corrected to the average of items present for that respondent (Ware et al 1993, Morris & Coyle 1994).

The final scores range from 1-100. For the functional scales, as a result of the linear transformation achieved using the equation above a **higher score** represents a **higher level of functioning.** For the symptom scores, the linear transformation is omitted therefore a **higher score** represents a **higher level of symptoms**.

The results are presented by functional domain and by individual symptoms. Because this represented a cumbersome method for reporting which differs from that used in the other questionnaires, I combined the symptom ratings to form a single overall score. The limitations of this approach were recognised, however to gain comparability, some manipulation of the data was necessary and I considered this method represented a reasonable interpretation for the purposes of this study.

7.1.2.2 Results EORTC QLQ C30

For the QLQ C30, 143 records were available for analysis. All participants completed the questionnaire fully so there was no requirement to correct for missing values. The scores were shown in Table 7.1.2.2. For this questionnaire, there are two aspects to consider, the functional domains and the symptom scores. The following tables present the functional scales and overall symptom score by sub-group to allow an overview of the scoring and the level of individual variation. As for SF-36, poorly scoring participants' records were marked in red. Again we saw a pattern of marked individual variation between the different sub-group, both for the functional domains and the overall symptom score.

Table 7.1.2.2 EORTC QLQ C30 Scores

Table 7.1.2.2.1. Early Larynx (EL): 17 responses

Group	PF Score	RF Score	EF Score	CF Score	SFScore	Symptom Score
EL1	100	100	100	83	100	0
EL10	54	33	42	33	33	30
EL11	14	17	8	33	0	48
EL12	33	17	67	67	67	45
EL13	93	100	67	100	100	6
EL14	47	17	50	83	50	37
EL15	100	83	83	50	83	13
EL16	54	83	50	50	100	20
EL18	100	100	100	100	100	0
EL19	93	100	58	83	83	19
EL2	100	100	83	100	100	0
EL3	63	67	8	33	67	38
EL4	47	50	58	50	67	18
EL5	20	0	67	100	33	22
EL6	40	0	92	83	0	11
EL7	87	100	100	100	100	0
EL8	87	83	67	67	100	33
EL Average	**66.58**	**61.76**	**64.71**	**71.47**	**69.59**	**20.00**

Table 7.1.2.2.2 Late Larynx (LL): 15 responses

Group	PF Score	RF Score	EF Score	CF Score	SFScore	Symptom Score
LL1	100	100	67	83	67	12
LL10	60	100	58	67	50	36
LL11	100	83	92	83	83	19
LL12	80	100	83	83	100	5
LL13	93	100	100	83	67	5
LL14	100	83	58	100	67	4
LL15	67	100	67	50	83	51
LL2	54	33	50	67	50	21
LL3	87	67	100	67	100	9
LL4	100	100	100	100	100	0
LL5	100	83	83	83	83	19
LL6	60	50	67	100	83	19
LL7	87	83	75	100	83	14
LL8	100	100	100	100	100	0
LL9	87	83	92	100	100	4
LL Average	**85.00**	**84.33**	**79.47**	**84.40**	**81.07**	**14.53**

Table 7.1.2.2.3. Early Oral (EO): 31 responses

Group	PF Score	RF Score	EF Score	CF Score	SFScore	Symptom Score
EO1	100	100	92	100	67	4
EO10	60	67	92	83	100	12
EO11	93	100	100	100	100	9
EO12	54	33	67	67	100	34
EO13	93	83	83	83	67	2
EO14	100	100	100	100	100	4
EO15	67	83	92	100	100	12
EO16	67	83	67	83	67	16
EO17	63	83	83	83	100	7
EO18	100	100	58	50	50	17
EO19	93	100	67	67	67	11
EO2	100	100	100	100	100	7
EO20	80	67	83	83	67	22
EO21	93	100	75	83	83	6
EO22	67	50	83	83	100	26
EO23	**27**	**0**	**58**	**33**	**50**	**38**
EO24	63	83	83	67	100	10
EO25	100	67	92	100	100	7
EO26	60	67	100	83	100	10
EO27	100	100	100	100	100	0
EO28	93	100	100	100	100	0
EO29	87	100	75	100	83	6
EO3	100	100	100	83	83	12
EO30	87	100	100	100	100	2
EO32	67	50	92	100	83	17
EO34	100	100	100	83	100	0
EO4	93	83	92	100	100	8
EO5	100	100	83	100	100	6
EO6	100	100	100	83	100	2
EO7	100	100	100	100	83	5
EO9	80	100	83	83	100	6
EO Average	**83.45**	**83.84**	**87.10**	**86.45**	**88.71**	**10.26**

Table 7.1.2.2.4. Late Oral (LO): 36 responses

Group	PF Score	RF Score	EF Score	CF Score	SF Score	Symptom Score
LO1	54	100	100	100	100	0
LO10	40	0	0	0	0	44
LO11	60	33	58	83	33	45
LO12	47	50	0	0	33	63
LO13	87	17	67	100	33	27
LO14	63	50	33	50	33	36
LO15	14	33	67	100	50	19
LO16	14	33	100	33	100	22
LO17	100	100	100	100	100	7
LO18	27	0	8	17	0	41
LO19	63	100	33	100	33	38
LO2	67	83	67	67	67	63
LO20	60	83	92	83	67	22
LO21	87	83	58	67	83	23
LO22	100	100	100	100	100	0
LO23	93	100	58	100	83	10
LO24	100	100	92	83	100	4
LO25	100	67	75	100	100	1
LO26	100	83	100	83	100	5
LO27	100	100	92	100	100	4
LO28	87	100	100	100	100	6
LO3	33	17	58	67	67	24
LO30	100	100	100	100	100	0
LO31	54	67	75	100	33	25
LO32	40	0	50	50	67	39
LO34	93	33	67	100	83	7
LO35	14	0	0	33	0	70
LO36	80	83	33	83	67	19
LO37	60	33	58	67	33	43
LO38	14	33	100	83	67	19
LO39	87	83	83	83	100	10
LO5	54	100	100	100	100	9
LO6	40	33	67	67	67	32
LO7	33	33	8	67	83	67
LO8	60	50	83	50	50	37
LO9	100	100	100	100	100	6
LO Average	**64.58**	**60.56**	**66.17**	**75.44**	**67.56**	**24.64**

7.1.2.2.5. Thyroid (Thy): 43 responses

Group	PF Score	RF Score	EF Score	CF Score	SF Score	SymptomScore
Thy1	100	100	100	100	100	1
Thy11	77	83	92	100	100	7
Thy12	80	100	75	83	67	21
Thy13	63	67	67	67	50	20
Thy14	100	100	100	100	100	0
Thy15	100	100	100	83	100	6
Thy16	87	100	100	83	100	0
Thy17	54	100	92	33	100	19
Thy18	100	100	100	100	100	0
Thy2	100	100	83	83	100	6
Thy20	100	100	67	83	100	0
Thy21	63	100	92	100	83	6
Thy22	63	100	83	100	100	5
Thy23	100	100	75	100	100	4
Thy24	87	67	50	83	83	14
Thy25	93	83	83	83	100	4
Thy26	87	67	58	83	67	20
Thy27	80	100	75	83	100	1
Thy29	63	67	83	83	67	11
Thy3	100	100	100	100	100	2
Thy30	87	100	92	67	100	28
Thy31	63	17	17	33	0	63
Thy32	80	67	67	83	100	22
Thy33	87	100	67	100	100	5
Thy34	100	100	75	83	100	0
Thy36	60	67	67	67	83	32
Thy37	100	100	75	67	100	1
Thy38	93	100	75	67	83	22
Thy39	100	100	83	100	67	7
Thy4	93	100	92	100	100	5
Thy40	93	100	100	100	83	0
Thy41	100	100	100	100	67	0
Thy42	100	100	67	100	100	6
Thy43	67	67	42	17	33	50
Thy44	100	100	92	83	100	5
Thy45	87	100	100	100	100	0
Thy46	87	100	67	33	83	14
Thy46	100	100	83	83	100	10
Thy48	100	100	100	100	100	0
Thy5	60	67	50	83	50	32
Thy6	100	100	100	100	100	0
Thy7	100	100	83	100	100	1
Thy9	93	100	92	100	100	4
Thyroid Av	**87.14**	**91.14**	**80.49**	**83.63**	**87.58**	**10.56**

The scores had some similarity to SF 36 in that thyroid patients reported the best QoL, followed by EO and LL. Again, the high scores entered by LL patients were surprising, as were the relatively low scores entered by EL patients. LO patients scored at a lower level than the other sub-groups. In terms of poorly scoring individual records, less patients were identified using the EORTC QLQ C30 than SF36 although 4 from the list of 6 EL patients appeared in both questionnaire subsets. One different patient (EL14) was identified as scoring poorly through the EORTC QLQ C30 but not through SF-36. Only one LL patient (LL2) appeared in both SF-36 and EORTC QLQ C30 subsets and only one (EO23) remained from the four EO patients identified from SF-36. EO27 was the one individual who scored very differently on the two questionnaires and this must raise a query about the accuracy of this participant's use of the touch-screen system. For LO, a smaller number of patients (5) were identified as low scoring using the EORTC QLQ C30 and all were also included in the SF-36 list. As with the SF-36, no thyroid patient scored at a low enough level to be considered in this category.

The second part of this questionnaire looked at specific symptoms and the final part of the questionnaire asked about health and QoL. These were combined as a global HQoL rating as advised in the manual.

The descriptive tables present the results for all items in the QLQ C30 by all participants and by sub-groups. In reading this data it should be remembered that in the functional scales a high score represents good status and this is also true for HQoL; however, for the symptom scales, a low score represents good status.

Table 7.1.2.4. EORTC QLQ C30 descriptive statistics: functional scales

Study group	PF Mean (SD)	RF Mean (SD)	EF Mean (SD)	CF Mean (SD)	SF Mean (SD)	Symptom Score Mean (SD)
All n=142	77.93	77.56	76.30	80.80	79.91	15.61
mean (SD)	(24.20)	(30.42)	(24.58)	(23.05)	(26.83)	(16.32)
EL n=17	66.59	61.76	64.71	71.47	69.59	20.00
mean (SD)	(30.17)	(39.34)	(28.11)	(25.57)	(35.00)	(16.25)
LL n=15	85.00	84.33	79.47	84.40	81.07	14.53
mean (SD)	(16.87)	(20.43)	(17.53)	(15.95)	(17.60)	(14.03)
EO n=31	83.45	83.84	87.10	86.45	88.71	10.26
mean (SD)	(18.87)	(24.14)	(13.28)	(16.36)	(16.27)	(9.29)
LO n=36	64.58	60.56	66.17	75.44	67.56	24.64
mean (SD)	(29.32)	(35.89)	(32.94)	(29.38)	(32.65)	(20.50)
Thy n=43	87.14	91.14	80.49	83.63	87.58	10.56
mean (SD)	(14.88)	(17.46)	(18.58)	(21.05)	(21.84)	(13.88)

Key: PF=Physical Function, RF=Role Function, EF=Emotional Function, CF=Cognitive Function, SF=Social Function.

Table 7.1.2.5 EORTC QLQ C30 descriptive statistics: symptom scales

	Study Group					
Symptom	**All (n=142)**	**EL (n=17)**	**LL (n=15)**	**EO (n=31)**	**LO (n=36)**	**Thy (n=43)**
PA	19.63	20.59	12.20	14.55	35.19	12.47
Mean (SD)	(27.21)	(22.34)	(17.14)	(17.58)	(37.28)	(22.78)
FA	31.15	39.71	41.60	20.58	42.69	22.07
Mean (SD)	(28.46)	(29.14)	(32.00)	(19.57)	(32.41)	(24.17
IN	29.56	37.24	35.53	18.23	35.19	27.88
Mean (SD)	(33.77)	(42.33)	(36.73)	(24.12)	(35.67)	(32.54)
AP	17.82	19.53	15.53	17.19	29.61	8.51
Mean (SD)	(29.64)	(28.99)	(30.53)	(30.91)	(33.67)	(21.94)
NV	9.58	11.71	6.60	5.35	13.81	9.28
Mean (SD)	(20.81)	(26.15)	(13.66)	(15.13)	(23.00)	(22.21)
DY	3.27	3.88	2.20	1.06	9.25	0.00
Mean (SD)	(13.34)	(10.96)	(8.52)	(5.93)	(23.40)	(0.00)
CO	11.23	9.76	13.33	8.55	17.53	7.72
Mean (SD)	(21.69)	(19.58)	(30.37)	(17.09)	(23.22)	(20.34)
DI	8.42	13.71	6.67	2.13	14.75	6.16
Mean (SD)	(19.60)	(29.02)	(18.73)	(8.24)	(24.46)	(14.95)
FD	13.68	22.88	8.87	5.00	26.83	6.95
Mean (SD)	(27.51)	(28.29)	(19.80)	(18.97)	(37.25)	(19.98)

Key: PA=Pain, FA=Fatigue, IN=Insomnia, Ap=Appetite, NV=Nausea&Vomiting, DY=Dyspnoea, CO=Constipation, DI=Diarrhoea, FD=Financial difficulties.

These tables indicated that functional status scores were lower for EL than the other groups, especially PF and RF. The PA and FA symptoms scores appeared to be the most problematic for patients and FA scores were particularly high in the LL and LO sub-groups. IN was also considered to be an issue across the groups and especially for EL, LL and LO patients. Given the return to work profile described in chapter 5 and the importance of work in living after cancer, the financial difficulties item might be expected to mirror those findings. However, it was EL and LO patients who reported difficulties and LL patients appeared not to rate this item highly compared to other aspects of their status. No thyroid patient reported dyspnoea using this scale, hence the nil return in the table.

Table 7.1.2.5 Significant ANOVA results by sub-groups EORTC QLQ C30.

Dependent Variable	**Study Group (I)**	**Study Group (J)**	**Mean diff (I-J)**	**Std Error**	**Significance (2 tailed)**	**95% Confidence Interval**	
						Lower Bound	**Upper Bound**
Physical Functioning (PF)	EO	LO	18.87	5.48	**p=0.008**	3.22	34.51
	Thy	LO	22.56	5.06	**p<0.0001**	8.13	36.98
Role Functioning (RF)	EO	LO	23.28	6.82	**p=0.008**	3.84	42.73
	Thy	EL	29.38	7.97	**p=0.003**	6.64	52.11
	Thy	LO	30.58	6.28	**p<0.0001**	12.66	48.51
Emotional Functioning (EF)	EO	LO	20.93	5.72	**p=0.004**	4.61	37.25
Social Functioning (SF)	EO	LO	21.15	6.25	**p=0.009**	3.31	38.99
	Thy	LO	20.03	5.77	**p=0.007**	3.58	36.47
Symptom Score	E O	LO	-14.38	3.76	**p=0.002**	-25.11	-3.65
	Thy	LO	-14.08	3.47	**p=0.001**	-23.98	-4.18

To explore these findings further the statistical method was followed as described above for the SF-36. The results of the ANOVA by sub-group were as shown in Table 7.1.2.5. Thyroid patients scored at the highest level for **PF**; significantly above the LO with EO also achieving a significantly higher score than LO. For **RF,** EO patients again scored significantly higher than LO and Thyroid significantly higher than both EL and LO. **EF** had significantly different scores in, again, EO v LO, and this item was unusual in that thyroid patients had a relatively high score. There were no significant results for **CF**. For **SF,** EO and Thyroid had significantly better scores than LO. Finally the same two sub-groups also had significantly better scores than LO for the combined symptom score.

When thyroid patients were compared with the H&N group, using an independent samples t-test; highly significant differences were seen for PF (p=<0.0001 95%CI -20,109 to -6.312), RF (p=<0.0001, 95%CI -27.884 to -11.082). and Symptom Score (p=0.009, 95%CI 1.867 to 12.633), This again confirmed the better status of the thyroid patients in terms of the items measured in these questionnaires.

For early v late, no statistically significant results were found although there was a trend towards better scores for the early group for each of the items scored.

No significant differences were found for oral v larynx with larynx patients scoring slightly higher for PF and RF but oral patients scoring slightly higher for EF, CF and SF and almost the same score for the combined Symptom Score (mean score= 17.44 for larynx and 17.99 for oral).

Stage I-II v III-IV had significant results for EF and Symptom Score, with the Stage I-II patients reporting better scores (Table 7.1.2.6).

Table 7.1.2.6 EORTC QLQ C30 Stage I-II v Stage III-IV

Dependent Variable	Study Group (I)	Study Group (J)	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
								Lower Bound	Upper Bound
Emotional Functioning (EF)	**Stage I-II**	**Stage III-IV**	2.90	94.78	**p=0.005**	14.38	4.96	4.53	24.22
Symptom Score	**Stage I-II**	**Stage III-IV**	2.87	95.60	**p=0.005**	-8.96	3.12	-15.16	-2.767

The symptom score explored important facets of patient experience in more detail. Analysing this part of the measure using the same statistical method I found significant results by sub-group for pain (PA) fatigue (FA), appetite (AP),

and financial impact (FI). The statistically significant results were as presented in Table 7.1.2.7.

Again, the main statistical significance was between thyroid and LO and other sub-groups, LL and EO also showed significantly better results than LO in some domains (PA, FA and FI).

Table 7.1.2.7 ANOVA Results for EORTC Symptom Score by Sub-Group

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Significance (2 tailed)	95% Confidence Interval	
						Lower Bound	Upper Bound
Pain (PA)	**Thy**	**LO**	-22,73	5.85	**p=0.002**	-39.41	-6.04
Fatigue (FA)	**EO**	**LO**	-22,11	6.60	**p=0.01**	-40.96	-3.27
Financial Impact (FI)	**Thy**	**LO**	-19.88	5.93	**p=0.01**	-36.80	-2.96

There were no statistically significant differences for Insomnia (IN), nausea and vomiting (NV), constipation (CO) and diarrhoea (DI), It should be remembered that these were follow up patients and also that they were treated in the time before chemotherapy was routinely offered. In this study group, I would not expect to see any significant difference or even a trend in these areas and that was confirmed by the results where the significance score was commonly p=1.000.

The relationship between the H&N and thyroid scores was significant for PA, FA, AP, DY and FI. The scores for the remaining domains (IN, NV, CO and DI) were higher for the H&N groups but did not reach statistical significance. The significant results were as presented in Table 7.1.2.8.

Table 7.1.2.8 Independent samples t-test for H&N v Thyroid, EORTC QLQ C30 Symptom Score

Dependent Variable	T	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
FA	2.76	96.23	**p=0.007**	13.02	4.72	3.65	22.40
AP	2.89	112.84	**p=0.005**	13.35	4.62	4.20	22.50
DY	2.96	98.00	**p=0.004**	4.70	1.59	1.559	7.85

For early v late, scores were consistently higher in the late group than the early group. This reached significance for FA as shown in Table 7.1.2.9.

Table 7.1.2.9 Independent samples t-test for Early v Late, EORTC QLQ C30 Symptom Score

Dependent Variable	T	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
FA	-2.64	93.09	**p=0.01**	-15.02	5.69	-23.32	-3.71

For Stage, the scores were again consistently higher for the Stage III&IV patients than for the Stage I&II but statistical significance was not reached for any individual symptom.

The final consideration was again for gender, where, although there were consistently lower scores for females, no individual item reached statistical significance.

The final element of the EORTC QLQ C30 was the overall rating of health and of quality of life. These were scored on a scale of 1-7 and transformed in the same way as the symptom scores such that a **high** score indicated **better** status. For reporting, these two scales were combined to given a single rating of HQoL.

Table 7.1.2.10 Descriptive Statistics for EORTC HQoL

	Study Group					
	All	**EL**	**LL**	**EO**	**LO**	**Thy**
HQoL score mean (SD)	72.21 (23.76)	70.71 (21.29)	76.60 (18.40)	80.35 (16.92)	59.47 (29.77)	76.07 (21.34)

EO reported the best HQoL, followed by LL and Thy which also had scores above the group mean. In line with the findings so far, EL and LO reported HQoL below the group mean with LO reporting a much lower mean score than the other sub-groups.

At individual level, two EL patients scored below the mid-point (EL5 [42] &EL14 [33]) and three thyroid patients (Thy31 [8], Thy32 [33] & Thy 43 [40]). For LO, twelve patients scored at this level and two of these entered a score of 0 (LO10 [17], LO11 [33], LO12 [8], LO14 [33], LO18 [0], LO19 [33], LO2 [33], LO3 [33], LO32 {25], LO35 [0], LO37 [33] & LO38 [33]).

The consistent finding was that LO patients individually and collectively reported poor QoL as defined by the EORTC QLQ C30. The core module is designed to be used in conjunction with the EORTC QLQ H&N module to give an understanding of status at both general and site specific levels as reported in the next section.

7.1.2.3 EORTC QLQ H&N Module

7.1.2.3.1 Scoring for EORTC QLQ H&N Module

The H&N 35 is scored in a similar fashion to the QLQC30. Again, it is a symptom scale, thus a **higher score** represents a **high level of symptoms**. The raw scores for the 35 questions are reduced to 13 main items, pain (HNPA), swallowing (HNSW), senses (HNSE), social eating (HNSO), social contact (HNSC), sexuality (HNSX), teeth (HNTE), opening mouth (HNOM), dry mouth (HNDR), sticky saliva (HNSS), coughing (HNCO), and feeling ill (HNFI), plus five additional questions on specific aspects of status; use of painkillers (HNPK), nutritional status (HNNU), use of feeding tube (HNFE), weight gain (HNWG) and weight loss (HNWL).

7.1.2.3.2 Results from EORTC QLQ H&N Module

The results were analysed using descriptive statistics to illustrate the characteristics of participants at study and sub-group level and then explored definitively using the method as for the previous questionnaires.

The items of concern for the entire study group were HNDR, HNCO, HNSS and HNSX. For sub-groups the items differed. EL reported HNDR, HNSP, HNCO, HNSS and HNSX. LL prioritised HNSE, HNCO, HNSO, HNSS and HNDR above HNSP. EO patients scored at a lower level but reported HNDR, HNOM, HNCO and HNSX as their main concerns, LO scored at the highest level overall reporting HNDR, HNOM, HNSO, HNCO and HNSX. Thyroid patients had much lower scores and only HNDR and HNCO had scores of note.
This scoring pattern emphasises the morbidity due to dry mouth and allowed the symptom profile for each sub-group to be compared. It was again remarkable that EL patients reported difficulties at a higher level than would be expected compared to LL. For the oral sites, the EO sub-group reported a generally higher QoL in terms of site specific items than LO.

Table 7.1.2.3.1 Descriptive Statistics by Group and Sub-Groups

	Study Group					
Item	**All (n=139)**	**EL(n-16)**	**LL(n=15)**	**EO(n=30)**	**LO(n=15)**	**Thy(n=43)**
HNPA mean (SD)	16.06 (19.97)	15.13 (15.08)	10.60 (13.95)	16.97 (17.63)	27.34 (25..84)	8..49 (15.27)
HNSW mean (SD)	15.17 (20.99)	17.19 (20.55)	21.07 (26.70)	7.83 (12.20)	29.23 (25.28)	6.05 (11.71)
HNSE mean (SD)	20.15 (26.93)	24.00 (21.90)	52.20 (33.24)	16.63 (27.29)	25.29 (25.28)	5.81 (12.50)
HNSP mean (SD)	18.96 (22.54)	38.56 (25.79)	25.07 (29.15)	7.70 (11.61)	27.46 (23.36)	10.43 (15.17)
HNSO mean (SD)	22.19 (30.56)	17.69 (25.29)	37.27 (44.80)	14.40 (19.89)	46.83 (32.17)	3.98 (9.13)
HNSC mean (SD)	8.54 (16.54)	10.00 (13.89)	4.73 (7.74)	5.27 (9.51)	16.86 (24.84)	4.84 (12.74)
HNSX mean (SD)	26.76 (34.61)	33.31 (38.98)	21.20 (31.18)	27.20 (39.24)	37.17 (36.18)	17.47 (27.22)
HNTE mean (SD)	20.85 (33.43)	25.00 (33.40)	20.00 (37.40)	23.27 (30.53)	31.43 (42.76)	9.30 (21.04)
HNOM mean (SD)	25.15 (36.23)	10.38 (25.40)	19.93 (35.16)	28.87 (34.78)	55.23 (41.23)	5.40 (14.38)
HNDR mean (SD)	43.86 (35.98)	52.12 (38.51)	35.47 (34.48)	42.20 (31.60)	62.83 (37.80)	29.42 (30.25)
HNSS mean (SD)	27.56 (35.92)	33.31 (36.58)	35.60 (38.84)	22.17 (33.15)	50.49 (39.97)	7.72 (17.56)
HNCO mean (SD)	31.84 (30.07)	37.50 (27.04)	42.20 (34.53)	27.70 (32.87)	39.94 (30.15)	22.42 (24.95)
HNFI mean (SD)	13.36 (21.09)	10.31 (15.80)	6.60 (13.66)	8.80 (14.84)	19.94 (24.56)	14.87 (24.45)

Key: HNPA=Pain, HNSW=Swallowing, HNSE=Senses, HNSP=Speech, HNSO=Social Eating, HNSC=Social Contact, HNSX=Sexuality, HNTE=Teeth, HNOM=Opening Mouth, HNDR=Dry Mouth, HNSS=Sticky Saliva, HNCO=Coughing, HNFI=Feeling Ill.

The findings were explored statistically as described above. The results which reached statistical significance were as tabulated below.

Table 7.1.2.3.2. EORTC QLQ H&N ANOVA by Sub-group

Study Group (I)	**Study Group (J)**	**Mean diff (I-J)**	**Std Error**	**Significance (2 tailed)**	**95% Confidence Interval**	
					Lower Bound	**Upper Bound**
EO	**LO**	20.88	5.57	**p=0.003**	5.00	36.77

As before, LO was the sub-group to score at the lowest level.

On direct comparisons using an independent t-test with equal variances not assumed no significant differences were found for H&N v Thyroid, Oral v Larynx

or Gender although the results for gender changed from a mean of 75.08 for females and 70.05 for males with thyroid patients included to 71.55 for females and 70.11 for males once thyroid patients were excluded. Significant results were as shown below.

Table 7.1.2.3.3 Independent t-test for EORTC HRQoL

Dependent Variable	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Stage I&II v III&IV	3.16	94.77	**p=0.002**	14.42	4.56	5.37	23.47

The variables which showed significance were those which relate most strongly to the impact of cancer therapy, i.e. EO v LO and Stage.
In terms of individual impact, I returned to the overall symptom score, presented in Tables 7.1.2.2.1-5. Taking a 'cut off' of <=50 no EL or EO patients scored at a level for concern, LL15 [score 51], LO12 [63], LO35 [70], LO7 [67], Thy31 [63] and Thy43 [50] were identified as the most symptomatic patients according to the symptom score. Of this group LL15, LO12 and LO35 had scored consistently poorly on SF-36, EORTC QLQ C30, EORTC HQoL and the symptom score, giving cause for concern about their status.

7.1.3.4. Summary of findings from EORTC QLQ C30 and H&N Modules

The three parts of the EORTC QLQ measure provided detailed and complementary information, allowing an understanding of the QoL status at sub-group level and statistically significant variation in some parameters which might affect status. The factors which most often emerged as significant were EO v LO and Stage I&II v III& IV, i.e. those which affected the therapeutic pathway and the burden of therapy. In terms of sub-group, thyroid patients might be expected to score more highly than the H&N sub-groups, given the fact that much of the H&N module addressed symptoms which may lie outside their experience, however, aspects of their status which caused them concern were identified. Significant differences were found in both the items which at individual level scored most highly but also across the measures as a whole with LO patients scoring significantly lower than the other groups in a number of analyses.

7.1.3 FACT-G and H&N Module

7.1.3.1 FACT-G

7.1.3.1.1 Scoring of the FACT-G questionnaire

The FACT-G consists of 27 questions scored on a Likert scale from 0-4. The mean scores from individual questions, after correction for negative items, are combined into the main domains of Physical (GP), Social (GS), Emotional (GE) and Functional (GF). The questionnaire aims to measure wellbeing. For each a **higher** score represents **better** quality of life. The domains can be added together to give a total score, the highest possible score attainable being 108.

7.1.3.1.2 Results from the FACT-G questionnaire

The results, by study group and sub-groups were as shown in Table 7.1.3.1.

Table 7.1.3.1 FACT-G Descriptive Statistics Study Group & Sub-groups

Domain	Study Group					
	All (n-143)	EL (n=17)	LL (n=15)	EO (n=32/31)	LO (n=36)	Thy (n=43)
GP	19.91	19.29	21.20	21.22	17.06	21.12
Mean (SD)	(4.19)	(4.25)	(2.46)	(2.56)	(5.49)	(3.14)
GS	21.07	17.76	22.67	21.37	19.64	22.79
Mean (SD)	(5.27)	(5.87)	(5.95)	(5.46)	(5.87)	(2.86)
GE	13.20	14.18	13.20	13.58	17.11	9.28
Mean (SD)	(3.90)	(4.48)	(2.43)	(2.13)	(2.18)	(2.20)
GF	19.11	17.65	19.60	20.45	16.72	20.53
Mean (SD)	(5.11)	(5.47)	(3.72)	(4.68)	(5.84)	(4.27)
FACT-G	73.25	68.88	76.67	76.48	70.53	73.72
Mean (SD)	(11.98)	(15.00)	(11.05)	(9.74)	(15.56)	(7.74)

For the whole study group GE gave the lowest score and this was also true at individual sub-group level for EL, LL and EO. GF was the lowest scored item for LO. GE was scored at a particularly low level for thyroid patients. On simply inspecting the data, the means appear to be relatively similar across domains and between study sub-groups than was the case with SF-36 or EORTC; the exception to this was GE as noted above. This is reflected in the SD which is much lower than those for the other questionnaires.

I reviewed the raw data to check which patients scored most poorly, again selecting 50% [score <=54] of the highest possible score as an arbitrary but consistent ‘cut off’. Two EL, one EO, one LL and five LO patients fell below a

score of 54 (EL11 [37], EL12 [47], EO18 [42], LL12 [40], LO10 [29], LO11 {51], LO12 [37], LO18 [51] and LO35 [39]. Of these, four, EL11, LO10, LO18 and LO35 fell into the poorly scoring category for all three general QoL questionnaires. The number of LO patients scoring poorly were reflected in the lower scores for the sub-group as a whole.

Comparisons between factors were carried out using the same methodology as for the previous questionnaires. The statistically significant results were as shown in the following tables.

The ANOVA showed a number of significant findings. For **GP** LL and EO recorded significantly and highly significantly better scores than LO. For **GS** the only result reaching significance was Thy v EL. **GE** was the domain with most significant findings. The LO sub-group, unusually, scored highest with a mean of 17.11 and Thy unusually low with a mean of 9.28. This led to all other sub-groups scoring at a significant level in relation to these with LO scoring significantly higher than EL and LL, EO and Thy at a highly significant level. Thy scored lower than all the other sub-groups at a highly significant level. For **GF** the LO sub-group returned to the lower level of scoring, with significant differences in relation to EO and Thy.

Table 7.1.3.2. FACT-G ANOVA Scores by Sub-group

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Sig (2 tailed)	95% Confidence Interval	
						Lower Bound	Upper Bound
GP	**LL**	**LO**	4.14	1.18	**p=0.006**	0.77	7.52
	EO	**LO**	4.16	0.94	**p<0.0001**	1.49	6.83
GS	**Thy**	**EL**	5.03	1.45	**p=0.007**	0.90	9.15
GE	**EL**	**Thy**	4.90	0.74	**p<0.0001**	2.79	7.00
	LL	**Thy**	3.92	0.79	**p<0.0001**	1.72	6.12
	EO	**Thy**	4.30	0.61	**p<0.0001**	2.57	6.03
	LO	**EL**	2.94	0.76	**p=0.002**	0.77	5.09
	LO	**LL**	3.91	0.79	**p<0.0001**	1.66	6.17
	LO	**EO**	3.53	0.63	**p<0.0001**	1.73	5.33
	LO	**Thy**	7.83	0.58	**p<0.0001**	6.17	9.49
GF	**Thy**	**LO**	3.81	1.11	**p=0.008**	0.65	6.97

Factors which might impact on scoring were tested as for the preceding questionnaires.

Table 7.1.3.3 FACT-G Independent t-test H&N v Thy

Dependent Variable	t	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
GP	-2.63	111.36	**p=0.01**	-1.73	0.66	-3.03	-0.43
GS	-3.16	94.77	**p=0.002**	-2.46	0.73	-3.91	-1.01
GE	12.17	112.87	**p<0.0001**	5.63.	0.46	4.71	6.55

The point of interest from this table was that three of the factors, GP, GS and GF showed significant differences with thyroid patients scoring better than H&N. For GE the reverse was true and this was such a highly significant result that, when the FACT-G total score was analysed, there was no significant difference as GE had skewed the entire score.

For Early v Late GP scores just reached our criteria for significance (p=0.01) with better scores for the early patients, however for GE the late patients scored higher than the early patients, due mainly to the influence of the LO score for this domain, although this result did not reach statistical significance..

Table 7.1.3.4 FACT-G Independent t-test Early v Late

Dependent Variable	t	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
GP	2.64	86.21	**p=0.01**	2.28	0.86	0.56	3.99
GE	-3.59	94.89	**p=0.001**	2.17.	0.60	-3.37	-0.97

For Oral v Larynx, no significant differences were found. Stage, reflecting the impact of therapy, showed significant results for GP, GE and GF (Table 7.1.3.5).

Table 7.1.3.5 FACT-G Independent t-test Stage I&II v III&IV.

Dependent Variable	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
GP	3.11	96.99	**p=0.002**	2.56	0.89	0.80	.4.31
GE	-3.25	68.56	**p=0.003**	-2.03	0.65	-3.33	-0.73
GF	2.85	84.18	**p=0.005**	2.97.	1.04	0.90	5.04

For gender, significant results again were higher for females for GP and GF but lower for GE when thyroid patients' scores were included, due to the low score entered by this group (Table 7.1.3.6).

Table 7.1.3.6 FACT-G Independent t-test Gender

Dependent Variable	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
GP	3.11	96.99	**p=0.002**	2.56	0.89	0.80	.4.31
GE	-3.25	68.56	**p=0.003**	-2.03	0.65	-3.33	-0.73
GF	2.85	84.18	**p=0.005**	2.97.	1.04	0.90	5.04

For H&N patients there were no significant results although there was a trend towards higher scores for females for GP, GS, GF and FACT-G total score but lower scores for females for GE.

7.1.3.2 Summary of FACT-G findings.

Results for FACT-G were influenced by the low score for thyroid patients for GE and the relatively high score, for LO patients in the same domain. This influence carried forward to some of the other groupings.

Nevertheless the questionnaire allowed findings at significant levels in a number of domains, reflecting on the whole, the better status of early stage patients compared to those diagnosed at a more advanced stage of disease.

In common with the other questionnaires, a small group of patients who scored particularly poorly could be identified, mainly from the LO sub-group.

7.1.3.3 FACT H&N Module

7.1.3.3.1 Scoring the FACT H&N Module

The H&N Module consists of 12 additional items. Two of these relate to risk factors, smoking and alcohol consumption, and are not scored. The other 10 items are scored according to the same scheme as in the FACT-G, reversing the scores on the questionnaire for negative items so that a **high** score represents **better** status. The maximum score attainable is 40.

7.1.3.3.2 Results from the FACT H&N Module

The method for scoring the module was the same as for previous questionnaires. The items have been abbreviated to allow tabulation using the following scheme:

I am able to eat the foods that I like Eat

My mouth is dry	DryM
I have trouble breathing	Breath
My voice has its usual quality and strength	Voice
I am able to eat as much food as I want	Food
I am unhappy with the way my face and neck look	App
I can swallow naturally and easily	Swallow
I am able to communicate with others	Comm
I can eat solid food	Solid
I have pain in my mouth, throat or neck	Pain

The H&N group reported lowest scores for breathing, pain and appearance and these items were repeated as the most problematic areas for each sub-group, with some variation in order. Speech was not covered as a single item but LL patients scored well for both voice and communication, the two questions linked to speech.

Table 7.1.3.3.1 FACT H&N Module Descriptive Statistics

Question	Study Group					
	All (n=138)	EL (n=16)	LL (n=15)	EO (n=30)	LO (n=35)	Thy (n=42)
Eat	2.71	2.81	2.53	2.90	1.89	3.29
Mean (SD)	(1.45)	(1.05)	(1.69)	(1.35)	(1.55)	(1.20)
DryM	1.69	2.00	1.47	1.53	2.51	1.07
Mean (SD)	(1.49)	(1.55)	(1.51)	(1.33)	(1.48)	(1.28)
Breath	0.52	1.25	0.73	0.13	0.63	0.36
Mean (SD)	(0.87)	(1.24)	(1.03)	(0.43)	(1.00)	(0.53)
Voice	2.38	1.00	2.07	3.20	2.14	2.62
Mean (SD)	(1.48)	(1.21)	(1.79)	(1.06)	(1.44)	(1.32)
Food	2.64	2.50	2.33	3.03	1.63	3.38
Mean (SD)	(1.53)	(1.41)	(1.63)	(1.40)	(1.61)	(1.04)
App	0.87	0.81	0.47	0.73	1.14	0.90
Mean (SD)	(1.30)	(1.47)	(0.92)	(1.20)	(1.26)	(1.43)
Swallow	2.65	2.38	2.40	2.93	1.71	3.43
Mean (SD)	(1.43)	(1.36)	(1.64)	(1.41)	(1.43)	(0.80)
Comm	3.51	3.19	3.27	3.67	3.37	3.74
Mean (SD)	(0.79)	(0.98)	(1.10)	(0.76)	(0.73)	(0.54)
Solid	2.88	3.06	2.73	3.10	1.51	3.83
Mean (SD)	91.51)	(1.06)	(1.67)	(1.32)	(1.62)	(0.49)
Pain	0.78	0.94	0.60	0.63	1.34	0.43
Mean (SD)	(1.10)	(1.12)	(1.06)	(0.85)	(1.37)	(0.83)

At individual level, a ‘cut-off’ at 50% highest possible score (<=20), as applied to the other questionnaires, did not discriminate between patients in sub-groups. The numbers scoring at <=15, an arbitrary choice to identify the lowest scoring patients, were EL=2, LL=4, EO=3, LO=12 and Thyroid=0. At the higher score the numbers were EL=6, LL=7, EO=9, LO=27 and Thyroid=7. Taking the lower ‘cut-

off' some patients identified were those who had been noted to score at a low level on other questionnaires but most had not previously been identified as reporting problems.

The patients who had previously scored poorly and who fell into that category again were EL5, LL6, LO18, LO32, and LO35.

Table 7.1.3.3.2 FACT-H&N ANOVA

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Sig	95% Confidence Interval	
						Lower Bound	Upper Bound
Eat	**Thy**	**LO**	1.40	0.31	**p<0.0001**	0.51	2.29
DryM	**LO**	**Thy**	1.43	0.32	**p<0.0001**	0.53	2.36
Breath	**EL**	**EO**	1.23	0.25	**p<0.0001**	0.39	1.84
	EL	**Thy**	0.89	0.24	**p=0.003**	0.21	1.58
Voice	**EO**	**EL**	2.20	0.42	**p<0.0001**	1.01	3.39
	Thy	**EL**	1.62	0.40	**p=0.001**	0.49	2.75
Food	**EO**	**LO**	1.41	0.35	**p=0.001**	0.42	2.39
	Thy	**LO**	1.75	0.32	**p<0.0001**	0.85	2.66
Swallow	**EO**	**LO**	1.22	0.32	**p=0.002**	0.31	2.13
Solid	**EL**	**LO**	1.55	0.38	**p=0.001**	0.48	2.62
	EO	**LO**	1.59	0.31	**p<0.0001**	0.70	2.47
	Thy	**LO**	2.32	0.28	**p<0.0001**	1.51	3.13
Pain	**LO**	**Thy**	0.91	0.24	**p=0.002**	0.23	1.60

The statistically significant ANOVA findings for the FACT-H&N were as tabled above: For 'I am able to eat the foods I like' [Eat] EO scored significantly and Thyroid highly significantly better than LO. LO patients, rather oddly given the responses to measures reported earlier, on this questionnaire scored highly for 'my mouth is dry' [DryM]. For interpreting the analysis of this question, it is important to remember that the scores have been reversed so that a good status gives a high score. This response reached significance in comparison to thyroid patients who scored at a low level for this item.

For 'I have trouble breathing' [Breath] all sub-groups entered low scores but EL had the highest score and this reached significance in comparison with EO and Thyroid, For 'voice quality and strength' [Voice], most scores were reasonably high with EL and LO scoring significantly worse than EO and Thyroid EL also significantly higher than EL.

LO patients indicated less 'ability to eat as much food as they desired' [Food] than the other groups, at a statistically significant level compared to EO and Thyroid and this relationship continued with LO scoring significantly lower than EO on the 'swallow easily and naturally' [Swallow] item and with all other sub-groups on 'able to eat solid food' [Solid]. On this latter question Thyroid also scored significantly higher than LL. On the final question, 'I have pain in my mouth, throat and neck' [Pain] LO patients scored surprisingly high considering they had had both surgery and radiotherapy to this area, This score reached significance compared to the Thyroid group, who scored particularly poorly on this item.

For the comparison between H&N and Thyroid, statistical significance was reached for all questions except 'trouble breathing; and 'voice quality and strength'. For 'able to eat as much food as I want', 'can swallow naturally and easily' and 'I can eat solid food' this difference was highly significant ($p<0.0001$).

Table 7.1.3.3.3 FACT-H&N Independent t-test Early v Late

Dependent Variable	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Able to eat food wanted	2.71	91.41	**p=0.008**	0.79	0.29	0.21	1.37
Eat as much food as want	3.24	93.67	**p=0.002**	1.01	0.31	0.39	1.63
Swallow naturally	2.75	93.99	**p=0.007**	0.82.	0.30	0.23	1.41
Eat solid food	4.00	88.86	**p<0.0001**	1.21	0.30	0.61	1.81

These eating related questions were again significant in the comparison between 'early' and 'late' giving the impression that early patients reported significantly better QoL. However these responses were clustered around a single physical entity (Table 7.1.3.3.3.).

For Oral v Larynx, statistical significance was reached for 'trouble breathing' and 'eating solid food' where the oral sub-groups scored at a low level. This relationship was reversed for 'voice quality and strength' where the oral sub-groups scored at a higher level than laryngeal patients (Table 7.1.3.3.4).

Table 7.1.3.3.4 FACT H&N Independent t-test Oral v Larynx

Dependent Variable	t	df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Voice quality & strength	-3.35	52.16	**p=0.001**	-1.15	0.33	-1.78	-0.45

For Stage, highly significant differences (P<0.0001), with Stage I&II scoring at a higher level for all, were found for ‘able to eat the foods I like’, ‘my mouth is dry’, I am able to eat as much food as I want’, ‘I can swallow naturally and easily’ and ‘I can eat solid food’. Again the emphasis is on oral problems and on eating. The only question to reach significance from another aspect of H&N QoL was ‘I have pain in my mouth, throat and neck, where again Stage I&II showed better status (p=0.008).

Finally, for gender, significant differences were seen when Thyroid patients were included in the analysis but not when H&N patients alone were scored.

Table 7.1.3.3.5 FACT-H&N Independent t-test Gender-All Groups

Dependent Variable	t	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Swallow naturally & easily	-3.36	133.00	**p=0.001**	-0.78	0.23	-1.24	-0.32

Men scored at a higher level on the ‘my mouth is dry’ question but women higher than men on the other questions. It seems most likely that this is a direct result of including the thyroid patients, which has skewed the results given that it is unlikely that they would have problems with these functions.

7.1.3.3.4 Summary of Findings from the FACT-H&N Module

This module forms part of a QoL assessment and yet holds 4 questions about eating which are closely related to each other when considered in terms of face validity. It was difficult, using this module, to gain a balanced view of the study population as the ‘eating’; items dominated the analysis. In terms of understanding the needs of this patient population the information derived from this questionnaire was limited in comparison to that from the other measures.

7.1.4 The University of Washington Quality of Life (UWQoLv4) Questionnaire

The UWQoL was designed specifically for use in H&N cancer. It has 12 symptom scores, a single question which allows the participant to choose the three most important domains, and a global rating of QoL (Chapter 4, Appendix 4.6).

7.1.4.1 Scoring the UWQoL Questionnaire

There are two methods of scoring the UWQoLv4 questionnaire. The first method applies the numerical score, as assigned in the manual, to each of the 12 symptom scores and presents the data by median and by quartiles for each question. This is in contrast to the recommendations for the other measures presented in this chapter and, for consistency, I have used the same method for the UWQoL as for the other questionnaires as my aim was comparison in terms of this study population rather than to reference the data to other studies. I have, therefore, presented the data using the mean and SD as for the other measures used in the study.

Using an overall composite score for this questionnaire is not recommended but recent work has suggested that groups of questions can be aggregated to form two composite scores, one for physical function derived from the simple average of chewing, swallowing, speech, taste, saliva and appearance and one for social function derived from the average of anxiety, mood, pain, recreation and social function (Rogers et al 2008).

7.1.4.2 Results from the UWQoLv4 Questionnaire

Both methods of scoring were used to explore the way the questionnaire could be used to report patient status. Table 7.1.4.2.1.

For the combined scores, PF and SF were highest for Thyroid and this sub-group again returned high scores overall, followed by EO, also with high scores throughout. EL scored higher than LL for PF but lower for SF, maintaining the LL sub-group's positive scoring for socially related items across the range of questionnaires. LO again had the lowest scores. At individual item level, the lowest scores varied by sub-group but saliva was prominent (All, EL, LO and second to lowest for EO). LL scored lowest for speech. This is the first time a question has achieved a low rating from this group who, by definition, have had a laryngectomy. The language of the question (Chapter 4, Appendix 4.6) relates

Table 7.1.4.2.1. UWQoLv4 Descriptive Statistics

Domain	Study Group					
	All (n=138)	EL (n=16)	LL (n=15)	EO (n=30)	LO (n=35)	Thy (n=42)
PF	79.39	80.10	74.00	82.53	62.81	92.62
Mean (SD)	(19.34)	(17.58)	(21.04)	(14.66)	(20.38)	(7.55)
SF	79.24	75.52	80.94	83.72	67.43	86.69
Mean (SD)	(17.32)	(18.38)	(14.34)	(12.03)	(22.31)	(9.84)
Pain	78.62	78.13	78.33	82.50	63.57	88.69
Mean (SD)	(27.11)	(28.69)	(29.68)	(19.86)	(33.40)	(18.48)
Appearance	85.69	87.50	83.33	90.83	77.14	89.29
Mean (SD)	(22.38)	(22.36)	(18.09)	(25.83)	(22.99)	(19.24)
Activity	73.55	64.06	80.00	80.83	62.86	78.57
Mean (SD)	(23.74)	(24.10)	(19.37)	(19.35)	(28.03)	(20.34)
Recreation	78.26	68.75	76.67	86.67	64.29	88.10
Mean (SD)	(21.95)	(23.27)	(25.82)	(18.26)	(22.01)	(13.79)
Swallowing	81.16	83.13	74.67	88.33	62.00	93.57
Mean (SD)	(24.91)	(15.37)	(28.75)	(20.36)	(29.69)	(12.46)
Chewing	77.17	84.38	70.00	75.00	54.29	97.62
Mean (SD)	(31.46)	(23.94)	(36.84)	(28.62)	(35.09)	(10.78)
Speech	85.07	79.38	66.67	89.00	77.14	97.62
Mean (SD)	(22.64)	(27.68)	((38.48)	(14.70)	(18.24)	(11.65)
Shoulder	81.01	79.38	76.00	85.33	64.00	94.52
Mean (SD)	(27.43)	(32.45)	(27.46)	(20.63)	(33.71)	(16.56)
Taste	76.09	74.38	68.67	80.00	56.86	92.62
Mean (SD)	(32.18)	(32.30)	(35.43)	(30.51)	(36.76)	(15.47)
Saliva	71.88	71.88	80.67	75.33	49.43	85.00
Mean (SD)	(31.52)	(34.30)	(24.92)	(27.64)	(35.72)	(20.87)
Mood	81.16	76.56	86.67	83.33	72.14	86.90
Mean (SD)	(24.13)	(28.09)	(12.91)	(23.06)	(29.56)	(19.32)
Anxiety	82.83	86.25	88.00	83.67	77.71	83.33
Mean (SD)	(21.61)	(26.55)	(15.21)	(18.10)	(28.19)	(17.20)

mainly to articulation and the level of understanding achieved in different settings (over the phone, family and friends) and this practical wording may be a factor in this response. EO scored lowest for chewing and then saliva, emphasising the local aspects of the disease and therapy. LO returned a score of 49.43 for saliva, the only item to fall below 50. The domains returning the highest scores were appearance (All, EO and second highest for LO). Anxiety scored at a high level, higher than might normally be expected in this cancer population, however, the item relates to anxiety *about your cancer* rather than an overall rating of anxiety. Thyroid patients reported a different experience and their lowest score was for activity and their highest for chewing/speech.

Looking at individuals, the arbitrary 'cut off' of <=50 in either PF, SF or both was applied. This produced 20 records, 2 EL (SF<50), 3LL (PF<50), 1 EO (SF,50) and 14 LO (5 PF & SF <=50, 6 PF<50, 3 SF <50). The domains in which low scores were recorded varied but chewing, speech, taste and saliva were commonly in this category and shoulder for the LO patients, who would be

expected to have had a neck dissection. This showed an interesting contrast with 'Early' sub-groups tending to have low SF scores and 'Late' sub-groups tending to have lower PF scores. In terms of individual participants, a number already noted to score at a low level in the SF-36, EORTC and FACT measures were identified by the 'cut-off', including EL10, EL11, EO23, LL10, LL15, LO10, LO11,

Table 7.1.4.2.2 UWQoLv4 ANOVA by Study Group and Sub-groups

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Sig (2 tailed)	95% Confidence Interval	
						Lower Bound	Upper Bound
Physical Function (PF)	EL	LO	17.29	4.79	p=0.004	3.63	30.97
	EO	LO	19.72	3.95	p<0.0001	8.44	30.99
	Thy	LL	18.62	4.78	p=0.002	4.99	32.25
	Thy	LO	29.81	3.63	p<0.0001	19.44	40.18
Social Function (SF)	EO	LO	16.29	3.92	p=0.001	5.10	27.49
	Thy	LO	19.26	3.61	p<0.0001	8.96	29.55
Pain	Thy	LO	25.12	5.89	p<0.0001	8.31	41.93
Recreation	EO	LO	22.38	4.90	p<0.0001	8.40	36.36
	Thy	LO	23.81	4.51	p<0.0001	10.95	36.67
Swallowing	EO	LO	26.33	5.44	p<0.0001	10.82	41.85
	Thy	LO	31.57	5.00	p<0.0001	17.30	45.84
Chewing	EL	LO	30.09	8.19	p=0.003	6.71	53.47
	Thy	LL	27.62	8.16	p=0.009	4.32	50.92
	Thy	EO	21.62	6.49	p=0.007	4.10	41.14
	Thy	LO	43.33	6.21	p<0.0001	25.60	61.06
Speech	EO	LL	22.33	6.45	p=0.007	3.91	40.75
	Thy	LL	30.95	6.14	p<0.0001	13.43	48.47
	Thy	LO	20.48	4.67	p<0.0001	7.15	33.81
Shoulder	EO	LO	21.33	6.26	p=0.009	3.45	39.21
	Thy	LO	30.52	5.76	p<0.0001	14.08	46.97
Taste	Thy	LO	35.76	6.76	p<0.0001	16.46	55.07
Saliva	LL	LO	31.24	8.86	p=0.006	5.93	56.54
	EO	LO	25.91	7.15	p=0.004	5.50	46.30
	Thy	LO	35.57	6.57	p<0.0001	16.81	54.34

LO12, LO18, LO35, LO6, LO7 and LO8. Therefore, these 13 patients were identified as being consistently low scoring across the range of measures. No Thyroid patient scored at a low enough level to be included in this section.

The same statistical comparisons were carried out as for the other questionnaires. and significant results noted. The results across the domains continued to mirror the main findings from the other questionnaires, that EO patients consistently reported the best scores from the H&N sub-groups, often coming close to the highest level which was consistently achieved by Thyroid patients. EL had the next best scores and LL achieved an intermediate status with LO patients scoring at the least functional and most symptomatic levels. This was highly significant compared to EO in recreation and swallowing and reached significance for most domains.

There were no significant differences for appearance, mood or anxiety.

For the direct comparisons the results were as tabulated below:

Table 7.1.4.2.3 UWQoLv4 H&N v Thyroid Independent samples t-test

Dependent Variable	t	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Physical Function	-8.07	133.89	**p<0.0001**	-19.02	3.20	-23.68	-14.35
Social Function	-4..37	131.78	**P<0.0001**	-10.71	2.45	-15.56	-5.86
Pain	-3.51	118.24	**p=0.001**	-14.47	4.12	-22.63	-6.32
Recreation	-4.41	124.53	**p<0.0001**	-14.14	3.21	-20.48	-7.97
Swallowing	-5.31	135.58	**p<0.0001**	-17.84	3.36	-24.49	-11.19
Chewing	-7.76	128.78	**p<0.0001**	-29.39	3.79	-36.89	-21.90
Speech	-5.92	134.62	**p<0.0001**	-18.04	3.05	-24.06	-12.01
Shoulder	-4.95	126.95	**p<0.0001**	-19.42	3.92	-27.18	-11.66
Taste	-5.55	135.95	**p<0.0001**	-23.77	4.29	-32.24	-15.29
Saliva	-4.00	120.33	**p<0.0001**	-18.85	4.71	-28.18	-9.53

These findings emphasised the differences between Thyroid and H&N, especially in a H&N specific questionnaire. All domains reached a highly significant difference except pain and mood for which significance was reached.

Table 7.1.4.2.4 shows that UWQoL was effective at differentiating between early and late cases and this was most marked in the physical function and swallowing domains, however, early patients had significantly better scores than late in all but activity, mood and anxiety.

Table 7.1.4.2.4 UWQoLv4 Early v Late Independent samples t-test

Dependent Variable	t	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Physical Function	4.13	90.05	**p<0.0001**	15.52	3.80	7.97	23.07
Recreation	2.68	93.18	**P=0.009**	12.44	4.63	3.24	21-63
Swallowing	4.12	83.61	**p<0.0001**	20.72	5.03	10.72	30.72
Chewing	2.97	90.66	**p=0.004**	19.26	6.48	6.39	32.13
Shoulder	2.75	89.06	**p=0.007**	15.66	5.69	4.35	26.97

For Oral v Larynx there were no significant differences.

For Stage a number of highly significant differences were apparent (Table 7.1.4.2.5).

Table 7.1.4.2.5 UWQoLv4 Stage I&II v III&IV Independent samples t-test

Dependent Variable	T	Df	sig (2 tailed)	Mean diff (I-J)	Std Error	95% Confidence Interval	
						Lower Bound	Upper Bound
Physical Function	6.09	93.83	**p<0.0001**	20.53	3.37	13.84	27.23
Social Function	3.48	93.94	**p=0.001**	11.95	3.44	5.13	18.78
Pain	3.88	90.42	**p<0.0001**	19.81	5.11	9.66	29.95
Appearance	3.19	70.66	**p=0.002**	15.40	4.83	5.78	25.03
Recreation	3.56	89.37	**P=0.001**	15.89	4.46	7.03	24-73
Swallowing	5.50	87.91	**p<0.0001**	24.49	4.45	15.64	33.34
Chewing	4.01	93.81	**p<0.0001**	24.27	6.05	12.26	36.29
Shoulder	3.02	93.91	**p=0.003**	16.37	5.43	5.59	27.17
Taste	3.80	92.52	**p<0.0001**	24.54	6.46	11.73	37.37
Saliva	4.46	93.67	**p<0.0001**	26.42	5.93	14.64	38.19

UWQoL proved effective at distinguishing between Stage I&II and III&IV disease across almost all domains, most of which reached a highly significant statistical difference with Stage I&II patients reporting better QoL. The only domains which did not reach significance were activity, mood and anxiety giving very similar results to the analysis between ‘early’ and ‘late’ cases, a relationship to be expected due to the nature of the queries for a questionnaire effective in measuring QoL in this patient population.

The final comparator in the main part of the questionnaire was gender. When thyroid patients were included the pattern seen in other questionnaires was repeated with physical function (p=0.007), swallowing (p=0.009) and speech (p=0.007) reaching statistical significance. Only for appearance did males score more highly than females but the difference was not statistically significant.

7.1.4.3 UWQoLv4: the Importance Question

For this question the participant is presented with the domains above, each presented as a single word. They are asked to choose the three which they consider to be the most important.

To allow comparison between the study group and sub-groups, I summed the responses thus indicating the frequency with which each domain was selected. The data was as shown in tabulated and graphical form below.

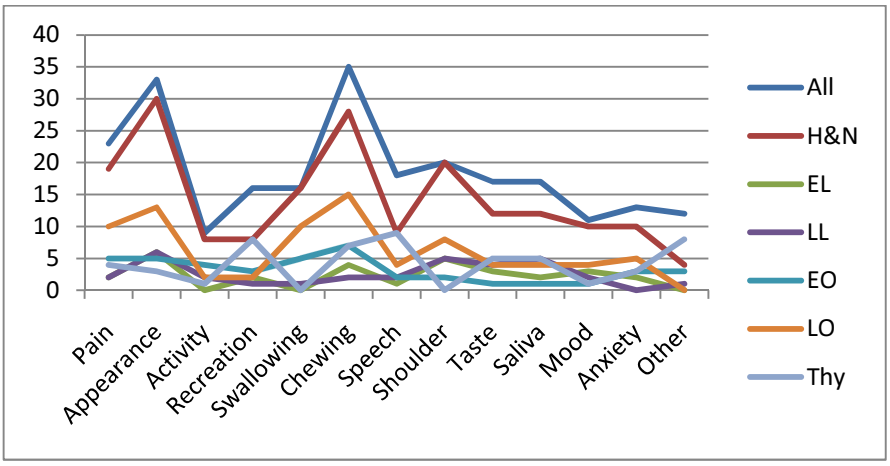
Table 7.1.4.3.1 Descriptives (Frequency) UWQoLv4 Important Domains Question

Domain	Study Group						
	All (n=137)	H&N (n=95)	EL (n=16)	LL (n=15)	EO (n=29)	LO (n=35)	Thy (n=42)
Pain	23	19	2	2	5	10	4
Appearance	33	30	6	6	5	13	3
Activity	9	8	0	2	4	2	1
Recreation	16	8	2	1	3	2	8
Swallowing	16	16	0	1	5	10	0
Chewing	35	28	4	2	7	15	7
Speech	18	9	1	2	2	4	9
Shoulder	20	20	5	5	2	8	0
Taste	17	12	3	4	1	4	5
Saliva	17	12	2	5	1	4	5
Mood	11	10	3	2	1	4	1
Anxiety	13	10	2	0	3	5	3
Other	12	4	0	1	3	0	8

This table allowed comparison between site specific priorities. Of all domains, chewing had the overall highest score, based mainly on the number of LO patients who selected this option. Appearance was next, both of these scoring considerably higher than the next two choices, pain and appearance. Pain is

acknowledged as important, not only for ensuring therapy but also as a marker of recurrent disease or a new primary cancer.

Figure 7.1.4.3.1 UWQoLv4 Graphical representation of domain choices



The graph emphasises the overall pattern of responses and that the biggest H&N group, LO, contributed to the domains prioritised overall as most important, whereas responses for the Thyroid patients had a very different profile.

Conclusions cannot be drawn from the questionnaire data alone but its prioritisation by patients may reflect the view that having pain is unacceptable or that it remains an unresolved issue for a sub-set of patients. Appearance was endorsed across the sub-groups, which is surprising as only a sub-set would be directly affected. The relatively high score for shoulder pain, as a consequence primarily of surgery, indicates that those who have had a neck dissection were likely to rank this as a priority. My hypothesis that thyroid patients represent a different population from the remainder of H&N was supported by their ranking of speech and recreation, which did not achieve high frequencies for the other sub-groups as their main priorities, followed by 'other'. Although the paper version of this questionnaire has a free text option, we were not able to explore this further in our study, as this was not available on the touch-screen.

7.1.4.4 UWQoLv4 The Global QoL Ratings

The global QoL rating enquires about HRQoL and general QoL over the month before developing cancer and the past week. Combining these items can be

done as they have a high correlation with each other (Rogers et al, 2008). This was the approach taken in analysis of my study data.

The mean scores for each group were as shown in Table 7.1.4.4.1.

Table 7.1.4.4.1 UWQoLv4 descriptive statistics: mean scores by sub-group

Domain	Study Group					
	All (n=137)	EL (n=16)	LL (n=15)	EO (n=29)	LO (n=35)	Thy (n=42)
QoL Mean (SD)	3.82 (0.85)	3.63 (0.59)	4.16 (0.73)	4.02 (0.51)	3.24 (1.10)	4.10 (0.67)

As for the previous measures, the relationships were explored using an ANOVA.

Table 7.1.4.4.2 UWQoLv4 ANOVA for comparison of sub-groups (QoL scores)

Dependent Variable	Study Group (I)	Study Group (J)	Mean diff (I-J)	Std Error	Sig (2 tailed)	95% Confidence Interval	
						Lower Bound	Upper Bound
QoL	EL	LO	0.92	0.24	**p=0.002**	0.11	1.72
	EO	LO	0.78	0.19	**p=0.001**	0.13	1.44
	Thy	LO	0.87	0.18	**p<0.0001**	0.27	1.46

This analysis, in one single question, confirmed the core findings to date, in terms of the poor status of LO compared to Thy, EO and EL. The level of significance tailed off in accord with the findings so far from analysis of all measures.

Considering the factors using the same method as for the previous analyses, significant differences were found for H&N v Thyroid with thyroid reporting better QoL (p=0.003, 95%CI -0.69 to -0.14) and Stage I&II v III&IV (p=0.005, 95%CI 0.15 to 0.78).

7.1.4.5 UWQoLv4 Summary

This questionnaire performed well in terms of reflecting QoL in this study population, mirroring the findings of more comprehensive measures. The limitations are the lack of measures of items which have been prioritised in those questionnaires which incorporate general scores and this factor carries the risk that important aspects of status may not be identified. Its strength lies in including aspects of QoL which appear to be endorsed by H&N patients. This is particularly true of shoulder function and this is the only questionnaire which includes this important parameter for those treated by surgery.

7.1.5 HADS & MHI5

7.1.5.1 HADS

The **HADS** incorporates a simple scoring system on a scale from 0-3 for each item. 7 questions measure depression and 7 measure anxiety. Scales for each question are scored so that a **high** score represents a **high** level of anxiety and/or depression. giving a maximum score of 21 for each item. There is much debate in the literature about the cut off levels which indicate psychological morbidity and different scores are suggested for different diseases, however, the main body of the very substantial literature about this questionnaire uses this scheme:

Subscale score	*Interpretation*
8-11	Probable borderline anxiety and/or depression
>11	Probable clinical case of anxiety and/or depression.

These scores were used in this evaluation.

From the descriptive statistics, the population for the whole study group and each sub-group could be considered.

Table 7.1.5.1.1 HADS scoring by Study Group and Sub-groups

Domain	Study Group					
	All (n=135)	EL (n=16)	LL (n=15)	EO (n=27)	LO (n=35)	Thy (n=42)
Anxiety Mean (SD)	4.93 (4.32)	5.63 (4.30)	3.40 (2.95)	2.93 (3.97)	6.03 (4.87)	5.60 (4.03)
Depression Mean (SD)	3.64 (3.84)	4.75 (3.79)	2.40 (2.20)	2.48 (3.46)	5.57 (4.87)	2.79 (2.87)

The scores followed the pattern seen so far with EL and LO scoring more highly than the other groups for both anxiety and depression however, in this questionnaire thyroid patients scored relatively high for anxiety but below the all participant mean for depression.

For this questionnaire, the core findings were gained by looking at the data at individual level and Table 7.1.5.1.1 showed the patients with a score above the ‘cut-off’ level.

The most likely sub-groups for borderline and probable case lay in the EL and LO groups, those who scored poorly in the QoL measures. Of probable cases,

Table 7.1.5.1.2 HADS individual scores

Key: **Red** numbers represent scores at probable 'case' level. Black entries are at borderline level.

Sub-Group	Gender	Age	Stage	TNM	Time from therapy	Occupation	Working	Changed	Anxiety	Depression
L L10	M	59	4	T4N0	64	Car restorer	Yes	Yes	8	8
EL 11	F	58	1	T1	36	Retired	No	No	**16**	8
EL 8	M	50	2	T2N0	44	Sales Man	No	No	8	8
EL3	M	54	4	TisN2	51	Sickness Benefit	No	Yes	11	**12**
EO 16	F	77	4	T4N0	30	Retired	No	No	9	na
EO 18	F	57	1	T1N0M0	12	Property developer	Yes	No	**18**	**15**
EO23	F	71	3	T3N0	19	Retired	No	No	8	10
LL12	M	69	4	T4N2	20	Unemployed	No	No	na	9
LO 1	M	53	1	T1N0M0	48	Accountant	Yes	No	**18**	**18**
LO 14	M	51	4	T4N+	51	Unemployed	No	Yes	**13**	10
LO 15	M	81	4	T4N1	29	Retired	No	No	na	11
LO 8	M	53	4	T4N2B	33	Unemployed	No	No	11	na
LO11	M	51	3	T1N1	54	Unemployed	No	Yes	na	11
LO21	F	77	4	T4N0	32	Retired	No	No	10	na
LO12	M	55	4	T2N2	60	Retired	No	No	**18**	11
LO18	M	63	4	TXN2 Oral excisions +++	26	Sickness Benefit	No	No	**14**	11
LO19	M	55	4	T4N3M0	12	Gardener	Not entered	Not entered	9	na
LO2	M	55	3	T2N1	43	Agency work	Yes	Yes	na	10
LO32	M	47	3	T3N0	28	Disabled	No	No	na	10
LO35	M	47	4	T4N1	33	Unemployed	No	No record	**16**	**19**
Thy 13	F	53		Follicular	56	Unemployed	No	Yes	**15**	na
Thy 23	F	61		Papillary	60	Retired	No	Yes	11	na
Thy 4	M	59		Medullary	59	Salesman	Yes	No	8	na
Thy 5	F	35		Papillary	29	Housewife	No	No	**13**	na
Thy29	M	57		Papillary	43	Retired	No	No	8	na
Thy30	F	49		Follicular	12	Care Worker	Yes	No	9	na
Thy31	F	40		Papillary	15	Housewife	No	No	8	na
Thy34	F	55		Medullary	15	Secretary	Not entered	Not entered	**16**	na
Thy40	F	48		Papillary	19	Sickness Benefit	No	No	8	na
Thy42	F	21		Papillary	14	Student	Not applicable	Not applicable	**13**	9
Thy43	F	45		Papillary	18	Psychiatric Nurse	Yes	Yes	9	**13**
Thy46	F	31		Papillary	30	Finance Assistant	Yes	No	10	Na

anxiety was the item to reach this level in 11 cases and depression in 5. 3 patients scored at a high level for both anxiety and depression, 2 LO and I EO patient.

The statistical comparisons for HADS did not show any significant results.

The patients' personal profiles were mixed in terms of stage, therapy, time from completion of therapy and occupational status. Two were retired, two on sickness benefit and three unemployed, however four were employed or were students; one property developer, one accountant, one secretary and one student. In this small series there did not seem to be any predictors of probable cases and there was no evidence that psychological distress was more common in the early time after therapy. For two patients, there. were possible confounding reasons for a low score. One had had a renal transplant (Thy40, Anxiety score-14) and the other had multiple oral excisions and considerable co-morbidity including pancreatitis (LO18).

7.1.5.2 MHI-5

The **MHI-5** is scored as a simple sum of the items. As yet, no formal 'cut off' has been agreed but a high score reflects higher psychological morbidity. The highest possible score for an item is 6, giving a maximum score for the questionnaire of 30.

Table 7.1.5.2.1 MHI-5 scoring by All Participants and Sub-groups combined: 135 responses

Group	Number	Minimum	Maximum	Mean	Std Deviation
All	135	0	30	13.34	6.57
EL	16	0	25	11.81	6.18
LL	15	5	22	13.47	6.77
EO	27	5	24	12.44	6.51
LO	35	5	30	14.46	6.95
Thy	42	5	24	13.52	6.49

It is interesting to note that, for this questionnaire, EL had the lowest mean score, in contrast to the other measures. LO had the highest score, followed by Thyroid. When the patients with the highest scores were identified, there was little correlation with HADS. Applying an arbitrary 'cut-off' of score >20; i.e. 2/3rds of the highest possible score, the following patients were identified (scores are in

brackets; those with an asterix also scored as borderline or probable cases using HADS: EL2 (25), LL10 (21), LL7 (22), EO10 (22), EO11 (22), EO18* (24), EO21 (21), EO30 (21), EO34 (21), EO5 (21), LO10 (28), LO12* (25), LO18* (21), LO27 (22), LO28 (22), LO32* (25), LO35 (30), Thy30 (22), Thy31(22), Thy33*(21), Thy34* (22), Thy36 (23), Thy37 (21), Thy39 (21), Thy42* (24), Thy44 (25), Thy45(22). In this series EO patients were present, although for the other measures this group has scored well in all domains. EL was under-represented compared with the results of the other questionnaires and Thyroid over-represented in terms of high scores.

Statistical analyses were carried out as for the other questionnaires, however, no significant differences were found.

7.1.5.3 Summary of findings HADS and MHI-5.

Both measures identified psychological morbidity in a number of patients, however, there were marked differences between those identified as having a high score. To establish which is more likely to represent an individual's status, a further study would be required. However, the pattern of results for the HADS followed that of the other questionnaires which suggests that this may be the preferred measure for H&N practice.

7.1.6 Test/retest data by questionnaire

The same considerations applied to each questionnaire in the chapter as was the case for the consultation questionnaires described in Chapter 6, Section 6.1.2. For each questionnaire the test/retest data was compared using an independent t-test and the reproducibility confirmed. The results showed that similar scores were attained by participants at both interventions.

7.2 Patient opinions and preferences for questionnaires

7.2.1 Importance and Well Written ratings by questionnaire

For the general questionnaires the patients were asked to rate each measure for 'importance' and 'well written' as described in Chapter 4 (4.9). They were also asked if they had a clear preference for an individual questionnaire. For the H&N

measures my main aim was to capture views at individual item level so the rating for ‘importance’ and ‘well written’ was attached to each question.

Table 7.2.1.1 Preferences and Ratings for General Questionnaires

	EORTC QLQ C30 All (H&N)	FACT-G All (H&N)	SF-36 All (H&N)	No Preference All (H&N)
Choice	12 (8)	25 (14)	25 (12)	87 (65)
Importance	3.65 (3.40-3.76)	3.66 (3.53-3.75)	3.66 (3.60-3.76)	n/a
Well Written	3.64 (3.47-3.74)	3.63(3.55-3.71)	3.61(3.51-3.69)	n/a

The choice of questionnaire item indicated a trend towards a preference for the FACT-G, which was particularly popular with Thyroid patients. However, the most important point in relation to questionnaire choice is that at test/retest no-one who expressed a preference for a questionnaire chose the same one on the second occasion. Nine participants expressed no preference on both occasions; thirteen supported one measure at intervention 1 and different choice at intervention 2. The only valid conclusion was that patients did not express a preference for a single general measure.

The ratings for ‘importance’ and ‘well written’ were subject to an obvious ceiling effect, with all measures being strongly endorsed. The measures chosen for the study were the lead questionnaires in clinical practice at international level so the high ratings were understandable. As with preference, the only conclusion could be that there were no clear grounds for choice using the ‘importance’ or the ‘well written’ ratings. This was also the case when the results were explored at sub-group levels.

Whilst for the general questionnaires ‘importance’ and ‘well written’ ratings were done for the whole questionnaire, for the H&N measures no overall rating was requested but instead, a rating was entered for each question. In terms of individual questions, for the H&N questionnaires, the highest and lowest scoring for each questionnaire was investigated.

LL scored consistently higher than the other sub-groups and Thyroid consistently lower across all measures. FACT H&N had the highest scores for importance.

Table 7.2.1.2 Importance and Well Written Scores H&N questionnaires by Sub-Group

Questionnaire	Rating	Group /Sub-Group						
		All	EL	LL	EO	LO	H&N	Thy
EORTC H&N	Importance	3.53	3.51	3.88	3.64	3.64	3.65	3.29
FACT H&N	Importance	3.60	3.57	3.90	3.55	3.69	3.66	3.47
UWQoLv4	Importance	3.54	3.49	3.74	3.58	3.64	3.61	3.49
EORTC H&N	Well Written	3.53	3.54	3.80	3.61	3.65	3.64	3.28
FACT H&N	Well Written	3.57	3.55	3.82	3.54	3.67	3.63	3.42
UWQoLv4	Well Written	3.58	3.58	3.86	3.60	3.67	3.66	3.38

For the EORTC QLQ H&N module the highest scoring questions were: dry mouth (mean score=3.76), pain in jaw (mean score=3.76) and painful throat (mean score=3.73). For FACT-H&N the highest scores were swallowing (mean score=3.75), dry mouth (mean score=3.73) and communication (mean score=3.73). For UWQoLv4 the highest scoring question was mood (mean score=3.76), chewing (3.74) and swallowing (3.71). No question scored consistently at other than a high level.

The scores depended on views about the content; no attempt was made to ask participants if there were any significant omissions at individual questionnaire level.

7.3 Patient Opinions about Questionnaires

Comments were analysed from a random sample of 25 patients. In terms of general questionnaires, two, EL16 and Thy30, stated that they preferred SF-36 as most relevant. Nine stated a preference for FACT-G, their reasons being ‘it gives a good summary of how you feel’. Thy32 stated simply ‘I liked the questions’ and Thy35 felt they were ‘more pertinent’. Thy36 said ‘it asks the right questions about H&N’. LO30 considered that FACT-G ‘allowed him to report how he felt’ and LO28 and LO29 considered that FACT-G was ‘relevant’. Thy31 preferred EORTC ‘it is the only questionnaire which explores tiredness and pain’. An EL sub-group patient very much supported the EORTC because ‘the emotional questions are so good’.

For H&N questionnaires Thy29 preferred UWQoL as he considered it ‘more detailed’ and LO30 came to the same conclusion and felt it was the only questionnaire which dealt with surgical issues, especially the ‘shoulder question’

which he considered an important aspect of his status as did LL13. Thy13 also liked UWQoL believing ‘it allowed people to describe how they feel’. There were some criticisms of individual questions, solely for UWQoL. The voice question was ‘confusing’ (LO27) and LO31 indicated that the aspects of the taste question ruled out any response which matched his status.

There was almost unanimous endorsement to the principle of using a psychological questionnaire. Typical responses were ‘they help you describe how you feel’. Of those who expressed a preference, 3 preferred HADS and 3 preferred MHI-5.

A number of participants prioritised domains. Ones which were endorsed by this subset of participants included pain, fatigue, eating, swallowing, appearance, numbness, dribbling and wearing of dentures, most of which, but not all, are part of the questionnaires. Important issues which went beyond questionnaire content were a wish to have all information even if it was bad news, to be given an honest assessment of long term status and to have more awareness of the impact of the disease on family and life in general. In terms of specific areas one patient requested more on tracheostomy.

There were numerous positive comments about the study. ‘A good thing to do;, ‘helps me think through what to talk to the doctors about’, ’helps me describe how I feel’, ‘very good, made me think.’ Some patients from the ‘early’ group pointed out that their status was good so some of the questions did not apply to them, however they were happy to have participated.

7.4 Summary

When I planned the study, my interest was in the opinions of patients about questionnaires and the statistical method described in Chapter 4 was powered to detect differences in preference by questionnaire choice and also by ‘importance’ and ‘well written’ ratings. In the event, choice proved unreliable, and the ratings exhibited a marked ceiling effect. The only valid conclusions from this part of the study were that patients were supportive of all the questionnaires tested. In the second part of the chapter their priorities and how this related to the content of the questionnaires was considered with clear indications as to needs for a clinic based questionnaire assessment.

The scoring proved informative with significant differences between Sub-groups and also for the other factors analysed (H&N v Thyroid, Early v Late, Oral v Larynx, Stage I&II v Stage III&IV and Gender).

In terms of questionnaire ratings, all scored well with FACT-G and H&N marginally achieving the highest scores.

Chapter 8 - The Opinions and Preferences of Clinicians on the Content of Consultations and the use of Questionnaires

8.1 Aims

The **aims** of the clinician study were:

- To gain knowledge about opinions on consultations and questionnaires to allow comparison with the patient views
- To look towards a consensus which might guide creation of a communication tool acceptable to patients and the MDT.
- To determine at what score a clinician would feel an item or issue was worthy of further exploration or assessment in consultation.
- To gain knowledge as to who in the MDT was considered most suitable to pick up on issues raised by patients.

8.2 Study subjects

The subjects were drawn from members of the Leeds / Mid-Yorkshire MDT which meets weekly at the Institute of Oncology, St. James's University Hospital, Leeds. This MDT is one of the UKs largest assessing approximately 250 new patients per year for therapy for H&N cancer and also acts as a tertiary referral centre. As the method included a detailed interview and subsequent analysis an exploratory level sample of convenience was used, ensuring representation across speciality, gender and age. Each participant completed the study according to the same method as described for the patients (Chapter 5). However, an added dimension was an enquiry at specific intervals as to which MDT member would be the best to manage this item if the situation was stable or, alternatively, if the situation was worsening.

All interviews were undertaken by myself and were taped and transcribed to allow careful and detailed analysis.

8.3 Method

The patient study was discussed at the outset and at 3 monthly intervals at the Yorkshire Cancer Network Head and Neck Cancer Site Specific Group meetings and all colleagues were aware of and agreed in principle to participate in the study.

Using the touch-screen computer, as previously described (Chapter 4.5.2), participants were asked to mirror the patient intervention as far as possible. Demographic data was collected on area of specialist practice, duration of specialist practice and communications skill training. We had held a team training day which all members attended so, for the purposes of this question, I was referring to the advanced course offered by the Yorkshire Deanery as a criterion for training in communication skills. Recruitment was designed to capture all disciplines, medical, dental, nursing and allied health professionals who contribute to the MDT discussions and to patient care. A clinician form was developed to guide the interview (Appendix 8.1). The touch-screen was selected for data collection as this allowed clinicians to gain familiarity with the system most likely to form the basis of a future routine in-clinic assessment. Participants completed the 'attitude to consultation' questionnaire, followed by the three generic QoL questionnaires and the three H&N questionnaires. As this was in progress the conversation between the participant and interviewer was taped, using a digital hand-held device (Olympus DS 2200) with the emphasis on gaining as much information as possible on clinician opinions. I personally performed all interviews for this part of the study. Interviews were transcribed verbatim. To ensure that comments could be 'tracked back' to the question, I annotated the hard copy using key words to identify the quote. A portion of a completed transcript, partly integrated with the comments and partly as transcribed, is appended (Appendix 8.2) to show the way the interviews were conducted, how the clinicians adapted to the way the questions were presented and the complexity of this part of the study.

In the first interview it became apparent that a wealth of discussion was possible but that this made completion of the data entry at a single session difficult to achieve. To allow clinicians to proceed at their own pace and to gather as much data as possible about their views the touch-screen was adapted to allow data to be collected over two sessions. Intervention 1 consisted of the 'attitude to

consultation' questionnaire and the generic QoL questionnaires; SF-36, EORTC QLQ C30 and FACT-G. Intervention 2 comprised the H&N specific questionnaires; FACT-H&N, EORTC H&N module and the UWQoLv4. Participants were asked to score items at the level at which they considered a check should be triggered in clinic; i.e. a score which would result in an action. Ratings of 'importance' and 'quality of wording' were more intense than in the patient study in that I asked for opinions on groups of questions rather than simply for the whole questionnaire. I arranged the groups of questions pragmatically to gain opinions on what might need to be done and who was best placed to take responsibility for that section. This usually mapped to the domains, but not always so and the clustering was agreed 'a priori' by myself and the clinicians. This allowed a discussion about who, in the team, would pick up the item in the MDT, once the chosen questionnaire was introduced to the routine setting. For the H&N questionnaires, the method was continued as in the patient study as each item was already individually scored. Discussions were included as to which team member would address specific concerns as already noted above.

8.4 Recruitment

Recruitment took place during the period September 2008 to April 2009. Colleagues were approached and a mutually convenient time agreed to conduct the interview and touch-screen assessment.

The technology performed well with few practical or technical problems until the end of the study when a major upgrade made further entries impossible. However the first participant completed his entry on the 'offline' version of PPM and, when synchronisation was attempted it was discovered that the data had been lost. This interview was subsequently repeated without any further hitch. On two occasions interviews were scheduled and had to be cancelled as PPM updates had been performed, a change which did not automatically take place on the stand alone touch-screen machines and which required a manual update through the IT support. department. When this occurred there were inevitably delays in recruitment and inconvenience to me as a researcher and to the subjects. To avoid the possibility of loss of data I added the scores to the 'hard copy' to allow later entry if further data loss occurred.

On four occasions, clinicians entered data and wished immediately to change their answer. Notes were made of these events to allow manual correction on the database.

Recruitment at pre-arranged times with doctors proved problematic, mainly due to clinical pressures and unplanned clinical events which called them away. The only way to achieve recruitment in a reasonable period was to act opportunistically, interviewing colleagues at the MDT clinic on days when they had a small clinic list. As the workload varies considerably from clinic to clinic, this proved an effective strategy.

At the point where 11 colleagues had completed the whole study and 14 had completed the first part, we had a major problem with the touch-screen. Updates to both the system and new firewall arrangements made the interface problematic. The Trust and University were actively working on a new wireless network and this would take time to introduce. Given the evidence that collection of data by either touch-screen or paper record is comparable, rather than delay the end of the study, a pragmatic decision was taken to end the study at this stage. I subsequently entered the data onto the PPM system to complete the database for analysis for 2 colleagues who completed part 2. One colleague had a period of sick leave so he was unable to complete the second part of the intervention. This gave 14 records for the first intervention and 13 for the second, sufficient for exploration given the detailed nature of the intervention.

8.5 Data validation

Data was exported from PPM as an Access database, transferred to an excel spreadsheet and manually checked against the hard copy. The errors of data entry were manually corrected.

8.6 Data analysis

The data was analysed by demographic characteristics, speciality, scores on the ‘consultation’ and QoL questionnaires, ratings of ‘importance’ and ‘well-written’ and questionnaire preference. After transforming the scores according to the manuals as described for the patient data, I entered it into SPSSv15 for

descriptive statistical analysis. The results were considered together with the transcripts to gain insight into reasons for scores. Note was made of positive and negative comments about each questionnaire and specific questions; this was also considered according to the speciality of the responder: e.g. SALT comment of questions on voice quality.

The final part of this analysis looked at how the MDT might be used to ensure that the most appropriate member looked at and addressed concerns,

8.7 Results

8.7.1. Clinician demographics

14 clinicians participated in the study, 12 completed all questionnaire based assessments and interviews. This sample constituted the majority of MDT members who had face to face clinical contact with patients. Their demographic, speciality data and level of advanced communication skill training were as shown in Table 8.1. All specialist groups currently working in the MDT were represented. Most participants were female which reflects the composition of the MDT, especially at Allied Health Professional and Nursing level, where we do not have any male members in the team.

Table 8.1
Clinician Demographics

Study Number	Gender	Age	Years Qual	Time in Spec	Speciality	Adv Commun
C01	M	45	15	6	MEDONC	Y
C02	F	42	10	4	SALT	N
C03	M	37	10	2	MFS	N
C04	F	44	25	8	CNS	N
C05	F				DIETITIAN	N
C06	M	44	20	11	ENT	Y
C07	F	45	23	11	CNS	Y
C08	F	31	9	8	CNS	N
C09	M	34	16	8	REST DENT	N
C10	F	28	6	3	DIETITIAN	N
C11	M	40	16	8	MFS	N
C12	F	52	28	11	ENT	N
C13	F	43	19	10	CLIN ONC	Y
C14	F	44	7	2	SP NURSE	Y

Key: MEDONC=Medical Oncology, CLINONC=Clinical Oncology, CNS=Clinical Nurse Specialist, ENT= Ear, Nose and Throat Surgeon, MFS= Maxillofacial Surgeon, REST DENT= Restorative Dentist, SALT= Speech and Language Therapist, SP NURSE= Specialist Nurse..

Of the 14 participants, 9 were female and 5 male. The females represented a range of specialities, medical (1), surgical (1) nursing (4) and AHPs (3). The 5 male participants were surgeons (3), a medical oncologist (1) and a restorative dentist (1). The mean age was 41 with a range of 28-52 and a mean of 41.63 for females and 40 for males. The mean time since qualification was 16.08 years with a range of 6 to 28 years and a mean of 16.5 for females and 15.4 for males. The mean time working in H&N was 8.46 years with a range of 2 to 16 years and a mean of 7.5 years for females and 8 for males. These results indicate that the opinions expressed below were those of a team well established in professional work at this cancer site. It is interesting to note that only five of the group had undertaken advanced communication skills. Some participants noted that they were still 'on the Deanery waiting list', a matter which they considered to be of concern.

8.7.2 The 'Consultation' questionnaire

The questionnaire adapted from the work of Detmar et al (2000) was completed by all participants. The results are presented in Table 8.2, showing the mean score to allow immediate comparison between the items according to scores from the whole group and also frequencies to indicate how many clinicians considered their scores to be in each category of response.

Table 8.2: Clinicians' preferences for consultations

			Frequency		
	Question	**Mean Score**	**Rather not**	**If patient mentions**	**Wish to discuss**
Q1	Physical symptoms of illness or side effects of treatment	2.0	0	0	14
Q2	Limitations in physical activity - general	1.7	1	2	11
Q3	Limitations in physical activity - specific to disease	2.0	0	0	14
Q4	How they feel emotionally	1.7	0	4	10
Q5	Impact of treatment on work, housework or leisure	2.0	0	0	14
Q6	Impact of treatment on social activities	1.3	2	6	6
Q7	Impact of treatment on relationships with partner or family	1.6	1	4	9
Q8	Impact of illness or treatment on appearance	1.9	0	2	12

On preferences for the content of consultations, the group were entirely supportive of raising physical symptoms and side effects of treatment, limitations specific to the disease and impact on work or leisure. Appearance followed next, followed by general activities, emotion and finally impact on social activities. The questionnaire had been slightly modified from that used in Chapter 6 as I wished to understand whether clinicians differentiated between close relationships with family and social relationships. In the patient study these two items were grouped together as both partners were often together and I felt a single question was less intrusive. In the clinician study that sensitivity did not apply. Responses were at a similar level for the two, although more clinicians indicated that they 'almost always' asked about family compared to the response for social activities. Within these lower categories the shift in scoring was between a score of 2, i.e. wishing to ensure the item was included towards a score of 1, i.e. allowing the patient to raise these areas if he/she wished. It was unusual for a clinician to state that he or she would not be willing to discuss an item. The clinician who did not wish to discuss general physical aspects of health was a dietitian who felt that this lay outside her specialist area and who also did not wish to explore relationships.

Ratings of what was included in a consultation were lower; comments were made that whilst it would be good to include items, clinic organisational constraints limited the time and the content of consultations. The areas which were considered to 'almost always' be covered were 'symptoms and side effects', to which 12 of the 14 clinicians responded at the highest level. The same response was given for 'limitations specific to the disease or its therapy' suggesting a strong focus in the H&N area and the functions affected by therapy (Table 8.3). 'Overall health' and 'general physical limitations' were the next most likely to be discussed with a gradual decline in probability of discussion as aspects of normal life, emotion and relationships were considered. This change was reflected across the disciplines of the respondents, therefore there must be risk that aspects of care which patients would wish to discuss are not covered in consultations as all members appeared to prioritise the same items.

Table 8.3 Clinicians' perceptions of the content of consultations

			Frequency				
	Question	**Mean Score**	**Never**	**Seldom**	**Some-times**	**Often**	**Almost Always**
Q1	Overall health	3.29	1	0	1	4	8
Q2	Symptoms and Side Effects	3.86	0	0	0	2	12
Q2	Limitations in physical activity - general	3.14	2	0	1	4	7
Q3	Limitations in physical activity - specific to disease	3.86	0	0	0	2	12
Q4	Impact of treatment on work, housework or leisure	2.71	0	3	2	5	4
Q5	Emotional distress	2.71	0	3	4	1	6
Q6	Impact of treatment on relation-ships with partner or family	2.29	1	3	5	1	4
Q7	Impact of treatment on social activities	2.36	2	2	2	5	3
Q8	Impact of illness or treatment on appearance	2.86	0	4	0	4	6

Even for the items which are scored at a lower level, clinicians still had a tendency to respond in the higher categories. Comparing this table with the preferences one above, although participants reported they were more likely to ask about family than about social activities, the response in this section indicates that conversations about close relationships were not common with only 5 clinicians responding in the 'often' or 'almost always' categories.

There appeared to be a strong bias towards physical impact of disease and therapy in both sets of responses.

8.7.3 Clinicians' statements on consultations

In the early part of the interview, some clinicians commented on their practice during consultations. Clinician 13 (C13), a female Clinical Oncologist provided a clear and informative description of her way of carrying out a consultation.

C13: 'for the physical symptoms, well I definitely want to do that, so tick 'yes' for that. The 'limitations' definitely want to do that, 'physical activities specific to the disease' absolutely. 'How they feel emotionally', absolutely. 'Impact on the illness or the treatment and their work', yes. And 'my social activities', yes. I ask them quite a lot as most of them tend to …… yes. In 'impact' - yes I would like to ask them about this, yes and 'their appearance' - yes'.

Sheila: ‘This section asks about how often you actually find that you do manage to include the areas we have just talked about. So it is very similar in terms of its questions’.

C13: ‘so ‘overall health’ ‘almost always’. Start off with open questions, ‘symptoms of disease, side effects of treatments’ ‘always’. ‘limitations in physical activity as a result of disease’ – ‘often’. Oh no sorry probably ‘sometimes’ ‘Limitations of physical as a result’ – ‘always’. ‘Limitations in doing housework’ – ‘often’. Not housework but things. ‘Emotional distress’ - in.. how often do you discuss them? Well we discuss them a lot but it depends in how much you discuss them during their treatment. If you say follow-up cases you may reach the stage where there is a lot of information that you have always wanted so I think sometimes that one gets picked up later. ‘Impact of the disease’ - well that again is something you tend to pick up when you meet them multiple times. So I would only ‘sometimes’ ask that. ‘Social activities - visiting friends and neighbours’ - wouldn’t ask about that, often ask about getting out of the house or getting to the pub but not about friends and neighbours so rarely. ‘Impact of disease on appearance’ - ask about that after surgery and when the radiotherapy has settled if they have any marks. That’s depending on what you see so that’s ‘rarely’ ‘sometimes’ probably because it depends on what they’ve done.’

This narrative hints at some adjustment to consultation content depending on patient’s experience. This was echoed by C12, a female ENT surgeon who indicated that her consultation style and content varied with the time since therapy. She said that with patients well into their follow up period she would always ask a very general question and then follow up issues raised. She would ask about specific symptoms her experience had taught her were important. For tonsillar cancer patients she would ask about pain on swallowing, for laryngeal cancer, speech. She was very aware of fatigue as a limiting and ongoing symptom and placed considerable emphasis on enquiring about whether patients of working age had had the chance to resume work. She expressed a will to talk to employers about the possibility of part-time work if issues such as fatigue made full-time work impossible. She also checked known surgical causes of symptoms which could impact on physical performance, such as manubrial splitting contributing to breathlessness. She was reluctant to engage on the ‘impact’ issues otherwise, considering that this was best covered by her specialist

nurse, having concern about opening lengthy discussions which may not require her medical training: 'Some anxious patients will discuss anything'. C0I, a male Medical Oncologist, accepting that he treated mainly advanced cases, was keen to undertake a wider consultation than he was able to do, simply because time constraints made it necessary to have a personal list of items which would prompt him to take action. This was balanced by the response of the CNS's who each indicated that they saw it as their role to explore with the patients the social aspects of living after cancer and ensuring that any practical help which might assist in this transition was offered. However they had some concerns that adding a questionnaire might 'open Pandora's box by raising a massive number of issues'.

From this part of the study it appeared that attention was paid to each of the items listed by at least one member of the MDT and that the level of practical support and engagement with issues was likely to be more thorough than indicated by the consultation questionnaire alone.

8.7.4 Scoring and importance ratings of questionnaires

8.7.4.1 SF-36

The descriptive statistics were as shown in the Table 8.4. The 'cut off' scores varied but appeared to be at a reasonable level to identify people who had problems. The domain which scored at the highest level was 'bodily pain' but it was interesting to note, in the light of the higher endorsement of physical items in the preferences and perceived content of consultation ratings that the physical function (PF) score was low and the general health rating the lowest.

Table 8.4 Descriptive statistics for SF-36.

Study group	PF Mean (SD)	RP Mean (SD)	BP Mean (SD)	GH Mean (SD)	Vitality Mean (SD)	SF Mean (SD)	RE Mean (SD)	MH Mean (SD)
All n=14	37.14 (21.55)	40.63 (11.69)	57.86 (13.11)	22.50 (15.65)	39.73 (15.23)	51.79 (15.39)	47.02 916.86)	49.64 (12.93)

Key: PF=Physical Function, RP=Role Physical, BP=Bodily Pain, GH=General Health, SF=Social Function, RE=Role Emotional, MH=Mental Health.
Maximum Score=100. High score =Good status.

On reviewing the raw data, only two questions were scored at a level which would require the patient to score very poorly to alert a clinician. These were the

two questions on vigorous activities. Two participants, C12 and C13 mentioned that they would not include these questions as their concern was whether patients could do the moderate tasks associated with everyday living and there was a consensus view that the physical questions were repetitive and a wish to reduce that section to a subset in any questionnaire adopted for clinic use. Similarly there was a consensus view that the general health question, as phrased in this questionnaire was not likely to be discriminating enough to identify problems. It appeared from these scores that the clinicians followed through their dislike of these questions with a rating low in the scale for triggering a check of patient status.

8.7.4.2 EORTC QLQ C30

The descriptive statistics were as shown in Table 8.5. The pattern of responses was a much better fit with the opinions expressed in the consultation questionnaires, with the lowest, i.e. most likely, threshold for checking status being for physical function but showing broadly similar responses across domains.

Table 8.5 Descriptive statistics for EORTC QLQ C30.

Study group	PF Mean (SD)	RF Mean (SD)	EF Mean (SD)	CF Mean (SD)	SF Mean (SD)	Symptom Score Mean (SD)
All n=14	46.93 (11.71)	44.00 (17.02)	39.21 (13.81)	39.21 (18.13)	41.79 (21.510	52.00 (17.10)

Key: PF=Physical Function, RF=Role Function, EF=Emotional Function, CF=Cognitive Function, SF=Social Function. Symptom Score is the aggregated scores from the symptoms list.
Maximum score = 100. Functional scales, high score = good status. Symptom score, high score = poor status.

I have again aggregated the symptom list, which is the way this part of EORTC QLQ C30 is usually presented, into a single score for convenience and to allow an overview of the level at which a check on status would be triggered. Within the individual symptom questions suggested ‘cut-off’ scores were set at a very similar level across items except for fatigue alone where a score of 66 would be required to reach the threshold for attention. The mean score for the overall rating of HQoL was 52.86 (SD 16.84).

During the interviews, there were no consensus negative comments about any item in the EORTC QLQ C30. There was some discussion of the sexuality

question which I have included in the section below on opinions and comments about questionnaires.

8.7.4.3 FACT-G

Table 8.6 shows the descriptive statistics for FACT-G.

Table 8.6 Descriptive statistics for FACT-G

Study Group	GP Mean (SD)	GS Mean (SD)	GE Mean (SD)	GF Mean (SD)
All (n-14)	1.97 (0.77)	1.28 (0.573)	1.82 (0.47)	1.39 (0.51)

Key: GP=General Physical, GS=General Social, GE=General Emotional, GF=General Functional Maximum score =4. High score= good status.

This pattern again followed the consultation data with GP triggering a check of status at the highest score, followed by GE. The scores needed to reach the cut-off threshold as defined by the clinicians in this study were low for both GS and GF.

8.7.4.4 EORTC QLQ H&N Module

The scores for this questionnaire are symptom scores so a higher 'cut off' derived from the clinician ratings means a review of patient status is less likely. The responses show insight into common concerns in that 'teeth' was a category for which there would be a low threshold for review and problems with teeth occur often and can lead to complications as well as pain.

Table 8.7 Descriptive statistics for EORTC QLQ H&N 35

Study Group	Domain						
	HNPA Mean (SD)	**HNSW Mean (SD)**	**HNSE Mean (SD)**	**HNSP Mean (SD)**	**HNSO Mean (SD)**	**HNSC Mean (SD)**	**HNSX Mean (SD)**
All (n=12)	43.67 (14.99)	43.00 (12.34)	52.75 (22.54)	49.92 (16.38)	48.58 (15.54)	49.58 (14.50)	55.67 (20.63)
Study Group	Domain						
	HNTE Mean (SD)	**HNOM Mean (SD)**	**HNDR Mean (SD)**	**HNSS Mean (SD)**	**HNCO Mean (SD)**	**HNFI Mean (SD)**	
All (n=12)	33.08 (14.29)	52.83 (17.51)	61.25 (19.45)	61.33 (13.23)	58.42 (20.95)	55.58 (21.96)	

Key: HNPA=Pain, HNSW=Swallowing, HNSE=Senses, HNSP=Speech, HNSO=Social Eating, HNSC= Social Contact, HNSX=Sexuality, HNTE=Teeth, HNOM=Mouth Opening, HNDR=Dry Mouth, HNSS= Sticky Saliva, HNCO=Coughing, HNFI=Feeling Ill.

On the other hand, the scores to trigger a review for dry mouth and sticky saliva were high, perhaps reflecting the fact that these are almost considered the norm for H&N patients.
The yes/no questions on painkillers (HNPK), nutrition (HNNU), feeding tube (HNFE), weight loss and weight gain (HNWL & HNWG) were also scored. For HNPK the intervention level was set at 55.42 (SD 21.96) but for the other questions it was very high (mean 75, SD 45.23). There was less satisfaction with these than with the main part of the questionnaire and this may have been reflected in the scores.

8.7.4.5 FACT H&N Module

This questionnaire has a list of questions, some positively phrased, some negatively. The scores are adjusted so that a high score reflects good status.

Table 8.8 Descriptive statistics for FACT H&N Module

Study Group	Domain					
	Eat Food Mean (SD)	**Dry M Mean (SD)**	**Breath Mean (SD)**	**Voice Mean (SD)**	**QuFood Mean (SD)**	**App Mean (SD)**
All (n=13)	1.31 (0.86)	2.38 (0.96)	1.62 (0.87)	2.15 (0.90)	2.25 (0.99)	1.92 (0.95)
Study Group	Domain					
	Swallow Mean (SD)	**Comm Mean (SD)**	**Solid Mean (SD)**	**Pain Mean (SD)**	**Smoke Mean (SD)**	**Alcohol Mean (SD)**
All (n=13)	2.31 (1.03)	2.15 (0.69)	1.54 (1.13)	1.54 (0.78)	1.85 (0.99)	1.92 (1.26)

Key: EatFood=Able to eat the foods I like, DryM=My mouth is dry, Breath= I have trouble breathing, Voice= My voice has its usual quality and strength, QuFood=I am able to eat as much food as I want, App=I am unhappy with how my face and neck look, Swallow=I am able to swallow naturally and easily, Comm=I am able to communicate with others, Solids=I can eat solid food, Pain= I have pain in my mouth, face or neck, Smoke=I smoke cigarettes, Alcohol= I drink alcohol.
Maximum score=4. High score =good status.

This response contradicted the one above in that dry mouth was the domain which was scored to trigger a review at the highest score, hence, most likely to happen. The next items were swallowing and communication, again well recognised concerns for this patient population.

8.7.4.6 UWQoLv4

Again, in these scores, clinicians showed vigilance in areas known to be problematic but for this questionnaire there was rather more consistency across

the domains. This may be because it has a physical focus with the exception of the two final questions, relating to mood and anxiety.

Table 8.9 Descriptive statistics for UWQoLv4

Study Group	Domain					
	Pain Mean (SD)	**App Mean (SD)**	**Activity Mean (SD)**	**Rec Mean (SD)**	**Swallow Mean (SD)**	**Chewing Mean (SD)**
All (n=13)	59.62 (21.74)	53.85 (22.47)	55.77 (23.17)	46.15 (13.87)	51.54 (20..76)	65.38 (37.09)
Study Group	Domain					
	Speech Mean (SD)	**Shoulder Mean (SD)**	**Taste Mean (SD)**	**Saliva Mean (SD)**	**Mood Mean (SD)**	**Anxiety Mean (SD)**
All (n=13)	57.69 (19.22)	54.62 (20.26)	66.15 (37.00)	57.69 (19.22)	53.85 (22.47)	56.15 (33.05)

Key: App=Appearance, Rec=Recreation, Swallow=Swallowing.
Maximum score = 100. High score= good status

12 clinicians completed the 'issues' section. Of these 10 chose swallowing, 7 pain, 4 speech, 2 chewing, 2 mood, 1 taste and 1 appearance. Items inserted into the 'other' category were eating and voice. During the discussion there was some unhappiness with the voice question as it was multidimensional, asking about voice quality and strength, and a number of clinicians also felt that eating had both physical and social aspects which were not captured by the swallowing and chewing questions.

8.7.4.7 Summary of questionnaire scoring

The pattern of setting a level at which a review might be triggered is a difficult one. In these results the striking figure is the standard deviation (SD) which is large even for a small group. In interpreting this it is important to remember that most of these scores have been scaled up from single figure scales to a score out of 100. The result is that a difference of one point in the raw data can easily translate to a difference of 25 in the final score. I looked at all raw data scores and found that, for most questionnaires, there was a single score favoured by most of the clinicians and this lay, for the majority of questions, at around 50% of the highest possible score. There is, therefore, more consensus around 'cut-off' scoring than these figures would seem to support. I have chosen to quote the mean in these tables as that, rather than frequency, allowed direct comparison between items in a single questionnaire and also between questionnaires.

The emphasis on physical symptoms and side effects appeared to carry over from the consultation questionnaire to levels for 'cut-off' scores. This was further explored in the analysis of consultations.

8.7.5 Clinicians' views on questionnaires

8.7.5.1 Questionnaire Choice and Importance and Well Written Ratings

For the general questionnaire, a simple choice was requested between measures. Nine chose FACT-G, two the EORTC QLQ C30 and two had no preference.

For the H&N questionnaires, clinicians rated each question for 'importance' and 'well written'

Table 8.10 Clinicians' Ratings: Importance and Well Written

Score	Questionnaire					
	SF-36 Mean (SD)	EORTC QLQ C30 Mean (SD)	FACT-G Mean (SD)	EORTC H&N Mean (SD)	FACT H&N Mean (SD)	UWQoL v4 Mean (SD)
Importance	3.00 (0.88)	3.64 (0.50)	3.64 (0.50)	3.66 (0.20)	3.71 (0.13)	3.69 (0.22)
Well Written	2.71 (0.73)	3.57 (0.51)	3.57 (0.51)	3.60 (0.29)	3.43 (0.33)	3.11 (0.18)

This rating gave identical scores for the EORTC QLQ C30 and FACT-G both of which were well regarded by clinicians. The SF-36 had lower scores and, in addition, had not been selected as the preferred questionnaire by any of the participants.

The H&N questionnaires all scored higher than the general measures by a small margin. For importance FACT H&N had the highest score, followed by UWQoL. EORTC was the best in terms of phrasing and, overall, the questionnaires scored highly. Some questions scored very highly. For the FACT H&N, 'I have trouble breathing?' and 'I have pain in my mouth, throat or neck?' both scored 3.92 for importance and the latter also scored 3.92 on the well written rating. For EORTC, eight questions achieved a score of 3.91 for importance. These were: 'have you had soreness in your mouth?', all of the questions about food consistency, 'have you had trouble eating?', 'have you had trouble talking on the telephone?' and

'have you lost weight?' These all also had high ratings for the quality of the writing with 'have you lost weight' achieving a maximum score at 4. The UWQoL had only one question scoring at 3.92 and that was the first one about pain.

To balance this, there were some questions which scored poorly. For FACT H&N all questions scored well for importance thereby contributing to the overall high score for this questionnaire. Question 5, 'I am able to eat as much food as I want' had the lowest 'well written' rating at 2.85, followed by question 4, 'my voice has its usual quality and strength' at 3.00. For EORTC two questions scored relatively badly, 'have you coughed?' and 'have you felt ill?' Both of these are slightly outside the mainstream H&N questions. For UWQoL, the 'issues' rating was disliked having an importance rating of 3.25 and a well written rating of 2.75 and the overall QoL question scored 3.17 for importance and 3.08 for well written.

Although this is a small group, clear views were expressed about the questionnaires which gave insight into what the qualities of a good question are from the end-users, both clinicians and patients.

The final consideration in this section was who should support the patient in each aspect of care, as described in subsets of questions. There was a remarkable level of agreement that the most effective way to provide care was to have a specialist nurse (the clinical insight was considered very important) who would 'screen' the responses and direct the patient towards the health professional who might meet their needs. The consensus view was that this would be a model which used professional time effectively and, although considerations of health economics lay outside the remit of my work, it was interesting to note that clinicians considered this would be an efficient and potentially cost effective model of care.

8.7.6 Clinicians' Opinions on Questionnaires, material from the interviews.

Although this section is inevitably subjective, it provides an insight into the way that clinicians approach issues and also their preferences in terms of structure of potential questionnaires. For comparison of structure and content, copies of each questionnaire are available as appendices to Chapter 4.

8.7.6.1 SF-36

C01 agreed with the presence of a general health question and indicated he would accept a rating of 'poor' as a cut-off score as his role is in managing people with advanced disease and his expectation is that their status will be poor. He liked the comparison with a year ago and rated it a 'fantastic question' gaining much insight from a single statement. C13 disagreed profoundly: 'This is not the best way to start when the answer is 'I've got cancer'. You need a much better way to ask about general health. H&N cancer is so difficult to live with that to ask them to compare now with how life was before….it might be counter-productive to ask people to compare what they have now to what they had before.' C12 concurred indicating that so much about general health 'depends on the patient's status and the time from therapy. Some we know are right at the bottom of the scale but for others a small change might be important. There is a risk of invoking a wild goose chase if someone's rating fell and that would not be to their benefit.' C02 (SALT) agreed that much would depend on 'where the patient was in the cancer pathway' C11, a Maxillofacial Surgeon, considered that general health was a core part of a standard medical history and thought that the question was poorly written. C12 also preferred including a general health question in the consultation so that the response could be explored and a proper judgement reached about any action to be taken, No participant made a positive comment about this question.

The physical function questions were considered next, providing a range of responses from good function to poor. There was a general feeling that these were repetitive and that there were too many options, although to ask about physical activity was thought to be a good principle and there was much more acceptance of asking patients to rate their ability to perform everyday tasks with which they would be familiar. It was also suggested by C02 that there was a need to have established where the patient was in the pathway to set the responses in context. C14 considered that the questions were far too general and that the focus of care was H&N cancer. Discussing full general status might, she thought, distract attention from the real needs which only the H&N team could support.

The limitations in physical activity questions were guardedly welcomed in that they might lead to interventions which could help improve status. The consensus was that it would be better to put a shorter time scale on this section and ask about the past week rather than the past year. The next questions which brought

together limitations due to physical or emotional factors were welcomed by some clinicians. C13 thought it was a ‘lovely question, further discussion would bring up real issues’ but others thought it would be difficult to define what the issues actually were as the question was so broad. The consensus in favour of ‘limitations due to emotional factors’ was high but the concern was summed up by C12 who said ‘It is what you can do that matters not the time you do it for, giving up a valued activity altogether is really bad in terms of recovery and a return to as much as possible of previous activities should be encouraged’. Attitudes to the question about ‘bodily pain’ differed from a belief that we may underestimate this to a belief that this was a ‘weird way of phrasing the question, why not just pain which is what I would ask about in clinic’.

The latter part of the questionnaire which asks about attitude to illness and how the patient feels, e.g. ‘I tend to get sick more than other people’ was highly criticised. ‘I feel calm and peaceful’, what sort of a question is that? ‘This whole section is simply weird, I don’t think patients would understand it or why we want ot ask these things’. C01 rated this section ‘the worst questions I have ever seen’ and C12 dismissed them as ‘impossible to answer and what would we be able to do with the answers anyway’.

On the whole, there were few positive comments about SF-36 and, although the early part of the questionnaire was acknowledged to address some relevant issues, the later part had no support.

The **EORTC QLQ C30** was generally felt to be clearer and better written. For the first questions which rate physical status there was again a feeling that the list was repetitive and C11 was concerned that the questions were not specific enough to pick up a deterioration in function, Others disagreed and considered a longitudinal rating would be useful in practice. C10 picked up on negativity in terms of language in the questions which began ‘have you had problems with?’ suggesting that this might infer that a problem was to be expected and leading to a report of less good status than was actually the case. The finance question was welcomed especially as three patients were noted by one clinician to have recently lost their homes – ‘we can never underestimate the challenges our patients and their families face and we need to engage with them on this, it can be a greater worry than their cancer’. In general, this questionnaire was much more acceptable to the clinicians than SF-36.

The third general questionnaire, **FACT-G**, had a mixed response despite being the measure most clinicians chose as their preferred option. There were marked positives, summed up by the comment ‘I like its snappiness;’ Similar comments such as ‘clear and concise’ were noted and ‘I like the way this is written, very simple and straight forward.’. However C13 thought that the language was negative with comments like ‘a lack of energy’. She considered that patients already carry the burden of their cancer, some of the questions might make them feel worse. There was a general dislike of the scoring system, especially when double negatives were apparent as in ‘I have trouble meeting the needs…..’, i.e. a negative statement with responses including ‘not at all’ and ‘very much’

For the head and neck questionnaires the **EORTC QLQ H&N** was again considered to be clearly and well written. For the first questions which ask about pain and soreness as separate entities there was some support. C02 said ‘separating these out is really good, patients certainly differentiate’, others however opted for a more simple question using pain alone. C12 was impressed with the EORTC H&N module saying ‘it has nice straightforward questions and it covers important things that the FACT H&N omits.’ She was the only clinician to pick up on the areas which were not covered by the FACT H&N. Questions which were not supported included ‘have you coughed?’ which was felt to be far too generic and difficult to interpret and the talking questions were thought to be repetitive. There was debate on whether a sexuality question or an intimacy one was better, it was agreed that close relationships were affected by H&N cancer and C13 put the broader context very clearly ‘The treatment is disfiguring, added to a poor sense of taste and a dry mouth. The chances of having physical satisfaction from oral contact must be poor. This is much more subtle than just sex’. C10 disagreed ‘I think intimacy is just too wide a term. You have to decide and be specific about what you are asking and a sexuality question achieves that’. C08 summed up the questionnaire as ‘well written and to the point’.

FACT H&N was supported for its brevity. C14 felt it was ‘a good length to use in clinic with some pertinent questions’. C12 was well aware of the omissions; ‘there is no specific question about voice, this needs much more probing’ and C08, another ENT surgeon felt that the voice question was ‘too imprecise and it communication rather than voice which concerns patients’. Of all the questions the final one ‘I have pain in my mouth, throat or neck’ was felt to be the one most likely from all the questionnaires to flag up matters of concern.

The **UWQoL** had supporters but also those who very much disliked it. C01 liked the main questions which were 'written in a way which patients would identify with' but he thought the last few questions 'ruined it'. C08 thought 'it started well and then went off'. C13 was aware of the effect of her previous experience: 'I feel on safe ground, I've used this before'. However she was concerned about the questions asking about more than one thing at once and that patients might not relate to both parts of the question and not know how to score it. C5, a dietitian, had issues with the taste question: 'It tries to simplify things but it doesn't, It encompasses a lot: 'taste food normally, taste most foods normally' well between those options there are lots of food groups. Not good. I don't like any of these.' 'What about I can swallow as well as ever, that could really be as badly as ever but the norm for them, it is open to far too much interpretation'. C10, a SALT, was unhappy with the chewing question: 'chewing with what? Dentures? Own teeth? I think some patients would feel there is no option which they fit'. She also did not like the saliva question, no option for 'too much' which is what the complaint often is 'too much but not effective in lubricating the mouth'; C02 was dismissive of the whole questionnaire: 'I really don't like this. It is not for patients. It focuses on the medical view of problems, I don't know but I am sure it was designed by doctors. Having more than one item in a question makes answering them very difficult and the whole thing is far too wordy'. In her professional capacity as a SALT she had concerns about specific questions: speech: 'very clinically written', taste: 'an awful question. I have read it two or three times and am still struggling with the gradation'. C12 also had concerns 'pain is an issue of change, not of severity, activity depends on what has been done, I would worry if a T1 larynx patient reported a lack of activity but not otherwise, speech question is really poor, the issue is the quality of sound, taste is distorted rather than present or absent. I think this is asking the wrong question'. The 'ratings of importance' question was universally disliked with comments from 'this is an attempt to put QoL in a single box', 'why three items, some people might only have one and others half a dozen.'

In terms of general comments, C13 suggested that QoL questionnaires should have positives. What about 'I am proud of the way I am coping?' She also summed up the findings from the narratives above by saying 'I would have to go with EORTC even though I know it is not easy to use – I have tried it'. C01 preferred EORTC: 'It is clearer and more precise – despite my dislike of the final

questions'. C06 also chose EORTC for precision and clarity. C07 and C08 chose FACT H&N as 'quickest to complete'

8.8 Summary

In summary the most favourable comments together with a lack of significant omissions would, from these narratives, support the EORTC QLQ C30 and H&N modules as the preferred measure for assessing QoL in H&N patients, however the scoring data was more supportive of FACT-G and H&N, showing the difficulties in attempting to identify a 'preferred measure'.

There was a clear preference to discuss physical issues rather than the wider range, although, from the perceived content of consultations responses there appeared to be a belief that most aspects of living with cancer were addressed.

Appendix 8.1

Clinician Interview form

Quality of Life Assessment in Individual Head & Neck Patients

Baseline clinicians' preferences for communication and attitude to QOL issues

Doctor-patient communication is at the centre of good clinical practice and is receiving increasing attention in clinical training. We are interested in which topics you feel you should discuss with your patient during outpatient appointments.

Please tick the appropriate box below.

Would you discuss with your patients during the clinic appointments:

	Rather not	***Yes, provided the patient mentions it first***	***Yes, I would like to discuss this topic***
Physical symptoms of illness or side effects of treatment (e.g. pain, sickness, cough, tiredness)?	☐	☐	☐
Limitations in physical activities (walking, climbing stairs, general fitness)	☐	☐	☐
Limitations in physical activities specific to their disease (eating, speech, swallow, shoulder function)	☐	☐	☐
How they feel emotionally (nervous, anxious, depressed) as a consequence of their illness or treatment	☐	☐	☐
The impact of illness or treatment on their work, housework, leisure activities?	☐	☐	☐
The impact on their social activities (visiting friends, neighbours, clubs)?	☐	☐	☐
The impact of illness and treatment on relationships with their partner or family?	☐	☐	☐
The impact of illness or treatment on their appearance?	☐	☐	☐

Generally, how often do you discuss these issues with your patient during clinic consultations?

	Never	Rarely	Sometimes	Often	Almost always
Overall health	☐	☐	☐	☐	☐
Symptoms of disease or side effects of treatment	☐	☐	☐	☐	☐
Limitations in physical activities as a results of disease / treatment (walking, climbing stairs)	☐	☐	☐	☐	☐
Limitations in physical activities specific to their disease (eating, speech, swallow, shoulder function)	☐	☐	☐	☐	☐
Limitation in doing work / housework or leisure activities	☐	☐	☐	☐	☐
Emotional distress	☐	☐	☐	☐	☐
Impact of disease on relationships with family/partner	☐	☐	☐	☐	☐
Impact of disease on social activities (visiting friends, neighbours)	☐	☐	☐	☐	☐
The impact of disease on appearance?	☐	☐	☐	☐	☐

Clinicians' Characteristics - socio-demographic and professional data

Date…….

Initials…….. **Age**…….. **Gender:** M /F

Doctors:

Speciality : medical oncology clinical oncology ENT surgery

maxillofacial surgery plastic surgery

Qualification level: Consultant Sp Reg

MDT members:

Speciality: CNS Nurse SALT Dietitian

Number of years practising medicine/nursing etc: …….

Number of years working in oncology : ……..

Formal communication skills training Yes /No When (approximate date)…….

Clinicians' opinions- tape for each question

'Cut off': at which score does this become a problem which requires assessment/intervention

Who should receive the information about that score? Doctor/ CNS / MDT member (state specialist area)

What action would you expect to be taken?

Are there any important areas which you feel the questionnaire assessment does not address?

8.2: Transcript of a portion of an interview

Sheila Fisher interview with Clinician (C06) Consultant ENT Surgeon.

Dated 24th November 2008.

Intervention 1 & 2.

Introduction:

SF: What this is is a series of questions and we will look at them here, I'll put the answers on the paper copy as a back up to the touch-screen so don't worry about my writing and I will talk you through how we do a series of questions, and what goes on in answering groups of items which fit together. At the beginning, we have some questions about what you would like to do in consultations and what you actually do. Then we go through some general quality of life questionnaires and finally head and neck ones.

So, here is the first part and I will give you a pen. When you get onto the screen you basically prod it with that and the screen moves on to the next question.

Consultation Preferences entries:

SF: The first 1,2,3,4,5,6,7, or so are to do with what you would like to do in a Consultation.

C06: This is a first visit or any?

SF: This is really during cancer care.

C06: is that locally?

THERE IS A LOT OF BACKGROUND NOISE WHICH IS MAKING IT DIFFICULT TO SEPARATE THE INTERVIEW WITH THE CLINIC NOISES

C06: The difficulty is in my mind is how practical this will be in clinic or what does it cost if we try to do all the things we would like to?

SF: That's fine; we are looking really for the ideal in this first part.

C06: This could be part of this computer - same as 'c' drive?

SF: No, it would need to be somewhere where the patient can easily fill it in and then the results come back to the doctor or staff.

Consultation Practice entries:

C06: Often the number of patients and the need to see different people limit what you can actually say.

SF: In this part we think about what we actually do, not what we want to do. If you're saying with all the standard normal constraints of life it can be difficult, how often do you raise these things when you see people in clinic?

SF: Thank you very much. Now we are going to go onto pressing…

(Entries are completed on the touch-screen)

You have been the most honest of anybody on those questions about consultation and the limitations of time, that is really helpful..

C06: I just say what I do, I mean.

SF: That was great, thank you.

General Questionnaires:

SF-36:

SF: So we are now going to start the SF-36 which is the first of the main quality of life questionnaires and if you want to look at printed version I can show you one. What I would like to do gets difficult at this stage because basically the questions are put to the patient so I would like you to try and answer it at a level at which you would have concerns about someone. So at which point you think somebody seems to be having a problem. I need a bit more info so from time to time I will stop you and ask you some extra questions.

C06: Sorry so are you saying this, that's when you're the patient or as a …

SF: As where you would be worried if a patient was to give that answer.

C06: Oh alright. OK.

SF: For example 'I can swallow,' 'I cough when swallowing'. You as a doctor would know at what level that matters so its that kind of threshold we are looking for. Now the first two are actually stand alone which is quite good because it takes us through who should look at the item in clinic. So yes, could you proceed and you get three questionnaires to look at and if you are trying to think which you like best as you go through, at the end if you can decide, it would be lovely to know which one you liked best of the three questionnaires. So it starts generally and then it goes on.

C06: So if it says what would make me worried?

SF: What would make you say somebody in the team probably ought to be doing something about this patient?

C06: OK,

SF: And do you think that's something that's in the question, is it reasonable to understand as it is written? We ask about this separately…… so how important do you think it is: we are going to do 1-4 on importance and how well written.

C06: Important, 'quite'

SF: 'Quite' so we have a screen for that, that's great. And 'well written' on 1-4

C06: Mm. ok 'well',

SF: That's lovely, OK so if somebody was going to look at that, who in the MDT would you have look at it.

C06: I say 'fair', so the patient has said they have said 'fair'. I mean its given that we have already seen this patient in the MDT and we have highlighted any, you know, serious medical defects so this is assuming the patient from the history did not have anything but they are saying, my …….

SF: This would be their first thing so……

C06: Oh, so this is before MDT, alright ok.

SF: That is the idea, before MDT, so there are 2 scenarios because they have already prompted me on that. The first thing is to think that they always come and say health is 'fair'. Who should look at it then? And the second thing is if they are actually getting worse because that might be somebody different. You have got the options of doctors, CNS, specialist nurses and the various AHP's and then dentist, benfits advisor, others.

C06: I just read it and think. I'm sorry I'm not trying to be silly but I'm trying to understand the scenario. So this is a head and neck cancer patient.

SF: Yes, tick that box.

C06: Right and so what I was saying is if I'm at the LGI on my own before they have come to the MDT, that's slightly different to me and the MDT. I would say ok, CNS.

SF: That's great and if they were actually getting worse, would you stick with the CNS for that as well.

C06: No the doctor, I'd say.

SF: That's lovely, now you have gone through the whole thing once so it now repeats this *ad infinitum*. But we do this in a stage where you do a whole lot of questions. Ok so now we are looking how someone is compared with a year ago. Go for worse again that's very reasonable and again is that something reasonable to ask and is a year ago a good time to compare with.

C06: No, its reasonable, 'quite a lot'. (*Enters this in 'importance' rating*)

SF: That's lovely, and how well written.

C06: 'Well'.

SF: So presumably you would keep this question. If so who would you have see them?

C06: Mm. again the CNS.

SF: Right and if its getting worse?

C06: The doctor.

SF: (*at the start of a list of questions covering aspects of physical status*): Right, now we will take this is a physical basic summary so it goes through various things and it goes through various degrees of difficulties so if we take the next 1,2,3,4,5,6,7,8,9,10 together and then we will see what you think about those as a physical survey.

TS completed.

SF: Right, thank you, and that's the end of that block. So again we are back to what we were doing before so do you feel that's an important or reasonable summary of things and can be quite a lot or very….

C06: 'Very important'.

SF: And how well written do you think?

C06: 'Well'.

SF: And who would you have review those?

C06: The physio.

SF: Right, they are very physical. Ok so we now change it. Basically we were looking at impact to physical health so we had rating of physical health and now its impact on life so the next 4 talk about how much you are able to do in life so we will take those together if we may. (Questionnaire at this stage, moves onto role function)

C06: Right

SF: And what do you feel about those being impact on life rather than a rating of how you are?

C06: (*thinking about 'importance'*) Yes, 'a little' rather than…….

SF: And how well written.

C06: 'Well written'.

SF: So would you actually keep those or would you be inclined to have a straightforward physical rating?

C06: Well I don't think you need all of them, I think you could just have instead of 3 or 4 you could have 2 or 1.

SF: I see, have a sub-set. Fine, and who would you have look at your sub-set?

C06: The OT probably

For comparison, I have added a portion of unedited script to show the need for the hard copy so that the responses and the item about which the participant was talking could be reconciled in the final transcript.

Sheila: now then it goes onto a collection of statements about people's health and if you haven't already guessed which country it comes from I think you will be certain after this one. So we will take the next 4 and then that's the end of this first one. So you are doing well.

?? what would make me worry.

Sheila: what do you think about those? That's the whole questionaire. So

?? I think I'm not sure what responses you would get from patients.

Sheila: that's great. So thinking about it would the good, bad and the ugly in exception that we have got some more to do how do you feel about this questionaire. Good bad or indifferent and we will do the important and well written because they are actually different.

?? that's good, its, you know I mean, any questions for patients are good. Its good.

Sheila: now we are giving it a quite?

?? yes I would say quite. Overall questionaire because obviously there are some bits that are very good and some so quite.

Sheila: so now we go onto basically the European version because it says it is. And this again is general so we are not getting into the specifics until we go through the 3. so this is about the same length as the other one and the 3rd one is shorter and then we get into the head and neck after that. So basically no right or wrong answers and I will be interested in which you like better of these two and then we will take the preferred one forward in comparison with the 3rd. and I will stop you after 5.

We are basically in a physical screen again but slightly different.

?? so again when I would be worried.

Sheila: so we are going to impact again so its really whether you like those better or whether you like the other ones better.

?? I think I like this one better because this is how most patients think

Sheila: so are you going to give it quite a lot or very.

?? very.

Sheila: what about the well written rate.

?? very well written.

Sheila: and who would you have look at it.

?? physio.

Sheila: ok here we have one. But it would be good because we could find something for the physio to do if we have one. We will take the next 2 on impact bit shorter on the impact. Again what do you feel about those.

?? quite a lot.

Sheila: and well written

?? yes, well written

Sheila: and who would you have look at them. Have to go with the other votes there has been a fair spread on this.

?? the last two would visit because asking them exactly particularly.

Sheila: limitations

?? OK, the OT probably ?? if its working out.

Sheila: now we have got a collection of symptoms which are derived from the list of what cancer patients in general described so we will take 1,2,3,4,5,6,7,8,9,10. we stop at diarrhoea just so we get a stop point.
What do you feel about those as a screen

?? yes, mean that I think they are quite a lot. And they are very well written

Sheila: alright and who would you have look at those and one or two people said it does depend a bit on the question, we have got nausea, a bit on appetite, we have got a bit on pain.

?? short of breath I think I would ask the doctor and the rest of them I think for the pain,

Sheila: pain, need to rest, trouble sleeping, weakness.

?? short of breath and pain - doctor, the rest I would say, these would be CNS and then that one you could say physio or …

Sheila: short of breath, ok.

This short portion illustrates the structure of the interview.This transcript ran to 17 pages, the range for the study was 12 to 29 pages.

Chapter 9 - Comparison of Patient and Clinician Opinions

The **aim** of this chapter is to bring together the findings from the previous three chapters and to consider how the findings from the patient study and the clinician study fit together, where there was consensus on which to build and where there were differences. This leads on to a consideration of what might be gained by the introduction of a **carefully designed questionnaire** into clinical practice. The final section builds on the evidence to consider the attributes required of a future questionnaire.

The scene was set by the patient narratives which brought up issues of care, particularly communication and honesty, even when the news is bad. The other aspect which was apparent from the narratives was the price paid for a diagnosis of and therapy for H&N cancer, whether or not the outcome was successful and that this burden is shared by the carer, arguably at a level beyond that for other cancers as the impact on personal, working and social life can be so profound.

The pilot study built on the narratives bringing the experience of patients from our own service into consideration. The important findings from this study were the views of the patients that using the questionnaire helped them talk to their doctors and the level of apparently unmet need that we discovered, indicating that we might improve the effectiveness of the pathway for our patients. The negative aspect was the concern of the doctors that the measure might interfere with priorities and the difficulty in introducing this to the routine setting. This was the experience of Mehanna and Morton (2006) and remained so as recently as earlier this year when Kanatas et al (2009) surveyed members of the British Association of Head and Neck Oncologists (BAHNO) to determine the current use of QoL measures in H&N practice. They found that 53% of clinicians used or had used QoL questionnaires. The main reason for not adopting them remained those which emerged from the pilot study, that they were too intrusive or time-consuming in a clinic setting. Doctors were reluctant to introduce them but would be willing to accept a short and simple measure. This philosophy on the part of clinicians might explain some of the enthusiasm for the FACT-G and H&N questionnaires seen in my study. The question has to be whether limiting the number and content of questions would result in a measure which is effective in

determining patient need or whether there may be an alternative approach to using questionnaires which does not impose a burden on clinical teams, Options for this latter approach include the use of IT or the inclusion of a designated co-ordinator, with the clinical expertise to direct the patient to the help they need, as part of the clinical team.

The definitive study looked to consider aspects of questions which might be important in making them acceptable to both patients and clinicians. This aspiration led to the inclusion of ratings for two key components, 'importance', does the question ask about something that matters and 'well written', is it phrased in such a way that the patient and doctors have a clear understanding of why the question is being asked and the information it seeks to gain?

To set the questionnaire study in context, I wished to explore the aspirations for and the perceived reality of the current 'gold standard' interaction between patients and their doctors, the medical consultation. To allow understanding of and to give some structure to this part of the study I adapted the measure used by Detmar et al (2000). The focus of their work was very much around the patient/doctor interaction and this provided the ideal resource from which to design the consultation assessment.

Both patients and doctors prioritised physical aspects of their status. The matter of most interest was that, for the patients, the 'preferences for consultation' results (Chapter 6, Section 6,1) were very similar across sub-groups whereas the 'perceptions of consultation' results indicated a trend whereby those with a higher therapeutic burden reported more issues being raised in consultation than those requiring single modality therapy. This indicated that doctors might tailor the consultation to their perceived needs of patients or, alternatively, patients with late stage disease and a higher therapeutic burden may feel able to raise a wider range of issues. The analysis of a series of consultations was remarkable for the number of issues raised by patients rather than doctors and that the issues raised by patients were those which merited a higher rating on our scoring system. The indication from this work was that, if patients can be prompted or reminded of issues which are troubling them, an effective interaction should be the result Misunderstandings, as illustrated by one example in this study, might be avoided and if the questionnaire acted as a core document to inform all MDT members of current status, a concept which is wider than the use of questionnaires for measurement alone, communication between team members might be improved.

The pilot study indicated that a well designed questionnaire might be such a prompt. For the clinicians, the level of endorsement of two items, ‘physical symptoms of disease or side effects of treatment’ and ‘limitations in physical therapy specific to disease’ was at a very high level with 12 from 14 participants claiming to discuss these items ‘almost always’ in consultations. This was echoed by the patients as 74.3% reported that ‘physical symptoms and side effects of disease’ were ‘almost always’ raised in consultations and 79.9% reported that ‘physical activities specific to illness’ were ‘almost always’ discussed. This view was further endorsed by the narratives of patients about their cancer care.

The emotional aspects were more uncertain. Of a group of 14 clinicians 6 indicated they ‘almost always’ discussed emotional distress, 89 (61.8%) of patients indicated they would value such a discussion but only 14 (9.7%) indicated this ‘almost always’ took place and, if the category of ‘often’ is added, the level of reported engagement with an important area of patient experience is 18% of clinicians. The levels of engagement, from the point of view of patients’ perception is even lower for social aspects of living with cancer, with only 9 (6.3%) of patients indicating that their doctor ‘almost always’ discussed the impact of their illness on work and leisure or on relationships. When the category of ‘often’ was added the level of communication about these issues remained at just over 10% of consultations.

The ‘consultation’ questionnaire was, in retrospect, limited, in that there was no rating of anxiety, depression or psychological morbidity beyond ‘emotional distress’, yet these issues are known to be important in H&N cancer and were one of the main areas of concern in the pilot study and raised repeatedly in the patient narratives and comments on questionnaires in the definitive study. The principle of including a psychological questionnaire in a future assessment was strongly supported.

The consensus opinion, from both patients and health professionals, was that the emphasis in clinical practice was on physical aspects of disease and this was further endorsed by the patient comments about professional roles and the setting of ‘cut off’ scores for reviewing status suggested by health professionals.

In summary, there was a mutual understanding between patients and their doctors about what was likely to be raised in a medical consultation.

How then does this relate to needs? 89 (61.8%) of patients indicated a wish to discuss how they felt emotionally, 82 (56.9%) wished to discuss the impact of their illness or treatment on work and leisure compared to the 6/14 already noted above who claimed to discuss 'emotional issues' 'almost always' and 4/14 who indicated that they discussed 'impact of treatment' on relationships with partner or family' or 3/14 who indicated that they 'almost always' discussed the impact of the disease or its treatment on work and social activities'. There was a consensus but this consensus indicated a limited model of care with important issues omitted from the care pathway. Against this, we had the narrative of C12 who indicated the care she took to discuss work and the potential for work with her patients and C13 who noted, with distress, the difficult financial circumstances in which some of her patients found themselves. Whether a questionnaire could improve the number of issues raised at consultation has not to date been shown in H&N but the pilot study offered anecdotal evidence that a questionnaire might provoke a wider range of discussion and this has been explored for other cancers with positive results (Velikova et al, 2004).

If a questionnaire is to be used to improve care, it is important that it captures the emotional and social aspects. From the patient narrative the EORTC QLQ C30 appeared to be most effective in capturing this wider, and critically important, dimension of cancer survivorship.

Moving on to the roles of health professionals the patients were very clear about roles – 'I have a wonderful surgeon but he is a surgeon and a specialist.' This raises further issues. Initiatives to date have focussed on equipping doctors to undertake a more holistic role in cancer care, hence the encouragement for senior doctors to attend the advanced communications skills courses. This may not be the most appropriate strategy. Especially in surgery, as a 'hands on' discipline, the consequences of complications of therapy can be difficult to cope with, as indicated in the narrative from 'Cancer Tales' (Chapter 1) and my own personal experience. To add the burden of counselling the patient and carer about the impact of disease may be one burden too many for the doctor. This aspect of professional team support has received less attention than patient needs but is an important aspect of the debate if the best holistic care is to be delivered. From the narrative above and from numerous similar examples, it appears that patients have an empathy with their doctor and there is a mutually protective association. The suggestion from the patient and partner that there

should be someone ‘with common sense in the middle’ has merit and this concept also emerged from consideration of who should address areas of concern in the clinician questionnaire study. The concept of someone who has solely the holistic care of the patient as a priority but is otherwise not responsible for their welfare has merit. It could be argued that this was part of the Improving Outcome Guidance when the concept of a ‘keyworker’ was introduced to clinical care. In practice the ‘keyworker’ has been a member of the current MDT who simply adopted an additional role but, if a questionnaire led consultation were to be trialled, such an individual might play a critically important clinical and collaborative role, placing patient needs at the core of the service and invoking the support of MDT members to best effectiveness. Such a service would be in the spirit of recent cancer reforms and a carefully designed questionnaire has the potential to provide the structure such a patient centred service would require.

H&N patients have considerable needs and their lives can be severely affected by their cancer as indicated by the first consultation reported in Chapter 6. This patient’s major needs were for psychological support and yet it was this aspect of care which was omitted. In his case, use of a psychological questionnaire (HADS) would have identified his need. As he indicated in his interview his mental scars might be invisible but they were no less real than the physical ones. Whether a questionnaire might help identify those in need of support or whether offering psychological support via the clinic is sufficient remains to be investigated. There would seem from both the pilot and the definitive study a need for something beyond clinical acumen to assist patients in gaining psychological support and a questionnaire may assist this aim. From the pilot study it was apparent that those with depression may not request help, so reliance on self-referral may not be effective. A questionnaire may well have a role to play. Within the limits of this study, the HADS would appear to have merit for this purpose. Certainly a higher level of psychological presence in the MDT as advised by Humphris (2008) would seem imperative for best care and support.

In terms of general and H&N specific questionnaires the ratings in terms of ‘importance’ and ‘well written’ indicated that all questionnaires performed well. Both clinicians and patients scored the FACT-G and H&N questionnaires at the highest level. On further exploration the main reason for support was that it contained ‘relevant questions’ and ‘was quick and simple to complete’. Given the primary outcome measure for my study was planned to be patient preference one

might simple endorse the FACT-G and H&N questionnaires as the patients' and clinicians' choice. However, as the study progressed I learned that this issue of a carefully designed questionnaire was not as simple as choice alone. There was not only the matter of what was included but also what was omitted. This was an issue for all measures. For the FACT H&N this was particularly the case as the questionnaire held a series of important questions but was dominated by a series of questions about eating. The EORTC questionnaires received the least criticism in terms of content but did lack questions which relate to the experience of patients who had undergone surgery. The UWQoL questionnaire was the best in terms of including surgical issues but attracted criticism for wording questions in such a way as to make it difficult for patients to communicate their experience using this measure. None of the questionnaires had an item relating to fear of recurrence yet this was frequently mentioned in interviews and consultations and is known to be a matter of distress and to be common in this group of patients (Humphris et al, 2003, Humphris and Ozakinci, 2006, Humphris et al, 2004, Hodges & Humphris, 2008). It may be possible to identify those at risk and develop strategies to help (Llewellyn et al, 2008) so it is important to ensure that fear of recurrence is built into any future questionnaire for routine clinic use. There is no ideal instrument at present for individual assessment but from consideration of both patient and clinician narratives a number of recommendations are possible:

- a future questionnaire should have the breadth of content to capture the patients' experience and assist in the transmission of useful information between the patient and their doctors and other health professionals.
- it should be responsive to all elements of therapy likely to be encountered during the cancer journey.
- it should be simple and easy to complete.
- it should include the ability to identify psychological and social needs.
- it should be acceptable to patients and to health professionals.

On the first of these, there is currently no measure which meets this criterion in full. Of the measures tested, the SF-36 had no support from clinicians and limited support from patients. The FACT questionnaires gained the highest rating but were also noted, especially by clinicians, to have significant omissions and to be skewed in favour of particular elements of patient experience. For capturing the

wider aspects, beyond the physical alone, the EORTC questionnaires were commended by both patients and health professionals. Their weakness is the omission of items highly relevant to surgical patients but, at a holistic level, of the currently validated measures, this study would support the EORTC QLQ C30 and H&N questionnaires as the preferred candidate for use in routine H&N practice. Of the two psychological measures the HADS appeared, in this study, to identify the cohort of patients who were scoring at a low level in other questionnaires and shows promise as a measure for use in H&N oncology practice.

In future consideration should be given to development of sub-modules to address the issues raised in this study and to capture the experience of patients in terms of therapy, side effects and long term morbidity arising from therapy and their cancer in the context of their normal lives. For this latter consideration, the social and financial experiences and challenges of a working parent with young children might be very different from that of a retired person whose children have reached social and financial independence and those of someone just completing radical chemoradiotherapy very different to someone well into the follow-up part of the cancer journey. It is probable that, to really capture individual experience a series of sub-modules would be required.

With the availability of modern IT, the development of an interactive, patient centred measure would seem feasible and access should be possible to a sufficiently large population to validate and evolve a patient centred measure, especially if a level of international collaboration can be achieved. However the burden of validating such a measure is considerable. The ideal starting point is to build on and to refine the characteristics of an existing measure and my recommendation, from this study is that a combination of the EORTC questionnaires and HADS, ideally with an item on fear of recurrence to address the main omission for current measures, provides the best foundation for future development of individual questionnaire assessments.

Chapter 10: Discussion

At the time of its design, this study was unique in seeking the opinions the opinions and preferences of patients on the validated measures designed to assess their QoL. In the interim one paper has been published looking at questionnaire preference (Mehanna and Morton, 2006) and a further study is in progress. My study has brought together the views of patients and health professionals at a level not previously achieved and including the measures which published papers suggest might have a role in QoL assessment in routine practice.

In terms of practical management I was fortunate in having access to touch-screen technology to assist data entry and I believe that this has been a very important factor in achieving the high level of completion of what was an ambitious dataset, The breadth of measures and inclusion of the preferences for consultation data and the psychological status questionnaire assessment and the tracking through to taped consultation provided a comprehensive dataset. This has allowed a holistic picture of the process of care to be considered to place what a questionnaire might add to the interaction with the healthcare multidisciplinary team in context. The study has also been unique in looking, in parallel, at the views of the health professionals who make up that multidisciplinary team using exactly the same assessments as those carried out by the patients. The depth of content of the clinician interviews gave a detailed narrative of contemporaneous views on team working and individual practices and philosophy. The patients, likewise, added greatly to the value of the quantitative data through thoughtful and incisive comments on consultations, on questions and on the process of care and team working. This detail depended, in the case of the patient interviews, on the presence of a trained researcher who would be seen as independent of the clinical team. The funding for the study was imperative in making this depth of investigation possible.

In developing the design, to power a study on preference as a primary endpoint was novel and I had to accept that this involved a degree of risk. Given the accepted place of the measures in clinical practice there was a strong probability that a clear preference may not emerge, as indeed was the case. The choice of measures to be investigated was led by the literature and my own previous experience of working in this field. What was difficult was determining how to assess questionnaires and questions. This involved numerous discussions about

‘what is a question?’ my decision was that there are two core components: what the question is about and whether that matters to the patient: i.e. ‘importance’ and whether the writing and phrasing is such that the person undertaking the intervention understands the question and answers the query intended: i.e. ‘is it well written?’ To add these queries to an already long intervention meant a substantial data burden for participants. I attempted to lessen this by adopting the style of responses used in the questionnaires themselves and also by repeating these questions in exactly the same format throughout the intervention so that participants would become familiar with them. The risk in doing this was that they might simply repeat the same rating, however, at least one questionnaire item was present between sets of importance and well written ratings, minimising the risk of repetition. The results showed different ratings for ‘importance’ and ‘well written’, supporting this approach.

Given the burden of questionnaires and ratings, there was need to ensure that this was reasonable for the patient population invited to join the study. This involved some compromise as the patient groups who could potentially benefit from inclusion of a questionnaire in their clinical care are those at the active and vulnerable stages in the pathway: at and shortly after diagnosis, during and in the immediate phase after therapy and at any stage where a cancer related event occurred, such as a diagnosis of recurrence. In discussion with the team, I decided that to subject patients at a vulnerable stage in their cancer journey to such an intense intervention was not acceptable. I, therefore, planned the study around recruitment of patients who were at least 1 year after completion of therapy and disease free, accepting that this group did not and could not represent the generality of H&N cancer patients. The alternative approach would have been to reduce the number of measures but a more simple design in this respect would not have allowed a valued judgement about the best measure for future practice. Although the data burden was considerable, completion of the intervention by almost all those who agreed to participate supported the view that this level of exploration was acceptable. Offering the questionnaires in random order also corrected for any fatigue or adaptation to the touch-screen and learned behaviours in making responses.

There is a substantial volume of literature on longitudinal assessments of QoL by questionnaire. This is undoubtedly a valuable use of questionnaires but did not form a primary element of this study which has focussed on choice, ratings and

interviews to gain opinions. To undertake a cross-sectional study has methodological limitations, to ensure we captured reproducible data, we built in a test/retest strategy. This proved invaluable when looking at the choice of questionnaire. The impracticality of making a simple choice became obvious when no participant chose the same measure twice despite making a cogent statement to support their choice during their interview.

A further decision worthy of comment is the inclusion of thyroid patients. The literature for this group is sparse and such studies as have been undertaken have used the QoL measures for H&N, mainly UWQoLv4. However, there have been no validation studies of any instrument for this patient group and my study, although it could not make definitive recommendations in view of its exploratory nature, gave a chance to explore whether thyroid patients had similarities to or differences from the remainder of the H&N cancer patients in terms of QoL. During the analysis of the results it became apparent that they were very different in terms of their characteristics, therapeutic burden, symptoms and side effects, return to work and QoL priorities. The data from this study has formed a base from which further work might be done to ensure a valid and reliable measure is available for these patients. The results of my study suggest that a separate instrument or module should be developed for thyroid patients.

I wished to set my findings in the context of living with cancer and core to this is return to ‘normal’ life, in terms of work and social activity. The latter is more subjective, so I chose work as the parameter for inclusion in my basic dataset. The results were notable for the difference in experience between the study groups. The difficulty in terms of return to employment for the late larynx group confirmed our clinical impression. The immediate assumption was that this would adversely affect QoL, however the findings from the quantitative study did not support this, a matter to which I will return later in this discussion.

The stratification of patient groups by impact of therapy is also a new concept, moving away from the traditional approach of using staging for this purpose. From the literature review there was a consensus that stage was the primary parameter for QoL and that this effect increased with time from diagnosis. Although worthy of exploration it has limitations especially in the laryngeal group where ‘early’ can range from narrow field radiotherapy to the larynx alone to much wider field irradiation plus or minus radiotherapy. In this study the main changes from ‘early’ to ‘late’ occurred in the oral rather than the laryngeal group

so this factor is unlikely to have had an impact on the results (Chapter 5, page 117). Consideration of therapeutic burden is supported by the comparative results from the 'early' and 'late' H&N subgroups compared to the stage results. Overall, more statistically significant differences were found using the 'therapeutic burden' derived sub-groups than by stage alone. The most prevalent difference was between LO patients who scored uniformly badly and the other sub-groups. EO performed particularly well. Much of the difference reflected known therapeutic morbidity and gave confidence in the ability of the QoL questionnaires to detect differences in a relatively small population, especially as we had chosen to set the statistical parameters at a challenging level. An unexpected and interesting finding was that LL patients reported relatively good QoL and EL patients appeared to struggle. The results for EO and LO showed a clear differentiation between the status of the patients, this was much less clear for larynx. Returning to the consultation results there was a suggestion that 'late' patients explored a greater depth of issues with their doctors and from the clinician responses some indication that some groups were more vulnerable and that consultations may vary depending on the clinician's perception of status. Whilst it is not possible to explain these findings through this study alone it raises some questions in terms of expectations. EL patients are often seen as fortunate, they are expected to do well and to return to a close to normal lifestyle, LL patients are acknowledged to have challenges and major efforts are made both by the hospital services and outside bodies to provide support. It may be that the expectation placed on EL patients gives insufficient recognition of the challenges that they face. In preferences for consultation, all sub-groups scored at a very similar level, the 'early' patients did not wish for a less thorough exploration of their status then the 'late' group. Exploration of these sub-group findings in terms of stresses and expectations for future living might allow strategies to improve QoL, not so much for the LL patients, but for the EL patients who appear to be reporting a lower QoL than would have been expected.

The consultation data emphasised the multidimensionality of the needs of this patient population. The evidence suggested that there were gaps in consultations and that these were related mainly to psychosocial needs. This is in line with the literature and adds further support to the need for better psychological support in the clinic. The HADS, in particular, appeared to have good sensitivity. At the end of a long intervention I had expected negative comments about 'yet another

questionnaire'. The positive responses of the patients towards a measure 'which lets me tell how I feel' supports the use of this measure for routine screening.

In terms of questionnaires and choices, I have brought together the findings from the patient study and the clinician study in Chapter 9. On breadth of enquiry and lack of criticism for content, it is my opinion that the EORTC QLQ C30 and H&N modules represent the best current screening questionnaire. They do not capture the whole experience of patients and it may well be that additional questions are needed, perhaps for subsets of patients, particularly those who have had surgery but the measure was sensitive in identifying sub-group differences and, critically important for clinic use, its strengths are in assessing the elements which this study indicates are most often not addressed in consultations.

In summary, my main conclusions are:

- The current practice of relying on consultations alone to manage the care of cancer patients does not ensure that all concerns are identified. This is particularly true for emotional and psychosocial issues.
- There are substantial differences in patient characteristics, therapeutic burden and status between thyroid patients and other H&N cancer patients. A specific QoL module should be developed to meet the needs of thyroid patients.
- Patients were not able to choose a questionnaire with any consistency.
- Patients and clinicians had clear and cogent views about the process of care, consultations and questionnaires which provided invaluable insight into the needs of this patient population.
- No current questionnaire is ideal for individual assessment but, from this study a combination of the EORTC QLQ C30/ H&N modules and HADS is recommended.
- The main area of omission from current assessments is 'fear of recurrence'. This is common and needs to be addressed in care for H&N and also Thyroid cancer patients.

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This study was hypothesis driven, our hypothesis being that **'carefully designed and structured questionnaires can be used to improve the quality of life of head and neck cancer patients'.** Whilst such a hypothesis can only be proven by development of such a measure and a randomised clinical trial the results of this exploratory study would indicate that use of a carefully chosen measure can

increase the range of areas discussed in consultations and assist doctors and MDT members in including emotional and psychosocial aspects of patient experience in their clinics. Questionnaires were sensitive at identifying important items in a small population which would support their use in routine care. The availability of advanced technology makes this less of a challenge and the increasing use of the internet is opening possibilities for questionnaire based assessments to the patient's convenience outside traditional hospital settings. For these reasons, I submit that the findings from this study strongly support the hypothesis.

Chapter 11: The Study in Context and Future Work

This study has provided the most detailed research to date on opinions and preferences of both patients and clinicians for questionnaire assessments in H&N cancer and has also provided an insight into many aspects of clinical care in a modern cancer centre setting. Its completion is timely as cancer networks are currently looking at support and rehabilitation as part of the Cancer Reform Strategy and the wider emotional and psychosocial issues are gaining prominence at a time when much of the 'hard' infrastructure for delivery of care is in place. The next advances in terms of routine care and patient and carer experience are likely to lie in the areas addressed by this study.

The first area in which I hope to continue to work is developing questionnaires which are truly designed to assist individuals in communicating with their doctors and health professionals, ideally in primary as well as secondary care settings. It is essential to preserve the validity of questionnaires designed to survey populations. However, when this comes at the price of eliminating an important element of patient experience from the measure, this raises doubts about its use at individual level. The elements emerging from this study relate to the therapy, as surgery and (chemo) radiotherapy carry a different but substantial therapeutic burden. It was noted by patients that the UWQoL was the only questionnaire to include the items which were important to them. The counter argument was that issues important to other groups such as fatigue, social eating and items strongly endorsed in other measures were not present in the UWQoL and emotional and wider issues were much better addressed by the EORTC questionnaires. Clinicians emphasised the importance of the stage in the cancer journey. If we are serious about the introduction of QoL measures into routine care there may well be a case for sub-modules which capture the experience of the individual such that a core measure is available but supplementary sub-modules are developed which capture elements of patient experience at different times and as a result of different therapies: a surgical module, looking at the primary site, the neck, the donor site and a chemoradiotherapy module looking at acute and long term consequences of these therapies. This is ambitious but, given the exponential expansion of IT there is potential to learn from patient experience in different settings and at different times in their journey.

A further area is to expand this work to look at the impact of adding a questionnaire to routine care for the more vulnerable groups. One obstacle to moving this field forwards has been the lack of evidence for any questionnaire or combination. I now plan to use the combination of EORTC QLQ C30 and HADS for further studies. To set this in context, it is recognised that the validated questionnaires were developed some years ago and that therapy and patient experience continues to evolve. The EORTC is currently developing an updated version of the H&N module which may overcome some of the weaknesses of the current questionnaire. I am working with this team and intend to continue to do so as, especially for work in less common cancer sites, strong collaborations are essential to gaining best evidence for care, as much if not more in psychosocial areas than therapeutic trials, as psychosocial is so much more multidimensional and complex.

One fascinating area emerging from the study is whether consultations vary depending on clinician perception of patient status. I still have a substantial resource in terms of the many taped consultations and intend to explore this in much more detail than has been possible to date and to continue work in this field.

The final area to emerge as a point of consensus was the need for a ‘person with common sense in the middle’, a concept voiced by a patient and his partner but strongly echoed by the clinicians when we discussed how information arising from a questionnaire assessment might best be used in clinic. Further to the IOG recommendations each patient has a ‘keyworker’. The reality of the service is that someone within the existing MDT is designated the ‘keyworker’ for part of the cancer pathway. This could represent a chance to establish a role to take the lead in providing a holistic model of care and use a QoL assessment as part of that pathway. This kind of initiative would open the door to inclusion of QoL measures into routine care but also access to additional elements of support, psychological and counselling, alternative therapies for which there is at present a suggestion that there may be benefits in terms of living with low-grade chronic pain and also the infrastructure to allow good research into the effectiveness of this wider model of cancer care and support.

In summary, this thesis has added to our knowledge about patient and clinician aspects of H&N cancer care and has provided a base from which further work can be developed to the benefit of patients and, I hope, assist those who care for

them, professionals and their families, in meeting patients' needs at the highest level.

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Supplementary Material

1. **Research Training and Personal Development**
2. **UKCRN/NCRN Adoption**
3. **Dissemination to date**

   : peer-reviewed presentations and posters

   : invited presentations

1. Research Training and Personal Development

1.1 Membership of Psychosocial Oncology and Clinical Practice Research Group.

The group, led in the early stages of this study by Professor Peter Selby and more recently by Professor Galina Velikova, is based in the Institute of Oncology, St James's University Hospital, Leeds.

It holds formal educational and research update meetings on a monthly basis and informal group meetings more frequently.

As part of this group, my data has been presented at meetings and more formally through the Leeds Institute of Molecular Medicine Research in Progress Seminars.

On a one-to one basis, supervision meetings have taken place in line with University recommendations. More frequent meetings and informal support and guidance has been offered on an ongoing basis.

Computer/IT and administrative support has been available through the research group. (www.pogweb.org)

1.1 University Training Courses

Managing a PhD as a Part-time Student:	2002
Statistics for Biomedical Research:	2005
Thesis Writing and Surviving your Viva:	2007
Working with Word for Long Documents:	2009
Excel Basics:	2009
Excel Intermediate:	2009

2. UKCRN/NCRN Portfolio Adoption

UKCRN CLINICAL STUDIES PORTFOLIO: Initial Study Registration Proforma

For further explanation of each of the data items listed below, please refer to the accompanying document:

UKCRN Description of Study Detail Data Items

DATA ITEM	STUDY DETAILS
Study Acronym/Short Name:	Development of a patient specific qualify of life assessment in head and neck cancer
Study Title:	Development of a patient specific qualify of life assessment in head and neck cancer
REC reference number: *(if this has been allocated)*	05/Q1205/26
Primary Topic:	Blood ☐ Ear ☐ Cancer ☒ Eye ☐ Cardiovascular ☐ Infection ☐ Congenital Disorders ☐ Inflammatory & Immune System ☐ Neurological ☐ Dementias & Neurodegenerative ☐ Diabetes ☐ Medicines for Children ☐ Renal and Urogenital ☐
Primary	Observational ☒

DATA ITEM	STUDY DETAILS
study design:	Interventional ☐ Both ☐
Is this a randomised study?	No ☒
Phase of study:	*Only applicable to clinical trials of investigational medicinal products (CTIMPS)* Pilot/Feasibility ☐ Experimental Medicine ☐ I [
Overall sample size:	150 approx
Geographical scope:	single centre ☒ UK multi-centre ☐

Study Coordinator Details:	Name: Mrs Sheila Fisher Address: Department of Oral and Maxillofacial Surgery Floor 6 Worsley Building Faculty of Medicine and Health, University of Leeds, Clarendon Way, Leeds, LS2 9LU.
Email:	Email: s.e.fisher@doctors.org.uk
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Email:	Email: s.e.fisher@leeds.ac.uk
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Chief Investigator Details:	Name: Mrs Sheila Fisher
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3. Peer-reviewed Presentations and Posters:

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova. Wishes for and perceptions of the content of medical consultations: a study of the views of patients treated for head & neck cancer. Poster at the NCRI Conference, Birmingham, 2009.

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova.

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova. Return to work in head and neck cancer patients after radical curative therapy. Poster at the NCRI Conference, Birmingham, 2009.

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova. Return to work after therapy for thyroid cancer with curative intent.
NCRI Conference, Birmingham, 2009.

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova. Which questionnaire? Assessing the health related quality of life in patients with head and neck cancer. Oral Oncology Supplement 3 (2009) Doi: 10 1016/j.oraloncology.2009.05.377. Paper at the International Academy Oral Oncology 2nd International Congress, Toronto, 2009.

SE Fisher, A Vikram, A Donnelly, AC Newsham, C Johnston, AB Smith, P Selby and G Velikova. Talking to patients: What are we perceived to include in consultations? Oral Oncology Supplement 3 (2009). Doi: 10. 1016/j.oral oncology. 2009.05.105. Poster presented at the International Academy of Oral Oncology 2nd International Congress, Toronto, 2009.

Fisher SE, Vikram A, Donnelly A, Newsham AC, Johnston C, Smith AB, Selby PJ, Velikova G. Towards PROs in Head and Neck Cancer: patients' views and opinions on consultations and QoL questionnaires. Poster presented at NCRI National Conference 2008 & BPOS 2008 (awarded Best Poster prize at BPOS meeting).

Fisher SE, Vikram A, Donnelly AM. Newsham AC, Johnston C, Smith AB, Selby PJ and Velikova G. Quality of life in Head and Neck Cancer: Patient Views on Medical Consultations. British Association of Oral & Maxillofacial Surgeons Meeting, Cardiff, July 2008

Fisher SE, Newsham AC, Johnston C, Smith AB, Selby PJ, Velikova G. Questionnaires and Consultations: a study of patients' opinions regarding QoL assessment in a Head and Neck Cancer Clinic. Poster presented at NCRI National Conference, October 2007.

Fisher SE, Donnelly AM, Newsham AC, Johnston C, Smith AB, Selby PJ, Velikova G. Communicating concerns: how do our patients perceive consultations and can a questionnaire based approach assist communication?
Poster presentation at BAHNO Annual meeting, London, 2007.

Fisher SE, Donnelly A, Newsham AC, Johnston C, Smith AB, Selby PJ, Velikova G. Individual Assessment of Quality of Life: a communication tool for modern practice. Presentation at the First World Congress of the International Academy of Oral Oncology, Amsterdam, May 2007.
Oral Oncology (Supplement), 2007, 2 (1), 92-93.

Fisher SE, Newsham AC, Johnston C, Smith AB, Selby PJ and Velikova G. Individual Patient Assessments: a Communication Tool for use in Clinical Oncology Practice. Poster presentation at the ISOQOL Conference on Patient Reported Outcomes in Clinical Practice, Budapest, June 2007.

Newsham AC, Donnelly AM, Johnston C, Smith AB, Selby PJ, Velikova G and **Fisher SE**. Bringing Patient Care and Clinical Trials Together: use of a new Integrated Database in a complex multidisciplinary setting. NCRI conference, Birmingham, 2006

Invited Presentations:

Fisher SE. How to look at Quality of Life in Clinics: lessons from listening to our patients. 6th International Workshop on Quality of Life in Head & Neck Cancer, Liverpool, 2008.

Fisher SE. Incorporating QoL into Clinical Practice: from theory to clinic.
Invited workshop lecture at EUFOS Conference, Vienna, July 2007.

Fisher SE. Health related quality of life assessment in clinical practice. 5th International Workshop on Quality of Life in Head & Neck Cancer, November 2006

Fisher SE, Donnelly AM, Velikova G and Selby PJ. Patient specific questionnaire: assessment of individual patients with H&N cancer. Head & Neck Cancer parallel session, NCRI conference, 2006.

Fisher SE Patients, MDTs, Patients and Quality of Life Assessments: a complementary or conflicting triangle? 4th International Workshop on Quality of Life in Head & Neck Cancer, Liverpool, October 2004.

Fisher SE. Health Related Quality of Life Assessment, the 'Individual' View. 3rd International Workshop on Quality of Life in Head and Neck Cancer, University of Liverpool, November 2002.

What do you want to talk about? What do we talk about? The opinions of patients with Head and Neck (H&N) Cancer on the content of medical consultations.

Sheila E Fisher [1,3,4], Alexander C Newsham [2,3], Colin Johnston [2,3], Aine Donnelly [3], Aditya Vikram [3], Adam B Smith [5], Peter J Selby [2,3], Galina Velikova [2,3]

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Aim

To determine patient opinions on areas for discussion in medical consultations and on their perceived content of such consultations.

Background & Clinical Setting

The medical consultation lies at the core of clinical care, providing the interaction between doctors and their patients. Both bring their own priorities to this interaction. There has been little research into which areas patients wish to discuss and how that relates to what is perceived to be addressed in a medical consultation.

This study reports the results of a prospective observational cohort treated in a large multidisciplinary (MDT) head & neck (H&N) cancer clinic in the UK.

Method

H&N cancer patients attending follow-up appointments were approached. To determine patients' views on medical consultations a questionnaire was adapted from Detmar [1]. The first group of questions related to wishes with regard to the content of consultations and the second covered a similar range of areas but considered whether patients felt these were included in consultations.

For the first set of questions the responses were:

0 = 'I would not wish to discuss this item'

1= 'I would like to discuss this item if the doctor raises it'

2= 'I would like to discuss this item'

For the second set of questions the patients rated how frequently the area was discussed in consultations in a range from 'never' through to 'almost always'. The questionnaires were presented using a computerised touch-screen system which automatically uploaded responses to a central server for analysis.

To ensure the range of experience and treatment related effects were included in the sample, we divided the participants into treatment groups. These were early oral [EO] (oral cancer with treatment restricted to a single modality), late oral [LO] (multimodality therapy including surgical ablation and reconstruction), early [EL] and late [LL] laryngeal cancer (similar criteria, with late cases having had a laryngectomy). We also studied thyroid patients [Thy] as their care is often offered through the same MDT.

To explore test /retest reliability a subgroup of patients comprising at least 10% of the overall study sample of 150 patients, were asked to complete the intervention twice.

Results

152 patients agreed to join the study and full records were achieved for 144 participants (33 EO, 36 LO, 17 EL, 15 LL and 43 Thy). 22 patients achieved 2 interventions (7 EO, 9 LO, 3 EL, 2 LL and 1 Thy). In general, patients most wanted to discuss 'physical activities affected by treatment', a category which includes key areas such as speech, swallowing and eating, with their doctors. This was closely followed by 'symptoms and side effects of treatment'. These matched the perception of what was most likely to be discussed, although 24% of patients indicated that symptoms and side effects were 'never' or 'rarely' mentioned and 29% gave the same results for physical limitations due to the disease or its treatment.

Figure 1. Patients' wishes for consultations

Total group= 144 responses

Item	0	1	2
Physical symptoms & side effects of illness	5 (3.5%)	32 (22.2%)	107 (74.3%)
General physical activities	9 (6.3%)	38 (26.4%)	97 (67.4%)
Physical activities specific to illness (e.g. speech)	8 (5.6%)	21 (14.6%)	115 (79.9%)
How you feel emotionally	17 (11.8%)	38 (26.4%)	89 (61.8%)
Impact of illness or treatment on work & leisure	18 (12.5%)	44 (30.6%)	82 (56.9%)
Impact of illness or treatment on social activities	29 (20.1%)	51 (35.4%)	64 (44.4%)
Impact of illness or treatment on relationships	25 (17.4%)	45 (31.3%)	74 (51.4%)
Impact of illness or treatment on appearance	24 (16.7%)	34 (23.6%)	86 (59.7%)

Key to scale: 0= 'rather not', 1= 'discuss if raised by doctor', 2= 'want to discuss'

Figure 2. Patients' perceived content of consultations

Total group=144 responses

Item	0	1	2	3	4
Overall health	12 (8.3%)	17 (11.8%)	45 (31.0%)	31 (21.4%)	39 (26.9%)
Symptoms of disease or treatment (e.g. pain, sickness, fatigue)	14 (9.7%)	19 (13.2%)	35 (24.3%)	38 (26.4%)	38 (26.4%)
General physical limitations as a result of disease or treatment	49 (34.0%)	26 (18.1%)	27 (18.8%)	15 (10.4%)	27 (18.8%)
Physical limitations specific to disease and treatment (e.g. speech)	21 (14.6%)	20 (13.9%)	35 (24.3%)	34 (23.6%)	34 (23.6%)
Emotional distress	49 (34.0%)	41 (28.5%)	28 (19.4%)	12 (8.3%)	14 (9.7%)
Impact of illness or treatment on work & leisure	65 (45.1%)	36 (25.0%)	27 (18.8%)	7 (4.9%)	9 (6.3%)
Impact of illness or treatment on relationships	60 (41.7%)	39 (27.1%)	30 (20.8%)	6 (4.2%)	9 (6.3%)
Impact of illness or treatment on appearance	60 (41.7%)	38 (26.2%)	24 (16.6%)	9 (6.3%)	9 (6.3%)

Key to scale: 0= 'never', 1= 'rarely', 2= 'sometimes', 3= 'often', 4= 'almost always'

Once the questions moved beyond 'hard' clinical evaluations, the gap between aspiration and reality became more marked. Although 61.8% of patients indicated a wish to discuss how they felt emotionally, this was perceived to be addressed 'almost always' or 'often' in only 11.2% of consultations. Patients endorsed a wish to discuss the impact of their disease on aspects of their daily living at a lower level and these aspects of living with a cancer diagnosis were unlikely to be raised in the consultation.

Patients rated a discussion about the impact of their disease on their appearance highly with 59.7% wishing to raise it, yet in only 12.6% of consultations was this issue 'almost always' or 'often' addressed.

Sub-group scores (EO, EL, LO, LL and Thy) followed the pattern of the study group as a whole across the range of issues addressed in this study.

Test/ Retest:

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NCRI, 2009

What do you want to talk about? What do we talk about? The opinions of patients with Head and Neck (H&N) Cancer on the content of medical consultations.

Sheila E Fisher [1,3,4], Alexander C Newsham [2,3], Colin Johnston [2,3], Aine Donnelly [3], Aditya Vikram [3], Adam B Smith [5], Peter J Selby [2,3], Galina Velikova [2,3]

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To determine patient opinions on areas for discussion in medical consultations and on their perceived content of such consultations.

Background & Clinical Setting

The medical consultation lies at the core of clinical care, providing the interaction between doctors and their patients. Both bring their own priorities to this interaction. There has been little research into which areas patients wish to discuss and how that relates to what is perceived to be addressed in a medical consultation.

This study reports the results of a prospective observational cohort treated in a large multidisciplinary (MDT) head & neck (H&N) cancer clinic in the UK.

Method

H&N cancer patients attending follow-up appointments were approached. To determine patients' views on medical consultations a questionnaire was adapted from Detmar [1]. The first group of questions related to wishes with regard to the content of consultations and the second covered a similar range of areas but considered whether patients felt these were included in consultations.

For the first set of questions the responses were:

0 = 'I would not wish to discuss this item'

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For the second set of questions the patients rated how frequently the area was discussed in consultations in a range from 'never' through to 'almost always'. The questionnaires were presented using a computerised touch-screen system which automatically uploaded responses to a central server for analysis.

To ensure the range of experience and treatment related effects were included in the sample, we divided the participants into treatment groups. These were early oral [EO] (oral cancer with treatment restricted to a single modality), late oral [LO] (multimodality therapy including surgical ablation and reconstruction), early [EL] and late [LL] laryngeal cancer (similar criteria, with late cases having had a laryngectomy). We also studied thyroid patients [Thy] as their care is often offered through the same MDT.

To explore test /retest reliability a subgroup of patients comprising at least 10% of the overall study sample of 150 patients, were asked to complete the intervention twice.

Results

152 patients agreed to join the study and full records were achieved for 144 participants (33 EO, 36 LO, 17 EL, 15 LL and 43 Thy). 22 patients achieved 2 interventions (7 EO, 9 LO, 3 EL, 2 LL and 1 Thy). In general, patients most wanted to discuss 'physical activities affected by treatment', a category which includes key areas such as speech, swallowing and eating, with their doctors. This was closely followed by 'symptoms and side effects of treatment'. These matched the perception of what was most likely to be discussed, although 24% of patients indicated that symptoms and side effects were 'never' or 'rarely' mentioned and 29% gave the same results for physical limitations due to the disease or its treatment.

Figure 1. Patients' wishes for consultations

Total group= 144 responses

Item	0	1	2
Physical symptoms & side effects of illness	5 (3.5%)	32 (22.2%)	107 (74.3%)
General physical activities	9 (6.3%)	38 (26.4%)	97 (67.4%)
Physical activities specific to illness (e.g. speech)	8 (5.6%)	21 (14.6%)	115 (79.9%)
How you feel emotionally	17 (11.8%)	38 (26.4%)	89 (61.8%)
Impact of illness or treatment on work & leisure	18 (12.5%)	44 (30.6%)	82 (56.9%)
Impact of illness or treatment on social activities	29 (20.1%)	51 (35.4%)	64 (44.4%)
Impact of illness or treatment on relationships	25 (17.4%)	45 (31.3%)	74 (51.4%)
Impact of illness or treatment on appearance	24 (16.7%)	34 (23.6%)	86 (59.7%)

Key to scale: 0= 'rather not', 1= 'discuss if raised by doctor', 2= 'want to discuss'

Figure 2. Patients' perceived content of consultations

Total group=144 responses

Item	0	1	2	3	4
Overall health	12 (8.3%)	17 (11.8%)	45 (31.0%)	31 (21.4%)	39 (26.9%)
Symptoms of disease or treatment (e.g. pain, sickness, fatigue)	14 (9.7%)	19 (13.2%)	35 (24.3%)	38 (26.4%)	38 (26.4%)
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Physical limitations specific to disease and treatment (e.g. speech)	21 (14.6%)	20 (13.9%)	35 (24.3%)	34 (23.6%)	34 (23.6%)
Emotional distress	49 (34.0%)	41 (28.5%)	28 (19.4%)	12 (8.3%)	14 (9.7%)
Impact of illness or treatment on work & leisure	65 (45.1%)	36 (25.0%)	27 (18.8%)	7 (4.9%)	9 (6.3%)
Impact of illness or treatment on relationships	60 (41.7%)	39 (27.1%)	30 (20.8%)	6 (4.2%)	9 (6.3%)
Impact of illness or treatment on appearance	60 (41.7%)	38 (26.2%)	24 (16.6%)	9 (6.3%)	9 (6.3%)

Key to scale: 0= 'never', 1= 'rarely', 2= 'sometimes', 3= 'often', 4= 'almost always'

Once the questions moved beyond 'hard' clinical evaluations, the gap between aspiration and reality became more marked. Although 61.8% of patients indicated a wish to discuss how they felt emotionally, this was perceived to be addressed 'almost always' or 'often' in only 11.2% of consultations. Patients endorsed a wish to discuss the impact of their disease on aspects of their daily living at a lower level and these aspects of living with a cancer diagnosis were unlikely to be raised in the consultation.

Patients rated a discussion about the impact of their disease on their appearance highly with 59.7% wishing to raise it, yet in only 12.6% of consultations was this issue 'almost always' or 'often' addressed.

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Aim

To determine the rate of return to previous employment in a group of patients with H&N cancer.

Background & Clinical Setting

H&N cancer patients are well recognised to face additional challenges after a cancer diagnosis because of the effect of the disease and therapy on important functional and social aspects of life. However, few studies have looked specifically at return to work. This study reports the results of a prospective observational cohort treated in a large multidisciplinary (MDT) head & neck (H&N) cancer clinic in the UK.

Method

H&N cancer patients attending follow-up appointments were approached as part of a larger study on opinions and preferences in terms of medical consultations and quality of life. We asked their permission to record their occupational status at diagnosis and current status.

To ensure the range of experience and treatment related effects were included in the sample, we divided the participants into treatment groups. These were early oral [EO] (oral cancer with treatment restricted to a single modality), late oral [LO] (multimodality therapy including surgical ablation and reconstruction), early [EL] and late [LL] laryngeal cancer (similar criteria, with late cases having had a laryngectomy).

Results

152 patients agreed to join the full study, of whom 61 indicated they were in work at the time of their diagnosis. A summary of work status is given in Figure 1.

61 patients were working at diagnosis and 43 remained in work at the time of the study, however 18 had had or chosen to change employment.

The experience was very varied across groups as indicated below.

Early larynx (EL): 10 patients

9 males: 4 in paid work: HGV driver, Builder and Salesman reported no change in occupation, car restorer did report a change in occupation.

1 patient unemployed (unchanged), 2 on incapacity benefits (unchanged)

2 no occupation noted.

1 female (no occupation noted)

Late larynx (LL): 11 patients.

8 males: 5 in paid work. Only one, a successful local politician, is known to have remained in his previous employment. One patient reported the change to highways inspector was due to his previous business entering receivership, an event he did not associate with his cancer. A bakery worker took early retirement as he could not cope with the dust and the current working status of a courier driver is uncertain. The final patient in this group reported a positive outcome from his cancer. He has come out of retirement in his 70s to teach communication with cancer patient skills to medical students and AHPs (Allied Health Professionals.

I patient was unemployed (status unchanged).

For two male patients no details were entered; one of these had had multiple primary cancers and the other reported with a second primary cancer shortly after completing the study and died a few months later. It would seem unlikely that either of these patients were able to undertake work.

3 females: none in paid employment. I was and remained a housewife, the other two were and remained unemployed. One noted that she felt very discriminated against when she applied for work and that her laryngectomy prevented her applying for posts which met her previous skills in telemarketing.

Early oral:

11 males: 10 were in paid employment at the time of diagnosis, of these seven reported continued employment in the same job. Work ranged from self-employed businessmen (2), civil service, TV presenter and broadcaster to haulier, engineering fitter and warehouseman. The remaining three whose current status is uncertain included a printer, warehouseman and a washing machine repairer. Only in one instance is a cancer related loss of job with subsequent continued unemployment noted.

5 females: 4 were in paid employment, as a manager (2 patients), a property developer and a dental nurse. All continued in their previous work. The remaining patient was and remained a housewife.

Late oral:

23 males: 19 were in paid employment at diagnosis.10 of whom continued in their previous employment (an accountant, engineers [4 patients], a manager, a postman a lorry driver, a welder and one man who did not state his occupation). One patient chose to train as a teacher and, although his previous employment is not noted, this may well represent choice; a further patient notes a change to agency work but not a reason for this. Outcomes are not noted for 2 patients, a gardener and a security officer.

Of the remainder a Carer in a Residential Home had to case work because of PEG feeding and continued severe morbidity, a medical physics technician struggled to return to work and achieved this transiently after prolonged absence but then developed paroxysmal atrial fibrillation and had to stop. Three patients reported losing their jobs (one manual worker and the other two occupation unknown) specifically as a result of their cancer and its treatment.

The four who were not in paid employment at diagnosis were unemployed (2) or on incapacity benefit (2).

1 female: She changed her occupation to carer as a result of her cancer.

Figure 1. Return to work by subgroup

Total group=61 responses

Group	Gender	Employment Status			
		Diagnosis	Working	Same	Changed
EL	Male	9	4	3	1
	Female	1	0	0	0
LL	Male	8	5	1	4
	Female	3	0	0	0
EO	Male	11	10	7	3
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Total		**61**	**43**	**25**	**18**

Comments

This study reports very different experiences by stage and site of H&N cancer.

The results would indicate that patients diagnosed with early stage disease and requiring single modality therapy have a good chance of returning to their previous employment, this being the case for 3 out of 4 early larynx patients and 11 out of 14 early oral patients who were in paid employment. In these patient groups only one patient reported loss of employment which he thought was related to his cancer diagnosis.

There is a contrast between early and late stage disease. The work experience of late larynx patients is particularly poor with two notable exceptions. Approximately 50% of the late oral patients in this study returned to work in their previous post.

Living with cancer and survivorship issues are increasingly important as more patients remain clear of their original disease. Work needs to be done with employers to assist those patients who are of working age, especially those presenting with late stage disease.

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Talking to Patients: what are we perceived to include in Consultations?

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PROs in Head and Neck Cancer: Patients' views on Questionnaires and Consultation Priorities and Content

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Abstract

This study focuses on the views of Head and Neck [H&N] Cancer patients on important topics for medical consultations and their preferences for formal questionnaire assessment of their Health Related Quality of Life [QoL]. We report ratings of questionnaires and the perceived content of consultations. Our long term aim is to introduce individual assessment of QoL by a patient centered, touch-screen based communication tool for use in clinics.

Aims

To determine patient opinions on the content and wording of a future health related quality of life assessment tool.
To assess wishes for and perceived content of medical consultations in a H&N Oncology clinical network.

Background & Clinical Setting

Head and Neck (H&N) patients are acknowledged to face significant challenges during their cancer journey, not only those common to all sites but also the loss of key functions. Aesthetic and functional outcomes after major surgery +/- chemoradiotherapy can make adjustment to social and working environments very difficult.

Our initial study, of simple cross-sectional design using the University of Washington (UWQoLv4) questionnaire, showed that 129 out of 147 patients scored below our 'a priori' cut-off level in at least one domain. Resources limited detailed assessment to the 40 with the lowest scores, of whom 30 reported unmet needs which had not been previously identified.

Our conclusion was that patients did have problems which were not identified as part of their standard care and that a screening questionnaire could help to identify these.

From this study we derived our hypothesis that:

'Carefully developed and structured questionnaires can be used to improve the quality of life of head and neck patients'.

We wished to place the patient at the core of development and the second phase of this programme, reported here, is exploration of their views on medical consultation as experienced in the head and neck clinic and on questionnaire content and wording.

Method

H&N cancer patients attending follow-up appointments were approached. Generic and head and neck specific (SF-36v2, EORTC QLQ C30 and H&N modules, FACT G and H&N and UWQoLv4) questionnaires were completed using touch-screens. Patients were interviewed regarding their preferences and invited to comment. To determine patients' views on medical consultations a questionnaire was adapted from Detmar [1].

Patients were asked to rate the importance of questions and the wording of questions on a 1-4 Likert scale, where 4 represents a 'very good' interpretation of patient need and 1 represents 'not at all'.

Figure 1. Patient views on questionnaires

	Important				Well written			
	1	2	3	4	1	2	3	4
EORTC n (167) %	2 (1.2)	11 (6.6)	59 (35.3)	95 (56.9)	1 (0.6)	6 (3.6)	60 (35.9)	100 (59.9)
FACT n (167) %	1 (0.6)	7 (4.2)	53 (31.7)	106 (63.5)	1 (0.6)	5 (3.0)	63 (37.7)	98 (58.7)
SF-36 n (166) %	1 (0.6)	17 (10.2)	53 (31.9)	95 (57.2)	1 (0.6)	8 (4.8)	72 (43.4)	85 (51.2)

Figure 2. Patients' wishes for consultations (169 returns)

Item	Not discuss	If doctor mentions	Like to discuss
Symptoms/Side Effects of Treatment	6 (3.6%)	40 (23.7%)	123 (72.8%)
Physical activity	11 (6.5%)	42 (24.9%)	116 (68.6%)
Disease specific limitations	9 (5.3%)	24 (14.2%)	136* (80.4%)
Emotional aspects	19 (11.2%)	44 (26.0%)	106* (62.7%)
Impact on work	22 (13.0%)	48 (28.4%)	99 (58.5%)
Impact on relationships	33 (19.5%)	58 (34.3%)	78 (46.2%)
Impact on appearance	28 (16.6%)	56 (33.1%)	87 (51.5%)

Figure 3. Patients' perceived content of consultations (168 returns)

Item	Never	Rarely	Some times	Often	Almost Always
Overall health	28 (16.9%)	29 (17.5%)	55 (33.1%)	18 (10.8%)	28 (16.6%)
Symptoms/Side Effects	16 (9.6%)	23 (13.6%)	43 (25.9%)	48 (28.9%)	51 (30.7%)
Physical activity	28 (16.9%)	22 (13.3%)	48 (28.9%)	43 (25.9%)	37 (22.3%)
Specific to disease*	47 (28.3%)	31 (18.7%)	32 (18.9%)	26 (15.7%)	29 (17.5%)
Limitation in work or leisure	33 (19.9%)	23 (13.6%)	48 (28.9%)	46 (27.7%)	32 (19.27%)
Emotional distress*	60 (36.1%)	51 (30.7%)	42 (25.3%)	13 (7.8%)	13 (7.8%)
Relationships with family	78 (47.0%)	37 (22.3%)	45 (27.1%)	8 (4.8%)	10 (6.0%)
Social relationships	71 (42.8%)	42 (25.3%)	45 (27.1%)	12 (7.2%)	10 (6.0%)
Appearance	56 (45.9%)	33 (27.0%)	22 (18.0%)	5 (4.1%)	6 (4.9%)

Results

150 patients were accrued to the study, including patients with oral, laryngeal and thyroid cancers. 19 patients completed a follow up assessment, providing a total of 169 records for analysis. Basic full group data is reported here. Patients did not endorse a particular questionnaire.101 patients (61%) stated no preference, 29 (18%) preferred the FACT-G, 20 (12%) the SF-36 and 16 (10%) the EORTC QLQ C30. Considering 'importance'; i.e. that the questionnaire raised the topics the patient would wish to see in an assessment, 63.5% considered that the FACT had greatest efficacy, followed by 57.2% for the SF-36 and 56.9% for the EORTC. For clarity of wording the EORTC and FACT-G gained similar scores at 59.9% and 58.7% respectively.

Ratings for content of a consultation indicated that 'disease specific limitations' (80.4% would wish to mention) was most important to patients, however it was perceived to be covered in only a third of consultations. 'Symptoms and side effects' as a medical rather than an impact on life rating was the area perceived to be included by doctors (59.6%). Emotional distress was rated as important but was perceived rarely or never to be addressed in the majority of medical consultations.

Conclusions

Although patients did not endorse a particular questionnaire, they demonstrated ability to comment on aspects of questionnaire design and the trend was towards preference of FACT-G which was reported in interviews as clear and addressing the important issues.

Patients' perceptions were that important issues were not being consistently raised in medical consultations.

This study raises interesting questions about the mutual understanding of the content of doctor/patient interactions and how communication can be improved so that the needs of patients are met.

Reference

Detmar S, Aaronson NK, Wever LDV, Muller M and Schomagel JH. *Journal of Clinical Oncology, 2000, 18, 3295.*

Acknowledgements

We wish to acknowledge the support of clinicians working in the Leeds/Mid-Yorkshire Head and Neck Clinic, the ENT and Maxillofacial Clinics and the patients for their time and commitment to the study.

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: The Head and Neck Oncology Fund
: British Association of Oral and Maxillofacial Surgeons
: Charitable Trustees of the Leeds Teaching Hospitals NHS Trust

Questionnaires and Consultations: a study of patients' opinions regarding QoL assessment in a Head and Neck Cancer clinic

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Abstract

This study focuses on assessment of health related quality of life in patients with Head and Neck Cancer. Our aim is to introduce individual assessment of QoL into patient care by developing a tool to assist patients in communicating their status to healthcare professionals in such a way that it forms a basis for their care and support.

Aim

To determine patient opinions on the content and wording of a future health related quality of life assessment tool.

Background & Clinical Setting

Head and Neck (H&N) patients are acknowledged to face significant challenges during their cancer journey, not only those common to all sites but also the loss of key functions. Aesthetic outcomes after major surgery can make adjustment to social and working environments very difficult.

In the UK, care is provided by multi-disciplinary cancer teams (MDTs) including all health professionals with expertise relevant to their care. Whilst this model of care provides access to a range of expertise, it is important that needs are identified. Our initial study, of simple cross-sectional design using the University of Washington (UWQoLv4) questionnaire which has been specifically developed as a screening tool for this patient group, showed that 129 out of 147 patients scored below our 'a priori' cut-off level in at least one domain. Resources limited detailed assessment to the 40 with the lowest scores, of whom 30 reported unmet needs which had not been previously identified.

Our conclusion was that patients did have problems which were not identified as part of their standard care and that a screening questionnaire could help to identify these.

From this study we derived our hypothesis that:

'Carefully developed and structured questionnaires can be used to improve the quality of life of head and neck patients'.

We wished to place the patient at the core of development and the second phase of this programme, reported here, is exploration of their views on medical consultation as experienced in the head and neck clinic and on questionnaire content and wording.

Method

H&N cancer patients attending follow-up appointments were approached. Generic and head and neck specific (SF-36v2, EORTC QLQ C30 and H&N modules, FACT G and H&N and UWQoLv4) questionnaires were completed using touchscreens. Patients were interviewed regarding their preferences and invited to comment. To determine patients' views on medical consultations a questionnaire was adapted from Detmar [1].

Patients were asked to rate the importance of questions and the wording of questions on a 1-4 Likert scale.

Figure 1. Patient views on questionnaires

	Important				Well written			
	1	2	3	4	1	2	3	4
EORTC n (120) %	2 (1.7)	10 (8.3)	42 (35.0)	66 (55.0)	1 (0.8)	4 (3.3)	42 (35.0)	73 (60.8)
FACT n (120) %	1 (0.8)	5 (4.1)	37 (30.6)	77 (63.6)	1 (0.8)	5 (4.1)	44 (36.4)	70 (57.9)
SF-36 n (119) %	1 (0.8)	11 (9.1)	37 (30.6)	70 (57.9)	1 (0.8)	6 (5.0)	49 (40.5)	63 (52.1)

Figure 2. Patients' wishes for consultations

Item	Not discuss	If doctor mentions	Like to discuss
Symptoms/Side Effects of Treatment	5 (4.1%)	30 (24.6%)	87 (71.3%)
Physical activity	7 (5.7%)	30 (24.6%)	85 (69.7%)
Disease specific limitations	6 (4.9%)	20 (16.4%)	96* (78.7%)
Emotional aspects	18 (14.8%)	28 (23.0%)	76* (62.3%)
Impact on work	18 (14.8%)	36 (29.5%)	68 (55.7%)
Impact on relationships	26 (21.3%)	44 (36.1%)	52 (42.6%)
Impact on appearance	24 (19.7%)	38 (31.1%)	60 (49.2%)

Figure 3. Patients' perceived content of consultations

Item	Never	Rarely	Some times	Often	Almost Always
Overall health	24 (19.7%)	26 (21.3%)	51 (41.8%)	5 (4.1%)	16 (13.1%)
Symptoms/Side Effects	12 (9.8%)	16 (13.1%)	39 (32.0%)	21 (17.2%)	34 (27.9%)
Physical activity	14 (11.5%)	13 (10.7%)	31 (25.4%)	35 (28.7%)	29 (23.8%)
Specific to disease*	41 (33.6%)	21 (17.2%)	26 (21.3%)	14 (11.5%)	20 (16.4%)
Limitation in work or leisure	18 (14.8%)	12 (9.8%)	33 (27.0%)	31 (25.4%)	28 (23.0%)
Emotional distress*	42 (34.4%)	35 (28.7%)	24 (19.7%)	10 (8.2%)	11 (9.0%)
Relationships with family	58 (47.5%)	25 (20.5%)	25 (20.5%)	7 (5.7%)	7 (5.7%)
Social relationships	52 (42.6%)	30 (24.6%)	26 (21.3%)	7 (5.7%)	7 (5.7%)
Appearance	56 (45.9%)	33 (27.0%)	22 (18.0%)	5 (4.1%)	6 (4.9%)

Results

To date 122 records are available for assessment. Patients did not endorse a particular questionnaire, 69 stating no preference, 11 favouring the EORTC QLQ C30, 14 the FACT G and 15 the SF-36 v2. Detailed assessments on the H&N questionnaires will be performed when accrual is complete (150 patients). In terms of raising important questions, 63.6% considered that the FACT had greatest efficacy, followed by 57.9% for the SF-36 and 55% for the EORTC. However, the EORTC gained the highest rating for wording (60.8%) followed by the FACT (57.9%) and SF-36 (52.1%).

Ratings for content of a consultation indicated that 'disease specific limitations was the most important area. 'Symptoms and side effects of treatment (71.3%), 'physical activity' (69.7%) and 'emotional aspects (62.3%) were considered important. When this was compared with the perceived content of consultations, less than a third of patients felt that these issues were consistently addressed by their doctors. Emotional distress was perceived rarely or never to be addressed in the majority of medical consultations.

Conclusions

Although patients did not endorse a particular questionnaire, they demonstrated ability to comment on aspects of questionnaire design.

Patients' perceptions were that important issues were not being consistently raised in medical consultations. This study raises interesting questions about the mutual understanding of the content of doctor/patient interactions and how communication can be improved so that the needs of patients are met.

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Bringing Patient Care and Clinical Trials Together:

Use of a new Integrated Database

in a complex multidisciplinary setting

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Introduction

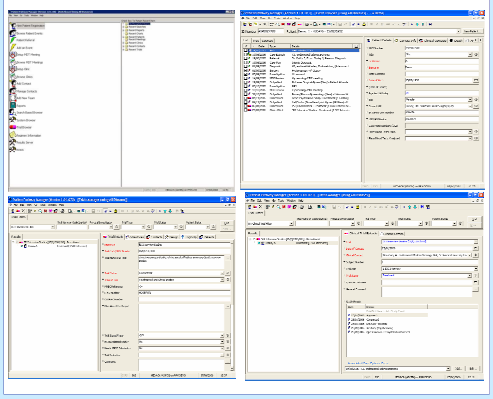
Secondary use of patient databases is essential if research and development (R&D) at point of care is to be expanded. However, integration of effective databases, primarily designed to facilitate patient care with R&D needs, represents a complex challenge. We present a system which allows online management of complex datasets for clinical trials within care records. This has been trialled in a complex multidisciplinary setting and represents an ideal resource for clinicians and researchers working together.

Clinical Trials Database

The trials database was developed for use in Oncology at the Leeds Teaching Hospitals NHS Trust and the University of Leeds. It integrates seamlessly with the electronic patient record, the patient pathway manager (PPM) which records the 'pathway' or sequence of events in a patient's care episode.
PPM is written in SQL Server, Microsoft's data warehousing and relational database management system, with a Visual Basic graphical user interface, facilitating easy management and browsing (Fig 1).

Eligible patients are identified by diagnosis, clinic or Consultant and 'flagged' for download. Thereafter their progress is tracked in PPM.

Figure 1. The PPM/Trials Browser Interface



Clinical Setting

We have used the database in a multi-site/ multidisciplinary setting, entering patients into a trial assessing HRQoLin patients with Head and Neck cancer. Responses are entered via a stand-alone touchscreen, which synchronises with the central database. Quantitative data (questionnaire scores) and qualitative data (transcripts of interviews and consultations) are entered directly at the time of intervention.

Prior to the clinic PPM is searched on-line and eligible patients can be identified by name, by disease, by Consultant or by clinic. The PPM record is uploaded from the central database into the trials browser. The study forms have been entered into the trials browser and the system tracks the patient through from approach to entry or refusal and to completion of episode(s). On return from the clinic, data is uploaded to the central database.

For the current trial, where entry can take place at multiple sites, the versatility of this system has been essential, allowing the use of a lap-top computer in a quiet environment to provide trial participants with the ideal setting in which to participate

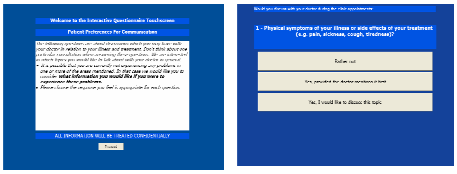
Figure 2. Use of database in the clinical setting

Data Entry

Trial data is entered onto the laptop using the questionnaires required for the study. The trial record is linked through to the PPM clinical record.

The entry screen provides information and the patient progresses through the screens until data collection is complete.

Figure 3. Collection of questionnaire data



To enter a response, the patient simply clicks the screen.

Data is automatically uploaded into the trials database and saved for analysis.

Summary

This system has proved reliable and user-friendly for clinicians and researchers. It combines core patient data with trial data, ensuring security, accuracy (avoids transcription errors) and ease of data exploration and analysis.

Combining advanced technology in the way demonstrated, can achieve much in optimising collaborations between clinical and research teams and encouraging accrual to clinical trials. It provides a practical tool for routine collection of trials related or clinically related data (such as collection of data on health related quality of life) and the technology allows immediate feedback to the clinician in any preferred format, tables, graphs and print outs, thus facilitating management in a complex clinical setting.

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