Guidance on Commissioning Cancer Services

Improving Outcomes in

Head and Neck Cancers

The Research Evidence

Draft, Spring 2004

Contents

Introduction

This document complements and is designed to be read alongside *Guidance on Cancer Services: Improving Outcomes in Head and Neck Cancer – The Manual*. It provides a condensed version of reviews of the evidence relevant to the recommendations made in the manual. The topic areas are dealt with in the same order as in the manual to facilitate cross-referencing.

This document presents a summary of a series of reviews undertaken by researchers at the Centre for Reviews and Dissemination (CRD), University of York (see Appendix 3). The review team constructed review questions in consultation with the editorial group and other experts in the field.

Comprehensive searches were carried out for each review question. Where appropriate, strategies were limited by methodological search filter or date. Searches were conducted for each question from a range of databases (Medline, Embase, CancerLit, Cochrane Library, DARE, AMED, HMIC, Cinahl, British Nursing Index, Science Citation Index, Social Science Citation Index, NHS EED, LILACS, SIGLE). Unpublished data were also identified through personal contact with researchers in the field. The search process was undertaken by Lisa Mather (CRD). Full details of the searches and strategies used are available from CRD (Tel: 01904 321042 or email: crd-info@york.ac.uk).

Literature searches were undertaken between October 2002 and April 2004.

Two reviewers screened titles and abstracts of all studies identified through electronic searching for relevance. Potentially eligible studies were retrieved in full and two reviewers selected studies. Selection of studies was based on pre-defined inclusion/exclusion criteria that specified for each question the participants, intervention, comparator(s) and outcomes of interest. The same inclusion/exclusion criteria were applied to studies identified from non-electronic sources. Disagreements

were resolved through discussion and any unresolved disagreements were discussed with a third reviewer. No restriction was made on publication language. Data were extracted from the included studies by one reviewer and checked for accuracy by another reviewer. However, some studies reported only as non-English language publications could not be data extracted (e.g. studies published in Japanese). Studies published in German, Dutch, Italian, Spanish and French were data extracted by one reviewer (sometimes it was only possible to extract minimal data owing to the language problems) and checked by a second reviewer.

Table 1: Grading of Evidence

<table>
<tr><th rowspan="2">Grade</th><th colspan="3">Evidence</th></tr>
<tr><th colspan="2">Diagnosis</th><th>Treatment</th></tr>
<tr><td>I</td><td colspan="2">Systematic review of at least level II (below) studies</td><td>Systematic review of randomised controlled trials (RCT's)</td></tr>
<tr><td>II</td><td colspan="2">A blind comparison with reference standard among an appropriate broadly defined consecutive sample of patients</td><td>RCT</td></tr>
<tr><td>III</td><td colspan="2">Systematic review of poorer than level II (above) studies</td><td>Systematic review of non-RCT's</td></tr>
<tr><td>IV</td><td>Any one of the following</td><td rowspan="3">• Narrow population spectrum.
• Differential use of reference standard.
• Reference standard not blind.
• Case control study design</td><td>Quasi-experimental studies (e.g. experimental study without randomisation)</td></tr>
<tr><td>V</td><td>Any two of the following</td><td>Controlled observational studies
• Cohort studies
• Case control studies</td></tr>
<tr><td>VI</td><td>Any three or four of the following.</td><td>Observational studies without control groups</td></tr>
<tr><td>VII</td><td colspan="2">Expert opinion, consensus and case studies (n = 1).</td><td>Expert opinion, consensus and case studies (n = 1).</td></tr>
</table>

Only systematic reviews that met the *DARE*[a] quality criteria were included. All primary studies meeting the inclusion criteria were included and their quality commented upon in the tables.

The studies were graded using agreed criteria as outlined in Table 1, which is derived from the CRD guidance.[b] This grading broadly corresponds with the Clinical Outcomes Group categories of evidence used in the Manual, where A = I or II, B = III, IV, V or VI and C = VII.[c]

The evidence was summarised in a narrative synthesis. The nature of the evidence concerning each question is described and the results summarised along with tables of studies giving fuller details of the research.

Two complementary pieces of research were commissioned; one to elicit patients' views about head and neck cancer services and the second to examine the cost impact of the recommendations. The National Cancer Alliance, Oxford, was commissioned to undertake a small-scale exercise to enable head and neck cancer patients to input their views, knowledge and experience into the development of the guidance, reported in Appendix 1. The School of Health and Related Research at the University of Sheffield was commissioned to examine the cost implications of the potential expansion in services based on the recommendations, reported in Appendix 2.

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[a] Centre for Reviews and Dissemination. *Database of Abstracts of Reviews of Effectiveness*. Available from http://www.york.ac.uk/inst/crd/

[b] NHS Centre for Reviews and Dissemination. *Report 4 - Undertaking systematic reviews of research on effectiveness: CRD's guidance for carrying out or commissioning reviews*. 2nd ed. York: NHS Centre for Reviews and Dissemination, University of York, 2001.

This document was prepared by Rosalind Collins, Adrian Flynn and Alison Eastwood at the CRD, University of York.

[c] Mann T. *Clinical Guidelines: using clinical guidelines to improve patient care within the NHS.* London: NHS Executive, 1996.

Referral

The Questions

a) In head and neck cancer does earlier detection of malignancy lead to improved outcomes?

b) In groups at a higher risk of developing head and neck cancers, do interventions aimed at raising awareness of the existence of head and neck cancers, the risk factors and the features of possible early disease lead to improved outcomes?

c) Does raising awareness of professionals (e.g. GPs, dentists, pharmacists, dietitians and speech and language therapists) of the existence of head and neck cancers, the risk factors, the features of possible early disease, the existence of certain high-risk groups and the referral pathway lead to improved outcomes?

d) Does opportunistic screening for head and neck cancers, including assessments of the salivary glands and neck nodes, result in improved outcomes for head and neck cancer patients?

e) What is the diagnostic yield of opportunistic screening, when it is performed by the various professions involved in this activity?

f) For patients with symptoms suggestive of head and neck cancers, what effect does rapid access to a specialist/dedicated diagnostic clinic, with appropriate diagnostic facilities (ultrasound scanning, laryngoscopy, fine needle aspiration cytology, flexible nasopharyngoscopy, selective staining, brush biopsy and scalpel biopsy as appropriate) have on patient and service outcomes?

g) For patients with symptoms suggestive of head and neck cancers, what effect does the provision of a clear route of referral have on outcomes?

The Nature of the Research Evidence

a) Earlier detection of malignancy

Two studies were located. These included a retrospective interview-based study of 336 patients attending one of three oral and oropharyngeal cancer services in Brazil.[1] This assessed where in the referral pathway delays occurred. The second study was an audit of services offered to patients in the West of Scotland region.[2] This was a retrospective analysis of prospectively collated data on 206, identified by the cancer registry system. These studies are summarised in Table 1a.

b) Raising awareness of groups at a higher risk of developing head and neck cancers

No evidence was found relating to raising the awareness of groups at a higher risk of developing head and neck cancers.

c) Raising professionals' awareness of the existence of head and neck cancers

One assessment of a brief, multi-component educational intervention was located; the intervention was aimed at health professionals.[3] The intervention consisted of a videotape, a slide presentation, a one-page handout and a laminated sheet containing 16 pictures showing normal and malignant sites in the oral cavity. The intervention was offered to 352 health professionals in total and was conducted in the USA. This study is summarised in Table 1c.

d) Opportunistic screening

One large uncontrolled observational study investigated the feasibility of conducting a systematic examination of the oral mucosa as part of the routine dental check-up.[4] Details are given in Table 1d.

e) Diagnostic yield of opportunistic screening

No evidence was found relating to the diagnostic yield of opportunistic screening.

f) Rapid access to a specialist/dedicated diagnostic clinic

One controlled and five uncontrolled observational studies assessed the effect of rapid access to a specialist or dedicated diagnostic clinic with appropriate diagnostic facilities, for patients presenting with a hoarse voice[5, 6] or head and neck lump.[7-10]

The controlled study compared two cohorts of 50 patients referred to a 'lump and bump' clinic, one before and one after the implementation of the two-week wait initiative. However, the study was presented in letter format with very few methodological details, therefore the quality of the study cannot be verified.[7]

The uncontrolled studies included a well-conducted observational study of 271 patients who attended a direct referral, immediate access hoarse voice clinic,[5] a small audit (n=34) of a pilot 'husky voice' clinic where patients were to be seen within 5 working days and underwent flexible fibre-optic nasendoscopy,[6] an audit[8] and re-audit[9] of a 'one-stop' clinic for patients with a possible neck lump, which was staffed by a senior cytopathologist who was able to undertake sample collection and immediate reporting of patients requiring fine needle aspiration cytology (FNAC) and a report of 100 patients referred to a direct referral clinic for patients presenting with a neck mass, where patients were to be seen within two weeks of referral.[10] Details are given in Table 1f.

No studies were identified relating to access to specialist teams, with access to diagnostic tools such as selective staining, brush biopsy and scalpel biopsy for patients with symptoms suggestive of oral cancer.

g) Provision of a clear route of referral

Two of the studies described in section (f) also included advising practitioners of the appropriate route of referral.[6, 10] No other studies investigated the provision of a clear route of referral.

Summary of the Research Evidence

a) Earlier detection of malignancy

A retrospective interview-based study in three hospitals in Brazil studied 336 patients with oral or oropharyngeal cancer.[1] The study measured, among other variables, delays in referral and the varying effects of delays at different points in the system. A majority of delays were caused by patients delaying consultation with health professionals (58.3%). However, health professionals were solely responsible for delay in 12.9% of cases and responsible for at least some of the delay in a further 11.3% of cases. Delays caused by doctors were on average longer than those caused by dentists (12 months compared with 6.5 months), while delays caused by pharmacy staff were shorter still (3.5 months).

The effect of these delays was investigated using the relative risk statistic. This assessed whether patients who had experienced delays were more likely to be diagnosed with late stage disease than those patients who had experience no delays. The assessment found that patients who did not delay in reporting symptoms to a professional were approximately half as likely to present with late stage disease. However, no statistically significant effect was demonstrated linking delay by health professionals with a greater likelihood of a patients' being diagnosed with late stage disease. It should be noted that, while data on the sex, age and tumour site were collected, the analysis of the effects of these delays was conducted without allowing for the effects of these variables.

The study went on to assess the effect of stage at presentation on the duration of hospital stay and the cost of care. These variables are closely linked as the former is a major determinant of the latter. Descriptive statistics indicated that a trend in longer stays and higher costs was seen in persons with late stage disease.

An audit conducted in the West of Scotland region compared clinical outcomes of patients treated at the various service providers in that area.[2] The audit found that late stage presentation was common. Patients presenting with Stage 1 disease fared significantly better than those presenting with all other

stages in terms of the hazard ratio (HR) for post-therapy disease-free interval. They also had a significantly better HR for overall survival than patients presenting with Stage III or IV disease. Point estimates of the HR were progressively worse for Stages II to IV for both these outcomes but the confidence intervals of the HR overlapped; this effect was therefore not statistically significant.

The study also found significant differences in outcomes experienced by patients treated at different centres. These are further discussed in Chapter 2, question k.

This audit used data collected prospectively by the local cancer registries but the categories and outcomes of assessment were defined after the data were collected. While the evidence should be viewed as suggestive rather than definitive, owing to the observation nature and the *post hoc* analysis, the study was very well conducted.

For fuller details of these studies, please see Table 1a.

Conclusions

Early detection of malignancy is difficult to study but observational methods may, as in the cases of both studies reviewed here, be informative. These suggest that patients whose cancers were detected later (whether defined in relation to an experience of delay in diagnosis or later stage at diagnosis) require more extensive treatment and yet experience poorer outcomes.

b) Raising awareness of groups at a higher risk of developing head and neck cancers

No evidence was found relating to raising the awareness of groups at a higher risk of developing head and neck cancers.

c) Raising professionals' awareness of the existence of head and neck cancers

A brief, multi-component educational intervention, aimed at health professionals, was examined in a before-and-after study using survey methodology.[3] The intervention was offered to 352 professionals but only 43% of these participated in the evaluation of the intervention. The study included 10 dentists, 14 doctors, 16 allied health professionals and 23 nurses. It also included 81 medical students. This response rate is very low and may affect the validity of the study's findings.

The study measured the knowledge levels of participants in the intervention, Those who agreed to evaluate the intervention were retested some time later. The "before" and "after" scores were then compared for those participants for whom two scores were available. While knowledge scores increased overall, the increase in knowledge was not evenly spread among the various knowledge-items tested and differences were seen in the professional groupings. Doctors, allied health professionals and medical students saw increases in knowledge levels while the dentists and nurses participating failed to see increased levels of knowledge. The dentists were the only group who did not feel they needed additional training following the intervention.

This study suggests that an educational intervention may be beneficial but the professional grouping at which it is aimed may be a factor in its usefulness. The failure of dentists and nurses to increase their levels of knowledge may be related to the level at which the intervention was pitched or its format.

Medical students were over-represented in the population assessing the intervention. They, as a group, may be more likely than those who have completed their education, to respond to an educational intervention. This may mean that their contribution to the results bias the overall findings of the study.

It is important to note that the study assessed knowledge not practice. The possibility of a theory-practice gap may not be discounted and changes in

knowledge levels may or may not have a discernable effect on the practice of participants.

Conclusions

An education intervention raised knowledge levels in some health professionals but it is unclear why its effects were inconsistent across professional groups or whether it would affect the practice of those individuals.

d) Opportunistic screening

A total of 1,949 employees who benefited from employer-sourced dental healthcare were invited to attend a mucosal screening session as part of their routine dental check-up, 1,947 employees agreed and were screened.[4] One hundred and fifty five patients (8%) were found to have oral lesions, the dentist diagnosed 151 of these as benign conditions. The remaining four were two cases of tobacco associated leukoplakia, one case of reticular lichen planus and one case of squamous cell carcinoma, which was resected and the patient remained free from disease 18 months later.

e) Diagnostic yield of opportunistic screening

No evidence was found relating to the diagnostic yield of opportunistic screening.

f) Rapid access to a specialist/dedicated diagnostic clinic

A well-conducted study of 271 patients who attended a direct referral, immediate access hoarse voice clinic found that the average waiting time for attendance at the clinic was three weeks, 39 (14%) patients were found to have suspicious lesions on indirect laryngoscopy at the clinic and were admitted for direct laryngoscopy and biopsy under anaesthetic, of which 10 patients were diagnosed with cancer of the larynx, three were diagnosed with dysplasia and one with cancer of the tongue.[5] The audit of 34 patients referred to a pilot 'husky voice' clinic with agreed referral protocols[6] reported that 94% of

patients were seen within five working days and five referrals (15%) were inappropriate. Nasendoscopy was abnormal in 14 patients, one of which was diagnosed with squamous cell carcinoma. Due to the small number of patients included in this study, the results should be seen as suggestive rather than definitive.

The controlled study compared two cohorts of 50 patients referred to a 'lump and bump' clinic[7] and found that the mean time between the date of the referral letter and the out-patient appointment increased from 13.8 days to 25.4 days after implementation of the two-week wait initiative. The pick-up rate for malignancy was 4% in patients referred via the two-week wait initiative and 14% for non-two-week wait 'lump and bump' clinic patients. However, the small number of patients included in the study, lack of methodological details reported and possible influence of other factors occurring at the same time as the implementation of the two-week wait initiative, reduce the reliability of the results presented.

The audit[8] and re-audit[9] of a 'one-stop' head and neck lump clinic with the provision of immediate FNAC assessment and reporting found that over two-thirds of 245 patients referred to the clinic were managed during only one visit. The accuracy of immediate FNAC was 94%. The mean number of days patients waited to be seen in the clinic was 17 in the first audit and 21 in the re-audit and the mean waiting time at the clinic was about an hour in both audits.

Of 100 patients referred to a direct referral clinic for a neck mass, for which practitioners were advised of the appropriate route of referral, 46 were referred with enlarged lymph nodes, 21 for thyroid swelling and 18 for salivary gland swellings.[10] Two referrals were considered to be inappropriate. Of the patients referred with enlarged lymph nodes ten were found to have squamous carcinomas and three had lymphoma. Three salivary gland swellings were malignant.

Conclusions

The results of the audits of a 'one-stop' head and neck lump clinic suggest that such clinics may enable the majority of patients to be managed during only one visit with an acceptable waiting time at the clinic and a high rate of accuracy of the immediate FNAC assessment. The direct referral, immediate access hoarse voice clinic had a waiting time of three weeks and only a very small proportion of patients were diagnosed with head and neck cancer, whilst a higher proportion of patients referred to a direct referral clinic for a neck mass were found to have cancer.

The results of a controlled study comparing patients referred to a 'lump and bump' clinic before and after the implementation of the two-week wait initiative found that mean waiting times increased after implementation of the two-week wait initiative and the pick-up rate for malignancy was lower in patients referred via the two-week wait initiative than in non-two-week wait 'lump and bump' clinic patients.

g) Provision of a clear route of referral

Two of the studies described in section (d) advised practitioners of the appropriate route of referral.[6, 10] An audit of 34 patients referred to a pilot 'husky voice' clinic with agreed referral protocols[6] reported that five referrals (15%) were inappropriate. However, owing to the small number of patients included in this trial, the results are only suggestive. Of 100 patients referred to a direct referral clinic for a neck mass, for which practitioners were advised of the appropriate route of referral, only two referrals were considered to be inappropriate.[10] It is not possible to state whether the effect on any other patient outcomes in these studies were owing to the clear route of referral or rapid access to a specialist/dedicated diagnostic clinic.

Table 1a: Earlier detection of malignancy

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Kowalski, 1994.[1]

Country:
Brazil

Aims:
To analyse the importance of various pre-treatment factors such as demographic and socio-economic factors and lateness of case referral, that could explain risk of advanced disease.

Grade of evidence:
VI</td>
<td>Participants:
Consecutive patients with oral and oropharyngeal carcinomas, which could be accessible to self examination, referred to three head and neck surgery services between 1 February 1986 to 30 December 1988.

Patients whose interviews were interrupted because of difficulty in communication owing to pain or speech problems were not included in the study.</td>
<td>Methods:
Prior to treatment patients were submitted to a 40min to 60min structured questionnaire-based standardised interview to elicit detailed information on socio-economic and demographic variables, history of tobacco smoking and alcoholic beverage consumption, including details of quantities consumed.

The odds ratio was the measure of association used to estimate the relative risk (RR) of advanced stage versus early stage disease owing to selected study factors. Point and interval estimates for the RR were obtained by multiple logistic regression using unconditional maximum likelihood estimations.

Outcomes measured:
Information on the first sign or symptom and the interval between recognition of it and the consultation with the first health professional (drug store clerk, pharmacist, dentist or medical doctor) and the subsequent admission to hospital were taken as time variables considered for the analysis. Patient delay was defined on the basis of median site-specific time interval between the perception of the first sign or symptom and initial consultation with the first health professional. Delay was considered if the patient's value for this variable exceeded that of the median. Health professional delay was considered present whenever the time interval between the first consultation and the admission to a head-and-neck service was</td>
<td>Included patients:
336 patients were included in the study, including 291 (86.6%) males. Ages ranged from 15 to 82 years (median 57 years). The sites of primary tumours were as follows: 55 lip, 71 tongue, 62 floor of mouth or lower gum, 16 hard palate or upper gum, 14 soft palate, 30 retromolar area, 67 tonsillar fossa and 21 other parts of the oral cavity or oropharynx. The proportion of patients with clinical stage I and II lip carcinoma was higher than in patients with primary tumours at other sites. 245 cases had tumours classified as advanced stage (T3 to T4 or pN+) and 91 as early stage (T1 to T2, pN-).

Delays in referral
<table>
<tr><th>Responsibility</th><th>Number of cases</th><th>Range (months)</th><th>Median (months)</th></tr>
<tr><td>Patient</td><td>196 (58.3%)</td><td>1 - 81</td><td>4.2</td></tr>
<tr><td>Medical doctor</td><td>19 (5.7%)</td><td>2 - 20</td><td>12.3</td></tr>
<tr><td>Dentist</td><td>11 (3.3%)</td><td>2 - 23</td><td>6.5</td></tr>
<tr><td>Pharmacist</td><td>13 (3.9%)</td><td>2 - 26</td><td>3.5</td></tr>
<tr><td>Patient and 1st health professional</td><td>38 (11.3%)</td><td>3 - 36</td><td>8.5</td></tr>
<tr><td>No delay</td><td>59 (17.6%)</td><td>-</td><td>-</td></tr>
</table>
Crude RR estimates for advanced stage of oral and oropharyngeal carcinoma according to characteristics of delay
<table>
<tr><th>Variable</th><th>Category</th><th>Early/ advanced</th><th>RR (95% CI)</th></tr>
<tr><td>Responsibility for delay</td><td>No delay
Patient
Health prof.
Combined</td><td>14/45
60/136
6/37
11/27</td><td>1.0 (ref)
0.71 (0.36 to 1.38)
1.92 (0.67 to 5.49)
0.76 (0.30 to 1.92)</td></tr>
<tr><td>Patient</td><td>No
Yes</td><td>20/82
71/163</td><td>1.0 (ref)
0.56 (0.32 to 0.98)</td></tr>
<tr><td>Doctor</td><td>No
Yes
Not consulted</td><td>77/196
10/36
4/13</td><td>1.0 (ref)
1.41 (0.67 to 2.99)
1.28 (0.40 to 4.04)</td></tr>
<tr><td>Dentist</td><td>No
Yes
Not consulted</td><td>8/40
1/14
82/191</td><td>1.0 (ref)
2.8 (0.32 to 24.43)
0.47 (0.21 to 1.04)</td></tr>
</table>
</td>
<td>Authors' conclusions:
Two of the most important immediate consequences of advanced stage were a conspicuous increase in treatment costs and a longer hospital stay. These consequences may be catastrophic especially for socio-economically disadvantaged people.

Comments:
The conclusions of this study appear to be valid, although the authors do not state how treatment costs were calculated and the findings may not be generalisable to practice in the UK.

It is important to note that this is an observational retrospective study and that neither the source of the data nor who analysed the data is reported. The data presented do not give long-term outcomes of importance such as cause-specific or overall survival. It would have been useful to conduct an analysis with appropriate adjustment for stage of disease, sex, age, differentiation, etc, to discover if the delays measured had an affect on these hard long-term outcomes.</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>greater than 1 month.

Staging of disease was categorised using the 1978 revision of the Union Internationale Contre le Cancer's tumour-nodes-metastasis (TNM) staging system. Early lesions were T1 or T2 N0 clinically and/or histologically (pN-), advanced lesions were all T3, T4 and cases with clinically or histologically positive nodes (pN+).

Costs and treatment duration were also measured.</td>
<td>
<table>
<tr><td>Pharmacist/ drug store clerk</td><td>No
Yes
Not consulted</td><td>6/17
6.18
79/210</td><td>1.0 (ref)
1.06 (0.29 to 3.93)
0.94 (0.36 to 3.47)</td></tr>
<tr><td>Total delay</td><td>No
1 to 3 months
4 to 6 months
>6 months</td><td>14/45
17/67
22/60
38/73</td><td>1.0 (ref)
1.23 (0.55 to 2.73)
0.85 (0.39 to 1.84)
0.6 (0.29 to 1.22)</td></tr>
</table>
Overall treatment costs and treatment duration
<table>
<tr><th>Site</th><th>Stage</th><th>Cost (mean)</th><th>Treatment duration</th></tr>
<tr><td>Lip</td><td>I</td><td>$296</td><td>8 days</td></tr>
<tr><td></td><td>II</td><td>$367</td><td>8 days</td></tr>
<tr><td></td><td>III</td><td>$678</td><td>19 days</td></tr>
<tr><td></td><td>IV</td><td>$1,768</td><td>66 days</td></tr>
<tr><td>Oral cavity</td><td>I</td><td>$560</td><td>9 days</td></tr>
<tr><td></td><td>II</td><td>$904</td><td>30 days</td></tr>
<tr><td></td><td>III</td><td>$1,275</td><td>91 days</td></tr>
<tr><td></td><td>IV</td><td>$1,499</td><td>55 days</td></tr>
<tr><td>Oropharynx</td><td>I</td><td>$688</td><td>21 days</td></tr>
<tr><td></td><td>II</td><td>$490</td><td>29 days</td></tr>
<tr><td></td><td>III</td><td>$1,332</td><td>54 days</td></tr>
<tr><td></td><td>IV</td><td>$1,180</td><td>54 days</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>Robertson, 2001.[2]

Country:
UK

Aims:
To identify treatment philosophies for oral cancer and investigate any survival differences associated with different treatment options.

Grade of evidence:
VI</td>
<td>Procedure:
1 of 5 treatment strategies:
Biopsy (other than excisional biopsy) only with no further treatment
Excisional biopsy only with no further treatment
Radical surgery only
Biopsy (excisional or non-excisional) in combination with radiotherapy
Radical surgery in combination with radiotherapy

These were given at 1 of 14 units throughout the West of Scotland.

Design and data source:
Patients diagnosed with oral cancers were identified from the West of Scotland Cancer Registry. Information was then taken from their medical records. Information was</td>
<td>Covariates adjusted for:
Information on demographic and disease-related factors adjusted for in the statistical analysis.

Statistical method:
The Kaplan-Meier and log-rank tests were used to conduct unadjusted analyses of disease-free and overall survival. The Cox proportional hazards model was used for assessment of the influence of treatment factors on survival. Association between treatment and tumour factors was assessed using the χ^2 test.

Information on the effect of volume was obtained by comparing the largest provider with the remaining providers.

Outcomes Measured:
Disease free period.</td>
<td>Included patients:
A total of 243 patients were identified. 16 were excluded owing to incomplete data and 21 were excluded as they had distant metastases at diagnosis. Total number of patients included was 206.

Number of units and patients:
Plastic 1 unit 124 (60%)
Otolaryngology 9 units 66 (32%)
Oral/Maxillofacial 4 units 16 (8%)

Stage at presentation:
<table>
<tr><th>Stage</th><th>Number</th></tr>
<tr><td>T1</td><td>44 (21.4%)</td></tr>
<tr><td>T2</td><td>66 (32%)</td></tr>
<tr><td>T3</td><td>35 (17%)</td></tr>
<tr><td>T4</td><td>61 (29.6%)</td></tr>
</table>
<table>
<tr><th>Stage</th><th>Number</th></tr>
<tr><td>N0</td><td>106 (51.5%)</td></tr>
<tr><td>N+</td><td>100 (48.5%)</td></tr>
</table>
Disease free period:</td>
<td>Authors' conclusions:
The study confirms that early stage tumours have a better prognosis than late stage tumours but a large number of patients present with late-stage disease.

The concentration of patients in the plastic surgery unit at one hospital has allowed the combined team to develop considerable experience in designing individual treatments and their results show that these treatment plans may be proving to be more effective than those designed by those seeing fewer patients.

Comments:
This was a well-conducted piece of research which, despite the limitations which must be acknowledged when dealing with studies based on a retrospective survey of records identified by registry data, provides an insight into the effects of both the tumour stage at presentation</td>
</tr>
</table>

	cross-checked with the West of Scotland Cancer Surveillance Unit. **Time period:** 1984 to 1990	Overall survival time.	T2 1.84 (1.04 to 3.26) T3 2.69 (1.40 to 5.15) T4 2.97 (1.61 to 5.50) **Overall Survival:** **Stage / Hazard Ratio** T1 1.00 T2 1.40 (0.83 to 2.37) T3 2.27 (1.28 to 4.03) T4 2.41 (1.38 to 4.21)	N+ 1.46 (0.93 to 2.28) **Stage / Hazard Ratio** N0 1.00 N+ 1.46 (0.98 to 2.16)	and the number of patients managed by the treatment centre. While the conclusions may only be viewed as suggestive owing to the nature of the evidence, they follow from the results presented. The study also examined other aspects of care outside the remit of the present review.

Table 1c: Raising professionals' awareness of the existence of head and neck cancers

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Barker, 2001.[3]

Country:
USA

Aims:
To address an apparent lack of oral/pharyngeal cancer (OPC) knowledge of health care professionals in an academic health centre and its referring community health centres.

Grade of evidence:
VI</td>
<td>Participants:
352 health care professionals including dentists, physicians, medical students, nurses and allied health professionals participated in the study.

Service:
An educational intervention was designed to teach health care professionals about the oral sites at risk, aetiological factors and early signs and symptoms of OPCs, as well as screening techniques. The program included a videotape (The Health Care Professional's Guide to Oral Cancer), a slide presentation of 18 intra-oral photographs to emphasise the areas of the mouth at highest risk for OPC and the clinical appearances of early lesions, a one-page handout summarising critical factors related to OPC and a laminated oral cancer reference chart of 16 colour photographs of normal sites of the oral cavity and OPC lesions. This multi-component intervention was designed</td>
<td>Methods:
A self-administered questionnaire was developed and pilot tested with a convenience sample of oral and maxillofacial pathologists to ensure content validity. Dichotomous items were developed to assess knowledge in three subscales: oral sites at risk for OPC, potential aetiological factors and whether different signs and symptoms are frequently or infrequently indicative of an early OPC. Two items using a five-point Likert response scale assessed participants' perceived competency with respect to their OPC knowledge and perceived needs for additional training to adequately examine patients.

The assessment questionnaire was administered immediately prior to the implementation of the educational intervention. A questionnaire containing the same questions as well as a section to evaluate the OPC educational program was mailed to participants three months after the intervention. Responses were anonymous.

Statistical methods:
The number of correct answers for each subscale (oral sites at risk, aetiological factors and signs and symptoms) was calculated. A total knowledge score was calculated by adding the subscale scores together. Changes in scores were examined using a dependent t-test. Additionally, item-level analyses were performed using a McNemar change test in order to examine shifts from incorrect to correct responses. In order to examine changes in knowledge as a</td>
<td>155/352 (44%) health professionals returned the post-intervention questionnaire, including 10 dentists, 14 physicians, 81 medical students, 23 nurses and 16 allied health professionals. The remaining 11 were pharmacists, audiologists and speech pathologists and were excluded from the subsequent analysis.

The total knowledge score and subscale scores for the collective group of respondents all increased significantly ($p < 0.05$). The score for total knowledge increased from a mean of 19.7 (SD: 3.4) before the intervention to 21.5 (SD: 3.3) after the intervention. Similar increases were found for the subscale scores.

In relation to specific items, changes in the proportions of correct responses were statistically significant ($p \leq 0.01$) for the following items:
<table>
<tr><th>Item</th><th>Before intervention</th><th>After intervention</th></tr>
<tr><td>Oral sites at risk:</td><td></td><td></td></tr>
<tr><td>Lateral tongue (high risk)</td><td>68</td><td>93</td></tr>
<tr><td>Gingiva (low risk)</td><td>53</td><td>72</td></tr>
<tr><td>Tonsillar pillar (high risk)</td><td>33</td><td>19</td></tr>
<tr><td>Etiologic factors:</td><td></td><td></td></tr>
<tr><td>Alcohol use (identified risk)</td><td>55</td><td>84</td></tr>
<tr><td>Bacteria (no risk)</td><td>25</td><td>36</td></tr>
<tr><td>Poor oral hygiene (no risk)</td><td>11</td><td>18</td></tr>
<tr><td>Tongue/cheek biting (no risk)</td><td>45</td><td>57</td></tr>
<tr><td>Early signs and symptoms:</td><td></td><td></td></tr>
<tr><td>Erythroplakia</td><td>54</td><td>86</td></tr>
<tr><td>Leukoplakia-erythroplakia</td><td>69</td><td>89</td></tr>
<tr><td>Non-healing lesion
(all frequent signs/symptoms of OPC)</td><td>83</td><td>92</td></tr>
</table>
Although the mean knowledge scores of the individual professional groups differed prior to the intervention, the overall magnitudes of the changes in knowledge for physicians, medical students and allied health professionals were relatively similar. In contrast, the knowledge levels of the dentists and nurses did not change over time. This difference in the levels of change in knowledge over time was statistically significant ($p < 0.01$; 2-factor repeated-measures ANOVA).

The increase in perceived knowledge was statistically significant ($p < 0.01$) for all professions except dentists. Overall, the respondents' perceived knowledge competence</td>
<td>Authors' conclusions:
A brief, multi-component educational intervention can increase health care professionals' knowledge regarding OPC.

Comments:
The conclusions of this study appear to be valid. However, no patient outcomes were measured and the authors do not investigate whether the increased knowledge was still evident in the long term. Furthermore, increases in knowledge may not lead to changes in practice.

The majority of health professionals who responded were medical students, who are less likely to be involved in the care of these patients. Also, as students, they may be more receptive to educational interventions than qualified caregivers. The number of professionals in each of the other groups was small.</td>
</tr>
</table>

	to be presented within a 45min period and was pilot tested with medical students in a clinical setting.	function of professional training (groups), data were analysed using a two-factor repeated-measures ANOVA. Changes in perceived knowledge and needs for additional training were analysed using the Wilcoxon signed-ranks test.	(responses on a Likert scale where 1 = strongly disagree and 5 = strongly agree that the participants' perceived OPC knowledge was adequate) increased significantly ($p < 0.01$) from before to after the intervention, mean 2.5 (SD: 1.0) prior to the intervention versus 3.6 (SD: 0.9) after the intervention. Participants' perceived needs for additional training in OPC decreased from 4.3 (SD: 0.8) prior to the intervention to 3.7 (SD: 1.1) after the intervention using the Likert scale, this was statistically significant for all respondents together ($p < 0.01$) and each of the different professionals ($p < 0.05$). The mean score for all professional groups except dentists suggested that they still agreed that they needed additional training in OPC.	

Table 1d: Opportunistic screening

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Field, 1995.[4]

Country:
UK

Aims:
To assess the feasibility of conducting a systematic examination of the oral mucosa as part of the routine dental check-up and in conditions similar to NHS-practice.

Grade of evidence:
VI</td>
<td>Service:
Patients were examined in the dental chair in good light by their usual dentist. A methodical examination of the mucosal surfaces was conducted using manual palpation as appropriate and the examination lasted about 5 minutes. Patients also completed a questionnaire relating to their smoking and drinking habits.

Design and data source:
A case-series design was used. Patients were invited to attend a mucosal screening session at the same time as 6-monthly dental checks.

Study population:
1,949 patients were invited to attend. 1,947 agreed to take part. All were employees of the UML Limited company. No information relating to socio-economic factors were presented.</td>
<td>1,369 men and 578 women were screened. 619 were aged over 50 years including 210 who were aged 60 or more.

306 participants smoked. Most smokers (96.7%) also drank alcohol.

155 patients (8%) were found to have oral lesions. 151 of these were diagnosed by the dentist as “innocent or benign” conditions. Details of the remaining 4 (0.2%) are as follows:

<table>
<tr><th>Sex</th><th>Age</th><th>Clinical Lesion</th><th>Site(s)</th><th>Diagnosis</th></tr>
<tr><td>M</td><td>49</td><td>Leukoplakia</td><td>Soft palate commissure (bilateral)</td><td>Tobacco associated leukoplakia</td></tr>
<tr><td>M</td><td>49</td><td>Leukoplakia</td><td>Buccal mucosa retromolar (bilateral)</td><td>Tobacco associated leukoplakia</td></tr>
<tr><td>F</td><td>51</td><td>Leukoplakia</td><td>Buccal mucosa retromolar</td><td>Reticular lichen planus</td></tr>
<tr><td>M</td><td>55</td><td>Ulcer with erythroleukoplakia</td><td>Buccal mucosa</td><td>Squamous cell carcinoma</td></tr>
</table>
</td>
<td>Authors’ conclusions:
This study has confirmed that a thorough examination of the oral mucosa can realistically be carried out as part of the routine dental inspection in NHS dental practice.

Comments:
This study appears to have been well conducted and generally well reported. No assessment of the cost of providing the service was made.

The study stated that it aimed to replicate NHS practice but the conclusion, given in the abstract, that the practice of oral mucosal screening was shown to applicable to the NHS did not follow from the evidence presented. The authors did not conduct their study in the NHS and while the length of time taken seeing patients was comparable to that spent in NHS practices, the population may not have been comparable to the NHS workload. In particular oral cancers are commoner among those of lower socio-economic groups and all the participants of this study were employees who benefited from employer-sourced dental healthcare. This may reduce the value of any comparisons.</td>
</tr>
</table>

Table 1f: Rapid access to a specialist/dedicated diagnostic clinic

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>McCombe, 2002.[7]

Country:
UK

Aims:
The aim appears to have been to compare typical waiting time before and after the 2-week wait (2ww) standard.

Grade of evidence:
IV</td>
<td>A “Lump and Bump” clinic was established at a DGH.

No details of the referral criteria advertised or the patients referred were given. No details of the clinic procedures used were provided.

2 cohorts, 1 before and 1 after the 2ww initiative, were compared.</td>
<td>Methods:
The methods used in collecting the information were not reported.

Outcomes measured:
Waiting Times.</td>
<td>Included patients:
50 patients were included in each group. The second group included 8 2ww patients and 42 non-2ww patients. Additional information was presented on another group consisting of the most recent 50 patients referred under the 2ww system.

Waiting time:
Before – 13.8days (SD: 6.4)
After (all) – 25.4 days (SD: 12.8).
After (non-2ww) – 29.0 days (SD: 10.4).
(Calculated from date of referral letter to the out patient appointment.)

Malignancy pick-up rate:
2ww patients – 4%
Non-2ww “Lump and Bump” clinic patients – 14%</td>
<td>Authors’ conclusions:
The authors consider their service to have significantly deteriorated with the introduction of the 2ww system.

Comments:
The study was presented in letter format and as such the key details about why and how the study was conducted were omitted. This prevents an assessment of its methodological quality. The conclusion that the increase in waiting times was owing to the introduction of the clinic was not justified based on the information presented. The authors have failed to account for a number of issues which could have lead to the different populations. Some but not all of these may have been related to the 2ww initiative.</td>
</tr>
<tr>
<td>Hoare, 1993.[5]

Country:
UK

Grade of evidence:
VI</td>
<td>Participants:
Patients were eligible to be referred to the service if they had hoarseness for a period of 4 weeks or more.

Service:
A direct-access hoarse voice clinic was established in a large academic hospital. Activity between February 1986 to April 1991 are presented.</td>
<td>Methods:
Patients brought a questionnaire completed by their referring GP. The questionnaire asked the GP to make a presumptive diagnosis of cancer, vocal cord palsy, laryngitis or “other”. A history was taken and examination was conducted, including flexible nasoendoscopic laryngoscopy if required.

Data were recorded prospectively and separately from the hospital notes.

Outcomes measured:
Delay to consultation with their GP.</td>
<td>Included patients:
300 referrals were made by GPs and 271 patients attended the clinic (90%). The larynx of each patient was visualised on the first clinic visit. Demographic details of referees were not presented.

Delay to consultation with their GP:
The mean duration of the patients’ symptoms before they attended their GP was 14 weeks. The time from this consultation to attendance at the clinic was on average 3 weeks. These times were not found to be different in malignant or benign conditions.

Initial clinic findings:
<table>
<tr><th>Diagnosis</th><th>Number of patients</th></tr>
<tr><td colspan="2">Patients admitted for examination under anaesthetic</td></tr>
<tr><td>Probable laryngeal cancer</td><td>19</td></tr>
<tr><td>Vocal cord polyp</td><td>8</td></tr>
<tr><td>Vocal cord nodule</td><td>7</td></tr>
<tr><td>Vocal cord oedema</td><td>3</td></tr>
<tr><td>Laryngeal papilloma</td><td>1</td></tr>
<tr><td>Cancer of the tongue</td><td>1</td></tr>
<tr><td colspan="2">Patients not admitted for examination under anaesthetic</td></tr>
<tr><td>No abnormality detected</td><td>86</td></tr>
</table>
</td>
<td>Authors’ conclusions:
The authors’ conclusions appear to be that a direct access clinic for patients with persistent hoarseness ensures rapid and accurate diagnosis of these patients and is feasible for the hospital to provide.

Comments:
This study was a medium size descriptive analysis of the service provided by a single clinic. The small numbers of patients with serious pathological conditions means that this study should not be over-generalised but the research is strengthened by the prospective nature of the data collection and the fact that it was collected independently of medical notes. While it is limited by the drawbacks of observational research, it has provided good evidence that the provision of this type of clinic is feasible in the NHS setting.</td>
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</table>

<table>
<tr>
<td></td>
<td></td>
<td>Initial clinic findings.

Management of admitted patients.

Findings of direct laryngoscopy.

Accuracy of diagnosis
GP diagnosis
Specialists' clinical diagnosis</td>
<td>
<table>
<tr><td>Laryngitis</td><td>68</td></tr>
<tr><td>Functional dysphonia</td><td>45</td></tr>
<tr><td>Globus pharyngeus</td><td>15</td></tr>
<tr><td>Vocal cord oedema</td><td>7</td></tr>
<tr><td>Vocal cord palsy</td><td>5</td></tr>
<tr><td>Candidiasis</td><td>5</td></tr>
<tr><td>Cancer of the oesophagus</td><td>1</td></tr>
</table>
Management of admitted patients:
A total of 39 patients were found to have discrete or otherwise suspicious lesions on indirect laryngoscopy (14%). All were admitted for examination under anaesthesia, consisting of direct laryngoscopy and biopsy.

Findings of direct laryngoscopy:
<table>
<tr><th>Diagnosis</th><th>Number of patients</th></tr>
<tr><td colspan="2">Patients diagnosed with Cancer of the Larynx</td></tr>
<tr><td>Stage T1 N0</td><td>3</td></tr>
<tr><td>Stage T1 N1</td><td>1</td></tr>
<tr><td>Stage T2 N0</td><td>4</td></tr>
<tr><td>Stage T3 N0</td><td>1</td></tr>
<tr><td>Stage T4 N2</td><td>1</td></tr>
<tr><td colspan="2">Patients given other Diagnoses</td></tr>
<tr><td>Other benign lesion (including polyp, cyst, oedema)</td><td>15</td></tr>
<tr><td>Inflammation</td><td>7</td></tr>
<tr><td>Dysplasia</td><td>3</td></tr>
<tr><td>No abnormality detected</td><td>3</td></tr>
<tr><td>Cancer of the tongue</td><td>1</td></tr>
</table>
Accuracy of diagnosis – GP diagnosis:
GPs indicated probable malignancy in 25 cases, 19 of whom had no malignancy. 7 patients with cancer or dysplasia were not identified as possibly having a neoplasm by their GP. This gives a sensitivity of 46% and a specificity of 24%. All vocal cord palsies were missed by GPs.

Accuracy of diagnosis – specialists' clinical diagnosis:
The specialists' clinical diagnosis correctly identified all 13 patients who were subsequently found to have cancer (Sensitivity = 100%) but this was from a total of 20 patients of whom they suspected as having a neoplasm (Specificity = 65%).
</td>
<td></td>
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<tr>
<td>Kishore, 2001.[9]

Country:
UK</td>
<td>Participants:
All patients referred to the clinic.</td>
<td>Methods:
Patients were seen in a special clinic run in tandem with the head and neck</td>
<td>Included patients:
This is the second phase of an audit covering a period of 10 months and including 135 patients.</td>
<td>Authors' conclusions:
Despite the measures taken, the waiting time was actually increased from 2 to 3 weeks. This would suggest that with current NHS facilities, it may be unreasonable to</td>
</tr>
</table>

Aims: To assess if modification of the means of referral reduces waiting time in a one-stop neck lump clinic and to assess if outcomes of clinical performance seen in an initial assessment of the clinic can be maintained or improved. **Grade of evidence:** VI	**Service:** A one-stop head and neck lump clinic managed by a senior member of the maxillofacial department, who co-ordinates and assesses patients and who is supported by a senior specialist cytopathologist who provides an immediate FNAC assessment. The clinic is run by the most senior specialist registrar under the supervision of a consultant in head and neck oncology. The cytological service is provided by 1 of 3 senior cytopathologists.	outpatient clinic. A special proforma was used to collect information about the patients' attendance at the clinic. **Outcomes measured:** The number of patients who fulfilled the "one-stop" criterion. The waiting time between referral and clinic review. The consistency between the initial FNAC (fine needle aspiration cytology) result provided at the clinic and the final report submitted a few days later.	**Results:** 70% of patients were successfully managed in only 1 appointment – 57% were discharged and 13% were placed on a waiting list. 30% of patients required more than 1 clinic appointment. The mean waiting time in the clinic was consistent with the first phase of the audit. The mean waiting time between referral and consultation increased from 17 to 21 days however. This occurred despite the availability of a fax number for direct referrals. Only 99 patients (74%) had a neck lump on examination but 36 (26%) did not. FNAC done in 76% of lumps (75 patients). The accuracy of FNAC was 71 of 75 (94.7%). In 4 cases the final diagnosis was 1 of cancer when the diagnosis suggested by FNAC was benign.	expect a waiting time of less than 3 weeks for such patients. **Comments:** This report is a re-audit of a service and should be read in conjunction with the previous report, by Murray, 2000.[8] The original audit had recommended that a more clear route of referral be made available as the delay between referral and consultation had been identified as occurring during the initial processing of referral letters by the medical records department. To this end, a fax referral system was made available to all GPs. However, the mean waiting time still increased compared with the previous audit. While the purpose of the study was clear, some of the methods used, both in conducting the research and in treating the patients, were not fully reported. For example, 24% of neck lumps were not subjected to FNAC. It is not clear why they were not assessed using this technique or what methods were used in place of FNAC in these cases.
Murray, 2000.[8] **Country:** UK **Aims:** To assess the number of patients who can be managed in a "one-stop" clinic setting. **Grade of evidence:** VI	**Participants:** Any referral to the oral and head and neck surgery department with a possible neck lump. **Service:** A clinic in a teaching hospital staffed by a senior cytopathologist who was able to undertake sample collection and immediate reporting of patients requiring FNAC (fine needle aspiration cytology).	**Methods:** Patients were seen in a special clinic run in tandem with the head and neck outpatient clinic. A special proforma was used to collect information about the patients' attendance at the clinic. **Outcomes measured:** The number of patients who fulfilled the "one-stop" criterion. The waiting time between referral and clinic review. The consistency between the initial FNAC (fine	**Included patients:** 110 patients were referred in the first 6 months. 51 male, 59 female, age range from 13 to 90 (mean 42). 20% did not have lump on examination. **Presenting symptoms:** 39% had cervical lymphadenopathy, 12% presented with malignant neck disease affecting lymph nodes and salivary glands. **Proportion managed in one visit to clinic:** 76% of patients were managed during only 1 visit to the clinic. 54% of patients were discharged and 22% were placed onto a waiting list for surgery. 15% of patients required radiological investigation and 10% required an additional review. **Proportion having FNAC:** 63% (69 patients) had aspiration performed, 2 specimens (3%) were unsuitable for interpretation. From those patients with diagnostic FNAC's, there were no substantive differences between the FNAC and the definitive reports. Of the 16 patients with immediate excision, when histopathology was compared with FNAC,	**Authors' conclusions:** The authors suggest that this evaluation of the clinic process has been useful to identify that good practice in accordance with national professional bodies was not achieved and that "one-stop" assessment is feasible for the majority of patients referred with neck masses. **Comments:** The methods used and results in this study were reported very briefly. While the aims of the study were clear, the very specific remit of research of this observational nature means that the findings are not very likely to be generalisable. However, the conclusions as drawn, appear to follow well from the results presented.

<table>
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<td>needle aspiration cytology) result provided at the clinic and the final report submitted a few days later. Initial and final FNAC compared to the histopathology reports.

Definition:
Patients were defined as having been managed within the one-stop criterion if they were discharged after the initial appointment or placed in a waiting list for surgery.</td>
<td>the overall pre-operative diagnostic accuracy of FNAC was 94%.

Waiting time:
Mean number of days waiting to be seen in the clinic was 17 (range from 0 to 50). The mean waiting time was 65 minutes (range: 10min to 160min) including the time waiting for the FNAC sample to be reported.</td>
<td></td>
</tr>
<tr>
<td>Resouly, 2001.[6]

Country:
UK

Aims:
To report the results of an audit of a newly established pilot husky voice clinic with agreed referral protocols for patients at risk of developing laryngeal malignancy

Grade of evidence:
VI</td>
<td>Participants:
Patients were eligible for referral if they had the following: hoarse voice for more than 3 weeks in current or ex-smokers and patients with dysphagia and hoarse voice.

Service:
An ENT Service covering a population of 100,000 with 1 consultant. All patients underwent flexible fibre-optical nasendoscopy. Referral criteria were agreed and circulated on proformas.

Patients were to be seen within 5 working days within existing clinics.</td>
<td>Methods:
A case report of a service was presented.

Outcomes measured:
Duration of hoarseness.

Presence or absence of dysphagia or otalgia.

Smoking and alcohol consumption.

Appropriateness of referrals.</td>
<td>Referrals:
34 patients referred to ENT endoscopy service, average age 58 (34 to 87), male to female ratio 12:22.

Timeliness:
94% seen within 5 working days.

Appropriateness of referral:
5 of 34 (15%) referrals were inappropriate. 2 had hoarseness but were non-smokers. 2 had hoarseness of shorter than 3 weeks' duration and 1 did not have symptoms which were eligible for referral.

Reason(s) for referral;
<table>
<tr><td>Hoarse voice</td><td>33 (97%) (mean duration 22.6 weeks (0.6 to 104 weeks))</td></tr>
<tr><td>Otalgia</td><td>1 (3%)</td></tr>
<tr><td>Lump in the neck</td><td>1 (3%)</td></tr>
<tr><td>Dysphagia</td><td>8 (23%)</td></tr>
</table>
Risk factors:
Smokers 23, ex-smokers 9, non-smokers 2
28 consumed alcohol averaging 11 units per week (1 to 40).

Findings:
Nasendoscopy was abnormal in 14 patients; rigid endoscopy was performed in 10 patients and supplemented by 8 biopsies. Diagnoses included 1 squamous cell</td>
<td>Authors' conclusions:
A rapid access clinic with agreed protocol that referring GPs adhered to, was useful for diagnosing laryngeal cancer and should meet the requirements of the government's 14-day rule.

Comments:
This was an incomplete report of a retrospective service description with no qualitative or patient satisfaction data. The limitations of small, retrospective, observational studies are relevant to this study.

The patients of the "Husky Voice" clinic were seen in the normal clinics and as such the intervention in this study should be considered a referral pathway rather than the clinic itself.

The results did not contain a comparison with the series of patients referred from the GPs before they received these guidelines. The comparison with patients living in areas other than on Portsea Island is problematic. This is an industrial inner city area and therefore the patients may not be comparable with those referred from the remainder of the hospital's catchments area (Southeast Hampshire and suburban Portsmouth).

Conclusions were made on only 1 case of cancer</td>
</tr>
</table>

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<td>carcinoma, 1 mild dysplasia and 8 benign pathologies.

Patients of GPs not participating in the study:
108 rigid endoscopies were conducted on patients referred by GPs not participating in the trial during the period it was being conducted. 13 of these patients were found to have tumours; of these 8 were found to have laryngeal cancer and 5 were found to have other cancers.</td>
<td>diagnosed in the study population.

Given these drawbacks, the study findings should be seen as suggestive rather than definitive.</td>
</tr>
<tr>
<td>Vowles, 1998.[10]

Country:
UK

Aims:
To assess a direct referral clinic established to rationalise the management of patients whose primary presenting complaint was a neck mass.

Grade of evidence:
VI</td>
<td>Service:
All patients with a neck mass as their primary presenting complaint could be referred by their general or hospital practitioner; practitioners were advised of the appropriate route of referral. Patients were to be seen within 2 weeks of referral.

The clinic was staffed by a consultant otorhinolaryngologist and a consultant radiologist. Following clinical examination, ultrasound assessment with FNAC where appropriate was conducted.

Participants:
Patients were eligible for referral to the clinic if their primary presenting complaint was a mass in the neck.</td>
<td>Methods:
A case report of a service was presented.

Outcomes measured:
Number of lesions stratified by type and anatomical location.

Proportion of lesions which were malignant.</td>
<td>Included patients:
100 patients were seen in the first year. 46 patients were seen for the assessment of enlarged lymph nodes. 21 patients were seen with thyroid swelling. 18 patients were assessed for salivary gland swellings. 15 additional patients were seen.

Clinic results:
<table>
<tr><th>Reason for Referral</th><th>Number of Referrals</th><th>Number of Benign Conditions</th><th>Number of Malignant Conditions</th></tr>
<tr><td>Lymph Nodes</td><td>46</td><td>33</td><td>13†</td></tr>
<tr><td>Thyroid Swellings</td><td>21</td><td>17</td><td>4</td></tr>
<tr><td>Parotid Swellings</td><td>10</td><td>9</td><td>1†</td></tr>
<tr><td>Submandibular Swellings</td><td>7</td><td>6</td><td>1†</td></tr>
<tr><td>Others</td><td>15‡</td><td>12§</td><td>0</td></tr>
</table>
† = Both the malignancies detected in patients referred with parotid and submandibular gland swellings were lymphomas. Of the 13 patients referred with lymphadenopathy, 3 had lymphoma.
‡ = 3 patients referred for reasons other than swellings had no abnormality detected.
§ = There were additionally 5 skin lesions, 3 cysts, 2 lesions consistent with normal scar tissue, 1 thymoma and 1 patient with angiodema.

5 of 21 patients with thyroid swelling underwent surgery. No submental gland swellings were identified.

Appropriateness of referrals:
From the first 100 referrals, only 2 were considered to be inappropriate. Both had a sensation of globus and were treated appropriately in the main clinic rather than the rapid access clinic.</td>
<td>Authors' conclusions:
The clinic enables patients with potentially serious disease to be seen, diagnosed and, if necessary, to be operated upon rapidly by a team with the diagnostic skills and surgical repertoire to deal with all major head and neck cancers.

Comments:
The authors have produced a log of their activity but have not attempted to assess how this activity related to their patients' experience. No account was taken of how patients were referred to the clinic. While they discuss the various diagnostic tools in their armamentarium, they do not provide an assessment of any of these tools using data from their series. The authors draw only the vaguest of conclusions and these are not fully based on the evidence presented.</td>
</tr>
</table>

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Structure of services

The Questions

a) In the management of patients with head and neck cancer, does participation in the management of the patient by a speech and language therapist (SLT) improve outcomes?

b) In the management of patients with head and neck cancer, does participation in the management of the patient by a dietitian improve outcomes?

c) In the management of patients with head and neck cancer, does participation in the management of the patient by a specialist nurse improve outcomes?

d) In the management of patients with head and neck cancer, does participation in the management of the patient by a social worker improve outcomes?

e) In the management of patients with head and neck cancer, does participation in the management of the patient by a clinical psychologist improve outcomes?

f) In those patients with head and neck cancer who require periodontic, endodontic or prosthodontic management, does management by a restorative dentist improve patient outcomes?

g) For patients with head and neck cancer, do MDT's improve outcomes?

h) What impact does the management of patients with head and neck cancer by a MDT have on the provision of information or support enabling the patient and carer to participate in the process of making decisions about his/her treatment?

i) In the management of patients with head and neck cancer, does the co-location of diagnostic and surgical and non-surgical oncological facilities affect either patient outcomes or service outcomes (such as attendance rates of the group's members, completeness of data collection and the effective use of resources)?

j) In the management of patients with head and neck cancer, does the location of the service in dedicated clinics, with suitable staffing and equipment levels, affect either patient outcomes or service outcomes (such as attendance rates of the group's members, completeness of data collection and the effective use of resources)?

k) For patients who have overt or suspicious thyroid cancer on fine needle aspiration, what effect does rapid access to a cancer centre, specialising in all aspects of the treatment of thyroid malignancy run by multidisciplinary teams have on outcomes?

l) In the management of patients with head and neck cancer, does the specialisation of the secondary care clinician who the patient is referred to (from primary care) affect outcomes?

m) Does specialisation of health service personnel working with head and neck cancers within an MDT affect either patient outcomes or service outcomes (such as attendance rates of the group's members, completeness of data collection and the effective use of resources)?

n) Does the volume of head and neck cancer related interventions performed by a clinician affect outcomes?

o) Does volume of head and neck cancer related interventions performed at a hospital affect outcomes?

p) For patients with symptoms suggestive of thyroid cancer (enlarged thyroid or thyroid lump) attending a dedicated diagnostic service, does the management of the service by a clinician responsible for the assessment of large numbers of patients with thyroid swellings improve outcomes?

q) For patients with symptoms suggestive of mid-face/craniofacial cancer attending a dedicated diagnostic service, does the management of the service by a clinician responsible for the assessment of large numbers of patients with suspected mid-face/craniofacial cancer improve outcomes?

r) In head and neck oncology, does the provision of a named team member with responsibility for ensuring that the patient and his or her carers receive appropriate support improve outcomes?

s) In head and neck oncology, does the provision of a nominated team member with responsibility for ensuring that the treatment plan is fully implemented, as communicated to the patient, improve outcomes?

t) In the treatment of patients with head and neck cancer, does special training for support and ancillary staff in dealing with this patient group, improve outcomes?

u) If interpreters are given special training to deal with patients with head and neck cancer, are services offered to these patients improved?

The Nature of the Research Evidence

a) Speech and language therapist

Three studies were located which assessed the role of SLTs.[1-3] Each measured the attitudes of patients who had had a laryngectomy. Two studies measured their opinions using interview methodologies[1, 2] and one using a combination of a structured questionnaire and interviews.[3] These studies were conducted in Switzerland[1] and the US.[2, 3] Details of these studies are presented in Table 2a.

The first study was interview-based and assayed the opinions of 332 patients, the majority of whom were members of the Swiss national association of laryngectomy patients.[1] A second interview-based study was located[2] that investigated 25 members of the New York laryngectomy club. The final study was questionnaire-based and investigated the opinions of 60 patients.[3] Both of the latter two studies were conducted in 1979 in the US, therefore, their generalisability to the current practice of professionals in the NHS is most probably limited.

Each study measured opinions sometimes asking about events that occurred sometime before the study. Attitudinal measurements are important to obtain an insight into the quality of patients' experiences but are prone to biases as discussed previously. The findings of these studies are suggestive rather than definitive.

Note: the included studies use the "terms logopedist"[1] or "speech pathologist";[2, 3] neither of these terms are in current usage in the NHS. For the purposes of this review, these terms have been considered synonymous with "Speech and language therapists", a term common in the NHS, approved by the Health Professions Council (HPC) and reserved in the UK for use by registrants of the HPC.

b) Dietitian

Two studies were located.[4, 5] One study was undertaken as part of a well conducted RCT of dietary supplementation conducted in the US.[4] The second study was a cohort study with historical controls which investigated a percutaneous gastrostomy (PEG) service.[5] The RCT, including only 61 patients, included three arms;[4] patients with malnutrition were randomly assigned to one of two groups. All malnourished patients in the intervention and control group received nutritional counselling from a dietitian. Patients without malnutrition acted as a second comparison group in this study; they did not receive dietetic support. This study does not allow us to draw a comparison between the group that received support and those who did not owing to the important difference in their pre-operative nutritional status. The cohort study compared 45 patients with a historical control group of 45 patients whom had not been managed by a nutritionist.[5] Patients in the control group at risk of malnutrition were offered a PEG as a prophylaxis while the remaining patients were offered dietary counselling and oral supplementation.

Neither study aimed to assess the role of dietitians in head and neck cancer care but both give information relevant to the question. See Table 2b for details.

c) Specialist nurse

While a number of case studies of the individual practice of nurses were located, only comparative studies were included. Only one comparative study was located and this was primarily an economic evaluation.[6] The study investigated the costs of nursing patients who had undergone definitive head and neck surgery in an academic hospital. It compared the costs incurred in caring for a patient in an acute ward setting with those incurred by treating them in a skilled nursing facility, based in the hospital but separate from the acute ward. The costs of the ward-based care were calculated for a cohort of 24 patients and those of the non-ward-based service were estimated. The cost-savings were calculated by obtaining the difference of the two. Details of this study can be seen in Table 2c.

d) Social worker

One study was located which assessed the participation of social workers in the management of patients who had undergone a laryngectomy.[3] This study used questionnaires and interviews as data collection tools and was conducted in the US among 60 patients. The study was conducted in 1979 and so the applicability of its finding to current NHS practice may be questionable. See Table 2d for details.

e) Clinical psychologist

No evidence was found relating to the participation of clinical psychologists in the management of patients with head and neck cancer.

f) Restorative dentist

A case series study described six cases of recurrent and second primary malignancies identified by a maxillofacial prosthodontist during a one year period[7] and a single case study described the restorative management of a patient ten years after hemi-maxillectomy.[8] Owing to the very small number of cases described, the results of both of these studies may not be generalisable. Details are given in Table 2f.

g) MDT

Three studies were located. Of these two were observations of clinics in practice.[9, 10] One, from Australia, was a description of a MDT which included both oncology and neurosurgery teams for the management of skull base tumours.[9] 57 patients with space occupying lesions in the base of skull region were studied. One study, from the UK, presented data on clinical outcomes of a series of patients attending a clinic staffed by members of 17 different professional groupings but was predominantly a cost study.[10] The remaining study was a UK focus-group study, presented as a report and subsequently as a peer-reviewed journal article which assessed patients' and professionals' opinions of a range of issues, one of which was the role of the MDT.[11, 12] Full details of these studies are shown in Table 2g.

It is not always possible to undertake experimental studies in subject areas such as service organisation. In these situations, observational studies are often the best available and most appropriate evidence. The focus-group gives good qualitative evidence as to the experience of its included patients but care should be taken to avoid over-generalising the results.

h) MDT provision of information or support

No evidence was found relating to the impact of management of patients with head and neck cancer by a MDT on the provision of information or support.

i) Co-location of services

No evidence was found relating to the co-location of diagnostic and surgical and non-surgical oncological facilities in the management of patients with head and neck cancer.

j) Location of the service in dedicated clinics

A focus-group study, published in report format and subsequently as a peer-reviewed journal article, investigated a range of issues pertinent to the management of head and neck cancer.[11, 12] In this well conducted study,

patients and professionals were asked, among other themes, for their opinions on appropriate accommodations for cancer services. Participants gave opinions about the appropriate organisation of wards but not about clinics. Owing to the qualitative nature of the study, its findings should not be over-generalised. See Table 2j for details.

k) Access to a thyroid cancer MDT

One study of an MDT in a UK university hospital was located.[13] This was a retrospective case-note review of a service staffed by a surgeon, an endocrinologist and an oncologist. The authors compared 134 patients who attended the clinic with a retrospective group of 71 patients who attended general clinics. Patients were not randomly assigned to either clinic and as such this comparison is weak. Details of the study are provided in Table 2k.

l) Specialisation of the secondary care clinician to whom the patient is referred from primary care

No evidence was found relating to the specialisation of the secondary care clinician to whom the patient is referred from primary care in the management of patients with head and neck cancer.

m) Specialisation within MDT

Two retrospective observational studies were identified.[13, 14] One study compared the management of 205 patients with differentiated thyroid cancer treated in a specialist unit (n=134) with those treated in a regular clinical setting (n=71)[13] whilst the other measured the differences in dental consultation and oral complication rates between 104 head and neck cancer patients treated at three different hospitals which had an oral and maxillofacial department, whilst only two of the hospitals also had an outpatient general dental clinic.[14] Details are given in Tables 2k and 2m.

n) Clinician volume

A large American cross-sectional analysis of hospital discharge data was identified that evaluated the effect of individual surgeon volume on clinical and economic outcomes of surgical procedures for benign or malignant thyroid disease.[15] The study included 658 surgeons that performed at least one thyroidectomy during the six year study period (1991 to 1996) on 5,860 patients at 52 hospitals. Appropriate adjustments were made for covariate factors. Surgeons were categorised according to the number of thyroidectomies they carried out over the study period; 1 to 9, 10 to 29, 30 to 100 and over 100. Details are given in Table 2n.

o) Hospital volume

A retrospective review of the medical records of 206 patients with oral cancer was conducted to evaluate different treatment strategies.[16]

This was a well-conducted piece of research which obtained data from cancer registries in Scotland. Despite the limitations of observational retrospective surveys, this study gives an informative picture of the effects of both the tumour stage at presentation and the number of patients managed by the treatment centre. Details are given in Table 2o.

p) Clinician volume managing a dedicated thyroid diagnostic service

No evidence was found relating to the management of a dedicated diagnostic service for patients with symptoms suggestive of thyroid cancer by a clinician responsible for the assessment of large numbers of patients with thyroid swellings.

q) Clinician volume managing a dedicated mid-face/craniofacial cancer diagnostic service

No evidence was found relating to the management of a dedicated diagnostic service for patients with symptoms suggestive of mid-face/craniofacial cancer by a clinician responsible for the assessment of large numbers of patients suspected mid-face/craniofacial cancer.

r) Provision of a named team member to ensure support

No evidence was found relating to the provision of a named team member with responsibility for ensuring that the patient and his or her carers receive appropriate support in head and neck oncology.

s) Provision of a named team member to ensure implementation of the treatment plan

No evidence was found relating to the provision of a nominated team member with responsibility for ensuring that the treatment plan is fully implemented, as communicated to the patient, in head and neck oncology.

t) Special training for support and ancillary staff

No evidence was found relating to special training for support and ancillary staff in dealing with patients with head and neck cancer.

u) Special training for interpreters

No evidence was found relating to special training for interpreters in dealing with patients with head and neck cancer.

Summary of the Research Evidence

a) Speech and language therapist

In the first study[1] a total of 80% of respondents were satisfied or reasonably satisfied with their speech therapy but 17% were dissatisfied and 3% gave no reply. Half of the respondents had been able to communicate with the outside world within three months of their operations but for 15% a period of more than six months elapsed before communication was restored and in 5% of cases, participants were still not able to communicate successfully with the outside world. The time period between patients' operations and their interview ranged from one to twenty years; as such it covers a significant period of time during which speech therapy services may have changed considerably. Some respondents reported that they received speech and language therapy from another laryngectomy patient. It is not reported if this

was in addition to or in place of, consultations with an SLT. The nature, format or frequency of consultations with SLTs were not reported.

In the second interview-based study[2] slightly more than a quarter of the surveyed patients had had formal consultations with an SLT. Only one patient did not find this helpful and a majority of those who did not have the opportunity to see an SLT reported that they would have like to have done so. A major limitation of this study in answering this question is that the service offered to patients who were seen by SLTs was not well reported. This study was conducted in 1979 in the US and as such, its generalisability to the current practice of professionals in the NHS is most probably limited. This, taken with the qualitative nature of the study and weaknesses in its reporting, limits the validity of its findings.

The final study was questionnaire-based and derived from the US and also was published in 1979.[3] Patients completed a questionnaire and were then interviewed to explore further their answers. No description was given of the services offered to the patients by their SLT or how many SLTs were involved in the care of the patients who responded to the questionnaire.

Just over half the patients were visited by a SLT pre-operatively. Of those seen, 72% felt that the consultation was adequate. Of those not seen, 77% felt that it should have been done. Post-operatively, 57% were visited by a SLT and of those seen, 91% felt that the consultation was adequate. In addition to the normal possibilities of bias inherent with attitudinal surveys, this study did not use a validated questionnaire and the interview section of the study was conducted by a clinician who may have been involved in the care of the participants. The study is rather old and so may not reflect modern practice.

Conclusions

Data from three research studies which investigated the opinions of patients who had undergone a laryngectomy suggest that patients feel they benefit from the opportunity to see SLTs both before and after surgery. The findings

are limited by the weak designs used and poor reporting of the SLT interventions in the studies. The age of the studies is also of concern.

b) Dietitian

While the RCT[4] found that the nutritionally healthy patients who did not receive nutritional counselling had fewer complications and had shorter in-patient stays than malnourished patients who received nutritional counselling from a dietitian, it is probable that their good standard of nutrition was the major determinant of these effects.

In the small study in which patients with nutritional management by nutritionists were compared with historical controls who had not been managed by a nutritionist[5] patients were comparable across groups and the study found that the intervention patients, most of whom received a PEG, had significantly lower relative weight loss and significantly fewer hospital admissions related to dehydration. They also showed a trend towards fewer overall admissions. Two control patients and no intervention patients died during the study but this was not statistically significant. By using a comparison with historic patients rather than with current patients, a number of biases were introduced. These may effect the validity of the results but are hard to quantify, particularly as key information about the conduct of the study was not reported.

Conclusions

Weak evidence suggests that patients receiving interventions which may be advised by dietitians or nutritionists has a beneficial effect on patients. The paucity of evidence and the low validity of the methods used in the research studies mean that this conclusion is only tentative.

c) Specialist nurse

The study[6] was a theoretical assessment and no measurements of the services of a non-ward-based skilled nursing facility were made. The findings, that it

was possible that substantial savings would be made, provide support for conducting a study of the service but cannot prove that the service would be beneficial in terms of cost. Neither can a study of this nature prove that specialist nursing is beneficial. Were a substantive study to be conducted, it would be important that other indicators of care be measured, particularly those relating to the quality of the clinical care received by patients.

Specialist nursing care has not been extensively studied in comparative studies. The evidence located was economic in nature but did suggest benefits of sub-specialisation in nursing. No definitive conclusions may be drawn.

d) Social worker

A study of laryngectomy patients asked about a number of factors relating to their care, one of which was the services of social workers.[3] No description was given of the services offered to the patients by their social workers or how many social workers were involved in the care of the patients who responded to the questionnaire.

Less than one-fifth of patients were seen pre-operatively by a social worker. Three-fifths were seen post-operatively. Two-thirds of those seen before their operation and four-fifths of those seen after it felt the contact had been adequate. Slightly more than half the patients who were not seen in the pre-operative phase of care reported that they would have like to be seen. Patients expressed surprise that the social worker could provide emotional support and psychological counselling as they had thought that the social worker could only provide technical assistance with filling forms and claiming benefits.

In addition to the normal possibilities of bias inherent with attitudinal surveys, this study did not use a validated questionnaire and the interview section of the study was conducted by a clinician who may have been involved in the care of the participants.

e) Clinical psychologist

No evidence was found relating to the participation of clinical psychologists in the management of patients with head and neck cancer.

f) Restorative dentist

In a case series[7] four patients were diagnosed with a recurrence and two patients were diagnosed with a second malignancy during a one year period of management by a maxillofacial prosthodontist, resulting in patients being seen an average 2.4 weeks earlier than their next scheduled visit to their surgeon. However, the total number of head and neck cancer patients managed by the prosthodontist during this time period was not reported.

A single case study[8] concluded that it is important that health workers in primary, secondary and tertiary care work together to make the delivery of care as effective and efficient as possible. However, owing to the nature of this single case study, the results may not be generalisable.

g) MDT

An Australian study of a skull-base MDT studied 57 patients with space occupying lesions in the base of skull region.[9] These tumours require the attention of both head and neck specialists and neurosurgeons as well as a panoply of other professional groupings. Access to the tumour and one-step removal of the lesion were possible in all cases and no patients required transfacial procedures. Post-operative complication rates and surgical mortality were low. The major limitation of the study is the poor reporting of the methodology used in the assessment.

A UK cost study provided some clinical details – the average in-patient stay was 25 days and the average time in the operating theatre was 8.5 hours – but the main focus of the study was economic.[10] Without comparators or fuller descriptions of the services on offer, it is difficult to discern the standard of service described.

The UK focus-group study provides excellent information on the opinions of patients and professionals about MDTs.[11, 12] Professionals spoke of the value of teamwork. All participated in joint clinics although the composition of these varied. Surgeons and oncologists reported that planning treatment in joint clinics with colleagues from different disciplines kept them up-to-date and ensured they consider all options for treatment. It also provided them with support and forum for discussing difficult cases. The role of the surgeon within the team had also changed. Whereas the surgeon was traditionally the leader or director of care, the team was now more democratic, with a each member being able to contribute. No patient views on MDTs were recorded by the focus-group study.

Conclusions

Professionals seem to value the opportunities afforded by the MDT system. Where appropriate procedures are in place, good clinical outcomes may be promoted by management by an MDT.

h) MDT provision of information or support

No evidence was found relating to the impact of management of patients with head and neck cancer by a MDT on the provision of information or support.

i) Co-location of services

No evidence was found relating to the co-location of diagnostic and surgical and non-surgical oncological facilities in the management of patients with head and neck cancer.

j) Location of the service in dedicated clinics

An extensive UK focus-group study found that patients and relatives were concerned about mixed sex and mixed speciality wards. They strongly felt that head and neck cancers should be managed on a dedicated ward or area within a ward, with adequate privacy and specialist nursing skills. Greatest

satisfaction with care received was expressed by those patients who had been cared for in this environment or in side rooms. Patients and relatives knew that head and neck cancer was rare and supported the establishment of a specialist centre.

Professionals supported the proposal in theory, but some had reservations about over-specialisation and the loss of variety in the work of non-specialists. They felt interaction with other patients with similar conditions could occasionally have a negative effect. This contrasted with the patients' reporting that non-specialist wards prevented their gaining mutual support from other cancer patients.

The limitations of focus-group methodologies have been discussed elsewhere in this report and apply equally to this question. The findings provide insight into the feelings and opinions of these patients and professionals and it is for each reader to consider their applicability to his or her own practice.

k) Access to a thyroid cancer MDT

A study which reported on 205 patients[13] found that compared to patients who attended general clinics, patients of the combined clinic (staffed by a surgeon, an endocrinologist and an oncologist) were more likely to have adequate surgery, to be treated if they had high thyroglobulin and not have Iodine-131 therapy when it was indicated. These differences reached statistical significance. Other differences were found but did not reach statistical significance. Vocal palsy and hypoparathyroidism were common in patients who attended normal clinics and these patients were less likely to receive thyroxine treatment or for that treatment to be adequate. Thyroxine monitoring was commoner in those treated by the combined clinic.

Limitations of the study include the reporting of process outcomes while omitting some clinically relevant outcomes. Whether thyroxine was given was reported but not if symptoms were controlled for example. While obtaining data on two groups of patients allowed comparisons to be drawn,

retrospective assessments of case notes are open to biases. For example, the doctor completing the notes did so not with a view to keeping records for further research but with a view to recording the care given to the patient. Patients were not randomly allocated to the clinics they attended. Systematic differences in the characteristics of patients sent to different clinics may have important effects on the outcomes experienced by patients. The small number of patients, in the control group most notably, could mean that the study is underpowered to detect some the differences the authors were attempting to quantify.

l) Specialisation of the secondary care clinician to whom the patient is referred from primary care

No evidence was found relating to the specialisation of the secondary care clinician to whom the patient is referred from primary care in the management of patients with head and neck cancer.

m) Specialisation within MDT

Thyroid cancer patients treated in a specialist multi-disciplinary clinical setting were more likely to have adequate surgery (90% versus 62%), be given thyroxin (91% versus 76%), have serum thyroglobulin measured (93% versus 68%) and treated (91% versus 33%) and were more likely not to have Iodine-131 therapy when it was indicated (7% versus 21%) than patients treated in a regular clinical setting.[13]

Dental consultation rates were higher at two hospitals that had an outpatient general dental clinic than at a hospital without an outpatient general dental clinic, although rates were still low at all three hospitals, ranging from 12% to 40%.[14] The proportion of patients with oral complications varied considerably with 13% and 61% of patients having oral complications at the hospitals with a general dental clinic and 33% of patients at the hospital without a general dental clinic. However, the numbers of patients seen at each hospital were relatively low (33, 33 and 38) and the authors did not adjust for any

demographic, cancer-related or co-morbid illness-related variables, so the results should be interpreted with caution.

n) Clinician volume

In the series of 5,860 patients who underwent thyroid surgical procedures from 1991 to 1996[15] the 658 surgeons performed a median of 25 thyroidectomies during the study period, however, about two thirds of the surgeons performed less than one thyroidectomy per year and 25% of patients were treated by surgeons who performed less than 10 thyroidectomies during the six year study period. Twenty-five percent of patients had cancer and the surgeons who performed more operations were more likely to operate on patients with cancer and to perform more complex surgical procedures, such as total thyroidectomy. The difference in complication rates for 'other subtotal thyroidectomy' procedures was significantly higher in patients treated by surgeons operating on less than ten patients than those operating on more than 100 patients during the study period. The length of hospital stay was lower in patients treated by surgeons who operated on more than 100 patients during the study period than any of the other volume categories for all surgical procedures, the difference was statistically significant in almost every category. The hospital charges varied by surgeon volume and surgical procedure, with the highest volume surgeons representing higher charges for unilateral lobectomy, other subtotal thyroidectomy and substernal thyroidectomy, but lower hospital charges for total thyroidectomy. Again, the differences were statistically significant in most categories. In conclusion, individual surgeon experience is significantly associated with complication rates, length of hospital stay and hospital charges for thyroidectomy.

o) Hospital volume

In a retrospective survey of Scottish cancer registry data, the effects of hospital volume were examined by comparing the largest provider with the remaining providers. The high volume provider saw 124 of the total 206 patients representing 60% of that total. The remaining 40% of patients were treated in 13 units. Patients treated at the high-volume provider had a

significantly lower risk of death (HR = 1.48; 95% CI 1.06 to 2.06) and a significantly lower risk of recurrence (HR = 1.43; 95% CI 1.02 to 2.02). This association between treatment centre and survival or risk of recurrence was not apparent when the treatment strategy was included as a covariate. This suggests that the improvement in patients outcomes seen in the high-volume provider may in part at least, be related to the choice of treatments offered to patients.

p) Clinician volume managing a dedicated thyroid diagnostic service

No evidence was found relating to the management of a dedicated diagnostic service for patients with symptoms suggestive of thyroid cancer by a clinician responsible for the assessment of large numbers of patients with thyroid swellings.

q) Clinician volume managing a dedicated mid-face/craniofacial cancer diagnostic service

No evidence was found relating to the management of a dedicated diagnostic service for patients with symptoms suggestive of mid-face/craniofacial cancer by a clinician responsible for the assessment of large numbers of patients suspected mid-face/craniofacial cancer.

r) Provision of a named team member to ensure support

No evidence was found relating to the provision of a named team member with responsibility for ensuring that the patient and his or her carers receive appropriate support in head and neck oncology.

s) Provision of a named team member to ensure implementation of the treatment plan

No evidence was found relating to the provision of a nominated team member with responsibility for ensuring that the treatment plan is fully implemented, as communicated to the patient, in head and neck oncology.

t) Special training for support and ancillary staff

No evidence was found relating to special training for support and ancillary staff in dealing with patients with head and neck cancer.

u) Special training for interpreters

No evidence was found relating to special training for interpreters in dealing with patients with head and neck cancer.

Table 2a: Speech and language therapist

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Johnson, 1979.[2] **Country:** USA **Aims:** To better understand and identify specific problems encountered by laryngectomised patients. **Grade of evidence:** VI	**Participants:** Participants with laryngeal cancer who had undergone laryngectomy and who had achieved a satisfactory means of communication were eligible. **Service:** Details were not reported relating to the content or format of the contacts between the participants and their SLT.	**Methods:** Structured interviews were conducted to obtain information from participants. Many patients were identified from the membership of the Central New York Laryngectomy Club. **Outcomes measured:** Outcomes assessed are not stated.	**Included patients:** 25 patients (21 males, 4 females) who had undergone laryngectomy participated in structured interviews. **Results:** Slightly more than a quarter of the patients met with a SLT pre-operatively. Only 1 person was not glad about this and the great majority of people who did not do so would have liked this opportunity.	**Authors' conclusions:** A study was designed wherein laryngectomees and their families were individually interviewed. These people suggested that their rehabilitation could have been facilitated had they been better informed pre-operatively. Many expressed a desire for exposure to a SLT and a successfully rehabilitated laryngectomee pre-operatively. **Comments:** This study was conducted in 1979 so the results may no longer be applicable. The authors acknowledge that the results cannot be considered as genuinely representative of all laryngectomised patients. All individuals interviewed had developed a satisfactory means of communication, all had readily agreed to the interview and many were located by virtue of their membership in the Central New York Laryngectomy Club. Additionally, self-report interview techniques tend to produce "socially-desirable" responses from interviewees. Very little detail was given regarding the structured interview, it is not stated whether the interviewer was known to the patients, which can bias the results. No details were given about the meeting with the SLT.
Lehmann, 1991.[1] **Country:** Switzerland **Aims:** To present the opinions of an interview-based opinion survey of patients who have undergone a laryngectomy. **Grade of evidence:** VI	**Participants:** All men and women who had undergone total laryngectomy for cancer of the larynx and who were resident in Switzerland were eligible for inclusion in this study. **Service:** Details of the individual patients' speech and language therapy were not reported.	**Methods:** Patients were identified using the membership lists of the Union of the Swiss Associations of Laryngectomees and with the help of treating hospitals for non-members. Thirty experienced and specially trained interviewers conducted the interviews, which took an average of 50min to 60min each, using standardised, pre-tested questionnaires. Around half of the interviews were conducted alone with the person concerned, in 4 out of 10 cases the spouse was present, rarely another person. The survey, concerning the living situation of laryngectomees, was intended to provide information about	**Included patients:** A study population of the 520 participants (from a national total of an estimated 600 to 800) identified was identified. 332 participants were interviewed. The majority (55%) were resident in the German speaking area of the country, but 18% of the participants were resident in the Italian speaking areas despite their having only 4% of the national population. 90% of participants were male. 80% of male participants and 40% of female participants were married. The longest interval between operation and interview was 20 years and the shortest was 1 year. **Attitudes to speech therapy:**	**Authors' conclusions:** A third of all patients were unsatisfied with the programme of speech therapy offered to them. Effective medial, psychological and social counselling and assistance for those affected are of great importance. Early speech therapy is a factor of great importance. **Comments:** The sample was drawn principally from the membership of a patient support group (with some additional inclusions) but 80 to 280 patients with laryngectomies were not included in the population from which the sample was drawn. This support group also funded the work. It is unclear if information drawn from those who were members of a support group can be extrapolated to include those patients who chose not to join the group. The authors do not report what proportion of the respondents were members of the organisation which funded the research or investigate the effects of support group membership. This study was conducted retrospectively and in some participants cases after a significant amount of time has elapsed. This introduces the possibility of recall bias. In addition, the survey reports the opinions of all those who have had a laryngectomy rather than those who have had the procedure recently. The experiences of a patient 20 years ago may not represent the experience of a patient in a current context. No attempt was made to control for this. It may be for example that while historically patients were not offered appropriate speech support services but that this is now commonplace (or vice versa).

		the medical, social, psychological, work-related and financial problems of laryngectomees. **Outcomes measured:** Participants' Opinions	65% of participants were satisfied with their speech therapy, 15% were reasonably satisfied with their speech therapy, 17% were dissatisfied with their speech therapy and 3% gave no reply. Half of the patients were able to communicate with the outside world within 1 to 3 months after their operations, 20% took 4 to 6 months while 15% took longer. 5% of participants were still not able to communicate successfully with the outside world.	The experiences of regaining the ability to speak with the outside world of 10% of patients were not reported in the study. The study did not provide any insight into why the Italian-speaking areas were overly represented in the sample.
Minear, 1979.[3] **Country:** USA **Aims:** To evaluate the rehabilitation program in use at the authors' institution and to provide suggestions for developing and improving rehabilitative programs. **Grade of evidence:** VI	**Participants:** Patients who had undergone laryngectomy. **Service:** Few details of the service were given but it appears that it included pre-operative visits by the surgeon, a social worker, a speech and language therapist and a patient visitor.	**Methods:** Each patient was given a questionnaire including 48 questions which explored both pre-operative and post-operative periods. Patients were then interviewed to discuss the responses given in the questionnaire and relate any other feelings about their pre-operative and post-operative experience. **Outcomes measured:** The questions mainly pertained to the pre-operative visitations and explanations which the patients received and attempted to ascertain their feelings regarding the adequacy of these explanations. With regard to the pre-operative explanations, the patients were asked to comment on the effectiveness and adequacy of the visits by the surgeon, social worker, speech and language therapist and another laryngectomy patient. Post-operative questions focussed on the role of these persons as well as on the patient's post-operative fears, nursing care and techniques of vocal rehabilitation.	**Included patients:** 60 patients (53 male and 7 female) with a mean age of 64 years who had undergone laryngectomy between 2 and 48 months (mean 19.1 months) earlier. **Results:** The majority of patients studied were generally satisfied with their care and with the instructions given to them. 51% patients were visited by a SLT pre-operatively. Of those seen 72% felt that the explanation given to them was adequate. Of those not seen, 77% felt that it should have been done. Post-operatively 57% were visited by a SLT and of those seen 91% felt that the explanation was adequate. Patients generally wished to have greater contact with the SLT.	**Authors' conclusions:** We must emphasise the need for an organised, thoughtful and individualised approach to each patient, identifying and anticipating he needs in the pre and post-operative periods. Such an effort will require a team approach with frequent discussions among various members of the team, even though each member need not necessarily see the patient primarily. **Comments:** This study was conducted in 1979 so the results may no longer be applicable. The questionnaire was not a validated scale and was not described in detail in the report; therefore, it is not possible to comment on its content. The interviews were conducted by one of the authors who was from the Department of Otolaryngology, it is not possible to determine whether he would have been known to the patients, in which case it may have biased the results. No details were given about the speech and language rehabilitation that the patients received.

Table 2b: Dietitian

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Piquet, 2002.[5]

Country:
Switzerland

Aims:
To assess the effects of early nutritional intervention.

Grade of evidence:
V</td>
<td>Participants:
Outpatients undergoing radiotherapy for oropharyngeal cancer (aged 61 years; SE: 1.5 years, 43 males, 69kg; SE: 2kg).

Service:
Patients were prospectively managed by nutritionists and those not offered a percutaneous gastrostomy (PEG) received dietary counselling and oral supplementation. A PEG was inserted before radiotherapy in patients with 1 or more of the following: weight loss of greater that 10%; BMI less than 20kgm^{-2} or aged 70 years or over. When patients had dehydration and severe dysphagia, but did not require a PEG, an NG tube was passed.

Comparators:
Data were compared with those recorded in an historical control group of 45 paired patients (aged 59 years; SE: 1.5 years, 42 males, 68kg; SE: 3kg).</td>
<td>Methods:
A cohort of patients was assessed and compared with a cohort of historical patients who were chosen so that the 2 groups represented similar populations.

Outcomes measured:
Form of nutritional support.

Percentage weight loss.

Overall hospital admissions.

Dehydration related hospital admissions.

Dehydration related deaths.</td>
<td>Included patients:
45 patients were included in the intervention group and matched with 45 historical controls.

Patients were comparable across the groups with respect to radiotherapy dose (70Gy; SE: 1Gy for participants compared with 68; SE: 1Gy for controls).

Form of nutritional support:
A PEG was inserted in 33 (74%) of the 45 patients in the intervention group, compared with 5 (11%) of the 45 in the control group ($p < 0.001$). 6 patients (13%) in the intervention group and 12 patients (27%) in the control group required late nasogastric feeding (not statistically significant).

6 patients (13%) in the intervention group and 28 patients (62%) in the control group were not enterically fed ($p < 0.001$).

<table>
<tr><th>Outcome</th><th>Intervention</th><th>Control</th><th>p - value</th></tr>
<tr><td>Percentage weight loss</td><td>3.5%; SE: 0.7%</td><td>6.1%; SE: 0.7%</td><td>p < 0.01</td></tr>
<tr><td>Overall hospital admissions</td><td>9 (20%)</td><td>14 (31%)</td><td>p = NS</td></tr>
<tr><td>Dehydration-related admissions</td><td>0</td><td>8 (18%)</td><td>p < 0.01</td></tr>
<tr><td>Dehydration related deaths</td><td>0</td><td>2 (4.4%)</td><td>p = NS</td></tr>
</table>
</td>
<td>Authors' conclusions:
Early nutritional intervention, including PEG insertion, is feasible and efficient in preventing dehydration in oropharyngeal cancer patients undergoing radiotherapy. It may improve quality of life by decreasing the frequency of hospital admissions.

Comments:
The authors simulated a case-control study using historic matched controls but have not provided key details of how the study was conducted. It is not clear how or by whom the matching was achieved; neither is it clear if the persons performing the matching were aware of the outcomes of the interventional or historic patients they were matching. In this type of research, bias may be introduced if professionals making decisions relating to patients or assessing patients were aware of the study, unlike those caring for historical controls at the time of their treatment.

The study included quite small numbers and no mention is made of whether a power assessment was conducted so it is unclear if errors relating to underpowering</td>
</tr>
</table>

				have occurred.
Flynn, 1987.[4] **Country:** USA **Aims:** To evaluate the relationship between the nutritional status of head and neck cancer patients and surgical treatment. **Grade of evidence:** VI	**Participants:** Patients with squamous cancer of the upper aerodigestive tract, identified as candidates for operative resection within 2 to 4 weeks of diagnosis. **Service:** The un-supplemented group received nutritional counselling and suggestions on ways to cope with eating problems. In addition to nutritional counselling, the supplemented group were given specific recommendations to meet their individual nutrient requirements or a nutritional supplement to fulfil their intake needs for the period between the first office visit and the scheduled hospital admission. This interval varied from 10 to 21 days. The patients in this group were contacted as necessary (determined by the dietitian) during this period to determine nutritional status and encourage compliance to the protocol.	An independent nutritional assessment was carried out by a registered dietitian, based on anthropometric and other relevant data. Patients were interviewed to determine the availability of family support, cooking facilities, economic status, food availability, medication intolerance and the intake of the basic food groups. Patients were designated either malnourished or nourished based on this assessment. A malnourished patient was defined as meeting at least 1 of the following criteria: 1) body weight of 80% of standard weight for height and reports impaired food intake, 2) loss of 5% or more of usual body weight over 1 month, 3) subnormal values for 3 or more nutritionally relevant laboratory parameters, specifically serum albumin, transferring, albumin-to-globulin ratio, lymphocyte count. Patients assigned to the nourished group did not receive further follow-up until hospital admission. Malnourished patients were assigned to a group receiving nutritional supplementation prior to operation or to another group not receiving supplementation. Patients were randomised to one or other of the groups based on a schedule determined at the beginning of the study, by a dietitian who was independent of the medical evaluation. Data pertaining to the nutritional evaluation and group designation were not provided to the treating surgeon and the results of the clinical evaluation by the surgeon were not shown to the dietitian. Upon hospital admission, all patients underwent a second nutritional assessment. The operative procedure was usually carried out within 2 days of admission. Appropriate nutritional support was carried out in the post-operative period and included oral diets, tube feedings and peripheral and central parenteral nutrition, either alone or in combination. A third nutritional assessment was performed at the time of hospital discharge and patients and relatives were counselled on ways to maintain a balanced nutritional	**Included patients:** 61 patients were eligible for inclusion. 25 patients were assigned to the nourished group with a mean age of 61, the majority of patients had cancer Stages I and II. 19 malnourished patients were assigned to the nutritional supplementation group and 17 were assigned to a group not receiving supplementation. The mean age of the malnourished group was 64 and the majority of patients had cancer Stages III and IV. A higher proportion of malnourished patients underwent major or extended procedures compared with the nutritionally healthy patients. The malnourished supplemented group was younger, contained a higher proportion of patients with advanced stage disease and a higher percentage of the patients had been previously irradiated. The number of patients undergoing limited-intermediate procedures was about equal between groups, but 5 malnourished supplemented patients underwent extended radical procedures compared with none in the malnourished un-supplemented group. **Withdrawals:** None. **Main results:** Complications occurred in 32% nutritionally healthy patients and 44% malnourished patients. Fewer complications occurred in the malnourished supplemented group (32%) than the malnourished un-supplemented group (59%). Nutritionally healthy patients experienced a mean length of hospital stay of 12 days compared with 18 days for malnourished supplemented patients and 21 days for malnourished un-supplemented patients. A 3 day decrease in length of stay at the current average cost in Louisville hospitals represents a saving of $2,298 per patient and a total cost of $43,662 for the entire group of 19 patients. **Adverse events:** None reported.	**Authors' conclusions:** Malnourished patients who received nutritional support pre-operatively demonstrated lower complication rates and shorter lengths of hospital stay compared with malnourished patients who underwent similar operative procedures without pre-operative nutritional supplementation. **Comments:** The study is an RCT comparing supplementation with routine care. However, for the purposes of this review of management by a dietitian, the study is coded as grade VI as all patients had the dietary intervention. This study included a small sample size and patients in the malnourished group were not comparable with nutritionally healthy patients. The only outcomes reported were length of hospital stay and number of complications. However, as nutritional assessment was carried out prior to randomisation, upon hospital admission and at the time of hospital discharge, it would have been helpful if the authors had reported the outcome of the nutritional assessments, to give an indication of compliance with the protocol. Patients in the malnourished supplemented group had more

		state. A clinical evaluation of the patient was carried out by the surgeon during the first office visit, including site and stage determination and documentation of previous treatment. The post-operative evaluation included documentation of the extent of the operative procedure (limited, intermediate, major or extended-radical, with or without complicated reconstruction) and clinical evaluation to determine morbidity and length of hospital stay. Morbidity was classified as major and minor local complications and systemic complications. **Outcomes measured:** Length of hospital stay and complications. **Length of follow-up:** Patients were not followed-up after discharge.		advanced disease, more had been previously irradiated and they had the most extensive procedures. Therefore, these patients may have been expected to fare worse than those in the malnourished un-supplemented group. However they had less complications and shorter length of hospital stay than malnourished patients who did not receive supplementation, which supports the use of pre-operative supplementation.

Table 2c: Specialist nurse

Study details and aims	Participants	Methods	Included patients and results	Comments
Seikaly, 2001.[6] **Country:** USA **Aims:** To determine whether the cost of treating patients with head and neck tumours would be reduced if the patients were to spend a portion of what would otherwise be acute care hospital days in a hospital-based skilled nursing facility (HB/SNF) **Grade of evidence:** VI	24 consecutive hospital admissions, at the University of Texas Medical Branch, for definitive surgical treatment of head and neck tumours were retrospectively reviewed.	**Methods:** The post-operative day on which the patient theoretically could have been transferred to the HB/SNF was determined. The criteria for transfer of the post-operative patients with head and neck tumours to the HB/SNF were established in conjunction with the nursing director. The patient had to be haemodynamically stable, afebrile, require minimal tracheotomy care, have no more than 2 intravenous medications, require no more than 2 daily dressing changes and have a drain output of less than 24mL/h. Each person's bill was itemised and reviewed by the Department of Healthcare Financial Management to determine the actual hospital charges for the entire stay. A theoretical charge was then calculated by subtracting from the total charge the charges covered by the HB/SNF (bed, nursing, physical therapy, speech therapy, radiology, laboratory, hospital supplies and pharmacy charges) that were accrued during the days that the patient could potentially have been transferred to the HB/SNF and then adding the BH/SNF per diem charge ($425) for those days. The actual cost to the hospital was estimated by the Department of Healthcare Financial Management to be 41.9% of the charges. **Outcomes measured:** The charge and the cost of each patient's actual hospital stay were compared with the theoretical counterparts had the patient been transferred to the HB/SNF on the determined day. The t test was used to analyse the data, with $p < 0.05$ considered statistically significant.	The total hospital stay for the 24 patients was 524 days; 182 of those days (35% of the total stay) could have theoretically been spent in the HB/SNF. The total charges were $1,299,045 and would have been $1,098,000 with the use of the HB/SNF. The total charge and cost savings with the use of the HB/SNF were $201,045 and $84,238 respectively (15% of the total charge and cost). This represents an average charge and cost saving of $8,377 and $3,510 respectively per patient. The difference was found to be statistically significant ($p < 0.005$).	**Authors' conclusions:** Use of HB/SNFs could reduce the cost of head and neck tumour treatment without diminishing the quality of care. An actual study in institutions that share demographic features with the University of Texas Medical Branch would confirm the data from this theoretical study and should be undertaken. **Comments:** The authors conclusion that an actual study should be undertaken to confirm the data from their theoretical study is agreed, the findings of this theoretical study can not be relied upon alone. Such a study should measure patient outcomes as well as cost savings.

Table 2d: Social worker

Study details and aims	Details of service and participants	Outcomes measured	Included patients and results	Comments
Minear, 1979[3] **Country: USA** **Aims:** To evaluate the rehabilitation program in use at the authors' institution and to provide suggestions for developing and improving rehabilitative programs. **Grade of evidence:** VI	**Participants:** Patients who had undergone laryngectomy. **Service:** Few details of the service were given but it appears that it included pre-operative visits by the surgeon, a social worker, a speech and language therapist and a patient visitor.	**Methods:** Each patient was given a questionnaire including 48 questions which explored both pre-operative and post-operative periods. Patients were then interviewed to discuss the responses given in the questionnaire and relate any other feelings about their pre-operative and post-operative experience. **Outcomes measured:** The questions mainly pertained to the pre-operative visitations and explanations which the patients received and attempted to ascertain their feelings regarding the adequacy of these explanations. With regard to the pre-operative explanations, the patients were asked to comment on the effectiveness and adequacy of the visits by the surgeon, social worker, speech and language therapist and another laryngectomy patient. Post-operative questions focussed on the role of these persons as well as on the patient's post-operative fears, nursing care and techniques of vocal rehabilitation.	**Included patients:** 60 patients (53 male and 7 female) with a mean age of 64 years who had undergone laryngectomy between 2 and 48 months (mean 19.1 months) earlier. **Results:** Only 19% of patients were seen pre-operatively by a social worker. Of those seen 64% felt that the explanation given to them was adequate. Post-operatively 60% patients were visited by a social worker and of those 82% felt that the explanation and counsel given to them were adequate. Among the patients not seen pre-operatively 55% felt that they would have liked this visit. In the interview many patients expressed surprise that the social worker could provide emotional support and psychological counselling. Most patients had previously thought of the social worker only in a technical sense; namely, as a person who could assist with filling out forms or arranging financial assistance. Patients generally wished to have greater contact with the social service personnel.	**Authors' conclusions:** We must emphasise the need for an organised, thoughtful and individualised approach to each patient, identifying and anticipating the needs in the pre and post-operative periods. Such an effort will require a team approach with frequent discussions among various members of the team, even though each member need not necessarily see the patient. **Comments:** This study was conducted in 1979 so the results may no longer be applicable. The questionnaire was not a validated scale and was not described in detail in the report; therefore, it is not possible to comment on its content. The interviews were conducted by one of the authors who was from the Department of Otolaryngology. It is not possible to determine whether he would have been known to the patients. If he had, this may have biased the results. No details were given about the content of the visit by the social worker.

Table 2f: Restorative dentist

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Casey, 1985.[7] **Country:** USA **Aims:** To report on the recurrent and second primary malignancies identified by a maxillofacial prosthodontist during a one year period. **Grade of evidence:** VI	**Design:** Series of 6 cases. **Service:** A maxillofacial prosthodontist saw a number of cases of recurrent and second primary malignancies detected over a one year period. **Participants:** 6 patients with recurrent or second primary malignancies.	**Methods:** A case series was presented. **Outcomes measured:** Number of recurrences and second primaries detected. The length of time between the date of diagnosis of recurrence or new malignancy and the date their next appointment was due.	**Number of recurrences and new malignancies detected:** 4 patients were diagnosed with recurrence and 2 patients were found to have a second malignancy. **Next appointment due:** 4 days (1) 1 week (1) 3 weeks (2) 1 month (1) Not scheduled (1) Patients were seen on average 2.4 weeks earlier by their surgeon following detection of disease by the prosthodontist.	**Authors' conclusions:** The author states that by earlier detection and immediate referral to the surgeon, there is a possibility of a higher long-term cure in head and neck cancer patients who are receiving maxillofacial prosthetic treatment. **Comments:** Conclusions based on a very small series of cases and based on opinions not grounded in the results. A significant failing in the reporting of the series is the omission of the total number of head and neck cancer patients being monitored by the prosthodontist for recurrence or development of second malignancies.
Bishop, 1997.[8] **Country:** UK **Aims:** To describe the restorative management of a single patient after 10 years of a hemi-maxillectomy **Grade of evidence:** VII	**Service:** A consultant led restorative dentistry service. The patient was treated immediately with stabilisation of caries and an evaluation of the long-term prognosis of the maxillary teeth, achieved by fluoride mouth rinse and advice on diet and oral hygiene. Definitive treatment involved the provision of a functionally and aesthetically acceptable denture with greater support and retention than the original prosthesis and the organisation of care that could be provided by the general dental practitioner (GDP) in the patient's home locality. **Participant:** A patient was diagnosed with	**Methods:** A case history was described. **Outcomes measured:** Stabilisation of teeth Appropriateness of definitive treatment.	**Definitive treatment:** An "open-topped" prosthesis was maintained. Restoration of the mandibular arch was achieved. The authors report that close liaison with the GDP and his involvement led to better co-operation and allowed part of the patient's follow-up to be done outside the hospital by his GDP working in parallel with the hospital. **Stabilisation of teeth:** Early carious lesions were stable with no problems reported at a 6 month evaluation.	**Authors' conclusions:** Surgical treatment in these cases is often provided in places with limited restorative service. It is important that health workers in primary, secondary and tertiary care work together to make the delivery of care as effective and efficient as possible. **Comments:** The conclusions are based on one case but the experience of this patient may not be generalisable beyond this study. His experiences were very dependent on the goodwill and experience of the involved professionals and this may vary significantly with each individual case.

	palatal, adenoid cystic carcinoma and treated by hemi-maxillectomy with post-operative radiotherapy. For 10 years after treatment, his dental care was managed by his GDP but specific problems led the GDP to refer to hospital services. The reasons for referral were increased movement of his maxillary obturator and repeated fractures of the remaining maxillary teeth (without pain or infection).			

Table 2g: MDT

Study details and aims	Details of Participants	Methods	Included patients and results	Comments
Anton, 1999.[9] **Country:** Austria **Aims:** To present clinical experiences regarding interdisciplinary surgical treatment of anterior skull base tumours and evaluate post-operative results. **Grade of evidence:** VI	**Service:** Cases where an interdisciplinary rhino-neuro-surgical skull base operating team was involved in the tumour resection were selected and post-operative mortality and morbidity were evaluated over a period of six months. **Participants:** Patients with benign and malignant neoplasms involving the anterior skull base.	**Methods:** Cases were retrospectively reviewed. **Outcomes measured:** Access to frontal fossa and the sinuses One-step tumour removal Necessity for transfacial procedures Surgical mortality Permanent post-operative complications Transient post-operative complications	**Included patients:** 57 patients were included (25 male, 32 female). Tumour diameter ranged from 12mm to 144mm. **Operation performed:** 43 of the patients (75.4%) underwent common transbasal tumour resection, 11 (10.3%) were operated on from an extended transbasal approach and an extensive transbasal approach was used in 3 patients (5.3%). **Access to frontal fossa/sinuses:** In all patients a good access to the frontal fossa and the sinuses was achieved. **One-step tumour removal:** By means of the transbasal approaches, one-step tumour removal was possible in all cases. **Necessity for transfacial procedures:** Even tumours extending as far as the hard palate required no additional transfacial procedures. **Surgical mortality:** Surgical mortality was 3.5%. **Post-operative complications:** Permanent post-operative complications were noted in 4 cases (7.02%) and transient post-operative complications in 7 (12.28%). **Transient post-operative complications:** The authors compare this result based on a transbasal access to eight studies using a cranio-facial access with a mean complication rate of 31.63%.	**Authors' conclusions:** In dealing with anterior skull base tumours, interdisciplinary surgical procedures using transbasal approaches provide a satisfactory outcome at a low rate of post-operative complications. When transbasal approaches are applied, no additional transfacial skull base exposure using midfacial incisions is required. **Comments:** The authors describe a transbasal rather than a cranio-facial access technique. Both procedures are carried out by interdisciplinary teams of a neurosurgeon and an ENT surgeon or a neuro-surgeon and a maxillofacial surgeon. The study is limited by it being observational in design and few details about how cases were selected for review were provided. For example, it is not stated whether this is a consecutive or random series.
Corbridge, 2000.[10] **Country:** UK	**Service:** A multidisciplinary team with seventeen different professions (ENT surgery, plastic surgery, clinical oncology, general surgery,	**Methods:** A retrospective case series is reported. A standard proforma was used to document involvement and	**Included patients:** 10 patients were included. **Average in-patient stay:**	**Authors' conclusions:** The authors state that the treatment of head and neck cancer patients is expensive and that the current funding strategies

Aims: To identify and quantify the cost of input from all members of a multidisciplinary team in the in-patient head and neck oncology service. **Grade of evidence:** VI	theatres, ENT ward, plastic surgery ward, specialist head and neck nurses, speech and language therapy, dietetics, physiotherapy, histopathology, radiology, occupational therapy, head and neck psychopathology, social services). **Participants:** A consecutive series of patients referred to the head an neck cancer service with SCC affecting a diversity of different sites within the upper aerodigestive tract.	costs for each profession in each patient's case. For the purpose of the analysis, a 35% overhead was added to the original costs. In addition, a minimum total cost of treating a head and neck cancer in-patient was calculated. **Outcomes measured:** Average in-patient stay. Average cost of surgery. Average operating time. Average cost of rehabilitation. Average imaging costs. Average total marginal costs. Average costs per day. Average minimum total cost (this is the average of the lower end of the range of total costs calculated for each patient).	25 days (range: 5 days to 90 days). **Average cost of surgery:** £1,698 (range: £582 to £2,883). **Average operating time:** 8.5 hours (range: 4 hours to 17 hours). **Average cost of rehabilitation (physiotherapy, dietetics, SLT and specialist head and neck nurse):** £255 (range: £47 to £498). **Average imaging costs:** £666 (range: £50 to £1,522). **Average total marginal costs:** £8,482 (range: £2,941 to £13,749). **Average costs:** £458 (range: £249 to £588). **Average minimum total cost:** £11,450	underestimate the cost of treatment. **Comments:** Case selection was by a consecutive series. 1 was still hospitalised when the study was concluded; the second underwent a planned two-stage procedure and required much more rehabilitation than the other patients. These cases, particularly the latter, could have a significant effect on the results. Patients offered primary radiotherapy or palliative care were excluded. No post-operative radiotherapy was priced. The process used for this research was deterministic and conduct sensitivity analyses to determine the robustness of the estimates generated were not conducted. As such it should be regarded as a cost listing study only.
Edwards, 1997.[11, 12] **Country:** UK **Aims:** To explore views of patients, their families and professionals about head and neck cancer services. **Grade of evidence:** VI	**Participants:** Patients and professionals from 4 hospitals and 2 patient support groups in South East England. Patients seen in the department within the past year and diagnosed more than 1 year previously were eligible. Patients were consecutively selected from lists of eligible patients compiled by the maxillofacial departments at the 4 hospitals. Additional patients were recruited from members of support groups who met at 2 of the	Focus group interviews were held. The issues for discussion were developed from informal conversations with professionals and patients before the study and adapted as important issues emerged. All focus groups were recorded and transcribed in full. The contents of the data were analysed for themes, key issues and for consistency. A map of each focus group was built up and analysed for inter-relationships between the different aspects of the	**Included patients:** 22 patients and 11 relatives took part in 6 focus groups. 33 professionals took part in 4 focus groups, including maxillofacial, ENT and plastic surgeons, medical and clinical oncologists, nurses, speech therapists and other professionals involved in rehabilitation and palliative care. **Effect of MDTs:** Professionals spoke of the value of teamwork. All participated in joint clinics although the composition of these varied. Surgeons and oncologists reported that planning treatment in joint clinics with colleagues from different disciplines kept them up to date and made sure that	**Authors' conclusions:** Patients and relatives were concerned about hospital accommodation, information about side effects, choice, support services and the impact of treatment. Professionals valued teamwork and joint clinics. They were concerned about lack of administrative flexibility, difficulties in communication and the high mortality of head and neck cancers. **Comments:** This study presents the views of a small number of patients and health

	hospitals. Patients had the option of bringing a family member with them.	findings.	they considered all options for treatment. It also provided them with support and a chance to discuss their difficult cases. The concept of the team spoken about by the professionals in the study had moved away from separate cure and care teams, to one team which included all professionals, the patient and the family. The role of the surgeon within the team had also changed. "*It used to be thought that the Captain (surgeon) knows it all and can fly the whole plane and all its contents and crew out of danger. And they have very sensibly abandoned that idea years ago and it's a team that flies the aircraft, taking due recognition of everybody's contribution… We are not there to cut out a tumour we are there to provide a route of survival for a person*."	professionals, those views may not be representative of the views of the larger population. The author acknowledges that the participants are not representative of advanced or terminal cancer or ethnic minority patients. The author also emphasises the qualitative nature of the research, which produces insight into an issue rather than measuring it. Whilst this study looked at many issues, only the results relating to the effect of a multidisciplinary team are reported here.

Table 2j: Location of the service in dedicated clinics

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Edwards, 1997.[11, 12] **Country:** UK **Aims:** To explore views of patients, their families and professionals about head and neck cancer services. **Grade of evidence:** VI	**Participants:** Patients and professionals from 4 hospitals and 2 patient support groups in South East England. Patients seen in the department within the past year and diagnosed more than 1 year previously were eligible. Patients were consecutively selected from lists of eligible patients compiled by the maxillofacial departments at the 4 hospitals. Additional patients were recruited from members of support groups who met at 2 of the hospitals. Patients had the option of bringing a family member with them.	Focus group interviews were held. The issues for discussion were developed from informal conversations with professionals and patients before the study and adapted as important issues emerged. All focus groups were recorded and transcribed in full. The contents of the data were analysed for themes, key issues and for consistency. A map of each focus group was built up and analysed for inter-relationships between the different aspects of the findings.	**Included patients:** 22 patients and 11 relatives took part in 6 focus groups. 33 professionals took part in 4 focus groups, including maxillofacial, ENT and plastic surgeons, medical and clinical oncologists, nurses, speech therapists and other professionals involved in rehabilitation and palliative care. **Effect of dedicated clinics:** Many patients and relatives were concerned about mixed wards both in terms of condition and sex, they felt that head and neck cancer should be managed on one ward or section of a ward with adequate privacy and nursing skills. The patients and relatives who were happiest with their accommodation were those who were nursed in side rooms and those who were on a cancer ward or section of a ward. Many patients who had been in wards with patients having different procedures felt that the nursing staff did not know anything about their condition. Being on a non-cancer ward made mutual support more difficult. Patients and relatives knew that their cancers were rare and supported the proposal of a specialist centre with expertise. Professionals supported the proposal in theory, but some were concerned that they would lead to over specialisation and that they would lose variety in their work. Interaction with other patients with similar conditions could occasionally have a negative effect. Some patients on arrival at the hospital were put in the same area of the ward as people who were recovering from major surgery. This could be upsetting and frightening for patients who had just been admitted for surgery. Many people with cancer felt that the principle of a 'specialist' team or hospital was very important. The 'ideal service' was one where there was sufficient expertise both in medical and nursing staff about management of the condition but which was small enough to give personal care. A small specialist hospital or a cancer centre within a big hospital was thought to be ideal.	**Authors' conclusions:** Patients and relatives were concerned about hospital accommodation, information about side effects, choice, support services and the impact of treatment. Professionals valued teamwork and joint clinics. They were concerned about lack of administrative flexibility, difficulties in communication and the high mortality of head and neck cancers. **Comments:** This study presents the views of a small number of patients and health professionals, those views may not be representative of the views of the larger population. The author acknowledges that the participants are not representative of advanced or terminal cancer or ethnic minority patients. The author also emphasises the qualitative nature of the research, which produces insight into an issue rather than measuring it. Whilst this study looked at many issues, only the results relating to the location of the service in dedicated clinics are reported here.

Table 2k: Access to a thyroid cancer MDT

<table>
<tr><th>Study details and aims</th><th>Case selection and numbers</th><th>Methods:</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Kumar, 2001.[13]

Country:
UK

Aims:
To examine well-defined points of good practice by identifying areas of deficiency and to compare management in patients with differentiated thyroid cancer treated in a specialist unit (staffed by a surgeon, an endocrinologist and an oncologist) with other clinical settings.

Grade of evidence:
V</td>
<td>Service:
A specialist multi-disciplinary clinical setting (surgeon, endocrinologist and oncologist).

Participants:
Patients with histologically proven diagnosis of papillary or follicular thyroid cancer.</td>
<td>Methods:
Retrospective audit of patients. Patients were identified from a specialised database, laboratory records and records of administration of ablative doses of radioiodine.

Patients were divided into two groups. Group A consisted of patients managed in a specialist setting in a joint surgical, endocrinological and oncological clinic. Group B consisted of patients treated in other settings, including those treated by single surgeons, endocrinologists or oncologists outside the specialist clinic setting.

Outcomes measured:
Adequacy of surgical treatment.

Surgical complications (post-operative vocal cord palsy, permanent hypoparathyroidsm).

Thyroxin therapy (adequate T4 therapy defined as dose sufficient to suppress TSH below 0.1mU/l).

Measurement of serum thyroglobulin as a marker of recurrent or persistent disease.

Administration of ablative radioiodine.</td>
<td>Included patients:
A total of 205 patients were included. 134 attended the combined clinic and 71 attended other clinics. Diagnosis had occurred from 12 months to 36 years previously. Patients were aged from 15 years to 86 years. There were 49 males and 156 females.

Adequate surgery:
<table>
<tr><td>Group A</td><td>120 (89.5%)</td><td rowspan="2">p < 0.001</td></tr>
<tr><td>Group B</td><td>44 (62%)</td></tr>
</table>
Vocal cord palsy:
<table>
<tr><td>Group A</td><td>5 (3.7%)</td><td rowspan="2">p = NS</td></tr>
<tr><td>Group B</td><td>2 (2.8%)</td></tr>
</table>
Hyperparathyroidism:
<table>
<tr><td>Group A</td><td>9 (6.7%)</td><td rowspan="2">p = NS</td></tr>
<tr><td>Group B</td><td>4 (5.6%)</td></tr>
</table>
Thyroxin given:
<table>
<tr><td>Group A</td><td>122 (91%)</td><td rowspan="2">p = NS</td></tr>
<tr><td>Group B</td><td>54 (76%)</td></tr>
</table>
Thyroxine treatment:
<table>
<tr><td>Group A</td><td>98 (80%)</td><td rowspan="2">p = NS</td></tr>
<tr><td>Group B</td><td>39 (72%)</td></tr>
</table>
Thyroglobulin monitored:
<table>
<tr><td>Group A</td><td>125 (93.3%)</td><td rowspan="2">p = NS</td></tr>
<tr><td>Group B</td><td>50 (67.6%)</td></tr>
</table>
High thyroglobulin treated:
<table>
<tr><td>Group A</td><td>38 (90.5%)</td><td rowspan="2">p = 0.006</td></tr>
<tr><td>Group B</td><td>18 (32.7%)</td></tr>
</table>
Ablative 131-I indicated but not given:
<table>
<tr><td>Group A</td><td>9 (6.7%)</td><td rowspan="2">p = 0.002</td></tr>
<tr><td>Group B</td><td>15 (21%)</td></tr>
</table>
</td>
<td>Authors' conclusions:
The authors state that their findings highlight the need for locally agreed protocols in managing thyroid cancer and argue in favour of centralisation of expertise and patient management in multi-disciplinary specialist clinical settings.

Comments:
Death and tumour recurrence were not considered to be useful measures because of the disease indolence and low mortality.

Questions involving rare diseases investigating long term morbidity are unlikely to be suitable for examination by RCTs. The retrospective nature of this study should not therefore be seen as a flaw. The process by which the study was conducted, including the population and data sources, for example was well described.</td>
</tr>
</table>

Table 2m: Specialisation within MDT

Study details and aims	Service and participants	Methods	Included patients and results	Comments
Pyle, 1997.[14] **Country:** USA **Aims:** To investigate if overall dental consultation rates were less than ideal and whether or not variation existed between hospitals in the study population. **Grade of evidence:** V	**Procedure:** Assessment by a dental practitioner. **Design and data source:** A retrospective review of medical notes at 3 Midwestern area university metropolitan hospitals. **Time period:** 1992 to 1993 (1.5 year period). **Study population:** 104 patients diagnosed with head and neck cancers. Of these 17 we female.	**Volume measure:** Patients were stratified by hospital. Each hospital; had an oral and Maxillofacial department while 2 (Hospitals A and B) also had an outpatient general dental clinic. **Covariates adjusted for:** No adjustment for covariates was conducted. **Statistical method:** The χ^2 test was used for no-parametric measures of association.	**Included patients:** Most patients in the series had radiotherapy either alone or in combination with chemotherapy and/or surgery. **Number of beds:** Hospital A – 748 Hospital B – 850 Hospital C – 860 **Number of patients' notes reviewed:** Hospital A – 33 Hospital B – 38 Hospital C – 33 **Dental consultation rate:** Hospital A – 16.5% Hospital B – 39.5% Hospital C – 12.1% ($\chi^2 = 9.154$, p = 0.01) **Proportion of patients with oral complications (by hospital):** Hospital A – 60.6% Hospital B – 13.2% Hospital C – 33.3% ($\chi^2 = 17.604$, p = 0.00015) **Proportion of patients with oral complications (by consultation):** Dental consultation – 38.8% No dental consultation – 20.8% (p = non-significant)	**Authors' conclusions:** Consultation rates were not influenced by the presence of a general dental clinic but the rate of oral complications was lower in the hospital which had a dental clinic. As dental interventions can reduce the severity or prevent oral complications in head and neck cancer patients, efforts to explain differences in complication rates between hospitals and enhance cooperative protocols represent a significant need. **Comments:** This study is probably a consecutive series. The authors have given scant details of the patients particularly in relation to co-morbid conditions. The authors have not adjusted for any demographic, cancer-related or co-morbid illness-related variables. The numbers of patients in the 'Consultation' and 'No consultation' categories were small and so the test for difference in complication rates may not have had sufficient power to detect meaningful differences. While the authors conclude that the provision of a general dental clinic had no influence on patient outcomes, difference in complication rates between the 2 hospitals providing this service were large. Given this and the lack of adjustment for covariates, it is difficult to assess whether the provision of a general dental clinic has an effect on outcomes or not.

Table 2n: Clinician volume

<table>
<tr><th>Study details and aims</th><th>Details of participants</th><th>Methods</th><th>Included participants and results</th><th>Comments</th></tr>
<tr>
<td>Sosa, 1998.[15]

Country:
USA

Aims:
To measure the effect of individual surgeon volume on clinical and economic outcomes (including in-hospital complications, length of stay and hospital charges) for surgical procedures for benign or malignant thyroid disease.

Grade of evidence:
V</td>
<td>The study involved surgeons that performed at least 1 thyroidectomy during the study period. Patients of interest were those adult patients for whom hospital discharges had been made between 1991 and 1996.

Procedures undergone by patients:
• unilateral thyroid lobectomy
• complete thyroidectomy
• substernal thyroidectomy
• other partial thyroidectomy
• excision of lingual thyroid
• other operations on thyroid glands.</td>
<td>Methods:
A cross-sectional analysis of hospital discharge data from the non-federal health system of 1 US state. Surgeons were categorised according to total volume of thyroidectomy as follows:

<table>
<tr><th>Group</th><th>No. of Thyroidectomies</th></tr>
<tr><td>A</td><td>1 to 9</td></tr>
<tr><td>B</td><td>10 to 29</td></tr>
<tr><td>C</td><td>30 to 100</td></tr>
<tr><td>D</td><td>> 100</td></tr>
</table>
Covariates adjusted for:
Age; race; co-morbidity score; thyroid diagnosis and procedure; insurance status; hospital volume; time period.

Outcomes measured:
In-hospital complications directly (e.g. recurrent laryngeal nerve injury) or indirectly (e.g. allergic drug reaction) related to surgery.

Mean length of stay in the hospital.

Mean total hospital charges.</td>
<td>Included surgeons:
The study included 658 surgeons. They performed a median of 25 thyroidectomies in the period of 1991 to 1996. About two thirds of surgeons performed fewer than 1 thyroidectomy per year however.

Proportion of surgeons per group:
<table>
<tr><th>Category</th><th>%</th></tr>
<tr><td>A</td><td>78.6</td></tr>
<tr><td>B</td><td>14.9</td></tr>
<tr><td>C</td><td>5.9</td></tr>
<tr><td>D</td><td>0.6</td></tr>
</table>
Included patients:
5,860 patients underwent thyroid surgical procedures from 1991 to 1996 in 52 hospitals. The average age was 48.6 years. 80.5% were females and 72.5% were white.

Proportion of patients per surgeon group:
<table>
<tr><th>Category</th><th>Number</th><th>%</th></tr>
<tr><td>A</td><td>1,457</td><td>24.9</td></tr>
<tr><td>B</td><td>1,906</td><td>32.5</td></tr>
<tr><td>C</td><td>1,651</td><td>26.2</td></tr>
<tr><td>D</td><td>846</td><td>14.4</td></tr>
</table>
Diagnosis:
<table>
<tr><td>Hyperplasia</td><td>51.4%</td></tr>
<tr><td>Adenoma</td><td>23.6%</td></tr>
<tr><td>Cancer</td><td>25.1%</td></tr>
</table>
Procedures:
<table>
<tr><th></th><th>Number</th><th>%</th></tr>
<tr><td>Unilateral lobectomy</td><td>2,705</td><td>46.2</td></tr>
<tr><td>Other subtotal thyroidectomy</td><td>1,766</td><td>30.1</td></tr>
<tr><td>Total thyroidectomy</td><td>1,144</td><td>19.5</td></tr>
<tr><td>Substernal thyroidectomy</td><td>220</td><td>3.8</td></tr>
</table>
Complication rate (%):
<table>
<tr><th>Surgeon Category</th><th>A</th><th>B</th><th>C</th><th>D</th></tr>
<tr><td>Unilateral lobectomy</td><td>7.7</td><td>5.8</td><td>5.6</td><td>6.2</td></tr>
</table>
</td>
<td>Authors' conclusions:
Individual surgeon experience is significantly associated with complication rates and length of stay for thyroidectomy.

Comments:
This retrospective assessment appears to have been well conducted. It takes into account the important variables which may be confounders in the study. The outcomes chosen were appropriate. In-hospital death was not considered because it was extremely rare (only 3 over the 6 years).

The authors do not justify their choice of cut-points between the various bands of surgeons. It is not clear if this was conducted a priori or post hoc.</td>
</tr>
</table>

			Other subtotal thyroidectomy	9.8*	5.9	5.5	6.6
			Substernal thyroidectomy	18.8	8.5	16.6	11.5
			Total thyroidectomy	16.1	11.7	11.2	4.3

* = *difference reached statistical significance when compared with Category Band D.*

Length of stay in days:

Surgeon Category	**A**	**B**	**C**	**D**
Unilateral lobectomy	1.7*	1.6*	1.5*	1.3
Other subtotal thyroidectomy	2*	1.7*	1.8*	1.5
Substernal thyroidectomy	2.5*	1.9	2.1*	1.8
Total thyroidectomy	2.4*	2*	2.1*	1.6

* = *difference reached statistical significance when compared with Category Band D.*

Hospital charges (US$):

Surgeon Category	**A**	**B**	**C**	**D**
Unilateral lobectomy	$3,652	$3,428*	$3,313*	$3,718
Other subtotal thyroidectomy	$3,808*	$3,549*	$3,393*	$4,309
Substernal thyroidectomy	$4,676	$3,915*	$4,219	$4,596
Total thyroidectomy	$4,866*	$4,684*	$4,472	$4,094

* = *difference reached statistical significance when compared with Category Band D.*

Complexity of surgery:
Group D surgeons were more likely to operate on complex cases; 29% of their patients underwent total thyroidectomies compared with 15% of patients of surgeons in Group A.

Proportion of patients with cancer:
Group D surgeons were more likely to operate on patients with cancer; 31% of their patients had cancer compared with 23% of patients of surgeons in Group A.

Table 2o: Hospital volume

<table>
<tr><th>Study details and aims</th><th>Case selection and numbers</th><th>Volume measure, variables controlled for and statistical methods</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Robertson, 2001.[16]

Country:
UK

Aims:
To identify treatment philosophies for oral cancer and investigate any survival differences associated with different treatment options.

Grade of evidence:
VI</td>
<td>Procedure:
1 of 5 treatment strategies:
Biopsy (other than excisional biopsy) only with no further treatment
Excisional biopsy only with no further treatment
Radical surgery only
Biopsy (excisional or non-excisional) in combination with radiotherapy
Radical surgery in combination with radiotherapy

These were given at 1 of 14 units throughout the West of Scotland.

Design and data source:
Patients diagnosed with oral cancers were identified from the West of Scotland Cancer Registry. Information was then taken from their medical records. Information was cross-checked with the West of Scotland Cancer Surveillance Unit.

Time period:
1984 to 1990</td>
<td>Covariates adjusted for:
Information on demographic and disease-related factors adjusted for in the statistical analysis.

Statistical method:
The Kaplan-Meier and log-rank tests were used to conduct unadjusted analyses of disease-free and overall survival. The Cox proportional hazards model was used for assessment of the influence of treatment factors on survival. Association between treatment and tumour factors was assessed using the χ^2 test.

Information on the effect of volume was obtained by comparing the largest provider with the remaining providers.

Outcomes Measured:
Disease free period.

Overall survival time.</td>
<td>Included patients:
A total of 243 patients were identified. 16 were excluded owing to incomplete data and 21 were excluded as they had distant metastases at diagnosis. Total number of patients included was 206.

Number of units and patients:
Plastic 1 unit 124 (60%)
Otolaryngology 9 units 66 (32%)
Oral/Maxillofacial 4 units 16 (8%)

Stage at presentation:
<table><tr><th>Stage</th><th>Number</th></tr><tr><td>T1</td><td>44 (21.4%)</td></tr><tr><td>T2</td><td>66 (32%)</td></tr><tr><td>T3</td><td>35 (17%)</td></tr><tr><td>T4</td><td>61 (29.6%)</td></tr></table><table><tr><th>Stage</th><th>Number</th></tr><tr><td>N0</td><td>106 (51.5%)</td></tr><tr><td>N+</td><td>100 (48.5%)</td></tr></table>Recurrence (Hazard Ratio, adjusted for stage (95% CI)):
Largest Volume Centre 1.00
Remainder 1.43 (1.02 to 2.02)

Risk of Death (Hazard Ratio (95% CI)):
Largest Volume Centre 1.00
Remainder 1.48 (1.06 to 2.06)

There were no significant associations between treatment centre and either survival (HR = 1.09; 95% CI: 0.74 to 1.61) or risk of recurrence (HR = 1.11; 95% CI: 0.73 to 1.69), when the treatment strategy was included as a covariate.</td>
<td>Authors' conclusions:
The study confirms that early stage tumours have a better prognosis than late stage tumours but a large number of patients present with late-stage disease.

The concentration of patients in the plastic surgery unit at one hospital has allowed the combined team to develop considerable experience in designing individual treatments and their results show that these treatment plans may be proving to be more effective than those designed by those seeing fewer patients.

Comments:
This was a well-conducted piece of research which, despite the limitations which must be acknowledged when dealing with studies based on a retrospective survey of records identified by registry data, provides an insight into the effects of both the tumour stage at presentation and the number of patients managed by the treatment centre. While the conclusions may only be viewed as suggestive owing to the nature of the evidence, they follow from the results presented.

The study also examined other aspects of care outside the remit of the present review.</td>
</tr>
</table>

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Initial investigation and diagnosis

The Questions

a) For patients with symptoms suggestive of thyroid cancer (enlarged thyroid or thyroid lump) what effect does performing fine needle aspiration (FNA) cytology, to confirm or exclude malignancy, have on stage of tumours at referral, diagnostic indices and patient outcomes including the number of patients receiving unnecessary or inappropriate surgery?

b) In patients undergoing assessment of a lump in the neck, which is suspicious of malignancy, what are the relative efficacies of FNA (ultrasound (US) guided FNA and FNA cytology) and biopsy in terms of diagnostic indices, the timeliness of primary lesion detection and patient outcomes.

c) For patients being investigated for head and neck cancers, would specialist histopathological/cytopathological opinion improve the diagnostic accuracy of biopsy results?

d) For patients with malignant cervical lymphadenopathy and occult primary, what are the relative efficacies of Positron Emission Tomography (PET), Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and US scanning for identifying the primary site of malignancy in terms of the early detection and treatment of the primary lesion, diagnostic error rates and patient outcomes?

e) In patients who are being investigated or treated for head and neck cancers, does written information about the disease, diagnostic tests and treatments that may be utilised if the disease is confirmed, improve outcomes?

The Nature of the Research Evidence

a) Fine needle aspiration cytology for patients with symptoms suggestive of thyroid cancer

A study investigating whether core needle biopsy (CNB) provides additional information over fine needle aspiration biopsy (FNAB) compared 29 patients diagnosed as having thyroid nodules on ultrasound, who had both the index tests as well as definitive histological diagnosis from surgery.[1] However, 13 CNBs were insufficient for diagnosis, resulting in a small sample size of just 16 patients, therefore, the results should be regarded as suggestive rather than definitive. Details are given in Table 3a.

b) Relative efficacies of fine needle aspiration and biopsy for patients undergoing assessment of a lump in the neck

No evidence was found relating to the relative efficacies of fine needle aspiration and biopsy for patients undergoing assessment of a lump in the neck.

c) Specialist histopathological/cytopathological opinion

No evidence was found relating to specialist histopathological/cytopathological opinion in patients being investigated for head and neck cancers.

d) Relative efficacies of Positron Emission Tomography (PET), MRI, CT and ultrasound scanning for patients with malignant cervical lymphadenopathy and occult primary

No evidence was found relating to the relative efficacies of Positron Emission Tomography (PET), MRI, CT and ultrasound scanning for patients with malignant cervical lymphadenopathy and occult primary.

e) Written information

Four studies pertinent to the use of written information in the care of the head and neck cancer patient were located.[2-5] Of these, one was conducted in Canada[2] and three were conducted in the UK.[3-5] Two studies investigated written information in combination with other information media; the Canadian study was an RCT which included 125 patients and investigated the

use of combined oral and written communication[2] and one of the British studies was a non-randomised comparison which included 85 patients and investigated a comprehensive package including nursing assessments, educational and counselling sessions, pre-operative assessments and community nurse involvement in addition to a comprehensive written information package.[3] The remaining British studies related to written information used alone.[4, 5] Both were observational in nature and included 70 patients and 15 patients and/or relatives and 14 health professionals respectively.

Details of all the studies are given in Table 3e.

Summary of the Research Evidence

a) Fine needle aspiration cytology for patients with symptoms suggestive of thyroid cancer

In 16 patients who were diagnosed as having thyroid nodules by ultrasound, the accuracy of FNAB was 93.8% compared with 100% for CNB.[1] The sensitivity of FNAB was 85.7% and the specificity was 100%.

b) Relative efficacies of fine needle aspiration and biopsy for patients undergoing assessment of a lump in the neck

No evidence was found relating to the relative efficacies of fine needle aspiration and biopsy for patients undergoing assessment of a lump in the neck.

c) Specialist histopathological/cytopathological opinion

No evidence was found relating to specialist histopathological/cytopathological opinion in patients being investigated for head and neck cancers.

d) Relative efficacies of Positron Emission Tomography (PET), MRI, CT and ultrasound scanning for patients with malignant cervical lymphadenopathy and occult primary

No evidence was found relating to the relative efficacies of Positron Emission Tomography (PET), MRI, CT and ultrasound scanning for patients with malignant cervical lymphadenopathy and occult primary.

e) Written information

Four studies were located which provided evidence relevant to this question.[2-5]

The evidence of the highest grade comes from a Canadian study which investigated recall rates among head and neck cancer patients in a study of a combined oral and written intervention.[2] This study utilised experimental methods. It intervention consisted of a pamphlet (which contained of both text and illustrations) and an oral explanation of the possible complications of surgery and the possible risks of the procedure. When compared to patients who received normal care, the patients who were included in the intervention group were more than two-thirds more likely to recall the potential complications of the procedure six weeks after they were explained.

This study was described by its authors as being an RCT but they did not report the method of randomisation or whether blinding of the outcome assessors was used. Patient outcomes other than their ability to recall what had been told to them were not measured. These factors may effect the generalisability of the results but the marked differences in the recall rates should still be considered supportive of information packages. The relative effects of the written and oral components of the current package were not investigated.

A British study involved a comprehensive supportive package.[3] This included nursing assessments, educational and counselling sessions, pre-operative assessments and community nurse involvement in addition to a comprehensive written information package. 90% of respondents to a questionnaire had received the information package and of these, all found it helpful. 85% of patients felt they had been given appropriate levels of information. When a sample of patients whose treatment pre-dated the package were asked the

same question, on 59% of patients felt that they had received adequate information.

It is important to note that the relative effects of the various co-interventions which made up the overall supportive package can not be easily unpicked. Using the information package in isolation from the remaining elements may not lead to the same results as those found in this study. While the use of questionnaire-based surveys can in the main, illicit only opinions, the evidence gathered in this study is suggestive that the use of written information as part of a comprehensive package may be beneficial.

A second British study, presented in the form of one constituent study in a multi-study PhD thesis, reported on both the pilot and substantive study of a new information booklet in a London hospital.[4] Following comments that the initial draft was "too medical", the version of the booklet submitted to the substantive study was found to be helpful and comprehensive by most patients and most patients found it beneficial in promoting their use of coping strategies. Health professionals reported that they found the booklet helped their interaction with their patients. Few details of the methods used in the study were reported and the contents and format of the booklet itself were poorly reported. However, the study appears to support the use of locally produced information materials.

The final British study investigated written information used in isolation.[5] This study also assessed a booklet designed for local use. Patients and/or relatives and staff members rated the booklet well in terms of its length, content, the usefulness of its pictures and whether it was informative; the staff members were marginally more pleased with the booklet. 7% of patients and 10% of staff found it frightening. 7% of patients and/or relatives found it shocking while twice as many found the booklet "worse than imagined". No staff members held either of the latter two opinions.

The population (both in terms of staff and former patients) already had significant knowledge on the topic area and as such, their views may not be representative of new patients. However, this was a preliminary evaluation of the booklet and a further evaluation may be warranted.

Conclusions

Studies from the UK and Canada suggest that written information may be helpful to patients, while not providing definitive evidence to support the benefits of this communication medium.

Written information is sometimes used in isolation and sometimes used in combination with other means of communication; where this is the case, the relative effects of the various concurrent interventions can not be identified but the evidence suggests that written information has a role to play in this setting.

Table 3a: Fine needle aspiration cytology for patients with symptoms suggestive of thyroid cancer

<table>
<tr><th>Study details and aims</th><th>Details of participants and diagnostic test(s)</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Pisani, 2000.[1]

Country:
Italy

Aims:
To estimate the diagnostic value of fine needle aspiration biopsy (FNAB) and the possible additional information of core needle biopsy (CNB).

Grade of evidence:
IV</td>
<td>Participants
136 consecutive patients aged between 25 years to 68 years. All patients had been diagnosed as having thyroid nodules ultrasonically. Both biopsies were conducted on the same day.

Diagnostic indices are calculated based on the 16 patients who had CNB (sufficient for diagnosis), FNAB and definitive gold-standard diagnosis.

Details of FNAB
FNAB was performed under ultrasound guidance using 23 to 35 gauge needles. These were interpreted by an experienced thyroid cytologist.

Details of CNB
CNB was performed under ultrasound guidance using 20 to 21 gauge needles. These were interpreted by an experienced thyroid pathologist.

Interval between tests
Information on the relative timing was not reported.

Reference standard
In patients who underwent surgery, the index test results were each compared with the definitive histological diagnosis. Patients with benign index tests were followed up using clinical examinations and ultrasound.</td>
<td>Included patients:
From a total of 32 patients having a CNB and 136 patients having FNAB, 29 patients had information on both modalities and definitive gold-standard diagnosis.

13 CNBs were insufficient for diagnosis. All FNABs provided sufficient material for diagnosis. Therefore, diagnostic indices are calculated based on 16 patients.

Diagnostic indices
<table>
<tr><th></th><th>FNAB</th><th>CNB</th></tr>
<tr><td>Sensitivity</td><td>85.71%</td><td>100%</td></tr>
<tr><td>Specificity</td><td>100%</td><td>100%</td></tr>
<tr><td>Accuracy</td><td>93.75%</td><td>100%</td></tr>
<tr><td>PPV</td><td>100%</td><td>100%</td></tr>
<tr><td>NPV</td><td>90%</td><td>100%</td></tr>
<tr><td>PLR</td><td>16.25*</td><td>18.75*</td></tr>
<tr><td>NLR</td><td>0.14</td><td>0.07*</td></tr>
<tr><td>DOR</td><td>82.33*</td><td>285*</td></tr>
</table>
* = The diagnostic index has been calculated with the addition of 0.5 to all cells in the 2x2 table to allow for cells with a value of 0.</td>
<td>Authors' conclusions:
The authors suggested that their study did not demonstrate any benefit of CNB over FNAB.

Comments:
This retrospective study provides some evidence for the lack of superiority of CNB over the more regularly used FNAB. The population studied is appropriate and the reference standard is reported. However, only a small proportion of the population had both the index tests as well as having the reference standard – only 21% of patients who had FNAB also had CNB. The rationale for which patient received each test(s) was not clear. If the 3 individual histological analyses were conducted by the same person, a degree of bias may have been introduced into the study.

Given these limitations and the small numbers of cases, the findings of this study should only be regarded as suggestive.</td>
</tr>
</table>

Table 3e: Written information

Study details and aims	Participants	Intervention	Methods	Included patients and results	Comments
Chan, 2002.[2] **Country:** Canada **Aims:** To examine the effects of an educational intervention, in the form of printed material, on patient knowledge and recall of possible risks from parotidectomy or thyroidectomy. **Grade of evidence:** II	125 consecutive adult patients seen at an academic tertiary care centre and undergoing thyroidectomy or parotidectomy. Patients were randomised into either an educational intervention or a control group. 89 patients were female and 36 male, average age 47 years (range 18 to 86). 63% patients had a postsecondary degree, 26% had high school education and 11% had less than a high school education. 95 thyroidectomies and 30 parotidectomies were performed by the 4 surgeons.	At the pre-operative visit, 4 participating surgeons were given a specific checklist of risks to outline to the patient according to the planned surgical procedure, with an equal emphasis on each risk. The educational intervention group was also given a pamphlet with written information accompanied by illustrations, in addition to the verbal checklist. The specific complications discussed with patients undergoing parotidectomy were facial scar, facial nerve weakness or paralysis, greater auricular nerve paraesthesia and Frey syndrome. Patients undergoing thyroidectomy were informed of the potential risks of a neck scar, recurrent laryngeal nerve weakness or paralysis and hypocalcaemia.	Within 3 weeks to 7 weeks after the initial visit, the patients in both groups were interviewed by telephone and asked to recall the specific risks of their operation. The effectiveness of the educational intervention was determined by comparing the mean rate of complication recall between the intervention and control groups. For each subject, the percentage of complications recalled was calculated (out of a possible 4 complications for parotidectomy and out of a possible 3 complications for thyroidectomy). The recall rates were compared between the intervention and control groups using the t test. Further statistical analyses were done, i.e. for the 2 subgroups of patients according to surgical procedure, for comparing the proportions recalling each of the individual complications and for calculating the percentage of risks recalled. Logistic regression models were fit to see if recalling 50% or more of the risks was related to the various demographic variables, including patient age, sex and highest level of education attained; the surgical procedure undergone; and the time from the consent interview to the recall interview. These variables were also examined to determine whether they altered the intervention effect. The mean length of follow-up was 33 days (range 22 days to 53 days).	**Exclusions and withdrawals:** 4/125 patients were excluded from the analysis because their follow-up interview was less than 3 weeks (n = 3) or at 12 weeks (n = 1) after their initial visit. **Included patients:** 56/121 patients received educational intervention pamphlets as well as the verbal checklist, while 65 received only oral communication of the same information. The groups were comparable in terms of age, education level, operation type and time between consent and recall. 77% of the intervention group were female, whilst 66% of the control group were female. **Main results:** The overall mean recall rate of potential complications for both procedures, regardless of group, was 39.1% (95% CI: 34% to 44.2%). The mean recall rate was significantly higher for the intervention group (50.3%; 95% CI: 42.6% to 58%) compared with the control group (29.5%; 95% CI: 23.5% to 35.4%) ($p < 0.001$, t test). The results for the 2 procedure subgroups were similar. The individual recall rates for each potential complication were also assessed. The intervention group, although not always statistically significant, had a higher recall rate for every complication. The results of logistic regression modelling showed that age ($p = 0.37$), sex ($p = 0.48$), type of surgical procedure ($p = 0.80$) and time from consent until recall interview ($p = 0.48$) were not related to whether a patient recalled less than 50% or 50% or more of the risks. Patients who had postsecondary education were more likely to recall 50% or more of the risks (45%) than those with a high school education or less (27%) ($p = 0.05$). Those who received a pamphlet recalled 50% or more of this risk significantly more often (29 of 56 patients) than those who did not receive the pamphlet (17/65 patients) ($p = 0.004$). This effect remained significant when the previously mentioned variables were controlled for in the model ($p < 0.01$ in each case). There were no significant interactions between the intervention and any of the variables considered.	**Authors' conclusions:** The intervention consistently improved risk recall for all patients regardless of age, sex and level of education. Patients' ability to recall potential risks was significantly increased by an educational intervention; all patients would benefit from this intervention. **Comments:** The authors' conclusion that the intervention consistently improved risk recall for all patients appears to be valid based on their study. However, details of the randomisation procedure are not reported and it is not stated whether clinicians giving information were blinded to study group. The study did not measure any other patient outcomes, other than recall, such as quality of life, anxiety and depression. The authors do not state the reasons for patients undergoing their operation. Given the age range and high proportion of female patients, it is unlikely that patients were all receiving surgery for head and neck cancer, therefore, results may not be generalisable to head and neck cancer patients.

				Adverse events: None reported.	

Study details and aims	Details of written information and participants	Methods	Included patients and results	Comments
Feber, 1998.[3] **Country:** UK **Aims:** In order to plan an evidence-based strategy, a literature review was carried out followed by a comprehensive audit of patients' and professionals' views of the current service. One year after implementation of the strategy patients who had undergone surgery during that year were sent questionnaires to elicit their levels of satisfaction in order to evaluate the effectiveness of the project. **Grade of evidence:** IV	**Service:** The support strategy included a comprehensive patient information pack on laryngectomy, containing current information booklets, supplies brochures, general cancer support information, information about the local laryngectomy club and financial benefits information, in order to provide the specific and detailed pre-operative education and preparation needed at the time of the decision to perform laryngectomy. The nurse uses the package to explain the operation and its consequences to the patient and family. It is then given to the patient to take home. **Participants:** Patient survey after implementation of the support strategy: questionnaires were sent to patients who had undergone total laryngectomy and laryngopharyngectomy prior to implementation of the strategy (50 patients) and to those undergoing surgery during the year after implementation (35 patients). There were 31 respondents in the first group and 20 respondents in the second group.	**Methods:** Patient survey after implementation of the support strategy. The questionnaires were posted to the patients and were self-completed and anonymous. **Outcomes measured:** The questionnaires asked about patient satisfaction with support and information before and after their operation.	90% patients in the second group received an information pack compared with none in the first group. Of these, 100% found it helpful. 85% patients in the second group felt that they were given as much information and support as they needed on diagnosis, compared with 59% in the first group. Of the 3 patients (15%) in the second group who did not feel they had enough information, 1 had not received the usual support due to undergoing emergency surgery and another patient had been prepared for a partial laryngectomy but unfortunately actually had to undergo a total laryngectomy. The third did not state any reason for his/her dissatisfaction.	**Authors' conclusions:** No specific conclusions were drawn relating to the provision of written information. **Comments:** The patient survey prior to implementation of the support strategy did not report any outcomes relating to written information, therefore, only the results of the survey after implementation of the support strategy are reported. The questionnaires were not validated and were not described in detail in the report, therefore, it is not possible to comment on their content. The authors do not report any negative effects of the patient information pack, however, it may be that these were not investigated. As the patient information pack was only part of the patient support strategy, it is not possible to attribute the greater number of patients feeling that they were given as much information and support as they needed, solely on the provision of the patient information pack. However, all patients who received the information pack found it helpful.
Clarke, 2001.[4] **Country:** UK **Aims:** To develop a model that facilitates the self-	Pilot **Intervention:** A booklet about facial cancer was developed by psychologists and tested among clients and professionals of a service. Initially the booklet contained much medical information.	**Methods:** A number of patients were asked to provide feedback on the booklet being developed. This was initially piloted and then, once changes were made, additional respondents were asked to comment on the booklet.	Pilot **Included patients:** A small number of clients (details were not given about who the clients were) and health professionals (details also not given). **Results:** Respondents felt that the booklet was very "medical" and suggested that more information about changes in appearance	**Authors' conclusions:** The active participant model for providing information was assessed as being effective both in terms of meeting the factual/medical and support/coping needs of the client population, being acceptable to health professionals and in promoting the active self management approach to the problems

management of facial disfigurement through using information to move from a passive recipient role to an active participant role. **Grade of evidence:** VI	Substantive Study **Intervention:** The second version of the booklet ("When cancer affects the way you look") started with a "psychological" introduction about the face: medical information was kept to a minimum. It focused on potential problems and coping strategies in order to stress the active managing role of the individual.	Neither the contents of the booklet nor the audience at whom it was aimed were reported. **Outcomes measured:** Comprehensibility Helpfulness Effectiveness in promoting changes. Acceptability to health professionals.	should be given. Substantive study **Included patients:** 70 clients evaluated the second version; again details were not given. **Comprehensibility:** 87% of patients felt it was comprehensible. **Helpfulness:** 73% of patients felt it was helpful. Both health professionals and patients commented that they had been unable to find information of this kind elsewhere. **Effectiveness:** 69% of patients found it effective in stimulating them to try out some of the suggested strategies. **Acceptability:** Health professionals reported that the booklet facilitated their own individual work with patients.	of facial disfigurement. **Comments:** While this work was interesting, the conclusions it drew were not fully grounded in the data presented. Some important data are omitted. For instance, the samples (of both patients and health professionals) in both initial and substantive assessments of the work are not described. No information is given about the survey used.
Semple, 2002.[5] **Country:** UK **Aims:** The authors' aims appear to be to produce and evaluate an information booklet for head and neck cancer patients undergoing surgery. **Grade of evidence:** VI	**Service:** A draft information booklet "General Information for Patients Undergoing Head and Neck Surgery" was developed by a multidisciplinary team involving the clinical nurse specialist, doctors, nurses, social worker, speech and language therapist, dietitian, physiotherapist and maxillo-facial technician in partnership with patients undergoing major head and neck surgery and their relatives. Topics covered were surgery and radiotherapy; before surgery; after surgery; feeding, eating and speaking; and discharge advice and health education. **Participants:** A convenience sample of 15 patients who had undergone major surgery for head and neck cancer within the last 9 months and/or their relatives was used.	**Methods:** The quality development officer compiled a self-administered questionnaire to identify patients' and relatives' opinions on a new booklet. This was sent to the patients and/or relatives with a letter explaining the study and inviting them to participate. **Outcomes measured:** Patients' and relatives' opinions on the style, content and comprehensibility of the proposed booklet. A similar tool was used for all members of the multidisciplinary team (n = 14) who provided direct care to patients with head and neck cancer. **Readability measures:**	14 patients/relatives responded (91%) and 10 health professionals responded (71%). All respondents rated the length of the booklet as about right. 43% patients/relatives and 20% health professionals were satisfied with the overall content covered in the booklet and 57% patients/relatives and 80% health professionals were very satisfied. 93% patients/relatives and 100% health professionals stated that pictures were helpful. 100% respondents rated the overall impact of the booklet as informative. 7% patients/relatives and 10% health professionals rated it as frightening, 7% patients/relatives rated it as shocking and 14% patients/relatives rated it as worse than imagined. 79% patients/relatives rated the clarity of the content as very clear and 21% rated it as clear. The majority of patients/relatives reported that the booklet contained enough detail, although some suggested that there was too much. 83% of respondents stated that the terminology was suitable, 9% felt that it was unsuitable. Suggested changes to terminology were made to the published booklet, e.g. 1 respondent suggested replacing the word "communicate" with "speak". 67% patients/relatives rated the information as very beneficial to them and 33% as beneficial.	**Authors' conclusions:** Considerable time and effort is required to produce accurate, comprehensible and attractive written information for patients that will be of benefit. Providing information in this way will do much to improve partnerships of care and the quality of life for patients and their relatives with cancer; therefore such practices can be seen as a cost-effective intervention for the health-care system. **Comments:** The authors acknowledge that this was a small-scale study for a specific population so the results cannot be generalised. They state that once an adequate sample of patients/relatives has received the written information, formal evaluation will be conducted.

		Readability was measured by asking patients/relatives to underline any words and/or sentences they did not understand. It was also measured using established readability formulae such as the Flesch-Kincaid index and the Gunning Fog index.	Additional comments included: "What is the role of each professional mentioned?", "How long will I have to fast before surgery?", "Terminology could be simpler – clearer explanations", "Mention should be made about co-ordination being impaired and that writing messages can be difficult due to the drugs being administered", "More information needed about physiotherapy after surgery" and "Information needed about the length of time for skin grafts to heal". The Flesch-Kincaid index for the patient information booklet was 8.5 and the Gunning Fog index was 10.8. One can therefore conclude that the booklet is easier to understand than the ten most popular newspapers. According to the Gunning Fog readability tool, the majority of the adult Western population should understand the booklet.	The authors appear to have produced a well received booklet for patients undergoing head and neck cancer surgery. However, this was assessed by patients and/or their relatives who had been treated within the last 9 months and health professionals, who may already have a better knowledge of head and neck cancer treatment than those patients who have not yet undergone treatment. This preliminary study appears to have been well conducted, but further evaluation of this patient information tool is warranted. The assessment of other patient outcomes such as quality of life and anxiety would also be beneficial.

References

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4. Clarke A. *Resourcing and training head and neck cancer nurse specialists to deliver a social rehabilitation programme to patients*. London: City University, 2001.
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Pre-treatment assessment and management

The Questions

a) For patients with stage III or IV cancers of the head and neck being considered for extensive therapy, what is the effectiveness of computed tomography (CT) of the chest and plain film radiography of the chest (CXR) for identifying the presence or absence of metastatic disease in the thorax in terms of diagnostic error rates and patient outcomes?

b) In patients with head and neck cancer who are being assessed for treatment, does the use of instruments for the assessment of comorbidity result in improved decision-making.

c) In the management of patients with head and neck cancer, does assessment by a percutaneous gastrostomy service result in improved outcomes?

d) In the management of patients with head and neck cancers (during any phase of care), does prompt and/or regular assessment by a dental professional improve outcomes?

e) In patients who are being investigated or treated for head and neck cancers, does the use of instruments for the assessment of anxiety and depression result in improved decision-making?

f) In patients with head and neck cancer does "shared decision making" between professionals and patients improve patient outcomes?

g) In patients who have been diagnosed with head and neck cancer, does the availability of psychosocial care (including psychological care, counselling and spiritual care) improve outcomes?

h) In patients with head and neck cancer, does the availability of counselling (including cognitive behavioural therapy (CBT)) improve outcomes?

i) For patients undergoing treatment for head and neck cancer, what effect does the provision of a patient visitor have on patient outcomes?

From the studies identified, that provide characteristics of the patient visitor, what are the desirable visitor characteristics that are associated with improved patient outcomes?

j) For patients undergoing treatment for head and neck cancer, what effect does the provision of smoking cessation programmes, such as nicotine replacement therapy, have on outcomes including adherence to treatment plan, incidence and severity of treatment induced morbidity, recurrence, second primary tumours, quality of life, anxiety and patient satisfaction?

k) For patients with head and neck cancer who are identified as being dependent on alcohol, what effects do alcohol cessation programmes have on outcomes including management of acute alcohol withdrawal during treatment, adherence to treatment plan, incidence and severity of treatment induced morbidity, recurrence, second primary tumours, quality of life, anxiety and patient satisfaction?

The Nature of the Research Evidence

a) Effectiveness of imaging

Three studies were identified that compared the use of chest radiography (CXR) versus chest computed tomography (CT) in screening for pulmonary malignancy in patients with head and neck cancers.[1-3] Two studies evaluated 26 patients[1] and 25 patients[2] with advanced disease (stage III or IV), whilst the other evaluated 44 patients, 18 of which had advanced disease.[3] There were methodological limitations in each of the studies, therefore, the results should be interpreted with caution. Details are given in Table 4a.

b) Use of instruments for the assessment of comorbidity

No evidence was found relating to the use of instruments for the assessment of comorbidity in patients with head and neck cancer who are being assessed for treatment.

c) Nutritional assessment

Two studies investigated the effects of early nutritional intervention in patients being treated with radiotherapy for head and neck cancers.[4, 5] One study

compared 45 patients with oropharyngeal cancer prospectively managed by nutritionists with 45 similar historical controls,[4] whilst the other study compared two different methods of nutritional support in 100 patients nutritionally assessed on admission to a radiotherapy department with head and neck cancer.[5] Details are given in Table 4c.

d) Dental assessment

Two controlled studies[6, 7] and two uncontrolled studies[8, 9] investigated the use of dental assessment prior to radiotherapy for head and neck cancer. An additional uncontrolled study described the outcome of cancer patients receiving radiotherapy at an institution where the dental care team was involved in their care from the time of initial observation, 65% of patients had cancers of the upper aero-digestive tract.[10]

A study was identified that measured the differences in dental consultation and oral complication rates between 104 head and neck cancer patients treated at three different hospitals which had an oral and maxillofacial department, whilst only two of the hospitals also had an outpatient general dental clinic.[11]

Six cases of recurrent or second primary malignancies which were detected by a maxillofacial prosthodontist during a one year period were presented[12] and a single case study described the restorative management of a patient ten years after hemi-maxillectomy.[13] Owing to the very small number of cases described, the results of both of these studies may not be generalisable.

Details of all the studies are given in Table 4d.

e) Use of instruments for the assessment of anxiety and depression

No evidence was found relating to the use of instruments for the assessment of anxiety and depression in patients with head and neck cancer who are being assessed for treatment.

f) Shared decision making

One focus group study was located;[14, 15] this study was initially published as a full report and later as summary article in a peer-reviewed journal. The comprehensive study used focus-group methodology to ascertain the views of patients and health professionals regarding the head and neck cancer service. The groups were asked to give their opinions on a range of topics including the value of patient-participation in the decision-making process. While the study was very well conducted and reported, it is important to remember that this is essentially a qualitative methodology. As the findings should be regarded as illustrating themes as experienced by the specific group of respondents and one should not attempt directly to extrapolate the conclusions to other populations, in other places, at other times. Details of this study are given in Table 4i.

g) Availability of psychosocial care

Seven studies relevant to the psychosocial care of head and neck cancer patients were located.[16-21] The studies included four controlled, but non-randomised, clinical trials, each of which had low numbers of patients and poor allocation to treatment arms.[16-18] One was conducted in Australia,[16] two (reported in one publication) in Sweden[17] and one in the USA.[18] The review also located a British study which reported patients' comments about a service[19] and two reports, one American[20] and one British,[21] where individual patients' experiences were reported. Details of these studies are presented in Table 4g.

h) Availability of counselling

The same focus group study identified in question 4f was located for this question;[14, 15] The study asked the groups to give their opinions on counselling, in addition to the range of other topics.[14, 15] The comprehensive focus-group study ascertained patients and health professionals views and was very well conducted and reported, but it is again important to remember its qualitative nature and that its findings illustrate themes rather than provide definitive statements about the generality of patients with head and neck cancer. Details of this study are given in Table 4i.

No specific assessment of CBT in head and neck cancer patients was located.

i) Provision of a patient visitor

Five research reports pertinent to this question were located.[Edwards, 1997 #127;Edwards, 1998 #6;Feber, 1998 #246;Minear, 1979 #225;Johnson, 1979 #655;Lehmann, 1991 #220] One, published as a full report and a peer-reviewed journal article, was a UK focus group study which asked professionals and patients for their opinions on a range of issues;[14, 15] one of the issues raised was the value of patient visitors. Two studies used questionnaires to assess the opinions of patients.[22, 23] One of these was a UK study which assessed patients opinions about a comprehensive package, one element of which was a visitor service where patients with a laryngectomy were visited by a trained patient who had had a similar procedure.[22] The second study, from the US, used a questionnaire to obtain general information from patients; this was supplemented by a structured interview.[23] Interviews were used in the remaining two studies.[24, 25] One was a US assessment of members of a laryngectomy club[24] and the second was a Swiss study predominantly of members of the national association of laryngectomies.[25] The focus-group study was open to patients who had any type of head and neck cancer[14, 15] whereas the remaining four studies were limited to patients with laryngectomies.[22-25] The two British studies were published in 1998;[14, 15, 22] the US studies both date from 1979[23, 24] and the Swiss study from 1991.[25] For details, please see Table 4i.

As with all assessments of attitudes and opinions, these studies are qualitative and should not be generalised beyond the population where they were conducted. Nevertheless, information may be illustrative and raise questions relevant to other settings.

No evidence was found relating to visitor characteristics from the studies identified.

j) Smoking cessation programmes

A randomised controlled trial evaluated 186 newly diagnosed head and neck cancer patients, who were current smokers or who had smoked within the past year, randomised to either a 12-month smoking cessation programme or usual care advice.[26, 27] This study was reported as three separate publications presenting the methodology, interim results and final results. However, owing to the lack of methodological data reported, the results cannot be verified. Details are given in table 4j.

k) Alcohol cessation programmes

No evidence was found relating to alcohol cessation programmes for patients with head and neck cancer who are identified as being dependent on alcohol.

Summary of the Research Evidence

a) Effectiveness of imaging

Two of the studies that compared the use of CXR with CT in screening for pulmonary malignancy in patients with head and neck cancers[1, 3] found that CT was more accurate than CXR with accuracies of 92.3% and 95.5% for CT versus 84.6% and 93.2% for CXR respectively. The other study, which evaluated CT with CXR versus CXR alone in patients with advanced head and neck cancer[2] found that CXR alone was more accurate than CT with CXR, with accuracies of 95.8% and 87.5% respectively. However, given the methodological limitations in each of the studies, the results should be interpreted with caution.

b) Use of instruments for the assessment of comorbidity

No evidence was found relating to the use of instruments for the assessment of comorbidity in patients with head and neck cancer who are being assessed for treatment.

c) Nutritional assessment

In a study that compared 45 patients with oropharyngeal cancer prospectively managed by nutritionists with 45 similar historical controls,[4] a percutaneous

endoscopic gastrostomy (PEG) was inserted before radiotherapy in 33 (74%) patients in the intervention group compared with 5 (11%) of the control group ($p<0.001$). The percentage weight loss was significantly lower in the intervention group (3.5% versus 6.1%) as were the dehydration related admissions (0 versus 8 patients). Overall hospital admissions and dehydration related deaths were also lower (9 versus 14 and 0 versus 2 respectively), but the differences were not statistically significant.

In a study of 100 head and neck cancer patients with a functioning gut who were nutritionally assessed on admission to a radiotherapy department,[5] 32 patients received PEG feeding and 68 patients received nasogastric (NG) feeding. The allocation of the different types of nutritional support was dependent on whether insertion of a PEG would interrupt an ongoing radiotherapy course and the anticipated duration that the nutritional support would be required. Around half of the patients in both groups gained weight, whilst another 28% of patients in both groups maintained their weight.

Conclusions

Early nutritional assessment and intervention, including PEG insertion, appears to be effective in preventing weight loss and dehydration in head and neck cancer patients undergoing radiotherapy.

d) Dental assessment

The results of four studies[6-9] with relatively large sample sizes suggest that dental assessment prior to radiotherapy for head and neck cancer is beneficial with the majority of patients in each study requiring active dental treatment before the commencement of radiotherapy. One of the studies,[8] including 92 patients, also reported that dental treatment was required for the adverse effects of radiotherapy including ten cases of mucositis, four patients with nutritional difficulties and two patients with oral candidiasis. In another of the studies[9] the majority of patients suffered from oral adverse effects of radiotherapy and seven out of 24 patients who underwent recommended pre-

treatment dental extractions experienced delayed healing, which led to one case of osteoradionecrosis.

In a series of 528 patients receiving radiotherapy, 65% of which had upper aero-digestive tract cancer and 16% had other cancers including sinus and salivary gland tumours, at an institution where a dental care team was involved in the care of the patient from the time of initial observation and pre-therapeutic dental assessment and management was performed,[10] 16 (3%) patients developed radiation caries, 11 of which had failed to adhere to the dental care program. Twenty-two patients developed problems post-irradiation, which led to the extraction of teeth and four patients developed osteoradionecrosis.

Dental consultation rates were higher at two hospitals that had an outpatient general dental clinic than at a hospital without an outpatient general dental clinic, although rates were still low at all three hospitals, ranging from 12.1% to 39.5%.[11] The proportion of patients with oral complications varied considerably with 13.2% and 60.6% of patients having oral complications at the hospitals with a general dental clinic and 33.3% of patients at the hospital without a general dental clinic. The hospital with the highest dental consultation rate (39.5%) had the lowest proportion of patients with oral complications (13.2%). However, the sample size at each hospital was relatively low (33, 33 and 38) and the authors did not adjust for any demographic, cancer-related or co-morbid illness-related variables, so the results should be interpreted with caution.

In the case series study[12] four patients were diagnosed with a recurrence and two patients were diagnosed with a second malignancy during a one year period of management by a maxillofacial prosthodontist, resulting in patients being seen an average 2.4 weeks earlier than their next scheduled visit to their surgeon. However, the author omitted to report the total number of head and neck cancer patients managed by the prosthodontist during this time period. The single case study[13] described the role of the restorative dentist in the management of a patient ten years after hemi-maxillectomy, after specific

problems led the general dental practitioner to refer the patient to the hospital based restorative dentistry service.

Conclusions

Pre-irradiation dental assessment of head and neck cancer patients is beneficial, as a significant number of such patients require active dental treatment before the commencement of radiotherapy. Patients may also suffer from oral adverse effects of radiotherapy, therefore dental management could also be required after treatment.

e) Use of instruments for the assessment of anxiety and depression

No evidence was found relating to the use of instruments for the assessment of anxiety and depression in patients with head and neck cancer who are being assessed for treatment.

f) Shared decision making

The focus-group study was well conducted and highlights themes which were key to the experience of those respondents who took part in the groups.[14, 15] It may have raised issues of importance to other patients but, owing to the characteristics of the research design, this can not be verified.

Most patient-participants in the focus-groups wanted to be involved in the decisions about their treatment, though often patients were not so involved. Younger patients wanted more involvement than some older patients, who believed that doctors would chose for them in any case. Some people were given choices but not the information to underpin this.

Doctors who participated in the study differed in their opinions about patient choice. Many felt that patients should be given choices about rehabilitation or palliation but hat only they could make decisions about treatment. Every doctor agreed treatment should only proceed with patients' approval, but few reported that they presented all options. This was sometimes owing to time

constraints and sometimes for philosophical reasons. One doctor commented that professionals make decisions and proceed with their implementation unless patients find this "totally unacceptable".

g) Availability of psychosocial care

A CCT comparing music therapy, aromatherapy and guided imagery with normal treatment found that, on each day their anxiety levels were measured, patients in the three intervention arms were less anxious than those patients in the control arm.[16] No appreciable clinical differences were noted between the three complementary therapies but that guided imagery was the most difficult to implement.

Two linked Swedish studies, published together, investigated the psychosocial care of patients.[17] The first investigated the effect on group therapy provided by a psychologist, where patients were invited to weekly sessions lasting about one and a half hours. The psychologist used cognitive and behavioural techniques and group exercises. From the participants in this study and after a delay of one year, participants and their spouses, were invited to attend a week-long residential event. The week included supportive and educational components and was facilitated by a psychotherapist, specialist nurses and clinicians. Interviews and validated questionnaires used in both studies showed that participants benefited from each intervention.

The final CCT assessed the use by a trained therapist, of hypnotherapeutic techniques, including guided-imagery.[18] Patients had a consultation with a therapist who recorded a patient-specific tape of a hypnosis-imagery narration. Anxiety and depression measures were not reported in the study. No statistically significant differences were found in requirements for psychoactive or analgesic medication, in post-operative complications or in blood loss during surgery. The study did however find that the duration of hospitalisation was less in those in the intervention group.

All four CCTs suffer from similar methodological flaws. Four patients acted as controls in the complementary therapy study and the music therapy, aromatherapy and guided imagery arms included 4, 3 and 3 patients respectively.[16] 13 patients joined the group therapy in the Swedish study.[17] A total of 36 patients were included in the hypnosis study.[18] Allocation methods were poor in each study; authors used allocation to arms in turn,[16] area of residence[17] or by comparing consenting patients with a control group who did not consent to undergo the intervention.[18] There flaws allow the introduction of possible biases into the study. Nevertheless, all the CCTs found that patients who received psychosocial support over and above the normal level care appeared to benefit from the care they received.

A British study was located which collated the opinions about a counselling service volunteered by patients.[19] A counsellor reported the opinions of patients which they had volunteered to her in this qualitative study and the study concluded that patients benefited from the service. The study was purely descriptive and patient contributions were not actively encouraged. Had all patients been asked to give their opinions about the service, the findings of the study may have been different.

Two studies where singles patients reported on their experience of counselling were located.[20, 21] The first, a traditional case study, reported on the care of a patient with acute anxiety and phobias following a maxillectomy.[20] Behavioural and desensitisation techniques were used. The patient was able to resume her normal daily activities. The second study asked a number of patients about their support mechanisms and one patient reported that she had attended two counselling sessions but had not found it helpful.[21] She did not elaborate on what type of counselling she received.

Studies of individual participants' opinions or care programmes such as the last three studies are useful in obtaining qualitative information and in generating avenues for further study. However, owing to the very specific nature of every individual case, it is not possible to generalise from these

patients to all patients with head and neck cancer or even to patients with similar conditions or having undergone similar procedures. This is particularly so in situations where the interventions or populations are poorly described. Evidence taken from experimental studies is more generalisable and so more informative.

Conclusions

While the types of psychosocial interventions and methods used varied between the studies found, most of the research suggested that psychosocial care was beneficial to patients with head and neck cancer. This was true of all of the experimental studies located. The methodological flaws and the low quality inherent in the methods used, mean that the findings are at best strongly suggestive.

h) Availability of counselling

The findings of a well-conducted focus-group study relating to counselling highlighted the experience of respondents who took part in the groups.[14, 15] Again, issues raised may have been of importance to other patients but this can not be verified.

Patients who responded reported a need to discuss their condition but that often they chose to do this with their partner or family. Some said that they needed more support than this. Few had been offered counselling; some found it difficult to request counselling as they feared this an admission that they could not cope.

The majority of the patients who had had counselling in this study, did not find it helpful. Counsellors had often not listened but attempted to problem-solve by offering solutions and not a listening ear. Some patients reported that non-counsellors, often junior professional carers had taken time to listen to them and that this was more useful.

The professional carers of head and neck cancer patients did not voice any comments on the subject of counselling services.

i) Provision of a patient visitor

A focus-group study of both patients and carers found that some clinicians introduced past-patients to patients about to undergo treatment and found that it benefited both past and new patients.[14, 15] Patients confirmed this view. The patient visitor provided understanding, encouragement and gave the new patient hope. While one professional expressed concern that introducing patients might prove counter-productive, she did not report any experiences to support her belief. A focus-group study gives us the opportunity to elicit key information about the experiences of the members of the groups but does not allow us to quantify the frequency or strength of those experiences.

A second study from the UK suggested that before a laryngectomy club was established, patients felt a need for one.[22] Once it was established, a laryngectomy friendship scheme increased the number of patients offered the opportunity to meet a visitor (85% compared with 35%) and increased the satisfaction the patients had with their visitor (95% compared with 35%). This study was well conducted but used non-standardised data collection tools including non-validated questionnaires and informal conversations. In addition, some of the data are based on small absolute numbers of patients.

In a US question/interview study, 55% of patients were visited by another laryngectomee pre-operatively and 85% of these patients felt that the visit was worthwhile.[23] Of those not seen, 83% felt that they would have liked to receive a patient visitor. Post-operatively, 56% were seen by another laryngectomee and 78% of these patients felt the visit to be beneficial. Of those not seen, 83% again felt that it should have been done. Although almost all agreed that the visits were worthwhile, some expressed a desire to have some choice as to the timing and circumstances of the visit. A second US study found that about one-fifth of the sample had met with a laryngectomy

club member pre-operatively and all were glad they had that opportunity;[24] again, the great majority of those who did not see a rehabilitated patient with a laryngectomy would have liked to see one. While the draw backs of opinion based research apply to these two studies, it should be noted that they were both published in 1979 and in the intervening time period, both practice and preferences may well have changed.

The last study was interview-based and assayed the opinions of 332 patients, the majority of whom were members of the Swiss National Association of Laryngectomy Patients.[25] The study was published in 1991. A total of 36% patients were in touch with another patient who had had a laryngectomy prior to their own operation but 13% refused such a meeting and 42% were not offered one. Where contact existed, the majority considered it to be useful: 69% of these patients stated that contact with a laryngectomee was helpful to them but 23% saw no advantages. The time period between patients' operations and their interview ranged from one to twenty years; as such it covers a significant period of time during which speech and language therapy services may have changed considerably.

Conclusions

It appears from five attitudinal surveys that patients are keen to have contact with rehabilitated patients who have previously undergone the same procedures. The individual preferences of the patient should be taken into account in deciding the timing of the meeting.

j) Smoking cessation programmes

In a randomised controlled trial of 186 newly diagnosed head and neck cancer patients, randomised to either a 12-month smoking cessation programme or usual care advice,[26, 27] 70% of patients followed up for a year were continuous abstainers. However, more patients in the control group were continuous abstainers than in the intervention group, although the difference was not

significant. No adverse effects were reported. Given the lack of methodological details reported, the results should be interpreted with caution.

k) Alcohol cessation programmes

No evidence was found relating to alcohol cessation programmes for patients with head and neck cancer who are identified as being dependent on alcohol.

Table 4a: Effectiveness of imaging

<table>
<tr><th>Study details and aims</th><th>Details of participants and diagnostic test(s)</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Warner, 2003.[1]

Country:
UK

Aims:
To evaluate the role of chest radiography versus chest computed tomography in screening for pulmonary malignancy in advanced head and neck squamous cell carcinoma.

Grade of evidence:
V</td>
<td>Participants:
26 patients with advanced head and neck SCC (Stage T3 or T4) were screened for pulmonary malignancy. Patients were recruited between February 2000 and February 2001.

CT:
CT images were obtained from the apex to below the diaphragm using a GE Lightspeed scanner.

CXR:
No details were provided about how the CXR images were obtained.

Interval between tests:
Information on the relative timing was not reported.

Reference standard:
Information on the reference standard used was not presented clearly. From the results given, it appears that clinical supervision was used as the reference standard in those patients with normal imaging investigations. Where both or either imaging investigations were abnormal, histological sampling appears to have been used.

Blinding:
No blinding was reported.</td>
<td>Included patients:
Of 26 patients, 4 had positive chest findings on gold standard investigations; incidence – 15.4%.

Diagnostic indices:
<table>
<tr><th></th><th>CCT</th><th>CXR</th></tr>
<tr><td>Sensitivity</td><td>100%</td><td>25%</td></tr>
<tr><td>Specificity</td><td>90.91%</td><td>95.45%</td></tr>
<tr><td>Accuracy</td><td>92.31%</td><td>84.62%</td></tr>
<tr><td>PPV</td><td>66.67%</td><td>50%</td></tr>
<tr><td>NPV</td><td>100%</td><td>87.52%</td></tr>
<tr><td>PLR</td><td>11</td><td>5.5</td></tr>
<tr><td>NLR</td><td>0.11*</td><td>0.79</td></tr>
<tr><td>DOR</td><td>73.8*</td><td>7</td></tr>
</table>
* = The diagnostic index has been calculated with the addition of 0.5 to all cells in the 2x2 table to allow for cells with a value of 0.</td>
<td>Authors' conclusions:
Chest CT is an effective tool in screening for malignant pulmonary disease in patients with advanced head and neck cancer and should be used instead of chest radiography to avoid false-negative results.

Comments:
This was a very small diagnostic accuracy study which demonstrates an increase in the accuracy of CT over CXR and appears to be a consecutive series of all patients referred with Stage T3 or T4 disease in a specified time period. However, the study is very small and the conclusions are drawn based on only 3 lung tumours. Some serious flaws in how the study was conducted and reported are seen. Few details about to how the images were obtained or analysed were presented. A serious concern about the reference standard relates to the length of follow-up. The authors do not report the length of clinical observation and if it is too short, some patients with negative findings on both CCT and CXR may have had sub-clinical metastasis and so may have inadvertently been classified as "true negatives" rather than "false negatives".

It is not clear if the radiologist interpreting each image was blinded to the other image or to other clinical details.

Patients whose imaging reports did not mention thoracic spread may also have been followed up less closely than others, introducing another area of possible bias. The interval between the CXR and CT was not reported.</td>
</tr>
<tr>
<td>Arunachalam, 2002.[3]

Country:
UK

Aims:
To assess the diagnostic yield of chest radiographs compared with computerised tomography (CT) in a</td>
<td>Participants:
44 consecutive patients with newly diagnosed SCC of the head and neck region attending the head and neck oncology clinic between January and December 2000. Patients with lip and skin lesions were excluded.

CT:
Post contrast helical views were obtained.</td>
<td>Included patients:
This series included only 18 of 44 patients with clinically Stage III or IV disease. Of 44 patients, 3 had positive chest findings on gold standard investigations; incidence – 6.8%.

Diagnostic indices:
<table>
<tr><th></th><th>CCT</th><th>CXR</th></tr>
<tr><td>Sensitivity</td><td>100%</td><td>33.33%</td></tr>
<tr><td>Specificity</td><td>95.12%</td><td>97.56%</td></tr>
</table></td>
<td>Authors' conclusions:
The study demonstrates the increased sensitivity of a CT scan as compared with a plain radiograph.

Comments:
This very small diagnostic accuracy study demonstrates an increase in the accuracy of CT over CXR. However, the study is small and is based on only 3 synchronous lung tumours. Some serious methodological flaws are seen in the</td>
</tr>
</table>

<table>
<tr>
<td>series of patients with head and neck cancer.

Grade of evidence:
VI</td>
<td>CXR:
PA views were obtained.

Interval between tests:
Information on the relative timing was not reported.

Reference standard:
Clinical observation was used as the reference standard.

Blinding:
No blinding was reported.</td>
<td>
<table>
<tr><td>Accuracy</td><td>95.45%</td><td>93.18%</td></tr>
<tr><td>PPV</td><td>60%</td><td>50%</td></tr>
<tr><td>NPV</td><td>100%</td><td>95.24%</td></tr>
<tr><td>PLR</td><td>20.5</td><td>13.67</td></tr>
<tr><td>NLR</td><td>0</td><td>0.68</td></tr>
<tr><td>DOR</td><td>110.6*</td><td>20</td></tr>
</table>
* = The diagnostic index has been calculated with the addition of 0.5 to all cells in the 2x2 table to allow for cells with a value of 0.
</td>
<td>process of the study. Few details about to how the images were obtained or analysed were presented. The authors reported that “a consultant radiologist” interpreted the films. In such a small series, if the same doctor read all films, his awareness of results of one imaging modality could easily bias his interpretation of the second modality. It is not clear if (s)he was blinded to other clinical details. As histological confirmation was not obtained, the reference standard was clinical observation. As the physician who decided that the “gold standard” decision was that no lung tumours were present most probably had access to the radiological reports, additional bias may have been introduced. Those whose imaging reports did not mention thoracic spread may also have been followed up less closely than others introducing another area of possible bias. The interval between the CXR and CT was not reported. In addition this series included only 18 of 44 patients with clinically Stage III or IV disease and the generalisability to a population of late stage patients of a study wherein less than half of the patients had late stage disease may be questionable.</td>
</tr>
<tr>
<td>Tan, 1999.[2]

Country:
USA

Aims:
To evaluate the benefit of chest CT (CCT) as a screening tool in patients with newly diagnosed advanced head and neck cancers.

Grade of evidence:
VI</td>
<td>Participants:
25 patients with newly diagnosed SCC of the head and neck region. Patients with oesophageal lesions were excluded. Patients were recruited between August 1994 and December 1996. All patients had Stage III or Stage IV cancer, according to the AJCC system.

CCT:
No details about how the CCT images were provided.

CXR:
No details about how the CXR images were provided.

Interval between tests:
CXRs were obtained and interpreted before the CCT.

Reference standard:
Clinical observation was used as the reference standard for most patients but 2 patients each underwent a biopsy to confirm a suspected thoracic metastasis.

Blinding:
The radiologist initially interpreted the CXR and then the CT</td>
<td>Included patients:
Of 25 patients, 1 patient was found to have a metastatic chest malignancy using the gold standard investigations; incidence – 4%. Another patient was found to have an abdominal metastasis.

Diagnostic indices:
<table>
<tr><th></th><th>CCT with CXR</th><th>CXR alone</th></tr>
<tr><td>Sensitivity</td><td>100%</td><td>100%</td></tr>
<tr><td>Specificity</td><td>86.96%</td><td>95.65%</td></tr>
<tr><td>Accuracy</td><td>87.5%</td><td>95.83%</td></tr>
<tr><td>PPV</td><td>25%</td><td>50%</td></tr>
<tr><td>NPV</td><td>100%</td><td>100%</td></tr>
<tr><td>PLR</td><td>7.67</td><td>23</td></tr>
<tr><td>NLR</td><td>0</td><td>0</td></tr>
<tr><td>DOR</td><td>17.57*</td><td>45*</td></tr>
</table>
* = The diagnostic index has been calculated with the addition of 0.5 to all cells in the 2x2 table to allow for cells with a value of 0.

In addition, there was 1 patient in who the CXR demonstrated a lesion which was not demonstrated on CT but the “Gold standard” decision for this patient was not reported.</td>
<td>Authors’ conclusions:
There is no justification for routine CT in the evaluation of the patient with newly diagnosed head and neck cancer.

Comments:
This very small diagnostic accuracy study demonstrates a marginal decrease in the accuracy of the radiologists reporting from the reading of CXR images alone to their being read in combination with CT. However, the study is small and is based on only 5 patients with lesions detected by imaging. Of these, definitive results for one are omitted. The differences between the statistics are based on the radiologist’s deciding to change his report in the case of one patient when he saw the CT.

Serious methodological flaws are seen in the process of the study. Few details about to how the images were obtained or analysed were presented. The authors reported that a radiologist interpreted the films. As histological confirmation was obtained in only one case, the reference standard was clinical observation. As the physician who decided the “gold standard” decision most probably had access to the radiological reports, additional bias may have</td>
</tr>
</table>

	in conjunction with the CXR. It is not clear if he was blinded to other clinical details.		been introduced. Those whose imaging reports did not mention thoracic spread may also have been followed up less closely than others introducing another area of possible bias. The study does not clarify how patients were recruited. It is not stated if this was a consecutive series or if a selection or sample of the patients seen within a timeframe were included. If patients were selected, the criteria are not reported in the paper.

Table 4c: Nutritional assessment

<table>
<tr><th>Study details and aims</th><th>Details of the service and participants</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Piquet, 2002.[4]

Country:
Switzerland

Aims:
To assess the effects of early nutritional intervention.

Grade of evidence:
V</td>
<td>Service:
Patients were prospectively managed by nutritionists and those not offered a PEG received dietary counselling and oral supplementation. A percutaneous endoscopic gastrostomy (PEG) was inserted before radiotherapy in patients with 1 or more of the following: weight loss of greater that 10%; BMI less than 20kgm^{-2} or aged 70 years or over. When patients had dehydration and severe dysphagia, but did not require a PEG, a nasogastric tube was passed.

Participants:
Outpatients undergoing radiotherapy for oropharyngeal cancer (aged 61 years ± 1.5 years, 43 males, 69kg ± 2kg).

Comparators:
Data were compared with those recorded in an historical control group of 45 paired patients (aged 59 years ± 1.5 years, 42 males, 68kg ± 3kg).</td>
<td>Methods:
A cohort of patients was assessed and compared with a cohort of historical patients who were chosen so that the 2 groups represented similar populations.

Outcomes measured:
Form of nutritional support.

Percentage weight loss.

Overall hospital admissions.

Dehydration related hospital admissions.

Dehydration related deaths.</td>
<td>Included patients:
45 patients were included in the intervention group and matched with 45 historical controls.

Patients were comparable across the groups with respect to radiotherapy dose (70Gy ± 1Gy for participants compared with 68 ± 1Gy for controls).

Form of nutritional support
A PEG was inserted in 33 (74%) of the 45 patients in the intervention group, compared with 5 (11%) of the 45 in the control group ($p < 0.001$). 6 patients (13%) in the intervention group and 12 patients (27%) in the control group required late nasogastric feeding (not statistically significant).

6 patients (13%) in the intervention group and 28 patients (62%) in the control group were not enterically fed ($p < 0.001$).
<table>
<tr><th>Outcome</th><th>Intervention</th><th>Control</th><th>p - value</th></tr>
<tr><td>Percentage weight loss</td><td>3.5% ± 0.7%</td><td>6.1% ± 0.7%</td><td>p < 0.01</td></tr>
<tr><td>Overall hospital admissions</td><td>9 (20%)</td><td>14 (31%)</td><td>p = NS</td></tr>
<tr><td>Dehydration related admissions</td><td>0</td><td>8 (18%)</td><td>p < 0.01</td></tr>
<tr><td>Dehydration related deaths</td><td>0</td><td>2 (4.4%)</td><td>p = NS</td></tr>
</table>
</td>
<td>Authors' conclusions:
Early nutritional intervention, including PEG insertion, is feasible and efficient in preventing dehydration in oropharyngeal cancer patients undergoing radiotherapy. It may improve quality of life by decreasing the frequency of hospital admissions.

Comments:
The authors simulated a case-control study using historic matched controls but have not provided key details of how the study was conducted. It is not clear how or by whom the matching was achieved; neither is it clear if the persons performing the matching were aware of the outcomes of the interventional or historic patients they were matching. In this type of research, bias may be introduced if professionals making decisions relating to patients or assessing patients were aware of the study, unlike those caring for historical controls at the time of their treatment.

The study included quite small numbers and no mention is made of whether a power assessment was conducted so it is unclear if errors relating to underpowering have occurred.</td>
</tr>
<tr>
<td>Lees, 1997.[5]

Country:
UK

Aims:
To compare the outcome of 2 methods of</td>
<td>Participants:
Patients referred to a regional radiotherapy department for radical or palliative radiotherapy for head and neck cancer.

Service:
The nutritional needs of patients referred to the department were</td>
<td>Methods
A full assessment was conducted using the Schofield Equation.

The weight and body mass index (BMI) of each patient was</td>
<td>Included patients:
A total of 100 patients were assessed (average age: 64 years; range: 33 years to 87 years).

68 patients received NG feeding and 32 received PEG feeding.

Nutritional status:
<table>
<tr><th></th><th>NG</th><th>PEG</th></tr>
</table>
</td>
<td>Authors' conclusions:
It is recommended that the nutritional status, potential nutritional problems and dietetic intervention for every patient to be addressed and incorporated into the treatment plan on diagnosis of head and neck cancer before definitive management commences.

Comments:
The study provides a description of the services offered by</td>
</tr>
</table>

<table>
<tr>
<td>nutritional support, namely nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) feeding implemented for head and neck cancer patients unable to maintain their nutritional status whilst receiving radiotherapy treatment at a regional oncology unit.

Grade of evidence:
VI</td>
<td>screened on admission. Those believed to be at risk were referred to the dietetics staff.

Those patients deemed at need with a non-functioning gut were given parenteral nutrition and were not considered for this study. Those with a functioning gut were given enteral nutrition using a PEG (unless the insertion would interrupt an ongoing radiotherapy course or unless their anticipated duration of need was 21 days or more) or using a NG tube (in either of the above circumstances).</td>
<td>monitored.

Outcomes measured:
Proportion of patients who gained weight, maintained their weight and who lost weight was calculated. The proportion who were transferred to diet and who had enteral feeding at discharge or at death was reported.</td>
<td>
<table>
<tr><td>Gained weight</td><td>48%</td><td>50%</td></tr>
<tr><td>Maintained weight</td><td>28%</td><td>28%</td></tr>
<tr><td>Lost weight</td><td>24%</td><td>22%</td></tr>
<tr><td>Range of weight change</td><td>-10.8% to +20.1%</td><td>-9% to +18%</td></tr>
<tr><td>Range of BMI change</td><td>-2.3 to +3</td><td>-2.4 to +4.0</td></tr>
</table>
Nutritional status at discharge:
<table>
<tr><th></th><th>NG</th><th>PEG</th></tr>
<tr><td>Transferred to diet</td><td>41%</td><td>0%</td></tr>
<tr><td>Transferred to hospital/hospice with feeding in situ</td><td>35%</td><td>16%</td></tr>
<tr><td>Transferred to home/nursing home with feeding in situ</td><td>16%</td><td>78%</td></tr>
<tr><td>Died during admission</td><td>7%</td><td>7%</td></tr>
</table>
Proportion alive at 6 months:
NG – 34% (23 of 68).
PEG – 22% (7 of 32).
</td>
<td>the dietetics service of a regional cancer-specialist hospital. The generalisability of the study is limited by a number of factors.

The study refers to screening “at admission” with patients at risk being referred for a dietitian’s assessment. While it is not clear from the report, this implies that only in-patients were studied and as the majority of head and neck radiotherapy is administered on an out-patient basis, this means most head and neck cancer patients would not have been eligible for inclusion in this study. The algorithm by which the decision to offer PEG or NG feeding includes the anticipated duration of need. As radical radiotherapy usually involves a long course (sometimes with major side-effects) and palliative radiotherapy usually involves a short course treatment (with minimal side-effects), this automatically includes biases into the assessment of the functioning of the 2 techniques. A preferable research methodology would have been the randomised allocation of patients to receive either form of feeding in an RCT.

The reporting of the proportion of patients alive at 6 months was informative but should not be seen as a suggestion that either NG feeding extends life or PEG feeding limits it. This was not the aim of the study and the above mentioned biases and others will have had significant effects on this parameter.</td>
</tr>
</table>

Table 4d: Dental assessment

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Lizi, 1992.[6] **Country:** UK **Aims:** To assess the need for dental assessment and expertise prior to radiotherapy. **Grade of evidence:** V	**Participants:** Patients treated with radiotherapy to the head and neck at the Mersey Regional Centre for Radiotherapy and Oncology. **Service:** 250 new sequential patients between January and June 1990 were examined and dentally assessed prior to radiation therapy for head and neck cancer by the author.	**Methods:** Information on new patients was recorded prospectively. This information was compared with that found in the case records of 1,980 historical control patients treated between May 1987 and June 1990. **Outcomes measured:** Patients' age, state of their dentition and the dental treatment received prior to radiotherapy were recorded, if available, on the 1,980 patients treated between May 1987 and June 1990. Patients' age, dental history, dental state on presentation, using subjective means and whether the patient received dental treatment or assessment elsewhere prior to treatment for the cancer were established by direct questioning and recorded for each of the 250 patients seen between January 1990 and June 1990.	In 1,719 (87%) of the case records of patients treated between May 1987 and June 1990, no information was found on the patients' dental condition or whether dental treatment was undertaken prior to radiotherapy. 261 (13%) patients were referred to the radiotherapy centre by oral and maxillofacial surgeons or were referred to oral and maxillofacial units by consultants in the Mersey Regional Centre for Radiotherapy and Oncology for a dental opinion prior to commencement of treatment. This group was identified as having received dental treatment prior to radiotherapy. 42 (16%) of these 261 patients had a full dental clearance and 219 (84%) had some teeth extracted prior to radiotherapy, but no record of any other form of dental treatment was found in the case notes. Of the 250 patients comprehensively dentally examined prior to radiotherapy, only 7 (3%) were referred by oral and maxillofacial surgeons. These patients had some extractions before the referral but when examined all had some carious teeth which required dental restorations. Oral hygiene was assessed as fair. 163 (65%) were dentate patients who had not seen a dentist for at least 3 years and their oral hygiene and dentition was in a very poor state. 24 (10%) of the 250 comprehensively examined patients required and received dental clearance, 146 (58%) required some extractions and restorations. 52 patients (21%) were edentulous wearing full dentures which were over 5 years old. Patients claimed that they were generally happy with their dentures, but clinically they were poorly retentive and aesthetically unsatisfactory and some had caused tissue damage. Only 28 (11%) were fully dentate with a history of regular dental attendance. Their dental health was very good and none required any dental treatment.	**Comments:** The authors do not state any conclusions based on their results, although the title of the study is "a case for a dental surgeon at regional radiotherapy centres". No conclusions can be drawn based on the results of the retrospective case note review as it is not clear whether the 1,719 patients, for whom no information was found on the patients' dental condition or dental treatment in the case notes, underwent any assessment or treatment which was not recorded in their case notes. Indeed, if no assessment was undertaken then it is not possible to draw any conclusions about their dental state. The use of case notes in a retrospective review is not very reliable as data may not be complete. The assessment of oral hygiene in the prospective study was subjective and the assessment of longer term patient outcomes would have been useful, such as whether patients developed post-irradiation caries, osteoradionecrosis, etc. However, the results suggest that dental assessment prior to radiation therapy for head and neck cancer is beneficial, as 65% of the 250 patients' oral hygiene and dentition was subjectively assessed as very poor, 10% patients required dental clearance and 58% required some extractions and restorations.
Pyle, 1997.[11] **Country:** USA	**Procedure:** Assessment by a dental practitioner. **Design and data source:**	**Methods:** Patients were stratified by hospital. Each hospital; had an oral and maxillofacial department while 2 (Hospitals A and B) also had an outpatient general dental	**Included patients:** Most patients in the series had radiotherapy either alone or in combination with chemotherapy and/or surgery. **Number of beds:**	**Authors' conclusions:** This project demonstrated a low dental consultation rate among 3 university affiliated teaching hospitals caring for patients with head and neck cancer. In our study, more than 60% patients were not being

Aims: To investigate if overall dental consultation rates were less than ideal and whether or not variation existed between hospitals in the study population. **Grade of evidence:** V	A retrospective review of medical notes at 3 Midwestern area university metropolitan hospitals. **Time period:** 1992 to 1993 (1.5 year period). **Study population:** 104 patients diagnosed with head and neck cancers. Of these 17 were female.	clinic. **Covariates adjusted for:** No adjustment for covariates was conducted. **Statistical method:** The χ^2 test was used for no-parametric measures of association.	Hospital A – 748 Hospital B – 850 Hospital C – 860 **Number of patients' notes reviewed:** Hospital A – 33 Hospital B – 38 Hospital C – 33 **Dental consultation rate:** Hospital A – 16.5% Hospital B – 39.5% Hospital C – 12.1% ($\chi^2 = 9.154$, p = 0.01) **Proportion of patients with oral complications (by hospital):** Hospital A – 60.6% Hospital B – 13.2% Hospital C – 33.3% ($\chi^2 = 17.604$, p = 0.00015) **Proportion of patients with oral complications (by consultation):** Dental consultation – 38.8% No dental consultation – 20.8% (p = non-significant)	referred or treated by a dentist while they underwent therapy for their cancer. Having both general dental and an oral and maxillofacial department did not ensure higher rates of dental consultation. **Comments:** This study is probably a consecutive series. The authors have given scant details of the patients particularly in relation to co-morbid conditions. The authors have not adjusted for any demographic, cancer-related or co-morbid illness-related variables. The hospital with the highest consultation rate had the lowest complication rate. However, there was a surprising disparity between complication rates at the other 2 hospitals, which makes meaningful comparisons difficult. The small number of patients involved make the statistical test difficult to interpret. Given this and that covariate factors were not adjusted for, it is difficult to be certain whether the provision of such a clinic has an effect on outcomes.
Brown, 1990.[8] **Country:** USA **Aims:** To examine the incidence of oral and dental disease in head and neck oncology patients prior to the initiation of radiotherapy. **Grade of evidence:** VI	**Participants:** Patients with head and neck cancer being treated with radical radiotherapy. **Service:** The dental status of patients with head and neck cancer was examined prior to radiation therapy between September 1986 and June 1989. The findings and recommendations relevant to each patient were notified to his or her primary dental practitioner. Dental interventions were conducted either before or during the early stages of radiotherapy.	**Methods:** Patients were identified from referrals sent by the ENT department or the Nuclear medicine department to the Oral Diagnosis department for oral assessment prior to radiotherapy. Demographic details and dental treatment recommendations were recorded. Extractions were recommended owing to impaction, periodontal infection, pulpal or periapical pathology or non-restorable caries. Restorations were recommended for restorable caries, fractures or previous defective restorations. Endodontic therapy was indicated when pulpal or periapical pathology was noted but extraction was	**Included patients:** 92 patients were studied. Their average age was 58.39 years (SD 3.889; range 14 years to 83 years). The group included 63 men and 29 women. 78 patients had SCCs. Planned treatment was radiotherapy with doses which ranged from 40Gy to 65Gy. One edentulous patient was excluded from the study. **Therapy required:** 48 patients required extractions (mean number required was 6.354 (SD 2.485)). 50 patients required restorations (mean number required was 5.24 (SD 2.145)). (25 patients required both extraction and restoration.) 5 patients required endodontic therapy and of these, 3 required additional dental therapy.	**Authors' conclusions:** Pre-irradiation dental evaluation and adjuvant oral and dental care for the head and neck radiotherapy patient is important. A significant number of patients require active treatment over prophylactic treatment only. **Comments:** This study provides an assessment of the dental health of the patients attending its service. The generalisability of the study is limited by the observational nature of the work but it is probable that this work would translate well to the situation in the NHS. The analysis suggests that head and neck cancer patients could benefit from pre-treatment dental monitoring.

		not indicated. Decisions were based on clinical and radiological examination and the dentist's assessment of the patient's ability to manage his or her oral or dental condition. **Outcomes measured:** Therapy required, management required for the adverse effects of radiotherapy.	No therapy was indicated in only 18 cases. **Therapy for the adverse effects of radiotherapy:** 10 patients required dental therapy for the management of mucositis, 4 with nutritional difficulties and 2 for the management of oral candidiasis.	
Casey, 1985.[12] **Country:** USA **Aims:** To report on the recurrent and second primary malignancies identified by a maxillofacial prosthodontist during a 1 year period. **Grade of evidence:** VI	**Design:** Series of 6 cases. **Service:** A maxillofacial prosthodontist saw a number of cases of recurrent and second primary malignancies detected over a 1 year period. **Participants:** 6 patients with recurrent or second primary malignancies.	**Methods:** A case series was presented. **Outcomes measured:** Number of recurrences and second primaries detected. The length of time between the date of diagnosis of recurrence or new malignancy and the date their next appointment was due.	**Number of recurrences and new malignancies detected:** 4 patients were diagnosed with recurrence and 2 patients were found to have a second malignancy. **Next appointment due:** 4 days (1) 1 week (1) 3 weeks (2) 1 month (1) Not scheduled (1) Patients were seen on average 2.4 weeks earlier by their surgeon following detection of disease by the prosthodontist.	**Authors' conclusions:** The author states that by earlier detection and immediate referral to the surgeon, there is a possibility of a higher long-term cure in head and neck cancer patients who are receiving maxillofacial prosthetic treatment. **Comments:** Conclusions based on a very small series of cases and based on opinions not grounded in the results. A significant failing in the reporting of the series is the omission of the total number of head and neck cancer patients being monitored by the prosthodontist for recurrence or development of second malignancies.
Epstein, 1999.[9] **Country:** Canada **Aims:** To study the need for dental treatment in patients with nasopharyngeal carcinoma prior to radiation therapy. **Grade of evidence:** VI	**Participants:** Patients with nasopharyngeal carcinoma being treated with radical radiotherapy. **Service:** The dental status of all patients with NPC of the British Columbia Cancer Agency was examined as part of their pre-radiotherapy assessment.	**Methods:** A complete oral/dental examination was provided. All dentate patients were provided fluoride carriers to apply a neutral pH sodium fluoride gel for a minimum of 5 min daily and were instructed to continue fluoride applications indefinitely, as long as dry mouth persisted. All teeth in the high-dose fraction with non-restorable caries or periodontal disease that were anticipated to require surgical management in the future were suggested for extraction prior to radiation therapy. Dental extractions were recommended if non-restorable caries were present, periodontal examination revealed pocket depths of 5	**Included patients:** 57 patients were seen in a 45 month period from November 1988 to July, 1992. Their mean age was 49.7 years (± 13.2 years, range 20 years to 83 years). There were 41 males and 16 females. The majority of patients were diagnosed with advanced stages of disease. **Past dental interventions:** Past dental treatment was reported as never by 7.0%; related to pain management only in 12.3%; regular visits in 28.1% and irregular (more than every 2 years) by 26.3%. Results were missing for 26.3% of patients. **Number of extractions recommended:** Dental extractions were recommended for 68% of dentate patients, in whom 164 teeth were recommended to be removed (mean of 5.9 teeth per dentate patient). The commonest reason for extraction was periodontal disease.	**Authors' conclusions:** The authors propose that integrated dental support services within the cancer treatment facility are important in preparation for delivery of dental care services. The long-term complications of head and neck radiation therapy for NPC must be understood and preventive actions taken owing to the frequency and severity of xerostomia and the frequency of long-term complications. Pre-radiotherapy dental assessment and management are required and must be expedited in order not to delay treatment of the malignancy. **Comments:** This study provides an assessment of the dental health of the patients attending its service. The generalisability of the study is limited by the

		mm or more, furcation involvement was present or teeth had poor crown to root ratio. The recommendation for extraction was affected by evidence of past oral care and current oral hygiene and those with more compromised care were managed more aggressively. **Outcomes measured:** Past dental interventions, number of extractions recommended, patient awareness of their dental needs and adverse effects of radiotherapy.	**Patient awareness of their dental needs:** Only 3 of the 28 patients who required dental treatment were aware they needed dental treatment at the time of their pre-radiation therapy visit. **Adverse effects of radiotherapy:** Oral complications following radiation therapy were noted in all but 9 of 57 patients (84%). Subjective xerostomia was noted by all of the patients in whom complications were identified and was rated as severe in 41 (72%) and moderate in 6 (11%). A clinical diagnosis of candidiasis was noted in 9 (16%), rampant caries in 4 patients and increased difficulties with dentures in 4 patients. **Adverse effects of dental interventions:** Of 24 patients who underwent recommended pre-treatment dental extractions, 7 (29%) experienced delayed healing and this led to 1 case of osteoradionecrosis (4%).	observational nature of the work but it is probable that this work would translate well to the situation in the NHS. The analysis suggests that head and neck cancer patients could benefit from close dental monitoring. (In addition, the risk factors for this form of cancer are investigated but this is beyond the scope of the review question and so these issues are not discussed here.)
Horiot, 1981.[10] **Country:** USA **Aims:** To summarise the results of 7 years of experience at the Department of Radiation Therapy, Centre Georges Leclerk. **Grade of evidence:** VI	**Participants:** Patients irradiated at Centre Georges Leclerk between June 1972 and December 1979. **Service:** The dental care team was involved in the care of the patient from the time of initial observation and diagnosis. A careful dental evaluation was done immediately, including radiographs, history and physical examination of the head and neck area. Patients were then placed into 1 of 4 dental categories:- • edentulous • bad state of dental hygiene • average state of dental hygiene • good state of dental hygiene. The ability and willingness of the	**Methods:** A case series of patients treated at 1 institution and followed up for a minimum of 6 months was presented. **Outcomes measured:** The proportion of patients who developed radiation caries and the reasons caries occurred. The proportion of patients who had to undergo tooth extraction. The proportion of patients who developed osteoradionecrosis. Patients' tolerance of dental prostheses.	**Included patients:** 528 patients. The tumour site was upper aero-digestive tract for 65% patients, lymphoma and Hodgkin's disease for 19% patients and miscellaneous including sinuses and salivary gland tumours for 16% patients. **Proportion of patients developing radiation caries:** 16 of 528 (3%) patients developed radiation caries; 11 of these patients had failed to adhere to the program. **Proportion of patients requiring dental extraction:** 22 of the patients developed problems post-irradiation which led to teeth extraction. The extractions occurred from 16 to 62 months post-treatment. 1 of the patients having post-irradiation extraction subsequently developed osteoradionecrosis with a partial mandibular resection. **Proportion of patients who developed osteoradionecrosis:** While 208 patients had significant irradiation to 40% or more of the oral cavity and thus were at high risk for development of osteoradionecrosis, only 4 patients developed osteoradionecrosis. **Patients' toleration of their prostheses:** Over 85% of patients who received a dental prosthesis had excellent tolerance without pain or mucosal irritation.	**Authors' conclusions:** Adherence to the principles of dental care can virtually eliminate post-irradiation decay and osteoradionecrosis. **Comments:** The conclusions of this descriptive study appear to be justified. The study however had no control group so it is not possible to know for certain if the intervention had an important effect on the outcomes of patients. However, there was a large sample size and a detailed description of the interventions. The number of patients who adhered to the program was reported only for those patients who developed dental caries and it is not known the level of adherence to the programme of patients who did not develop dental complications. The results are not presented separately for patients with head and neck cancer.

	patient to cooperate in the dental therapy was assessed. Pre-therapeutic dental care included careful cleaning of existing teeth and application of fluoride gel, polishing and elimination of irritating spicules, filling of superficial caries and, where indicated, restoration of teeth. Under certain circumstances extraction of teeth was conducted prior to radiotherapy.			
Lockhart, 1994.[7] **Country:** USA **Aims:** To determine the dental status of patients before multi-modality therapy for head and neck cancer. **Grade of evidence:** VI	**Participants:** Patients referred to a multi-disciplinary head and neck clinic for consideration of enrolment to entry into a combined surgery, radiotherapy and chemotherapy trial. Only patients who had not received cancer treatment for their presenting disease, who were to be treated radically and who were to receive maxillofacial radiotherapy were included in the current study. **Service:** A multi-disciplinary group of head and neck cancer specialists located in an academic setting.	**Methods:** Eligible patients referred for consideration of entry into a trial were each seen by 1 of 2 dentists who conducted a clinical examination including assessment of relevant patient outcomes. Each patient was counselled as to the need for a full dental examination. The assessment was repeated on subsequent visits to the clinic. **Outcomes measured:** Hygiene, periodontium, caries, type of prosthesis, dentition, overall dental needs and compliance with recommendations.	**Included patients:** 131 patients (93 men and 38 women) were examined during their initial visit to a head and neck clinic. Their mean age was 60 years and ranged from 17 years to 86 years. The majority had late stage squamous cell carcinoma. **Hygiene:** 94% of patients had some plaque or calculus on their teeth. 16% had gross debris around all teeth. **Periodontium:** 7% of patients had clinically normal-appearing periodontium. **Caries:** 71% of patients had caries by gross inspection. **Type of prosthesis:** 72% of patients required a maxillary prosthesis and 57% of patients required a mandibular prosthesis. **Dentition:** 43% of patients were edentulous. Of the remaining 57%, only 9% had excellent dentition. **Overall dental needs:** 73 (97%) of the dentulous patients were recommended dental care before radiotherapy. This included scaling (95%), replacement of failing restorations (64%), extraction of 1 or more teeth (49%), **Compliance with recommendations:**	**Authors' conclusions:** These data suggest that thorough oral examinations should be performed on all patients before radiotherapy that involves the oral cavity. **Comments:** This study provides a good assessment of the baseline characteristics of its patient population. As the patient profile of the institution was of middle and upper socio-economic populations, it is possible that the situation in the "average" head and neck patient population may be poorer. The statistical methods used in the study were not clarified and the report could have benefited from this. However, the descriptive analysis alone suggests that head and neck cancer patients could benefit from close dental monitoring. Applying the information to the NHS situation can be problematic. One reason for this is that most patients will be managed by one hospital team which may or may not take responsibility for their patients' dental care. The situation of the authors, that they were assessing patients for eligibility for a study but not managing the care of the patient, is not likely to be widely replicated in the NHS.

			59 of 73 (81%) patients advised to have a dental intervention did not seek dental care or follow through with the indicated treatment. **Effects of age:** Younger patients had more frequent dental visits (p = 0.051), better hygiene (p = 0.001), better state of repair (p = 0.045), less severe caries (p = 0.042) and better periodontal health (p = 0.001). **Effect of diagnosis:** Patients with SCCs had more advanced periodontal disease (p = 0.002) and fewer mandibular and maxillary teeth (p = 0.021) than those with other diagnoses.	
Bishop, 1997.[13] **Country:** UK **Aims:** To describe the restorative management of a single patient after 10 years of a hemi-maxillectomy **Grade of evidence:** VII	**Service:** A consultant led restorative dentistry service. The patient was treated immediately with stabilisation of caries and an evaluation of the long-term prognosis of the maxillary teeth, achieved by flouride mouth rinse and advice on diet and oral hygiene. Definitive treatment involved the provision of a functionally and aesthetically acceptable denture with greater support and retention than the original prosthesis and the organisation of care that could be provided by the General Dental Practitioner (GDP) in the patient's home locality. **Participant:** A patient was diagnosed with palatal, adenoid cystic carcinoma and treated by hemi-maxillectomy with post-operative radiotherapy. For 10 years after treatment, his dental care was managed by his GDP but specific problems led the GDP to refer to hospital services. The reasons for referral were	**Methods:** A case history was described. **Outcomes measured:** Stabilisation of teeth Appropriateness of definitive treatment.	**Definitive treatment:** An "open-topped" prosthesis was maintained. Restoration of the mandibular arch was achieved. The authors report that close liaison with the GDP and his involvement led to better co-operation and allowed part of the patient's follow-up to be done outside the hospital by his GDP working in parallel with the hospital. **Stabilisation of teeth:** Early carious lesions were stable with no problems reported at a 6 month evaluation.	**Authors' conclusions:** Surgical treatment in these cases is often provided in places with limited restorative service. It is important that health workers in primary, secondary and tertiary care work together to make the delivery of care as effective and efficient as possible. **Comments:** The conclusions are based on one case but the experience of this patient may not be generalisable beyond this study.

	increased movement of his maxillary obturator and repeated fractures of the remaining maxillary teeth (without pain or infection).			

Table 4g: Availability of psychosocial care

Study details and aims	Details of interventions and participants	Methods	Included patients and results	Comments
Elith, 2001.[16] **Country:** Australia **Aims:** To investigate if the implementation of relaxation techniques, including music therapy, aromatherapy and guided imagery, will reduce anxiety levels in patients immobilised for treatment of head and neck cancers. Additionally, this study will attempt to validate the methodology used to conduct the study. **Grade of evidence:** IV	**Participants:** 14 patients being treated for varying malignant and benign head and neck diagnoses, including larynx cancer, macular degeneration and brain metastases, who presented to the Radiotherapy Department between May and July 2000. All patients had to be immobilised during their radiation therapy treatment using a customised mask. **Intervention:** For the first 7 days of treatment the intervention groups received radiation therapy treatment with the relaxation intervention applied. For the same period of time the control group received normal treatment. Patients in the music therapy intervention group were required to listen to background music during their treatment, patients were encouraged to bring in a personal selection of music if they so desired. Patients in the aromatherapy intervention group were required to wear an aromatherapy patch during treatment. The patch contained 2 to 3 drops of concentrated lavender aromatherapy oil, positioned close to the patient's face, but outside the treatment field. For the guided imagery intervention, a script was developed in collaboration with a professional psychologist. The script was recorded onto audiocassette by a female narrator. The patients were required to listen to the recording, on headphones, immediately prior to their treatment.	**Methods:** Patients were non-randomly, consecutively assigned to either a control group, not receiving the relaxation intervention (n = 4) or 1 of 3 validated relaxation intervention techniques; music therapy (n = 4), aromatherapy (n = 3) or guided imagery (n = 3). **Outcomes measured:** On days 1, 3, 5 and 7, after completion of their daily treatment, patients completed the 20-item State Anxiety Inventory (STAI) survey. The STAI survey has a 4-response Likert-type format ranging from "not at all" to "very much so" for each of the 20 items. Higher summated scores indicate higher anxiety.	**Withdrawals and exclusions:** There were 2 withdrawals, 1 member of the control group who no longer wanted to be included and 1 member of the guided imagery group who stated extended treatment time as the reason for leaving. The results of these patients are excluded from the results reported. **Average anxiety over time:** Day 1: control = 42, music therapy = 28, aromatherapy = 27, guided imagery = 26 Day 3: control = 40, music therapy = 23, aromatherapy = 25, guided imagery = 24 Day 5: control = 31, music therapy = 22, aromatherapy = 22, guided imagery = 20 Day 7: control = 30, music therapy = 22, aromatherapy = 21, guided imagery = 20 On each day that anxiety was measured, the patients in the relaxation intervention groups clearly demonstrate less anxiety than those in the control group. The reduction of anxiety levels observed in each of the 3 relaxation interventions compared to the control group is clinically significant. There is no observable clinically significant difference in the levels of anxiety measured between the intervention techniques themselves. The average anxiety level for each study group reduced from 1 treatment to the next, the reduction in anxiety between treatments is seen to plateau by day 7. The authors state that the music therapy and aromatherapy interventions were very easy to implement in the clinical environment. The guided imagery technique was the most difficult to implement and involved the patient listening to the prepared cassette 10 minutes prior to treatment. On occasions it was discovered that some efficiency problems could be encountered such as patients being minimally late for treatment. They suggest that this problem could be overcome with improved forethought and organisation.	**Authors' conclusions:** While caution should be taken in accepting the results owing to the small numbers of patients involved in the study and the non-randomised assignment of patients within the study, the results of the study demonstrate a clinically significant reduction in anxiety levels in each of the 3 relaxation interventions compared to the control group. The study demonstrated good study validity owing to the ease of implementation, the unambiguous results generated and the use of already validated anxiety interventions and measurement tools. **Comments:** The authors acknowledge the limitations of their study; the small sample size and non-randomised assignment of patients. However, their use of validated anxiety interventions and measurement tool increase the validity of the findings.

Hammerlid, 1999.[17] **Country:** Sweden **Aims:** Study 1: To evaluate the effect of group psychological therapy, led by a psychologist, in newly diagnosed head and neck cancer patients. Study 2: To examine the effect of a 1-week psycho-educational program for head and neck cancer patients 1 year after diagnosis. **Grade of evidence:** IV	Study 1: **Participants:** 25 patients with primary head and neck cancer, attending a weekly head and neck cancer conference at the university hospital who lived within 40 km of the hospital were invited to participate in the group therapy, 13 accepted (mean age 53 years, 5 female patients, site, stage and treatment varied amongst participants). 2 therapy groups were formed with 7 participants in the first group and 6 in the second. At 1-year follow-up 3 patients were dead. 42 patients living further away were asked to answer only the questionnaires to serve as the control group, only 34 patients completed the first questionnaire and these patients formed the control group (mean age 65, 4 female patients, site, stage and treatment varied amongst participants). At 1-year follow-up 26 patients were alive without tumour, 1 had been treated for recurrence, 6 were dead and 1 was missing for unknown reasons. **Intervention:** The supportive psychological group therapy was led by a psychologist and groups met for 1.5 hours once a week during the first 2 months, every second week for the next 2 months and then once a month for 6 months. The goal was to create a supportive and secure environment, to establish an intimate atmosphere in which expressions of anxiety and other feelings were encouraged, to talk about death, to enable the patients to learn more about themselves through others and their experiences and to support decisions about lifestyle changes. A combination of cognitive and behavioural techniques was applied, including relaxation and group dynamics exercises.	**Outcomes measured:** The same standardised quality of life questionnaires were used in both studies: the European Organisation of Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), a preliminary version of the EORTC head and neck cancer module (QLQ-H&N37) and the Hospital Anxiety and Depression (HAD) scale. **Methods:** Study 1: Quality of life: questionnaires were completed 6 times during 1 year: at the time of diagnosis and 1, 2, 3, 6 and 12 months after the treatment had started. All but the first questionnaire were mailed to patients. Patients who did not return the questionnaire within 10 days were reminded once. At diagnosis the patients also answered the Eysenck Personality Inventory (EPI). A study specific questionnaire contained 8 self-report questions relating to family, education, work and smoking habits. The group therapy was also evaluated by an interview with open-ended questions, performed 2 months after the end of therapy. The physician also collected data about other relevant diseases, weight, height, weight loss, time of onset of tumour-related symptoms and evaluated	Study 1: **Included patients:** Only 8/13 patients participated more than once in the group therapy. 1 patient died, 2 patients considered it too tiring, 1 patient did not want to talk about his illness and 1 dropped out for unknown reasons. Patients continuing the group therapy answered all 6 sets of questionnaires. Of the 34 control study patients, 26 completed all 6 questionnaires. To compare the 2 groups over time, only the results for patients completing the study are presented. **EORTC QLQ-C30 and EORTC QLQ-H&N37:** Scores that changed by 10 or more were considered a possibly clinically relevant change. Patients participating in the group therapy scored worse at diagnosis for a majority of the questions in both QL questionnaires. At 1-year follow-up, however, the therapy group had improved in most areas compared with the control group. The improvement was 10 points or more for 6 of 15 of the functions and symptoms in the EORTC QLQ-C30 in the intervention group, compared with 1 of 15 in the control group. The greatest benefit in the intervention group concerned emotional functioning, followed by social functioning and global quality of life. The improvement was more than 10 points for 10 of the 20 symptoms/problems in the EORTC QLQ-H&N37; "felt ill" improved the most, followed by "mucus production" and "hoarseness" together with "trouble eating". Only 1 item (hoarseness) improved more than 10 points in the control group. Problems with dry mouth increased in both groups during the study and was the problem with the biggest score at the 1-year follow-up. **HAD scale:** At diagnosis the percentage of patients scoring as a possible or probable clinical case of anxiety or depression was much higher in the therapy group than the control group. At 1-year follow-up the therapy group had improved considerably compared with the control group and fewer patients were considered probable or possible cases of psychiatric morbidity than the control group. **EPI:** No differences were found between the therapy and control groups with regard to neuroticism and extroversion, both groups were within the normal range.	**Authors' conclusions:** Patients participating in these pilot studies benefited from the supportive group therapy and the short-term educational program and the standardised questionnaires were of value in assessing their quality of life. It seems worthwhile to replicate the findings in larger studies of psychological support for head and neck cancer patients. **Comments:** The limitations of these pilot studies are the small sample sizes and non-randomised assignment of patients. However, their use of validated measurement tools increase the validity of the findings. The authors' conclusions that patients benefited from these interventions and that it seems worthwhile to replicate the findings in larger studies appears valid.

	Study 2: **Participants:** Together with their spouses, patients with oropharyngeal and laryngeal cancer who participated in an earlier longitudinal quality of life study were invited to a rehabilitation centre for a 1-week psycho-educational program. About 1 third of the invited patients wanted to participate, including 11 men and 3 women, mean age 57 years. There were 3 patients with laryngeal carcinoma, 3 with tonsillar carcinoma, 7 with oral cavity carcinoma and 1 with hypopharyngeal carcinoma. Mean time between diagnosis and the rehabilitation program was 16 months, range 12 to 22 months. 8 patients brought their spouses. **Intervention:** The program included an individual appointment with an oncologist, an educational program about cancer given by a physician, separate group sessions for patients and their spouses led by specially trained nurses, individual and group education by a physiotherapist and leisure activities such as painting, walking, music and dancing. A "home-like" environment with good food was emphasised. A report was sent to the patient's ordinary physician after the rehabilitation.	Karnofsky Performance Status. Study 2: Quality of life: was measured before and 4 weeks after the intervention. A research nurse conducted a standardised telephone interview 3 weeks after the intervention for further evaluation of the program.	7/8 therapy patients were interviewed 2 months after the last group meeting, 1 patient had moved. The majority of participants found the group therapy very valuable, even though they considered the number of patients disrupting the group too high, thus disturbing the "group atmosphere". The opportunity to talk to other patients in the same situation about their feelings and reactions to the disease seemed to be the most important benefit. Study 2: Results from the interview showed that patients appreciated all activities, learned new things and considered this knowledge useful. 5 patients mentioned spontaneously that the opportunity to socialise with other guests meant a lot to them. All patients would recommend a week of rehabilitation in this format to other cancer patients. 4/5 spouses considered the rehabilitation week to be "very good" and 1 "acceptable". Some of the patients thought they would have benefited more from the activities if they had been given the opportunity to go earlier (i.e. 2 to 3 months after finishing the treatment). **EORTC QLQ-C30 and EORTC QLQ-H&N37:** For most questions no great differences were found between values before and after the rehabilitation. However, the majority of variables reflecting functioning and symptom burden improved somewhat after the rehabilitation (26 or 34 variables). Only 6 variables scored worse. The greatest improvement was noted for "trouble eating", "problems enjoying your meals", dry mouth and emotional functioning. Another 5 variables showed improvement of more than 5 points. The only question showing a deterioration of 5 points or more concerned financial problems. **HAD scale:** The number of probable clinical cases of anxiety and depression was almost constant throughout the study. The number of possible cases decreased slowly. The number of patients scoring more than 7 on 1 of the scales decreased after the rehabilitation week.	
Rapkin, 1991.[18] **Country:** USA **Aims:** To augment the	**Participants:** All English speaking, literate adult patients scheduled for surgery for malignant tumours at the University of California Los Angeles division of Head and Neck Cancer between May 1986 and May 1987 were invited to take part.	Personality questionnaires were administered before the narration. Following arousal from the suggestive state, the Stanford Hypnotic Clinical Scale	**Included patients:** 15 patients volunteered for the active arm and 21 matched patients were chosen from the remainder (who did not volunteer) to act as the control arm. The intervention group contained 11 men and 4 women and the control group of 10 men and 11 women. The mean age of the intervention group was 55.2 years (SD: 10.5 years) and that of the intervention group was 61.2 years (SD: 12.2	**Authors' conclusions:** The authors state that their findings suggest that imagery-hypnosis may be prophylactic, benefiting patients by reducing the probability of post-operative complications and thereby keeping hospital stay within the expected range. An RCT is suggested.

accumulating data set of small sample investigations, to test the worth of continuing research in this area, to provide information about the sample size necessary for a randomised study and refine hypotheses regarding the relationship between guided imagery and surgery outcome. **Grade of evidence:** IV	**Intervention:** Patients were seen between 1 and 3 days pre-operatively. Consultations lasted about 90 minutes. The imagery-hypnosis, which lasted 20 minutes, was then narrated. This included suggestions for relaxing imagery, comfort during and after surgery, for an optimistic attitude, for minimal blood loss and for a rapid and smooth, recovery after surgery. General suggestions were given in preference to specific physiological suggestions. Patients were given a tape-recording of their consultation. A second narration, focusing on long term recovery, was given on tape. This was given 6 to 8 days after the operation.	(SHCS) was administered. 6 to 8 days post-operatively, patients were re-contacted. Personality tests were re-administered. **Outcomes measured:** Psychological: Anxiety and depression measures (including the State-Trait Anxiety Inventory and the Beck Pessimism Scale (intervention group only)), post-operative affective state-effecting medication requirements. Physiological: Duration of post-operative hospitalisation, blood loss during surgery, post-operative administration of pain medications and post-operative complications. Additional data were collected on the length of stay, use of medication and physiology of the intervention group and the control group. **Length of follow-up:** Follow-up was limited to the post-operative hospitalisation period only.	years). 6 of 15 intervention group patients and 10 of 21 control group patients underwent a laryngectomy. **Withdrawals and exclusions:** There were no withdrawals or exclusions reported. **Psychological:** Results of anxiety and depression measures were not reported. **Post-operative affective state-effecting medication requirements:** No significant differences found (Wilcoxon's rank test). **Duration of post-operative hospitalisation:** Hypnosis – mean 8.7 days. Control – mean 13.9 days (Wilcoxon's rank $Z = -1.98$, $p < 0.05$.) **Blood loss during surgery:** No significant differences found (Wilcoxon's rank test). **Post-operative administration of pain medications:** No significant differences found (Wilcoxon's rank test). **Non-Minor Post-operative complications:** Hypnosis – 9 of 15 (60%) Control – 15 of 21 (71%) ($\chi^2 = 0.13$, d.f. = 1, $p > 0.20$.) **Length of stay:** Patients in the intervention group stayed in the hospital for a mean 8.7 days (SD: 3.8 days) while those in the control group stayed for a mean 13.9 days (SD: 9.7 days). This difference was statistically significant ($Z = -1.9$, d.f. = 1, $p < 0.05$.) **Adverse events:** The authors do not report an assessment of the adverse effects of the treatment. **Effect of the degree of hypnotic susceptibility:** Higher hypnotisability was associated with lower rates of	**Comments:** This non-randomised controlled study is suggestive that guided-imagery is beneficial in relation to surgical outcomes. However, it should be seen as a pilot study only. As it is not randomised and questions of blinding and concealment are not addressed, the methodological weaknesses mean that the no clear conclusions should be drawn. The authors' suggestion of an RCT is well founded.

			complications (r = -0.54; p < 0.04). There was a non-statistically significant trend towards improvements in other outcomes with increasing hypnotisability.	
Hull, 1994.[19] **Country:** UK **Aims:** To undertake a study of the emotional needs of patients from first knowledge of diagnosis, as an initial step to understanding their cancer experience and to explore the role of counselling in increasing the quality of life. **Grade of evidence:** VI	77 patients attending the combined surgical and radiotherapeutic clinic for head and neck cancer and 23 patients with other cancers, who were regarded as suitable for the scheme by their consultants, were offered counselling by a trained psychotherapist. 48 patients enrolled in the project, the remaining 52 were not sure about joining, 11 of these were lost and 41 were followed up until December 1991 or until death. Most of the counselling was undertaken in outpatients departments or an adjacent office but a number of patients were followed up in the wards, a local hospice and nursing homes. Most face to face counselling between patient and psychotherapist lasted an hour; telephone counselling was estimated at 15 minutes. The 100 patients required 733 hours of the psychotherapist's time, not including travelling time. Help given to the 48 enrolled patients consisted of counselling, provision of information, teaching of relaxation techniques and self-hypnosis. The remaining 52 all received information and some received counselling or relaxation. Care was also offered to that patient's carers. 29 carers of 27 patients were offered help, they required 146 contacts totalling 160 hours. Most carers received counselling and information, 1 requested information only, 2 were taught relaxation techniques and 3 received hypnotherapy in addition to self-hypnosis, counselling and information.	**Outcomes measured:** Assessment of patients' experiences with illness, treatment and the health care system and their response to psychological interventions were largely qualitative. 117 verbatim statements made by 23 different patients were reported. Some patients attended very frequently and therefore had many comments.	**Quality of life:** Increased quality of life was mentioned on 4 occasions e.g. "I value being alive, being here. At least I will enjoy what I've got, rather than fret over what I haven't got". **Emotions:** Emotions were mentioned on 13 occasions, e.g. "I'm glad that you are in the clinic explaining things afterwards to the patients… when their stomachs are all knotted up with fear". Anger was expressed on 3 occasions, in 1 instance directed at the patient's family. Emotional reaction to treatment was only mentioned once "I wouldn't have got into the radiotherapy department if you hadn't helped me by going there before my treatment". Emotional reaction to cancer was expressed 3 times, e.g. "Feeling secure on the ward with someone there all the time, when you are at home there is no panic button to press, so you panic, because the can't handle it yourself". **Thoughts and feelings:** Thoughts and feelings were the most commonly expressed comments, denial was surprisingly rare. A sense of rejection was the subject of 4 comments and hopelessness was vocalised with 3 comments. Increase in confidence, the second most common response was mentioned 44 times e.g. "You gave me the confidence to do it all. I don't think I could have done it otherwise". Loss of control was noted as a cause of anxiety on 2 occasions, e.g. "Through talking with you I have learnt to accept things in my mind and have started to take control of lots of things in my life…". Insecurity and uncertainty were each mentioned twice, e.g. "I'm like a dog going round in circles catching its tail. I'll be glad to talk to you". "Uncertainty continues but, having come here and talked it through, I have decided to create my own certainty". There were 8 comments about increased ease of speaking about cancer. 11 comments related to coming to terms with beliefs about cancer "… careful counselling has helped me to come to terms with my health". **Physical reactions:** Drinking and smoking were each only commented on once "You don't judge me on my drinking" and "I've given up smoking after	**Authors' conclusions:** Apart from the benefits received by cancer patients and their families in terms of improved quality of care and quality of life, oncology counselling services can be seen as an increased utilisation of hospital resources with resulting long-term financial benefits as noted by others. **Comments:** Patients were selected as suitable for the scheme by their consultant, which may have resulted in a biased sample. Only 23 patients made statements, therefore, the findings may not be representative of a larger population. The authors only report positive comments made by patients about the counselling intervention, they do not state whether any negative comments were made. The authors' conclusions relating to the financial benefits of counselling are based upon 2 other studies, rather than their own findings, therefore, the validity of this part of their conclusions cannot be verified. However, it does appear that the counselling intervention improved quality of care and quality of life of the cancer patients and their families who commented in this survey.

			37 years… I couldn't have done it without your help". Sleeping and relaxation were mentioned 8 times "Using this relaxation tape is enormously helpful…". Alteration of appearance produced 3 comments and reaction to treatment was mentioned 6 times. Reaction to the symptoms of cancer was mentioned very little, e.g. "The hypnosis has helped me and reduced my pain". Weeping was referred to 3 times "I'll never forget it when you just held me…". No patients mentioned eating or sexual issues. **Attitudes and beliefs:** 64 comments referred to the help and support provided by the scheme. Increased understanding of the self was mentioned 22 times. 9 comments referred to strain in patients towards the family and 3 in the family towards patients. The relatives of a patient who said she was not allowed to talk about her death to her family telephoned the ward requesting that the psychotherapist did not see the patient again because therapy "had a bad influence on her". Changed attitudes to self were commented on 4 times but death and dying were raised only 3 times. Increased self reliance was commented on twice. **Reactions to interventions:** 54 comments related to the patients' reactions to the intervention, 6 comments referred to "insurance" e.g. "This is a sort of insurance somehow – I can cash in if I want to". 23 comments concerned patients' perceptions of counselling and 14 comments indicated that hypnosis and relaxation helped patients to regain an inner sense of control over aspects of living. Comments about doctors included a mixture of respect for skills and criticism of their communication.	
Hutton, 2001.[21] **Country:** UK **Aims:** To investigate the prevalence and nature of psychological distress in a small group of people who have been treated for head and neck cancer and who attend a follow-up clinic	18 patients who had been treated for cancer of the head or neck and attended the follow-up clinic on 1 of 4 days or the support group on 1 occasion, there were 9 from each setting.	**Methods:** The patients were interviewed using a brief semi-structured format and responses were recorded verbatim and themes considered. **Outcomes measured:** Anxiety and depression were screened for using the Hospital Anxiety and Depression Scale. Scores of 8 or above on the anxiety and depression	Only 1 patient had had formal support (from a counsellor) and she had not found it helpful. When asked "What has helped you to cope with these problems?" the patient responded "I keep going for the children. I love to see my grandson. I went to see a counsellor but that was no help. I saw her twice and then we decided there was no point talking about it. It didn't make me any more confident". The authors state that it was surprising that only 1 person had had any formal support, as there is a large centre providing information and psychological support located within the Trust. They did not ask people why they did not use this service, but state that some possible reasons could be reluctance to	**Authors' conclusions:** The authors do not draw any conclusions regarding the counselling intervention. **Comments:** This very small study only included 1 patient who mentioned that they had undergone counselling, therefore, it has been graded as a case study, which does not provide very reliable evidence as the attitudes of the patient may not be representative. The authors report that only 1 patient

or support group; to add to the available information on psychological distress in patients at this stage of the illness; to consider some possible predictors of distress in this group; and to consider how these data may be used to offer further useful treatments. **Grade of evidence:** VI		subscales (borderline or appreciable anxiety/depression) were classed as clinically important. A global score for psychological distress was calculated by adding the anxiety and depression scores together and the score of 15 was used to define clinical relevance. The Rosenberg Self-Esteem Scale was also used to evaluate general levels of self-esteem.	acknowledge psychological needs or lack of knowledge about the centre, which is some distance from the clinic.	attended counselling, when in fact they did not ask patients whether or not they had attended counselling, merely "What has helped you to cope with these problems?".
Breitbart, 1988.[20] **Country:** USA **Aims:** To outline the common psychological issues confronting patients with head and neck cancer, their impact on rehabilitation, their management and common alcohol-related effects experienced by this group of patients. **Grade of evidence:** VII	**Participant:** A 54 year old female suffering from acute phobias and anxiety 4 days after a radical maxillectomy. The patient had a history of mild phobias and panic attacks prior to her cancer diagnosis. She suffered from pain, difficulty breathing and drooling immediately after surgery and refused further treatment including antibiotic cover. She found it difficult to look at herself in the mirror for some time after her operation, found it difficult to accept her prosthesis and refused to see friends following her discharge. While at home she developed insomnia, poor concentration, depression and anorexia and was withdrawn and wanted to die, with suicidal thoughts being frequent and troubling. **Care:** During the period post surgery, she was assessed at her request by a psychiatrist. She was prescribed an oral anxiolytic, the benzodiazepine alprazolam. She was also cared for with behavioural techniques such as desensitisation, rehearsal, imagery and cognitive reinterpretation. Following discharge, she was seen frequently in crises-oriented psychotherapy	**Methods:** A case report is presented. **Outcomes measured:** Control of phobias and anxiety Completion of prescribed treatment Psychological well-being Return to normal activities	The authors report that she controlled her phobias and anxieties sufficient to undergo antibiotic therapy which the patient successfully completed. Following her psychological treatment post-discharge, her depression lifted rapidly and she was able to return to her normal activities.	**Authors' conclusions:** While the ordeal of the head and neck cancer patient is psychologically difficult and challenging, most patients are able, with the proper help, to resume full and productive lives. **Comments:** The paper reported on a number of cases and on the theoretical background to the service in addition to the case report here, but these fell outside of the remit of the current question. The paper lists a number of problems from which the patient in question suffered, but does not report whether all of the problems were resolved through the care she received. The authors do not report who offered some of the interventions. While it is reported that the patient improved, no measurement of the severity of her condition or of the improvements made were presented. As this is a case study, extreme caution should be taken in attempting to generalise the findings and conclusions of this study

	both alone and with her family. Desensitisation techniques were used. She was given oral alprazolam and the tricyclic antidepressant, amitriptyline hydrochloride.			beyond the care of the individual patient concerned.

Table 4i: Provision of a patient visitor

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Edwards, 1997.[14, 15] **Country:** UK **Aims:** To explore views of patients, their families and professionals about head and neck cancer services. **Grade of evidence:** VI	**Participants:** Patients and professionals from 4 hospitals and 2 patient support groups in South East England. Patients seen in the department within the past year and diagnosed more than 1 year previously were eligible. Patients were consecutively selected from lists of eligible patients compiled by the maxillofacial departments at the 4 hospitals. Additional patients were recruited from members of support groups who met at 2 of the hospitals. Patients had the option of bringing a family member with them.	Focus group interviews were held. The issues for discussion were developed from informal conversations with professionals and patients before the study and adapted as important issues emerged. All focus groups were recorded and transcribed in full. The contents of the data were analysed for themes, key issues and for consistency. A map of each focus group was built up and analysed for inter-relationships between the different aspects of the findings.	**Included patients:** 22 patients and 11 relatives took part in 6 focus groups. 33 professionals took part in 4 focus groups, including maxillofacial, ENT and plastic surgeons, medical and clinical oncologists, nurses, speech therapists and other professionals involved in rehabilitation and palliative care. **Effect of "shared decision making":** Most patients wanted to be involved in their treatment and more wanted to be involved in decisions about their treatment than actually were. In general, younger patients wanted more involvement whereas some older patients felt that it made no difference as doctors would only do as they wanted anyway. Some people were given choices in their treatment but did not have enough information on which to base a choice. Most patients wanted to make a joint decision with the advice of their clinician and have their views taken into account. There were different opinions among clinicians about how much choice patients should be given in their treatment. Many felt that patients should be involved in choices about rehabilitation and palliative care but the choice of primary treatment should be the role of the consultant. Everyone agreed that the patient should have a veto on their treatment but few clinicians presented a range of options with their relative merits either owing to time constraints or philosophical reasons. "*Very often what we do is to make a decision and test with the patient whether that decision is completely unacceptable, which is probably paternalistic. It may be the wrong way round but I suspect that's what we do*." **Effect of counselling:** Most patients said that they needed to talk about their condition. Often they talked to their partner or family, but some people needed more support than this. Most	**Authors' conclusions:** Patients and relatives were concerned about hospital accommodation, information about side effects, choice, support services and the impact of treatment. Professionals valued teamwork and joint clinics. They were concerned about lack of administrative flexibility, difficulties in communication and the high mortality of head and neck cancers. **Comments:** This study presents the views of a small number of patients and health professionals, those views may not be representative of the views of the larger population. The author acknowledges that the participants are not representative of advanced or terminal cancer or ethnic minority patients. The author also emphasises the qualitative nature of the research, which produces insight into an issue rather than measuring it. Whilst this study looked at many issues, only the results relating to shared decision making, counselling and the provision of a patient visitor are reported here.

			patients had not been offered counselling and some patients found it difficult to ask for as they felt that this was an admission that they could not cope. Most of the patients who had had counselling from various sources found that they had not helped as the counsellors had often not listened to them but tried to provide solutions to their problems. In contrast, people who had taken time to listen to them, e.g. a junior doctor or student nurse, had helped them to come to terms with what they were going through. Provision of a patient visitor: Some clinicians introduced past patients to patients about to undergo treatment and found that it benefited both patients. Patients confirmed this view. The other person provided understanding, encouragement and gave the person undergoing treatment hope and something to aim for. In some cases people maintained contacts for many years. One professional expressed concern that introducing patients might prove counter-productive but did not report any experiences to support her belief.	
Feber, 1998[22] **Country:** UK **Aims:** In order to plan an evidence-based strategy, a literature review was carried out followed by a comprehensive audit of patients' and professionals' views of the current service. One year after implementation of the strategy patients who had undergone surgery during that year were sent questionnaires to elicit their levels of satisfaction in order to evaluate the effectiveness of the project.	**Service:** The support strategy included establishing a laryngectomy friendship scheme (a panel of ex-patients trained in basic listening and responding skills, who were good role models to provide extra support for current patients).	**Methods:** Patient survey prior to implementation of the support strategy: Questionnaires were sent to 50 patients who had undergone laryngectomy or laryngopharyngectomy. Informal conversations were also held with local laryngectomees. Patient survey after implementation of the support strategy: questionnaires were sent to patients who had undergone total laryngectomy and laryngopharyngectomy prior to implementation of the strategy and to those undergoing surgery during the year after implementation. The questionnaires were posted to the patients and were self-completed and anonymous. **Outcomes measured:** Outcomes assessed in the first	**Included patients:** The study included 50 patients who had undergone total laryngectomy and laryngopharyngectomy prior to implementation of the strategy and 35 patients undergoing surgery during the year after implementation. 31/50 patients who had undergone total laryngectomy and laryngopharyngectomy prior to implementation of the strategy and 20/35 patients who had undergone surgery during the year after implementation responded to the questionnaire. Patient survey prior to implementation of the support strategy: Many patients felt that peer support was very important: "*A laryngectomee visitor really helped me – I thought 'If he can do it, so can I'. It's really important – everyone should see a visitor"*. "*We need a local club for help and support"*. Patient survey after implementation of the support strategy: The laryngectomy friendship scheme increased the number of patients offered the opportunity to meet a	**Authors' conclusions:** The laryngectomy friendship scheme was extremely effective, not only increasing the number of patients offered the opportunity to meet a visitor (85% in the second group compared to 35% in the first group), but also increasing the satisfaction the patients had with their visitor (95% in the second group compared to 35% in the first group). **Comments:** Only results relating to provision of a patient visitor have been reported here. The questionnaires were not validated and were not described in detail in the report, therefore, it is not possible to comment on their content. No details were given about the 'informal conversations' held with local laryngectomees prior to implementation of the support strategy. The number of patients commenting on their satisfaction with their visitor was small (i.e. only

Grade of evidence: VI		questionnaire are not stated. The questionnaires sent to patients after implementation of the support strategy asked about patient satisfaction with support and information before and after their operation.	visitor (85% in the second group compared with 35% in the first group) and increased the satisfaction the patients had with their visitor (95% in the second group compared with 35% in the first group).	35% of 31 respondents were offered the opportunity to meet a visitor). However, it seems that the scheme was effective in increasing the number of patients offered the opportunity to meet a visitor and satisfaction with their visitor. This study is qualitative in nature and results are presented with descriptive but not inferential statistics. Therefore, the findings should be interpreted as suggestive rather than definitive.
Johnson, 1979.[24] **Country:** USA **Aims:** To better understand and identify specific problems encountered by laryngectomised patients. **Grade of evidence:** VI	**Participants:** Participants with laryngeal cancer who had undergone laryngectomy and who had achieved a satisfactory means of communication were eligible. **Service:** Details were not reported relating to the content or format of the contacts between the participants and their patient visitor.	**Methods:** Structured interviews were conducted to obtain information from participants. Many patients were identified from the membership of the Central New York Laryngectomy Club. **Outcomes measured:** Outcomes assessed are not stated.	**Included patients:** 25 patients (21 males, 4 females) who had undergone laryngectomy participated in structured interviews. **Results:** About one-fifth of the sample had met with a laryngectomy club member pre-operatively. All of these individuals were glad they had that opportunity and the great majority of those who did not see a rehabilitated laryngectomee would have liked to see one.	**Authors' conclusions:** A study was designed wherein laryngectomees and their families were individually interviewed. These people suggested that their rehabilitation could have been facilitated had they been better informed pre-operatively. Many expressed a desire for exposure to a speech pathologist and a successfully rehabilitated laryngectomee pre-operatively. **Comments:** This study was conducted in 1979 so the results may no longer be applicable. The authors acknowledge that the results cannot be considered as genuinely representative of all laryngectomised patients. All individuals interviewed had developed a satisfactory means of communication, all had readily agreed to the interview and many were located by virtue of their membership in the Central New York Laryngectomy Club. Additionally, self-report interview techniques tend to produce "socially-desirable" responses from interviewees. Very little detail was given regarding the structured interview, it is not stated whether the interviewer was known to the patients, which can bias the results. No details were given about the content of the meeting with the laryngectomee.
Lehmann, 1991.[25] **Country:** Switzerland **Aims:**	**Participants:** Men and women who had undergone total laryngectomy owing to carcinoma of the larynx and who were living in Switzerland at the beginning of 1989.	**Methods:** Patients were identified using the membership lists of the Union of the Swiss Associations of Laryngectomees and with the help of treating hospitals for non-members. A sample of patients was	**Included patients:** 332 patients (90% male) who had undergone total laryngectomy owing to carcinoma of the larynx. On average 7 years had passed since the operation (range 1 year to more than 20 years).	**Authors' conclusions:** Preparation of patients and their relatives for the operation and its consequences should be the task not of one person but of an interdisciplinary team, including another laryngectomee, with whom contact is often very valuable for the patient.

To present some of the results of a patient opinion survey. **Grade of evidence:** VI	**Service:** Details were not reported relating to the content or format of the contacts between the participants and their patient visitor.	contacted from the list of laryngectomees. Thirty experienced and specially trained interviewers conducted the interviews, which took an average of 50min to 60min each, using standardised, pre-tested questionnaires. Around half of the interviews were conducted alone with the person concerned, in 4 out of 10 cases the spouse was present, rarely another person. **Outcomes measured:** The survey measured participants' opinions about the living situation of laryngectomees and was intended to provide information about the medical, social, psychological, work-related and financial problems of laryngectomees.	36% patients were in touch with a laryngectomee prior to their own operation. 13% refused such a meeting; 42% were not even offered one. Where contact existed, the majority considered it to be useful: 69% of these patients stated that contact with a laryngectomee was helpful to them, while 23% said that this contact provided no advantages. For the whole of Switzerland approximately 20% laryngectomees received speech training from another laryngectomee; in the Italian-speaking part the figure was 80%. The interviewees stated definite wishes and their needs for improved and new services. In the social area, the list of wishes included: (1) Better and more speech courses, refresher seminars and repeat courses. Also, speech courses should be conducted by laryngectomees. (2) Improved possibilities for contact with laryngectomees: for example, visiting those freshly operated upon; more outings, congresses, group discussions after the operation; a contact person close to where one lives, something to alleviate the isolation of singles.	**Comments:** A large sample of laryngectomees were included in this survey. However, the sample was drawn principally from the membership of a patient support group that funded the work. Whilst the study did attempt to identify participants from outside the group, the authors do not report what proportion of the respondents were members of the support group or investigate the effects of support group membership. The study was conducted retrospectively and in some cases after a significant amount of time had elapsed, which introduces the possibility of recall bias. The experiences of a patient who had a laryngectomy 20 years ago may not be representative of the experiences of a patient undergoing laryngectomy more recently.
Minear, 1979.[23] **Country:** USA **Aims:** To evaluate the rehabilitation program in use at the authors' institution and to provide suggestions for developing and improving rehabilitative programs. **Grade of evidence:** VI	**Participants:** Patients who had undergone laryngectomy. **Service:** Few details of the service were given but it appears that it included pre-operative visits by the surgeon, a social worker, a speech and language therapist and a patient visitor.	**Methods:** Each patient was given a questionnaire including 48 questions which explored both pre-operative and post-operative periods. **Outcomes measured:** The questions mainly pertained to the pre-operative visitations and explanations which the patients received and attempted to ascertain their feelings regarding the adequacy of these explanations. With regard to the pre-operative explanations, the patients were asked to comment on the effectiveness and adequacy of the visits by the surgeon, social worker, speech and language therapist and another laryngectomy patient. Post-operative questions focussed on the role of these	**Included patients:** 60 patients (53 male and 7 female) with a mean age of 64 years who had undergone laryngectomy between 2 and 48 months (mean 19.1 months) earlier. 55% of patients were visited by another laryngectomee pre-operatively. Of those seen, 85% felt that the visit was worthwhile. Of those not seen, 83% felt that it should have been done. Post-operatively, 56% were seen by another laryngectomee and of those seen 78% felt the visit to be beneficial. Of those not seen, 83% again felt that it should have been done. In reference to the pre- and post-operative visits by another laryngectomee, several patients expressed very strong feelings about having a choice as to whether they wished to have this visit at these times. The practice of having a patient visited by another	**Authors' conclusions:** We must emphasise the need for an organised, thoughtful and individualised approach to each patient, identifying and anticipating he needs in the pre and post-operative periods. Such an effort will require a team approach with frequent discussions among various members of the team, even though each member need not necessarily see the patient primarily. **Comments:** This study was conducted in 1979 so the results may no longer be applicable. The questionnaire was not a validated scale and was not described in detail in the report; therefore, it is not possible to comment on its content. The interviews were conducted by one of the authors who was from the Department of Otolaryngology, it

		persons as well as on the patient's post-operative fears, nursing care and techniques of vocal rehabilitation. Patients were then interviewed to discuss the responses given in the questionnaire and relate any other feelings about their pre-operative and post-operative experience.	laryngectomee was discussed with the patients at some length. Although almost all agreed that the visits were worthwhile, some felt particularly ill at ease during the visit and expressed a desire to have some choice as to the timing and circumstances of the visit. They generally preferred to have the contact with another laryngectomee delayed until the post-operative period.	is not possible to determine whether he would have been known to the patients, in which case it may have biased the results. No details were given about the content of the visit by the laryngectomee.

Table 4j: Smoking cessation programmes

<table>
<tr><th>Study details and aims</th><th>Participants</th><th>Intervention</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Gritz, 1993.[26-28]

Country:
USA

Aims:
To compare patients undergoing a smoking cessation intervention with those having usual care advice.

Grade of evidence:
II</td>
<td>Patients with newly diagnosed head and neck cancers (oral cavity, pharynx or larynx). Patients had to be current smokers or ex-smokers who had smoked within 1 year of enrolment.</td>
<td>A 12-month smoking cessation programme. The programme consisted of a contract, 3 booklets and 6 reminder postcards. It also contained an initial advice session and 6 monthly booster sessions designed to provide on-going tailored advice dependent on the needs of individual patients.

The contract was signed by the patient and a friend/partner/carer. The booklets included 2 self help guides (one to help participants stop smoking and one to help them stay stopped) and a booklet to help their friend/partner or carer help the participant. Reminder postcards contained helpful cessation and abstinence tips.</td>
<td>Outcomes measured:
Self reported questionnaires collected information on smoking habits, predictive variables, demographic data, nicotine dependence, attitudes to and beliefs about smoking and social support for cessation. The readiness to stop was classified according to the “stage of change” theory. Abstinence was verified by biochemical analysis of the urine. Additional outcomes were collected but not presented in the reports. Measurements were planned for baseline and after 1, 6, 12 24 and 36 months of follow-up.

Length of follow-up:
1-year outcomes were presented.</td>
<td>Patients included:
Subjects were 186 patients with newly diagnosed first primary squamous cell carcinomas of the upper aerodigestive tract who had smoked cigarettes within the past year. At randomisation, 88.2% of subjects were current smokers. The number of patients randomised to each arm was not reported. Principal findings were based on 114 patients who were followed up for 1 year. The number in each arm is not presented.

Withdrawals:
72 patients did not complete. 33 died and 4 became too ill to complete the study. 16 dropped out, 14 were lost to follow-up, 4 did not receive initial advice from their care provider and 1 was found not to have met inclusion criteria.

Smoking status at 12 months of patients who were smokers at baseline (n = 96):
<table>
<tr><th></th><th>Intervention</th><th>Control</th></tr>
<tr><td>Smoker</td><td>5</td><td>6</td></tr>
<tr><td>Relapser</td><td>13</td><td>6</td></tr>
<tr><td>Short term abstainer</td><td>3</td><td>1</td></tr>
<tr><td>Long term abstainer</td><td>29</td><td>33</td></tr>
</table>
Fisher’s Exact test: p = 0.318

70.2% of 114 subjects completing the trial were continuous abstainers at 12 months follow-up. 63.8% of patients in the intervention group and 76.8% of patients in the control group were continuous abstainers at 12 months follow-up.

Among those who smoked at enrolment the continuous abstinence rate was 64.6%. The biochemical validation rate at 12 months was 89.6%.

Adverse events:
The authors do not report if adverse effects were examined in the study.</td>
<td>Authors’ conclusions:
The intervention effect was not significant, although the sign of the effect was positive. Based on these findings, we recommend systematic brief advice to stop smoking for head and neck cancer patients, with a stepped care approach for patients less able to quit.

Comments:
The study was conducted with a “per-protocol” analysis of results. The attempt to allow for those patients who did not complete by using a model rests on a number of assumptions, which have not been fully justified. It was not possible to know how many patients were randomised to each arm or if their arm of randomisation affected whether they stayed in follow-up for 12 months. In a paper presenting the methodology of the trial, the authors suggested that 180 patients would be recruited to each arm.[28] They did not explain why this number were not recruited or whether their confidence in their conclusions was affected by the apparent underpowering evident in the final number of patients recruited. The method of randomisation was not reported. These methodological flaws mean that this study should be seen as suggestive rather than definitive.</td>
</tr>
</table>

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Primary Treatment

The Questions

a) In patients with head and neck cancer (primary disease) what are the relative efficacies of brachytherapy, normal fractionation external beam radiotherapy, accelerated fractionation external beam radiotherapy, altered fractionation external beam radiotherapy, chemoradiotherapy, surgery, chemotherapy and endoscopic/laser excision, alone or in combination, in terms of long term survival, peri-treatment mortality, recurrence rates, incidence and severity of morbidity, voice outcomes, facial nerve outcomes, xerostomia, complication rates, quality of life, anxiety, patient satisfaction or any other patient outcomes?

b) In the management of patients with head and neck cancer, does adherence to a treatment protocol and specified timescales improve outcomes?

c) In the management of patients with head and neck cancer, does adherence to the specified radiotherapy timescales (i.e. no unplanned breaks in treatment) improve patient outcomes?

d) In the management of patients with head and neck cancer, do delays in initiating radiotherapy treatment effect patient outcomes?

e) In patients receiving treatment for head and neck cancer, do interventions such as dietetic support, enteric feeding or counselling, for the prevention and/or treatment of mucositis, alteration in oral flora (including candidal infection) or dysphagia, improve patient outcomes?

f) In patients having radiotherapy for head and neck cancer, do interventions aimed at reducing the severity of the symptoms of xerostomia (including artificial saliva, mouth washes, access to oral health care, counselling, nicotinic acid or pilocarpine) improve patient outcomes?

The Nature of the Research Evidence

a) Relative efficacies of treatment modalities

This search was limited to systematic reviews that investigated cross-modality treatments. Comparisons of fractionation schemes within radiotherapy or comparisons of different chemotherapy regimens were excluded.

Six systematic reviews, reported in seven publications, investigated whether the addition of chemotherapy to radiotherapy improves outcomes for head and neck cancer patients.[1-7] Whilst the reviews only included other reviews and RCTs, details of the included studies were limited, particularly in relation to their quality, which limits the assessment of the reliability of the results. None of the reviews included information on costs.

Three systematic reviews investigated the use of different fractionation schedules for patients with head and neck cancer. Two of the reviews included RCTs of patients with newly diagnosed, locally advanced head and neck cancer[8, 9] whilst the other included patients with head and neck cancers of different stages.[10] Again, whilst the reviews only included other reviews and RCTs, details of the quality of included studies were not reported, limiting the assessment of the reliability of the results. None of the reviews included information on costs.

A good quality systematic review was identified which attempted to compare the effectiveness of open surgery, endolaryngeal excision (with or without laser) and radiotherapy in the management of early glottic laryngeal cancer.[11] However, the review only identified one poor quality study that fitted the inclusion criteria, therefore, the results should be interpreted with caution.

Details of the reviews are given in Table 5a.

b) Adherence to a treatment protocol and specified timescales

Two cohort studies investigated the implementation of a clinical care pathway for patients with head and neck cancer.[12, 13] One study consisted of three groups of patients who underwent unilateral neck dissection at a

multidisciplinary head and neck surgical unit.[12] Thirty patients managed according to the clinical pathway and 64 patients managed during the same time period (1996 to 1998) but not according to the pathway were compared with 96 historical controls (1993 to 1994). However, owing to the methodological flaws in the trial, such as the small sample size in the clinical pathway group, potential differences between the historical controls and the other two groups and the omission of other relevant outcomes, the results cannot be verified.

The other cohort study retrospectively evaluated three groups of patients who underwent laryngectomy, intraoral resection or a complete resection of head and neck cancer and required tracheostomy or enteral feeding.[13] Eighty-seven patients were treated in 1995, before the introduction of the clinical care pathway, 43 patients were treated during a one month period (July 1996) of the first year of the clinical care pathway and 82 patients were treated in the third year of the clinical care pathway (1999).

Details of the studies are given in Table 5b.

Three studies which investigated adherence to radiotherapy timescales were also located, but have not been described here as they are included in question c, below.[14-16]

c) Adherence to specified radiotherapy timescales

A systematic review of individual patient data from five large randomised trials, with a total of 2,564 head and neck cancer patients randomised to receive either conventional fractionation or altered fractionation radiotherapy, investigated compliance with prescribed dose-fractionation schedules and overall treatment times.[14]

Two studies reanalysed data from randomised controlled trials to determine the effects of delays/prolongation of treatment time during radiotherapy. The first study[17] reanalysed data from two randomised controlled trials including 828 patients with node-negative cancer of the larynx randomised to receive radical radiotherapy in three or five fractions per week or in less than or

greater than four weeks. The other study[18] was a reanalysis of 366 head and neck cancer patients undergoing radical radiotherapy, enrolled in the conventional arm of the CHART trial.

A case control study, not included in the above reviews, investigated the effect of interruptions and prolonged overall treatment time for 229 patients receiving continuous course radiotherapy and 567 patients receiving split course radiotherapy for nasopharyngeal carcinoma.[15]

Two additional case series were identified which used mathematical models to estimate the effect of gaps in radiotherapy treatment schedules.[16, 19] The first included a series of 629 patients with glottic node-negative larynx cancer[16], the other included a series of 2,225 patients with cancer of the larynx.[19]

Details of the studies are given in Table 5c.

d) Delays in initiating radiotherapy

To answer this question, a search of systematic reviews was conducted. This search located one review pertinent to the question.[20] This was a well conducted review which searched MEDLINE and CANCERLIT from 1975 to 2001. The review was not limited to any type of cancer but the results were stratified by cancer type and the intention of the radiotherapy (i.e. as radical primary treatment or as adjuvant treatment post-operatively). Appropriate follow-up searching was conducted. The authors assessed the quality of included studies and this was incorporated into their review. Analysis was well conducted and issues relating to differences between the studies were addressed. Details of the review are given in Table 5d.

e) Interventions for the prevention and/or treatment of mucositis

This search was limited to systematic reviews. A systematic review from the Cochrane collaborative of 52 studies, with a total of 3,594 cancer patients[21] and a systematic review of 15 randomised controlled trials with a total of 1,022 head and neck cancer patients[22] evaluated the effectiveness of various prophylactic agents for oral mucositis.

A systematic review performed for the Cancer Care Ontario Practice Guidelines Initiative[23] identified eight randomised controlled trials, one quality of life paper and one practice guideline to evaluate the safety and effectiveness of amifostine treatment in ameliorating side effects of radiotherapy for head and neck cancer patients.

Details of the studies are given in Table 5e.

f) Interventions to reduce the severity of the symptoms of xerostomia

This search was limited to systematic reviews. Two systematic reviews investigated the use of pilocarpine hydrochloride for radiation-induced xerostomia in patients with head and neck cancer.[24, 25] Both reviews included four randomised controlled trials with a total of 401 patients, three of the randomised controlled trials were included in both studies. Details are given in Table 5f.

A systematic review performed for the Cancer Care Ontario Practice Guidelines Initiative[23] identified eight randomised controlled trials, one quality of life paper and one practice guideline to evaluate the safety and effectiveness of amifostine treatment in ameliorating side effects of radiotherapy for head and neck cancer patients.

Summary of the Research Evidence

a) Relative efficacies of treatment modalities

A systematic review of concomitant radiotherapy in combination with chemotherapy treatment for patients with locally advanced head and neck cancer included four previous reviews of effectiveness and a review of adverse effects.[1, 2] The pooled analysis of all 18 included RCTs showed an overall survival benefit for concomitant chemotherapy and radiotherapy (OR = 0.62; 95% CI: 0.52 to 0.74; p <0.00001; RR = 0.83, risk difference = 11%), however concomitant therapy produced more adverse effects than radiotherapy alone. Subgroup analyses showed that platinum-based chemotherapy produced a survival benefit of 12% (p≤0.00001), mitomycin C

based chemotherapy produced a survival benefit of 14% (p=0.032), the survival benefits for FU- and bleomycin-based chemotherapy were not statistically significant.

A systematic review of neoadjuvant chemotherapy for patients with locally advanced head and neck cancer included three previous reviews and 26 primary studies.[3] A meta-analysis using individual patient data from 31 RCTs demonstrated no significant survival benefit for neoadjuvant chemotherapy compared with locoregional treatment alone (HR = 0.95; 95% CI: 0.88 to 1.01; p = 0.10). However, a subgroup analysis of 15 RCTs detected significantly improved survival with neoadjuvant chemotherapy using fluorouracil in combination with either cisplatin or carboplatin (HR = 0.88; 95% CI: 0.79 to 0.97; p < 0.05). When individual patient data from three RCTs of larynx-preservation versus surgery were pooled, the hazard ratio for death favoured surgery, although this was not statistically significant (HR = 1.19; 95% CI: 0.97 to 1.46; p = 0.10). In a larynx preservation RCT including 547 patients allocated to neoadjuvant chemotherapy, radiotherapy alone or concomitant chemotherapy and radiotherapy, patients allocated to the latter group had similar overall survival, but significantly greater loco-regional control and laryngectomy preservation than patients in the other two treatment groups. The mental health and pain assessment scores of 46 laryngeal cancer survivors who completed health status assessment instruments were compared, 21 patients who had been randomised to neoadjuvant chemotherapy in combination with radiotherapy scored significantly better than 25 patients who had been randomised to surgery and radiotherapy.

A systematic review of 54 RCTs of the addition of chemotherapy to standard therapy for patients with head and neck cancer[4] found that the addition of chemotherapy increased survival (risk difference 6.5%; 95% CI: 3.1 to 9.9; OR 1.37; 95% CI: 1.24 to 1.5) and locoregional control (risk difference 7.9%; 95% CI: 1.9 to 13.9; OR 1.44; 95% CI: 1.28 to 1.63) and decreased the occurrence of distant metastases (risk difference –1.9%; 95% CI: -4.8 to 1.1; OR 0.79; 95% CI: 0.67 to 0.93). Subgroup analyses suggested that single-agent chemotherapy was particularly effective at increasing survival (risk

difference 12.1%; 95% CI: 5.0 to 19.0; OR 1.77; 95% CI: 1.51 to 2.1) but neoadjuvant chemotherapy was less effective (risk difference 3.7%; 95% CI: 0.9 to 6.5; OR 1.2; 95% CI: 1.04 to 1.35). Platinum/5-FU regimens were not statistically significantly effective at increasing survival (risk difference 10.1%; 95% CI: -4.7 to 25.0; OR 1.56; 95% CI: 0.81 to 2.99). A separate systematic review investigated acute and late radiation morbidity in 19 of the RCTs included in this review[5] and found that the addition of chemotherapy significantly enhanced both acute (OR = 2.86; 95% CI: 2.15 to 3.81) and late (OR = 1.82; 95% CI: 1.02 to 3.26) radiation morbidity effects.

A systematic review and meta-analysis using individual patient data on 10,741 patients from 63 trials[6] found no significant survival benefit associated with adjuvant or neoadjuvant chemotherapy, but a significant benefit of concomitant chemotherapy, although there was significant heterogeneity between the included trials. Overall the hazard ratio for death was 0.90 (95% CI: 0.85 to 0.94; $p<0.0001$), corresponding to an absolute survival benefit of 4% at two and five years.

In a systematic review of 17 RCTs of patients with newly diagnosed locally advanced nasopharyngeal cancer, patients treated with radiochemotherapy had significantly higher rates of disease-free survival than patients treated with radiotherapy alone (OR: 0.69; 95% CI: 0.54 to 0.87; p = 0.002; NNT = 13).[7] This was found for neoadjuvant chemotherapy (OR = 0.77; 95% CI: 0.59 to 0.99; p = 0.04; NNT = 17), concurrent chemotherapy (OR = 0.62; 95% CI: 0.45 to 0.86; p = 0.004; NNT = 10) and concurrent adjuvant chemotherapy (OR = 0.32; 95% CI: 0.11 to 0.95; p = 0.04; NNT = 4). Overall survival was found to be significantly improved with concurrent chemotherapy (OR = 0.42; 95% CI: 0.23 to 0.76; p = 0.004; NNT = 10) and concurrent adjuvant chemotherapy (OR = 31; 95% CI: 0.17 to 0.57; p = 0.0001; NNT = 6). However, the improvement in overall survival was not statistically significant when neoadjuvant chemotherapy was included in the analysis. Increases in treatment related deaths were found in one trial, which utilised an aggressive chemotherapy regimen. One trial reported significantly greater mucositis in

the radiochemotherapy arm, but no other significant differences were found in acute radiation toxicity.

The two systematic reviews investigating different fractionation schedules for patients with newly diagnosed, locally advanced head and neck cancer[8, 9] both focussed on a multi-arm RCT simultaneously comparing accelerated, hyperfractionated and conventionally fractionated regimens. The two-year loco-regional control rate was 48% for accelerated radiotherapy with a split course, 55% for accelerated radiotherapy with a concomitant boost, 54% for hyperfractionated radiotherapy and 46% for conventional treatment ($p = 0.05$ for conventional compared with accelerated treatment, $p = 0.045$ for conventional compared with hyperfractionated treatment). However, overall survival was not statistically different between the arms. In addition to this study, three RCTs reported statistically significant improvements in overall survival and loco-regional control between conventional and accelerated radiotherapy and most trials reported increased acute toxicity with accelerated radiotherapy compared with conventional radiotherapy.[8] The results of six trials of hyperfractionated versus conventional radiotherapy suggested that hyperfractionated radiotherapy was associated with increased mucosal and skin toxicity compared with conventional radiotherapy.[9] The other review which compared the effectiveness of hyperfractionated and conventionally fractionated radiotherapy for head and neck cancer patients[10] pooled survival data from three studies, which gave an odds ratio for death of 0.48 (95% CI: 0.40 to 0.58; $p < 0.0001$) for hyperfactionation, representing a statistically significant reduction in the risk of death. Patients treated with hyperfactionation were less likely to respond incompletely to treatment (OR = 0.43; 95% CI: 0.32 to 0.57; $p < 0.0001$) or to suffer local recurrence (OR = 0.35; 95% CI: 0.28 to 0.45; $p < 0.0001$).

The systematic review that compared the effectiveness of surgery with radiotherapy in the management of early glottic laryngeal cancer[11] reported that for patients with stage T1 tumours, five-year survival was 92% following radiotherapy and 100% following surgery and for T2 tumours five-year survival was 89% following radiotherapy and 97% following surgery. For

patients with stage T1 tumours the five-year disease free survival rate was 71% following radiotherapy and 100% following surgery and for T2 tumours the five-year disease free survival rate was 60% following radiotherapy and 79% following surgery. There was no statistically significant difference in survival between the two groups. These results should be interpreted with caution, given the poor quality of the study from which they originate.

Conclusions

The evidence suggests that concomitant chemotherapy increases survival and locoregional control for patients with head and neck cancer. No statistically significant survival benefit has been demonstrated with adjuvant or neoadjuvant chemotherapy, other than in a subgroup analysis which detected significantly improved survival with neoadjuvant chemotherapy using fluorouracil in combination with either cisplatin or carboplatin. The evidence relating to specific agents is contradictory with regard to the efficacy of platinum-based chemoradiation.

Patients with newly diagnosed locally advanced nasopharyngeal cancer treated with radiochemotherapy had significantly higher rates of disease-free survival than patients treated with radiotherapy alone. This was found for neoadjuvant chemotherapy, concurrent chemotherapy and concurrent adjuvant chemotherapy.

The use of concomitant chemotherapy has been found to significantly enhance both acute and late radiation morbidity effects.

In a large trial of patients with newly diagnosed, locally advanced head and neck cancer, two-year loco-regional control rates were higher in patients receiving accelerated radiotherapy with a concomitant boost or hyperfractionated radiotherapy than those receiving accelerated radiotherapy with a split course or conventional treatment. However, overall survival was not statistically different between the arms. Trials have reported increased acute toxicity with accelerated radiotherapy compared with conventional radiotherapy and hyperfractionated radiotherapy has been associated with

increased mucosal and skin toxicity compared with conventional radiotherapy. A reduction in the risk of death has been found in patients receiving hyperfractionated radiotherapy over those receiving conventional radiotherapy in one review; patients treated with hyperfactionation were less likely to respond incompletely to treatment or to suffer local recurrence.

In a larynx preservation trial patients allocated to a concomitant chemotherapy and radiotherapy group had significantly greater loco-regional control and laryngectomy preservation than patients allocated to neoadjuvant chemotherapy or radiotherapy alone. In another study patients who had been randomised to neoadjuvant chemotherapy in combination with radiotherapy scored significantly better in mental health and pain assessments than patients who had been randomised to surgery and radiotherapy.

b) Adherence to a treatment protocol and specified timescales

In the cohort study comparing 30 patients managed according to the clinical pathway and 64 non-pathway controls with 96 historical controls[12] the median length of hospital stay reduced from 4 days in the historical control group to 2 days in both the clinical pathway group and the non-pathway control group. The median total costs were reduced from $8,459 in the historical control group to $6,227 in the clinical pathway group and $6,885 in the non-pathway control group. However, there were serious methodological flaws in the study and the results should be interpreted with caution.

In the cohort study comparing 87 patients treated before the introduction of the clinical care pathway with 43 patients treated during the first year of the pathway and 82 patients treated in the third year of the pathway[13] the median length of hospital stay reduced from 13 days in the first group to 8 days in the latter two groups. The length of stay in the intensive care unit and length of stay following the intensive care unit were both statistically significantly reduced. The readmission rate, costs and serious adverse effects were lower in the patients treated in the third year of the pathway than either of the other two groups.

Conclusions

The results of two studies suggest that the introduction of a clinical care pathway reduced the average length of hospital stay and total costs.

c) Adherence to specified radiotherapy timescales

The systematic review of individual patient data[14] found that compliance with the prescribed radiation therapy schedule was relatively poor, with an agreement between overall and ideal treatment time in only 30% of cases; 7% completed treatment sooner than planned. In 5% of cases radiotherapy was protracted by 1 day, 9% by 2 days and in 27% more than 5 days. Patients treated in the conventional arms had a median excess time of 2.6 days, compared with 1.3 days for the altered fractionation arms. 87% of patients received the full prescribed dose of radiotherapy.

The reanalysis of data from two randomised controlled trials including 828 patients[17] found that only 278 patients received radiotherapy exactly as per their protocol. Their analysis identified a time factor of 0.8Gy per day as the extra dose required to counteract the reduction in tumour control probability with extension of the treatment time. Despite the theoretical nature of the calculations, the results appear to be valid.

The remaining four studies found that prolonged overall treatment time led to worse loco-regional control and disease-free survival.[15, 16, 18, 19] In the reanalysis of data from the CHART trial[18] patients receiving radiotherapy for 49 days or more (mean 51.5 days) had an increase in relative risk of death of 19% compared with patients receiving radiotherapy for 48 days or fewer (mean 45.7 days). When adjusted for factors collected before treatment, the increase in risk of death was 9%. There was a non-statistically significant increase in the hazard of local recurrence by 23% among patients whose therapy was prolonged. In the case control study[15] 12% of patients in the continuous course radiotherapy group and 17% of patients in the split course radiotherapy group had prolonged overall treatment time (treatment that extended more than 1 week beyond the schedule). Each day of interruption of

treatment was found to increase the hazard rate by 3.3% for loco-regional control and 2.9% for disease free survival. The case series' which used mathematical models to estimate the effect of gaps in radiotherapy treatment schedules found that a gap leading to an extension of treatment time by more than 3 days (179/629 patients) increased the hazard of local failure[16] and that elongation of the treatment time by 1 day or a gap of 1 day was associated with a decrease in local control rates at 2 years or more of 0.68% per day.[19] A significant decrease in the disease-free period with increasing gaps was found for one of the centres studied (p=0.0002).

Conclusions

The evidence suggests that compliance with prescribed radiotherapy schedules is poor and that prolonged overall treatment time my adversely affect locoregional control and disease-free survival rates.

d) Delays in initiating radiotherapy

From a total of 4 RCTs and 42 case series included in the review[20], 12 case series related to head and neck cancer. Of these five related to primary radiotherapy (n = 2,427) and seven to post-operative radiotherapy (n = 851).

Within the group of studies assessing primary radiotherapy, four studies were suitable for statistical pooling. Meta-analysis did not demonstrate a difference on local control rates in patients whose radiotherapy was initiated within 30 days of diagnosis and patients whose treatment started 30 days or more after diagnosis. A further study reported in the review suggested however, that those treated late had statistically significantly higher rates of local and regional failure. Details from the same study suggest that five-year survival was statistically significantly better in those treated earlier; five-year survival was 73% for those treated within 30 days, 62% for those treated from 31 to 40 days after diagnosis and 54% for those treated more than 40 days after diagnosis. The remaining included studies did not address survival.

Seven studies assessed the effects of delay on the local control rates of patients treated post-operatively. Patients whose treatment started within six weeks of their operation were compared to those whose treatment started later. A statistically significant association was found whereby those treated later had poorer local control. Heterogeneity was found in this group of studies and study quality was found to be a factor in this heterogeneity. A sensitivity analysis was conducted with the removal of the poorest quality studies leaving four higher quality studies. When these studies were meta-analysed, the pooled estimate still favoured those treated earlier. The result was still significant and no heterogeneity was seen. Two studies which could not bee pooled addressed survival rates in this group of patients. One found that patients treated 1 to 6 weeks after surgery had an actuarial five-year survival of 61%, those treated 7 to 8 weeks after their operation had a rate of 46% and those who waited longer had a 30% rate. The differences were statistically significant. In the second study, a non-statistically significant 7% difference was seen in patients treated with radiotherapy within or more than 30 days after surgery for pharyngeal cancer (35% compared to 28%).

Conclusions

Studies of delays in initiating treatment in patients being treated primarily with radiotherapy suggest that delays in initiating radiotherapy may adversely affect locoregional control rates. This is based on inconsistent results from studies, not all of which could be pooled. One study suggested that long-term survival was improved for those treated sooner.

Studies of delays in initiating treatment in patients being treated with post-operative radiotherapy indicate that delays in initiating radiotherapy adversely affect locoregional control rates. Two studies reported contradictory findings relating to long-term survival.

Insufficient information was presented in the review to identify an appropriate time-frame either from diagnosis to treatment initiation or from surgery to initiation of radiotherapy.

e) Interventions for the prevention and/or treatment of mucositis

The systematic review from the Cochrane collaborative[21] assessed 21 interventions, nine of which showed some evidence of a benefit for either preventing or reducing the severity of mucositis. For six separate interventions, there was more than one trial showing a significant difference compared with placebo or no treatment. Amifostine provided minimal benefit in preventing mucositis (RR 0.95, 95% CI: 0.91 to 0.99), antibiotic paste or pastille demonstrated a moderate benefit in preventing mucositis (RR 0.87, 95% CI: 0.79 to 0.97) and GM-CSF and ice chips prevented mucositis (RR 0.51, 95% CI: 0.29 to 0.91 and OR 0.42, 95% CI: 0.19 to 0.93 respectively). Hydrolytic enzymes reduced the severity of mucositis (RR 0.49, 95% CI: 0.30 to 0.81) and there was evidence from two small studies for a reduction in the severity of severe mucositis with allopurinal (OR 0.01, 95% CI 0 to 0.03). The three interventions showing some benefit in one study each were benzydamine oral care protocols and povidone. In order to prevent one patient experiencing mucositis over a baseline incidence of 60% for amifostine, 33 patients would need to be treated (95% CI: 20 to 100), for antibiotic paste or pastille 13 patients would need to be treated (95% CI: 8 to 50), for GM-CSF 3 patients (95% CI: 2 to 20) and for ice chips 5 patients (95% CI: 2 to 31).

The systematic review which included only head and neck cancer patients[22] pooled thirteen studies of patients who developed severe mucositis, as assessed by the clinicians and found a beneficial effect of prophylactic interventions compared with no active treatment (OR 0.64, 95% CI: 0.46 to 0.88). When only the 9 higher quality studies were pooled the finding was still statistically significant (OR 0.68, 95% CI: 0.48 to 0.96). The use of prophylactic antibiotics showed a significant beneficial effect in five studies (OR 0.47, 95% CI: 0.25 to 0.92). This was made up of results from broad-spectrum antibiotics (three studies) and narrow-spectrum antibiotics (two studies) (OR 0.52, 95% CI: 0.14 to 1.98 and OR 0.45, 95% CI: 0.23 to 0.86 respectively). When the studies of patients who developed severe mucositis, as assessed by the patients, were pooled, the beneficial effect of prophylactic

interventions compared with no active treatment was not statistically significant.

In the systematic review of amifostine treatment[23] data from four studies that reported standard outcome measures (Radiation Therapy Oncology Group (RTOG) and World Health Organisation (WHO) acute and late scoring criteria) were pooled and showed no significant difference in mucositis scores between patients receiving amifostine and those not receiving amifostine (OR 0.11, 95% CI: 0.01 to 1.26, p=0.08). However, a subgroup analysis of two studies showed that amifostine was beneficial in patients undergoing radiochemotherapy (OR 0.03, 95% CI: 0.00 to 0.83, p=0.04). The results also indicated that amifostine does not affect the anti-tumour effectiveness of radiotherapy with or without concurrent chemotherapy with carboplatin. Nausea, vomiting, hypotension and allergic reactions were the most commonly reported adverse effects associated with amifostine, but they were rarely severe. Patients treated with amifostine compared to those that were not, had significantly better quality of life scores at one, seven and eleven months.

Conclusions

The evidence relating to head and neck cancer patients suggests that the use of prophylactic narrow-spectrum antibiotics is beneficial for preventing severe oral mucositis in patients receiving radiotherapy. Amifostine was beneficial in patients undergoing radiochemotherapy, without affecting the anti-tumour effectiveness of radiotherapy and rarely severe adverse effects, but it was not found to significantly benefit head and neck cancer patients undergoing radiotherapy.

In patients with different types of cancer, ice chips and GM-CSF prevented mucositis and antibiotic paste or pastille and amifostine provided moderate and minimal benefits in preventing mucositis, respectively. Hydrolytic enzymes reduced the severity of mucositis, as did allopurinal, although the evidence for the latter was unreliable.

f) Interventions to reduce the severity of the symptoms of xerostomia

Two systematic reviews investigating the use of pilocarpine hydrochloride for radiation-induced xerostomia in patients with head and neck cancer found statistically significant differences in favour of pilocarpine treatment groups compared with placebo or artificial saliva.[24, 25] In one review, patients reported improvements in a number of areas such as oral dryness oral comfort, chewing and the ability to speak without requiring liquids.[24] Two studies appeared to show a time-dependent drug-related benefit, with patients reporting increased improvements after several weeks of pilocarpine treatment. No severe or life threatening adverse effects were reported in any of the studies. Adverse effects included sweating, urinary frequency, headache, rhinitis and abdominal cramping. In two studies, systemic doses over 5 mg appeared to produce increased side effects, adverse events affected about one-quarter of patients taking 5mg three times per day and about one-half of patients taking 10mg. One of the reviews included a randomised cross-over study comparing pilocarpine with artificial saliva.[25] On a visual analogue scale patients favoured pilocarpine, although this finding was not statistically significant.

In the systematic review of amifostine treatment[23] data from three studies that reported standard outcome measures (Radiation Therapy Oncology Group (RTOG) and World Health Organisation (WHO) acute and late scoring criteria) were pooled and suggested that amifostine was beneficial in acute xerostomia (OR 0.10, 95% CI: 0.02 to 0.48, P=0.004; X^2=6.87, d.f.=2, P=0.032) and late xerostomia (OR 0.19, 95% CI: 0.05 to 0.64, P=0.008; X^2=5.32, d.f.=2, P=0.07) but that significant heterogeneity existed between studies. The results also indicated that amifostine does not affect the anti-tumour effectiveness of radiotherapy with or without concurrent chemotherapy with carboplatin. Nausea, vomiting, hypotension and allergic reactions were the most commonly reported adverse effects associated with amifostine, but they were rarely severe. Patients treated with amifostine compared to those that were not, had significantly better quality of life scores at one, seven and eleven months.

Conclusions

Pilocarpine hydrochloride and amifostine were found to significantly reduce the effects of radiation-induced xerostomia in patients with head and neck cancer. Adverse effects of both agents were common, but not severe or life threatening. However, these conclusions should be interpreted with caution owing to the lack of methodological data reported in two of the reviews and possible heterogeneity between included studies.

Table 5a: Relative efficacies of treatment modalities

Study details and Aims	Inclusion/exclusion criteria	Methods	Results	Comments
Browman, 2000.[1, 2] **Country:** Canada **Aims:** To assess if the addition of concomitant chemotherapy to radiotherapy improves survival with acceptable toxicity, for patients with locally advanced Stage III or IV squamous cell head and neck cancer in whom radiotherapy is considered the initial curative modality. **Grade of evidence:** I	**Study design:** Only RCTs, systematic reviews and meta-analyses of RCTs were considered. Only studies that analysed the data using an 'intention-to-treat' approach were included. **Participants:** Only studies of patients with Stage III or IV squamous cell carcinomas of the head and neck region without distant metastases were considered for inclusion. Studies that included more than 20% of patents with nasopharynx cancer were excluded. No information was presented on the participants of the included studies. **Intervention:** All forms of concomitant schedules of CT with RT were considered for inclusion in the review. An adequate dose of RT had to be used in both arms (equivalent to at least 65Gy total dose to the primary lesion). Studies that included CT in both the randomised and control arms were excluded, as were studies involving the use of radiation sensitising agents that were not antineoplastic. The types of CT used in the included studies were: 5-fluorouracil (5FU); infusional 5FU; bleomycin; bleomycin in combination with methotrexate; methotrexate in combination with leucovorin; cisplatin (CP); CP in combination with bleomycin; CP in	**Sources searched:** MEDLINE (from 1970 to March 2000), CANCERLIT (from 1983 to February 2000), HealthSTAR (from 1975 to February 2000), the Cochrane Library (Issue 1, 2000) and relevant conference proceeding were searched. The search strategy included a combination of the Medical subject Headings (MeSH) 'Head and neck neoplasms' and 'combined modality therapy'; the text-words 'concomitant or combined', 'radiotherapy', 'chemotherapy', 'surgery', 'malignant neoplasms'; and search terms relating to the study design, i.e. RCTs, systematic review, meta-analysis, double blind method, practice guideline and review. Additional trials were identified from the citation lists of relevant studies and from the personal files of oncologists. The PDQ database was also searched. **Quality assessment:** The authors do not state how included studies were assessed for validity or how many of the reviewers performed the validity assessment. **How studies were combined:** The studies were pooled using a random-effects model. The pooled results were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). The absolute risk difference between the groups and the relative risk (RR) of death were also calculated where appropriate. The studies were also pooled according to the following stratifications: (1) the RT fraction schedule used in the control arm, i.e. conventional continuous versus non-conventional; (2) whether the RT schedules in the control and experimental arms were the same; and (3) whether the CT regimen used was single agent versus multiple agent and platinum-containing CP versus others. Differences between the studies were discussed in the text and investigated statistically (statistical test used not stated), along with a graphical presentation (forest plot) of	The present review located 4 previous systematic reviews of concomitant RT in combination with CT treatment. An additional systematic review showed that concomitant therapy produced more adverse effects than RT alone. **Efficacy:** 3 of the 4 included systematic reviews detected an overall survival benefit for concomitant RT in combination with CT treatment. The additional systematic review showed that concomitant therapy produced more adverse effects than RT alone. The pooled analysis of all trials (18 RCTs, 20 comparisons, n = 3,192) showed a reduction in mortality for concomitant RT in combination with CT therapy, compared with RT alone: the OR was 0.62 (95% CI: 0.52, 0.74, $p < 0.00001$), the RR was 0.83 and the risk difference was 11%. The benefit remained roughly consistent across most of the subgroups. Concomitant RT in combination with CT therapy produced more acute adverse effects than RT alone. **Subgroup analysis of RT schedules:** Same RT schedule in both treatment groups (16 RCTs with 17 comparisons, n = 2,700): the OR was 0.62 (95% CI: 0.52, 0.75, $p < 0.00001$) and the risk difference was 10.7%. Conventional fractionation RT in both treatment groups (12 RCTs with 13 comparisons, n = 2,133): the OR was 0.66 (95% CI: 0.52, 0.83, $p = 0.00041$) and the risk difference was 9.2%. Same non-conventional RT in both treatment groups (4 RCTs, n = 567): the OR was 0.51 (95% CI: 0.36, 0.71, $p = 0.00008$) and the risk difference was 16.6%. Conventional RT in control group only (3 comparisons, n = 492): the OR was 0.58 (95% CI: 0.31, 1.09, $p = 0.093$) and the risk difference was 12.5%. **Subgroup analysis of CT:**	**Authors' conclusions:** Platinum-based CT and RT is superior to conventional RT alone on improving survival in locally advanced squamous cell head and neck cancer. Subgroup analyses can be used to help choose the most appropriate concomitant regimen. **Comments:** Pre-specified inclusion and exclusion criteria were clearly reported. Information about the methodology of the review process was not presented. The search strategy was fair but the addition of EMBASE could have improved the geographical coverage of the search. The information presented on the included studies, e.g. the specific CT and RT regimens used and details of the included participants, was limited. While the review only included RCTs, the validity of these studies was not investigated. The authors used a random-effects model to compensate to some degree for the questionable comparability across the trials. Bearing in mind the clinical diversity between the studies, it might have been preferable to only pool the results of studies looking at similar interventions.

	combination with infusional 5FU; CP in combination with infusional 5FU and leucovorin; mitomycin C (MMC); MMC in combination with infusional 5FU; MMC in combination with bleomycin; carboplatin; and carboplatin in combination with infusional 5FU. The type of RT schedules used were conventional, accelerated, hyperfractionated or split-course. **Outcome:** Only studies that reported mortality as an outcome measure were included. Information relating to the toxicity profiles of the included platinum-based CT studies was also presented in the results.	the results of the individual studies. A sensitivity analysis was performed with and without the inclusion of a study (n = 319 evaluable patients) that had not yet published detailed mortality data.	Platinum-based CT (10 comparisons, n = 1,514): the OR was 0.57 (95% CI: 0.46, 0.71, $p \leq 0.00001$) and the risk difference was 12.1%. MMC-based CT (4 comparisons, n = 522): the OR was 0.54 (95% CI: 0.30, 0.95, p = 0.032) and the risk difference was 14%. FU-based CT (3 comparisons, n = 535): the OR was 0.66 (95% CI: 0.39, 1.10, p = 0.11) and the risk difference was 10.2%. Bleomycin-based CT (5 comparisons, n = 641): the OR was 0.80 (95% CI: 0.50, 1.29, p = 0.36) and the risk difference was 5% **Heterogeneity:** A formal statistical test for heterogeneity across all trials was not significant for the calculation of the OR ($p > 0.10$), but it was significant for calculation of the overall risk difference ($p < 0.05$). A statistical test for heterogeneity across the platinum-based CT trials was not significant, despite some differences in the baseline risk across the studies. **Cost:** No cost information was reported.	
Browman, 2003.[3] **Country:** Canada **Aims:** To assess the role of neoadjuvant chemotherapy for patients with locally advanced squamous cell head and neck cancer, other than nasopharyngeal cancer. **Grade of evidence:** I	**Study design:** RCTs of neoadjuvant chemotherapy prior to local treatment with conventional radiation and/or surgery versus local treatment alone as the control. Abstracts published in 1994 or later were included if their data could be extracted for analysis. **Participants:** Only studies of patients with squamous cell carcinomas of the head and neck region without distant metastases were considered for inclusion. Studies where a significant fraction of patients had nasopharynx cancer were excluded. No information was presented on the participants of the included studies. Trials were excluded if they concerned recurrent or metastatic disease or patients	**Sources searched:** MEDLINE search was done for the years 1980 to January 2003 using the subject heading 'head and neck neoplasms' in combination with the text words 'chemotherapy' or 'neoadjuvant' or 'adjuvant' and the publication type 'randomised controlled trials', 'meta-analysis' and 'clinical trials' were added as publication types. A CANCERLIT database search (to October 2002) and a Cochrane Library (Issue 4, 2002) search were also conducted. The Physician Data Query (PDQ) database, clinical trial and practice guideline Internet sites, abstracts published in the proceedings of the annual meetings of the American Society of Clinical Oncology (1999 to 2002), the American Society for Therapeutic Radiology and Oncology (1999 to 2002) and the European Society for Medical Oncology (1998, 2000). Article bibliographies and personal files were also searched to November 2002.	**Number of studies:** 3 reviews and 23 primary studies were located. Data from a number of the primary studies were found to be included in the most rigorous systematic review (which used individual patient data pooling as opposed to statistical pooling of published results) and were not considered separately. 3 additional primary studies were located. **Efficacy:** A meta-analysis using individual patient data from 31 RCTs (5,269 patients) demonstrated no significant survival benefit for neoadjuvant chemotherapy compared with locoregional treatment alone (HR = 0.95; 95% CI, 0.88 to 1.01; p = 0.10). However, a subgroup analysis of 15 RCTs (2,487 patients) detected significantly improved survival with neoadjuvant chemotherapy using fluorouracil in combination with either cisplatin or carboplatin (hazard ratio, 0.88; 95% CI, 0.79 to 0.97; $p < 0.05$). Individual patient data from 3 RCTs of larynx-preservation versus surgery were pooled in a separate analysis (602 patients). The hazard ratio for death, though non-significant, favoured surgery	**Authors' conclusions:** Neoadjuvant chemotherapy should not be used in the routine management of patients with locally advanced squamous cell carcinoma of the head and neck if the main objective is improved survival. **Comments:** Pre-specified inclusion and exclusion criteria were clearly reported and the literature search was acceptable but could have included other databases such as EMBASE. Inclusion of non-English studies would have been beneficial. Information about the methodology of the review process was not presented. The information presented on the treatment regimens used and details of the included participants, was limited. While the review only included RCTs and systematic

	had been previously treated. **Intervention:** Studies were excluded if chemotherapy was not the first modality used, if the control arm did not use conventional radiotherapy with or without surgery, if chemotherapy was used either with alternating or concurrently with radiation or if intra-arterial chemotherapy was used. **Outcome:** An inclusion criterion relating to outcomes was not reported. Outcomes in included studies were reported in terms of the odds ratio (OR) with 95% confidence intervals.	The search was restricted to English language publications. **Quality assessment:** The authors do not state how included studies were assessed for validity or how many of the reviewers performed the validity assessment. **How studies were combined:** The primary results were obtained from a published pooled analysis using individual patient data which included the other studies located by the review.	over larynx preservation (HR = 1.19, 95% CI, 0.97 to 1.46; p = 0.10). 2 additional RCTs found no significant survival benefit from the addition of neoadjuvant chemotherapy. An RCT, in abstract form compared 547 patients allocated to neoadjuvant chemotherapy, radiotherapy alone or concomitant chemotherapy and radiotherapy in a trial of larynx preservation. There were no significant differences in 5-year overall survival (~75% vs. ~75%; p = not reported), loco-regional control (61% versus 56%; p = not reported) or number of laryngectomies (43 versus 49; p = not reported) between patients randomised to neoadjuvant therapy or to radiotherapy alone. Patients allocated to the concomitant treatment arm had similar overall survival, but significantly greater loco-regional control and laryngectomy preservation than patients in the other 2 treatment arms. **Quality of life:** Of 76 survivors who had had participated in the Veterans Affairs Laryngeal Cancer Study, 46 completed health status assessment instruments, including a validated head and neck cancer-specific quality of life questionnaire (HNQOL). Of the 46 respondents, 21 had been randomised to neoadjuvant chemotherapy in combination with radiotherapy and 25 to surgery and radiotherapy. Scores on the mental health and pain domains were significantly better for patients randomised to neoadjuvant chemotherapy and radiation compared with patients randomised to surgery and radiation ($p < 0.05$). **Cost:** No cost information was reported.	reviews and the primary results derive from one of those reviews, the validity of these studies was not investigated and few details were reported about them.
Dey, 2003.[11] **Country:** UK **Aims:** To compare the effectiveness of open surgery, endolaryngeal excision (with or without laser) and	**Study design:** RCTs which compared open surgery, endolaryngeal resection and/or radiotherapy were included. Trials which compared different radiotherapeutic techniques were not considered. Trials which were primarily a comparison of treatments for advanced laryngeal cancer were also excluded. Trials with a radiotherapy arm were only included when patients were predominantly recruited from 1980	**Sources searched:** An electronic search was performed in MEDLINE from 1966 to October 2000 for abstracts in any language. The following search strategy was used: 'cancer', 'precancer', 'malignancy', 'premalignancy', 'neoplasm', 'carcinoma', 'dysplasia', 'tumour', 'larynx', 'vocal-cord', 'glottis', 'laryngeal-neoplasm', 'radiotherapy', 'laser', 'surgery', 'radiation therapy', 'cordectomy', 'laryngectomy', 'hemilaryngectomy', 'vocal cord stripping', 'excision biopsy', 'endoscopy', 'endolaryngeal', 'transoral', 'randomised controlled trials', 'controlled clinical trials', 'random allocation', 'double blind method', 'single blind	**Number of studies:** Of 3 studies which initially appeared to fit the inclusion criteria, the authors could only include one study (in one study for reasons of the intervention being studied and in the second the low proportion of patients in the study with the stage of disease of interest to the review). **Mortality:** 5 year survival rates are presented for each tumour stage (T1 and T2) for patients with glottic cancer. The number of events and the number of patients at risk in each arm at each specified time point are not presented. For T1 tumours, the 5 year survival was 91.7%	**Authors' conclusions:** There is no good evidence available from RCT to guide treatment choice for patients with early stage glottic cancer of the larynx. **Comments:** This review was well conducted and addressed an appropriate question using well-defined inclusion and exclusion criteria for the participants, intervention and study design. The search for relevant

radiotherapy in the management of early glottic laryngeal cancer. **Grade of evidence:** I	onwards because of concerns that regimens prior to that date may have been suboptimal. **Participants:** The study population was limited to patients diagnosed with early squamous cell carcinoma of the glottic larynx following laryngoscopy and biopsy. Early stage tumours were defined as carcinoma in situ (Tis) or invasive cancers confined to the vocal cords or with supraglottic or subglottic extension without cord fixation or nodal metastases (T1 to T2, N0). **Intervention:** Open surgery, endolaryngeal excision (with or without laser), radiotherapy. **Outcome:** Different modalities of treatment were compared using the following outcome measures: mortality - survival at 5 years; morbidity - post-treatment complications (bleeding, mucositis, necrosis, weight loss), immediate and delayed; voice quality - at 1 year; recurrence of disease - at 5 years; quality of life - at 1 year; and cost.	method' and 'randomised trials'. This was replicated for CINAHL (from 1982), EMBASE (from 1980) and CANCERLIT (from 1963). The Cochrane Controlled Trials Register was also searched using the above terms. The reference lists of retrieved review articles were scanned to identify other trials and the authors wrote to a number of researchers who had published in this area. A hand search was conducted of the Proceedings of the 2nd World Congress on Laryngeal Cancer and the 5th International Conference for Head and Neck Cancer for abstracts of and references to, other relevant studies. **Quality assessment:** An adaptation of the method used by the Cochrane Collaboration Musculoskeletal Injuries Group was used to assess methodological quality and studies were scored according to whether they met the following criteria: adequate concealment prior to allocation; description or analysis of withdrawn patients; blinding of the assessor(s) to the treatment status; comparability the treatment and control groups on entry; clear definition of the inclusion and exclusion criteria; clear definition of the interventions; clear definition of the outcome measures used; clinical usefulness of the diagnostic tests used in outcome assessment and clinical appropriateness of the duration of surveillance. **How studies were combined:** Studies were combined in a narrative synthesis.	following radiotherapy and 100% following surgery and for T2 tumours, 88.8% following radiotherapy and 97.4% following surgery. There are no significant differences in survival between the 2 groups. **Recurrence rates:** 5 year locoregional recurrence rates are presented for each tumour stage for patients with glottic cancer. Again the number of events and the number of patients at risk in each arm at each specified time point are not presented. There is some inconsistency in the text regarding the number of locoregional recurrences in the whole group. For T1 tumours, the 5 year disease free survival rate was 71.1% following radiotherapy and 100% following surgery and for the T2 tumours, 60.1% following radiotherapy and 78.7% following surgery. Only the latter comparison is statistically significant (chi 1.8 p = 0.036) but statistical significance would not have been achieved for a 2-sided test. **Quality:** The method of randomisation appeared to be weak. The total number of patients randomised to each treatment arm is not provided and data are not available on the baseline characteristics of treatment groups at study entry. The number of patients evaluated in each group is unbalanced; 76 were allocated surgery but 129 allocated radiotherapy. There is no evidence that the trial was designed with 2:1 allocation but the authors do admit that follow-up was poor and the imbalance may be owing to differential follow-up. The number of patients with glottic cancer evaluated in each arm is not provided. The method of diagnosis and pre-operative staging is not detailed but the investigators suggest that patients had been inadequately staged before treatment. The reviewers were concerned that surgical interventions had not been standardised and that radiotherapy regimens may be suboptimal; patients received gamma irradiation suggesting the use of cobalt units and neither treatment volume nor technique are reported. Outcome was not assessed blind and no detail is provided on how and when this was performed. The number of patients in each arm available for outcome evaluation at specified time points is not available. Survival is compared using a Mantel Haensel test and the chi statistic at 1 degree of freedom is reported at the one-sided 5% significance level. **Cost:** No cost information was reported.	trials was comprehensive and included efforts to retrieve unpublished material. The validity of the included study was assessed fully and the results of the assessment were incorporated into the review. Adequate details of the study were presented. The authors' conclusions appear justified by the paucity of evidence on this subject and the low methodological quality of the located study.

Henk, 1997.[5] **Country:** UK **Aims:** To review the trials of simultaneous chemotherapy with radiotherapy in a pre-existing published systematic review for data concerning both acute and late radiation morbidity. **Grade of evidence:** I	**Study design:** RCTs were included. **Participants:** People with head and neck cancer of any type. **Intervention:** Comparisons of simultaneous chemotherapy and radiotherapy with radiotherapy alone. 3 RCTs were of multi-agent and 16 of single-agent chemotherapy. In 17 RCTs, the same dose of radiotherapy was given with and without chemotherapy; in the other 2, an effectively lower radiation dose was given in the chemotherapy arm. The chemotherapy agents used were: cisplatin, methotrexate, bleomycin, mitomycin C, fluorouracil, hydroxyurea, 'multiple', mitomycin C in combination with fluorouracil, cisplatin in combination with fluorouracil and mercaptopurine. **Outcome:** Acute and late radiation toxicity, including acute mucositis, bone necrosis, soft tissue necrosis and fibrosis, were assessed.	**Sources searched:** All the RCTs from the published systematic review which investigated synchronous chemotherapy and radiotherapy for head and neck cancer, were included. In the original review, MEDLINE and the PDQ clinical trials database were searched between 1963 and August 1993. Relevant textbooks and the proceedings of the American Society of Clinical Oncologists were searched from 1979 to 1993. If the same data had been published more than once, the most recent data were used. **Quality assessment:** Not reported. **How studies were combined:** The pooled ORs and 95% confidence intervals (CIs) were calculated using the Mantel-Haenszel fixed-effects method. The author states that in a trial in which there is a difference in survival between the 2 arms, the method of calculating late-effect morbidity will tend to underestimate the relative risk in the arm with the lower survival. However, in most of the RCTs, the survival differences were small. Statistical heterogeneity was investigated using the χ^2 test.	**Number of studies:** 19 RCTs (n = 2,926) were included. The pooled OR for acute mucosal morbidity in RCTs using the same radiotherapy dose in both arms was 2.86 (95% CI: 2.15, 3.81). There was significant heterogeneity in this result ($\chi^2 = 24.5$, $p < 0.001$); the author states this reflects the different drugs and dosages used in the various RCTs. **Toxicity:** The pooled OR for late effects in RCTs using the same radiotherapy dose in both arms was 1.82 (95% CI: 1.02, 3.26; $p < 0.05$). There was no significant heterogeneity in this result ($\chi^2 = 4.5$). The author states that bleomycin appears to have the greatest enhancing effect on both acute and late radiation toxicity (although the late toxicity result was not statistically significant). **Cost:** No cost information was reported.	**Authors' conclusions:** It was found that chemotherapy significantly enhanced both acute and late radiation morbidity effects, suggesting that the chemotherapy drugs may be merely dose-modifying. Future trials should be designed to determine whether or not chemotherapy improves the therapeutic ratio. **Comments:** The review question and the study selection criteria were clear as they related to the previous review. The search carried out for the previous review[4] was reasonably comprehensive, but may have benefited from the inclusion of other databases such as EMBASE. (Full details of the review which this study supplements are given elsewhere in this table.) The review from which the included studies were taken was published 2 years previously; it is unclear whether other relevant RCTs had been published in the meantime, although it was not the stated objective of this review to update the previous review. No validity assessment was performed and no attempt was made to obtain unpublished data, which may have led to an approximation of the data in some cases and, therefore, inaccuracies in the results. No details of the review process were given although, with only one author, it is likely that only one reviewer was involved. Pooling of the results seems appropriate with regard to the stated review objective. However, it should be noted that when pooled ORs are calculated for each chemotherapy agent, rather than all together, none show a significant increase in late radiation morbidity and 2 (cisplatin and mitomycin C) do not show a significant increase in acute radiation morbidity.

				The author's conclusions should be treated with caution owing to these observations and while the results of further research, preferably on an individual patient basis, are awaited.
Mackenzie, 2003.[8] **Country:** Canada **Aims:** To determine if accelerated radiotherapy improves loco-regional control or survival compared with conventionally fractionated radiotherapy in patients with newly diagnosed, locally advanced (Stage III to Stage IV) squamous cell carcinoma of the head and neck who are deemed suitable for radiotherapy with curative intent. **Grade of evidence:** I	**Study design:** RCTs and meta-analyses of RCTs. **Participants:** Patients with newly diagnosed, locally advanced (Stage III to Stage IV) squamous cell carcinoma of the head and neck who are deemed suitable for radiotherapy with curative intent. **Intervention:** Accelerated radiotherapy with a control arm using conventional radiotherapy (daily Monday to Friday). 3-arm RCTs investigating the addition of chemotherapy or radiosensitisers were eligible if there was a comparison of accelerated radiotherapy versus conventional treatment and relevant and complete information could be extracted. Forms of acceleration used in included studies included rapid acceleration (giving standard doses of radiotherapy in 4 as opposed to 7 weeks) and modest acceleration (giving standard doses of radiotherapy in 5 to 6 as opposed to 7 weeks). **Outcome:** Overall survival and loco-regional control were the primary outcomes of interest. Change in the therapeutic ratio comparing benefits to toxicity was also considered.	**Sources searched:** MEDLINE (1966 to October 2002), CANCERLIT (1983 to September 2000), the Physician Data Query database and the Cochrane Library (Issue 3, 2002) were searched. No language restrictions were applied. Medical subject Headings (MeSH) "Head and neck neoplasms" and "carcinoma, squamous cell" were combined with Mesh terms "fractionation", "dose fractionation", "radiotherapy dosage" and the text word "accelerated". These terms were then combined with the search terms for the following study designs or publication types: practice guidelines, meta-analyses, RCTs. The citation lists of all retrieved articles were reviewed to identify additional RCTs. The proceedings of the 1999 annual meeting of the American Society of Clinical Oncology (ASCO) and the American Society for Therapeutic Radiology and Oncology (ASTRO) were searched for reports of new RCTs. **Quality assessment:** Not stated. **How studies were combined:** The results for survival and loco-regional control were pooled in separate analyses. The random effects model was used. Results were expressed as risk ratios (RR) with 95% confidence intervals.	**Number of studies:** 11 RCTs (with 12 comparisons) of accelerated radiotherapy compared with conventional radiotherapy were included. **Efficacy:** The authors report that one study deserves special attention. This was the only multi-arm RCT to give a simultaneous comparison of accelerated, hyperfractionated and conventionally fractionated regimens. The 2-year loco-regional control rate was 47.5% for accelerated radiotherapy with a split course, 54.4% for accelerated radiotherapy with a concomitant boost and 46% for conventional treatment ($p = 0.05$ for congenital compared with accelerated treatment). Overall survival not statistically different between the arms; 46.2% for accelerated radiotherapy with a split course, 50.9% for accelerated radiotherapy with a concomitant boost and 46% for conventional treatment ($p > 0.05$ for conventional compared with accelerated treatment). A second meta-analysis published in abstract form was conducted using Individual Patient Data (IPD) methods was located but it was unclear which RCTs were included in this study. The hazard ratio for death was 0.96 and for loco-regional failure was 0.80, but confidence limits for this statistics were not reported. When the review was initially conducted, 8 RCTs (including 2 published as abstracts) investigated rapid acceleration and 4 RCTs (including 2 published as abstracts) investigated modest acceleration. Full reports from 3 RCTs, located when the review was updated, confirmed the statistical significance of improvements in overall survival and loco-regional control between conventional and accelerated radiotherapy. **Quality of life:** An abstract presentation, subsequent to the full publication of the multi-arm study discussed above, reported that patients having accelerated radiotherapy had "worse diet, eating and speech" at 1 year but gave no additional details.	**Authors' conclusions:** This group of patients should be considered for concomitant chemotherapy and conventional radiation. It would be reasonable to offer modestly accelerated radiotherapy to patients with locally advanced (Stage III and IV) disease who are not candidates for concomitant chemotherapy and conventional radiation. Rapid acceleration of radical radiotherapy cannot be recommended as standard therapy. Although the improvements in loco-regional control and survival are promising, longer follow-up and more complete information on late complications will be needed to meaningfully compare these results to those achieved with concomitant chemoradiation in locally advanced squamous cell carcinoma of the head and neck region. **Comments:** This review supports an evidence-based practice guideline and has been updated 2 years after its original publication. Some, but not all of the evidence base has been re-assessed for the updated review. This appears to be a fairly good quality review. Pre-specified inclusion and exclusion criteria were clearly reported. The literature search was fairly comprehensive but the reporting of the search terms was limited. Few details of the review process were presented.

			Significant improvements with accelerated radiotherapy in some domains of quality of life, measured by the Rotterdam Symptom Checklist were seen in 1 included study. Domains included coughing ($p = 0.006$), hoarseness ($p < 0.001$), sexual interest ($p = 0.012$) and sore muscles ($p = 0.010$) with continuous hyperfractionated acceleration radiotherapy (CHART) than with conventional radiotherapy. However, more patients on CHART experienced moderate or severe pain at day 21 (63% vs. 39% on conventional RT, $p < 0.0001$). There were no significant differences between CHART and conventional radiotherapy on measures of anxiety and depression, measured with the Hospital Anxiety and Depression Scale (HADS). **Toxicity:** Increased acute toxicity with accelerated radiotherapy compared with conventional radiotherapy was reported in most trials; some reports gave no details of the effects seen. **Cost:** No cost information was reported.	While the information presented on the included studies was fair, no details about the methodological quality of studies were provided. As an example, the review only included RCTs and meta-analyses of RCTs but the validity of these studies was not discussed. The first edition of this report included a meta-analysis of the then-included studies. However, this was not re-done to include updated results research identified when the review was updated. As the pooled estimates derived from the first edition of the review represent an incomplete dataset, they have not been included in this summary report. Notwithstanding these criticisms, the authors' conclusions appear to follow from the results presented.
Mackenzie, 2003.[9] **Country:** Canada **Aims:** To assess if hyperfractionated radiotherapy improves loco-regional control or survival compared with conventionally fractionated radiotherapy in patients with newly diagnosed, locally advanced (Stage III to Stage IV) squamous cell carcinoma of the	**Study design:** RCTs and meta-analyses of RCTs. **Participants:** Patients with newly diagnosed, locally advanced (Stage III to Stage IV) squamous cell carcinoma of the head and neck who are deemed suitable for radiotherapy with curative intent. **Intervention:** Hyperfractionated radiotherapy with a control arm using conventional radiotherapy (daily Monday to Friday). Three-arm trials investigating the addition of chemotherapy or radiosensitisers were eligible if there was a comparison of hyperfractionated radiotherapy versus conventional treatment and relevant and complete information could be extracted.	**Sources searched:** MEDLINE (1966 to January 2003), CANCERLIT (1983 to October 2002), the Physician Data Query database, the Canadian Medical Association Infobase, the National Guideline Clearinghouse and the Cochrane Library (Issue 4, 2002) were searched. No language restrictions were applied. The Medical Subject Headings (MeSH) 'Head and neck neoplasms' and 'carcinoma, squamous cell' were combined with Mesh terms 'fractionation', 'dose fractionation', 'radiotherapy dosage' and the text word 'hyperfraction'. These terms were then combined with the search terms for the following study designs or publication types: practice guidelines, meta-analyses, RCTs. The citation lists of all retrieved articles were reviewed to identify additional RCTs. The proceedings of the 1997 to 2002 annual meetings of the American Society of Clinical Oncology (ASCO) and the American Society for Therapeutic Radiology and Oncology (ASTRO; 1999 to 2002) were searched for reports of new RCTs. The personal files of the researchers were also searched.	**Number of studies:** 7 RCTs (two reported in abstract form) of hyperfractionated radiotherapy compared with conventional radiotherapy were included. There was a total of 2,925 patients. **Efficacy:** The authors report that the best evidence comes from 1 large well-conducted study. Evidence originating in other studies was presented in tables accompanying the report and did not contradict this large study. This multi-arm trial giving a simultaneous comparison of accelerated, hyperfractionated and conventionally fractionated regimens was located. The 2-year loco-regional control rate was 54.4% for hyperfractionated radiotherapy and 46% for conventional treatment ($p = 0.045$). Overall survival was not statistically different between the arms; 54.5% at two years for those treated with hyperfactionation and 46.1% for conventionally treated patients ($p > 0.05$). The results of a published meta-analysis of RCTs of hyperfractionated radiotherapy were reported, but this pooled analysis was weakened by the methodological problems inherent	**Authors' conclusions:** Hyperfractionated radiotherapy yields higher rates of acute toxicity compared with conventional radiotherapy (one fraction per day, five days per week). Data on the incidence and severity of late complications associated with hyperfactionation are incomplete. It is premature to conclude that hyperfactionation with dose escalation does not increase late tissue complications. Conclusions regarding loco-regional control are limited by the quality of the published data. **Comments:** Pre-specified inclusion and exclusion criteria were clearly reported. The literature search was fairly comprehensive but the reporting of the search terms was limited. Few details of the review process

head and neck who are deemed suitable for radiotherapy with curative intent. **Grade of evidence:** I	**Outcome:** Overall survival and loco-regional control were the primary outcomes of interest. Change in the therapeutic ratio comparing benefits to toxicity was also considered.	**Quality assessment:** Not stated. **How studies were combined:** The authors reported that owing to the small number of trials with complete information and the methodological flaws in a number of the studies, they opted to provide a descriptive analysis and not to pool data from included studies.	in several of the studies. A second meta-analysis published in abstract form conducted using Individual Patient Data (IPD) methods was located but it was unclear which RCTs were included in this study. The hazard ratio for death was 0.78 and for loco-regional failure was 0.76, but confidence limits for this statistics were not reported. **Quality of life:** An abstract presentation subsequent to the full report of the multi-arm trial mentioned above, reported that quality of life was "related to the intensity of RT" but gave no additional details. **Adverse effects:** Data on acute mucosal and/or skin toxicity were available from 6 trials of hyperfractionated versus conventional radiotherapy and these suggested that hyperfractionated radiotherapy was associated with increased mucosal and skin toxicity compared with conventional radiotherapy. Data were often incompletely reported; for example the p-values or confidence intervals were omitted. The number of patients analysed in the assessment of toxicities was not reported in the review. **Cost:** No cost information was reported.	were presented. The summary indicates that clinicians and methodologists were involved in the review but their respective roles was not clear. While the information presented on the included studies was fair, no details about the methodological quality of studies were provided. For example, while the review only included RCTs and meta-analyses of RCTs, the validity of these studies was not investigated. Relying in the results section on one study so heavily may lead to the introduction of bias or error. Notwithstanding these criticisms, the authors' conclusions appear to follow from the results presented.
Munro, 1995.[4] **Country:** UK **Aims:** To discover whether the addition of chemotherapy to definitive standard therapy improved survival in patients with cancer of the head and neck **Grade of evidence:** I	**Study design:** RCTs were included. **Participants:** People with head and neck cancer of any type. **Intervention:** Any chemotherapy for head and neck cancer, compared with a control arm in which patients did not receive chemotherapy. Chemotherapy could be neoadjuvant (given before definitive therapy), synchronous (given synchronously with radiotherapy) or post-definitive (given after definitive therapy). RCTs that combined more than 1 of these components were classified according to the earliest appearance of	**Search:** MEDLINE and the PDQ clinical trials database were searched between 1963 and August 1993. Relevant textbooks and the proceedings of the American Society of Clinical Oncologists were searched from 1979 to 1993. If the same data had been published more than once, the most recent data were used. **Quality assessment:** Not reported. **How studies were combined:** Fixed- and random-effects models were used to calculate the pooled odds ratios (ORs) and risk differences (RDs), along with 95% confidence intervals (CIs), for the following: all RCTs which gave survival data; RCTs which reported locoregional control; RCTs which reported distant metastases; RCTs which gave survival data for platinum/5FU regiments; RCTs of neoadjuvant	**Number of studies:** 54 RCTs (n = 7,599) were included. **Efficacy** **All drugs – survival:** 52 studies; n = 7,443. The pooled RD was 6.5% (95% CI: 3.1, 9.9) and the pooled OR was 1.37 (95% CI: 1.24, 1.5). **All drugs – locoregional control:** 43 studies; n = 5,389. The pooled RD was 7.9% (95% CI: 1.9, 13.9) and the pooled OR was 1.44 (95% CI: 1.28, 1.63). **All drugs – distant metastases:** 29 studies; n = 4,883. The pooled RD was -1.9% (95% CI: -4.8 to, 1.1) and the pooled OR was 0.79 (95% CI: 0.67 to 0.93). **Platinum/5FU – survival:** 8 studies; n = 1,636. The pooled RD was 10.1% (95% CI: -4.7 to 25.0) and the pooled OR was 1.56 (95% CI: 0.81 to 2.99).	**Authors' conclusions:** The results suggest that the investigation of optimal agents and scheduling for synchronous radiotherapy and chemotherapy might still be important in clinical trials in head and neck cancer. **Comments:** The review question and the study selection criteria were clearly stated. The literature search was reasonably comprehensive, but could have included more electronic databases such as EMBASE. Details of the included studies were given but no validity assessment seems to have been performed. Information on how the data were cross-checked for accuracy were given but no details of the review process were

	chemotherapy in the protocol. Many different chemotherapy regimens were used in the included studies such as methotrexate, carboplatin, cisplatinum, 5FU, hydrocortisone, doxorubicin, hydroxyurea, bleomycin, cyclophosphamide and 6 mercaptopurine. **Outcome:** The studies had to report survival, disease-free survival or local control to be included in the review.	chemotherapy which gave survival data; and RCTs of a synchronous single agent. Publication bias was addressed in sensitivity analyses using the single large trial method, the number of clinical RCTs of reasonable size that would be required to overturn a positive conclusion and the effect of a single positive trial being dominant. Heterogeneity of the pooled studies was assessed graphically and by the Q statistic. Sensitivity analyses were carried out to deal with possible bias in data publication and extraction.	**Neoadjuvant – survival:** 28 studies; n = 4,141. The pooled RD was 3.7% (95% CI: 0.9, 6.5) and the pooled OR was 1.2 (95% CI: 1.04, 1.35). **Synchronous single agent – survival:** 16 studies; n = 2,506. The pooled RD was 12.1% (95% CI 5.0, 19.0) and the pooled OR was 1.77 (95% CI: 1.51, 2.1). The results were robust to the sensitivity analyses dealing with possible bias in data publication and extraction. **Cost:** No cost information was reported.	provided, although as there is only a single author it is likely that only 1 reviewer was involved in the review process. The author made no attempt to obtain individual patient data or unpublished data and in the absence of raw numbers in the published data, has estimated numbers from survival curves. No account was taken of censoring within the trials. As the author admits, this will have led to inaccuracies in the data. Some attempt is made to address this by the use of sensitivity analyses, but this is not the optimal approach. The author states in the "Discussion" section of the paper that an individual patient data analysis is underway and the results of this are likely to supersede the results and conclusions of this review. The author's conclusions should, therefore, be treated with caution given that they are likely to be out-of-date and based on inaccurate data. Note: additional analyses of the studies presented in this review with particular attention to adverse events were presented in a linked publication.[5]
Pignon, 2000.[6] **Country:** France **Aims:** To conduct meta-analyses of the impact on survival of chemotherapy added to locoregional treatment for head and neck squamous cell carcinoma, based on updated individual patient data (IPD).	**Study design:** RCTs in which the investigators were unaware of the assigned treatment before deciding whether the patient was eligible (adequate allocation concealment) were eligible for inclusion. Trials were eligible if recruitment began after January 1st 1965 and ended before December 31st 1993. **Participants:** Studies in previously untreated patients with non-metastatic head and neck squamous cell carcinoma were eligible for inclusion. Trials were eligible if all participants had undergone a potentially	**Sources searched:** MEDLINE and EMBASE were searched. Abstracts of meetings and the references in review articles were searched by hand. Trial registers (PDQ, CLINPROT) were also consulted. Experts, pharmaceutical companies and all trial investigators who took part in the meta-analysis were asked to identify other trials. Published and unpublished trials were included. **Quality assessment:** Data from all of the included RCTs were checked for internal consistency and were compared with the protocol and published reports of each trial. **How studies were combined:** Intention to treat meta-analyses of IPD were conducted.	**Number of studies:** The review contained data on 10,741 patients from 63 RCTs. These were 92% of all patients randomised in these RCTs (data were unavailable for 898 patients from 11 RCTs). **Effect of chemotherapy:** The meta-analysis of locoregional treatment with or without chemotherapy included 8 RCTs (n = 1,854) of adjuvant therapy, 31 RCTs (n = 5,269) of neoadjuvant therapy and 26 RCTs (n = 3,727) of concomitant therapy. The meta-analysis showed no significant benefit associated with adjuvant or neoadjuvant therapy. Concomitant therapy showed significant benefit but heterogeneity between the RCTs was significant. Overall, the HR for death was 0.90 (95% confidence interval, CI: 0.85, 0.94, $p < 0.0001$), which corresponds to an absolute survival benefit of 4% at 2 and 5 years.	**Authors' conclusions:** The routine use of chemotherapy is debatable because the meta-analysis showed only a small significant survival benefit. Larynx preservation must remain investigational. **Comments:** The objectives of the review were clearly stated in terms of the participants, interventions, outcomes and study design of interest. The search for relevant data was adequate and a collaborative group of trial investigators was established to maximise the retrieval of IPD and to conduct the meta-analysis. Details of the

Grade of evidence: I	curative locoregional treatment and had not been treated for another cancer. Trials in tumours of the oral cavity oropharynx, hypopharynx and larynx were included. Trials in nasopharyngeal carcinoma only were excluded. The cancer sites varied among the patients in the included studies. **Intervention:** Studies of interventions relevant to any of the following 3 comparisons were eligible for inclusion: The effect of chemotherapy: locoregional treatment compared with locoregional treatment in combination with chemotherapy. The effect of the timing of chemotherapy: neoadjuvant chemotherapy in combination with radiotherapy compared with concomitant or alternating radiochemotherapy with the same drugs. Larynx preservation with neoadjuvant chemotherapy: radical surgery in combination with radiotherapy compared with neoadjuvant chemotherapy in combination with radiotherapy in responders or radical surgery and radiotherapy in non-responders. **Outcome:** Overall survival was the primary outcome. Disease-free survival (DFS) was the secondary outcome in the meta-analysis of larynx preservation; the events taken in to account were local or distant recurrence, second primary and death.	The median follow-up was calculated. Survival analyses were stratified by trial. The log rank observed minus expected (O-E) number of deaths and its variance were used to calculate the individual and overall pooled hazard ratios (HRs) using a fixed-effects model. The RCTs were weighted in proportion to the variance of O-E. The absolute differences at 2 and 5 years were calculated with the baseline event rate in the control group and the HR. An analysis stratified by trial was conducted to investigate interaction between treatment and covariates (age, gender, performance status, stage, site). Heterogeneity in the meta-analyses was assessed by χ^2 tests.	**Effect of timing of chemotherapy:** The meta-analysis of 6 RCTs (n = 861) gave a HR for death of 0.91 (95% CI: 0.79, 1.06) in favour of concomitant or alternating chemoradiotherapy, although the difference was not statistically significant (p = 0.23). Heterogeneity between the RCTs was not statistically significant (p = 0.16). **Larynx preservation with neoadjuvant chemotherapy:** No significant difference was shown by a meta-analysis of 3 RCTs (n = 602) that compared neoadjuvant chemotherapy in combination with radiotherapy in responders or radical surgery and radiotherapy in non-responders, with radical surgery in combination with radiotherapy (HR 1.19, 95% CI: 0.97, 1.46). Heterogeneity between the RCTs was significant (p = 0.05). **Cost:** No cost information was reported.	excluded RCTs are available on the Lancet website. The number of patients in RCTs for which data could not be retrieved is stated. The validity of the eligible RCTs was assessed by checking the raw data, comparing them with the trial protocol and published reports and resolving inconsistencies and anomalies with the trial investigators. 1 trial was reported to have been excluded following the data checking process. The data were analysed using appropriate techniques for meta-analysis of IPD. Subgroup analyses were specified in the review protocol, which is available from the primary author. Heterogeneity was assessed and possible reasons for it were investigated. The results of the sensitivity analyses are available on the website of the journal publishers. The conclusions are consistent with the evidence presented.
Stuschke, 1997.[10]	**Study design:**	**Sources searched:**	**Number of studies:**	**Authors' conclusions:**

Country: Germany **Aims:** To assess the effectiveness of hyperfractionated and conventional fractionated irradiation. **Grade of evidence:** I	Only RCTs were eligible. **Participants:** No patient inclusion criteria are given. 2 studies included patients with oropharynx cancer. 1 study included patients with cancers of the oropharynx, nasopharynx oral cavity, hypopharynx, larynx and cardinal sinuses. The last study did not report diagnostic categories. The stage of cancer in patients varied by trial. **Intervention:** For inclusion studies were required not to have a planned break of more than 14 days in the treatment arm. Overall treatment times in both arms could differ by no more than 2 weeks and the total radiation doses in the hyperfractionated arm had to be equal to or greater than those in the conventionally-fractionated arm. Radiotherapy had to be the major treatment modality. Conventional radiotherapy total doses ranged from 60Gy to 70Gy delivered at 2Gy per fraction daily over a period of 6 to 7 weeks; hyperfractionated radiotherapy total doses ranged from 70.4Gy to 80.5Gy delivered at 1.1Gy to 1.2Gy per fraction twice daily over a period of 6 to 7 weeks. **Outcome:** The outcomes were survival, tumour response and local recurrence.	MEDLINE and CANCERLIT were searched from January 1980 to February 1995, using the terms: ("random*" or "phase III") AND ("hyperfraction*" OR "b.i.d." OR "t.i.d." OR "twice daily" OR "2 fractions" OR "3 fractions" OR "multiple fractions") AND ("radiation" or "radiotherapy"). **Quality assessment:** The quality of the studies was scored using a validated method incorporating aspects of design and conduct as well as analysis and presentation and gives a score ranging from 0 (poor) to 1 (high quality). The authors do not state how the papers were assessed for validity or how many of the authors performed the validity assessment. **How studies were combined:** The observed and expected number of events were calculated for each study along with the variance according to the Peto method. Odds ratios were calculated and 2-sided t-tests of the hypothesis of no difference between treatment arms were undertaken. Survival rates (up to 5 years) were obtained from published survival curves. Standard errors of the survival and local recurrence rates were calculated according to Greenwood's formula. No statistical tests for heterogeneity are reported.	There were 4 RCTs (1,158 patients) of head and neck cancer. **Efficacy:** Survival data were available from 3 of the 4 studies and gave a pooled odds ratio for death of 0.48 (95% CI: 0.40 to 0.58; $p < 0.0001$) for hyperfactionation giving a statistically significant reduction in the risk of death. Patients treated with hyperfactionation were less likely to respond incompletely to treatment (OR = 0.43; 95% CI: 0.32 to 0.57; $p < 0.0001$) or to suffer local recurrence (OR = 0.35; 95% CI: 0.28 to 0.45; $p < 0.0001$). **Toxicity:** There was insufficient data to perform a meta-analysis of late normal tissue effects. However, in no trial with a minimum time interval between fractions of 4.5 hours to 6 hours was there a significant increase in severe late effects. **Quality:** The quality scores varied across the RCTs with a median value of 0.43. **Cost:** No cost information was reported.	The effectiveness of radiotherapy is consistently higher for hyperfactionation than for conventional fractionated irradiation. The assumption that tumours have a small effective fractionation sensitivity seems to be fulfilled especially for head and neck cancers. **Comments:** This review used a restricted search of only 2 computerised databases. The authors do not report having checked reference lists or searched for unpublished studies. Although the inclusion criteria are given, it is not clear how the authors have judged whether the primary studies evaluated treatment of localised cancer with curative intent. The process used in conducting the review was not reported. Insufficient information about patient characteristics is provided to judge whether the results are generalisable (for example, some of the studies may be restricted to patients with good performance status). More details of the primary studies included and clearer explanation of the statistical analysis would have been helpful. Importantly, neither the stage of disease nor the treatments given to patients in the studies were described in detail. The conclusions follow from presented data. Given the lack of detail in the authors' description of the included patients, the generalisability of the results is uncertain.
Thephamongkhol, 2003.[7] **Country:** Canada **Aims:**	**Study design:** Practice guidelines, systematic reviews, meta-analyses and RCTs were included. **Participants:** Only studies of newly diagnosed patients with locally advanced squamous cell or	**Sources searched:** The literature was searched using MEDLINE (1966 to October 2003), EMBASE (1980 to October 2003), the Cochrane Library (Issue 3, 2003), the Physician Data Query database, the Canadian Medical Association Infobase and the National Guideline Clearinghouse, as well as abstracts published in the proceedings of the	**Number of studies:** 17 RCTs (13 published and 4 in abstract form) with 20 comparisons were eligible for inclusion in the review. Chemotherapy was delivered with radiotherapy in the neoadjuvant (8 RCTs), concurrent (4 RCTs) and adjuvant settings (3 RCTs) or was delivered in the neoadjuvant in combination with adjuvant setting (2 RCTs) or as concurrent in combination with adjuvant	**Authors' conclusions:** Cisplatin-based concurrent radiochemotherapy should be routinely offered to patients with newly diagnosed locally advanced squamous cell or undifferentiated nasopharyngeal cancer (Stage III or IV).

To assess whether the addition of chemotherapy to radiotherapy improves the survival of adult patients with newly diagnosed locally advanced squamous cell or undifferentiated nasopharyngeal cancer and, if so, to ascertain the best timing and chemotherapy regimen. **Grade of evidence:** I	undifferentiated nasopharyngeal cancer. RCTs that did not report separate results for patients with nasopharyngeal cancer were excluded. **Intervention:** Studies were eligible if they assessed patients who were receiving any combination of chemotherapy and radiation in the neoadjuvant, concurrent or adjuvant setting compared with a control; group receiving radiotherapy alone. **Outcome:** Primary outcomes were disease-free survival and/or overall survival. The secondary outcomes of interest were local control, response, toxicity and/or quality of life.	meetings of the American Society of Clinical Oncology (1997 to 2003), the American Society for Therapeutic Radiology and Oncology (199 to 2003), the Asian Clinical Oncology Society (2001), the International Congress of Radiation Oncology (1997 and 2001), the European Society of Therapeutic Radiology and Oncology (1992, 1994, 1996, 1998, 2000, 2002) and the European Society for Medical Oncology (2000, 2002). Article bibliographies and personal files were also searched to October 2003 for evidence relevant to this practice guideline report. The literature search combined nasopharyngeal disease specific terms (such as "nasopharyngeal neoplasms/" or "nasopharyn.mp." or "nasopharyngeal.tw.") with treatment specific terms ("drug therapy/" or "chemotherapy/" or "chemotherapy.tw." or "radiochemotherapy.mp." or "chemoradiotherapy.mp.") and search specific terms for the following study designs: practice guidelines, systematic reviews, meta-analyses, reviews, RCTs and clinical trials. **Quality assessment:** The authors appear to have graded the quality of included studies by comparing their description of the method of randomisation and the reported completeness of follow up. **How studies were combined:** The studies were pooled using a random-effects model. Given the presence of crossing survival curves in 7 RCTs, indicating that the assumption of a constant HR has been violated, the proportion of patients who relapsed and those who died at a specified time point were pooled across studies. To avoid error associated with loss to follow-up or patient censoring, the common time point of 2 years was selected, as most of the RCTs reported sufficient follow-up (greater than 50%) at 2 years and 2-year survival is a clinically reliable point for relapse and/or recurrence. Where 2-year survival data were not reported, data were estimated from published survival curves. In the case of missing data, authors were contacted for further information. Outcomes were reported in terms of the NNT (with 95% CI's) calculated	therapy (2 RCTs). 1 trial reported as an abstract did not report the timing of chemotherapy (18). 2 meta-analyses were also included. **Disease-free survival** Data were pooled from 12 studies with 14 comparisons at 2 years. Pooled data, with significant heterogeneity, suggest that patients treated with radiochemotherapy had higher rates of disease-free survival than had patients treated with radiotherapy alone (OR: 0.69; 95% CI: 0.54 to 0.87; p = 0.002; χ^2 = 26.98, d.f. = 13, p = 0.013). The number-needed-to-treat (NNT) was calculated at 13 (95% CI: 7 to 33). Radiochemotherapy was significantly superior to radiotherapy alone. This was found for neoadjuvant chemotherapy (OR = 0.77; 95% CI: 0.59 to 0.99; p = 0.04; NNT = 17), concurrent chemotherapy (OR = 0.62; 95% CI: 0.45 to 0.86; p = 0.004; NNT = 10) and concurrent adjuvant chemotherapy (OR = 0.32; 95% CI: 0.11 to 0.95; p = 0.04; NNT = 4). In a sensitivity analysis removing a study with an outlying treatment effect, the heterogeneity was no longer apparent (p = 0.66). The odds ratio and NNT remained significant (OR: 0.75; 95% CI: 0.64 to 0.88; p = 0.003; NNT = 14; 95% CI: 10 to 33). **Overall survival** Data were pooled from 13 studies at 2 years. Pooled data, with significant heterogeneity (p = 0.045), suggest that patients treated with radiochemotherapy showed a trend towards higher rates of overall survival than patients treated with radiotherapy alone (OR: 0.77; 95% CI: 0.59 to 1.01; p = 0.06; χ^2 = 24.07, d.f. = 14, p = 0.045). Radiochemotherapy was significantly superior to radiotherapy alone. This was found for concurrent chemotherapy (OR = 0.42; 95% CI: 0.23 to 0.76; p = 0.004; NNT = 10) and concurrent adjuvant chemotherapy (OR = 0.31; 95% CI: 0.17 to 0.57; p = 0.0001; NNT = 6). In a sensitivity analysis removing the study with an outlying treatment effect, the heterogeneity was no longer apparent (p = 0.38). The odds ratio was still found not to be significant	**Comments:** Pre-specified inclusion and exclusion criteria were clearly reported and the literature search was fairly comprehensive. Information about the methodology of the review process was not presented, such as how many of the reviewers were involved in making decisions on the relevance of primary studies and in extracting the data. The information presented on the included studies was limited. While the review only included RCTs and the validity of these studies was investigated by assessment of items which have been validated, the authors did not state how these quality items were used to assess quality nor what the results of this quality assessment exercise were. As such it is not clear whether the validity assessment was appropriate. This limits any assessment of the reliability of the results. The authors' conclusions appear to follow from the results presented.

		using the inverse of the risk difference. Heterogeneity was assessed statistically.	(p = 0.38). The odds ratio was still found not to be significant (OR: 0.85; 95% CI: 0.69 to 1.06; p = 0.14). **Treatment-related deaths** 8 of 17 RCTs reported rates of death owing to treatment. Death rates ranged from 0% to 8% for patients in the radiochemotherapy arms compared with 0% to 2.5% for patients in the radiotherapy arms. The differences in death rates were significant in only 1 trial which utilised an aggressive chemotherapy regimen. **Toxicity** With the exception of significantly greater mucositis in the radiochemotherapy arm of 1 trial, where reported, acute radiation toxicity did not differ significantly between any of the treatment groups. **Cost:** No cost data were examined.	

Table 5b: Adherence to a treatment protocol and specified timescales

Study details and aims	Details of Service and Participants	Methods:	Included patients and results	Comments
Chen, 2000.[12] **Country:** USA **Aims:** To develop and implement clinical pathways in a unit for head and neck oncological surgery in an effort to define critical aspects of care and provide a cost-effective care. **Grade of evidence:** V	**Service:** A multidisciplinary team in a unit of head and neck surgery inside a university hospital in Texas. Clinical pathway was defined as "an optimal sequencing and timing interventions by physicians, nurses and other staff for a particular diagnosis or procedure". Specific details of the pathway were provided in the report. **Participants:** 190 patients who underwent unilateral neck dissection with or without one of the following additional procedures: direct laryngoscopy, rigid oesophagoscopy and/or dental extractions.	**Methods:** A cohort of patients was recruited and compared with a contemporaneous cohort and a cohort of historical controls. The methods of allocation between the pathway group and the contemporaneous control cohort were not explained. **Outcomes measured:** Main outcomes • length of hospital stay • total costs (include hospital and professional fees) Secondary outcomes: • surgery related costs • treatment related costs • medications costs • consultation, assessment and diagnostic tests costs	**Included patients:** Patients were divided into 3 groups: • Historical control group – 96 patients treated from 1993 to 1994 prior to the implementation of the clinical pathway. • Contemporaneous non-pathway group – 64 patients treated from 1996 to 1998, after implementation of the clinical pathway, but not managed based on the recommendations of the pathway • Pathway group – 30 patients treated from 1996 to 1998 and managed in the clinical pathway. The median age for the whole group was 59 years old. The percentage of females varied from 24% to 36% in the 3 different groups. **Median length of stay:** Historical control group – 4 days Contemporaneous non-pathway group – 2 days Pathway group – 2 days. **Median total costs:** Historical control group – $8,459 Contemporaneous non-pathway group – $6,885 Pathway group – $6,227 **Decrease in costs:** Treatment costs – 38% (room/board and nursing costs) Surgery-related and diagnostic tests costs – 16% each.	**Authors' conclusions:** Development and implementation of this clinical pathway played a statistically significant role in decreasing length of stay and total costs of care associated with neck dissection between non-pathway and pathway patients. Thus a more cost-effective practice environment has resulted for all our patients. **Comments:** The authors pointed out that there was a problem with the sample size for the pathway group in that it was much smaller than the other groups and of not measuring relevant outcomes. Contemporaneous patients were not randomly allocated to receive the pathway management or control management and the method of allocation was not reported. The same members of staff treated both the contemporaneous groups and this may have introduced serious bias into their comparison while the similarity of the historical controls to the other 2 groups is not certain and could be affected by factors other that those listed. Outcomes such as readmissions, deaths, complications of surgery and patient satisfaction were not measured even though the authors reported that these may influence the results. The conclusions drawn do not readily follow from the results presented.
Gendron, 2002.[13] **Country:** USA **Aims:** To assess the durability of improvements seen in the first year of introduction of a clinical care	**Procedure:** A CCP was developed and continually refined by a multidisciplinary team including surgeons, nurses and allied health care representatives. **Design and data source:** This was a retrospective cohort study with patients identified using an administrative	**Methods:** Differences between any 2 groups were assessed using the Mann-Whitney U test and differences between all 3 groups were assessed using the Kruskal-Wallis one-way analysis of variance (ANOVA). Categorical variables were analysed using the Pearson's χ^2 method (with Yates' correction in the case of 2x2	**Length of stay (any co-morbidity):** **Group** / **Median/days** / **Range/days** 1 / 13.0 / 5 to 152 2 / 8.0 / 3 to 30 3 / 8.0 / 3 to 27 ($p < 0.001$) / ($p < 0.001$) **Length of stay in the ICU:**	**Authors' conclusions:** The CCP for head and neck cancer maintained the improvement in the length of stay and charges seen in its first year and continued to decrease resource utilisation and enhance the quality of care. **Comments:** The authors did not assess those cases where

pathway (CCP) and assess the effects of revisions to the CCP.

Grade of evidence:
V

database that was searched for those who had undergone tracheostomy. Information was obtained from a review of the patients' medical records and billing information.

Time period:
Group 1: 01.01.95 to 31.12.95 (before the introduction of the CCP)
Group 2: 01.07.96 to 01.07.96 (in the first year of the CCP)
Group 3: 01.01.99 to 31.12.99 (in the third year of the CCP).

Study population:
The CCP was used in the management of patients who had undergone laryngectomy, intraoral resection or a complete resection of head and neck cancer. Patients requiring tracheostomy or enteral feeding were included. Only those patients who underwent tracheostomy were identified for the current study.

Group 1: 87 (Median age = 65, 71% male),
Group 2: 43 (Median age = 61, 79% male),
Group 3: 82 (Median age = 60, 73% male).

All groups were similar in terms of demographic variables and the site and stage of their primary disease but Group 3 included fewer persons who consumed alcohol and more persons who were hypertensive. These differences were statistically significant.

tables). Adjustment was made for demographic factors, use of alcohol and tobacco, co-morbidity and disease related factors.

Outcomes measured:
Length of Stay (Any co-morbidity).

Length of Stay in the ICU.

Length of Stay following the ICU.

Within 30 days readmission rate.

Cost.

Serious adverse effects.

Discharge destination.

Group	Median/days	Range/days
1	2.2	0 to 38.4
2	1.8	0 to 20.0
3	1.1	0 to 14.3
	(p = 0.001)	(p = 0.001)

Length of stay following the ICU:

Group	Median/days	Range/days
1	10.5	0.6 to 136.2
2	6.3	2.2 to 18.2
3	6.4	0.2 to 22.2
	(p < 0.001)	(p < 0.001)

Within 30 days readmission rate:
Group 1: 18%,
Group 2: 21%,
Group 3: 11% (p =0.37).

Cost:
Group 1: $105,410
Group 2: $78,930
Group 3: $65,919.

Serious adverse effects:
Group 1: 44%
Group 2: 47% (estimated from graph)
Group 3: 40%.

Discharge destination:

	Home	Visiting Nursing Service	Skilled Nursing Facility
1	49%	33%	11%
2	56%	35%	9%
3	2%	85%	11%
(p < 0.001)			

individuals were not treated as per the protocol that had been agreed. Neither did they give any indication of the number of patients in this category. The authors did however report that a review of the protocol was initiated in such cases.

No adjustment for the 25% increase in costs during the period was made and costs of professional fees were excluded from the analysis. These factors and their basis on US data, could have a significant bearing on the information's relevance to modern UK practice. While a number of covariates are listed and assessed for differences between the groups, it is not clear whether they were adjusted for in the analysis of the principle outcomes.

Table 5c: Adherence to specified radiotherapy timescales

Study details and aims	Inclusion/exclusion criteria	Methods	Results	Comments
Khalil, 2003.[14] **Country:** UK **Aims:** To investigate compliance to prescribed dose-fractionation schedule and overall treatment time in a pool of 5 randomised trials (IMPACT database) of altered fractionation in radiotherapy for head-and-neck carcinomas and to advise on new improved fractionation schedules for specific subgroup of patients. **Grade of evidence:** I	**Study design:** Individual patient data analysis (IMPACT database) of 5 large RCTs (4 of them multicentre trials) of altered fractionation in radiotherapy for head and neck carcinomas. Trials were performed from 1980 to 1995. The IMPACT database contains basic information and treatment characteristics of patients. **Participants:** The IMPACT database includes 3 EORTC trials, the CHART trial and an in-house trial from the Princess Margaret Hospital in Toronto. The database contained information on 2,564 randomised patients with squamous cell carcinoma of the head and neck (primary sites: oropharynx 1,225 patients, larynx 704 patients oral cavity 337 patients and hypopharynx 221 patients. **Intervention:** Patients on these trials were randomised to receive either conventional fractionation (n = 1,111 patients; daily fractions, 51Gy in 20 fractions to 70Gy in 35 fractions) or altered fractionation (n = 1,453 patients; hyperfactionation of 80.5Gy in 70 fractions over 7 weeks, multiple fractions per day for 2 weeks followed by a rest of 3 weeks before completing the schedule of 67.22 to 72Gy, accelerated split-course regime of 72Gy in 45 fractions over 5 weeks with a 12 day to 14 day split in weeks 2 and 3, hyperfractionated radiotherapy with 2 fractions per day delivering 58Gy in 40 fractions over 4 weeks and continuous hyperfractionated accelerated radiotherapy with 54Gy in 36 fractions in 12 days). **Outcome:** Overall treatment time (days). Compliance to overall treatment time. Compliance to prescribed treatment dose. Total dose lost.	**Sources searched:** The sources used to identify trials for inclusion on the trials database were not listed. **Quality assessment:** Not performed/reported **How studies were combined:** An intention-to-treat analysis was used but with the exclusion of 11 cases for whom details regarding the overall treatment time were unavailable. Differences in compliance between conventional and altered fractionation tested using Mann-Whitney's U test. Compliance across studies compared using Kruskal-Wallis test. The "total dose lost" was calculated as a composite measure of compliance to both the prescribed treatment dose and the overall treatment time. It was calculated by adding the dose not given to the estimated dose lost owing to prolongation of treatment).	**Number of included studies:** 5 large RCTs. They included a total of 2,564 patients. **Protocol violations:** 9 randomised cases failed to receive any radiotherapy but were included in the ITT analysis. For 11 cases, information regarding the overall treatment time was unavailable and these were excluded. **Excess of ideal overall treatment time** 2,555 cases, range from -45 to 97 days, mean = 3.9 days, median = 2 days. In only 30% of cases there was an agreement between overall and ideal treatment time; 6.8% had a "negative excess" (i.e. completed treatment sooner than was envisioned). In 5% of all cases radiotherapy was protracted by 1 day only, 9% by 2 days and in 27% more than 5 days. Patients treated in the conventional arms (1,111 patients) had a median excess time of 2.6 days compared to 1.3 days for the altered fractionation arms (n = 1,453). Occurrence of treatment interruptions was documented in only 3 trials (EORTC 22811, 22851 and CHART). 1,613 (87%) were described as not having their treatment interrupted, of these 830 (52%) had their treatment protracted and in 348 (22%) protraction was of more than 5 days. 2,229 (87.3%) received the full prescribed radiotherapy and 323 (12.7%) did not. In these 323 patients, the median reduction in dose was 4.5Gy. For all patients the estimated composite measure of compliance, total dose lost, had an average of 3.6Gy (SE = 0.12) and a median of 1.9Gy. There was a significant difference in compliance as measured by the average total dose lost among centres in the 3 EORTC trials and on the conventional arm of the CHART trial.	**Authors' conclusions:** Awareness of the importance of overall treatment time has increased from 1980 to 1995 and conventional radiotherapy schedules have been intensified by 4Gy to 5Gy, corresponding to more than 10% increase in local tumour control probability. Even in RCTs compliance to the prescribed radiation therapy schedule may be relatively poor, especially after conventional fractionation. This affects the interpretation of the outcome of these trials. **Comments:** The authors reported few of the details of how the IPD meta-analysis was conducted. They did not report any detail about selection of trials, their inclusion or exclusion criteria or quality assurance procedure. The authors' suggestion that compliance to the prescribed overall treatment time should be included as a quality assurance parameter in radiotherapy trials warrants attention.

Study details and aims	Case selection and numbers	Statistical methods	Included patients and results	Comments
Roberts, 1994.[17] **Country:** UK **Aims:** To re-analyse data from 2 RCTs in order to quantify the effect of delays during radiotherapy. Specifically the authors aimed to find out if delays in treatment affect patients' outcomes and at what point such effects begin to occur. **Grade of evidence:** IV	**Procedure:** Radical radiotherapy for carcinoma of the larynx. Patients had been randomised to receive 3 or 5 fractions per week or to receive their treatment in less than or greater than 4 weeks. **Design and data source:** Data were sourced from 2 multi-centre RCTs conducted by the British Institute of Radiology. Cases omitting data on the total dose received, the number of fractions delivered or the total time over which radiotherapy wad given were excluded. **Time period:** 1965 to 1985. **Study population:** Patients with cancer of the larynx who had node-negative disease. **Outcomes:** Tumour control (defined as local control for 2 or more years after treatment).	**Covariates adjusted for:** Not reported. **Statistical method:** A direct maximum likelihood approach was used to fit a double-logarithmic model including a repopulation term which commences after an initial lag period.	**Included patients:** Data from 828 patients were analysed. **Results:** The analysis yields a time factor of $0.8Gyd^{-1}$ (95% CI: $0.5Gyd^{-1}$ to $1.1Gyd^{-1}$) as the extra dose required to counteract the reduction in tumour control probability (TCP) with extension of the treatment time. The latter reduction amounted to between 5% and 12% TCP per week, depending on the stage and time period. The best estimate of the time lag period was 21 days (95% CI: 0 days to 27 days). The subset of patients (n = 278) who received radiotherapy exactly as per their protocol was too small to allow for a meaningful estimation of either the time factor or lag period.	**Authors' conclusions:** The report appears to suggest that the dataset provides evidence that an additional $0.8Gyd^{-1}$ is required to counteract each day added to the treatment time which had been prescribed. **Comments:** While this is a retrospective study, it is restricted to data collected prospectively and as such is free from some of the biases that apply to many studies attempting to analyse the radiobiological effects of delays in radiotherapy. It appears well conducted but is based on a number of assumptions. The authors give full and appropriate arguments for these assumptions. As such and even given the theoretical nature of the calculations, it is probable that this study has a good degree of validity and that its conclusions are appropriate.
Robertson, 1999.[18] **Country:** UK **Aims:** To determine whether prolongation of treatment time had any influence on tumour control or survival and to assess if this could have influenced the results of the randomised comparison of CHART against conventional radiotherapy. **Grade of evidence:** IV	**Procedure:** Conventionally fractionated radical radiotherapy for head and neck cancer (including both the regional (phase I) treatment and reduced volume local (phase II) treatment). **Design and data source:** This study presents a post-hoc re-analysis of data collected prospectively in the CHART Head and Neck trial. Data on those patients included in the conventional arm of that trial were re-evaluated. Patients were divided into approximate tetriles according to the duration of radiotherapy. The tetriles were as follows:	**Volume measure:** Approximate tetriles were used. As the first and second tetriles were similar in terms of their outcomes, a post-hoc decision to amalgamate these was made. **Covariates adjusted for:** Age, sex, T and N stage, differentiation, tumour size, site (larynx compared with other head and neck cancer), performance status, length of time from first symptom to randomisation.	366 patients were eligible for inclusion. **Compliance to planned treatment:** 7 patients (all treated in less than 45 days) were found to have received less than 90% of their planned radiotherapy dose and were excluded in the analysis, leaving 359 patients. Of these 232 received radiotherapy in 48 days or fewer (mean duration 45.7 days, median 45 days) and 127 patients received radiotherapy in 49 days or more (mean duration 51.5 days, median 50 days). **Survival:** An increase of 19% in the relative risk of death in the prolonged group was found. This translates into a 2-year survival non-significant difference of 6% in favour of the standard group (60% compared with 54%; p = 0.25,	**Authors' conclusions:** The randomised comparison of CHART with conventional radiotherapy is unlikely to be affected by conventionally treated patients who took longer than 48 days to complete their treatment. **Comments:** The study data was well collected and as such the results have face validity but some concerns remain about this study. It is important to note however, the CHART trial was powered to test for differences in survival between conventional and CHART treatments (randomised at 2:3) and was not powered to investigate the effects of unplanned delays in

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Patients whose treatment lasted up to 45 days
Patients whose treatment lasted 46 to 48 days
Patients whose treatment lasted 49 days or more

Time period:
April 1990 to March 1995.

Study population:
Patients with head and neck cancer who had been randomised to receive conventionally fractionated radiotherapy as part of the CHART trial.

Outcomes:
Local tumour control and overall survival.
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Statistical method:
Relative risk ratios were compared. A one-step Cox regression model was used to adjust these and pre-and post adjustment ratios were compared.
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95% CI: -0.89 to 1.60).

When adjusting for factors collected before treatment the increase in risk of death was 9% (95% CI: -22% to 49%). This translates to a non-significant 2-year survival difference of 3% in favour of the standard group (60% compared with 57%; p = 0.62).

Local control:
There was a non-statistically significant increase in the hazard of local recurrence by 23% among those patients whose therapy was prolonged (HR = 1.23; 95% CI: 0.91 to 1.67). This equates to a non-statistically significant 7% reduction in local control (43% compared with 50%, p = 0.18)
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treatment duration within 1 of those arms. The study can not exclude the possibility that if a fully powered study were conducted, the trend for better outcomes in the standard group may have reached statistical significance.

The study excluded some patients for non-conformance and as such is a per protocol analysis. An intention-to-treat analysis may have been more appropriate, particularly as all exclusions were in the same category.

The post-hoc definition of categories and the amalgamation of 2 categories was not sufficiently justified by the authors.
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Kwong, 1997.[15]

Country:
Hong Kong

Aims:
To investigate the effect of interruptions and prolonged overall treatment time on tumour control for different fractionation schedules and the clinical significance of the timing of interruption.

Grade of evidence:
V
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Interventions:
Continuous course (CC):
3.5Gy per fraction, 3 fractions per week to a total of 59.5Gy. Mostly used in patients with small tumours.

Split course (SC):
40Gy in 2.5Gy per fraction, 4 fractions per week, a planned gap of 1 week before phase II treatment, a total dose of 61Gy for nasopharynx and 54Gy for neck carcinomas. This was often used in patients with upper cervical lymph nodes metastases or with parapharyngeal or oropharyngeal extension of tumour.

The fractionation schedules were fixed with no dose adjustment for stage of disease.

Participants:
1,225 records of patients treated from 1984 to 1994 were scrutinised with the following inclusion criteria:

Radiotherapy was used as the sole modality of primary treatment,
1 of the fractionation schedules was prescribed,
There were at least 3 months of follow up

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Methods:
Patients were given the treatment their clinician felt most appropriate to them. Data on the patients were stratified by the fractionation scheme used. The stratifications were then compared in a post-hoc analysis.

Outcomes measured:
Overall treatment time. (Treatment that extended more than 1 week beyond the schedule was considered as prolonged.)

Duration of interruption.

Loco-regional failure (at 3 months post-radiotherapy).

Loco-regional failure-free survival.

Distant metastases-free survival.

Disease-free survival.
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<table>
<tr><th></th><th>CC</th><th>SC</th></tr>
<tr><td>No. of cases</td><td>229</td><td>567</td></tr>
<tr><td>Age (range)</td><td>17 to 78</td><td>19 to 85</td></tr>
<tr><td>Female</td><td>76 (33%)</td><td>161 (28%)</td></tr>
<tr><td>T1 stage</td><td>152 (66%)</td><td>143 (25%)</td></tr>
<tr><td>N0 stage</td><td>163 (71%)</td><td>131 (23%)</td></tr>
<tr><td>Prolonged treatment time</td><td>27 (12%)</td><td>96 (17%)</td></tr>
<tr><td>Overall treatment time</td><td>37 days to 82 days</td><td>38 days to 80 days</td></tr>
<tr><td>Treatment interruptions</td><td>516</td><td>705</td></tr>
<tr><td>Loco-regional failures</td><td>54</td><td>164</td></tr>
<tr><td>Overall failures</td><td>75</td><td>248</td></tr>
</table>
68% of patients on SC had a planned gap of no more than 1 week.
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Authors' conclusions:
The clinical significance of prolonged overall treatment time during split course therapy is great and should not be ignored and it would be prudent to consider that the same occurs for other fractionation schedules.

Every effort should be made to keep treatment on schedule and interruptions for whatever reason should be minimised.

Comments:
There was a major difference in baseline characteristics between the groups. The patient populations are widely divergent. A comparison of the effects of treatment prolongation would have been better effected by comparing those within the 2 groups who had treatment as planned with those who had a prolonged treatment time. This would have provided better evidence as to the effects of prolongation.
Additionally, over 40% of the original patients were excluded from the analysis and this is not satisfactorily explained; it is not clear why so many of the patients treated by the centre failed to meet the inclusion criteria.
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<td>after completion of radiotherapy.

796 patients met the inclusion criteria; these included 229 on CC and 567 on SC. All interruptions in the course of radiotherapy, their timing and reason were recorded.</td>
<td></td>
<td>Treatment times prolonged by more than 1 week led to significantly worse loco-regional control and disease-free survival than those who completed treatment within 8 weeks.

From the multivariate Cox step-wise logistic regression analysis of SC patients, each day of interruption of treatment was found to increase the hazard rate by 3.3% for loco-regional control and 2.9% for disease free survival.</td>
<td>failed to meet the inclusion criteria.</td>
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<td>Robertson, 1998.[16]

Country:
UK

Aims:
To report results of an audit of the treatment of patients with glottic node-negative carcinoma of the larynx and assesses the impact of gaps on the radiotherapy treatment schedule

Grade of evidence:
VI</td>
<td>Service
5 hospitals which provide primary radiotherapy for larynx cancers in Scotland.

Participants
All patients (n = 629) with clinically node-negative squamous cell glottic cancer of the larynx. Radiotherapy was the primary treatment for all patients (only 3% had any prior surgery).

Only 352 patients were used for 5-years follow-up.</td>
<td>Methods:
A database of all newly diagnosed cases of carcinoma of the larynx between 1986 and 1990 inclusive was assessed. Mathematical models were used to estimate the effect of delays on the completion of treatment. Coverage was assessed using both national and local registration schemes.

Outcomes measured:
The primary outcome was disease-free period defined as the time from the start of the treatment until recurrence of the tumour in the same site or death from the disease.

Secondary outcomes:
• Number of gaps in the treatment,
• Number of days of treatment extension because of gaps.</td>
<td>Included patients:
629 patients with node-negative and primary tumour originating in the glottis. 321 T1, 216 T2, 78 T3, 14 T4.

Primary treatment:
Radiotherapy doses ranging from 43 to 70Gy. Patients were treated with between 15 and 41 fractions, with planned treatment ranging from 12 to 49 days.

Recurrence:
152 cases had tumour recurrence. The local control rates at 5 years were 82, 72 and 46% for T1, T2 and T3 to T4 respectively. Disease-free curves showed that a gap leading to an extension of treatment time by more than 3 days increased the hazard of local failure. However even a gap of 1 day was found to be detrimental if it led to a treatment extension of 3 or more days as a result of an extra weekend. 21 patients who experienced a gap of 1 day’s duration had prolongation of 3 or 4 days.

Number of cases with gaps:
<table>
<tr><td>No gap:</td><td>293</td></tr>
<tr><td>1 day:</td><td>94</td></tr>
<tr><td>2 to 3 days:</td><td>168</td></tr>
<tr><td>4+ days:</td><td>74</td></tr>
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Number of days of treatment extension because of gaps:
<table>
<tr><td>1 to 2 days:</td><td>149</td></tr>
<tr><td>3 to 4 days:</td><td>79</td></tr>
<tr><td>5 to 7 days:</td><td>76</td></tr>
<tr><td>8+ days:</td><td>24</td></tr>
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<td>Authors’ conclusions:
The authors stated that gaps in the treatment schedule have a detrimental effect on the disease free period. Any gap in the treatment was considered potentially damaging, with the position of the gap in the schedule showing not to be important.

Comments:
The authors had a straightforward goal and used a reasonable size database to achieve their goals. It is not clear if this study was envisioned as a purpose for the database or whether this project was conducted using what data were available in the database. However, the mathematical assumptions which were made in the study made it difficult to interpret and the findings should be regarded as speculative.</td>
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</table>

Robertson, 1998.[19] **Country:** Italy **Aims:** To analyse data on patients with cancer of the larynx using statistical models to estimate the effect of gaps in the treatment time on the local control of the tumour. **Grade of evidence:** VI	**Procedure:** Patients were treated by radiotherapy alone. **Design and data source:** Retrospective analysis of local centres' records. **Study population:** Patients with carcinoma of the larynx from 4 centres: Edinburgh – dates not given. Glasgow – 1958 to 1977. Manchester – 1971 to 1984. Toronto – 1960 to 1982. **Outcomes:** Local control rates. Disease-free period.	**Length of follow-up:** Data on the length of follow up are inconsistent between the included centres. Both Scottish centres had full follow-up of patients and survival analyses included a sub-group containing only these patients. **Statistical methods:** The local control rates were analysed by log linear models and Cox proportional hazard models were used to model the disease-free period. The linear quadratic model was used to facilitate comparison of different radiotherapy regimens.	**Included patients:** Data on 2,225 patients were included in the study. **Local control:** Elongation of the treatment time by 1 day or a gap of 1 day, was associated with a decrease in local control rates at ≥ 2 years of 0.68% per day; 95% CI 0.28 to 1.08%) (for local control rates at ≥ 2 years of 80%). An increase of 5 days was associated with a decrease in local control rates at ≥ 2 years of 3.5% from an 80% probability of control to a 77% probability. The time factor in the Linear Quadratic model, gamma/alpha, was estimated as $0.89 Gyd^{-1}$, (95% CI: $0.35 Gyd^{-1}$ to $1.43 Gyd^{-1}$). **Survival:** There was no evidence that a gap in treatment had an effect on the disease-free period for patients treated in Edinburgh ($p = 0.21$; $n = 375$). With a larger group of patients ($n = 675$) and a wider array of lengths of gaps, the cohort of patients treated in Glasgow however did see a significant decrease in disease-free period with increasing gaps ($p = 0.00022$),	**Authors' conclusions:** Any gaps in the treatment schedule have the same deleterious effect on the disease-free period as an increase in the prescribed treatment time. For a schedule, where dose and fraction number are specified, any gap in treatment is potentially damaging. **Comments:** This was a post-hoc analysis of data, which was not collected for the purposes of the current study. Some of the data sets were not complete and the authors do not report methods used to validate the accuracy of the data they did collect. However, their methods used appear to be appropriate for the question asked and provide useful information to answer the question.

Table 5d: Delays in initiating radiotherapy

Study details and Aims	Inclusion/exclusion criteria	Methods	Results	Comments
Huang, 2003.[20] **Country:** Canada **Aims:** To assess the relationship between delay in radiotherapy and the outcomes of radiotherapy in patients with cancer. **Grade of evidence:** III	**Study design:** There were no specific inclusion criteria in relation to study design. Four randomised controlled trials (RCTs) and 42 case series studies were included in the review in total; the 12 studies pertinent to head and neck cancer were all retrospective case series. Studies that commented on the relationship between delay and outcomes without presenting any analytical results were excluded. **Participants:** Studies which included cancer patients undergoing treatment with radiotherapy were eligible for inclusion. The primary site of cancer in the included studies was the breast (21 studies), head and neck (12 studies), lung (5 studies), brain (4 studies), prostate (1 study) and not reported (3 studies). **Intervention:** Studies that assessed the timing of radiotherapy regimens in which the delay in initiating RT was defined and described were eligible for inclusion. RT could be used either in conjunction with chemotherapy, surgery or alone. **Outcome:** Studies which reported the local control rates, distant metastasis or survival rates were eligible for inclusion in the review.	**Sources searched:** The electronic databases MEDLINE and CANCERLIT were searched from 1975 – June 2001 without any language restrictions. The search terms are provided in the paper. In addition manual searches of studies presented in the American Society for Therapeutic Radiology and Oncology conferences and the annual meeting of the Royal College of Physicians and Surgeons of Canada were undertaken. Experts in the field were also contacted to identify any further unpublished studies. Reference lists of key articles were checked. Searches on the names of published researchers were conducted. **Quality assessment:** The authors developed a nine point quality scale designed to distinguish between studies with a greater or lesser potential for bias. The scale assessed the following factors: demographic characteristics (age and sex), disease-related factors (tumour stage or size, histology or tumour grade and status of surgical margin), intervention related factors (RT dose and fractionation, surgical procedure and chemotherapy regimen) and completeness of follow-up. Studies with a score of 5 or more on the scale were classified as high-quality studies, whilst those with a score of less than 5 were classified as low-quality studies. Two reviewers independently assessed the validity of the included studies, with any discrepancies being resolved before data extraction. **How studies were combined:** Studies were pooled using the Der Simonian and Laird random effects model. An OR of more than 1.0 indicated a worse outcome in the delayed	**Included studies:** Overall, 46 studies were included in the review (total n=15,782); 4 RCTs (n=934) and 42 case series (14,848). 5 studies investigated the effects of delays initiating radiotherapy in unresected head and neck cancer. The total number of patients in these studies was 2,427. 7 studies investigated the effects of delays initiating post-operative radiotherapy in resected head and neck cancer. 851 patients were included in these studies. **Effects of delays in initiating RT on local control (unresected cancers):** 1 of 5 studies dichotomised the data into those relating to patients who experienced delays of more than 40 days and those who experienced delays of less than 40 days. The relative risk ratio and for local failure was 2.6 (95% CI: 1.1 to 6.4) and was 2.7 (95% CI: 1.4 to 5.4) for neck failure. The remaining studies calculated a Hazard Ratio (HR) for each day of delay. The review authors calculated the HR of a 30 day-delay and this was pooled. The pooled result was not significant (OR = 1.17; 95% CI: 0.96 to 1.44). There was no significant heterogeneity found in this group of studies ($\chi^2 = 4.64$, $p = 0.20$). **Effects of delays in initiating RT on local control (post-operative radiotherapy):** Studies dichotomised the data into those relating to patients whose radiotherapy started up to 6 weeks after surgery and those whose radiotherapy started more than 6 weeks after surgery. The pooled result was statistically significant (OR = 2.89; 95% CI: 1.6 to 5.21). Heterogeneity was observed in this group of studies ($p = 0.01$). Following a regression analysis, study quality was found to be a possible source of heterogeneity. When the 3 low quality studies were excluded, the result was still statistically significant but the OR was reduced (OR = 2.29; 95% CI: 1.15 to 4.59). **Effects of delays in initiating RT on survival (unresected cancers):** Data were available from one study. Data were reported for three groups of	**Authors' conclusions:** Delay in the initiation of RT is associated with lower rates of local control in head and neck cancer. Delays in starting RT should be as short as reasonably achievable. **Comments:** This review was conducted using an appropriate review question and appears to have included an adequate search of the literature pertinent to the topic. The authors gave few details of the included studies but this may be related to the large number of studies in the review as a whole. The authors used their own quality assessment scale and it is not clear to what extent they tested or validated this. However, their principal results for each diagnostic category were drawn from a comparison of all studies in that category and not just those of higher quality. The authors appear to contradict themselves in the section relating to head and neck cancer at one point. They divide studies into those involving primary radiotherapy and post-operative radiotherapy. However, for the primary radiotherapy group, they present their results in relation to interval between surgery and radiotherapy. As such, it is not clear from which point the delay was calculated. The analysis of the studies appears to have been well conducted. The conclusions seem to follow from the evidence presented.

		group compared to the non-delay group.	patients depending on the interval between the diagnosis and initiation of radiotherapy. Five-year survival was 73% for those treated within 30 days, 62% for those treated from 31 to 40 days after diagnosis and 54% for those treated more than 40 days after diagnosis. This difference was significant at the 5% level in a multivariate analysis. **Effects of delays in initiating RT on survival (post-operative radiotherapy):** 2 studies gave information on survival. In one, patients treated 1 to 6 weeks after surgery had an actuarial five year survival of 61%. Those treated 7 to 8 weeks after their operation had a rate of 46% and those who waited longer had a 30% rate of survival. This trend was statistically significant (Cox model, p = 0.046). In the second study, a 7% difference was seen in patients treated with radiotherapy within or more than 30 days after surgery for pharyngeal cancer (35% compared to 28%), but this was not significant. **Cost:** No cost information was reported.	

Table 5e: Interventions for the prevention and/or treatment of mucositis

Study details and aims	Inclusion/exclusion criteria	Methods	Results	Comments
Clarkson, 2003.[Clarkson, 2003 #365] **Country:** UK **Aims:** To evaluate the effectiveness of prophylactic agents for oral mucositis in patients with cancer receiving treatment, compared with other potentially active interventions, placebo or no treatment. **Grade of evidence:** I	**Study design:** Studies were included if they had random allocation of participants. **Participants:** Studies were included if they included patients with cancer receiving chemotherapy or radiotherapy treatment. **Intervention:** Studies were included if they investigated any treatment prescribed to prevent oral mucositis. Included studies investigated the following interventions: acyclovir, allopurinol mouth rinse, amifostine, antibiotic pastille or paste, benzydamine, camomile, chlorhexidine, clarithromycin, folinic acid, glutamine, GM-CSF, hydrolytic enzymes, ice chips oral care, pentoxifyline, povidone, prednisone, propantheline, prostaglandin, sucralfate and traumeel. **Outcome:** Studies were included if they assessed the prevention of mucositis, pain, amount of analgesia, dysphagia, systemic infection, length of hospitalisation, cost or patient quality of life.	**Sources searched**: The Cochrane Oral Health Group's Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE were searched. Keyword search were: "neoplasms*", "leukemia*", "lymphoma*", "radiotherapy*", "bone-marrow-transplantation", "neoplasm*", "cancer*", "leukemi*", "leukaemi*", "tumour", "tumor*", "malignan*", "neutropeni*", "carcino*", "adenocarcinoma*", "lymphoma*", "radioth*", "radiat*", "irradiat*", "radiochemo*", "bone", "marrow", "transplant*", "chemo*", "stomatitis*", "candidiasis-oral", "stomatitis", "mucositis", "oral", "cand*", "oral", "mucos*", "oral", "fung*", "mycosis", "mycotic" and "thrush". Reference lists from relevant articles were scanned and the authors of eligible studies were contacted to identify trials and obtain additional information. Date of most recent searches June 2002. **Quality assessment:** The quality assessment of included trials was undertaken independently by 2 reviewers. Trials were assessed on concealed allocation of treatment, blinding of patients, carers and outcome assessors and information on reasons for withdrawal by trial group. The agreement between the reviewers was assessed by calculating the kappa score. **How studies were combined:** Pooled relative risk values were calculated using random effects models.	**Number of studies:** 52 studies (n = 3, 594) were included. **Efficacy:** Of the 21 interventions included in trials, 9 showed some evidence of a benefit for either preventing or reducing the severity of mucositis. For 6 separate interventions, there was more than 1 trial and a significant difference compared with a placebo or no treatment: Allopurinal with unreliable evidence for a reduction in the severity of mucositis OR = 0.01 (95% CI: 0 to 0.03). Amifostine provided minimal benefit in preventing mucositis RR = 0.95 (95% CI: 0.91 to 0.99). Antibiotic paste or pastille demonstrated a moderate benefit in preventing mucositis RR = 0.87 (95% CI: 0.79 to 0.97). GM-CSF prevented mucositis RR = 0.51 (95% CI: 0.29 to 0.91). Hydrolytic enzymes reduced the severity of mucositis RR = 0.49 (95% CI: 0.30 to 0.81). Ice chips prevented mucositis OR = 0.42 (95% CI: 0.19 to 0.93). 3 interventions showed some benefit (each in only 1 study); benzydamine oral care protocols and povidone. The NNT to prevent 1 patient experiencing mucositis over a baseline incidence of 60% for amifostine is 33 (95% CI: 20 to 100), antibiotic paste or pastille 13 (95% CI: 8 to 50), GM-CSF 3 (95% CI: 2 to 20) and ice chips 5 (95% CI: 2 to 31). **Cost:** No cost information was reported.	**Authors' conclusions:** Several of the interventions were found to have some benefit at preventing or reducing the severity of mucositis associated with cancer treatment. The strength of the evidence was variable and implications for practice include consideration that benefits may be specific for certain cancer types and treatment. There is a need for well designed and conducted trials with sufficient numbers of participants to perform subgroup analyses by type of disease and chemotherapeutic agent. **Comments:** This is a well conducted systematic review which answers a clearly defined question. The literature search was extensive and studies reported in any language were accepted. The quality assessment method appears to be appropriate but it is not reported if this has been systematically validated. The level of reporting of included studies and of the review methods was good. The conclusions appear to follow from the data presented.
Hodson, 2003.[23]	**Study design:**	**Sources searched:**	**Number of studies:**	**Authors' conclusions:**

Country: Canada **Aims:** To evaluate for patients with squamous cell head and neck cancer, whether amifostine safely and effectively ameliorates important side effects of radiotherapy with acceptable toxicity and no tumour protection. **Grade of evidence:** I	Primary studies were included in the review if they had random allocation of participants. (Phase I and II trials and editorials and letters were not excluded a priori but a decision to exclude them was made before the review was updated.) The authors also include practice guidelines, reviews and meta-analyses. **Participants:** Studies were included if they included patients having conventionally fractionated radical radiotherapy or concurrent radiochemotherapy, encompassing at least 75% of the parotid glands. Conventionally fractionated radiotherapy was defined as single daily fractions ranging from 1.8Gy to 2.5Gy to a total of 50Gy to 74Gy. **Intervention:** Studies were included if they compared patients with or without amifostine in adults with any stage squamous cell head and neck cancer. **Outcome:** Xerostomia (defined as ≥ Grade 2), mucositis (defined as ≥ Grade 3) and the anti-tumour effects of amifostine were the main outcomes of interest. **Further exclusion criteria:** Non-English language studies were excluded.	The literature was searched using MEDLINE (1966 through October 2003), CANCERLIT (1983 through October 2002), EMBASE (1980 to October 2003), the Cochrane Library (Issue 3, 2003), the Physician Data Query (PDQ) database, the Canadian Medical Association Infobase and the National Guideline Clearinghouse and clinical trial and practice guideline Internet sites and abstracts published in the proceedings of the meetings of the American Society of Clinical Oncology (1998 to 2003), the American Society for Therapeutic Radiology and Oncology (1999 to 2003) and the European Society for Medical Oncology (1998, 2000). Reference lists from relevant articles and reviews were searched for additional trials. **Quality assessment:** No assessment of the quality of studies was reported. **How studies were combined:** Studies were combined using a narrative synthesis and where common outcome measures were used, by meta-analyses of odds ratios. The meta-analysis was done using both fixed and random effects models with the latter being the primary outcome if statistically significant heterogeneity was found to be present. Publication bias was investigated using funnel plots, Begg's test and Egger's test. Analysis was done using the RevMan computer programme.	8 RCTs (7 published and 1 presented as an abstract), 1 quality-of-life paper and 1 practice guideline were eligible for inclusion in the systematic review of the evidence. **Efficacy:** Pooled data suggest no significant difference between mucositis scores when amifostine was used or not (OR = 0.11; 95% CI: 0.01 to 1.26; p = 0.08; χ^2 = 13.31, d.f. = 3, p = 0.004). These data were based on the 4 studies which reported standard outcome measures. A pre-specified sub-group analysis found that amifostine was beneficial in patients undergoing radiochemotherapy (2 studies; OR = 0.03; 95% CI: 0.00 to 0.83; p = 0.04; χ^2 = 2.07, d.f. = 1, p = 0.15). **Tumour protection:** Results indicate that amifostine does not affect the anti-tumour effectiveness of radiotherapy with or without concurrent chemotherapy with carboplatin. **Adverse effects:** Nausea, vomiting, hypotension and allergic reactions were the most commonly reported side effects of amifostine, but they were rarely severe (≥ grade 3). **Quality of life** No differences were seen at baseline between patients with or without amifostine but those treated with amifostine had significantly better quality of life scores at 1, 7 and 11 months than did those patients not treated with the drug. **Route of administration:** Similar results were found in 1 small study for patients treated with subcutaneous (19% incidence) and intra-venous (23% incidence) amifostine (p-value or confidence intervals were not reported). **Publication bias:** Results of publication bias analysis were not presented but the authors reported that while the funnel plots	Data on the protective effect of amifostine on mucositis are inconclusive at this time. There were no statistically significant differences in the incidence of mucositis in the studies found. The recommended dose is 500mg or doses in the range of 200mgm^{-2} to 300mgm^{-2} given as an intravenous infusion 15mins to 30mins before radiotherapy. **Comments:** This systematic review answers a clearly defined question. The literature search was extensive but the exclusion of non-English language studies may mean some information relevant to the question was omitted. No quality assessment method was reported. The level of reporting of included studies and of the review methods was fair. While studies were combined even in the presence of statistical heterogeneity, the authors were clear in their reporting of this limitation in their results. The conclusions appear to follow from the data presented.

			appeared to be asymmetrical, Egger's and Begg's tests did not prove publication bias. **Cost:** No cost information was reported.	
Sutherland, 2001.[22] **Country:** Canada **Aims:** To identify, classify and evaluate agents used in the prophylaxis of oral mucositis in irradiated head and neck cancer patients **Grade of evidence:** I	**Study design:** All studies that met the review's eligibility criteria were included for the purpose of developing the classification scheme and assessing trends in and possible future directions for research. Only RCTs were included in the analysis of effectiveness. **Participants:** Patients receiving radiotherapy to the head and neck, in whom any intervention to prevent oral mucositis were used, were eligible for inclusion. Studies where patients were treated with radiation therapy alone, but which included patients with disease at sites other than the head and neck, were deemed ineligible. **Intervention:** All interventions used for the prevention of oral mucositis were eligible for inclusion. The intervention had to be compared with a no-active treatment control. **Outcome:** Studies were included if they reported the following: clinician-assessed oral mucositis scores; proxy measures of oral mucositis, such as radiotherapy interruptions or G-tube placements; or patient-assessed ratings of oral mucositis or other symptoms.	**Sources searched:** MEDLINE, EMBASE, CINAHL and Cancerlit were searched from 1966 to June 2000 using combinations of the following search terms: "head and neck neoplasms", "radiotherapy or drug therapy", "stomatitis" and "clinical trial". The individual agents identified from this search were listed and then the search repeated for each agent. Unpublished studies were identified by searching Cancerlit for abstracts from major oncology conference proceedings and ongoing studies were searched for on the National Cancer Institute's PDQ database. The reference lists of all the retrieved articles were also checked. **Quality assessment:** Validity was assessed using the validated assessment tool developed by Jadad et al. including components relating to method of randomisation, allocation concealment and attrition. 2 reviewers independently assessed the methodological quality of the studies. How studies were combined: Studies were combined in a meta-analysis. The pooled odds ratios (ORs) were calculated using the random-effects model of Der Simonian and Laird, along with the 95% confidence intervals (CIs). The χ^2 test was used to test for heterogeneity (significance level set at a p-value of 0.1).	**Number of studies:** 15 RCTs (n = 1,022) were included in the analysis. **Quality:** The median quality of the RCTs was 3 (range: 1 to 5). **Efficacy:** 13 studies were included in the meta-analysis of patients diagnosed as having severe mucositis by their clinicians; the pooled OR was 0.64 (95% CI: 0.46 to 0.88; χ^2 10.59, d.f. = 11, p > 0.10), indicating a beneficial effect of prophylactic interventions. When only studies with a quality score of at least 3 were included (9 studies, n = 812), the OR compared with no-active treatment was 0.68 (95% CI: 0.48 to 0.96). 10 studies were included in the meta-analysis of patients who reported that they developed severe mucositis; the pooled OR was 0.79 (95% CI: 0.56 to 1.12; χ^2 7.38, d.f. = 9, p > 0.10), indicating no significant effect for prophylactic interventions. When only studies with a quality score of at least 3 were included (8 studies, n = 756), the OR compared with no-active treatment was 0.78 (95% CI: 0.54 to 1.13). In patients whose clinician diagnosed severe mucositis, the efficacy of antibiotics (5 studies, n = 509): the OR was 0.47 (95% CI: 0.25 to 0.92). This was made up of results from broad-spectrum antibiotics (3 studies, n = 122) and narrow-spectrum antibiotics (2 studies, n = 387), the ORs for which were 0.52 (95% CI: 0.14 to 1.98) and 0.45 (95% CI: 0.23 to 0.86) respectively. In patients who self-reported severe mucositis, the efficacy of antibiotics (3 studies, n = 439): the OR was 1.04 (95% CI: 0.36 to 2.95). This was made up of results from broad-spectrum antibiotics (1 study, n = 52) and narrow-spectrum antibiotics (2 studies,	**Authors' conclusions:** Overall, interventions chosen on a sound biological basis to prevent severe oral mucositis were effective. In particular, narrow-spectrum antibiotic lozenges appeared to be beneficial when oral mucositis was assessed by clinicians. Methodological limitations were evident in many of the studies. **Comments**: This review addressed an appropriate question using well-defined inclusion and exclusion criteria for the participants, intervention and study design. The search for relevant trials was comprehensive and included efforts to retrieve unpublished material. Some studies may have been missed since the full manuscripts were only obtained for English language articles. The validity of the studies was assessed appropriately and the results of the assessment were incorporated into the review. Adequate details of the identified studies were presented and the classification of all interventions was helpful. The meta-analysis of the data from RCTs was conducted appropriately; however, the large number of subgroup analyses performed is of questionable validity.

			n = 387), the ORs for which were 8.40 (95% CI: 0.95 to 74.14) and 0.69 (95% CI: 0.37 to 1.27) respectively. No significant effect was found for direct cytoprotectants, sucralfate or other agents. **Cost:** No cost information was reported.	

Table 5f: Interventions to reduce the severity of the symptoms of xerostomia

Study details and aims	Inclusion/exclusion criteria	Methods	Results	Comments
Hawthorne, 2000.[24] **Country:** UK **Aims:** To examine the use of pilocarpine hydrochloride for radiation-induced xerostomia in patients with head and neck cancer. **Grade of evidence:** I	**Study design:** RCTs with more than 10 patients were eligible for inclusion. **Participants:** Head and neck cancer patients with post-radiation xerostomia of at least 2 months' duration. Studies using pilocarpine for xerostomia in patients with advanced cancer and other medical conditions, not necessarily radiation-induced xerostomia, were excluded. Where given, the participants' ages ranged from 16 to 82 years. **Intervention:** Systemic or topical pilocarpine. Topical pilocarpine was used as a mouthwash. Systemic pilocarpine was used in doses ranging from 2.5 to 10 mg, 3 times a day. **Outcome:** The authors did not define any a priori inclusion or exclusion criteria relating to the outcomes. The outcome measures used in the included studies were both objective and subjective. The objective evaluations were of parotid and whole saliva flows. The subjective outcomes included feelings of oral dryness oral comfort, speaking and chewing; these were assessed by patients' diaries, questionnaires and visual analogue scores. **Further exclusion criteria:** Non-English language studies were excluded.	**Sources searched:** The following databases were searched for studies published in the English language: MEDLINE from 1966 to 1999; CINAHL from 1982 to 1999; and Cancerlit from 1982 to 1999. The reference lists from the identified studies were also searched manually. Abstracts and review articles were not considered and the authors of the included studies were not contacted for additional information. **Quality assessment:** Studies were scored for methodological quality on a range from 0 to 5, based on the 3-item Jadad scale. **How studies were combined:** A qualitative narrative synthesis was undertaken. Publication bias was not assessed. Differences between the studies were investigated within the text of the review.	**Number of studies:** 4 studies were included. They had a total of 401 patients. **Efficacy:** All studies reported statistically-significant differences in favour of pilocarpine-stimulated treatment groups. The patients reported improvements in a number of areas, e.g. oral dryness oral comfort, chewing and the ability to speak without requiring liquids. There was an apparent time-dependent drug-related benefit noted in 2 studies, with patients reporting increased improvements after several weeks of pilocarpine treatment. **Adverse events:** All studies reported adverse side-effects from pilocarpine, but none were severe. 16 per cent of the patients withdrew from the studies. Sweating and urinary frequency were the most common side-effects noted, but headache, rhinitis and abdominal cramping were also reported. In 2 studies, doses over 5 mg appeared to produce increased side-effects. **Recommendations:** When considering both the side-effects and the efficacy of pilocarpine, all studies advocated 5 mg 3 times a day to be the optimum dose. The data supplied were insufficient to draw any conclusions as to the efficacy of systemic pilocarpine over topical usage. **Cost:** No cost data were included in the review.	**Authors' conclusions:** The persistent findings of symptomatic improvement following pilocarpine use merit consideration. However, there is insufficient evidence from these studies alone to generalise results to the wider population. Further research is required to determine the efficacy of systemic pilocarpine over topical application or vice versa. Clarification is also needed regarding any time-related drug-benefit relationship. Larger studies conducted over a longer period of time could help determine the nature of any time-related drug benefit relationship. **Comments:** The review question was clearly stated and was well supported by the inclusion and exclusion criteria. The literature search was adequate, although it was restricted to published studies. Relevant studies may therefore have been omitted and, as the authors acknowledged, publication bias (which was not assessed) may be present. Some non-English language studies were missed. Some key information on the process of the review was not given; these included the search terms, how the studies were chosen, how information was extracted from the studies and the role of the various reviewers involved. The validity of the included studies was assessed appropriately. Details of the studies were provided in both the text and in a table; however, information concerning the comparator used was not given for all of the studies. The data were synthesised

				narratively in the text of the review. The authors' conclusions appear to follow from the results, but should be treated with caution given the limitations highlighted.
Hodson, 2003.[23] **Country:** Canada **Aims:** To evaluate for patients with squamous cell head and neck cancer, whether amifostine safely and effectively ameliorates important side effects of radiotherapy with acceptable toxicity and no tumour protection? **Grade of evidence:** I	**Study design:** Primary studies were included in the review if they had random allocation of participants. (Phase I and II trials and editorials and letters were not excluded a priori but a decision to exclude them was made before the review was updated.) The authors also include practice guidelines, reviews and meta-analyses. **Participants:** Studies were included if they included patients having conventionally fractionated radical radiotherapy or concurrent radiochemotherapy, encompassing at least 75% of the parotid glands. Conventionally fractionated radiotherapy was defined as single daily fractions ranging from 1.8Gy to 2.5Gy to a total of 50Gy to 74Gy. **Intervention:** Studies were included if they compared patients with or without amifostine in adults with any stage squamous cell head and neck cancer. **Outcome:** Xerostomia (defined as ≥ Grade 2), mucositis (defined as ≥ Grade 3) and the anti-tumour effects of amifostine were the main outcomes of interest. **Further exclusion criteria:** Non-English language studies were excluded.	**Sources searched:** The literature was searched using MEDLINE (1966 through October 2003), CANCERLIT (1983 through October 2002), EMBASE (1980 to October 2003), the Cochrane Library (Issue 3, 2003), the Physician Data Query (PDQ) database, the Canadian Medical Association Infobase and the National Guideline Clearinghouse and clinical trial and practice guideline Internet sites and abstracts published in the proceedings of the meetings of the American Society of Clinical Oncology (1998 to 2003), the American Society for Therapeutic Radiology and Oncology (1999 to 2003) and the European Society for Medical Oncology (1998, 2000). Reference lists from relevant articles and reviews were searched for additional trials. **Quality assessment:** No assessment of the quality of studies was reported. **How studies were combined:** Studies were combined using a narrative synthesis and where common outcome measures were used, by meta-analyses of odds ratios. The meta-analysis was done using both fixed and random effects models with the latter being the primary outcome if statistically significant heterogeneity was found to be present. Publication bias was investigated using funnel plots, Begg's test and Egger's test. Analysis was done using the RevMan computer programme.	**Number of studies:** 8 RCTs (7 published and 1 presented as an abstract), 1 quality-of-life paper and 1 practice guideline were eligible for inclusion in the systematic review of the evidence. **Efficacy:** Pooled data suggest that amifostine was beneficial in acute xerostomia but that significant heterogeneity was present (OR = 0.10; 95% CI: 0.02 to 0.48; p = 0.004; χ^2 = 6.87, d.f. = 2, p = 0.032). These data were based on the 3 studies which reported standard outcome measures. Pooled data suggest that amifostine was beneficial in late xerostomia but again, that significant heterogeneity was present (OR = 0.19; 95% CI: 0.05 to 0.64; p = 0.008; χ^2 = 5.32, d.f. = 2, p = 0.07). These data were also based on the 3 studies which reported standard outcome measures. **Tumour protection:** Results indicate that amifostine does not affect the anti-tumour effectiveness of radiotherapy with or without concurrent chemotherapy with carboplatin. **Adverse effects:** Nausea, vomiting, hypotension and allergic reactions were the most commonly reported side effects of amifostine, but they were rarely severe (≥ grade 3). **Quality of life** No differences were seen at baseline between patients with or without amifostine but those treated with amifostine had significantly better quality of life scores at 1, 7 and 11 months than did those patients not treated with the drug.	**Authors' conclusions:** Amifostine is recommended as an effective treatment option for the reduction of acute and chronic xerostomia associated with radical conventionally fractionated radiotherapy, given to patients in the head and neck region encompassing at least 75% of the parotid glands, with or without standard dose carboplatin. The recommended dose is 500mg or doses in the range of 200mgm^{-2} to 300mgm^{-2} given as an intravenous infusion 15mins to 30mins before radiotherapy. **Comments:** This systematic review answers a clearly defined question. The literature search was extensive but the exclusion of non-English language studies may mean some information relevant to the question was omitted. No quality assessment method was reported. The level of reporting of included studies and of the review methods was fair. While studies were combined even in the presence of statistical heterogeneity, the authors were clear in their reporting of this limitation in their results. The conclusions appear to follow from the data presented.

			Route of administration: Similar results were found in 1 small study for patients treated with subcutaneous (19% incidence) and intra-venous (23% incidence) amifostine (p-value or confidence intervals were not reported). **Publication bias:** Results of publication bias analysis were not presented but the authors reported that while the funnel plots appeared to be asymmetrical, Egger's and Begg's tests did not prove publication bias. **Cost:** No cost information was reported.	
Hodson, 2002.[25] **Country:** Canada **Aims:** To investigate if there are effective interventions for symptomatic xerostomia following conventionally fractionated radical radiotherapy for head and neck cancer. **Grade of evidence:** I	**Study design:** RCTs and practice guidelines, meta-analyses or systematic reviews related to the guideline question were eligible for inclusion in the systematic review of the evidence. Phase I and II studies and letters and editorials were not considered. **Participants:** Persons being treated for head and neck cancer by radiotherapy, with radiation-induced xerostomia. **Intervention:** Any intervention. **Outcome:** Symptomatic relief. **Comparator:** The authors did not define an inclusion criterion relating to the comparator with which interventions were to be compared. **Further exclusion criteria:** Non-English language studies were excluded.	**Sources searched:** The literature was searched using MEDLINE (1980 to October 2002), CANCERLIT (1980 to September 2002), the Cochrane Library (Issue 3, 2002), the Physician Data Query (PDQ) databases, clinical trial and practice guideline Internet sites, abstracts published in the proceedings of the annual meetings of the American Society of Clinical Oncology (1995 to 2002), the American Society for Therapeutic Radiology and Oncology (1999 to 2002) and the European Society for Medical Oncology (1998, 2000). Article bibliographies and personal files were also searched to October 2002. **Quality assessment:** No assessment of the methodological quality of studies was reported. **How studies were combined:** Pooled results were given as relative risks, expressed as risk ratios (RR), with 95% Cls. A RR of greater than 1.0 favours the active treatment group. Data were analysed using the random-effects model. All significance tests were 2-sided.	**Number of studies:** 4 placebo-controlled RCTs (n = 401) of oral pilocarpine were identified. 1 randomised cross-over study comparing pilocarpine with artificial saliva was included. 1 cohort of patients followed-up after their enrolment in a previous dose-finding trial, was included in the review. **Efficacy:** Pilocarpine at 5mg to 10mg orally 3 times per day produced subjective responses to treatment including improvements in overall xerostomia symptoms (RR, 1.83: 95% Cl: 1.34 to 2.49; p = 0.00013) oral dryness (RR, 1.60; 95% Cl: 1.17 to 2.19: p = 0.0035) and the need for salivary substitutes (RR. 2.51; 95% Cl: 1.51 to 4.15; p = 0.00035). In a study comparing pilocarpine to artificial saliva, visual analogue scoring by participants favoured pilocarpine (mean change = 22.5% compared with 15.2% for those treated with artificial saliva). This was not statistically significant. **Long term effects:** In a non-comparative cohort study, 136 of 265 patients (51%) were still on pilocarpine therapy after 36 months of follow-up. 34 patients (13%) cited ineffectiveness as their reason for stopping therapy. The reason why others stopped is not reported.	**Authors' conclusions:** For head and neck cancer patients with symptomatic xerostomia following radiation therapy using conventional fractionation schedules, pilocarpine at 5mg 3 times per day is recommended. Patients must have evidence of pre-existing salivary function and no medical contraindications to pilocarpine therapy. It is reasonable to use pilocarpine for patients with symptomatic xerostomia following hyperfractionated or accelerated fractionation radiotherapy. The ideal duration of pilocarpine therapy is unclear. **Comments:** The review is based on what appears to be an appropriate search strategy developed in response to a well defined question. The review could have benefited from additional details about the process used to conduct the study and from an assessment of the methodological quality of the included studies. While the authors pooled data from methodologically similar studies, they did not formally assess the heterogeneity of the studies using either statistical or graphic methods.

			Adverse effects: Adverse events were dose-related. Adverse parasympathetic events were reported; the most frequent and troublesome being increased sweating which occurred in about one-quarter of patients taking 5mg 3 times per day and about 1 half of patients taking 10mg. During the course of a 36-month study 18% of patients discontinued treatment because of adverse effects. No severe or life threatening adverse events were reported in any study. **Cost:** No cost information was reported.	The section on long term effects consisted of 1 small non-randomised study which appears to have been poorly reported. It is not possible to know the long-term effects of pilocarpine from this study. The conclusions regarding the use of pilocarpine appear to follow from the evidence presented but the suggestion that patients undergoing non-standard radiotherapy fractionation schedules would benefit from the drug should only be taken as an assumption as no included study used accelerated or continuous radiotherapy techniques.

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After-care and rehabilitation

The Questions

a) For patients who have been treated for head and neck cancer, what is the effect of rehabilitation services such as dietetics, physiotherapy and speech and language therapy on outcomes?

b) In patients who have been treated for head and neck cancer, does involvement in the management of the patient by a restorative dentist, in the after treatment care period, improve outcomes?

c) For patients who have been treated for head and neck cancer, what is the effect of osseointegrated implant on outcomes?

d) In patients who have head and neck cancer, does early participation in a "patient support group" improve patient outcomes?

e) In patients who have head and neck cancer, does participation in a “patient education group” improve patient outcomes?

f) In patients who have an altered body image, do psychological interventions aimed at improving body image improve patient outcomes?

g) In head and neck oncology, does the use of patient held records (e.g. a ‘teamwork file’) a) improve patient outcomes? and b) improve communication between professionals?

The Nature of the Research Evidence

a) Rehabilitation services

Twelve studies were located which assessed the affect of rehabilitation services on outcomes of patients who had been treated for head and neck cancer.[1-13] Specifically, the review located one case series of patients who

were offered art therapy[1] and eleven studies relating to speech and language therapy.[2-13] Details are given in Table 6a.

The study relating to art therapy contained reports of 14 cases from one US hospital. No details of the service provided by the art therapist were provided.[1]

The majority of studies of speech and language therapy were case series.[3-5, 7-9, 11, 12] However, one RCT,[2] one case study[10] and two questionnaire-based studies[6, 13] were also included in the review.

The RCT assessed a comprehensive programme, one element of which was speech and language therapy.[2] One of the case series studied range of movement, placement and co-ordination exercises.[11] The remainder of the studies gave no details about the type of speech and language therapy received by patients.[3-10, 12, 13]

No studies conducted in the UK were located. Two included studies, one of which was reported in two publications, came from Germany,[2-4] and one each came from India,[5] Switzerland,[6] Slovenia,[7] the Netherlands[8] and Australia[9], while four were conducted in the USA.[10-13]

While studies relating to specific dietetic and physiotherapeutic techniques were located for this review, no assessments of the role of dietitians or physiotherapists were located.

b) Involvement in management by a restorative dentist

No evidence was found relating to involvement by a restorative dentist, in the management of patients who have been treated for head and neck cancer in the after treatment care period.

c) Osseointegrated implant

No comparative experimental studies were located which addressed this question. The review did locate a number of case series and non-experimental comparisons. Only those which had included thirty or more patients were eligible for this review; eight such studies were located.[14-23] These studies were conducted in Germany,[14-19] Sweden,[20, 21] the USA[23] and Japan.[22] Details of the studies are given in Table 6c.

The studies investigated a number of proprietary systems which have been used to achieve osseointegrated implantation and they included a number of different indications for head and neck reconstructive surgery. All but one study only included head and neck cancer patients,[14-21, 23] in the remaining study the majority of patients also had cancer.[22]

All the studies were retrospective assessments of case series. In the three German studies, the factors affecting whether the implant integrated with local bone were examined by means of a descriptive assessment.[14-18] The remaining studies included a quantitative comparison which assessed individual factors which may influence integration.[19-23] The two Swedish studies, from the same institution, investigated the effects of radiotherapy with or without hyperbaric oxygen therapy (HBO).[20, 21] Radiotherapy was also the factor of interest in the Japanese assessment of osseointegration.[22] Two proprietary systems were investigated in the US study.[23]

Each study reported the methods used to achieve osseointegration and some reported the other treatments the patients received. However, with only one exception, none listed the methods, other than statistical tests, used in conducting the study. It is not clear from the reports how information was recorded or collated or by whom this was done. Where comparisons were conducted, it is often unclear how patients were allocated to the different treatments. Systematic differences in the populations determining what treatments they had may have affected the results of osseointegration. As such the information here can only be regarded as suggestive. Details are given in Table 6c.

d) Patient support group

Three observational assessments of support groups were located.[24-27] The studies were conducted in Norway,[24] Canada[25] and the UK.[26, 27] One was conducted using questionnaire methodology,[24] one using interview techniques[25] and one study, published in report format with a subsequent peer-reviewed article publication, used focus group methods.[26, 27]. A case study of the practice of a therapist in the US who acted as a facilitator for a support group was also identified.[28] The therapist reported her experiences with the groups she had attended. As all the studies used methods designed to elicit personal experiences, it is important that care must be taken not to over-generalise from the findings. The findings should be regarded as suggestive rather than definitive and application to other populations should be done with caution. Details are given in Table 6d.

e) Patient education group

Two uncontrolled observational studies reported the experiences of a series of head and neck cancer patients attending a monthly educational self-help group[29] and a one-week psycho-educational program one year after diagnosis.[30] Details are given in Table 6e.

f) Psychological interventions aimed at improving body image

No evidence was found relating to psychological interventions aimed at improving body image for patients who have an altered body image.

g) Patient held records

One controlled study was identified which evaluated the use of a 'log-book' that had been developed to improve continuity of information in the treatment and care of head and neck cancer patients.[31] Out of 71 patients given the log-book, 60 returned their evaluation questionnaire and their responses were compared with 39 of 54 control patients who responded, who were not given the log-book and were being treated at a different hospital. Details are given in Table 6g.

Summary of the Research Evidence

a) Rehabilitation services

The authors of a study of 14 individual cases seen by an art therapist reported that patients were initially hesitant about having the therapy but that, in the opinion of their therapist, the MDTs understanding of the patients was improved by the treatment.[1] This study had few details of the therapy and did not illicit patients' perceptions but it does suggest that there may be a role for art therapy in patients with head and neck cancer. The authors felt it could be particularly helpful for patients with communication problems owing to either the disease or its treatment.

An RCT compared patients given a comprehensive care package with those given usual care; one element of this package was assistance with communication.[2] Patients who received the package of care had greater influence over their communication skills than had patients in the control group. The package was multi-facetted and as such it is difficult to know the relative contribution of speech and language therapy on patient outcomes.

A number of case series have been included in this review.[3-5, 7-9, 11, 12] The findings of these studies were similar to each other. Patients appeared to have benefited from their access to speech and language therapy. However, speech and language therapy was poorly defined in almost all studies. Few details of the treatments given or techniques used were reported. Similar findings were seen in the case study included in this review.[10]

Patients' opinions were canvassed in two questionnaire-based studies.[6, 13] Their findings were, again, consistent. In the Swiss questionnaire study, many patients received speech therapy only from patient visitors and not from trained speech and language therapists.[6] This may adversely effect its relevance to practice in the NHS where rehabilitation is supervised by qualified health professionals. The US survey, among female patients who had had a laryngectomy, found that most patients (87%) received services from a speech and language therapist and 68% of these were satisfied with the

service they received.[13] However, the duration of therapy was shorter than is common in NHS practice; most having had only 3 months of speech and language therapy or less. Both surveys were conducted among members of laryngectomee associations. This may limit their generalisability to patients not in associations. Neither was UK-based.

Conclusions

Given the retrospective nature of these studies, the biases this introduced and the lack of detail on the content of art therapy speech and language therapy interventions, it is not possible to make an definite conclusion. However, the research suggests that speech and language therapy has an important role to play in the rehabilitation of patients with head and neck cancer. Further research is needed to identify the role of art therapy.

b) Involvement in management by a restorative dentist

No evidence was found relating to involvement by a restorative dentist, in the management of patients who have been treated for head and neck cancer in the after treatment care period.

c) Osseointegrated implant

Similar rates of implant survival were found when implants were placed in the maxilla in patients who had been treated by radiotherapy and those who had not.[14] This German study reported differences in the rates of implant survival when using different proprietary systems to place implants in the mandibles of patients who had undergone radiotherapy, but no test for statistical significance was conducted.

Another German study also reported similar rates of implant survival in patients who had been treated by radiotherapy and those who had not.[18] This study found that the interval between procedure to implant the fixations in the bone and the procedure to attach the prosthesis to those fixations had a significant influence on the probability of integration.

A number of reports were located which gave the results of implantations at a German academic hospital.[15-17, 32-34] Only those that presented unique data were included in this review.[15-17] This study reported an overall success rate of 85.5%. This was not adversely affected by the addition of chemotherapy to the treatment schedule. Most patients expressed contentment with their level of rehabilitation and were able to resume normal eating habits, however in some patients this took up to a year.

Overall findings of a case series and a comparative analysis of patients treated with and without radiotherapy were reported in a fourth German study.[19] They reported a 91% overall integration rate. In contrast to some of the other studies, they reported a lower rate of success in patients who had been irradiated. The authors defined success using criteria they had devised but did not give full details; this definition of success does not appear to have been validated.

In a Japanese study, a case series was stratified according to both the radiotherapy status of the patients and whether their implants were placed in grafted or original bone.[22] The survival rates for the implants original bone was 85.9% compared with 93.1% for grafted bone. The study reported survival rates of 79.7% for irradiated bone and 93.5% for non-irradiated bone. While one thirds of the patients included in this study did not have malignancies, no differences were found in the results reported for patients with cancer and those with benign tumours, cysts or osteomyelitis.

Two studies reported on the use of HBO in combination with radiotherapy.[20, 21] Data pertaining to some patients may be included in both of these Swedish series. The studies found that HBO was beneficial. While rates of survival were higher in non-irradiated than in irradiated patients, those who had had HBO in addition to radiotherapy had rates of implant survival similar to non-irradiated patients.

In a study comparing two types of implants,[23] normal practice was changed from using solid screw (SS) steel and titanium plates to using titanium hollow-screw osseointegrating reconstruction plates (THORP) and subsequently assessed the different performances of the methods, finding improved rates of implant survival when using THORP implants.

As with all retrospective studies, it is important to remember that important biases may have influenced the findings of all of these reports and unlike in prospective designs, that these are less likely to have been allowed for. These biases are particularly problematic in reading reports of research, such as these, which do not report sufficient details of the methods used to collect their data.

Conclusions

It appears that the probability of osseointegration may be reduced in patients who have had radiotherapy. Some evidence exists that suggests that HBO may reduce the effect of radiotherapy on osseointegration. While treatment-related factors have an important influence on the outcome of osseointegration procedures, it appears that anatomical factors may play an especially important role. Grafted bone appears to be more likely to permit osseointegration than local bone and integration is more likely in the mandible than in the maxilla. Given the uncertainties to which the methods used in these studies are exposed, these conclusions should be regarded as suggestive.

d) Patient support group

A questionnaire was sent to all members of a laryngectomy association in Norway.[24] This study stratified respondents according to their level of participation association activities; including local branch meetings, an annual national convention, an association-organised holiday and a "Patient as Educator" programme. Regarding local and national meetings and the holiday, participating members performed statistically better than non-participants relating to the functional aspects of disease. There were no

statistical differences in the functional effects of participants and non-participants in the "Patient as Educator" programme. When the level of symptoms was examined, only active participants in the local branches had statistically significant improvements over non-participants; participation in national meetings, the educator programme or the holiday did not appear to affect symptoms.

An interview-based study of 45 participants asked patients being followed-up for head and neck cancer about a range of variables, one of which was social support.[25] During the course of their interviews, four patients volunteered they had attended support groups and that they were very satisfied with the support they received from the group. No details of the groups were provided.

An extensive focus-group study, involving both patients and professionals was conducted in the UK. It asked about a large range of issues, one of which was the role of support groups.[26, 27] Patients felt that support groups provided a lifeline and described the relief they felt on meeting someone who understood what they had been going through and the benefits of peer-support. Some patients had not heard about support groups and felt that they may have benefited from the chance to decide if they wished to attend.

Additional surveys, including questionnaires, interviews and focus groups, are useful research methodologies in eliciting individuals' experiences but often are prone to important biases. As they often ask respondents to report past experience, they can be open to recall bias. As interviews and focus-groups are led by professionals, in cases where the interviewer/facilitator was a member of the treatment team, participants may say what they think their professional wants to hear. Also, as all these methodologies depend on who chooses to take part, the population of respondents is an important factor in the information gathered. Those with very positive or negative experiences may be more likely to complete a questionnaire or join a focus group while those with no strong opinions may be less inclined to do so.

A case study of the practice of one therapist reports collated data from a number of group meetings she facilitated.[28] All patients were male and the majority were inpatients; relatives were welcomed to join the group. Following each session the therapist completed a form summarising the session. The subjective impressions of the therapists were that the group was beneficial to its participants. There appeared to be an increased cohesion among the participating patients, even outside the group setting. Patients developed an increased ability to discuss sensitive issues openly. However, it is important to note that the opinions of one individual about the performance of her service, while illustrative, cannot be generalised to the population of head and neck cancer patients in general.

Conclusions

Three surveys and a case study have provided evidence to suggest that patients who are members of support groups derive benefits from their membership.

e) Patient education group

Fourteen patients who attended a one-week psycho-educational program a year after diagnosis appreciated all activities, learned new things, considered this knowledge useful and would recommend a week of rehabilitation in this format to other cancer patients.[30] No great differences in quality of life scores were found before and after the intervention, with the exception of variables reflecting functioning and symptom burden, which improved after the rehabilitation.

Patients reported satisfaction with a monthly educational self-help group and suggested that they had a better understanding of cancer, the views of patients and doctors, reconstructive possibilities and better cooperation in relation to giving up smoking or drinking alcohol, a reduced sense of isolation and more help with financial problems.[29]

f) Psychological interventions aimed at improving body image

No evidence was found relating to psychological interventions aimed at improving body image for patients who have an altered body image.

g) Patient held records

The majority of patients who were given a log-book, containing sections on communication and information, had read the whole log-book and said that it clarified things for them.[31] Patients in a control group who were not given the log-book were more likely to have fear, anxiety, depression and tension, but there were no differences in the incidence of loneliness, insomnia, loss of control or reduction in self-esteem. The majority of professionals involved in treating patients who had received the log-book thought it was a good means of information giving and it made a considerable contribution to the continuity of information, also being useful in giving them an overview of the patient's case history and contributing to harmonising care between professionals.

Table 6a: Rehabilitation services

<table>
<tr><th>Study details and aims</th><th>Details of service and participants</th><th>Methods</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>de Maddalena, 1993.[2]

Country:
Germany

Aims:
To analyse the effectiveness of a psychological training program aimed at improving the communication behaviour of persons having undergone a laryngectomy.

Grade of evidence:
II</td>
<td>Service:
Psychological communication training (6 to 8 sessions) within a structured psychological rehabilitation program for laryngectomy patients. The communication training comprised the 4 elements
• improvement of communication over the disability,
• discrimination of factors affecting intelligibility,
• development of behavioural strategies for improving intelligibility in daily conversation,
• transferring the strategies to daily life.

Participants:
All patients were diagnosed with larynx-carcinoma or pharynx-carcinoma before the laryngectomy.</td>
<td>Methods:
Patients were randomly assigned to a training program (24 participants) or a control group (27 participants).

Outcomes measured:
Word comprehensibility.

Sentence comprehensibility.

Actively influencing the own communication behaviour.

Actively influencing the behaviour of typical communication partners.

Withdrawal from conversations.

Length of follow-up:
First data collection within a psychological assessment setting (4 to 5 1-hour sessions) before the operation.

Second data collection at a final evaluation event at the hospital 6 months after hospital discharge.</td>
<td>Included patients:
The study included 51 patients aged between 32 years and 78 years (mean: 53.3 years; SD: 9.5 years).

Withdrawals and exclusions:
Intervention group:
7 dropouts for training (3 transport problem, 2 physical problems, 2 lack of interest in psychotherapy after a couple of training sessions)
19 patients available for second data collection (15 with training, 4 dropouts). Data were missing relating to 5 patients (3 died, 2 refused survey).

Control group:
20 patients available for second data collection, missing data from 7 patients (3 died, 4 refused survey).

Results:
As a result of the intervention the patients influenced more effectively their own communication behaviour and also influenced more adequately the behaviour of typical communication partners.

Word comprehensibility:
<table>
<tr><th>Time</th><th>Intervention</th><th>Control</th></tr>
<tr><td>Before surgery</td><td>36.7 (SD: 30.6)</td><td>28.8 (SD: 26.8)</td></tr>
<tr><td>6 months post discharge</td><td>48.7 (SD: 29.9)</td><td>47.5 (SD: 26.8)</td></tr>
</table>
Sentence comprehensibility:
<table>
<tr><th>Time</th><th>Intervention</th><th>Control</th></tr>
<tr><td>Before surgery</td><td>49.6 (SD: 39.6)</td><td>42.2 (SD: 35.2)</td></tr>
<tr><td>6 months post discharge</td><td>62.6 (SD: 33.3)</td><td>54.0 (SD: 37.6)</td></tr>
</table>
Actively influencing the own communication behaviour:
<table>
<tr><td>Intervention</td><td>16.1 (2.6)</td><td rowspan="2">F = 2.6 (p < 0.05)</td></tr>
<tr><td>Control</td><td>14.1 (2.8)</td></tr>
</table>
Actively influencing the behaviour of communication partners:
<table>
<tr><td>Intervention</td><td>14.9 (2.9)</td><td rowspan="2">F = 2.6 (p < 0.05)</td></tr>
<tr><td>Control</td><td>12.1 (3.7)</td></tr>
</table>
Withdrawal from conversations:
<table>
<tr><td>Intervention</td><td>22.8 (5.3)</td><td>F = ns</td></tr>
</table>
</td>
<td>Authors' conclusions:
The communication behaviour of persons having undergone a laryngectomy can be improved significantly by a communication training programme.

Comments:
The methods used to allocate the patients to each group were not described. Patient blinding was not feasible with this type of intervention but it was not stated if outcomes assessment was conducted by professionals blinded to allocation. Withdrawals were listed but the reasons why some patients lost interest in the intervention were not probed. The authors conducted both a per-protocol and intention-to-treat analysis. As the latter is regarded as the most useful measure, only these results are presented here.

The communication training formed a relatively small part of the comprehensive psychological rehabilitation training programme that constituted the intervention.

Given the methodological flaws and the difficulty in differentiating the effects of various aspects of the</td>
</tr>
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			Control 22.4 (5.3)	programme, it is not possible to be sure whether this study supports rehabilitative communication training.
Gates, 1982.[12] **Country:** USA **Aims:** To investigate the current status of laryngectomee rehabilitation. **Grade of evidence:** V	**Participants:** Patients recruited from otolaryngology services of the 4 teaching hospitals in San Antonio and from private physicians in the community. Every patient with a clinical diagnosis of cancer that could potentially necessitate laryngectomy for treatment was eligible to be a prospectively studied participant (PS) unless their condition was too poor to permit testing. Patients who had undergone laryngectomy previously (1 to 23 years prior to evaluation) or who had otherwise not been included in the PS group were studied retrospectively (RS) **Service:** PS patients were visited in hospital by the study team (comprising an audiologist, otolaryngological head and neck surgeon, clinical psychologists, speech and language therapists, a gastroenterologist and statistician) to provide support, counselling, instructions in the use of the electrolarynx and other	**Methods**: PS patients were assessed pre-operatively and 6 months after completion of their cancer therapy. RS patients underwent the post-operative assessment. **Outcomes measured:** Assessment included the patients providing information about themselves, their feelings and concerns (pre-operatively), a series of psychological tests: • Bender-Gestalt test • Attitude Toward Disabled Persons Scale • Sixteen Personality Factor Questionnaire • Fundamental Interpersonal Relations Orientation Behaviour Test • A 9 question Criterion Learning Task • An Existential Evaluation (developed by the authors) • Wechsler Adult Intelligence Scale • A biographical questionnaire	**Included patients:** 93 patients were recruited: 53 PS patients and 40 RS patients. The mean physical strength and vigour score of the RS group was statistically significantly higher ($p = 0.0005$) than that of the PS group (RS group 3.52 ± 0.3 versus 2.5 ± 0.1 in the PS group). PS patients received an average of 5.3 months of speech and language therapy (range 1 to 6 months) with an average of 12.5 lessons (range 1 to 62); 57% used an electrolarynx during their instruction period. The RS group received an average of 17 speech lessons (range 1 to 97) in an average period of 3 months (range 1 to 12); 41% used an electrolarynx during their instruction period. 47 PS patients were available for the sixth post-therapy month evaluation, 12 (26%) used oesophageal speech in daily communication; 3 also used the electrolarynx when tired or the need for greater loudness or rate arose. 16 (34%) used the electrolarynx exclusively, 16 (34%) depended on writing and 3 (6%) on signing to communicate. Only 35 (74%) of these patients attempted to learn oesophageal speech; thus, the rate of oesophageal speech acquisition was 12/35 (34%). In the RS group 25 of the 40 patients (62%) used oesophageal speech as their primary means of communication. 47% of the PS group showed substantial denial post-operatively and 35% had distorted perceptions of reality, 18% had no denial. Denial was absent in 36% and substantial in only 15% of the RS group with 49% having distorted perceptions of reality. Self-image was similar in both the PS and RS groups. 69% PS patients had poorer self-image post-operatively, 27% felt the same and 4% felt better than they had pre-operatively. Attitudes to life were poorer in 57% PS patients, the same in 41% and better in 2% (1 patient). Social activities of 59% PS patients were reduced to various extents. The RS group reported similar findings. The average cost of rehabilitative measures (based on the average 1978 charges in San Antonio) was estimated to be $413. The total costs of illness averaged $8,062. The outcome of rehabilitation for the 47 PS patients available for post-operative evaluation was judged to be successful for 26 patients (55%) and a failure for 21 patients (45%). Criteria for success were: effective communication ability, a lifestyle equivalent to the pre-treatment situation and an adequate psychological adjustment to their disability.	**Authors' conclusions:** These data indicate that the rehabilitative needs of today's laryngectomee are not being met successfully with traditional methods. The authors also conclude that the psychosocial changes which occurred were highly inter-correlated but showed little relationship to success or failure of rehabilitation. **Comments:** The PS group received the additional 'support, counselling, instructions in the use of the electrolarynx and other measures as necessary' provided by the study team in hospital. No further details of this additional intervention were given. Therefore, it is difficult to ascertain the difference in the interventions received by the 2 groups or make conclusions about the effectiveness of the additional intervention. The authors' conclusions that the rehabilitative needs of today's laryngectomee are not being met successfully appear to be valid. However, the use of historical controls over such a long period, along with the differences between the historical and the

	measures as necessary. Oesophageal speech lessons were offered to all patients and were carried out until maximum benefit had been reached or the patient discontinued. Two thirds of patients were visited pre-operatively by a laryngectomised speech teacher from the American Cancer Society (ACS). Current state-of-the-art speech instruction was given by experienced lay-laryngectomees from the ACS and speech and language therapists, including a laryngectomised speech and language therapist.	There was also a videotaped interview to record speech characteristics, an audiogram and oesophageal manometry. Naive listeners judged the intelligibility and acceptability of the speech produced post-operatively. Speech and language therapists judged phonation time, number of syllables, consistency, type of air injection and communication effectiveness.		intervention group, may have biased the results of this study. Many of the participants were recruited from army and air force medical centres, therefore they may not be generalisable to the general public and the age of the study reduces the meaningfulness of the cost data.
Anand, 1997.[1] **Country:** USA **Aims:** To report a hospital-based art therapy programme's experiences of managing laryngeal cancer. **Grade of evidence:** VI	**Participants:** Patients who have undergone a laryngectomy for larynx cancer. **Service:** A 593-bedded in-patient teaching hospital provided care for 109 laryngeal cancer patients from 1982 for a period of 14 years. An art therapist was a member of the multi-disciplinary team. The art therapist designed interventions specific to each patient dependent on their particular disease and their physical and psychological characteristics.	**Methods:** A case series is presented representing the cases seen by the authors. **Outcomes measured:** Patients' and staff's subjective experiences.	**Included patients:** 6 case reports of individual patients were presented. In addition, data were presented on a group with an unspecified number of participants. **Results:** Most patients were initially hesitant. Constant reassurance and interventions to reduce anxiety were key to promoting active participation from participants. The art therapist's perceptions of the psychological and functional status of the patient was believed to be valuable to the multi-disciplinary team's understanding of the patient. Participation in art therapy and the resulting artwork can assist the treating team in assessing psychological changes and adaptation to surgery. The therapy was believed to be particularly suited to those patients who had communicative deficit either from their disease or its treatment.	**Authors' conclusions:** The authors did not present conclusions but appear to suggest that art therapy is beneficial to patients in the pre- and post- operative phase of treatment for larynx cancer. **Comments:** This retrospective piece of work consists of the authors' experiences of their service as evidenced by a number of case exemplars. The total number of patients undergoing laryngectomy was 109 but the total number who had art therapy was not reported. The case studies reported are neither consecutive nor a random sample and should not be regarded as representative of the

<table>
<tr>
<td></td>
<td>Consultations often began on the first day of admission, (that is the day before surgery) but in the cases of patients treated in an emergency, post-operative consultations were often the patient's first contact with the art therapy service.

An unstructured approach was used most commonly.</td>
<td></td>
<td></td>
<td>total population. The research should be regarded as a qualitative and ethnographic assay of the service.

The discussion of the examples gives a good overview of the service and the study is informative.</td>
</tr>
<tr>
<td>Bachher, 2002.[5]

Country:
India

Aims:
The authors aims are not reported in the paper but appear to be to assess the demographic and clinical characteristics of a group of patients who were treated by glossectomy.

Grade of evidence:
VI</td>
<td>Service:
The authors do not describe their service in detail but it appears that this service provides care for persons from a wide area within India.

Speech and language therapy included exercises to improve swallowing initially, followed by the introduction of exercises to correct problems with speech at a later date.

Sessions were for 25 to 30 minutes with the patient being advised to repeat their exercises for 15 minutes in every hour. Patients were seen daily in the first 2 weeks, 3 times in the third week and twice in the fourth at which time they were discharged to follow-up.

Participants:</td>
<td>Methods:
Questionnaires which were specially designed to obtain information on patient demographics, functional deficits and articulation capabilities were administered to participants. The questionnaires were given before and 3 months after surgery. Outcomes were measured by a speech and language therapist and a maxillo-facial prosthodontist.

Outcomes measured:
Articulation

Speech intelligibility

Tongue movement and mobility

Oral Phase Swallowing</td>
<td>Included patients:
25 patients were sent the questionnaire. These included 18 men and 7 women from a range of religious and linguistic backgrounds.

Articulation:
<table>
<tr><td>No errors</td><td>5 (20%)</td></tr>
<tr><td>2 consonants defective</td><td>7 (28%)</td></tr>
<tr><td>3 to 4 consonants defective</td><td>5 (20%)</td></tr>
<tr><td>3 placements defective</td><td>4 (16%)</td></tr>
<tr><td>Greater than 3 placements defective</td><td>2 (8%)</td></tr>
<tr><td>Severe</td><td>2 (8%)</td></tr>
</table>
Speech intelligibility:
<table>
<tr><td>No sound errors in continuous speech</td><td>1 (4%)</td></tr>
<tr><td>Occasional sound errors in continuous speech</td><td>4 (16%)</td></tr>
<tr><td>Intelligible speech with noticeable errors</td><td>15 (60%)</td></tr>
<tr><td>Unintelligible speech</td><td>5 (20%)</td></tr>
</table>
Tongue movement and mobility:
<table>
<tr><th></th><th>Movement</th><th>Mobility</th></tr>
<tr><td>Poor</td><td>3 (12%)</td><td>8 (32%)</td></tr>
<tr><td>Fair</td><td>5 (20%)</td><td>8 (32%)</td></tr>
<tr><td>Good</td><td>17 (68%)</td><td>9 (36%)</td></tr>
</table>
Oral phase swallowing:
The results relative to this outcome appear to have been omitted. However the authors comment on their results that patients had improved deglutition 3 months after surgery.</td>
<td>Authors' conclusions:
Rehabilitation of speech and swallowing plays an important role in socialisation and speech and language therapy to improve speech and swallowing in patients who have undergone glossectomy is essential.

Comments:
This is a poorly reported study. While it describes the contact time between the therapist and patient, few details are given of the therapy offered. The service as a whole is poorly reported and some of the results appear to have been omitted.

The study appears not only to have a very small sample, but to draw this from a very select group of patients. The demographic profile of the patient does not appear to mirror the population of India as a whole. Additionally, some of the methods used in the study are unclear.</td>
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	Patients were chosen at random to complete a questionnaire. All patients underwent partial glossectomy for cancer of the tongue with an anterior two-thirds resection.			
Dejonckere, 1998.[8] **Country:** The Netherlands **Aims:** To investigate possible prognostic factors for the success of therapy for swallowing after curative treatment of head and neck cancer. **Grade of evidence:** VI	**Participants:** Consecutive head and neck cancer patients treated in the ENT or maxillofacial departments of the University Hospital of Utrecht between 1992 and 1995. Patients who underwent total laryngectomy were not included. All patients were referred to the Swallow Team for swallowing rehabilitation; most were also referred for concomitant speech rehabilitation. **Service:** All patients received intensive rehabilitation.	**Methods:** At the time of referral all patients underwent a detailed investigation of their anatomical/physiological status. The Swallow Team conducted at least 1 comparative clinical evaluation for every patient. Where possible this was done before the patient left the hospital, otherwise it was done during or at the end of outside rehabilitation. **Outcomes measured:** In each patient 18 parameters were registered and quantified on the basis of the intake data, clinical and endoscopic findings and videofluroscopic observations. Those relating to rehabilitation were: (1) swallow status after oncological treatment, at the beginning of the swallowing rehabilitation; (2)	**Included patients:** Of the 100 head and neck cancer patients identified, 18 patients who developed recurrence or metastases during the observation period were excluded, leaving 82 patients; 58 males and 24 females. The majority of patients scored 3 for impairment of swallowing before rehabilitation (exclusively tube feeding), whereas after rehabilitation the majority of patients scored 1 for impairment of swallowing (oral feeding with limited impairment). Impairment was higher in patients who were aspirating than in patients with transport problems, both before and after treatment. For 45% patients the rehabilitation process lasted less than 12 weeks. For 78% the duration was less than 24 weeks. **Results:** The overall pre-treatment and post-treatment distributions differ significantly ($p = 0.0001$), indicating improvement. Improvement was statistically significant in the following parameters: loss of sphincteric function of the larynx, presence of palatum reflex and gag reflex.	**Authors' conclusions:** Overall, a major improvement in swallow quality was observed after rehabilitation, although some cases (9/82) remain therapy-resistant. Patients with transport problems have a significantly better functional prognosis than patients with aspiration. **Comments:** The conclusions of this study appear to be valid, however the only information given about the rehabilitation programme is that it was intensive and a small amount of data on its duration. The authors acknowledge that the absence of a control group means that information about spontaneous improvement is lacking. Impairment in swallowing before and after rehabilitation data are shown in a graph only, not in the text or tabulated, therefore, exact figures cannot be ascertained from the paper.

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<td>duration of rehabilitation (in weeks); (3) swallow status at the time of the last contact of patient with the Swallow Team; (4) improvement in swallowing quality – this amounts to the difference between (3) and (1).</td>
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<td>Hocevar-Boltezar, 2000.[7]

Country:
Slovenia

Aims:
To identify the factors adversely influencing the post-treatment rehabilitation in patients with head and neck cancer.

Grade of evidence:
VI</td>
<td>Participants:
Consecutive patients with oral cavity, pharyngeal or laryngeal cancer who were surgically treated in 2 successive years were included in the study.

Service:
Before the beginning of therapy patients were examined by an otorhinolaryngologist, a phoniatrician and a speech and language therapist. The post-treatment rehabilitation (medical and respiratory physical therapy, speech and swallowing therapy, prescription or hearing aids and proper training) was planned according to the findings obtained.</td>
<td>Methods:
The data about the factors influencing the success of post-treatment rehabilitation (hearing impairment, effects of previous neurological, pulmonary and gastroenterological diseases) were obtained from the patient's history and clinical examination. The hearing acuity was assessed by audiometry. The dental status was assessed with respect to the ability of chewing and speech. Pulmonary function was assessed on the basis of clinical examination, chest x-ray and spirometry for pulmonary function. The site and stage of cancer were determined. The articulation disorders which could hinder speech after surgical treatment were assessed by a speech and language therapist.</td>
<td>Included patients:
171 patients were included in the study. During the study 13 patients died, 29 refused to participate, 19 patients were lost to follow-up; 110 patients were included in the analysis (102 males (93%) and 8 females). Patients' age ranged from 37 to 81 years (mean 56.2 years).

24 patients (22%) had oral cancer, 17 (15%) had nasopharyngeal cancer, 21 patients (19%) had hypopharyngeal cancer and 48 patients (44%) had laryngeal cancer. 8 patients had stage T1 disease, 43 had stage T2 disease, 29 had stage T3 disease and 30 had stage T4 disease. 61 patients were node negative, 19 had stage N1 disease, 28 had stage N2 disease and 2 had stage N3 disease.

19 patients had tumour excision, 16 had tumour excision and partial mandibulectomy, 20 had conservative laryngectomy and 55 underwent total laryngectomy. 101 patients had uni- or bilateral functional neck dissection, 8 patients had radical neck dissection and 1 patient had no surgery of the neck. 85 (77%) patients received post-operative radiotherapy.

48 patients (44%) were free of any disease that could hinder their rehabilitation after treatment for head and neck cancer. 62 patients (56%) had different neurological disorders (11 patients), gastroenterological diseases (24 patients), pulmonary diseases (20 patients) and other malignant diseases (7 patients) which could influence their rehabilitation.

In 60 patients (55%) the hearing acuity was slightly impaired but did not hinder the patients in their every-day communication. In 10 patients (9%) the hearing loss was moderate and in 3 patients (3%) the loss was severe.

Articulation disorders were not found in any of the examined 57 patients.

Results:
Patients' self-assessment of their ability to swallow 12 months after treatment (n=110)
<table>
<tr><th>Swallowing</th><th>Poor</th><th>Satisfactory</th><th>Excellent</th><th>Unknown</th><th>Total</th></tr>
<tr><td>Laryngectomised patients</td><td>7</td><td>16</td><td>30</td><td>2</td><td>55</td></tr>
<tr><td>Oral cavity cancer patients</td><td>8</td><td>10</td><td>6</td><td>0</td><td>24</td></tr>
<tr><td>Other patients</td><td>7</td><td>10</td><td>13</td><td>1</td><td>31</td></tr>
<tr><td>All patients</td><td>22</td><td>36</td><td>49</td><td>3</td><td>110</td></tr>
</table>
</td>
<td>Authors' conclusions:
Early identification of unfavourable factors before the beginning of treatment, individually planned rehabilitation and intensive help of different professionals (an otorhinolaryngologist-surgeon, a phoniatrician, a speech and language therapist) after the treatment can ensure a proper rehabilitation of the affected functions and a suitable quality of life for patients that have undergone surgery for head and neck cancer.

The authors also conclude that they cannot be satisfied with the results of speech rehabilitation of the laryngectomised patients; only 1/3 of such patients were satisfied with their oesophageal speech.

Comments:
The authors' conclusions appear to be valid, with the exception of their reference to quality of life, which was not investigated in their study.</td>
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<td>12 months after the completed treatment, the patients assessed the success of their rehabilitation in general and their speech and capability of swallowing (excellent, satisfactory or poor).

Statistical Methods:
The influence of possible unfavourable factors on speech, swallowing and reintegration competence was determined using χ^2 test and Fisher exact test.</td>
<td>Patients' self-assessment of their ability to speak 12 months after treatment (n=110)
<table>
<tr><th>Swallowing</th><th>Poor</th><th>Satisfactory</th><th>Excellent</th><th>Unknown</th><th>Total</th></tr>
<tr><td>Laryngectomised patients</td><td>34</td><td>11</td><td>7</td><td>3</td><td>55</td></tr>
<tr><td>Oral cavity cancer patients</td><td>6</td><td>8</td><td>10</td><td>0</td><td>24</td></tr>
<tr><td>Other patients</td><td>7</td><td>7</td><td>17</td><td>0</td><td>31</td></tr>
<tr><td>All patients</td><td>47</td><td>26</td><td>34</td><td>3</td><td>110</td></tr>
</table>
Patients' self-assessment of their rehabilitation in general 12 months after treatment (n=110)
<table>
<tr><th>Swallowing</th><th>Poor</th><th>Satisfactory</th><th>Excellent</th><th>Unknown</th><th>Total</th></tr>
<tr><td>Laryngectomised patients</td><td>6</td><td>19</td><td>15</td><td>15</td><td>55</td></tr>
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<tr><td>Other patients</td><td>0</td><td>4</td><td>20</td><td>7</td><td>31</td></tr>
<tr><td>All patients</td><td>8</td><td>26</td><td>48</td><td>28</td><td>110</td></tr>
</table>
There were no significant differences in swallowing assessment between the laryngectomised patients and all other patients. Speech was significantly poorer in laryngectomised patients than in all other patients. Patients treated for oral cavity cancer assessed their ability to speak as "poor" more often than other cancer patients, but the difference was not statistically significant.

The assessment of rehabilitation in general was approximately the same in all patients irrespective of site of tumour or type of surgery.</td>
<td>This prospective case series appears to have been well conducted with adequate assessment prior to rehabilitation. However, patient assessment of their rehabilitation is highly subjective and it is not stated whether the assessor was known to the patients, which may bias the results.</td>
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<td>Lehmann, 1991.[6]

Country:
Switzerland

Aims:
To present some of the results of a patient opinion survey.

Grade of evidence:
VI</td>
<td>Participants:
332 patients (90% male) who had undergone total laryngectomy owing to carcinoma of the larynx. Patients were identified using the membership lists of the Union of the Swiss Associations of Laryngectomees and with the help of treating hospitals for non-members. A representative sample of patients were contacted from the list of laryngectomees.

Service:
90% laryngectomees received speech and</td>
<td>Methods:
Thirty experienced and specially trained interviewers conducted the interviews, which took an average of 50 to 60 minutes each, using standardised, pre-tested questionnaires. Around half of the interviews were conducted alone with the person concerned, in 4 out of 10 cases the spouse was present, rarely another person.

The survey, concerning the living situation of laryngectomees, was</td>
<td>Included patients:
On average 7 years had passed since the operation (range 1 year to more than 20 years).

Results:
Half of the laryngectomees took 1 month to 3 months to communicate with the outside world through speech, 20% needed 4 months to 6 months and 15% took longer. For 5% speech communication was still not possible at the time of interview. 65% were satisfied with the results of speech rehabilitation, 15% reasonably satisfied, 17% dissatisfied and 3% gave no answer. 2 thirds of relatives said that they had adapted well to the new method of communication; 1 third reported initial difficulties.

51% laryngectomees used the oesophageal voice as their most frequently used means of communication, 31% used electronic voice prosthesis, 25% used pseudo-murmur (whisper), 11% used written communication and 2% used gestures and mime. 20% frequently used 2 or more communication techniques. For those patients where the desired success had not materialised, at least the will and the effort from all sides were regarded as definitely worthy of praise.

The interviewees stated definite wishes and their needs for improved and new services. In the social area, the list of wishes included: Better and more speech courses, refresher seminars and repeat courses. Also, speech courses should be conducted by laryngectomees.</td>
<td>Authors' conclusions:
A third of the laryngectomees were totally or partly unsatisfied with the speech rehabilitation program. There appear to be remarkable differences within the various language regions in Switzerland with regard to speech rehabilitation. Early speech and language therapy is a factor of great importance.

Comments:
A large and seemingly representative sample of laryngectomees were included in this survey. The authors' conclusions appear to be valid, however the method of data collection was highly subjective</td>
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	language therapy to learn the oesophageal voice. This therapy was provided in 80% to 90% of cases in the German- and French-speaking parts of Switzerland by speech and language therapists; in the Italian-speaking part, only 24% were trained by speech and language therapists. For the whole of Switzerland approximately 20% laryngectomees received speech training from another laryngectomee; in the Italian-speaking part the figure was 80%. The period between the operation and the start of speech and language therapy varied from 1 week to more than 12 weeks, approximately half of the patients received speech and language therapy during the first 6 weeks after the operation. Usually, medical reasons were the cause of this delay. The duration of speech and language therapy also depended mainly on the post-operative anatomical situation as well as on age and mental condition. The average duration was 12 weeks (range 1 week to more than 1 year). An average of 20 lessons were received (range less than	intended to provide information about the medical, social, psychological, work-related and financial problems of laryngectomees.		and patients had been treated between 1 and over 20 years prior to the interview.

	10 to more than 50).			
Logemann, 1997.[11] **Country:** USA **Aims:** To determine whether there was a relationship between the total amount of speech and swallowing therapy received between 1 and 3 months post-operatively and changes in global measures of speech and swallowing functions. **Grade of evidence:** VI	**Participants:** Patients with surgically treated oral and oropharyngeal cancer. The patients were participants in a large study on the effects of oral cancer resection and reconstruction procedures on speech and swallowing. **Service:** All patients received therapy for speech problems and 92 also received therapy for swallowing problems. The patients were given instructions in how to perform range of motion (ROM) exercises for the lips, tongue, jaw and larynx; other types of therapy to improve placement of the tongue and lips for production of speech sounds; and/or exercises to improve the co-ordination of structural movements during swallowing. Patients were instructed to do the ROM exercises for a total of 5 to 10 minutes, 10 times daily, if possible. Patients were given the exercises by their speech and language therapist and practiced them with the clinician until the patient was able to perform the	**Methods:** Data were collected on the type of speech and swallowing therapy the patient received. **Outcomes measured:** At 1 and 3 months post-treatment data were collected on 4 global measures of speech and swallowing function: (1) understandability of speech as judged by naïve listeners; (2) percent accuracy of production of consonant sounds (using the sentence version of the Fisher-Logemann Test of Articulation Competence) judged by a trained speech and language therapist; (3) oropharyngeal swallow efficiency (OPSE) on liquid; and (4) OPSE on paste. OPSE is calculated from video-fluorographic studies of swallowing. To generate the OPSE measure, the percentage of each bolus type swallowed into the oesophagus is divided by the total oral and pharyngeal transit time. Changes in the 4 global measures of speech and swallowing between 1	**Included patients:** 102 patients were included in the study. **Results:** The only statistically significant correlation ($p < 0.05$) found was between the total time spent on ROM exercises and mean change in OPSE on liquids (t-test for zero correlation). The Pearsons coefficient was used to calculate the correlations between total speech/swallow therapy time and mean change in global measures of speech and swallowing between 1 and 3 months post-operatively, as well as the total time spent doing ROM exercises and mean change in global measures of speech and swallowing between 1 and 3 months post-operatively. Because ROM exercises appeared to have some effect on at least 1 of the global measures of speech and swallowing, a second analysis was performed to compare the extent of change in global measures of speech and swallowing from 1 to 3 months in patients who did and did not receive instruction in ROM exercises. Statistically significant differences (by the unpaired t-test, $p < 0.05$) were found between the 2 groups of patients with respect to both global swallowing measures. Differences in speech intelligibility approached, but did not reach, statistical significance. In all 3 of these measures, patients who performed ROM exercises exhibited significantly better function, as compared with those who did not do these exercises.	**Authors' conclusions:** The results of this pilot study support the use of ROM exercises to improve both speech and swallowing in patients who undergo surgical procedures for oral and oropharyngeal cancer. The authors also state that to prevent formation of restrictive scar tissue, it is particularly critical to begin ROM exercises in the early post-operative period. **Comments:** The conclusions of this good quality study with an adequate sample size, sufficient detail of the interventions and appropriate outcome measures appear valid. However, the methods section indicates that all patients received instruction in ROM exercises, whereas the results suggest that a large number did not receive instruction in ROM exercises (though it is not stated how many, the table suggests that 69 patients did not receive ROM training and 33 patients did). The table presents this as patients who did and did not "perform" ROM exercises, rather than those who did or did not "receive training" in ROM exercises. This discontinuity in the text is misleading. Few details of the main study, into which this study was nested, were given. Therefore, it is difficult to know what effect any

	exercise(s) well. Patients were seen for 1 to 2 follow-up sessions to check their performance of the exercises.	and 3 months post-operatively were calculated. The total amount of therapy provided during the first 3 months post-treatment and the time spent doing ROM exercises during the first 3 months were calculated for each patient.		other intervention studied may have had on the patient group as a whole or whether there may be any interaction between treatments.
Perry, 2000.[9] **Country:** Australia **Aims:** To examine the outcomes of a speech and language therapy service for the rehabilitation of patients following head and neck cancer therapy. **Grade of evidence:** VI	**Participants:** Head and neck cancer patients of the speech and language therapy services of 8 hospitals across the state of Victoria, Australia. **Service:** No details of the individual services contributing data were provided.	**Methods:** A collaborative, prospectively compiled database was collected from each hospital. Data on each head and neck cancer patient attending speech and language therapy services treated in the 8 centres were added to the database prospectively by means of a common proforma. Information was collected on diagnosis, surgery, radiotherapy or chemotherapy and on functional status (the last section being completed by both the speech and language therapist and patient). Data were recorded immediately post treatment and at intervals of 3, 6 and 12 months. **Outcomes measured:**	**Included patients:** 158 patients (84 new patients and 74 recurrence patients) were recorded on the database, of whom, 141 had surgery (including some who had combined surgery and radiotherapy). Patients included 123 men and 53 women. Status forms on 98 patients were returned by both the therapist and the patient. **Swallowing status 3 months post therapy:** Only 12% of patients treated by surgery alone and 13% of patients treated by combined surgery and radiotherapy had normal eating habits 3 months post surgery. In both groups, 16% of patients required a percutaneous gastrostomy (PEG) or nasogastric (NG) feeding. **Voice status 3 months post therapy:** 63% of patients treated by surgery alone and 55% of patients treated by combined surgery and radiotherapy had functional speech 3 months post surgery. 22% and 26% of patients respectively were found to have speech which was intelligible in a known context. 12% and 19% of patients respectively were found to be able to speak only occasionally or not at all. **Voice restoration methods used:** 38 patients underwent a total laryngectomy and 19 of these used an electronic larynx (EL) only, 9 used tracheo-oesophageal puncture (TEP) only, 3 used both EL and TEP, while 2 patients used oesophageal speech. 5 used other methods.	**Authors' conclusions:** This work represents the development of an appropriate, usable tool for data collection on functional outcomes. Clinicians need to define speech impairment and develop treatments to reduce morbidity and improve the quality of life. **Comments:** This study provides a description of the outcomes of therapy but omits key information. It is unclear what therapy was given or if each hospital used the same protocol of speech and language therapy. All patients had some form of speech and language therapy so the benefits derived from the therapy can not be isolated. Information on the differences and similarities between the study patients and the population from which they were drawn would have been useful. The authors mention that the referral rate of head and neck patients to speech and language therapy

<table>
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<td>Swallowing status 3 months post therapy

Voice status 3 months post therapy

Voice restoration methods used</td>
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<td>was lower than expectations. They did not however investigate the reasons for this or assess the characteristics of the referred patients compared with the population as a whole.

These factors may reduce the generalisability of this research to other populations.</td>
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<td>Sittel, 1998.[3, 4]

Country:
Germany

Aims:
To identify the influence of type and extent of surgery on post-operative voice parameters after endoscopic laser resection for glottic carcinoma.

Grade of evidence:
VI</td>
<td>Participants:
Patients were asked to participate in the assessment study during a follow up check-up appointment, at least 6 months after the surgery. Only those with no concurrent laryngeal disease were eligible.

Service:
A university hospital offered endoscopic laser surgery to suitable patients with laryngeal cancers. Post-operative speech and language therapy was offered to some of these. No details of the therapy were provided.</td>
<td>Methods:
Information about medical conditions and surgery details were taken from the medical records.

2 speech and language therapists and an otolaryngologist rated each voice independently and were blinded as to the diagnosis and treatment groups. Voices were evaluated on a scale from 1 to 5, with 1 being very poor, barely perceptible; 2 being poor but understandable; 3 being fair, perceptible only by a listener who is concentrating; 4 being good for communication but still clearly pathological; and 5 being normal or almost normal. Patients rated their communication ability on the same scale, once for a speech situation in a family setting and once for an</td>
<td>Included patients:
80 patients were included with varying extension of primary tumour (T1 or T2 glottic carcinoma) and forms of resection extension during surgery. 70 men (mean age: 59 years) and 10 women (mean age: 55 years) were included in the study.

Speech quality:
Ratings for speech quality: 3.29 (speech and language therapist), 3.1 (doctor), 3.74 (patient, familiar situation), 3.38 (unfamiliar situation).

Speech quality assessment for different resection types:
<table>
<tr><th></th><th>Doctor</th><th>Speech and</th><th>Relative</th></tr>
<tr><td>Supraglottic (n = 8)</td><td>3.9</td><td>3.9</td><td>32.8%</td></tr>
<tr><td>Decortication (T1) (n = 5)</td><td>4.8</td><td>4.6</td><td>62.1%</td></tr>
<tr><td>Classic chordectomy (T2)</td><td>3.26</td><td>3.33</td><td>22.9%</td></tr>
<tr><td>Extended chordectomy</td><td>2.82</td><td>3</td><td>17.2%</td></tr>
<tr><td>Transglottic resection (T4)</td><td>2.3</td><td>2.86</td><td>14.1%</td></tr>
</table>
Speech quality assessment for different phonation types:</td>
<td>Authors' conclusions:
Post-operative phonatory results correlate with the post-operative mechanism of phonation. There is no linear correlation with the amount of tissue removed. Comparing similar types of resection preservation of the anterior commissure plays a key role. In this study there is no evidence of a significant benefit from speech and language therapy. The relative phonetogram is an effective and relatively simple parameter to complete auditive voice assessment.

Comments:
The authors' conclusions relating to speech and language therapy follow from the data presented in the discussion section, however very little data is presented in the results of the study relating to speech and language therapy and no information is given about the speech and language therapy itself.

The only data given regarding speech outcomes for patients with and without speech and</td>
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		setting and once for an unfamiliar surrounding, e.g. in a shop. Means for the rating scale were calculated for the otolaryngologist rating and the speech and language therapists rating. A simultaneous registration of both pitch and intensity range was produced in every case using a phonetogram procedure (the difference between maximal and minimal sound pressure level recorded at 30 cm microphone distance). Reference phonetograms for both males and females were obtained from previously published data. The patients' phonetograms were compared with the reference phonetogram to give a numerical variable. This was called a "relative phonetogram" the authors. Sustained vowels and a standard sentence were recorded digitally on an audiotape and the parameters maximal phonation time and	**Glottic phonation (n = 45)**	3.67	3.8	34.1%	with and without speech and language therapy is the mean "relative phonetogram" value, which is a value that the authors devised and is difficult to put into context. The sample was drawn from a limited number of patients. Only those considered "Worst cases" were included. The authors acknowledge that their speech and language therapy conclusions cannot be generalised from the study. For other patients speech and language therapy was not considered necessary and the effect that the therapy may have on patients can not be addressed by this study. The authors state that the reason that the data show no evidence of a benefit from speech and language therapy may, in part, be the result of negative selection. They also discuss unnecessary training of false cord phonation as a possible reason for no evidence of a benefit from speech and language therapy. The authors' conclusions cannot be verified owing to the lack of data presented in their report.
			Non-glottic substitute phonation (n = 34)	2.35	2.63	8.8%	
			Supra-glottic substitute (n = 8)	3.9	3.9	32.8%	
			Voice production at glottic level yield better results for every parameter than supraglottic substitute phonation. Patients without speech and language therapy have a better relative phonetogramme and a better speech quality rating as graded by clinicians. The overall mean of the relative phonetogram was 23.0% but the relative phonetogram values for patients with and without speech and language therapy were 16.5% and 28.1% respectively. 60% of the patients without speech and language therapy regained voice production at glottic level. Only 51% of patients who saw a speech and language therapist achieved this. 59% of patients with speech and language therapy developed a supraglottic substitute phonation. The authors state that discussions with the speech and language therapists revealed the need for better communication between doctor and speech and language therapist. According to the authors some speech and language therapist assumed wrongly that patients with partial larynx resection cannot regain phonation at the glottic level and might have supported a sub-optimally functioning speech mechanism.				

		fundamental frequency were measured. All 3 variables are presented for 5 resection types, for 5 phonation mechanisms and for 2 main phonation mechanisms consisting of 2 of the phonation mechanisms each (glottic compared with supraglottic substitute phonation). These results were also plotted graphically. **Outcomes measured:** Speech Quality		
Smithwick, 2002.[13] **Country:** USA **Aims:** To survey a large sample of female subjects to answer some basic questions regarding their demographic characteristics, communication methods used, the difficulty in learning these new communication methods, their satisfaction with communication, how "feminine" they consider the new	**Participants:** Patients who were members of their local laryngectomee support organisation or who were on the mailing lists of these organisations were included in the study.	**Methods:** Using a stratified random sampling process, contact persons for every fifth laryngectomee club in the United States listed in the International Association of Laryngectomees Club Directory 1996 were contacted and asked to participate. A 14-item postal questionnaire regarding satisfaction with communication methods as post-laryngectomees and speech and language therapy services, along with demographic	**Included patients:** 40/53 clubs contacted agreed to participate. 351 questionnaires were mailed to individual members of these clubs and 132 (38%) were returned. The mean age of respondents was 67.3 years (range 29 years to 83 years). Most had surgery within the last 6 years; of these 62% reported having a total laryngectomy. 40% reported a secondary surgical procedure related to the primary laryngectomy, with tracheoesophageal puncture most common. **Results:** 87% participants received services from a speech and language therapist and 68% were satisfied with such services despite most respondents having had only 2 or 3 months of speech and language therapy or less. Participants' answers to the questions indicated that 48% used an electrolarynx as their primary communication method, 27% used oesophageal speech and 21% used trachoeosophageal speech. 19% found it "difficult" or "very difficult" to learn their new means of communication. Such difficulty in learning ranged from 22% for users of oesophageal speech and 20% for electrolarynx users to 8% for users of tracheoesophageal speech. 74% reported that they were satisfied with their primary communication method but satisfaction ranged from 62% for electrolarynx users to 89% for both users of oesophageal and tracheoesophageal speech. 56% considered their new voice neither feminine nor masculine and 64% would be interested in using a device or method of communication that provided a more feminine-sounding voice. 63% reported the use of a secondary communication method, usually an electrolarynx, however, 45% were not satisfied with their secondary method and 31% found it "difficult" or "very difficult" to learn.	**Authors' conclusions:** Present results suggest that female laryngectomees are satisfied in the main with their primary communication methods and with speech and language therapy services. With an increasing incidence and prevalence of laryngeal cancer among females, perhaps owing to smoking, comparisons of large samples of female with male laryngectomees can provide significant information for speech and language therapists, other health care providers, researchers and product manufacturers. **Comments:** The authors' conclusions appear to be valid. However, no details were given regarding the

voice and whether they are receiving and are satisfied with speech and language therapy services. **Grade of evidence:** VI		information.		questionnaire sent to patients and it is not stated whether the questionnaire was piloted or validated. The response rate was very low which may reduce the generalisability of the results. No details of the rehabilitation offered by the speech and language therapist were reported.
Meyerson, 1980.[10] **Country:** USA **Aims:** To document the speech rehabilitation of a patient who sought help following ablative surgery. **Grade of evidence:** VII	**Patient:** The patient was a physician with squamous cell carcinoma of the tongue. The tumour recurred and a complete mandibulectomy and partial glossectomy were performed. Much of the mylohyoid, hyoglossus, genioglossus and digastric muscles were also excised. Skin flaps to the mouth had been performed during the following months. A mandibular prosthesis was inserted, but had to be removed owing to breakdown of irradiated tissues. **Service:** The patient referred himself for diagnostic evaluation at a university speech clinic 8 months after the mandibulectomy and partial glossectomy, he had been communicating primary through writing since the ablative surgery.	**Methods:** A case study is described. **Outcomes measured:** Intelligibility measures were derived from written transcriptions of the patient's speech by graduate students who had no familiarity with the client or his problem. The percentage of correctly interpreted words constituted the intelligibility score. In order to determine the acoustic range of the vowel sounds produced by the patient in isolated words, an acoustic analysis was performed at the conclusion of formal therapy. An audiometric evaluation was undertaken.	The patient reported that the use of pharyngeal constriction for improved consonant production also improved swallowing behaviour. Although the tongue stump mobility remained restricted, there was obvious improvement in the range and extent of movement. General intelligibility progressed from 0 at the time of the initial evaluation to 50% in connected speech at the initiation of formal therapy. Upon conclusion of therapy, intelligibility was judged to be 80% in connected speech. Intelligibility of single words devoid of contextual cues was significantly lower, an approximate level of 30%. The results of the acoustic analysis of vowel sounds showed that the oral vowel space is much smaller than that of a normal speaker. The audiometric evaluation revealed a mild bilateral sensorineural loss for pure tones but essentially normal hearing for speech. The patient was prevented from returning to his medical practice and suffered periods of discouragement as a result. Nevertheless he developed a number of hobbies and interests and remained socially active.	**Authors' conclusions:** Following a number of radiological and surgical procedures for the treatment of oral cancer, a patient with severe facial disfigurement and alteration of the vocal tract acquired acceptable speech. Consultation among referring physicians and speech and language therapists can aid such a patient by facilitating the rehabilitative process through improvement of communicative skills. **Comments:** This case report provided adequate detail of the patient's medical history, speech and language therapy received and evaluation of the intelligibility and acoustic range of his speech. However, a case report does not provide very strong evidence as it lacks generalisability. Few details about the interventions used by the speech and language therapist were given and, as such, it is not possible to know what was done

	The patient was encouraged to begin attempts at verbal communication, which he did. He did not wish to initiate regular therapy but contacted the speech and language therapists often and was provided with practice suggestions and continued encouragement. 18 months after the initial speech evaluation he embarked on a year of formal therapy. The major goal was to maximise the intelligibility of consonants through compensatory adjustments.			in this specific case.

Table 6c: Osseointegrated implant

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Esser, 1997.[14] **Country:** Germany **Aims:** The aims of the study appear to be to assess the success of osseointegrated dental implants following radical oral cancer surgery and adjuvant radiotherapy. **Grade of evidence:** VI	**Participants:** A consecutive series of patients who had undergone radical resection for carcinoma of the tongue or floor of mouth and adjuvant radiotherapy between 1985 and 1995. **Service:** Between 1985 and 1987 the IMZ system (cylindrical implants, type DH, 13 to 15 mm) was used. After 1988 the Brånemark system (standard screw implants, 13 to 18 mm) has been used. For routine prophylaxis, a standard dose of an oral antibiotic was given. The abutment operation was generally performed 6 months after implant placement. Adjunctive hyperbaric oxygen therapy was not used. Patients who had undergone a radical resection of a carcinoma of the tongue and floor of the mouth and primary reconstruction of the soft tissue defect by a free vascularised forearm flap transfer without adjuvant radiotherapy were included in the study as a control group. All suprastructures were implant-supported cantilevered prostheses.	**Methods:** A case series is described. **Outcomes measured:** Results and perioperative complications for all 249 implants. Clinical stability, function without pain or infection and radiographic evidence of osseointegration were considered the criteria for success. **Statistical methods:** The statistical analysis was based on the life table method described by Cutler and Ederer.	**Included patients:** 60 consecutive patients received 249 dental implants **Results:** 71 IMZ and 150 Brånemark implants were placed into the irradiated mandibles of 58 patients and 28 Brånemark implants were placed into the irradiated maxilla of 6 patients. The interval between the end of radiotherapy and implant placement was at least 9 months (average 18.9 months IMZ and 13.2 months Brånemark). **IMZ implants in the irradiated mandible (n = 21):** 8 patients with 21 functional implants died. 2 osseointegrated implants in 1 patient were removed because of an operation for tumour recurrence. Of the 71 IMZ implants, 9 (12.7%) in 7 patients were not osseointegrated when surgically exposed. After surgical exposure 5 implants in 4 patients lost osseointegration after intervals of 18 to 30 months. Osteoradionecrosis of the mandible occurred in 1 patient. The cumulative success rate, defined as persistent osseointegration, was 77.5% at both the 3 and 5-year intervals. **Brånemark implants in the irradiated mandible (n = 37):** 8 patients with 31 functional implants died. 15 implants in 3 patients were removed because of an operation for tumour recurrence. Of the 150 Brånemark implants, 9 (6%) in 4 patients were not osseointegrated at the time of abutment operation. After surgical exposure 12 implants lost osseointegration after intervals of 6 to 24 months. Osteoradionecrosis of the mandible occurred in 1 patient and soft tissue necrosis occurred after implantation in 3 patients. The cumulative success rate, defined as persistent osseointegration, was 83.5% at both the 3 and 5-year intervals. **Brånemark implants in the irradiated maxilla (n = 28):** 3 patients with 13 functional implants died. Of 28 implants, 5 (17.8%) were not osseointegrated when surgically exposed. In 1 patient an antral fistula was found; it was treated by suture only. 1 implant lost its osseointegration 26 months after placement. The success rate was 85.5%. All deaths were as a result of recurrent cancer metastasis, secondary carcinoma or stroke. **Brånemark implants in the non-irradiated mandible (n = 14):** 1 patient with 5 functional implants died because of multiple distant metastases. Of 71 implants, 4 (5.6%) were not osseointegrated at the time of the abutment operation. 3 implants (4.2%) showed an asymptomatic loss of osseointegration within an interval of 6 to 30 months after placement. The cumulative 5-year success rate was 85.6%. The relatively poor results are mainly based on a continuous loss of 5 implants in 1 patient. Excluding this patient, only 1	**Authors' conclusions:** Because of the favourable psychosocial effects, early implant-supported prosthodontic rehabilitation is recommended. Improvements in food intake, speech and balance of the contour of the lower third of the face distinctly ease social reintegration. A minimum interval of 9 to 12 months between the end of radiotherapy and implant placement is recommended. Radiotherapy under the conditions reported in this study is not regarded as a contraindication for implantation. **Comments:** The authors do not state the aims of their study. The number of patients included in the study was inconsistently reported. The authors' conclusions refer to the favourable psychosocial effects of osseointegrated implants, despite no psychosocial patient outcomes being measured in the study. They also recommend a minimum interval of 9 to 12 months between radiotherapy and implant placement, although their sample only included patients who had at least a 9-month interval between radiotherapy and implant placement, so they have no data on patients who had implant placement within 9 months of radiotherapy. The authors state that the statistical

			implant failed to osseointegrate and 1 implant was lost after loading in 1 patient.	analysis was based on the life table method described by Cutler and Ederer, for calculating the success rates of dental implants, however no further description is given, so it is not possible to comment on the validity of this method.
Goto, 2002.[22] **Country:** Japan **Aims:** To investigate the effects of bone grafting and radiotherapy on implant survival rates. **Grade of evidence:** VI	**Participants:** Patients treated between January 1989 and December 2000 by prosthodontic rehabilitation using osseointegrated implants following jaw resection. They comprised 20 patients with malignant tumours, 12 with benign tumours, 2 patients with osteomyelitis and 2 patients with cysts. Radiotherapy was performed in patients with malignant tumours but not in patients with benign tumours, cysts or osteomyelitis. **Service:** The jaw-resection procedures performed for the mandible, included peripheral resection (n = 16) and segmental resection (n = 12). For the maxilla, partial resection was performed in 8 patients. Bone grafting was performed in 19 patients undergoing mandibular resection and in 2 patients undergoing maxillary resection. Fresh autogenous iliac bone was used for grafting and anastomosis was not performed. In the maxilla, mandible and residual grafted bone, implants of 13mm length of more were used in the majority of cases. Implants with diameters of 4 or 5 mm were	**Methods:** The clinical course of the implants were followed for a minimum of 72 days and a maximum of 3,901 days, with a mean follow-up period of 1,811 days. The radiographs used for reference were mainly panoramic films. For the quantitative evaluation of bone resorption, peri-apical dental films obtained by standardised imaging techniques are required. However, in resected-jaw patients, it was sometimes difficult to obtain standardised x-ray films because of limitations in mouth opening or deformity of the oral soft tissues. **Outcomes measured:** Implants were classified as successful when the patient did not complain of pain or discomfort, no mobility was observed in each implant, no marked resorption was noted in surrounding bone, no inflammation was found in surrounding soft tissues and the implants properly supported the prosthesis in function. These criteria for successful implantation conform with those for ITI implants advocated by Buser and associates. **Statistical methods:**	**Included patients:** 36 patients (26 male, 10 female aged 20 to 83 years, mean age 52.9 years) with 180 implants **Results:** 112 implants were placed in residual bone and 68 were placed in grafted bone. 47 residual bone implants were in the maxilla and 65 were in the mandible. 5 grafted bone implants were in the maxilla and 63 were in the mandible. The overall cumulative survival rate for the 180 implants was 88.6% as determined by the Kaplan-Meier method. The cumulative survival rates for the implants at 10 years in residual bone (n = 112) was 85.9% and in grafted bone (n = 68) 93.1%. The cumulative survival rate for residual bone in the mandible was 95.2% and for the maxilla 73.8%. The cumulative survival rate for grafted bone in the mandible was 94.1% and for the maxilla 80%. Comparison of irradiated and non-irradiated bone showed survival rates of 79.7% for irradiated bone and 93.5% for non-irradiated bone. No differences were found in the results for implants placed owing to jaw resection for malignant tumours and those placed owing to benign tumours, cysts or osteomyelitis. 15 implants were lost. Implants lost varied in length from 7 to 18 mm. Among these, loss was more frequent with shorter implants, i.e. lengths of up to 10mm. Of the 15 implants lost, 11 were in the maxilla and 4 in the mandible.	**Authors' conclusions:** The clinical results obtained in the present study compare favourably with those obtained by others. However, jaw reconstruction and rehabilitation should not be performed by the oral surgeon alone; oral and maxillofacial function should be restored using a team approach in close cooperation with specialists in prosthodontics and periodontics to improve the result of implant treatment. **Comments:** Only 20/36 patients in this study had malignant tumours and were treated with radiotherapy, however, the authors state that no differences were found in the results for implants placed owing to jaw resection for malignant tumours and those owing to benign tumours, cysts and osteomyelitis. Therefore, the results appear to be generalisable to patients undergoing jaw resection owing to malignancy. Implant survival rates are the only outcomes measured, with no assessment of other patient outcomes.

	used less frequently.	The Kaplan-Meier method was used to evaluate the clinical outcomes of the implants by providing comparisons between residual and grafted bone, the maxilla and mandible and irradiated and non-irradiated patients.		
Granstrom, 1999.[20] **Country:** Sweden **Aims:** To study whether osseointegration of implants in irradiated tissues is subject to a higher failure rate than in non-irradiated tissues. Also, to study whether hyperbaric oxygen treatment (HBO) can be used to reduce implant failure. **Grade of evidence:** VI	**Participants:** A consecutive sample of cancer patients rehabilitated using osseointegrated implants between 1 December 1981 and 1 October 1997 Patients were categorised as irradiated patients, non-irradiated patients and irradiated and HBO-treated patients. In addition, irradiated patients who had lost most of their implants received new ones after HBO treatment. **Service:** Osseointegrated implants of the Brånemark system type of implants were used. All implants were inserted in the host bone without bone grafting or covering with expanded polytetrafluoroethylene membranes.	**Methods:** Patients were followed-up postoperatively, initially at 3-month intervals and, after 1 year, at 6-month intervals. Implant stability was checked by clinical inspection and radiographic investigation. **Outcomes measured:** Implant losses and adverse soft tissue reactions were registered. **Statistical methods:** Statistical comparisons were performed using Mantel's test and Fisher's test for paired comparisons.	**Included patients:** 78 patients were rehabilitated using 335 osseointegrated implants. 47 were male and 31 were female. The mean age was 64.9 years (range: 23 to 94). There were 32 irradiated patients, 26 non-irradiated patients, 20 irradiated and HBO-treated patients and 10 irradiated patients who had lost most of their implants received new ones after HBO treatment. 47 patients had orbit defects, 16 had temporal defects, 9 had nose defects, 8 had maxillary defects and 3 had mandibular defects in which endosseous implants had been installed. **Results:** 99/335 Brånemark implants were lost during follow-up, for a total loss rate of 29.5%. In the irradiated group, 147 endosseous implants were installed, of which 79 were lost (53.7%). A mean of 4.6 implants were inserted and 2.5 were lost per patient. The radiation field covered the implant area in all patients. Mean observation time in this group was 5.8 years (range: 0.1 to 15.1). 7 patients died in this group, mortality rate 21.8%. Only 4 patients had not lost a single implant during the follow-up. In the non-irradiated group, 89 endosseous implants were installed, of which 12 were lost (13.5%). Mean observation time in this group was 7.4 years (range: 0.3 to 14.7). 4 patients died in this group, mortality rate 15.4%. 19 patients had not lost a single implant during the follow-up. In the irradiation and HBO group, 99 endosseous implants were installed, of which 8 were lost (8.1%). Mean observation time in this group was 3.4 years (range: 0.9 to 8.2). 3 patients died in this group, mortality rate 15%. 14 patients had not lost a single implant during the follow-up. In the irradiated patients retreated after HBO, 43 endosseous implants were inserted in the first treatment period, of which 34 were lost (79%). Mean implant survival time was 2.4 years in a mean follow-up period of 4.7 years (range: 1.7 to 14.9). In the second treatment period (after preoperative HBO), 42 endosseous implants were inserted, of which 5 were lost (11.9%). Mean implant survival time was 3.1 years in a mean follow-up period of 3.5 years. 1 patient died in this group, mortality rate 10%. A statistical comparison using Fisher's test for paired comparisons shows a better implant survival after HBO treatment; $p = 0.0078$.	**Authors' conclusions:** Irradiation causes significant changes in the host bone bed that reduce the potential for osseointegration, thus increasing implant loss. Adjunctive HBO treatment can improve osseointegration. **Comments:** The conclusions of this study appear to be valid. However, implant survival rates are the only outcomes measured, with no assessment of other patient outcomes. No cause of death is reported for those patients who died. The number of patients in the retreated group was rather low.

			A statistical comparison between the irradiated group and the non-irradiated group using Mantel's test showed the difference to be significant (p = 0.0023). A statistical comparison between the irradiated group and the irradiation and HBO group showed the difference to be significant (p = 0.0010). A statistical comparison between the non-irradiated and irradiation and HBO group was not significant (p > 0.30).	
Granstrom, 1993.[21] **Country:** Sweden **Aims:** To investigate the capacity for osseointegration of titanium implants in the irradiated bone tissue, which is known to have a reduced healing capacity. Also, to investigate if hyperbaric oxygen (HBO) could improve the osseointegration of implants in the irradiated patients. **Grade of evidence:** VI	**Participants:** Patients intended for rehabilitation with bone-anchored facial epistheses or dental bridges after tumour surgery between 1979 and 1992 and who had undergone irradiation as part of tumour treatment were studied. **Service:** The irradiation field in all patients included the implantation field. A total of 200 fixtures were installed. 12 of the patients were treated in combination with HBO, given at 20 preoperative and 10 postoperative sessions. Implantation of titanium fixtures and evaluation of osseointegration were performed according to Albrektsson et al. Appropriate areas for implants were the superior and inferior orbital rims, the anterior part of the zygoma, the medial and lateral aspects of the maxilla and the mastoid process. The concept of osseointegration is based on a 2-stage operation procedure. During the first stage the titanium fixture is inserted. The second stage operation is performed after 4 to 6 months, when osseointegration has occurred. An abutment is applied on top of the fixture and this part is penetrating	**Methods:** A consecutive sample of patients were reinvestigated. Follow-up time after implant surgery varied from 0.5 to 11 years, with a mean of 4.4 (SD: 3.5 years). **Outcomes measured:** To determine the healing rate and bone quality of the implanted skeleton, the patients were preoperatively and postoperatively investigated with plain x-ray films, x-ray tomography, computed tomography or magnetic resonance imaging, technetium scintigraphy and selective angiography of the common carotid artery. Selective biopsies were taken from the irradiated tissue during operation and morphological methods used to determine the condition of the irradiated tissue were routine histology of serially sectioned soft tissue and decalcified bone, ground sections of bone and microradiography of ground sections of bone. Skin reactions around the abutments were registered at each patient visit and graded from 0 to 4. 0 = reaction, 1 = reddish, 2 = moist, 3 = granulation, 4 = removed.	**Included patients:** 40 patients who had undergone irradiation as part of tumour treatment were studied, at the time of tumour surgery they were aged 12 to 80 years (mean 58.7). In all cases the irradiation field comprised the implantation field. A total of 200 fixtures were installed. **Results:** 6 patients died during the investigation time, owing to tumour recurrences, cerebrovascular diseases or heart failure. Of the 134 fixtures installed in patients who did not receive HBO, 86 were stable after an average follow-up time of 56 months. 48 of the fixtures were removed, mainly for not having osseointegrated or because of loss of integration. This gives a total fixture loss with time of 35% in irradiated bone. Fixture loss was highest in frontal bone (50%), followed by zygoma (46%), mandible (33%), maxilla (14%) and temporal bone (9%). In the HBO treated group, 66 fixtures were installed, 65 of which were stable after an average follow-up time of 28 months. This gives a total fixture loss with time of 1.5%. The only fixture lost was in the maxilla. There is a significant difference between patients receiving HBO and those not receiving HBO at 1 year. After 4 years the difference is significant at the p < 0.001 level using the Student's t-test or the Wilcoxon Signed Rank test. Most implants were lost during the first 3 years after implantation and there seems to be a plateau after 6 years, when most implants are retained. Around 4 of the implants, soft tissue infection was observed and successfully treated with topical antibiotic and antimycotic ointment. No implants had to be removed for reasons of bone infection and in no case did osteoradionecrosis develop. Skin reactions in the whole group of implants were grade 0, 88.5%; grade 1, 7.5%; grade 2, 3.1%; grade 3, 0.9% and grade 4, 0%.	**Authors' conclusions:** It is concluded that the bone-anchored epithesis system is a good alternative to conventional reconstructive surgery in the rehabilitation of cancer patients. Titanium implants can be integrated in bone tissue in patients who have undergone previous radiotherapy, even at high-dose levels. No major complications such as wound infection, fistulation or osteoradionecrosis occurred after implant surgery. There was, however, an increased loss of implants with time after irradiation – especially in the orbital region. The combined treatment with hyperbaric oxygen reduced implant losses with time. **Comments:** The conclusions of this study appear to be valid. However, implant survival rates are the only outcomes measured, with no assessment of other patient outcomes. The number of patients in the HBO treated group was rather low.

	the skin. After a healing period of 3 to 4 weeks, the prosthetic construction (episthesis) can be applied to the abutment with metal clips or magnets. The time interval between irradiation and implant surgery varied from 1 month to 37 years. 8 of the patients received irradiation after implant surgery.			
Koch, 1994.[23] **Country:** USA **Aims:** To evaluate the outcome of both THORP and SS plates at the author's institution. **Grade of evidence:** VI	**Participants:** Patients who had mandibular reconstruction with metal plates between April 1986 and August 1992. **Service:** Patients were treated by reconstruction with titanium hollow-screw osseointegrating reconstruction plates (THORP) or solid screw (SS) steel and titanium plates. All patients had a history of malignancy, but 3 patients were reconstructed after mandibular resection for osteoradionecrosis occurring after successful radiation therapy. Primary radiation therapy had been given to 10 SS patients and 6 THORP patients prior to surgery and reconstruction. 13 SS and 6 THORP patients received postoperative radiation.	**Methods:** The results of reconstruction using the THORP and SS techniques were compared. The senior surgeons involved were identical for both groups. The length of follow-up in the SS group ranged between 3 and 66 months and in the THORP group ranged between 5 and 45 months. **Outcomes measured:** Failure rates and complications were reported. **Statistical methods:** The χ^2 test and Fisher Exact Test were used to assess the statistical significance of the difference in the number of plates removed and the difference in long-term results.	**Included patients:** 40 patients were included. The mean age of patients was 59 years in the SS group and 61 years in the THORP group (range: 31 years to 85 years), the male-to-female ratio was 2:1 in both groups. Tumour site and stage were comparable between the 2 groups. **Results:** There was 1 perioperative death and 1 patient lost to follow-up after 3 months in the THORP group. The THORP results are based on the remaining 12 patients. 20/28 SS patients were deceased and 5/12 THORP patients were deceased. Half of the patients in the SS group experienced significant complications related to their plates. The plate was removed owing to exposure in 3 cases, 2 during the first 2 post-operative months and the other at 5 months, following postoperative radiation. In each case there was a massive soft-tissue necrosis of the pectoralis major myocutaneous flap covering the implant. 2 other cases of soft-tissue loss and plate exposure were corrected with local musocal flaps. Problems with loosened screws and plates were seen as early as 3 months and as late as 4 years postoperatively. Problems following placement of the THORP devices were less common and less severe. Soft-tissue dehiscence was managed with meticulous wound care in 3 cases and all plates were retained with eventual complete healing by secondary intention. 1 late, minor external exposure of a plate at a dehiscent suture line of the pectoralis major myocutaneous flap in the mental region was repaired successfully with a nasolabial flap. 1 THORP device was removed owing to plate fracture after 14 months, the mandible was then reconstructed using a scapular free flap held in place by a new titanium SS reconstruction plate. 14/28 SS plates were removed and 1 is planned to be removed in the near future. 4 were owing to recurrent tumour, 3 owing to soft tissue loss/exposure, 5 owing to loosening/osteoradionecrosis, 1 owing to trismus and 1 planned second stage. Excluding cases where the bar was removed owing to recurrent tumour or planned second stage bony reconstruction 10 plates have or will, come out, for a plate related failure rate of 36% (2 early, 4 intermediate, 4 late). The difference in the number of plates removed, 1/12 versus 14/28, was	**Authors' conclusions:** The THORP system incorporates a number of technical innovations and has been promoted as a permanent method of mandibular reconstruction. While significantly more patients in this series retained THORP implants than retained SS plates, critical analysis indicates that a larger number of patients must be followed for a longer period of time before claims of permanence can be substantiated. The THORP results are promising, however and THORP has become the authors' method of choice for alloplastic mandibular reconstruction in cases where this method is deemed appropriate. **Comments:** The conclusions of this study appear to be valid. However, implant survival rates and side effects are the only outcomes measured, with no assessment of other patient outcomes.

			statistically significant ($\chi^2 = 7.17$, $p < 0.01$). The difference in long-term results after eliminating all patients who had tumour recurrence within the first year and those with early plate removal owing solely to flap failure was not statistically significant, 1/9 THORP versus 8/17 SS failures (Fisher Exact Test, $p = 0.077$).	
Kovacs, 2000.[15] **Kovacs 1998.**[16] **Kovacs, 2001.**[17] **Country:** Germany **Aims:** To follow-up implant patients over a period of 6 years, with special attention on peri-implant health. **Grade of evidence:** VI	**Participants:** Patients who received dental implants after oral tumour resection and immediate soft tissue reconstruction from June 1990 to December 1997. **Service:** The bone-lock endosseous implant system (Howmedica Leibinger, Freiburg) was used exclusively. A paper published in 2001 (which reported that from June 1990 to December 1999, 90 patients received 320 dental implants) included 47 patients, 30 of which had received adjuvant systemic chemotherapy and 17 who did not receive adjuvant chemotherapy. No radiation therapy was performed on these patients. A paper published in 1998 (which reported that from June 1990 to June 1996, 58 patients received 210 dental implants) included 45 patients who had over 1 year follow-up. Patients were given a satisfaction questionnaire to complete, in addition to the outcomes measured by the studies described above.	**Methods:** A case series is reported. Patients with implants loaded for at least 1 year were studied. Patients were followed up for between 1 and 6 years, consisting of detailed medical history and evaluation of periodontal parameters by clinical and radiological examination. Orthopantomograms were taken directly after placement (as base findings) then 6 months, 12 months and annually thereafter. Bone resorption was ascertained at every follow-up date. The author did all examinations. Patients in the 1998 study were given questionnaires to determine the ease of restoration. **Outcomes measured:** Parameters measured included the Plaque Index, Sulcus Bleeding Index, Pocket Probing Depth and Periotest Instrument. For patients in the 1998 study, the ease of restoration was determined by means of a subjective rating of satisfaction by the patient (1 = poor; 2 = average; 3 = good), ease of care (1 = difficult; 2 = average; 3 = easy), acceptability of chewing and talking functions, acceptability of masticatory capabilities and absence of pain or discomfort.	**Included patients:** 90 patients received 320 dental implants after oral tumour resection and immediate soft tissue reconstruction and 45 patients with 162 implants loaded for at least 1 year were studied. **Results:** 7 times more implants were placed in the mandible than in the maxilla. The probability of holding a placed implant after 6 years is 83.5%. Looking at implants in place for more than 1 year (after the critical healing time), the survival probability is 93%. Causes of loss were lacking osseointegration during the healing time (28.3%) and tumour recurrences (28.3%). Other causes were inflammatory reactions, bone resorption and biomechanical overloading. Most implants were lost early (76%) before fabrication of the prosthesis. After restoration, there was a nearly 100% probability of function, if the prosthesis was well implanted. No implant in function caused any pain or other persistent damage. The Plaque Index had an overall mean value of 1.79 ± 1.07 (range: 1.5 to 2). For each period of time, the value differences compared to the first measurement did not show a clear-cut trend. The level remained the same. For the Sulcus Bleeding Index, there was a strong decrease of bleeding disposition after reaching its highest value at the end of the first year. After 3 years, there was practically no clinical sign of inflammation, compared to the baseline. The overall mean value was 1.42 ± 0.99 and varied between 1.83 and 0.71. The mean values of the probing depths per implant varied in their course between 5.75 mm in the beginning and 4.57 mm at the end, having an overall mean value of 5.25 ± 1.81 mm. The differences to the first recall examination show a decrease of 1 mm during the period of 3 years, having a tendency to decrease further. Periotest values ranged between –3 and +8.5, with a mean value of 2.25 ± 3.82. The mean value of all measurements of horizontal bone resorption over 5 years was 1.04 ± 1.58 mm. The vertical bone loss could be divided into a medial (1.24 ± 1.59 mm) and a distal value (1.43 ± 1.95 mm). This means that general horizontal bone loss constituted 73% to 84% of the peri-implant bony pocket. Both kinds of bone loss reached a steady state of about 2.5mm after 2 years of increase. The curves were in the same range over the third, fourth and fifth year of observation. In the 30 patients post-chemotherapy, healing of the implants was uneventful. Despite loss of 1 implant, the prosthesis could be fabricated. The mean time of function of prostheses was 35.8 months, during this time, no implant loss occurred. 15/30 patients died during the observation period of 10 years. In the 17 patients who did not receive chemotherapy, 1 implant was lost after nearly 6 years in function, owing to progressive peri-implant bone loss, the prosthetic construction remained in function. In 1 patient 3 implants fractured after 3 years of function and had to be removed by osteotomy since they remained osseointegrated. 9/17 patients died during the observation period. There was no significant difference between the implant survival rates in	**Authors' conclusions:** Prosthetic restoration of patients after oral ablative tumour surgery followed by hard and soft tissue reconstruction can be achieved with dental implants with similar long-term efficacy as found in healthy subjects adhering to internationally established requirements. Chemotherapy with cisplatin or carboplatin and 5-fluorouracil was not detrimental to the survival and success of dental implants in the mandible. Patient satisfaction with the described prosthodontic treatment was satisfactory. **Comments:** The results of this series of patients have been reported in a number of publications. Only those with unique data have been listed here. A publication followed 76 patients with 279 Bone-lock implants placed between June 1990 to December 1996. The results relating to implant loss were identical. No other relevant data were reported.[34] A further paper followed 58 patients with 210 Bone-lock implants placed between June 1990 to December 1996. The results relating to implant loss and complications were identical. No other relevant data were reported.[33]

		Statistical methods: Kaplan-Meier statistical analysis was used to assess the probability of implant loss, from the date of implant placement for a period of 6 years.	both groups. The answers to the satisfaction questionnaire showed a high level of contentment among the 45 patients who were restored (mean score 2.8). There were no patients who failed to wear their dentures. Ease of care was judged with a score of 2.5. Scores for chewing function were 2.5 and for speaking function 2.4. The patients with implant-supported prostheses complained of lack of sensitivity during biting and mastication. Transport and swallowing of the bolus was difficult. However, in these cases, no prosthetic fault could be found. The patients, however, did suffer from the usual postoperative difficulties. Over time, these patients reported a learning effect. 3 of the 6 patients with interconnected bridges first reported that they were chewing on the contralateral side only. 1 year later, all reported normal masticatory habits. Implant function did not cause any pain in any case.	A German language paper also reported identical results.[32] The conclusions of these reports appear to be valid. However, the numbers of patients treated have been inconsistently reported between the multiple publications of the study.
Wagner, 1998.[18] **Country:** Germany **Aims:** To better define the risks of this treatment policy, we have assessed our patients who received Brånemark implants after cancer therapy. **Grade of evidence:** VI	**Participants:** Consecutive oropharyngeal cancer patients after radical surgery, between 1987 and 1997. **Service:** All patients underwent radical surgery. Implantation was done in regional bone of the anterior mandible. Implants in the secondary reconstructed and non-irradiated mandible were excluded. All implants were loaded using a suprastructure (bar-supported overdenture or implant-supported removable bridge). None of the patients received hyperbaric oxygen therapy.	**Methods:** A case series is reported. **Outcomes measured:** Clinical stability, function without pain or infection and radiographic evidence of osseointegration were considered the criteria for success. **Statistical methods:** A statistical analysis was carried out according to the Kaplan Meier life-table method.	**Included patients:** 63 patients were included. 275 Brånemark dental implants were placed. The median age of the patients was 55 years (range: 40 years to 76 years), 35 patients (145 implants) had irradiation after surgery, the sex ratio was 5.7:1 (male to female). **Results:** The mean time between end of the tumour therapy and implantation was 13.02 months (range: 4 months to 107 months); median time between implantation and the abutment operation was 5 months (range: 2 months to 24 months). The cumulative success rate for osseointegration for all implants was 97.9% after 5 years and 72.8% after 10 years. There was no significant difference, according to outcome (osseointegration rate) in patients who had received radiotherapy in contrast to patients without irradiation, although an osteoradionecrosis occurred in 1 patient, with a loss of 5 implants. The authors were unable to document a significant influence of the time interval between the end of tumour therapy and the time of implantation. There was no significant influence of patients' age, sex or localisation of the implant on the osseointegration rate. The only significant influence concerning success rate for osseointegration was observed in the time interval between implantation and the reconstruction operation, patients who had been abutted less than 4 months after implantation had a significantly poorer outcome than those who had been reconstructed later than 4 months after implantation ($p = 0.0001$). Osteoradionecrosis occurred in 1 patient, with a defect situated in the mandible continuity after implantation. Soft tissue necrosis occurred after implantation in 3 patients with primary soft tissue reconstruction of the anterior floor of the mouth, 1 case had 5 osseointegrated implants removed on the assumption of better healing conditions, these were recorded as secondary loss of osseointegration and implant failure. In the other 2 patients, healing was induced through local conservative treatment. All 4 patients with osteoradionecrosis or soft tissue necrosis had received radiotherapy.	**Authors' conclusions:** Radiotherapy (60Gy) in patients with head and neck cancers should not be regarded as a contraindication for dental implantation. **Comments:** The conclusions of this study appear to be valid. However, implant survival rates and side effects are the only outcomes measured, with no assessment of other patient outcomes.
Weischer, 1999.[19]	**Participants:**	**Methods:**	**Included patients:**	**Authors' conclusions:**

Country: Germany **Aims:** To develop, based on clinical experiences, both surgical and prosthetic protocols for the rehabilitation of patients with oral cancer in the mandible and floor of the mouth and special criteria for determining the success of implant-supported prostheses in these patients. **Grade of evidence:** VI	Patients with squamous cell carcinoma in the mandible and floor of mouth who received implants between 1988 and 1997. **Service:** Implants were placed in original mandibles or in free or microvascular anastomosed bone grafts, following conventional reconstructive surgery. None of the patients received hyperbaric oxygen therapy.	A case series was reported. Patients were divided into 2 groups. Group 1 comprised all irradiated patients (n = 18) and group 2 comprised all non-irradiated patients (n = 22). **Outcomes measured:** Special criteria for evaluating the success of implant-supported maxillofacial prostheses were created. These criteria consider difficult surgical and prosthetic conditions, taking into account the compromised anatomic conditions in oral cancer patients and the patient's subjective evaluation of the prosthetic rehabilitation as well. They also emphasise the prosthetic utilisation of implants and the avoidance of prosthesis-related lesions. To assess treatment against the criteria patients were asked to give their subjective evaluation of prosthesis stability, function and aesthetic improvement. Prosthesis-related lesions and implant-related lesions were evaluated and treatment complications noted. Oral hygiene was evaluated according to Quigley and Hein and peri-implant pocket depth and implant stability were measured. Peri-implant bone resorption was measured by a comparison of radiographs. **Statistical methods:** The product-limit-estimates method according to Kaplan-Meier was used to calculate the cumulative success rate (accomplishment of the	Between 1988 and 1997, 40 patients with squamous cell carcinoma in the mandible and floor of mouth received a total of 175 implants in original mandibles or in free or microvascular anastomosed bone grafts, following conventional reconstructive surgery. Patients were divided into 2 groups, group 1 comprised all irradiated patients (n = 18) and group 2 comprised all non-irradiated patients (n = 22). **Results:** The mean interval between cancer resection and implant placement was 44 months (range: 12 months to 186) in group 1 and 36 months (range: 6 months to 159) in group 2. The mean interval between end of irradiation to implant placement in group 1 was 48 months (range: 13 months to 189). The mean interval between mandible reconstruction to implant placement was 31 months (range: 8 months to 168) in group 1 and 21 months (range: 3 months to 132) in group 2. At the time of reporting, 39 of 40 patients had undergone restoration. With a mean follow-up period of 37 months (range: 6 months to 117), 160 endosseous implants (91%) were osseointegrated without any complications. Wound disturbances with bone and cover-screw denudation occurred in 4 group 1 patients, following systemic antibiotic coverage and artificial feeding through a gastrointestinal tube, bone coverage occurred by secondary intention. The Quigley-Hein Plaque Index ranged between 0 and 3. A peri-implant inflammation caused by plaque was observed around 1 implant in 6 patients, 4 in group 1 and 2 in group 2, the inflammation was eliminated by plaque control, antiseptics and antibiotics. Oral hygiene was satisfaction in all other patients. Periotest values and the peri-implant bone resorption measurements were nearly equal in both groups. During implant treatment, no neuropathy, nerve injuries, continuous pain or infections were observed. 15 (9%) implants had to be removed (10 implants in 6 irradiated patients and 5 implants in 4 non-irradiated patients). In 7 patients, implants had failed before prosthetic restoration; in 1 patient 5 implants had to be removed because of mandibular facture 1 week following implant placement, in another patient 2 implants did not osseointegrate because of biomechanical overloading by a provisional restoration during the healing period, the reasons for implant failure were unknown in 5 patients. In 3 patients, implants failed after prosthetic restoration because of biomechanical overloading or microbiological infection. Although there was a 2-fold increase in implant failure in irradiated patients, there was no statistical significance in the increased failure rate. All other implants osseointegrated without complications and were prosthetically loaded. 2 patients were unable to adapt to their restorations, all other patients were satisfied with regard to the stability and function of their prostheses and the resulting aesthetic improvement. Prosthesis-related pressure lesions were observed only after initial rehabilitation and correction of the base of implant-tissue-supported prostheses or bar-supported, ball-attachment or telescopic prostheses. Denture-related lesions were more marked in irradiated patients. No osteoradionecrosis developed. Based on the special criteria for determining the success of implant-supported maxillofacial	On the basis of positive results with implant-supported prostheses, surgical and prosthetic implant rehabilitation has become recognised as an accepted treatment option for tumour patients. Irradiated jaws themselves present few contraindications for the placement of endosseous implants whenever the conceptual requirements are maintained. Special criteria for success should preferably be used to evaluate implant-supported maxillofacial prostheses. Oral rehabilitation is possible after the removal of malignant tumours in the lower portion of the oral cavity, using either restorations supported completely by 5 or 6 implants or implant-tissue-supported restorations based on 4 implants. However, prior to implant surgery, the prosthetic design concept should be determined so that the number of implants and implant positions can be ascertained. Totally implant-supported prostheses do not derive support from the mucosa and are recommended following irradiation. Implant-tissue-supported prostheses may be an option for non-irradiated patients. **Comments:** The conclusions of this study appear to be valid. The authors assessed patient satisfaction with their prostheses as well as implant survival rates and side-effects. They developed special criteria for determining the success of implant supported maxillofacial prostheses which evaluated various relevant outcomes.

		modified criteria for success) on the basis of the clinical examination.	prostheses, the cumulative success rate was approximately 75% at the 7-year interval for irradiated patients and approximately 86% at the 10-year interval for non-irradiated patients. With regard to implants placed after the treatment strategy change in 1992 (n = 157), the success rates were approximately 86% for irradiated patients and 94% for non-irradiated patient after 5 years.	Results based on a subset of the patients included in this study appear to have been reported previously.[35] However, dates of patient recruitment were not reported in that publication.

Table 6d: Patient support group

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Birkhaug, 2002.[24] **Country:** Norway **Aims:** To study whether the quality of life is lower in a population of people with laryngectomies compared to a general population of patients treated for head and neck squamous cell carcinoma. To determine whether active participation in Norwegian Society for Laryngectomies (NSL) activities is associated with better quality of life. **Grade of evidence:** V	**Service:** The Norwegian Society for Laryngectomies (NSL) is a patient-interest organisation supported by the Norwegian Cancer Society. All patients scheduled for laryngectomy in Norway are asked to become members of the NSL. Thus, membership in the NSL is widespread among people with laryngectomies in Norway. **Participants:** The questionnaire was sent to all members of the NSL. **Participants in the comparison group:** All patients diagnosed with head and neck squamous cell carcinoma between 1 July 1992 and 31 December 1997 who had survived their disease were interviewed in a separate study. Of this group, patients less than 80 years old, who were able to communicate intelligibly and not newly diagnosed with another serious disease were included in the control group.	**Methods:** Anonymous questionnaires were mailed to all registered members of the NSL (approximately 230). **Outcomes assessment tools:** NSL activity questionnaire: Questions were asked about participation in the following NSL activities: 1) activity in 1 of 8 local branches of the NSL; 2) participation in the yearly convention of the NSL; 3) participation in a holiday financed by the NSL offered the first year after laryngectomy; 4) participation in the educator school organised by the NSL. These educators later taught about the hazards of smoking, primarily in high schools. Quality of life inventory: EORTC QLQ-C30 version 3.0 and the EORTC QLQ-H&N35, aimed at head and neck cancer patients. Depression inventory: The 13 question version of the Beck Depression Inventory (BDI). Social support inventory: A 15-item questionnaire developed by Murberg and co-workers was employed to measure social support.	**Included patients:** 105 laryngectomy patients answered the questionnaires and were included in the study. It was 10 years (± 7) since the laryngectomy. About 30 patients returned the questionnaire because they had not had laryngectomies. **Patients included in the comparison group:** The control group consisted of 122 persons, 12 of which had laryngectomies. **Effect of participation in local NSL activities on laryngectomy patients:** Responses were significantly different when patients were divided into 2 groups based on the level of participation in the local branch of the NSL as measured by MANOVA, for the QLQ-C30 functional scales ($F = 3.49$; $p < 0.01$), QLQ-C30 symptoms scales ($F = 2.36$; $p < 0.05$) and QLQ-H&N35 ($F = 1.92$; $p < 0.05$). Patients who participated in the activities were associated with better quality of life, with the most widespread effect coming from participation in the local branch of the NSL. The indexes that scored differently were related to physical symptoms, social contact and emotional functioning. **Effect of participation in annual conventions of the NSL on laryngectomy patients:** The people with laryngectomies who reported participating in the yearly conventions sponsored by the NSL scored higher on both the QLQ-C30 ($F = 3.81$; $p < 0.01$) functional scales and the QLQ-C30 symptom scores ($F = 3.67$; $p < 0.01$), but not the	**Authors' conclusions:** The quality of life is similar within a population of people with laryngectomies and a general population of patients treated for head and neck squamous cell carcinoma. An active membership in the NSL seems to be associated with a better quality of life. To some extent, mood is a variable that relates to the positive association between quality of life and active membership of the NSL. **Comments:** The first part of this study, which compares the quality of life in a population of people with laryngectomies with a general population of patients treated for head and neck squamous cell carcinoma is not reported, as this is not a valid comparison and does not help answer the question on the outcome of patients participating in a patient support group. Results are presented on whether active participation in Norwegian Society for Laryngectomies (NSL) activities is associated with better quality of life. The authors' conclusions that an active membership in the NSL seems to be associated with a better quality of life appears to be valid, although only 50% of

		Statistical methods: The student's t-test, Pearson's r partial correlation analysis or (multivariate) analysis of variance ((M)ANOVA) were used in the statistical analyses. Factor and reliability analyses were also performed. Statistical significance was considered if $p < 0.05$.	QLQ-H&N35, as analysed by MANOVA. **Effect of participation in the NSL-organised holiday on laryngectomy patients:** The people with laryngectomies were also divided in 2 groups dependent on participation in a holiday organised by the NSL and offered the first year after laryngectomy. There was a significant difference dependent on participation in the holiday when the QLQ-C30 functional scales were included in the MANOVA ($F = 3.32$; $p < 0.01$), but not when the symptom scales of QLQ-C30 or QLQ-H&N35 were included in the MANOVA. **Effect of participation in the "Patient as Educator" programme on laryngectomy patients:** The quality of life indexes were also analysed dependent on the experiences of the patient as an educator as organised by the NSL. No overall significance was determined in any of the quality of life scales when analysed by MANOVA. **Effect of the mood of patients with a laryngectomy:** The authors also tested whether mood could account for the relationship between NSL activity and the quality of life scores. When the BDI score was introduced as a control variable in analysis of the NSL sum-scores and the quality of life indexes, the significance was to some extent reduced in strength but still present with the QLQ-C30 functional scores, but it disappeared with the QLQ-C30 symptom scores. **Effect of social support:** No significant relationship was determined between the reported level of quality of life and the amount of reported social support by family, friends and neighbours.	NSL members responded to the questionnaire, so the results may not be generalisable to all members of the NSL.
Edwards, 1997.[26, 27] **Country:** UK **Aims:** To explore views of patients, their families and professionals about head and neck cancer	**Participants:** Patients and professionals from 4 hospitals and 2 patient support groups in South East England. Patients seen in the department within the past year and diagnosed more than 1 year previously were eligible. Patients were consecutively selected	Focus group interviews were held. The issues for discussion were developed from informal conversations with professionals and patients before the study and adapted as important issues emerged. All focus groups were recorded and transcribed in full. The contents of the data were analysed for themes, key issues and for consistency. A map of each focus group was built up and analysed for inter-relationships between the different	**Included patients:** 22 patients and 11 relatives took part in 6 focus groups. 33 professionals took part in 4 focus groups, including maxillofacial, ENT and plastic surgeons, medical and clinical oncologists, nurses, speech therapists and other professionals involved in rehabilitation and palliative care. **Effect of support groups:** The patients who were members of support groups felt that these	**Authors' conclusions:** Patients and relatives were concerned about hospital accommodation, information about side effects, choice, support services and the impact of treatment. Professionals valued teamwork and joint clinics. They were concerned about lack of administrative flexibility, difficulties in communication and the high mortality of head and neck cancers.

services. **Grade of evidence:** VI	from lists of eligible patients compiled by the maxillofacial departments at the 4 hospitals. Additional patients were recruited from members of support groups who met at 2 of the hospitals. Patients had the option of bringing a family member with them.	aspects of the findings.	provided a lifeline. They described the relief when they met someone who understood what they had been going through. There was access to someone at the other end of the telephone if they needed to talk. Many patients had not heard about support groups and said that they would like to have known about them even if they decided that they did not want to attend.	**Comments:** This study presents the views of a small number of patients and health professionals, those views may not be representative of the views of the larger population. The author acknowledges that the participants are not representative of advanced or terminal cancer or ethnic minority patients. The author also emphasises the qualitative nature of the research, which produces insight into an issue rather than measuring it. Whilst this study looked at many issues, only the results relating to patient support groups are reported here.
Harris, 1985.[28] **Country:** USA **Aims:** To report the 2-year experience of a weekly support group attended by 142 hospitalised head and neck cancer patients and 33 family members. **Grade of evidence:** VI	**Participants:** Head and neck cancer patients, their close friends and family members were invited to attend, excluding those who were bedridden, acutely psychotic or delirious. Group size was usually 4 to 8 patients and 2 to 4 therapists. **Service:** The major goal for the group was to provide an open forum for discussion of any problems that faced the patient. Groups met weekly for 50 minutes in a community room adjacent to the unit. The research nurse, whose background was psychiatric nursing, served as senior therapist and attended all but 13 sessions, providing continuity and stability for the group. The group became a place for practice with the electrolarynx, oesophageal speech, tracheoesophageal puncture and writing. Feelings about death and dying were discussed openly but the group's emphasis was on living and making the most of the time remaining. Other	**Methods**: After each session, the therapists completed a group summary form. This form collected the subjective views of the therapists on the effect the group sessions had on patient outcomes. Patients themselves were not surveyed. **Outcomes measured:** The group summary form included such data as staff members present, patients present, themes, most active member, least active member and changes indicated for future meetings.	**Included patients:** 142 male patients (mean age 62 years) and 33 family members attended groups during the first 2 years (104 sessions). The majority of group members were inpatients. **Results:** 13 patients (9%) attended 10 or more sessions. 23 patients (16%) had laryngectomies. Nearly all patients had communication problems from disease or treatment and some Mexican-American patients whose primary language was Spanish had trouble communicating with English-speaking group members. The most common subject discussed by the patients was the anticipation of and reactions to treatment, discussed at 48 sessions. Other topics frequently dealt with were adaptation following treatment (26 sessions), interaction with family (20 sessions), losses owing to cancer (17 sessions), peer support (14 sessions), smoking (9 sessions) and eating difficulties (9 sessions). The fear that patients might panic or become depressed by listening to other peoples' problems was dissipated after the first month of group meetings when no adverse effects were noted. The subjective impressions of the therapists and other staff members were that the group was beneficial. There appeared to be an increased cohesion among the patients outside of the group	**Authors' conclusions:** Group psychotherapy has been a valuable treatment modality for addressing the complex psychosocial needs of the head and neck cancer patient. No adverse effects related to the group experience have been noted among the participating patients. **Comments:** This study presents data collected by the therapists, recorded after each session and the subjective views of those therapists on the effect of the group sessions on patient outcomes. Patients themselves were not surveyed.

	issues discussed included responses of family and friends to diagnosis and treatment, myths about cancer, side effects of treatment, changes in lifestyle and adjustment to losses. The therapists were well informed of each patient's treatment plan and facilitated the explanation of the plan to the patient.		setting including spending leisure time together, assisting each other in learning self-care and helping family members with financial and housing problems. The patients have developed an increased ability to discuss openly such issues as marital and financial problems. This openness has led to better planning of comprehensive care and outpatient treatment. No group members signed out against medical advice. This contrasts with a "pre-group" against medical advice discharge rate of approximately 1 patient every 4 to 6 weeks. There seemed to be higher motivation toward independent functioning and better self-care while patients were in the hospital.	
Mathieson, 1996.[25] **Country:** Canada **Aims:** To determine whether social support contributes to better quality of life and psychological state of head and neck oncology patients. **Grade of evidence:** VI	**Service:** No details of the support groups were given. **Participants:** Patients with head and neck squamous cell carcinoma who attended follow-up appointments at the Head and Neck Oncology clinic and who were not undergoing active medical treatment. The time since diagnosis ranged from less than 6 months to more than 60 months; almost half of patients were diagnosed 13 months to 24 months earlier.	**Methods:** The structured questionnaire asked about 6 areas: demographics, medical variables, disruption of functional activities, social support, quality of life and psychological state. Each patient was interviewed individually by the primary investigator or the research assistant, using the questionnaire, however, patients were willing to elaborate on their answers. All data were obtained orally and all answers were recorded by the interviewer. Comments about satisfaction with social support were also recorded. Patients were given the option of having their partners present during interviewing. **Outcomes measured:** The social support questionnaire scored the perceived number of supports and the degree of satisfaction (on a scale of 0 to 10) with those supports, including special support groups.	**Included patients:** The study included 45 patients (33 men, 12 women). 1 patient did not complete the interview. **Opinions about support groups:** 4 patients reported special groups as a source of social support. All of these patients reported that they were totally satisfied with this source of support. **Effect of the presence of a partner during the interview:** Preliminary statistical analysis confirmed that the presence or absence of a partner during the interview did not affect results.	**Authors' conclusions:** The authors do not draw any conclusions relating to special support groups. **Comments:** Only the data relating to special support groups have been reported. This includes data on only 4 patients, therefore, results may not be representative of head and neck cancer patients. The data were collected by the primary investigator or research assistant, it does not state whether they were known to the patients. Answers were obtained orally and recorded by the interviewer, which may result in errors, misinterpretation or incomplete responses being recorded.

Table 6e: Patient education group

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Hammerlid, 1999.[30] **Country:** Sweden **Aims:** To examine the effect of a 1-week psycho-educational program for head and neck cancer patients 1 year after diagnosis. **Grade of evidence:** VI	**Participants:** Together with their spouses, patients with oropharyngeal and laryngeal cancer who participated in an earlier longitudinal quality of life study were invited to a rehabilitation centre for a 1-week residential psycho-educational program. **Intervention:** The program included an individual appointment with an oncologist, an educational program about cancer given by a physician, separate group sessions for patients and their spouses led by specially trained nurses, individual and group education by a physiotherapist and leisure activities such as painting, walking, music and dancing. A "home-like" environment with good food was emphasised. A report was sent to the patient's ordinary physician after the rehabilitation.	**Methods:** Quality of life was measured before and 4 weeks after the intervention using the European Organisation of Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), a preliminary version of the EORTC head and neck cancer module (QLQ-H&N37) and the Hospital Anxiety and Depression (HAD) scale. A research nurse conducted a standardised telephone interview 3 weeks after the intervention for further evaluation of the program. **Outcomes measured:** Quality of life.	**Included patients:** About one third of the invited patients wanted to participate, including 11 men and 3 women, mean age 57 years. There were 3 patients with laryngeal carcinoma, 3 with tonsillar carcinoma, 7 with oral cavity carcinoma and 1 with hypopharyngeal carcinoma. Mean time between diagnosis and the rehabilitation program was 16 months (range 12 to 22 months). 8 patients brought their spouses. Results from the interview showed that patients appreciated all activities, learned new things and considered this knowledge useful. 5 patients mentioned spontaneously that the opportunity to socialise with other guests meant a lot to them. All patients would recommend a week of rehabilitation in this format to other cancer patients. 4/5 spouses considered the rehabilitation week to be "very good" and 1 "acceptable". Some of the patients thought they would have benefited more from the activities if they had been given the opportunity to go earlier (i.e. 2 to 3 months after finishing the treatment). **EORTC QLQ-C30:** Between the 1-year follow-up and the start of rehabilitation the figures were almost unchanged. **EORTC QLQ-H&N37:** For most questions no great differences were found between values before and after the rehabilitation. However, the majority of variables reflecting functioning and symptom burden improved somewhat after the rehabilitation (26 of 34 variables). Only 6 variables scored worse. 8 variables showed improvements of 5 points or more, those with the greatest improvements were "trouble eating", "problems enjoying your meals", dry mouth and emotional functioning. The only question showing a deterioration of 5 points or more concerned financial problems. **HAD scale:** The number of probable clinical cases of anxiety and depression was almost constant throughout the study. The number of possible cases decreased slowly. The number of patients scoring more than 7 on one of the scales decreased after the rehabilitation week.	**Authors' conclusions:** Patients participating in these pilot studies benefited from the supportive group therapy and the short-term educational program and the standardised questionnaires were of value in assessing their quality of life. It seems worthwhile to replicate the findings in larger studies of psychological support for head and neck cancer patients. **Comments:** Limitations of this pilot study include the small sample size and lack of a control group. However, the authors' use of validated measurement tools increase the validity of the findings, although some results were not fully reported. The authors' conclusions that patients benefited from these interventions and that it seems worthwhile to replicate the findings in larger studies appears valid. This is one of two pilot studies conducted by Hammerlid, written up as one publication.

<table>
<tr>
<td>Hell, 1987.[29]

Country:
Germany

Aims:
The aims of the study appear to be to report on the initial experiences with a patient education group.

Grade of evidence:
VI</td>
<td>Participants:
Patients diagnosed with head and neck cancer.

Service:
A patient education group met once a month and was based in a hospital oral and maxillofacial surgery department. The group was facilitated by a professional, depending on the subject matter, who gave a presentation about topics of interest to the subject group.</td>
<td>Methods:
A qualitative description of a new group was presented.

Outcomes measured:
Attendance

Patients' experiences.</td>
<td>Attendance:
<table><tr><th>Topic</th><th>Attendance</th></tr><tr><td>Feeding</td><td>4</td></tr><tr><td>Post operative nutrition</td><td>23</td></tr><tr><td>Life assurance and pensions</td><td>26</td></tr><tr><td>Cancer</td><td>36</td></tr><tr><td>Radiotherapy</td><td>25</td></tr><tr><td>Alcohol and Nicotine</td><td>32</td></tr></table>
The total number of patients was not reported.

Experiences:
Patients expressed satisfaction with the group. They fed back suggestions for improving the group and the hospital's service in general. These included:

• Having someone of whom patients can ask questions while in clinic if they did not want to ask the doctor.
• Advertising the group in press and on radio.
• Selection of a lead individual to invite persons to the group and act as a contact point outside of its sessions.

Patients suggested they had a better understanding of cancer, a better understanding of the views of patients and doctors so that they would be more able to be proactive in consultations, better understanding of reconstructive possibilities, better cooperation in relation to giving up smoking or drinking alcohol, reduced sense of isolation and more help with financial problems.</td>
<td>Authors' conclusions:
A patient group can assist with the physical, psychological and rehabilitation needs of patients with head and neck cancer.

Comments:
A brief description of a patient education forum was well presented. While this is very qualitative and so may be unique in the service and outcomes it describes, it does suggest that patients may wish to learn about their disease, its implications and treatments.</td>
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Table 6g: Patient held records

<table>
<tr><th>Study details and aims</th><th>Participants and Service</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>van Wersch, 1997.[31]

Country:
The Netherlands

Aims:
To assess a logbook developed to improve continuity of information in the treatment and care of head-and-neck cancer patients.

Grade of evidence:
IV</td>
<td>Participants:
All patients had head and neck cancer. Patients included in the active arm were given a log-book (n = 71). Patients being treated at a different hospital were enrolled in the control arm (n = 54).

Patients were eligible if they had undergone 1 of the following procedures: laryngectomy, commando surgery (a radical form of surgery for patients with carcinoma of the mouth or pharynx), facially mutilating surgery or intensive radiotherapy.

Most participants were male (intervention 80%, control 70%), were living with another person (intervention 75%, control 60%) and the average age was in the early sixties for both groups (intervention: 61 years, SD: 11 years, range 37 years to 85 years; control: 64 years, SD: 12 years, range 35 years to 92 years).

Service:
A log-book was developed. It consisted of sections dealing with communication and</td>
<td>Methods:
A questionnaire was sent to patients and professional carers of all participants.

The patient questionnaire examined the following: Perception of the nature and quality of the different types of information and social support received, psychosocial variables and use of both sections of the log book (intervention group only).

The questionnaire sent to professional carers of those patients in the intervention group examined their experiences of caring for head and neck cancer patients, their normal attitudes to information giving practices, their use of the logbook and their suggestions for its modification.</td>
<td>Completeness of data:
Evaluations were returned by 60 (84%) intervention patients and by 39 (72%) control patients.

Results:

Use of the log-book:
91% of 60 patients had read all the log-book. 91% had given the book to the person closest to them to read and 94% had given it to a professional carer; this included the GP (78%), ENT specialist (70%) and nursing staff (67%).

47% reported making entries in the book. Patient experiences were the most common patient entries (32% of patients) followed by questions for professional carers (by 24% of patients). Most patients who wrote in the patients' notes section, used it as a diary. Some patients did not write in their book as they had no questions (27%), did not like writing (21%) or felt their feelings were not the concern of others (21%).

Most communication forms were used by professional carers. 12 patients recorded on average 4 comments each. 15 family members recorded on average 3 comments each. 1 patient had recorded 8 comments.

The most used sections were those explaining "what cancer is", "treatment" and "social nursing". The glossary, list of addresses and staff contact details were rarely used.

Reactions to the log-book:
88% said the book clarified things for them. Most did not find it difficult to read. The information sections were found to be clear and well organised (100%) comprehensive (92%), not too difficult (84%) not too brief (82%) and not too long (78%). 98% said they did not suffer disadvantages from using the book and only 3 suggestions were made to change it, each of an organisational nature.

Psychosocial support:
More intervention group patients reported receiving support and fewer reported negative feelings than did patients in the control group.

Considerably fewer intervention group patients were dissatisfied with the answers to their questions.

Psychosocial problems:
Control patients were more likely to have fear, anxiety, depression and tension but there were no differences in the incidence of loneliness, insomnia, loss of control or reduction in self-esteem.

<table>
<tr><th>Indicator</th><th>Intervention patients</th><th>Control Patients</th><th>P - value</th></tr>
</table>
</td>
<td>Authors' conclusions:
Use of the logbook by patients in the trial led to their being better informed. They received better and more comprehensive information with less apparently contradictory information as well as instruction on specific aspects of care.

Comments:
The allocation to the active and control arms of this study was non-random. Systematic differences in the patients referred to the hospital whose patients were entered in the active arm and the hospital whose patients were entered in the control arm can not be ruled out.

The authors did not provide a list of their outcome measures in advance. The authors reported only those comparisons which reached statistically significant differences. It is not certain how many comparisons were made and as such, the possible role of chance in achieving a certain number of falsely significant differences can not be assessed. The results as presented do not</td>
</tr>
</table>

	information. The communication section contained details about the following:- • the patient • the disease • patient contact details • professional carers and their contact details • general care history • oncological case history • medication • status at discharge • psychosocial data including living arrangements, household composition and support. Additionally, there was space provided so that anyone could record questions or comments. The information section contained information on the following:- • what cancer is • social nursing • diet • treatment • speech therapy • physiotherapy • care of canulas • care of stomas • radiotherapy	Social nursing staff and the study co-ordinator completed a 23-item checklist 1 year into the use of the logbook. **Length of follow-up:** Not stated.	Clear written information: 67 / 33 / 0.005 Sufficient written information: 78 / 39 / 0.001 Clear information from the ENT doctor: 93 / 78 / 0.05 Clear information from the nursing staff: 69 / 41 / 0.05 Clear information from the social staff: 72 / 22 / 0.001 Insufficient information about post-discharge: 19 / 49 / 0.01 Need for information about the disease and treatment: 17 / 52 / 0.001 Need for information about how to solve specific problems: 8 / 38 / 0.001 Contradictory information from different staff: 4 / 23 / 0.01 Less uncertain about which test was to come: 19 / 42 / 0.01 Less uncertain about the operation procedure: 19 / 40 / 0.05 Less uncertain about how to achieve physical fitness: 38 / 59 / 0.05 Support from social staff with tension or other problems: 61 / 15 / 0.001 Dissatisfaction with answers to questions: 6 / 27 / 0.01 Experience of fear: 21 / 49 / 0.01 Experience of anxiety: 21 / 47 / 0.01 Experience of depression: 29 / 43 / 0.01 Experience of tension: 33 / 100 / 0.001 *Result values are percentages, p-values are for the χ^2 test. Only comparisons with significant differences are presented here.* 59 (54%) professionals involved in treating the intervention patients returned questionnaires. 35 (45%) of those involved in treating control patients did so. 2/3 of cancer patients' caregivers had made "reasonable" use of the book. 82% of carers had given patients the module of the information section pertaining to their practice and had explained it. 79% had read the sections concerning other professionals' care. 97% of carer information forms were completed but allergic reaction details were completed least frequently (29%). 59% of cases included information on medication but terminated medication was not recorded in 19% of cases. Speech and language therapists (116 comments in 34 log-books) and ENT physicians (114 comments in 37 books) were most likely to add comments to the communication section of the form. Community nurses made 38 entries in 9 books and family doctors, 22 in 7. 90% of those who had worked with the book thought it was a good means of information giving and 79% said it made a considerable contribution to the continuity of information. About 2 thirds found it useful in giving them an overview of the patient's case history. Some carers found that the ease of initiation of a conversation with the patient (35%) and the quality of contact (32%) were improved. 2 thirds felt patients asked better questions of their carers. 63% of carers felt it contributed to harmonising care between professionals. 27% reported knowing better to whom to refer		exclude the possibility of "data-dredging". All those evaluating the book were aware of the allocation of the patient to receive the book. This could have biased their perceptions of information need, understanding and usefulness of the information given. The conclusions drawn appear to follow from the results presented. While the limitations in the methods used should be acknowledged, it is difficult to perform a truly randomised comparison in this setting as cross-contamination of the professionals in the arms would be a significant barrier to a successful RCT. As such this evidence should be viewed, if not as definitive proof, as strongly suggestive of the benefit of this form of structured information.

	• brachytherapy • dentistry • prosthetics • home-care • contacts for associations of other patients • coping. Half of all patients in the control group had not been given written information about their treatment.		patients and 48% reported referring more patients. 56% reported that the book made a considerable contribution to information exchange. 77% found it beneficial in aligning hospital and home-based care. 42% of carers who used the book wanted changes to its format in terms of size and presentation. 23% suggested changes in the content and layout. The duplication of information between nursing and medical entries was highlighted particularly. Professionals in the control setting reported no formal method of transfer of information between professional carers. They reported regular breakdowns in communication, particularly in relation to the information other team members had given to patients.	

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Follow-up and recurrent disease

The Questions

a) For patients who have been treated for head and neck cancer, what is the effect of routine follow-up on outcomes including timeliness of detection of local recurrence or second primary tumour?

b) For patients who have been treated for head and neck cancer, what effect does the provision of routine follow-up performed at the cancer unit/District General Hospital, rather than at the cancer centre, have on outcomes including timeliness of detection of local recurrence or second primary tumour?

c) In patients who have been treated for head and neck cancer, what are the relative efficacies of Positron Emission Tomography (PET), MRI, CT and ultrasound scanning in the detection of recurrence?

d) In patients with head and neck cancer (recurrent disease) what are the relative efficacies of brachytherapy, normal fractionation external beam radiotherapy, accelerated fractionation external beam radiotherapy, altered fractionation external beam radiotherapy, chemoradiotherapy, surgery, chemotherapy and endoscopic/laser excision, alone or in combination, in terms of long term survival, peri-treatment mortality, recurrence rates, incidence and severity of morbidity, voice outcomes, facial nerve outcomes, xerostomia, complication rates, quality of life, anxiety, patient satisfaction or any other patient outcomes?

The Nature of the Research Evidence

a) Routine follow-up

One study pertinent to this question was located.[1] This was a systematic review of follow-up strategies offered to patients who had been treated for upper aerodigestive tract (UAT) cancer. Unfortunately, the study assessed

quantitative differences in the frequency of consultations and a number of haematological, biochemical and imaging and their costs, but did not assess the qualitative differences in the outcomes of these varying schedules in terms of patients' experiences or the timeliness of detection of recurrent or new malignancies. The study was limited in its searching to only one database and its methodology was poorly reported so it is difficult to comment on its validity. Details are given in Table 7a.

b) Routine follow-up performed at the cancer unit/District General Hospital

No evidence was found relating to the provision of routine follow-up performed at the cancer unit/District General Hospital, rather than at the cancer centre.

c) Relative efficacies of imaging techniques in the detection of recurrence

Two studies compared the use of CT and MRI in the detection of recurrence of head and neck cancers.[2, 3] The better quality study evaluated 34 patients being followed up after treatment of nasopharyngeal cancer, all patients had received radiotherapy.[2] The other study compared CT with MRI in 50 patients with a facial or neck stage 3 or 4 cancer for which they had received radiotherapy.[3] However, owing to the lack of methodological data reported, the results of this study cannot be verified.

Two studies compared CT with PET in patients who were suspected of having a recurrence[4, 5] The studies included 56 patients who had been treated with surgery and/or radiotherapy for a head and neck cancer[4] and 80 patients who had been treated with high dose radiotherapy for laryngeal cancer.[5] However, owing to the lack of methodological data reported in the latter study, its results cannot be verified. One study compared CT, PET and Colour-Doppler Echography (CDE) in 43 patients who had been treated for head and neck cancer.[6]

A well-conducted study compared ultrasound with PET in 28 patients who had been treated for oral oropharyngeal, hypopharyngeal or laryngeal cancer.[7]

Details of the studies are given in Table 7c.

d) Relative efficacies of treatment modalities

Systematic reviews and RCTs comparing the relative efficacies of different modalities of treatment for recurrent disease were sought. Comparisons of fractionation schemes within radiotherapy or comparisons of different chemotherapy regimens were excluded. No systematic reviews or RCTs were identified.

Summary of the Research Evidence

a) Routine follow-up

In a systematic review of follow-up strategies advocated by the authors reports of primary research articles indexed in MEDLINE or published in textbooks, US researchers located 37 separate follow-up strategies.[1] These were either common to all forms of UAT cancer (n = 23) or specific to individual UAT cancers (n = 25). Results were presented in terms of the number of times an intervention was recommended by the study over five years. The most commonly recommended means by which deterioration in the status of the patient could be detected was follow-up clinic consultation. This was recommended in every strategy. Chest X-rays were recommended by 10 of 12 general strategies and 21 of 25 site-specific ones. Blood counts (7 of 12 general and 6 of 25) and liver function tests (2 of 12 general and 11 of 25) were the only other tests widely recommended. For full details of the study, including the other tests recommended and the range of suggested frequencies, please see Table 8f.

The review reported few details about its methods. While the principal results of interest, the recommended follow-up strategies in each primary research study were reported, the review did not give further details about its included studies. The validity of contributing studies was not assessed. This could affect the validity of the review. It is not clear what treatments patients had undergone before entering the follow-up phase of management. This is key as

patients on highly experimental and novel therapies are often followed-up more frequently than those treated with methods where the adverse-event profiles are better understood.

The costs of strategies were also investigated in the review. Medicare cost-equivalents for each strategy were calculated. The authors found striking differences between the costs of the strategies; there was a twelve-fold difference in the costs of the least and most expensive general strategy and a nineteen-fold difference in the lest and most expensive strategy overall.

Conclusions

While the array of follow-up strategies is fairly represented in this review, the underlining issues which are important in deciding the follow-up appropriate or effective in the cases of individual patients with UAT cancer is not investigated by the study. No conclusion as to the cost effective or appropriate follow-up regimen can be drawn.

b) Routine follow-up performed at the cancer unit/District General Hospital

No evidence was found relating to the provision of routine follow-up performed at the cancer unit/District General Hospital, rather than at the cancer centre.

c) Relative efficacies of imaging techniques in the detection of recurrence

In a well-conducted diagnostic study that compared CT with MRI,[2] both CT and MRI were found to have relatively low sensitivity and moderate specificity in detecting tumour recurrence and in distinguishing recurrence from post-radiation therapy changes. However, MRI was found to be more accurate than CT (73.3% to 77.8% compared with 64.4%). MRI was also found to be more accurate than CT in the study of uncertain quality.[3]

The two studies which compared CT with PET in patients with a suspected recurrence[4, 5] found that PET was more accurate than CT. In the better quality

study[4] the accuracy of PET in patients with a moderate clinical suspicion for cancer was 88% compared with 81% for CT. The accuracy of PET in patients with a strong clinical suspicion for cancer was 90% compared with 84% for CT. In the lower quality study[5] the accuracy of PET was 92.5% compared with 60.6% for CT.

The study which compared CT, PET and Colour-Doppler Echography (CDE)[6] found that the accuracy of CT and CDE were comparable at 79.1% and 79.2%, but the accuracy of PET was superior at 86.1%.

In the study which compared ultrasound with PET,[7] PET was found to be more accurate than ultrasound (85.7% versus 64.3%).

Conclusions

The evidence reviewed consistently showed both MRI and PET to be more accurate than CT in detecting a recurrence of head and neck cancers. PET was also found to be more accurate than CT in patients where a recurrence was clinically suspected. The accuracy of CDE was found to be similar to that of CT. PET was also found to be more accurate the ultrasound.

d) Relative efficacies of treatment modalities

No systematic reviews or RCTs were identified which compared the relative efficacies of different treatment modalities for recurrent disease.

Table 7a: Routine follow-up

<table>
<tr><th>Study details and aims</th><th>Inclusion/exclusion criteria</th><th>Methods</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Virgo, 1998.[1]

Country:
USA

Aims:
To determine the range of recommended follow-up strategies for patients with upper aerodigestive tract cancer treated with curative intent and to estimate cost of follow-up.

Grade of evidence:
III</td>
<td>Study design:
Not specified.

Participants:
Patients undergoing curative treatment for primary upper aerodigestive tract (UADT) carcinomas.

Intervention:
Generic and site-specific UADT cancer surveillance strategies.

Outcome:
Type and costs of different surveillance strategies.

Further exclusion criteria:
Not specified.</td>
<td>Sources searched:
Medline searched from 1978 to 1997; textbooks in the field of otolaryngology and upper aerodigestive tract cancer (no specific terms mentioned).

Authors were contacted for clarification and updating of their strategies.

Quality assessment:
Not specified.

How studies were combined:
Results were described for each study, no meta-analysis was attempted.

Cost:
Average charges from the 1992 Part B Medicare Annual Data File and the first quarter 1992 Hospital Outpatient Bill File were computed for a single patient with UADT cancer for 5 years follow-up. For each identified strategy, charges were assigned to all tests and the total costs of follow-up estimated. Treatment charges for new primary UADT cancer, recurrences and other conditions detected during surveillance were ignored. Total charges were converted to a 1997 charge proxy using a conversion ratio of 1.62.</td>
<td>Number of included studies:
22 articles or book chapters depicting 37 separate follow-up strategies were identified. Articles were grouped into 2 categories: 12 generic (and 25 site-specific surveillance strategies.

Results:
General recommendation for 5 years follow-up strategies varied widely. Details of the number of strategies recommending an intervention and the minimum and maximum number of times that intervention were recommended are as follows:

<table>
<tr><th colspan="4">Generic Strategies (n = 12)</th></tr>
<tr><th>Test</th><th>Number of Strategies</th><th>Minimum Number</th><th>Maximum Number</th></tr>
<tr><td>Office Visits</td><td>12</td><td>8</td><td>27</td></tr>
<tr><td>Full Blood Counts</td><td>7</td><td>2</td><td>26</td></tr>
<tr><td>Liver Function Tests</td><td>2</td><td>2</td><td>8</td></tr>
<tr><td>Electrolytes</td><td>2</td><td>1</td><td>8</td></tr>
<tr><td>Thyroid Function Tests</td><td>2</td><td>2</td><td>8</td></tr>
<tr><td>Erythrocyte Sedimentation Rate</td><td>3</td><td>8</td><td>24</td></tr>
<tr><td>Serum Calcium Levels</td><td>1</td><td>8</td><td>8</td></tr>
<tr><td>Chest Radiography</td><td>10</td><td>5</td><td>18</td></tr>
<tr><td>Head CT</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>Neck CT</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>Chest CT</td><td>1</td><td>3</td><td>3</td></tr>
</table>

<table>
<tr><th colspan="4">Site-specific Strategies (n = 25)</th></tr>
<tr><th>Test</th><th>Number of Strategies</th><th>Minimum Number</th><th>Maximum Number</th></tr>
<tr><td>Office Visits</td><td>25</td><td>11</td><td>40</td></tr>
<tr><td>Full Blood Counts</td><td>6</td><td>12</td><td>12</td></tr>
<tr><td>Liver Function Tests</td><td>11</td><td>5</td><td>12</td></tr>
<tr><td>Thyroid Function Tests</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>SCC-Antigen</td><td>1</td><td>12</td><td>12</td></tr>
<tr><td>Nucleotidase</td><td>2</td><td>18</td><td>18</td></tr>
<tr><td>Chest Radiography</td><td>21</td><td>5</td><td>10</td></tr>
<tr><td>Barium Swallow</td><td>2</td><td>3</td><td>5</td></tr>
</table>
</td>
<td>Authors' conclusions:
Charges varied extensively across surveillance strategies, particularly if site-specific strategies were considered, although the potential benefit of more intensive, higher-cost strategies on survival or quality of life has yet to be demonstrated.

Comments:
While the question addressed by this review appears to have been well formed, the methods used in the review were not described in sufficient detail to allow for a judgement of its quality to be made. It is not clear how or by whom, important steps in the review process were conducted. The search was limited to a single database, therefore, other relevant studies may have been missed.

Very few details about the original studies were provided. As such the results may not be generalisable beyond the study population, even within the country where it was conducted. The possibility of translating the findings to the NHS setting would prove very difficult as it was located in a different country and organised in such a different manner to the service being studied.</td>
</tr>
</table>

			Head CT	1	1	1	
			Head MRI	2	1	8	
			Maxillofacial CT	2	4	4	
			Maxillofacial MRI	3	4	5	
			Cost: Medicare-allowed charges for 5-years follow-up ranged from US$739 to US$14,079 for the generic and site-specific strategies combined and from US$739 to US$4,646 for the 12 generic strategies alone. When converted to 1997 values the range was US$1,198 to US$22,807 for all strategies combined (19-fold difference in charges) and US$1,198 to US$7,597 for generic strategies (5-fold).				

Table 7c: Relative efficacies of imaging techniques in the detection of recurrence

<table>
<tr><th>Study details and aims</th><th>Details of participants and diagnostic test(s)</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Chong, 1997.[2]

Country:
Singapore

Aims:
To compare the use of MR imaging and CT in detection of recurrent nasopharyngeal carcinoma.

Grade of evidence:
IV</td>
<td>Participants:
Patients who were being followed-up after treatment of nasopharyngeal squamous cell cancer were included in the study. All patients had received radiotherapy.

CT:
CT was conducted using compromise contrast medium (80ml, 370gml^{-1}, 29.6g of iodine). A Picker scanner was used.

MRI:
MRI was conducted using gadopentetate dimeglumine contrast medium (0.01mmolkg^{-1}). A Magnetom scanner was used. T1, T2 and spin echo sequences were acquired.

Interval between tests:
CT and MR images were obtained within 1 week of each other.

Reference standard:
Positive findings were validated by nasopharyngoscopy and histological examination. Disease still visible at 6 months after radiotherapy was defined as persistent. Negative or equivocal findings were compared with clinical and additional radiographic follow-up. Follow-up lasted a mean 32 months (range: 29.6 months to 34 months).

Blinding:
2 radiologists interpreted the images independently of each other. CT and MRI were viewed independently of each other. Images were interpreted without knowledge of the clinical history of the patient, the nasoendoscopic findings or the histological diagnosis.</td>
<td>Included patients:
The study included 34 patients. Staging results of the primary disease were not presented. 11 patients had 2 sets of MR and CT scans during the period of the study and both were included separately in the dataset.

Withdrawals:
All patients were included in the review. However, the patients were identified from a previous study of 114 patients. Those who were available for follow-up from the previous study were included in the current study.

Demographic details:
Data from 12 females and 22 males with a mean age of 46.3 years (range: 28.2 years to 66.8 years).

Incidence of active disease:
The number of patients with recurrent tumour or metastases was not reported.

Diagnostic indices:
<table>
<tr><th></th><th colspan="2">CT</th><th colspan="2">MRI</th></tr>
<tr><td></td><td>Observer 1</td><td>Observer 2</td><td>Observer 1</td><td>Observer 2</td></tr>
<tr><td>Sensitivity</td><td>44%</td><td>67%</td><td>56%</td><td>56%</td></tr>
<tr><td>Specificity</td><td>69%</td><td>64%</td><td>83%</td><td>78%</td></tr>
<tr><td>Accuracy</td><td>64%</td><td>64%</td><td>78%</td><td>73%</td></tr>
<tr><td>PPV</td><td>27%</td><td>32%</td><td>45%</td><td>38%</td></tr>
<tr><td>NPV</td><td>83%</td><td>88%</td><td>88%</td><td>88%</td></tr>
<tr><td>PLR</td><td>1.5</td><td>1.9</td><td>3.3</td><td>2.5</td></tr>
<tr><td>NLR</td><td>0.8</td><td>0.5</td><td>0.5</td><td>0.6</td></tr>
<tr><td>DOR</td><td>1.8</td><td>3.5</td><td>6.3</td><td>4.4</td></tr>
</table>
</td>
<td>Authors' conclusions:
Both modalities have relatively low sensitivity and moderate specificity in detection of tumour recurrence and in distinguishing recurrence from post-radiation therapy changes.

Comments:
This diagnostic assessment study was conducted very well. The methods used were well reported and appropriate to the aims of the study. It appears to have been conducted prospectively. The reference standard was appropriate to the population being studied and was applied well. The findings appear to be supported by the evidence. The authors did not explain the unavailability for follow-up of the 80 patients who were included in the original study but who were not included in this one. Systematic differences in the populations may affect the applicability of the current study's findings. Additionally the small number of participants should be noted.</td>
</tr>
<tr>
<td>Falchetto Osti, 1998.[3]</td>
<td>Participants:
Patients who had been treated using mega voltage</td>
<td>Included patients:
The study included 64 patients between January, 1992 and October,</td>
<td>Authors' conclusions:
MRI was more accurate than CT in demonstrating post-</td>
</tr>
</table>

<table>
<tr>
<td>Country:
Italy

Aims:
To assess the recurrence rate of a group of head and neck cancer patients treated using several reconstruction techniques.

Grade of evidence:
V</td>
<td>radiotherapy for a facial or neck cancer were included in the study. All patients had T-Stage 3 or 4 cancer and had undergone radical radiotherapy to a dose of 50Gy to 60Gy.

CT:
CT imaging was conducted using an iodine-based contrast medium (given in 5 boluses of 20ml to 40ml to a total of 150ml to 200ml).

MRI:
PET imaging was using contrast medium conducted 90min after injection of Gadolinium based contrast medium (given at a dose of 0.2mlkg^{-1}). T1, T2, spin echo and fast spin echo images were acquired.

Interval between tests:
Information on the relative timing was not reported.

Reference standard:
Positive findings were validated by histological examination and/or clinical follow-up.

Blinding:
Information as to whether those interpreting images, histology or follow-up clinical assessments were aware of the findings of previous tests assessments was not presented.</td>
<td>1995.

Withdrawals:
14 patients did not have both CT and MRI images and were excluded.

Demographic details:
Data from 22 females and 42 males with a median age of 52.3 years (range: 32 years to 63 years).

Incidence of active disease:
26 patients were diagnosed with recurrent tumour or metastases.

Diagnostic indices:
<table>
<tr><th>Index</th><th>CT</th><th>MRI</th></tr>
<tr><td>Sensitivity</td><td>73%</td><td>92%</td></tr>
<tr><td>Specificity</td><td>84%</td><td>95%</td></tr>
<tr><td>Accuracy</td><td>78%</td><td>94%</td></tr>
<tr><td>PPV</td><td>76%</td><td>92%</td></tr>
<tr><td>NPV</td><td>82%</td><td>95%</td></tr>
</table>
The likelihood and diagnostic odds ratios were not reported.</td>
<td>operative and post-irradiation changes thanks to its higher sensitivity in depicting tumor tissue on T2-weighted and post-Gd-DTPA images. CT was useful in the early post-operative period because its acquisition time is short. MRI should be performed when CT findings are questionable and the revascularised flap is used to repair a large defect at the skull base.

Comments:
The methods used in the diagnostic accuracy section of this study were poorly reported. The methods used to compare the interpretations of the images and reference were not reported. The raw results were not presented and the data reported here are taken directly from the study report. As such no arithmetic accuracy checks were possible and the other indices, which had not been reported, were not calculated. It is unclear if this series was conducted prospectively or retrospectively. It is unclear if interpretation of MRI and CT were done with or without knowledge of the other imaging findings.

Note: The series also assessed the success rates of various surgical flap techniques; this topic is outside of the remit of the question and as such data were not reported here.</td>
</tr>
<tr>
<td>Lapela, 2000.[4]

Country:
Finland and Denmark.

Aims:
To confirm the efficacy of FDG PET in differential diagnosis between malignancy and benign lesions in head and neck cancer.

Grade of evidence:
IV</td>
<td>Participants:
Patients who had been treated with surgery and/or radiotherapy for a head and neck cancer and were suspected of having a recurrence were included in the study.

CT:
CT imaging was conducted on GE CT Pace scanner. Iopromid contrast material was used in all patients (100ml to 120ml). Images were interpreted as “Negative for malignancy” (Grade 0), “Inconclusive for malignancy” (Grade 1) or “Malignant” (Grade 2).

PET:
PET images were acquired using Siemens or GE scanners. The scan was conducted 90min after injection of contrast material given in a mean dose of 340MBq (range 228MBq</td>
<td>Included patients:
The study included 56 patients. There were 48 SCCs, 2 adenocarcinomas, 2 adenoid cystic carcinomas, and 1 carcinoma of each of lymphoepithelial, transitional cell, acinar cell and mucoepidermoid types. Staging results of the primary disease were as follows:
<table>
<tr><th>T-stage</th><th>No.</th></tr>
<tr><td>1</td><td>6</td></tr>
<tr><td>2</td><td>22</td></tr>
<tr><td>3</td><td>12</td></tr>
<tr><td>4</td><td>12</td></tr>
<tr><td>Unknown</td><td>4</td></tr>
</table>
<table>
<tr><th>N-stage</th><th>No.</th></tr>
<tr><td>0</td><td>33</td></tr>
<tr><td>1</td><td>9</td></tr>
<tr><td>2</td><td>11</td></tr>
<tr><td>3</td><td>2</td></tr>
<tr><td>Unknown</td><td>1</td></tr>
</table>
Withdrawals:
No withdrawals were reported.</td>
<td>Authors’ conclusions:
In clinical practice it may be preferable to identify the presence of tumour recurrence within this patient group by qualitative interpretation of the PET images.

Comments:
The methods used to compare the interpretations of the images and reference were well reported but the raw results were not presented and the data reported here are taken directly from the study report. As such no arithmetic accuracy checks were possible and the other indices, which had not been reported, could not be calculated. It is unclear if this is a consecutive, random or other form of series or if it was conducted prospectively or retrospectively. Also, all patients had suspected recurrence so it is doubtful that this study would inform</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>to 429MBq). Imaging was obtained 35 minutes to 60 minutes after contrast injection. Images were interpreted as “Negative for malignancy” (Grade 0), “Inconclusive for malignancy” (Grade 1) or “Malignant” (Grade 2).

Interval between tests:
Information on the relative timing was not reported.

Reference standard:
Positive findings were validated by histological examination. Negative findings were compared with clinical follow-up for a mean period of 15.8 months (range 5.6 months to 58 months). Recurrences identified by subsequent follow-up were deemed positive at the time of the study.

Blinding:
Images were interpreted with knowledge of the clinical suspicion and history but without knowledge of the histological findings or the results of the other imaging modality.</td>
<td>Demographic details:
Data from 16 females and 40 males with a mean age of 61 years (range: 34 years to 79 years).

Incidence of active disease:
37 of 81 lesions proved to be malignant on pathological examination and 3 patients presented with confirmed recurrences at 6, 7 and 9 months after the study.

Diagnostic indices:
Predictive values, likelihood ratios and the diagnostic odds ratio were not reported. Sensitivity, specificity and accuracy were calculated based on the number of lesions detected rather than the number of patients with lesions.

<table>
<tr><th>Cut-Point</th><th>Index</th><th>CT</th><th>PET</th></tr>
<tr><td rowspan="3">Grades 0 to 1</td><td>Sensitivity</td><td>59%</td><td>84%</td></tr>
<tr><td>Specificity</td><td>100%</td><td>93%</td></tr>
<tr><td>Accuracy</td><td>81%</td><td>88%</td></tr>
<tr><td rowspan="3">Grades 1 to 2</td><td>Sensitivity</td><td>91%</td><td>95%</td></tr>
<tr><td>Specificity</td><td>78%</td><td>84%</td></tr>
<tr><td>Accuracy</td><td>84%</td><td>90%</td></tr>
</table>
</td>
<td>decisions about whether to incorporate the test into normal follow-up protocols.

Note: The series also assessed standardised uptake values of PET studies. These were outside of the remit of the question and as such were not reported here.</td>
</tr>
<tr>
<td>Bongers, 2002.[5]

Country:
The Netherlands

Aims:
To evaluate the effectiveness of F-FDG PET on the coincidence camera for patients suspected of having recurrent laryngeal cancer (who had undergone radiotherapy for their primary laryngeal tumour) when compared to histopathological biopsy.

Grade of evidence:
VI</td>
<td>Participants:
All patients recruited were previously treated with high dose radiotherapy for primary laryngeal squamous cell carcinoma and had suspected recurrent disease. Patients recruited consecutively from those referred to laryngoscopic biopsy between November 1996 and September 1999.

CT:
Information about how CT images were obtained was not presented.

PET:
PET imaging was performed using 185MBq of FDG on a Vertex dual-head gamma camera a few days before laryngoscopy.

Interval between tests:
Information on the relative timing was not reported.</td>
<td>Included patients:
The study included 80 patients. Staging results of the primary disease were as follows:

<table>
<tr><th>T-stage</th><th>Number</th></tr>
<tr><td>1</td><td>25</td></tr>
<tr><td>2</td><td>37</td></tr>
<tr><td>3</td><td>12</td></tr>
<tr><td>4</td><td>6</td></tr>
</table>

Withdrawals:
It appears that all patients were included in the calculations of diagnostic indices for PET. Only 33 of 80 patients had CT.

Demographic details:
The study included 71 males and 9 females with a mean age of 60.5 years (range: 36 years to 85 years).

Incidence of active disease:</td>
<td>Authors’ conclusions:
A single application of F-FDG-PET in the 80 patients was definitively superior to alternative methods in differentiating between post-therapy sequelae such as radiation necrosis and tumour recurrence. In addition, they stated that the relatively small additional costs of this strategy are clearly acceptable, considering the incremental cost-effectiveness ratio of other interventions in the oncological patient group.

Comments:
This study was of low methodological quality. It drew its population from a limited group of patients, those with suspected recurrence and as such may not be applicable to decisions regarding the follow-up surveillance and screening of well post-therapy patients. Few methodological details were provided and no information was given about blinding. Information was not given on how or by whom the reference standard was applied. The methods used to obtain the CT scans were not reported</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Reference standard:
Imaging results were compared with the histological findings and clinical follow-up. A true positive was defined as those confirmed by a positive histopathological biopsy result and true negative when, on clinical follow-up, there was relapse-free survival of at least 1 year (mean 31.6 months ± 9.8 months).

Blinding:
No information was presented relating how images were interpreted, by whom or what additional information the interpreters had at their disposal.

Cost:
The cost categories sought for in a retrospective way were staff, materials, maintenance and investments.</td>
<td>39 patients were diagnosed with tumour re-growth during the study.

Diagnostic indices:
<table>
<tr><th></th><th>CT (n = 33)</th><th>PET (n = 80)</th></tr>
<tr><td>Sensitivity</td><td>71%</td><td>100%</td></tr>
<tr><td>Specificity</td><td>33%</td><td>85%</td></tr>
<tr><td>Accuracy</td><td>61%</td><td>93%</td></tr>
<tr><td>PPV</td><td>74%</td><td>87%</td></tr>
<tr><td>NPV</td><td>30%</td><td>100%</td></tr>
<tr><td>PLR</td><td>1.0</td><td>6.8</td></tr>
<tr><td>NLR</td><td>0.9</td><td>0.01*</td></tr>
<tr><td>DOR</td><td>1.2</td><td>431.5*</td></tr>
</table>
* = The diagnostic index has been calculated with the addition of 0.5 to all cells in the 2x2 table to allow for cells with a value of 0.

Cost:
The per-patient cost of PET was €682. The costs saved by reducing CT studies and panendoscopies were €618. Routine implementation of F-FDG-PET resulted in an additional cost of €64 per patient.</td>
<td>and the reason that only 41% of patients were examined by CT was not given. Systematic differences in characteristics between the patient population as a whole and those who underwent CT may account for substantial differences in the diagnostic performance of the test. As such the reader is precluded from basing a judgement of the validity of the tests on this study.

The analysis of the costs was carried out from the perspective of the hospital and it appears that all the relevant categories of costs were included in the study. The unit costs were reported separately and the price year was indicated, enhancing the reproducibility of the analyses in other contexts. The source of the cost data was reported but costs and quantities were treated deterministically and no sensitivity analyses were performed. These costs were specific to the study settings, limiting the generalisability of the cost results.</td>
</tr>
<tr>
<td>Di Martino, 2002.[6]

Country:
Germany

Aims:
To survey the relevance of regular colour-duplex echography examinations in the follow-up for detection and therapy of recurrent head and neck carcinomas.

Grade of evidence:
IV</td>
<td>Participants:
Patients who were being followed-up after treatment for head and neck cancer. 36 of 43 patents had had surgery to remove the primary disease. 28 of these and 3 patients with occult primaries had had bilateral neck node dissection. 2 patients had primary radiotherapy and 2 post-operative radiotherapy.

Colour-Doppler Echography (CDE):
CDE was conducted using a linear array transducer at 5.2MHz to 9.0MHz. Contrast media were used in only 1 case.

CT:
CT images were conducted using a Tomoscan or Somatom scanner and used contrast media in all cases.

PET:
PET images were acquired using a ECAT scanner. No information on the time between the injection of the medium and data acquisition was given.

Interval between tests:
Information on the relative timing was not reported.</td>
<td>Included patients:
The study included 43 patients. Staging results of the primary disease were as follows
<table>
<tr><th>Stage</th><th>1</th><th>2</th><th>3</th><th>4</th><th>Total</th></tr>
<tr><td>Oropharynx</td><td>1</td><td>3</td><td>1</td><td>6</td><td>11</td></tr>
<tr><td>Larynx</td><td>1</td><td>2</td><td>2</td><td>4</td><td>9</td></tr>
<tr><td>Mouth</td><td>2</td><td>1</td><td>4</td><td>4</td><td>11</td></tr>
<tr><td>Hypopharynx</td><td>-</td><td>-</td><td>-</td><td>3</td><td>3</td></tr>
<tr><td>Nasopharynx</td><td>-</td><td>-</td><td>-</td><td>3</td><td>3</td></tr>
<tr><td>Others</td><td>2</td><td>-</td><td>-</td><td>4</td><td>6</td></tr>
<tr><td>Total</td><td>6</td><td>6</td><td>7</td><td>24</td><td>43</td></tr>
</table>
Withdrawals:
All patients were included in the review.

Demographic details:
Not reported.

Incidence of active disease:
17 of 43 patients were diagnosed with a recurrent tumour.

Diagnostic indices:</td>
<td>Authors' conclusions:
CDE is the imaging procedure of choice for the routine follow-up of head and neck cancer patients. In order to perform a comprehensive assessment of the head and neck region, for re-staging and to exclude second primary tumours additional panendoscopy is necessary. This procedure can significantly contribute to the successful treatment of recurrences in head and neck cancer.

Comments:
This was a small prospective diagnostic assessment study and the methods used were not well reported. The reference standard was appropriate to the population being studied. The findings appear to be supported by the evidence. The study suffers from some methodological flaws. Not all patients had all tests; only 24 patients had CDE.

The results were at times reported inconsistently between the text and tables in the report.</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Reference standard:
Positive findings were validated by histological examination or clinical follow-up. Negative findings were compared with clinical follow-up.

Blinding:
No information was given about whether those who interpreted the image were aware of other imaging modalities or the clinical course of the patients disease.</td>
<td>
<table>
<tr><th></th><th>CDE (n = 24)</th><th>CT (n = 43)</th><th>PET (n = 43)</th></tr>
<tr><td>Sensitivity</td><td>80%</td><td>80%</td><td>82%</td></tr>
<tr><td>Specificity</td><td>79%</td><td>79%</td><td>88%</td></tr>
<tr><td>Accuracy</td><td>79%</td><td>79%</td><td>86%</td></tr>
<tr><td>PPV</td><td>73%</td><td>67%</td><td>82%</td></tr>
<tr><td>NPV</td><td>85%</td><td>88%</td><td>88%</td></tr>
<tr><td>PLR</td><td>3.7</td><td>3.7</td><td>7.1</td></tr>
<tr><td>NLR</td><td>0.3</td><td>0.3</td><td>0.2</td></tr>
<tr><td>DOR</td><td>14.7</td><td>14.7</td><td>35.8</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>Goerres, 2000.[7]

Country:
Switzerland

Aims:
To compare screening ultrasound (US) obtained in patients with squamous cell carcinoma of the head and neck with F-18-FDG PET and to evaluate if US obtained before F-18-FDG PET has the potential to enhance patient management by the detection of additional lesions.

Grade of evidence:
II</td>
<td>Participants:
Consecutive patients who had been treated and were being followed up for an oral oropharyngeal, hypopharyngeal or laryngeal SCC were included in the study.

Ultrasound:
An Aloka SDD-500 portable ultrasound system using a 7.5MHz linear probe was used to image the neck. A proforma was used to record the investigator's interpretation of the image and hard-copy paper images were produced.

PET:
PET images were acquired using a Siemens whole body scanner. The scan was conducted 90min after injection of contrast material given in a dose of 2.64MBqkg^{-1}.

Interval between Tests:
US and PET were conducted on the same day.

Reference standard:
Positive findings were validated by histological examination. Negative findings were compared with clinical follow-up for a minimum period of 6 months.

Blinding:
The US was conducted before PET and the authors reported that PET scans were read without knowledge of other imaging techniques. Ultrasound was performed without knowledge of the patient history, clinical information or previous imaging.</td>
<td>Included patients:
The study included 30 patients. Staging results of the primary disease were as follows:
<table>
<tr><th>T-stage</th><th>No.</th></tr>
<tr><td>1</td><td>6</td></tr>
<tr><td>2</td><td>9</td></tr>
<tr><td>3</td><td>3</td></tr>
<tr><td>4</td><td>12</td></tr>
</table>
<table>
<tr><th>N-stage</th><th>No.</th></tr>
<tr><td>0</td><td>15</td></tr>
<tr><td>1</td><td>7</td></tr>
<tr><td>2</td><td>8</td></tr>
</table>
All patients were M0.

Withdrawals:
2 patients were withdrawn. 1 (T2 N0 M0) died of GI problems before follow-up. Adequate follow up was unavailable in another (T1 N0 M0).

Demographic details:
Data from 7 females and 21 males with a mean age of 53.5 years (range: 28 years to 82 years).

Incidence of active disease:
Recurrent tumour or metastases were found in 8 of 28 patients.

Diagnostic indices:
<table>
<tr><th></th><th>US</th><th>PET</th></tr>
<tr><td>Sensitivity</td><td>63%</td><td>88%</td></tr>
<tr><td>Specificity</td><td>65%</td><td>85%</td></tr>
<tr><td>Accuracy</td><td>64%</td><td>86%</td></tr>
<tr><td>PPV</td><td>42%</td><td>70%</td></tr>
<tr><td>NPV</td><td>81%</td><td>94%</td></tr>
<tr><td>PLR</td><td>1.8</td><td>5.8</td></tr>
<tr><td>NLR</td><td>0.6</td><td>0.2</td></tr>
<tr><td>DOR</td><td>3.1</td><td>39.7</td></tr>
</table>
</td>
<td>Authors' conclusions:
F-18-FDG PET is better than ultrasound for the detection of clinically relevant lesions in the follow-up of patients with squamous cell carcinoma of the head and neck. In this study, the additional value of morphological information obtained by screening US performed before the PET scan is limited. US may not be a suitable test to improve interpretation of PET examinations.

Comments:
This was a well conducted diagnostic assessment of the value of 2 methods of imaging. The study appears to be a prospective consecutive series. It was conducted using appropriate methods. The reference standard was appropriate to the population being studies and was applied well. The findings appear to be supported by the evidence but caveats relating to the small number of participants and the relatively short follow-up period should be noted.</td>
</tr>
</table>

References

1. Virgo KS, Paniello RC, Johnson FE. Costs of posttreatment surveillance for patients with upper aerodigestive tract cancer. *Archives of Otolaryngology Head and Neck Surgery* 1998;**124**:564-72.
2. Chong VF, Fan YF. Detection of recurrent nasopharyngeal carcinoma: MR imaging versus CT. *Radiology* 1997;**202**:463-70.
3. Falchetto Osti M, Padovan FS, Sbarbati S*, et al.* CT and MRI in radical and reconstructive surgery with pedunculated and revascularized flaps in advanced head and neck cancer. Recurrences (part II). *Radiologia Medica* 1998;**95**:315-21.
4. Lapela M, Eigtved A, Jyrkkio S*, et al.* Experience in qualitative and quantitative FDG PET in follow-up of patients with suspected recurrence from head and neck cancer. *European Journal of Cancer* 2000;**36**:858-67.
5. Bongers V, Hobbelink MG, van Rijk PP*, et al.* Cost-effectiveness of dual-head F-18-fluorodeoxyglucose PET for the detection of recurrent laryngeal cancer. *Cancer Biotherapy and Radiopharmaceuticals* 2002;**17**:303-6.
6. Di Martino E, Hausmann R, Krombach GA*, et al.* Relevance of colour-duplex echography for detection and therapy of recurrences in the follow-up of head and neck cancer. *Laryngo-rhino-otologie* 2002;**81**:866-74.
7. Goerres GW, Haenggeli CA, Allaoua M*, et al.* Direct comparison of F-18-FDG PET and ultrasound in the follow-up of patients with squamous cell cancer of the head and neck. *Nuklearmedizin* 2000;**39**:246-50.

Palliative interventions and care

The Questions

a) In patients with head and neck cancer being managed palliatively, what are the relative efficacies of brachytherapy, external beam radiotherapy, chemoradiotherapy, surgery and chemotherapy, alone or in combination, in terms of patient outcomes?

b) In the management of patients with head and neck cancers (including the pre-treatment, on treatment, post-treatment and rehabilitation phases of care), does prompt and/or regular assessment by a pain control service improve outcomes?

The Nature of the Research Evidence

a) Palliative treatment

A search for systematic reviews was conducted to locate reviews relevant to this question. No such reviews were found. Therefore, a search of primary studies was conducted. This search was limited to RCTs that investigated cross-modality treatments. Comparisons of fractionation schemes within radiotherapy or comparisons of different chemotherapy regimens were excluded.

The review located one RCT which compared radiotherapy alone with radiotherapy and chemotherapy.[1] 66Gy to 70Gy radiotherapy was administered in 2Gy daily fractions. The chemotherapy used in this study consisted of bleomycin, given twice weekly for up to seven weeks and mitomycin C, given during the first week of radiotherapy and again on the last day of radiotherapy. See Table 8a for full details of the study.

The RCT was well reported. Patients were randomly allocated to the treatment arms and the method of randomisation was explained. Outcomes

were clearly set out in the report. However, there were a number of concerns about the methods used. It did not report blinding of any of the groups involved – patients, clinicians, nurses, outcome assessors or those who conducted the analysis. The authors reported that a power calculation had been done and that it indicated a number of participants of 50 in each arm. However, only 49 patients were enrolled in total. The authors did not assess this concern. Overall survival was not assessed. Finally, the follow-up period was only two months.

b) Assessment by a pain control service

One study was located which observed the use of the WHO Pain Ladder as a treatment algorithm.[2 273] This research came from Israel and studied 62 patients with terminal head and neck cancer. In the study all patients were seen by a pain control service; analgesia was prescribed in line with WHO recommendations. Details of this study are given in Table 8b.

Summary of the Research Evidence

a) Palliative treatment

An RCT compared patients treated with normally fractionated radiotherapy with a group of patients treated with the same radiotherapy and the addition of bleomycin and mitomycin C chemotherapy.[1] Those treated with chemotherapy were also given chemo-potentiator treatments. Of 49 patients included, 4 had Stage III disease and the remaining 45 had Stage IV cancers. Two-thirds of the patients had oropharyngeal cancers.

A 39% improvement was seen in the complete response rate of patients treated by chemo-radiotherapy compared with those treated by radiotherapy alone. This difference was statistically significant ($p = 0.015$). Sub-group analysis suggested that this benefit was strongly related to the anatomical location of the cancer. The benefit was very pronounced in patients with oropharyngeal carcinoma (18% compared with 81%; $p = 0.0003$). However, patients with non-oropharynx cancers treated with chemotherapy had marginally poorer

response rate than those treated by radiotherapy alone, but this was not statistically significant (30% compared with 38%; p = 0.359).

Disease-free survival of patients treated by radiotherapy alone was significantly lower than in patients with combination therapy (9% compared with 48%; p = 0.001). Again, marked differences were seen between patients with oropharyngeal cancer and other cancers. Disease-free survival of patients with oropharyngeal cancers was 66%, while all other patients recurred (p = 0.00001).

There were no treatment related deaths. Leucopoenia was more common in those treated with combination therapy. All patients developed mucositis but Grade 4 mucositis was seen only in combined modality patients.

b) Assessment by a pain control service

A study of the services offered by a pain control service to terminally ill head and neck cancer patients undergoing palliative care in Israel included 62 patients.[2 273] Patients were prescribed analgesia in accordance to the WHO pain control ladder. All patients were given regular medication; the "as needed" approach was avoided. The main outcome measure relating to the intensity of pain used in the study was a Visual Analogue Scale (VAS). The VAS score, from a maximum of 10, was a mean 4.7 before analgesic therapy and 1.9 after therapy. This difference was statistically significant.

There were important flaws in the study however; these are most obvious in the process by which outcomes were assessed. The study had aimed to used the McGill Pain Questionnaire but it appears not to have been accepted by the study population; few completed it and of those who did, only half completed all of it. In addition, few patients completed the third recording of the VAS, intended to give longer-term results.

All patients were assessed by the pain control service so it is difficult to ascertain if assessment had an affect on the outcome of patients over and

above the intervention that was decided upon by the service – in this case the level of analgesia to be administered.

Table 8a: Palliative treatment

<table>
<tr><th>Study details and aims</th><th>Participants</th><th>Intervention</th><th>Methods</th><th>Included patients and results</th><th>Comments</th></tr>
<tr>
<td>Smid, 1995.[1]

Country:
Slovenia.

Aims:
To assess the efficacy of simultaneous application of irradiation, mitomycin C and bleomycin in treatment of patients with inoperable head and neck carcinoma.

Grade of evidence:
II</td>
<td>Patients with previously untreated histologically confirmed inoperable head and neck carcinoma.

Patients were eligible only if they had a WHO performance status of 0 to 2, a haemoglobin level of greater than 100g/l, a leukocyte count of greater than 3.5 x 10^9, a platelet count of greater than 100 x 10^9 and normal levels of creatinine and bilirubin, a normal prothrombin time and normal diffusion of CO.

Patients with distant metastases, other previous or current cancers (other than cured skin carcinomas) were excluded. Also excluded were patients with psychosis and dementia.</td>
<td>Group A:
Radiotherapy alone.

Group B:
Radiotherapy combined with simultaneous application of mitomycin C and bleomycin.

Radiotherapy schedule:
Radiotherapy was given five times per week with 2Gy fractions, to a total dose of 66Gy to 70Gy.

Chemotherapy regimen:
Bleomycin – An intramuscular application of bleomycin (5 Units, twice a week, up to a total planned dose of 70 Units). mitomycin C – An intravenous dose of $5mgm^{-2}$ applied one week into the radiotherapy course and a dose of $10mgm^{-2}$ on last day of radiotherapy.

Chemotherapy was potentiated by nicotinamide ($650mgd^{-1}$), chlorpromazine (200mg with bleomycin) and dicoumarol (300mg on the evening and morning before injections of mitomycin C).</td>
<td>Allocation:
Patients were randomly assigned to receive either radiation therapy alone or radiotherapy and chemotherapy. Allocation was by means of permuted blocks and stratified according to tumour site and whether the tumour was locally inoperable, regionally inoperable or both.

Outcomes measured:
Response rates.

Disease-free survival.

Toxicity.

Statistical methods:
The difference in response rates was investigated using the χ^2 and Fischer's exact tests. Patients were grouped into those with oropharyngeal and non-oropharyngeal cancers for a sub-group analysis.

Length of follow-up:</td>
<td>Included patients:
49 patients were enrolled between March, 1991 and October, 1993. Amongst all patients, 4 had Stage III cancers and 45 had Stage IV cancers. The sample consisted of 46 men and 3 women. The median age of patients was 50 years (range: 37 years to 68 years).

Treatment by site:
<table>
<tr><th>Site</th><th>A</th><th>B</th><th>Total</th></tr>
<tr><td>Paranasal sinuses</td><td>2</td><td>2</td><td>4</td></tr>
<tr><td>Oral cavity</td><td>5</td><td>3</td><td>8</td></tr>
<tr><td>Oropharynx</td><td>17</td><td>16</td><td>33</td></tr>
<tr><td>Hypopharynx</td><td>1</td><td>3</td><td>4</td></tr>
<tr><td>Total</td><td>25</td><td>24</td><td>49</td></tr>
</table>
Reason for inoperability:
<table>
<tr><th>Site</th><th>A</th><th>B</th><th>Total</th></tr>
<tr><td>Locally inoperable</td><td>13</td><td>14</td><td>27</td></tr>
<tr><td>Regionally inoperable</td><td>1</td><td>0</td><td>1</td></tr>
<tr><td>Both</td><td>11</td><td>10</td><td>21</td></tr>
<tr><td>Total</td><td>25</td><td>24</td><td>49</td></tr>
</table>
Withdrawals:
No withdrawals were reported.

Response rates:
The complete response rate differed between the treatment groups; 24% in Group A and 63% in Group B. The difference was statistically significant ($p = 0.015$). Sub-group analysis showed that the benefit was very pronounced in patients with oropharyngeal carcinoma (18% compared with 81%; $p = 0.0003$). Among patients with non-oropharynx cancers, those treated with chemotherapy had marginally poorer response rates than those treated by radiotherapy alone; this difference was not statistically significant (30% compared with 38%; $p = 0.359$).

Disease-free survival of patients treated by radiotherapy alone was significantly lower than in patients with combination therapy (9% compared with 48%; $p = 0.001$).</td>
<td>Authors' conclusions:
From results of our prospective randomised study it seems that the group of patients that received multidrug treatment with mitomycin C, bleomycin, nicotinamide, chlorpromazine and dicoumarol as enhancers of radiotherapy fared better than patients treated by radiotherapy alone.

Comments:
This RCT appears to have been well reported. Patients were randomly allocated to treatment arms but the authors did not report if the study was blinded. While blinding of care staff and patients would probably not have been possible, it would have been possible to blind outcome assessors and those conducting statistical testing but neither of these steps appear to have been conducted.

The principle outcome was the rate of complete response. The definition for complete response to therapy was not provided.

The authors reported a power calculation which suggested that a total of 100 patients should be included. The study only included 49 patients. The authors do not explain this.

Outcome assessment was principally conducted at 2 months post therapy. This is a short period and long term follow up is necessary for the preliminary findings to be fully validated.</td>
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<td></td>
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<td></td>
<td>Response was assessed at 2 months post therapy.</td>
<td>The difference between both treatment groups was even greater in patients with oropharyngeal carcinoma: disease-free survival of these patients in Group B was 66%, while in Group A, all recurred (p = 0.00001).

Adverse events:
There were no treatment related deaths.

Leucopoenia was more common in those treated with combination therapy. All patients developed mucositis but Grade 4 mucositis was seen only in combined modality patients (11 of 24). Chemotherapy doses had to be lowered in response to increased toxicity.

<table>
<tr><th rowspan="2">Toxicity</th><th rowspan="2">Group</th><th colspan="5">Grade</th></tr>
<tr><th>0</th><th>1</th><th>2</th><th>3</th><th>4</th></tr>
<tr><td rowspan="2">Mucositis</td><td>A</td><td>0</td><td>2</td><td>8</td><td>15</td><td>0</td></tr>
<tr><td>B</td><td>0</td><td>1</td><td>1</td><td>11</td><td>11</td></tr>
<tr><td rowspan="2">Leucopenia</td><td>A</td><td>24</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>B</td><td>13</td><td>7</td><td>3</td><td>1</td><td>0</td></tr>
<tr><td rowspan="2">Infection</td><td>A</td><td>23</td><td>1</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>B</td><td>15</td><td>4</td><td>3</td><td>2</td><td>0</td></tr>
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Table 8b: Assessment by a pain control service

Study details and aims	Details of service and participants	Methods	Included patients and results	Comments
Talmi, 1997.[2] **Country:** Israel **Aims:** To investigate prospectively the incidence, severity and duration of head and neck carcinoma (HNC) pain. This was a prospective study of the effectiveness of the World Health Organisation (WHO) analgesic ladder in the treatment of a cohort of terminal HNC patients. **Grade of evidence:** VI	**Participants:** Terminal head and neck cancer patients receiving palliative care only. **Service:** Patients were seen as early as possible after admission, usually within 24 to 36 hours. Patient history was obtained and pain localisation, duration, intensity, aetiology and pathophysiological type were defined. All patients underwent physical examination and sites of pain were marked on a body chart by the patients. Severity of pain was determined by asking patients to rate their pain level by using a validated 100mm 10-point standard visual analogue scale (VAS). The endpoints of the VAS were labelled "no pain" and "worst possible pain". Pain intensity was also graded with a validated Hebrew version of the McGill Pain Questionnaire (MPQ). Pain was assessed at first visit and again 72 hours later. An attempt was made to assess pain after an additional 3 days. Treatment was given according to the guidelines of the WHO analgesic ladder. Analgesics were prescribed regularly.	**Methods:** Sites of pain were marked on a body chart by the patients. **Outcomes measured:** Severity of pain was determined using a validated VAS and a validated Hebrew version of the MPQ. Pain was assessed at first visit, 72 hours later and after an additional 3 days. Mean results of the first and second evaluation were compared by the paired Student's t test and verified by Wilcoxon's nonparametric test.	**Included patients:** 62 patients were included. **Results:** 14 patients denied having any pain and did not provide a MPQ, body map or VAS score. Duration of pain as reported by the patients prior to the study varied from 3 weeks to over 1 year. Six patients had pain lasting 3 to 6 weeks, 15 had pain lasting 6 to 12 weeks and 27 had pain of over 12 weeks' duration. Pain as depicted by the body maps involved the locoregional area of the tumour and only 10 patients had pain localised to sites other than the head and neck. Mild discomfort or a burning sensation were experienced by 10 patients with oral candidiasis that was treated with nystatin administered orally. The MPQ was completely filled in by only 7 patients and partially filled in by an additional 7 and its results could not be assessed. The results of the first reading of the VAS score were available for all patients with pain (n = 48); the score ranged from 1.1 to 9.6, with a mean of 4.7 (SD: 2.0). A second VAS score reading, obtained after initiation of treatment, was unavailable in 10 cases because an examiner was unavailable. The VAS score from the second reading ranged from 0.4 to 4.8 with a mean of 1.9 (SD: 1.1). The difference between the first and second score was statistically significant ($p < 0.001$). A third reading was available for 6 patients only; the mean score was 1.6. Pain did not improve after 72 hours of treatment in only 2 cases, both had bone involvement.	**Authors' conclusions:** Our study of 62 terminal HNC patients showed that 78% of them had mostly severe pain caused by recurrent, advanced, locoregional tumour. We concluded that pain induced by combined treatment may be less common than formerly reported. Incorporating the WHO analgesic ladder with adequate administration of narcotic analgesics and supportive measures allowed significant reduction of pain in nearly all cases, with acceptable side effects. **Comments:** All patients in this study were assessed for pain and treated according to the WHO analgesic ladder. It is not possible to attribute the reduction in pain to the pain assessment or state whether patients would have received adequate treatment of their pain without the assessment. This study was reasonably well conducted with appropriate outcome measures, however it does not provide reliable evidence of the effectiveness of the pain assessment.

References

1. Smid L, Lesnicar H, Zakotnik B*, et al.* Radiotherapy, combined with simultaneous chemotherapy with mitomycin C and bleomycin for inoperable head and neck cancer--preliminary report. *International Journal of Radiation Oncology, Biology, Physics* 1995;**32**:769-75.
2. Talmi YP, Waller A, Bercovici M*, et al.* Pain experienced by patients with terminal head and neck carcinoma. *Cancer* 1997;**80**:1117-23.

Appendix I - Patients' Views of Head and Neck Cancer Services and Developing National Guidance

Introduction

Following the publication in 1995 of the report of the Expert Advisory Group on Cancer, "A Policy Framework for Commissioning Cancer Services", a number of national guidance documents have been produced on site-specific cancers for commissioners. This work is managed by the National Cancer Guidance Group (NCGG), chaired by Professor Bob Haward, and now under the auspices of the National Institute for Clinical Excellence (NICE). As part of this work, a national guidance document on the management of Head and Neck Cancers is under development. The NCGG commissioned the National Cancer Alliance (NCA) to undertake a small-scale exercise to enable people who have had a diagnosis of head and neck cancer to input their views, knowledge and experience into the development of this guidance.

Aim and Objectives

The overall aim of the exercise was to input patient perspectives into the development of the national guidance on head and neck cancers.

To achieve this aim, the following objectives were set:

- To provide patient perspectives about head and neck cancer services
- To provide patient feedback on the series of proposals that have been drafted to inform the development of the guidance.

Structure of Report

This report is structured in the following way. Research methods used, how recruitment was conducted and details about the discussion group held are described. The profile of the respondents recruited to the discussion group is also given. The main findings are then presented, structured around the key themes identified in the series of proposals, namely: raising awareness, getting to a diagnosis, hospital-based tests and investigations, treatment and care, and follow up and after treatment. Respondent perspectives on raising awareness are given, their views on their own presenting symptoms considered, and their subsequent experiences at the GPs or dentists are discussed. Respondents' experiences of hospital tests and investigations and receiving a diagnosis of cancer are explored. The findings relating to treatment choices, treatment and care and information and support issues are set out. Consideration is given to issues relating to follow-up and after treatment. Recommendations on each theme, based on respondent findings, are given at the end of each of these sections. Finally conclusions based on the findings and their implications for developing the head and neck guidance are considered.

Methods

As explained above, the broad aim of the project was to ensure patient input into the national guidance, through eliciting an in-depth response from patients who had recently, or were currently, receiving head and neck cancer services.

Qualitative research methods lend themselves to this approach and so, for this reason, holding a discussion group was the chosen method. This allowed a group of respondents to meet together in an informal environment under the direction of an experienced moderator. Using a discussion brief, themes identified in the series of proposals drafted to inform the guidance were discussed rather than specific questions asked. This greater flexibility allows issues considered salient to the members of the group to be explored in-depth. Due to the substantial overlaps in the proposals in how the different cancers of the head and neck should be managed, it was decided to hold a mixed discussion group, rather than having separate, cancer site-specific groups. Full details of the discussion brief and the format of the interviews may be obtained from the Centre for Reviews and Dissemination, York, or from the National Cancer Alliance, Oxford.

In order to augment the findings from the discussion group, those attending the group could additionally give written submissions and patients unable to attend the group were also given the opportunity to contribute in this way.

Recruitment

The majority of the recruitment to the discussion group took place during an intensive recruitment process in August and September 2001. A variety of recruitment methods were used and included sending publicity information to: Head and Neck Clinics, Cancer Information Centres, national and local support groups, cancer charities and National Cancer Alliance (NCA) contacts. In addition, press releases were sent to local radio stations and local newspapers throughout England. Using these methods, people who had had a diagnosis of one of the head and neck cancers were invited to participate in a discussion group and asked to contact the NCA if interested. The Project Consultant then contacted each of the respondents to tell them about the Project and establish their eligibility to participate in the discussion group. A standard recruitment form was used to confirm eligibility. All respondents were advised that participation in the discussion groups was voluntary and their contributions would be anonymised. Details of the respondent profiles are given in below (see *Profile of Respondents*).

Prior to attending the discussion group all respondents received a letter of invitation and the summary of the proposals described in above (see *Methods*). Respondents were also given a list of all the proposals and offered copies of all the proposals or those that were specific to their cancer. Where reference is made in the report to respondents who made a written submission only, this is clearly indicated, otherwise, all references to respondents refer to those that participated in the discussion group.

Discussion group

The discussion group took place at the Novartis Foundation in London and was facilitated by Becky Miles, Director of the NCA, with Catherine Smith, Project Consultant. Nicky Vinton, NCA Research Associate, also attended as an observer. The discussion was tape-recorded for transcribing with the permission of the respondents.

Profile of Respondents

Using the recruitment methods described above, ten respondents were recruited to the discussion group, nine patient respondents and one carer respondent who wished to attend with her husband. Numbers recruited were restricted in order to ensure an in-depth discussion.

Summary Profile of Patient Respondents in the Discussion Group							
How they heard about the Project		Year of diagnosis		Diagnosis		Age Range	
Publicity via support groups	2	1995	1	Laryngeal Cancer	4	40 to 49	1
Head and neck clinics	5	1997	2	Tonsil Cancer	1	50 to 59	3
		1998	1				
		1999	3	Mouth Cancer	3	60 to 69	3
NCA Contacts	2	2000	2	Thyroid Cancer	1	70 to 79	2

Table 1: Patient Respondents' profile – Discussion Group

Six of the patient respondents in the discussion group were male and three female. One female respondent, carer of one of the laryngeal patient respondents, also attended. Respondents were from the following areas: Avon, Denbighshire, Devon, Buckinghamshire, West Midlands, and Somerset. All nine of the patient respondents in the group also gave written submissions. Six respondents, one of whom was a carer, who were unable to attend the discussion group gave a written submission only.

Summary Profile of Respondents: Written Submissions Only							
How they heard about the Project		Year of diagnosis		Diagnosis		Age Range	
Publicity via support groups	4	1991	1	Laryngeal Cancer	2	40 to 49	1
		1992	1				
Head and Neck Clinics	1	1994	1	Adenoidal Cancer	1	50 to 59	1
NCA Contact	1	2000	2	Mouth Cancer	2	60 to 69	4
		2001	1	Neck Cancer	1		

Table 2: Respondents' profile – Written Submissions only

Those giving written submissions only were from the following areas: Devon, Cambridgeshire, West Midlands and Yorkshire.

It is worth noting that compared to the two previous studies the NCA has undertaken for the NCGG, considerably more respondents in this study were recruited via publicity material given to health professionals (consultants and specialist nurses).

Getting To A Cancer Diagnosis

With the aim of earlier diagnosis, the proposals drafted to inform the national guidance place emphasis on raising awareness about head and neck cancers with the public and GPs and dentists. As well, explicit reference is made about the importance of primary care professionals undertaking routine examinations or assessments and making rapid referrals to hospital-based diagnostic services. This section considers respondents' views about raising awareness, their experience of presenting symptoms, consulting their GP's, and being referred onto hospital.

Raising Awareness

The group as a whole seemed to be generally supportive of the idea of public health education strategies. A few suggested having "awareness" weeks to help raise the profile of head and neck cancers. Several suggested using leaflets and posters in GP and dental surgeries to raise awareness. One respondent, whose mouth cancer was initially picked up at a routine check-up at her dentist's, said that she had noticed there were now posters and leaflets in his surgery. Another respondent commented that he thought there was enough health education but that it seems to be ignored, he cited as evidence of this the number of young people who smoke and drink heavily. A suggestion from another respondent was that awareness raising should start at school using a teacher trained in health education or a visiting nurse. This suggestion was echoed by a respondent who gave a written submission only, recommending that children at primary school should learn anatomy, physiology, and body awareness. Another respondent, who gave a written submission only, proposed advising the public to have regular dental check-ups.

Presenting Symptoms

Most respondents described having clear initial symptoms and a few had had concurrent symptoms. Symptoms mentioned were: loss of voice, on going sore throat, irritation in the throat, sensing an obstruction when swallowing, discovering a lump. One respondent was not aware of any initial presenting symptoms. How respondents interpreted and acted upon their initial presenting symptoms varied. It appeared that a few first thought that their symptoms were possibly innocuous while others knew early on that, "*something was wrong"*. It may be that those who first thought their symptoms might have been innocuous did so because they could be linked to having a commonplace minor health ailment, for example, a sore throat, and

this perhaps gave initial false reassurance. Whereas those that were more concerned at the outset, had symptoms, a lump or loss of voice, that were less easily explained away:

"I knew there was something wrong with my voice, I was very worried ... sometimes I could talk alright, sometimes I would be a bit hoarse".

(Respondent, laryngeal cancer patient)

Going to the GPs or Dentists

The prompt for deciding to go to the GPs or dentists varied. Two respondents had routine check-up visits at the dentists. The remaining patient respondents explained that they went to the GPs because of concerns about a range of presenting symptoms listed above (see *Presenting symptoms*). The time that had elapsed before consulting their GP varied greatly. Four respondents went to their GP's quite promptly, two waited several months, and one delayed for five years. The respondent who delayed for five years described himself as not in control of his life for that period due to heavy drinking. After five years, knowing that something was seriously wrong, he finally decided to go to his GP's.

GP/ Dentist Variation in Practice

The two patient respondents who attended their dentists for a routine check-up were referred straightaway to hospital:

"... he was very astute at picking something up".

(Respondent, mouth cancer patient)

Of those respondents who consulted their GP, four were referred straightaway and three were not. Of those that had a speedy referral, one said he was scolded by his GP for delaying consulting her and another described his practice as:

"...marvellous,... tends to be ultra cautious".

(Respondent, mouth cancer patient)

All of the respondents who had a speedy referral were appreciative of the intervention of their primary care professionals even if some had a sense of foreboding of what was to happen next. For those three respondents who did not have a speedy referral it seemed that the onus was on these respondents to get access to the tests and

investigations that they needed. Two respondents described consulting another GP as they had been unable to get a satisfactory resolution from the first GP they had consulted. One of these respondents, who emphasised throughout the very positive view he had of the treatment and care he had received said:

"The only negative thing I've got about my treatment … the first doctor I saw said it was a virus and gave me treatment for five days and then when I said I wasn't any better, he said, 'Well it's something you have to live with'…I love to sing and I found that I couldn't keep the notes…I didn't have any pain but it was just something. So I went to another GP and he took a swab and found nothing, and eventually, they referred me to a surgeon, but not as urgent".

(Respondent, tonsil cancer patient)

Another respondent related consulting another GP at her practice with a sore throat she had had for ten days as her own GP was away. She said that she was advised that she had a sore throat and to return in two weeks if it had not gone. In the interim, a family member noticed that she had a lump on her neck and this prompted her earlier return to the practice. Her own GP still being away, she then saw a different GP, at her insistence, to the one she had first consulted. She described this GP as 'panicking', she thought in response to seeing the lump on her neck, and referring her straightaway to the hospital. The third respondent whose referral was delayed said his GP treated him for laryngitis for three months:

"Some weeks I had loss of voice, it lasted two or three days and then it would come back…Swallowing was like I had a piece of phlegm stuck and I couldn't get rid of it. I went to my GP, three months he treated me for laryngitis

(Respondent, laryngeal cancer patient)

After this time he insisted on being referred to an ENT specialist and although the respondent related that his GP was quite confident that there was nothing wrong, the GP agreed and instigated his referral. The respondent also stated that at no point had his GP undertaken any examination. A carer respondent, in a written submission only, related that his wife had consulted her dentist and was treated by gingivectomy without success. His experience had led him to conclude that dentists needed improved awareness of the appearance of cancerous lesions.

Referral

For clarity, it is re-iterated that this is a small-scale qualitative study that is not representative of head and neck cancer patients. Nonetheless, for these respondents, the elapsed time before being referred by the GP for specialist investigation ranged from a matter of days to several months. This would indicate that, as suggested in the proposals, to use elapsed time before a referral is made by the GP as a performance measure would be of real value.

Once the GP or dentist had made a referral, the time it took to be seen at the hospital varied a good deal. Several respondents were seen within a matter of days. One respondent waited several weeks and another four months and then, on the morning of the appointment, he was notified that it was cancelled and would be re-scheduled five weeks later. His GP, finding out about the cancellation by chance, intervened and arranged a hospital appointment for him a few days later. Another respondent, who had been given a non-urgent referral was offered an appointment eight months later, this prompted him to seek a private consultation.

Information and Support for Patients

There was limited discussion in the group of information and support needs of patients at the GPs and dentists. It appeared that the consensus was information and support needed to be offered and tailored to the needs of the individual. There was also agreement that too much information at this stage, prior to diagnosis, could be precipitative and unhelpful. It seemed that the priority was for the GP or dentist, in response to patient need, to be supportive of the patient as, at this stage, they play a critical role as patient advocate and gateway to diagnostic services.

Summary of Recommendations

All respondents were in agreement that early diagnosis of cancer was of paramount importance. They believed that it was essential, therefore, for GPs and dentists to have an improved awareness of presenting symptoms and to make speedy referrals to hospital-based diagnostic services.

Raising Awareness - General Population

- Health education strategies, including "awareness weeks", should be used to help raise the profile of head and neck cancers. Leaflets and posters should be displayed and be readily available in GP and dental

surgeries. Health education in schools, using trained personnel, should be considered.

At the GPs - Patients

- Patients should be encouraged to go back to their GP if symptoms persist and supported, if needed, in having an assertive dialogue with their GPs.

- Patients, if dissatisfied with their GP, should be able to seek a second opinion from another GP.

Clinical Practice and Organisational Issues

- GP and dentist awareness of the symptoms that could be related to a diagnosis of head and neck cancers needs to be raised.

- GP management of the patient consultation needs to be improved. In particular GPs should be trained and encouraged to take a more systematic and holistic approach to investigations, using protocols or checklists, and drawing them to a 'conclusion'. If GP investigations are inconclusive, GPs should be able to consult a specialist for advice and patients should be encouraged by their GP to return if symptoms persist and further investigation or a referral for specialist investigation should then take place.

- GPs need to listen more to their patients and the medical reasons for any presenting symptoms should be discounted before social or psychological reasons are presumed.

- Once a GP has made a referral this needs to be monitored to ensure that their patient has access to a specialist diagnostic service within a reasonable time scale.

- GPs need easy and speedy access to and information about specialist diagnostic services.

Hospital Based Assessment and Diagnosis

This section outlines respondent responses relating to:

- hospital-based tests

- investigations and assessment

- the point when they were given their diagnosis of cancer

- the general response to the proposals relating to this phase.

The proposals advocate the need for a rapid, systematic and streamlined approach to assessment and diagnosis. Another aspect of the service emphasised in the proposals is the importance of multi-disciplinary teams at the diagnostic phase. The proposals also recommend that a consultant should tell the patient their diagnosis with a trained nurse specialist present and that information and support should be available for both patients and their families.

Hospital Based Tests, Investigations and Assessment

All respondents referred to the need for speedy referral and a rapid diagnostic service so that the very difficult state of limbo experienced at this stage is as brief and as well managed as possible. Respondents wanted this approach in order to alleviate stress and ensure a diagnosis is given promptly and treatment and care started.

At this stage, respondents described a range of experiences of hospital services. One respondent saw a registrar, all the others a consultant. A few described their consultant as not obviously being part of a team, several were aware that they were being managed by a team. Some respondents commented on staff seeming to be over-stretched and this constraining the service that could be provided. The degree to which GPs or dentists were kept informed seemed to vary widely.

Reflecting respondent priorities, this part of the discussion was dominated by their recall of how this stage was managed, especially being given a diagnosis of cancer, rather than in depth discussion of the tests and investigations that they underwent. However, one respondent stressed the need for mouth biopsies to be done under a light general anaesthetic as she had found it terrifying to be awake during this procedure.

Communication, Information and Support

The degree of communication and information that respondents received at this stage varied considerably. Nearly all respondents were told what tests would be undertaken and two respondents received written information at this point. Some had the reasons for the tests explained to them but were not always given as much information as they wanted, even if they actively sought it. One respondent said her consultant had been supportive but that he was reluctant to answer her many questions, saying that, "…*he was paid to do the worrying*". For this respondent, this

response heightened her fears and anxieties. Where information was given this was valued and respondents generally expressed a need to be kept informed. Several related being treated in a very sympathetic and supportive way and this seemed to make this stage easier. A few who had little support or information described how difficult this time was. This was especially so for those who waited for their test results and they described feelings of stress, worry, and isolation at this time. All felt that written information and ready access to support, for example, specialist nurses and counsellors, was needed at this stage.

From both the discussion group and written submissions, it is apparent that at this stage of assessment, information and support services need to be an integral part of the treatment and care provided. The management of this is clearly a sophisticated process as it needs to be tailored to the needs of the individual, delivered by personnel with specialist expertise, offered in an incremental way, and in no way pre-empting patients receiving a definitive diagnosis of cancer.

Receiving the Diagnosis of Cancer

As was reported in the NCA's urological and haematological patient experience studies, the moment when patients are told they have cancer is often recalled vividly. All members of the discussion group and all those who sent written submissions highlighted that how their diagnoses of cancer was given, and whether information and support was available and readily offered, was for all of the utmost importance. There seem to be two key and inter-related reasons why the point of diagnosis was such an important juncture for respondents. Firstly, it was again very evident and important to continue to reiterate, from the discussion group and written submissions, that receiving a diagnosis of cancer is a life-changing event. Therefore respondents explained that they needed to be told in privacy and in a clear, sensitive, and supported way, and to be allowed time to assimilate the diagnosis. A few described these elements as being present when they were told their diagnosis and they were positive about how it had been managed. It seemed that where these elements were present it had helped these respondents and their families to better manage their diagnosis emotionally. Secondly, it appeared that how a diagnosis is given may impact on how, at least initially, respondents viewed their treatment and care. The words frequently used by respondents to describe what they needed following the

diagnosis were 'reassurance' and 'confidence'. It appeared that where the giving of a diagnosis was well managed, it was then easier for respondents to feel reassured and to have confidence in the treatment and care they were about to receive.

Most respondents were told by a consultant their diagnosis of cancer, one was told by a registrar, and one by a GP at her request. Several recalled a nurse specialist being present when they were told. Although respondents said they appreciated being told in a clear and straightforward way, one respondent, who was very positive about the support and treatment he received subsequently, related how difficult it was when he was told in a very stark way:

"My surgeon said well you have cancer, but you have a choice. We can do nothing and it will kill you or you can have surgery".

(Respondent, mouth cancer patient)

Another recalled her diagnosis consultation being handled badly:

"My husband and I were told that I had a tumour and it would mean surgery. Cancer, the word was not mentioned, and no-one offered counseling or any assistance just we would hear when surgery could be performed…I was scared to death, I was fighting not to break down and did not, as I did not want to embarrass any of us, but I broke down as soon as I got outside".

(Respondent, mouth cancer patient)

Two respondents, both in written submissions, said that how they were given their diagnosis, in both cases by registrars, was not well managed. One wrote that she was given her diagnosis alone by a registrar, although he was aware that her husband had attended the hospital with her. She described feeling emotionally traumatised and isolated at the time the diagnosis was given and that this led to her feeling overwhelmingly out of control. She wrote that her predicament was compounded by a lack of information and for the moment she has decided not to embark on treatment. Another respondent wrote she was told her diagnosis by a registrar on a ward. She explained that she was asking about some of the drugs she had been prescribed, as she was breastfeeding at the time and she was anxious about whether she should continue to breast-feed. The registrar then told her, in anger, that she had cancer.

From the discussion group and the written submissions it was again apparent that those involved in imparting a diagnosis of cancer usually need to be consultants,

specialist nurses need to be present and those involved, wherever possible, should have a stake in the patient's on going treatment and care. Respondents needed those imparting the diagnosis, to be able to give then, or at a later point according to individual needs, specialist information about the diagnosis and how treatment and care was to be managed.

A few respondents said how important it was for their spouses to be supported at the point of diagnosis and this was highlighted by two respondents' contrasting experiences:

"The support and the back up was tremendous, there was even a head and neck specialist nurse. I am glad she was there because my wife wasn't with me, she came afterwards and so the head and neck nurse had to look after her and coming away from hospital we knew that if we had any questions whatsoever to phone this number".

(Respondent, mouth cancer patient)

"I felt so sorry for her. She was walking outside crying her eyes out. I did warn her. I think that is one of the things that should be there, a nurse or somebody who actually specialises in cancer and it should be a room set aside where you can go and have a consultation, where you can get it out of your system".

(Respondent, larynx cancer patient)

Post- Diagnosis Information and Support

For all, it was clear that this was a crucial time to know that information and support was there:

"You are frightened aren't you. And you do feel alone".

(Respondent, larynx cancer patient)

"*…the word* 'cancer' *shouldn't be the only thing a patient is given at this stage".*

(Respondent, larynx cancer patient)

Respondents' had mixed experiences of the level of information and support they were given following their diagnosis. Respondents said they needed those giving the diagnosis to provide: easy access to specialist support (including counselling), written information about the cancer and its treatments (tailored to individual needs), and advice on who to contact for further verbal information and with queries/ questions/ concerns after the consultation. For several this provision was made routinely, for a

few, even if the diagnosis consultation had been well-handled, this information and support was absent and much needed.

At one end of the spectrum, a respondent said:

"From the minute I was diagnosed I have nothing but positive comments to make. All staff who dealt with me were clearly experts in their field and time was never a problem."

(Respondent, tonsil cancer patient)

Whereas another respondent, who had a more mixed experience said:

"It's the lack of information. I mean I didn't know they had a support group,… why didn't anyone tell me? And I found out quite by accident…, I phoned and this man that answered said we've had this support group for seven years".

(Respondent, thyroid cancer patient)

This respondent received no written information and tried to get more information from her consultant, she then resorted to seeking help from a library:

"All my consultant kept saying was he was going to do a good job on me, and stop worrying. But it's easy for them to say when it's your body, and the word cancer is very frightening".

(Respondent, thyroid cancer patient)

Another respondent explained:

"I would like to think right back to when you are told 'cancer' and then you are left alone; I would like that stopped. I would like for that person who is told cancer, to know what I know now, to put it in a package, …and it should be given to that person…. You know you're going on a journey. You want a map. You want a few clues, whether to turn left or right".

(Respondent, larynx cancer patient)

Two respondents, from different parts of the country, mentioned how useful they had found a booklet, that they had come across at a later point, called, "Managing the Stress of Cancer" produced by the Bristol Haematology and Oncology Centre.

Summary of Recommendations

Hospital based Assessment

- Once the need for specialist hospital based investigation is decided, the patient and GP need to be kept fully informed of the process.

- The overall time scale for completing tests and investigations should be as rapid as possible and closely monitored by the hospital.

- The purpose of tests and investigations and what they will entail should be explained to the patient and written information made available.

Breaking the news of a diagnosis of cancer

- It should be suggested that patients bring a relative or friend to the 'getting your results' consultation (irrespective of the potential good or bad news) and the patient, if unaccompanied, should not be left alone once the diagnosis is given unless they ask to be.

- The diagnosis should always be given in a private, quiet setting.

- The diagnosis should always be given face-to face, in person (rather than by phone) unless the patient states expressly otherwise.

- Health professionals need to have very good communication skills and experience to impart a diagnosis of cancer.

- Senior specialist medical staff, who preferably will have an on going role in the patient's treatment and care, should give the cancer diagnosis.

- During the 'breaking bad news interview', the number of health professionals present should be restricted to as few as absolutely needed.

- The diagnosis and its implications need to be fully explained, unless patients do not wish this, and time needs to be given to patients to understand and assimilate the diagnosis.

- An appointment for the patient to return again to discuss the diagnosis together with any possible treatment plans, should be made before the patient leaves.

- A trained and experienced clinical nurse specialist should be present at the diagnosis consultation and able to provide on going information and emotional support tailored to the needs of the patient and their partners.

- Written information, ideally talked through by health professionals – at the time or later according to the needs of the patient, should be freely available and offered.

- Information about professional support available, for example, social work support, should be provided routinely.
- Information about help lines, information and support centres, support groups and patient to patient support should be readily available.
- A key contact name and number should always be given at the point of diagnosis so the patient knows who to contact with queries or for further information.

Treatment

The proposals drafted to inform the development of the national guidance recommend planned and coordinated treatment provided by a specialist multi-disciplinary team, with specialist equipment and facilities. The core team who will have weekly team meetings and keep patient notes, and treatment plans – which are also sent to the GP and, if appropriate, the patient. All patients should undergo pre-operative assessments. Side effects of treatment should be fully explained to patients and written guidance and support should be provided.

Most respondents, once they had received a definitive diagnosis, started treatment fairly promptly except for one respondent whose radiotherapy did not commence until several weeks later. One respondent, who gave a written submission, decided not to embark on treatment, the reasons for this are referred to above (see *Communication, Information and Support*).

Deciding on Treatment Options

It seemed that most respondents were steered into a particular course of treatment by their consultant. One respondent said she was told about a clinical trial. How much respondents were told about their proposed course of treatment and its ramifications appeared to vary a good deal. A few described their consultants as simply telling them what the treatment would be:

"They said to me this is going to happen".

(Respondent, mouth cancer patient)

"I was informed by the surgeon that he would take a slice off my tongue, and remove the floor of my mouth, and the skin for the graft, would be taken from my leg".

(Respondent, mouth cancer patient)

"I was told I couldn't have radiotherapy because it was too big, it wouldn't do me any good and I could be wasting their time. The only option that was left was a laryngectomy which I jumped at because I knew it was going to save my life".

(Respondent, larynx cancer patient)

One respondent described her consultant as being reluctant to elaborate on the treatment she required and, when she was told that she would have to have a period in isolation she explained that she was initially fearful of what this would entail. She therefore asked to see the room where she would have to stay in isolation, her consultant was surprised at this request but agreed that she could see it:

"I didn't go in for about six weeks, but at least in that six weeks I didn't have a vision of this horrible room, with big bars on the window".

(Respondent, thyroid cancer patient)

Another respondent recalled her surgeon telling her quite explicitly what her treatment would entail and all the possible side effects. This respondent spoke very highly of the treatment and care that she received but this description of her treatment by the surgeon was so daunting that she initially delayed undergoing surgery. It was prompting by a family member that encouraged her to rethink:

"Well the surgeon ... was a marvellous man, but he made it sound so terrible, that I really didn't have the will to live after that. It was his style to tell you everything that could happen, but as it was, half the things he mentioned didn't happen".

(Respondent, mouth cancer patient)

One respondent described in very positive terms how he and his wife were told about his treatment and that the consultant took some time to explain the treatment and what would happen subsequently. It seemed that this approach helped the respondent and his family to prepare for treatment.

Multi-disciplinary team working

Most respondents were aware of there being a team, although many had worked this out for themselves rather than being told about their team or receiving written information. Most of those who thought they had a team felt their team worked in a reasonably planned and coordinated way. Having a team that took a consistent approach and had a common purpose was clearly important:

"...from diagnosis to aftercare, nurses to consultant, everybody worked as a team and the consultant was always available if I had any queries".

(Respondent, larynx cancer patient)

A few respondents highlighted not having access to a specialist nurse and felt this was a significant gap. Others were able to relate how important access to a specialist nurse had been to them:

"Mine actually came to my house, before the surgery...and spent two hours drawing diagrams, showing what was going to happen, what was going to happen afterwards".

(Respondent, tonsil cancer patient)

In the discussion group, one respondent described having access to a social worker and had found this invaluable in terms of having a caring professional to talk to and also having the expertise to give benefits advice.

The other most frequently mentioned members of the team were speech therapists and dieticians. However, access to these professionals appeared to vary widely and some had sought out this help for themselves. This is discussed further below (see *Undergoing Periods of Treatment*).

Patient Information

All respondents wanted information and wanted it to be readily available, although it was also suggested that this might not be the case for all patients. All respondents received information verbally about their treatment and felt this information needed to be provided by 'specialists', professionals who were able give a truly informed response and had good communication skills. A constraint identified by several respondents was that their health professionals did not really have the time to give full explanations or respond to queries. A few visited cancer information centres and had found this helpful. Some respondents said they also received written information but

several said this did not meet their needs. A couple had received individually tailored patient information – one in the form of a patient held record, and another, a copy of their treatment plan. All respondents were very positive about the idea of receiving a copy of their treatment plan.

It appeared that all respondents needed to know, at least in outline, what their overall treatment plan was and what the estimated time scales might be, both for treatment periods and recovery. It seemed that for many there was a need to explain the overall treatment plan at the outset and to give detailed information incrementally or as required by the patient. There appeared to be several reasons why having this information was important. First and foremost, at a psychological and practical level, respondents and their families needed to know the scale of the challenge they faced. One respondent, having undergone one operation was unaware that further surgery was likely to be required although it became clear that her surgeon knew this from the outset and she found this approach unhelpful. Another who needed radiotherapy was given no indication of what this would entail:

"... no counselling and warning me of what was to come, with the making of the mask, fitting etc"

(Respondent, mouth cancer patient)

This series of NCA studies has indicated that some health professionals, possibly in order to try and protect the patient, may have a tendency to understate how long treatment and recovery will take or the possible severity of side-effects and how long these will last. The studies have also suggested that it is perhaps inevitable for patients to want to 'benchmark' their side effects and recovery. Therefore, it seems that if they are told that side effects will wear off fairly quickly or that the period of recovery is likely to be relatively brief and this does not happen, patients then worry that the treatment has "gone wrong" or "failed". This also has an impact on families and carers as they are likely to have underestimated the length of time for which active support is going to be needed. One respondent illustrated this when she said she was advised she would lose her sense of taste for two to three days after radiotherapy. However, her loss of taste lasted for over six weeks and this led her to worry that something was wrong and she anxiously followed it up with her hospital team.

Support

In the discussion group, respondents used the term, 'support' to describe both the emotional support and practical inputs a patient might need at different stages. Descriptions of support included: receiving emotional and psychological support in the form of advice and counseling from professionals, emotional and practical help from other patients, and practical inputs from professionals – specialist nurses, social workers, complementary therapists, so that patients could manage the treatment process as well as possible.

In terms of emotional support, all respondents agreed it was important for all patients to be aware of what support services were available and how they could be accessed. A couple of respondents said that their own families had met their emotional support needs but they knew how to get support elsewhere if needed. It was again agreed that, at least in part, the support available also needed to be specialist – that is, offered by professionals who understood head and neck cancers and the psychological and physical impact of these diseases and their treatments. Practical support, such as advice about benefits or help with travelling to and from hospitals for treatments, was also felt to be needed.

In addition to specialist professional support, all agreed that there was potential value in receiving support from other patients, either on a one-to-one basis, or as part of a support group. A few respondents had been able to join patient groups where others had had the same diagnosis and treatment and they felt this had been very important. The complexities of patient to patient support were readily recognised but it seemed that most felt making 'befriending' or 'buddy' schemes available was valuable and important. There was general agreement that any such scheme needed careful management to ensure all those recruited worked within clear boundaries. A couple of respondents commented that laryngectomee clubs at local hospitals were starting to close as specialist nurses moved to work in large head and neck teams at regional centres. There was general agreement that specialist support needed to be maintained at a local as well as at a regional level.

A few respondents also gave particular emphasis to the importance of families getting the support they need during periods of treatment. The carer respondent agreed that she had found it important to be able to have other carers to talk to at the hospital while her husband was undergoing treatment.

Undergoing Periods of Treatment

The main themes that emerged during the discussion around undergoing treatment were: the need for specialist medical, nursing and related inputs and the importance of treatments and their side effects being managed in a patient-centred, holistic way. Wherever possible, respondents were keen to praise their professionals and express their appreciation for the treatment and care that they had received. There was also a high level of awareness of the burdensome workload many professionals face and several commented on the impact of staff shortages, especially in nursing. Where there were criticisms, the majority of these related to the absence of specialist care or where professionals did not seem to take a responsive, holistic approach. In describing the need for a holistic approach, there was no expectation of professionals to have professional knowledge on all issues but that they should be able to signpost or provide access to other professional expertise or support as needed. It was apparent that any criticisms were given because they had been of immediate, short-term or long-term consequence.

"The surgeons only really seem interested in their particular area of expertise. They seem to show little interest in after effects such as difficulty in swallowing and eating".

(Respondent, tonsil cancer patient)

Specialist Input

The need for 'specialist' medical and nursing input was an on going and much emphasised theme throughout the discussion. Once in receipt of specialist care, this made respondents very much aware of the knowledge, skills and experience their professionals needed to give effective treatment and care for their cancer. Hence, respondents often spoke very highly of their specialist professionals:

"And they were experts, all the nurses were absolute experts on what they had to do, nothing was too much trouble".

(Respondent, tonsil cancer patient)

It was also clear that respondents were very much aware if specialist input was not available:

"My first operation, I was in a ward that specialised in head and neck surgery. All the nurses and doctors involved were specialists in that area and it gave you a lot of confidence knowing that they were so specialised. By the time my second operation came along …I was in a general surgical ward and the difference was quite remarkable, it was nowhere near as good, the nurses were nowhere near as expert in my particular disease".

(Respondent, larynx cancer patient)

Another related being on a newly opened specialist ENT ward:

"None of the staff had been through a laryngectomee before…One ENT sister, who'd worked in London, knew what to do".

(Respondent, larynx cancer patient)

One respondent, in a written submission, said she experienced particular difficulties due to the lack of specialist nursing care post-operatively and, she wrote that as a consequence the pain relief she needed was not administered:

" I came round in terrible pain, rang my bell again and again, …a nurse came, she was an agency nurse, she did not know what I could have so she went away and never came back…

(Respondent, mouth cancer patient, written submission only)

The few respondents who had a dedicated nurse specialist thought that it was not just desirable, but essential that every patient, as suggested in the guidance proposals, should have a key worker.

Dietetics

Prior and during treatment several respondents mentioned receiving varying levels of dietetic advice and support. Several had found that their consultants were simply not interested in this area although it was causing them significant difficulties. All felt that this was a very important area of care and for most it was not systematically or well provided:

"I think something ought to be done about food, because I think a lot of trouble is caused by diet".

(Respondent, mouth cancer patient)

Several respondents mentioned their eating difficulties being compounded by the poor quality of the food available in the hospital and/ or it being unsuitable for their needs:

"The irony was that the catering department couldn't cater for the food, they didn't seem to understand what liquidised food was, whatever came up…, it was always solid, and we kept sending it back. In the end they were sending up these same drinks, day after day".

(Respondent, tonsil cancer patient)

One respondent had found that he experienced intense pain on eating certain foods but was unable to get professional advice, his surgeon said he could do nothing about it. The respondent proceeded to keep a record of his diet himself in order to establish what foods triggered this adverse reaction.

Speech Therapy

All respondents agreed that speech therapy had a key role to play in their rehabilitation after treatment. Respondents explained that this was for speech and determining whether oesophageal speech would be possible, as well as for learning swallowing techniques. Most respondents had access to speech therapy in hospital, some described having a very good service but others had found it less satisfactory.

One respondent sought out speech therapy support for himself once he had returned home.

The need for this specialist input seemed especially important for head and neck cancer patients. This was because, for some, having undergone radical surgery, the difficulties they faced could be compounded by a sense of isolation due to being unable to communicate freely:

"I seemed all alone as I couldn't talk, so no-one spoke to me".

(Respondent, larynx cancer patient)

Patient Centred Treatment and Care

Several respondents described the emotional and physical energy it took to undergo treatment, especially if they had to summon up the stamina to embark on further treatment once one course was finished. It was felt by some that their consultants, even where they held them in the highest regard, needed to be more aware of the overall impact and consequences of treatments. It was also felt important for health professionals to be mindful of the physical and psychological consequences of the cancer and/ or its treatment to ensure that patients received medical help, not necessarily oncological, and the support that they needed. Where this was present it was appreciated greatly:

"all the staff I had looking after me were very aware of what I, as a patient, was going through, and made every effort to assure me of the success of my op".

(Respondent larynx cancer patient)

"... the whole team went out of their way with patient's care and sensitivity, especially for cancer care. This special treatment or caring attitude included the team's attitude to family and friends, it is difficult to explain, but very special and certainly did not go unnoticed".

(Respondent mouth cancer patient)

It was also very clear, especially where several respondents had just undergone radical surgery and were at their most vulnerable, just how important the human touch was:

"You are drifting in and out of consciousness because the anaesthetic is wearing off and you see all these machines and then a smiling face which is reassuring, you know somebody is taking care of you".

(Respondent larynx cancer patient)

"The surgeon came night and morning to see me to make sure all the nurses knew exactly what they had got to do if something went wrong…He never said very much, but he was just there".

(Respondent mouth cancer patient)

In contrast, a few respondents had instances where they had been treated less sensitively in the period prior to treatment or in the post-operative period and these events had clearly stayed in their minds. One respondent described how difficult it was when she was having her mask fitted prior to radiotherapy:

"the screws and mask would not align up in my case, the eyes of the mask were not cut out at that time, and for two hours I was frightened to death with not being able to see… The nurses, at one time three and four trying to fit my mask, were naturally getting very frustrated and cross, …when they certainly should have been considering the patient"

(Respondent mouth cancer patient)

Another respondent, who felt that overall his treatment and care had been good, still recalled vividly the first time a suction tube was used to clear his lungs:

"I've been frightened in my life several times. But that absolutely had me coming off the bed – screaming, trying to scream. For me, that's the worst thing".

(Respondent larynx cancer patient)

This respondent then explained that a difficult procedure had been made worse because he felt it had been administered badly and he had not been told what was to happen:

"…not knowing what they're going to do next is one of the most frightening parts".

(Respondent larynx cancer patient)

Many respondents spoke of the routine communication difficulties they experienced with staff post-operatively. A couple of respondents commented on nursing staff trying to guess what they wanted, before they had finished their sentence, and invariably getting it wrong. Another said he had been reluctant to write his requests as he was embarrassed by his writing skills and as a result had been unable to communicate his needs adequately.

Hospital Environment

Several respondents commented on the hospital environment where they received treatment. Some had attended out patient clinics where they had had to wait, often for considerable periods of time and sometimes having travelled long distances, in areas that were bleak and depressing. A few suggested that there should always be access to beverages, even if just via a vending machine, and that using volunteers could create a friendlier environment. A few respondents had attended the same hospital for radiotherapy treatment and a couple described this experience as quite isolating as facilities were dispersed across different floors and this also meant waiting in different areas.

Several respondents, as in-patients, had had private rooms and appreciated this, one commented that having had radical surgery, a general ward would not have been appropriate.

A respondent in a written submission emphasised the need for neutropenic sepsis beds having access to a TV, radio, and telephone to ease the isolation.

Side effects

Many of the respondents said they had been advised about most of the short-term side effects of their treatments and appreciated that side effects could vary greatly from patient-to-patient.

One respondent, in a written submission, said she found out by chance that she would have ulcers as a side effect of the treatment. One respondent mentioned suffering a great deal from receiving too much radiotherapy treatment but the GP and the radiotherapy department had been unable to help. Eventually, after 18 months of trying to get help, she resorted to contacting a network of mouth cancer patients for

advice. Another related being warned that as a result of radiotherapy he would lose his sense of taste for a time, he said that this still did not prepare him for just how strange this was:

"I'll tell you what, they never prepare you for it. It is the weirdest thing in the world and its horrible. I couldn't have anything, no food, it's horrible".

(Respondent, tonsil cancer patient)

Other respondents then echoed this statement, agreeing that losing sense of taste is very strange.

All respondents displayed a stoical and often pragmatic approach to their treatments and side effects. Despite this being a common overall attitude to treatment, several had still found it difficult to cope with some of the side effects they had experienced. It was clearly very important that professionals are responsive and sensitive and make available any additional professional input that was required.

Summary of Recommendations

Deciding Treatment

- Regardless of where you live, the most effective and up-to-date treatments, including those on clinical trial, should be offered and available to all.
- Treatment options should be clearly presented to patients in a sensitive way. The evidence base for those options clearly stated, and written information on the options and evidence supporting those options should be readily available and always offered.
- Technology should be used to ensure that doctors have speedy and easy access to nationally accredited and regularly updated information on cancers, available treatments, and clinical practice.
- Trained and experienced clinical nurse specialists, or similar, should be available to provide information and support, including psychosocial support, when deciding treatment, and throughout periods of treatment.

Undergoing Treatment

- A designated key worker, probably a clinical nurse specialist, should be provided for every patient.

- An overall treatment plan, outlining what the treatments entail and the estimated time scales involved should be discussed with the patient and a written copy given.

- Known side effects of proposed treatment options (short and longer term) should be given to patients in a considered and straightforward way. (If side effects of a treatment are unknown or uncertain but considered likely, this should be stated clearly.)

- Professionals should take full account of the potential physical and psychological impact of side effects on a patient and provide ready access to relevant professional expertise and support as required.

- Monitoring of side effects should take place and, where present, should be actively managed and patients referred for relevant professional expertise.

- All 'in –patients' should be treated on a specialist ward with specialist nurses.

- Systematic access to specialist dieticians and speech therapists should be made available prior and during treatment.

- Hospital catering services should be obliged to be able to routinely cater for the needs of head and neck cancer patients.

Support and Information

- Systematic access to experienced counsellors and complementary therapists should be made available and routinely offered to <u>all</u> patients during the treatment process. Counselling should also be available to patients' families.

- Befriending schemes, so that people can be in touch with others who have undergone the same treatment, should be offered and facilitated by the hospital.

- Access to benefits and housing advice should be facilitated by the hospital and routinely offered to all patients at an early stage.

- Patient information should include a list of who is in their team, a summary of how the clinics and doctors function together, their various responsibilities, a written explanation of the appointment system, and who a patient or carer can contact if necessary. The use of patient held records should be encouraged.

Follow-Up And After Treatment

For follow-up, the proposals drafted to inform the guidance propose that follow-up should be for up to five years. In terms of post treatment care, the proposals suggest

that there should be a dedicated service for the provision of post-treatment care for patients. Post-treatment care should include: speech and swallowing support, nutritional support, oral care support, physiotherapy, pain control and psychosocial help. It is also proposed that non-head and neck professionals should be educated on the special needs of patients with tracheotomies and speech difficulties.

Follow-Up

There was limited discussion of follow-up within the group. However, all saw on going follow-up as important and reassuring. Some thought follow-up should continue for life whereas others felt that up to five years was quite adequate. There was also a mixed response as to how follow-up had been managed, with some who felt that their follow-up was well organised and planned and others who felt there follow-up was virtually self-managed.

A couple of respondents said, if they needed to they could go straight to their ENT clinic or ward if they were experiencing problems. This direct and flexible approach was valued.

After Treatment

One respondent, in a written submission, described the period after treatment as a state of "nothingness", and went onto write:

"…this is a common cancer patient experience. People feel as if they are 'in-limbo', suddenly left to their own resources"

(Respondent, adenoid cancer patient, written submission only)

A few respondents in the discussion group described feeling alone at this point and one described the difficulty of adjusting back to daily living:

"I was happy the op was over but at the time did not know just how back to normal I would get…"

(Respondent, larynx cancer patient)

In this study, almost all respondents had found their speech had been affected as a consequence of their treatment, for some the treatment had also affected their physical appearance, and many had faced radical changes in their diets. These significant changes meant that on a day-to-day basis most respondents were continually

reminded, often in a quite overt way, of living with the consequences of having a head and neck cancer and how this had also impacted on how others related to them. Several respondents related how these differences, for example, in speech, could be easily misunderstood by others and that this ignorance could be an added strain. One respondent, in a written submission, wrote how in her dreams she had 'normal' speech, but had to face reality when she awoke.

It seemed that some respondents had quite limited contact with their GPs both before and during and after treatment episodes, and several respondents felt their GPs needed more knowledge about their post treatment needs:

"The GP could have benefited from after care information".

(Respondent, larynx cancer patient)

It appeared that how this after treatment stage was managed varied a great deal for respondents. At one end of the spectrum were a couple of respondents whose transition home was actively managed and supported, with the involvement of their specialist nurses,. Another had the help of a district nurse although he had to guide her in what to do, and others seemed to access help and services through a mix of planning and chance or had had to actively seek out what they needed for themselves:

"The District Nurse said would I like a palliative care nurse to come in. And she is super, absolutely super, but why didn't somebody else tell me about her before, she could have helped me or my family, for four years I have had no one".

(Respondent, mouth cancer patient)

Another respondent, who had sought out speech therapy and physiotherapy help for himself, said that he thought what was needed at this point was,

"written information, access to head and neck nurses, list of information and support services, and a diary to note: symptoms, progress, questions for visits etc".

(Respondent, mouth cancer patient)

A couple of respondents had had particular difficulties relating to the removal of peg tubes. Both had returned home with the peg tube still inserted and for one, this had been the cause of considerable discomfort and stress, it was removed only when she threatened to pull it out herself.

It was again agreed that patient to patient support and support for families and carers needed to be readily available at this time.

Summary of Recommendations

- Follow up should be provided by the specialist team and be planned and managed by a key worker in consultation with the patient.
- Information on how to access the specialist team between appointments, if needed, should be given to all patients.
- Particular attention should be paid to supporting patients to adjust back to daily living in the period immediately after treatment. A priority should be to address the speech and dietary needs of every patient.
- Primary care professionals need to be educated in the after treatment needs of head and neck cancer patients so that they can play an active role in managing and supporting their after treatment needs.
- Information about palliative care services and its potential value from diagnosis onwards should be given to the patient.

Conclusions

This section draws together overall conclusions. Specific recommendations on the drafting of the head and neck guidance, based on the collective experience of all the respondents who participated in the project, are given at the end of each of the previous sections.

It is important to note that although we talked to patients with different head and neck cancers, who had received different treatments at hospitals around England and Wales, many expressed similar needs and views. The strong, underlying themes in the discussion group and in the written submissions was the need for services to be patient-centred and systematic, specialist and holistic. Retrospectively, all in the discussion group felt that to get a diagnosis as speedily as possible, necessitated that a systematic approach was taken from the GPs or dentists onwards. As well, when exploring what patients needed, the need for specialist services staffed by specialist

professionals was repeated frequently and with great emphasis. This emphasis was perhaps a direct result of many being able to compare and contrast their experiences of dealing with specialists and specialist services and non-specialist services. Relating to the themes identified above, the key issues that were repeatedly raised related to the need for:

- good communication and information between health professionals and their patients
- good communication and information between health professionals within the hospital and between the hospital and the community
- services to be well organised and for treatment and care to be planned and delivered in a patient centred and holistic way
- all health professionals to be aware and remain aware of the impact a diagnosis of cancer can have on the patient and to understand that it is frightening and some treatments may also be frightening and an ordeal for the patient
- all health professionals to be aware and remain aware of the short and longer term consequences of undergoing treatments for head and neck cancer and the whole life impact that this may have for the patient. For example, changes in appearance, changes in speech, eating difficulties.

Respondents reflected in a measured and considered way about the services they had received. All respondents wanted to be constructive as possible about their experiences and, wherever possible, wanted to relate positive examples. They were therefore very keen to give praise where they felt praise was due and to note any improvements they had seen. However, it seemed that for all the greatest shortfall in their overall experience of head and neck cancer services was the lack of a holistic approach to their needs. As the diagnostic process and subsequent treatment and care got underway, the need for professionals to take a holistic approach came to the fore. Even those respondents who, overall, had a positive experience and expressed very positive views about their health professionals still found that some of the day to day problems they experienced during and after treatment, for example dietary matters, were neglected or simply ignored. If these needs are ignored, this may well affect a patient's emotional and physical well being and therefore may undermine the effectiveness of their treatment and care. Respondents clearly did not expect their professionals to be able to address all their needs but needed them to be able to refer

or sign-post them to the help or support they needed. This need for a holistic approach links back to the need for a systematic and co-ordinated approach to be taken so that the best use of the multi-disciplinary team, including the wider team, and existing services and resources can be utilised.

Again, as was found in the previous NCA studies commissioned by the NCGG, patients and carers who participated in this project gave very generously to share their knowledge and experience of head and neck cancer services and their views on developing guidance for these cancers. This was demonstrated by all those who attended the group, many travelling some considerable distance to do so, and those unable to attend but still contributing by sending a written submission. The driving reason for this generosity was a strong desire to help improve health services and a real concern and willingness to directly help other patients.

On the basis of these findings, it is appropriate to partially re-iterate the final conclusion given in the previous studies. If the overall aim of the head and neck guidance is for commissioners to provide patient-centred, efficient and effective services, it will need to not only address the detailed 'content' of the services, but to also focus as much on the structures, systems, and professionals needed to deliver the service, together with the linkages between them. Staying focused on the needs of the patient and the patient perspective is the most likely way of achieving this successfully. This approach will help ensure that the specialist services needed are accessible, the content of the services remains appropriate and patient-centred, and service delivery is successful.

Appendix II – An Analysis of the potential economic impact of the guidance

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Work in Progress

This work is currently in progress. This report outlines the scope of the work, details the methods used and provides *preliminary* cost estimates. Further work is being undertaken in relation to the estimation of the number of clinical nurse specialists, dietitians, speech and language therapists and nurse practitioners required to achieve successful implementation of the guidance.

CONTENTS

1. Executive Summary

An economic modelling exercise was carried out to estimate the cost implications for England and Wales of implementation of the main recommendations of this guidance.

The major impacts on costs fall in 5 broad areas. A summary of these costs is given in Table 1.

Table 1: <u>Cost Summary</u> (All costs in £ million per year)

Lump Clinics		**£2.4**
Multi-disciplinary teams		
Additional costs of staff time for MDT meetings		**£3.0**
Low scenario	£1.4	
High scenario	£4.3	
MDT co-ordinator / data manager for all teams		**£0.5**
Centralisation of Surgery		**£4.7**
Chemo-Radiotherapy		**£1.0**
Patient-Centred Care, including local support teams		**£33.2 to £47.2**
Clinical Nurse Specialists	£11.9 to £13.2	
Speech and language therapists	£5.8 to £9.3	
Dietitians	£4.7 to £7.1	
Nurse Practitioners	£3.6 to £5.8	
Other Staff	£7.1 to £11.8	
Of which £18.3 to £36 .6 million are associated with the local support team role.		
TOTAL : RANGE		**£43.2 to £60.1**

Rapid-Access Lump Clinics

The guidance recommends the establishment of rapid-access lump clinics for patients presenting to their GP with a lump in the neck. Although such clinics exist in the majority of hospitals which deal with head and neck cancer patients, the majority do not have on-site cytological support, which is recommended in the guidance. It has been assumed that such clinics would be run on a weekly basis, and be of length six hours in total (four hours clinic time, plus two hours administration).Coupled with the need for each clinic to have support from a biomedical scientist, the annual cost impact is estimated to be £2.4 million per annum.

Multi-disciplinary Teams

Multi-disciplinary team (MDT) working allows patients to benefit from the expertise of a range of specialists for their diagnosis and treatment, and helps ensure that that care is given according to recognised guidelines. Head and Neck MDTs are already well established in many Trusts. However additional time for meetings will be required and more staff will need to be involved in order that MDTs can function in accordance with the guidance. Thyroid MDTs are generally less well developed. Many MDTs currently suffer from lack of administrative and data management support. The cost of additional staff time for MDT meetings and for ensuring that all MDTs have a co-coordinator/data manager is estimated to be an additional £3.5 million per annum.

Centralisation of Surgery

Two scenarios have been assessed in carrying out the economic review of the centralisation of head and neck cancer surgery. Firstly, that under the guidance, all "radical" surgery would be carried out in the Cancer Centres and secondly that all surgery is transferred to the Centres. Data from two sources were used in the analysis, reflecting the uncertainty in the cost of transferring surgery from the Units to the Centres. Using NHS Reference Cost data, the expected costs across the whole of England and Wales under the first scenario of centralising radical surgery would be around £4.7 million (the whole of this cost would be attributable to the Centres), compared with around £6.7 million under the scenario of centralising all surgery. These costs include the cost of the surgical procedure, in addition to the cost of any in-patient stay required. Cancer Centres are also likely to incur costs through the need for additional staff and ward space. The cost at individual Network level will vary depending on the degree to which centralisation has already taken place, and the population base of the Network.

Chemoradiotherapy

The guidance is expected to lead to an increase in the proportion of head and neck cancer patients who are treated with chemo radiotherapy. Through discussions with a number of clinical oncologists, it has been assumed that, of the patients being treated with radiotherapy, 30% of these will be treated with chemoradiotherapy in the future, compared with 20% currently. The costs associated with this include the cost of the

chemotherapy drugs, plus the costs associated with patient care, which vary depending on whether patients are treated on an in-patient or an out-patient basis.

It is estimated that this change would lead to an annual additional cost of £1.6 million across the whole of England and Wales.

Patient Centred Care and Local Support Teams

Clinical Nurse Specialists

The guidance emphasises the central role that clinical nurse specialists should take in providing care for patients.. At present, many clinical nurse specialists are over-stretched, having to cover other nursing work, leading to an inadequate consultation time with each patient. Some Units providing care and treatment for head and neck malignancies do not currently have a full-time clinical nurse specialist. The requirement within the guidance that every patient should be seen by the CNS before a treatment decision is made is not current practice and implementation of this recommendation is expected to significantly increase the workload of CNSs.

An order of magnitude estimate of the additional number of nurses required was made, based on the CHI report, the preliminary feedback from Cancer Services Collaborative Questionnaire and discussions with a number of clinical nurse specialists. The preliminary estimate for the cost impact of providing additional clinical nurse specialists is between £11.9 and £13.2 million per annum.

Speech and Language Therapists

A speech and language therapist (SLT) who specialises in head and neck cancer should be available to work with every patient whose primary treatment disrupts the ability to speak, eat or swallow. The guidance will increase the workload for SLTs, particularly within Cancer Centres, where additional posts or part-time posts may be required to allow the duties of existing SLTs to be expanded to a greater volume of patients and to allow cover for attendance at clinics, MDT meetings as well as training, holidays, sickness etc. The role of SLTs within the local support teams is more uncertain and further feedback is being obtained. Preliminary estimates suggest that the cost implications may range between £5.8 to £9.3 million per annum for England and Wales

Dietitians

Dedicated dietitians play an important role throughout the patients cancer journey providing nutritional support, advice on tube feeding and coping with the after-effects of treatment. Discussions with dietitians around the country have confirmed that current levels of input vary considerably between hospitals. It is assumed that as a minimum, Cancer Centres should have between3 and 4 WTE dedicated dietitians, implying a typical increase of around over 2 WTE per Centre over current levels. It is assumed that Units will require an additional 0.5 to 1.0 WTE . In total this corresponds to an additional 167 to 250 WTE dietitian posts in England and Wales, resulting in an estimated total cost impact of between £4.7 and £7.1 million per annum.

Nurse practitioners

The role of the nurse practitioner has been widened to act as a support to the CNS, and based on consultations with nursing staff, it has been estimated that the guidance would required two nurse practitioners per Center and one per Unit i.e. a total of 6 or 7 per Network (depending on the number of Units in each Network), or a total of between 241 for the whole of England and Wales. Currently, this role is often covered by the CNS, with only a small number of Centres and Units having a full-time nurse practitioner. The cost of providing the necessary additional posts is estimated to be between £3.7 and £5.8 million per annum.

Local Support Teams

The provision of additional staff for post-treatment patient support teams is expected to have significant cost implications. Each hospital which deals with patients with head and neck cancer should establish such a team, and given the current low provision of many of the roles required in the team, this would necessitate the recruitment of a large number of staff. Two scenarios have been used to assess the cost impact, by varying the assumptions made about the extent to which these teams already exist, and the variability in the level of input required between Cancer Centres and Units. The provisional estimate of the cost impact is the range £18.3 to £36.6 million. Further analysis is being undertaken to provide a central estimate of the cost implications for England and Wales and will be presented in the final report. The costs for the roles of CNSs, SLTs , dietitians and nurse practitioners within local support teams are included in the cost estimates above. The cost estimate for local support teams excluding these posts is between £7.1 and £11.8 million.

1. Introduction

Guidance has been developed for the optimal organisation of service provision for head and neck cancers. Before commissioners and trusts can implement this guidance they need to assess the resource and cost implications. The School of Health and Related Research at the University of Sheffield (ScHARR) has been commissioned to support this process by analysing the potential cost implications of the recommendations for head and neck cancers.

1.1 Scope

The objective of this economic analysis is to:

1. Identify how the guidance may affect commissioners and different types of service providers (e.g. specialist Cancer Centres, local Units) in terms of changes in patient flows and services that need to be provided;

2. Identify different possible models of implementation, which will vary depending both on the baseline position and on the chosen means of achieving the targets set out in the guidance;

3. Identify the key economic issues and cost drivers of guidance implementation;

4. Estimate the costs of implementing the guidance according to the different models identified, and in so doing provide a structure and methodology that trusts may use to do their own analysis;

Estimate the national cost implications of adopting the cancer guidance.

The analysis does not aim to:

- give a definitive answer as to the cost implications of the guidance for specific Cancer Centres or Units (but to produce an indication of the scale of costs involved for different paradigms);
- address in detail the training and workforce implications of the guidance;
- analyse the health outcome measures of meeting the guidance;
- estimate the cost-effectiveness of guidance implementation.

1.2 Methods

The research on cost implications was developed in parallel with the production of the guidance. Members of the ScHARR team attended the Editorial Board meetings, facilitating a full understanding of the guidance as it developed.

Literature searches were carried out to identify any existing costing exercises, audits of cancer activity, cost of illness studies or models of treatment pathways. Limited costing data were found in the UK literature. Reviews of the literature on cost effectiveness found extremely limited evidence. There was also insufficient evidence on which to base a calculation of health benefit, quality of life or other benefits arising from implementation of the guidance.

Advice was sought from the Editorial Board to ensure that appropriate assumptions were made and data sources identified, as well as to assist in the interpretation of data. Numerous additional clinicians and business managers were contacted to discuss their current activity and the likely resource implications of guidance implementation.

The guidance, Editorial Board discussions, preliminary data analysis and consultations with both clinicians and service managers were used to identify and prioritise the key cost issues. For each of the key issues, an estimate of the local and national cost consequences is made. The approach adopted for each issue is detailed in the relevant chapter.

All staff costs are based on NHS salaries, using the mid point of the pay spine per staff type grade unless indicated otherwise. The impact of the Agenda for Change and the European Working Time Directive on future staffing levels is not known with certainty and will vary by Cancer Network.

The cost of implementing the guidance will vary by Cancer Network, depending on existing service levels and configurations. Estimates of the cost of future provision are based on a series of working assumptions regarding the level of service provision, the model of future provision adopted and the associated staffing levels required to achieve the recommendations.

2. Rapid-Access Lump Clinics

2.1 Background

The guidance states that *"Patients who present with masses in the neck should be referred to rapid-access lump clinics for investigation. Networks which do not have lump clinics should establish them at selected hospitals. Networks should decide which hospitals will provide diagnostic services for patients with symptoms that might be due to head and neck cancers. Hospitals which do not have the capacity to provide the type of service specified in this Manual should have mechanisms for onward referral to Trusts where appropriate expertise is available. There should be specific referral routes for patients with neck lumps and thyroid nodules. These arrangements should be clear, agreed within each Network by all Trusts that are likely to deal with these patients"*.

Traditionally, patients with a neck lump have been referred to a range of disciplines and may find themselves being managed by clinicians with little experience of investigating such lumps; however, this can result in delays in diagnosis and inappropriate diagnostic procedures. The provision of rapid access lump clinics should ensure that all patients who are referred from primary care with symptoms which suggest head and neck cancer should be seen within the target maximum waiting time of two weeks.

2.2 Current Activity

Discussions with a number of clinicians and surgeons have indicated that many hospitals in England and Wales already provide lump clinics; it is likely that district general hospitals which have an ENT department and at least four surgeons would already run such a clinic. These clinics are not necessarily separate rapid-access clinics, but have the capacity to meet the Department of Health's criteria for urgent referrals under the "two-week wait" bureau for patients whose symptoms may represent head and neck cancer.

At present, lump clinics are run on a weekly basis by ENT and lymphoma services, with sufficient expertise in the cytology departments to report reliably on FNAC. The clinics are generally open to all hospital departments and in some cases to general practitioners. All appropriate investigations are carried out or booked at the first visit, with patients given a follow-up appointment one week later.

Preliminary results from the 2004 Cancer Services Collaborative Improvement Partnership Questionnaire on Head and Neck Cancer[1] suggest that only around half of hospitals in England run a rapid-access lump clinic, with the majority of the remaining hospitals providing a rapid-access service, but not running a separate clinic for these patients.

2.3 Future Activity

The number of new clinics which would be established in accordance with the guidance is expected to be small. However, there is expected to be an increased role in these clinics for on-site cytologists, which is likely to have some cost impact. The cytology service for lump clinics is not currently required to be on-site, however, the new guidance implies that added cytological support would be required, to enable test results to be reported immediately. This would require one session of consultant cytopathologist time plus a similar amount of time for a biomedical scientist for each clinic.

2.4 Costs

In the following analyses, the salary of a grade 1 consultant cytopathologist has been assumed to be £89,754 per annum (including on-costs), and that of a biomedical scientist has been assumed to be the mid-point of a BMS-2 salary (£26,318 including on-costs).

2.5 Cost Impact

In order to provide a rapid-access service, it has been assumed that clinics would be held on a weekly basis, and would cover either a morning or afternoon session of length 6 hours (this includes four hours of actual clinic time, plus an estimated two hours for report-writing). The cost of the biomedical scientist's time would therefore incur a cost of around £90 per week, while the cytopathologist's time would cost around £325 per week. In total, the annual cost of running one clinic would therefore be around £21,500. Assuming that, within each Network, there are three hospitals running lump clinics, this is equivalent to an annual cost to each Network of around £65,000. Applying this to the 37 Cancer Networks in England and Wales, this is expected to cost £2.4 million per annum.

3. Multidisciplinary Teams

3.1 Background

The guidance states

"All patients with head and neck cancers (including thyroid cancer) should be managed by appropriate multidisciplinary teams (MDTs). Each Network should ensure that a comprehensive range of professionals is available for all the MDTs in the area it covers, and organise the service so that every patient can be managed by a full MDT. These MDTs should deal with minimum of 100 new cases of UAT (upper aerodigestive tract) cancer per annum (excluding glandular tumours), which implies a population base of over a million; most will be based in tertiary centres which have radiotherapy facilities. Some Networks in sparsely populated areas may, however, elect to develop teams for smaller number. Where more than one Trust provides services in close geographical proximity (for example, where two Trusts operate in a single conurbation), Networks should consolidate services under a single MDT."

and

"All patients with thyroid cancer, including those whose cancer is discovered during surgery for apparently benign disease, should be referred for management by thyroid cancer MDTs. These teams may take one of two alternative forms, being either designated head and neck cancer teams, joined by experts in endocrinology for the relevant part of the MDT meeting or specialised endocrine oncology teams. Since thyroid cancer is a relatively rare condition, with an incidence rate of roughly two patients per 100,000 population per year, these MDTs will also only be required in large centres (those which serve populations in excess of a million). Thyroid cancer MDTs may manage patients with both malignant and non-malignant disease."

3.2 Activity

3.2.1 Current Activity

Head and Neck MDTs

The concept of multi-disciplinary team working is well-established in many Cancer Networks, but current teams may not have a full membership, or may meet outside working hours and/or may meet less frequently than recommended.

For instance, of the 22 trusts included in the nine-Network CHI/Audit Commission survey (2000/2001) [2], just under half held regular MDT meetings to plan the management of patients with head and neck cancer, usually during lunch time. Six trusts provided information on the frequency of MDT meetings; in three, the team met weekly; other teams met fortnightly or monthly. Of the head and neck cancer MDTs that met regularly, 30% kept minutes of their meetings.

Thyroid MDTs

Service for patients with thyroid cancer are particularly fragmented. In the Northern and Yorkshire Cancer Registry (NYCRIS) area in 1998 to 1999, patients with thyroid cancer were most likely to be treated by general surgeons working outside MDTs. 59% of patients were treated by surgeons who dealt with fewer than ten cases in the two-year period studied (i.e. an average of five or fewer cases per year); and in over a third of cases, treatment was given by surgeons whose case-load averaged two or fewer per year. Audit based on questionnaires, with a response rate of 60%, revealed that half of the consultants who performed surgery for thyroid cancer worked in MDTs; of those who did not, 62% met regularly with oncologists and 81% discussed

the diagnosis with a pathologist or imaging specialist. Only 56% of MDTs managing thyroid cancer patients discussed every case. 44% of these MDTs also dealt with other endocrine cancers, 22% were head and neck cancer teams, whilst 31% did not specify any other cancers in their remit. [3]

3.2.2 Future Activity

Head and Neck MDT

The guidance recommends that members of the core team should comprise:

- Surgeons. Each MDT should include three or more designated surgeons, who are likely to be ear, nose and throat (ENT), maxillofacial, or plastic surgeons.
- Clinical oncologists (radiologists): each MDT should, if possible, include two clinical oncologists, one of whom should always be present at meetings.
- Specialist restorative dentist
- Specialist pathologists, with expertise in both histopathology and cytopathology
- Radiologist with expertise in head and neck cancer.
- Speech and language therapist with expertise in rehabilitation of patients who have undergone treatment for head and neck cancer
- Clinical nurse specialists (CNSs)
- Senior nursing staff from the head and neck ward
- Palliative care specialist (doctor or nurse), who should work with palliative care services in the community.
- Dietitian with a specialist interest in patients with head and neck cancer.
- Team secretary
- Data manager.
- MDT co-ordinator, who should take responsibility for organising MDT meetings. The co-ordinator may also take the role of team secretary and/or data manager, but should not be a Clinical Nurse Specialist.

It is recommended that meetings are held weekly or fortnightly, depending on availability of members and case-load. Sessional commitments should be formally agreed for all MDT members in their job planning process. It is also recommended that the following patients are discussed at MDTs :

- Every patient with a new diagnosis of cancer in any head and neck site with which the MDT deals.
- All patients who have undergone initial surgery.
- All patients with newly identified recurrent or metastatic disease.
- Any other patient whose management is thought by any member of the MDT to require discussion.

Thyroid MDT

Members of the thyroid cancer MDT should comprise:

- Endocrinologist.
- Surgeon who specialises in thyroid/endocrine oncology.
- Oncologist.
- Radiologist
- Nuclear medicine specialist.
- Specialist pathologists (both histopathology and cytopathology).
- Clinical Nurse Specialist (who may be a head and neck cancer CNS).
- Secretarial and support staff, as above.

One or more members of the team must be trained and licensed to give radioiodine.

Configuration of MDTs

For the purposes of cost analysis it is assumed that there are 5 hospitals operating within a typical Cancer Network covering a population of 1.5 million: one Cancer Centre (A), two large DGHs (B1 and C1) offering diagnostic services and two smaller DGHs.

3.3 Costs

The cost of operating MDTs is principally made up of the staff time involved. In order to meet the requirements of the guidance additional staff time is likely to be incurred for all members of the MDT. Annual meeting costs are derived estimating the time spent attending meetings by different staff multiplied by their hourly rate (salary and on-costs). The costs do not include the cost of time spent by extended team members in MDT meetings.

Factors impacting on the cost of developing fully functioning MDTs within any given network include:

- the number of MDTs needed to serve the network and the configuration of these MDTs within the network
- the type, number and location of staff involved in MDT meetings;
- the frequency and duration of meetings;
- the requirement to travel / availability of teleconferencing facilities.

Travel costs are not included in the analysis. It is assumed that the majority of MDT members will be based at the Centre. In Cancer Networks where staff are required to travel to MDT meetings the use of teleconferencing facilities should be considered. Tele-conferencing facilities are becoming more widely available. If, however, new equipment is required the cost will vary according to the type of system specified and the number of sites involved. A system comprising a basic unit, 2 monitors, a document camera, video camera, network points, installation and software could cost up to £20,000 per site. Line charges depend on the number of sites involved in the conference and the package purchased. Line costs and service charges are estimated to be £1.00 per minute inclusive although this may well be an over estimation as discounts can be obtained, particularly where usage is high. Optimum packages should be negotiated based on individual network requirements.

3.4 Cost Impact

The current level of activity of MDTs is not known with certainty. The working assumptions regarding type of staff currently attending head and neck MDT meetings are taken from the CHI audit [2]. Additional information on current MDT activity is being collated from the recent Cancer Services Collaborative Questionnaire on Head and Neck Cancer [1]

[CURRENT MDT ACTIVITY DATA TO BE UPDATED BASED ON RESULTS OF CSC QUESTIONNAIRE FOR FINAL REPORT]

It is assumed that there are 52 MDTs currently operating (one per million population in England and Wales). It is assumed that Head and Neck meetings typically last for 2 hours and that meetings are held fortnightly and that 50% of them are run outside normal working hours. In addition it is assumed that thyroid MDT meetings are held monthly and follow on from the Head and Neck MDT meeting, lasting for an hour. For thyroid MDTs it is assumed that all meeting are currently attended by an endocrinologist and the surgeon the but that only 50% of teams have the other team members listed in the guidance.

Based on the above assumptions it is estimated that the typical cost of running an MDT is currently £10,000 per annum. Assuming 52 MDTs in England and Wales this corresponds to an estimated total cost of £0.5 m for England and Wales

The cost of running MDTs, based on guidance recommendations, is derived on the assumption that, on average, there is one MDT per Cancer Network – therefore there will be 37 MDTs within England and Wales. For the purposes of cost analysis it is assumed all the members recommended by the guidance attend 100% of MDT meetings and that 100% of meeting are undertaken within normal working hours. It is assumed that all MDT meetings are held weekly, with the Head and Neck meeting (UAT only) lasting three hours and the thyroid meeting lasting one hour. It is assumed that the post of MDT co-coordinator/team secretary and data manager are combined into one full-time post, which covers both the Head and Neck and the thyroid teams. It is assumed that 3 hours of preparation per meeting are required by the MDT co-coordinator.

Based on these assumptions the future cost of MDTs is estimated to be just over £93,000, an increase of around £83,000 per annum. Extrapolating this figure to England and Wales gives an estimated additional cost of £3.0 million. These costs exclude the cost impact of any additional traveling and/or use of videoconferencing facilities.

Sensitivity Analysis

The cost impact of running MDTs based on guidance recommendations is estimated to be around £3.0 million. This will vary according to the current membership of MDTs, frequency of attendance at MDTs meeting and the frequency and duration of meetings. In some Cancer Networks MDTs may already be well established and the impact of the guidance may be well below this estimate.

It is assumed that 50% of MDT meetings are currently being held outside normal working hours and therefore there will be cost implications in relation to moving towards formally agreeing sessional commitments for all MDT members in their job planning process. If it is assumed that all MDT meetings are held within normal working hours the estimated cost impact is reduced to £2.5 m.

The frequency of meetings and the number of MDTs have a significant impact on costs. If meetings are assumed to be held fortnightly rather than weekly then the cost impact is reduced to £1.4 m per annum . If the number of teams nationally is assumed to be assumed to be 52 (one team per one million population) rather that 37

(one team per Network population) to the estimated cost impact is £4.3 m per annum.

For a Cancer Network with one MDT the cost impact is estimated to be £83,000. In some Cancer Networks MDTs may already be well established and the impact of the guidance may be well below this estimate. If there are two head and neck MDTs within the Cancer Network the estimate of cost impact will increase. Although the meeting duration will be shorter for both teams the total time involved in meetings is likely to be longer and more travel is likely give that some experts will need to travel.

Costs may be slightly higher if the thyroid team operates separately to the head and neck team as some clinicians will need to attend two separate meetings.

3.5 Additional Staff Requirements

Staffing issues will be significant. More staff will need to be involved in the MDT process, with additional time spent in meetings and potentially additional travelling requirements, in order that MDTs can function in accordance with the guidance. In some trusts the posts of clinical nurse specialists and palliative care consultants do not currently exist. Existing shortages of radiologists, pathologists and oncologists will hamper development of full MDTs in the short term. The development of MDTs will need to evolve gradually over a number of years.

In order to ensure fully operational MDTs are developed in accordance with the guidance it is assumed that a dedicated MDT co-coordinator/secretarial support post is required in each Trust which supports a head and neck MDT. The role of MDT co-ordinator is not necessarily a full time role but many combine the co-ordination of meetings with data collection, which is also currently under-resourced, so a full time post is used in the costing. The CHI/Audit commission report indicated that, at the time of their survey (winter 2000/2001) approximately 33.3 % of head and neck MDTs had administrative support. [2] Assuming that 37 MDTs covering England and Wales and that one third of these teams are currently operating without support it is estimated that £0.5 m will be required to provide support to the remaining teams.

The impact on the guidance as a whole on the role and required number of CNS, dietitians and SLTs is discussed elsewhere in this report

4. Clinical Nurse Specialists

4.1 Background

The guidance emphasises the need for improved information and support for patients with head and neck malignancies, and the central role that clinical nurse specialists should play in delivering high quality patient-centred care. From the time of diagnosis each patient should have access to a clinical nurse specialist who can offer psychosocial support and continuity of care. Clinical nurse specialists should be full members of head and neck cancer MDTs, providing knowledge of the patient's clinical condition and acting as patient advocates during discussions on their future management. A named head and neck cancer clinical nurse specialist should be available to support each patient through the course of the disease.

The CNS should work closely with other groups, including patient self-help groups, speech and language therapists and with other members of specialist and extended teams. They should be involved in co-ordinating care for individual patients, but should not be expected to take on the administrative burden of co-ordinating MDT meetings.

4.2 Current Provision

Head and neck clinical nurse specialists

Data on current numbers of head and neck and thyroid clinical nurse specialists are limited, but preliminary results from the Cancer Services Collaborative Questionnaire on Head and Neck Cancers [1] in 2004 have shown that the majority of Centres, along with some Units, currently have a head and neck CNS. Identification of current numbers is problematic given that the title used for clinical nurse specialist posts may vary between institutions and the role of nurse specialists varies considerably. Based on the questionnaire data and consultations with a number of CNSs, it has been assumed that every Centre currently has one dedicated CNS, whilst 25% of Units have a whole time equivalent CNS.

[TO BE UPDATED FOR FINAL REPORT BASED ON ALL COMPLETED RESPONSES TO QUESTIONNAIRE]

Thyroid clinical nurse specialists

The current provision of thyroid CNSs is thought to be very low. In many Centres, the work with thyroid patients is often carried out by the head and neck CNS. It is assumed that only 10% of Centres currently have a dedicated thyroid CNS.

Based on these assumptions, the following estimates have been made relating to the number of CNSs currently in England and Wales: -

Table 2: Current provision of clinical nurse specialists

	Cancer Centres	**Cancer Units**
Number of head and neck CNSs	37	42
Number of thyroid CNSs	4	-
Total	**41**	**42**

4.3 Future Provision

Head and neck clinical nurse specialists

The guidance will impact on the need for CNSs in a number of ways. The centralisation of radical surgery will increase the workload at the Centres, requiring additional CNSs for both pre- and post-treatment patient care. Additional CNSs will be required to allow CNS to play an increased role in the post-treatment support as part of the local support teams (see Chapter 10). These additional roles are expected to lead to a need for two CNSs per Centre, and one per Unit. The additional requirement within the guidance that ***every*** patient should be seen by the CNS before a treatment decision is made is not current practice and implementation of this recommendation is expected to significantly increase the workload of CNSs, potentially doubling the future number of CNSs required to four per Centre and two per Unit.

[ADDITIONAL FEEDBACK IS BEING OBTAINED ON FUTURE NUMBERS OFCNS's REQUIRED]

At present, since the majority of Centres and Units do not currently have a dedicated ENT nurse practitioner, the CNS often has to cover this additional nursing work (including duties such as care of stomas and naso-gastric tube-feeding). This is not expected to continue in the wake of the guidance, which recommends the recruitment of significant numbers of nurse practitioners to carry out these tasks (see Chapter 7).

Thyroid clinical nurse specialists

Because of the low incidence of thyroid cancer (around 30 new cases per annum in a typical Cancer Network of 1.5 million population), it is assumed that a whole time equivalent thyroid CNS would not be required either at the Centres or the Units. Instead, it is assumed that each Centre would require a 0.5 WTE thyroid CNS, in addition to the head and neck CNSs mentioned previously.

Based on the assumption that a typical Cancer Network serves a population of 1.5 million and contains one Cancer Centre and four or five Cancer Units, it is estimated that each Network would require 12 to 14 head and neck CNSs (depending on the number of Units in the Network), in addition to half a thyroid CNS. Applying these figures to the whole of England and Wales gives a total of 481 head and neck CNSs, and 19 thyroid CNSs.

4.4 Costs

For the purposes of this analysis, it has been assumed that clinical nurse specialists in head and neck and thyroid cancer are Grade H nurses, with a salary of £31,525 per annum (including salary on-costs).

4.5 Cost impact

The following table summarises the current provision and costs, along with the estimated future requirements and additional annual costs of providing sufficient clinical nurse specialists across the whole of England and Wales: -

Table 3: Cost impact of additional clinical nurse specialists

Role	Current number	Current costs	Future number	Future costs	Additional costs
Head and neck cancer	79	£2.5 million	481	£15.2 million	£12.7 million
Thyroid cancer	4	£0.1 million	19	£0.6 million	£0.5 million
Total	83	£2.6million	500	£15.8 million	£13.2 million

The total additional cost of providing the necessary additional clinical nurse specialist care is estimated to be £13.2 million per annum, equivalent to around £350,000 per Network. Of this it is assumed that £5.1 million (or £140,000 per Network) is associated with the cost of time spent in the role of local support teams (this is discussed further in Chapter 10). Making a different assumption about the current provision of CNSs, by assuming that every Centre and 50% of Units already have a

CNS (as opposed to 25%), this would reduce the total cost impact (for all roles of the CNS) to £11.9 million per annum.

5. Speech and Language Therapists

5.1 Background

Speech and language therapy for people who have been treated for head and neck cancer demands a high level of expertise over a substantial period of time. A speech and language therapist (SLT) who specialises in head and neck cancer should be available to work with every patient whose primary treatment disrupts the ability to speak, eat or swallow. The SLT should discuss the planned treatment and rehabilitation with the patient before treatment begins, and should be responsible both for assessment of speech and swallowing and for helping patients to deal with problems with eating, drinking and face-to-face communication.

The majority of patients are likely to be supported by specialist head and neck SLTs, based at Cancer Centres. If the specialist SLT in the MDT delegates rehabilitation work to a SLT working in the community, the specialist SLT should remain available to provide expert advice and to assist the community SLT in meeting the specific needs of these patients.

Guidance Recommendations on the role of SLTs

Guidance recommendations on the role of SLTs working with patients with head and neck cancers include :

> (a) membership of MDTs should include a speech and language therapist with expertise in rehabilitation of patients who have undergone treatment for head and neck cancer
>
> (b) pre-treatment assessment is required for patients in advance of radical treatment which is likely to affect their speech or ability to swallow
>
> (c) treatment for head and neck cancers can cause problems with eating, swallowing, breathing and speech, and specific support should be provided for all patients who may need it, both during and after treatment. Radiotherapy support clinics should ensure that patients have access to a speech and language therapist, who should liaise with local support teams
>
> (d) membership of local support teams (which are to be established within all Cancer Units or Cancer Centres, which deal with patients with head and neck

cancer) should include a SLT. A full range of techniques, products and facilities should be available for functional voice rehabilitation.

5.2 Provision of Services by SLTs

5.2.1 Current provision

The role of SLTs within MDTs is well-established and it is assumed that the around 70% of MDTs currently have a SLT as a full member of the team, based on the Head and Neck Cancer Caseload and Education and Training Survey Results [4] and supported by preliminary results from the 2004 Cancer Services Collaborative Questionnaire on Head and Neck Cancers. [1]

Although many patients currently receive pre-treatment assessment, in some Centres the resources are not available to provide this service to all patients who would benefit. [1] The SWAHNII audit showed that 80%, 72% and 32% of patients who had surgery to the larynx, hypopharynx and posterior third of tongue, respectively, saw a speech therapist. Overall, just 48 of 75 these patients – 64% – saw a SLT, despite an agreed standard throughout the region covered by the audit that all should do so. [5]

The level of input by SLTs to radiotherapy support clinics varies across hospitals. In some Centres there is insufficient resource or expertise available for SLTs to provide support to all appropriate patients. In particular in Cancer Networks where radiotherapy is not provided at the main Centre there may not be a suitable experienced SLT available to advise patients. In addition, although the majority of hospitals offer some SLT input for long term rehabilitation of patients significant additional resources are likely to be required in the majority of Cancer Networks to ensure that all patients receive the full support they require.

No formal audits of the current numbers of SLTs providing services to head and neck patients have been identified. Discussions with SLTs around the country have confirmed that current levels of input by SLTs vary considerably between hospitals. Based on these discussions and informal feedback from the Special Interest Groups of the Royal College of Speech and Language therapists it is assumed that, on average, there is currently 1 WTE at larger Cancer Centres and 0.5 WTE at smaller Cancer Centres

[AWAITING FURTHER INPUT FROM THE SPECIAL INTEREST GROUPS OF ROYAL COLLEGE OF SPEECH AND LANGUAGE TEHRAPISTS]

5.2.2 Future Provision

The guidance will increase the demand for SLTs, particularly within Cancer Centres, where additional posts or part-time posts may be required to allow the duties of existing SLTs to be expanded to a greater volume of patients and to allow cover for attendance at clinics, MDT meetings as well as training, holidays, sickness etc. The centralisation of surgery to the Cancer Centres will also increase the demand on SLTs within the centres. Given the complexity of these cases it is assumed that the majority of the workload will fall on specialist SLTs within the Cancer Centres. Some additional demand will also be placed on SLTs working within the community.

[ADDITIONAL FEEDBACK IS BEING OBTAINED ON THE POTENTIAL ROLE OF SLTs WITH THE LOCAL SUPPORT TEAMS – IN THE CURRENT REPORT IT IS ASSUMED THAT THE LOCAL SUPPORT TEAM TAKES ON A SIGNIFICANT ROLE IN THE LONG TERM REHABILITATION OF PATIENTS. HOWEVER THIS MAY NOT BE PRACTICAL GIVEN THE COMPLEXITY OF MANY OF THE CASES AND IT MAY BE NECESSARY FOR SPECIALIST SLTs AT THE CENTRE TO PLAY A GREATER ROLE THAN CURRENTLY ASSUMED]

There may be a knock on effect from the Supportive and Palliative Care guidance, with the likelihood of more queries from palliative care sector plus a greater demand for supporting head and neck patients in the community /hospice settings.

Equipment for surgical voice restoration is currently available, although the equipment options available vary between Cancer Networks. There is also an issue with regard to who pays for the products. A Macmillan/DOH project on surgical voice restoration is in the process of estimating current spending on this equipment in a sample of hospitals and will report in approximately 6 months time. [6] This issue is not covered within this report as it is not a direct impact of the guidance.

Discussions with a number of leading SLTs suggest that, as a minimum, Cancer Centre should have a minimum of 2.0 to 2.5 WTE SLTs, suggesting an increase of at least 1.25 to 1.5 WTE per Centre (This excludes any research commitments. Currently the finance /time for research is sought outside the normal post and cover is sought for clinical commitments while research is being undertaken). It is assumed

that the Units will require an additional 0.5 TO 1.0 WTE , providing support to specialist SLTs within the Cancer Centres.

5.3 Costs

For the purposes of this analysis it is assumed that SLTs at the Cancer Centre are typically employed at the mid-point of band 3 at a cost of around £41,834 (including on costs), although it is recognised that some posts, which incorporate research functions and special responsibilities may be at a higher grade.

Training costs are excluded.

5.4 Cost Impact

Based on the assumption that 1.5 WTE additional SLT posts are required per Cancer Centre and that there will be 37 Centres in England and Wales (one per Cancer Network) , it is assumed that around 55 WTE posts will be required in England and Wales. At a cost of £41,834 per post the total cost of providing additional SLTs for head and neck cancers in England and Wales is estimated to be £2.3 million. It is currently assumed that all Units will require an additional 0.5 to 1 WTE SLT post at a cost of £3.5 to £7.0 million, producing a total cost of £5.8 to 9.3 million. This is a preliminary estimate only.

[FURTHER WORK IS BEING UNDERTAKEN TO PROVIDE A MORE ROBUST ESTIMATE OF THIS COST AND WILL BE PRESENTED IN THE FINAL REPORT]

6. Dietitians

6.1 Background

Clinical specialist head and neck dietitians should be available to work with all patients who may require their help. The dietitian plays an important role throughout the patients cancer journey assessing patients' nutritional needs, evaluating how different treatments will impact on a patient's nutritional status, providing nutritional support, advice on tube feeding and coping with the after-effects of treatment.

The guidance recommends that the membership of MDTs should include a specialist dietitian and pre-treatment assessment by a specialist dietitian is required for patients

in advance of radical treatment. Patients should also have access to a specialist oncology dietitian at the Cancer Centre to provide support during treatment, including management of nutritional problems and ensuring that the patient is prepared for interventions that may be required beforehand. In addition specialist dietetic support is required on wards where patients with head and neck cancer are nursed and specialist dietitians should be member of the local support teams to be established within Cancer Units and Cancer Centres to support the long term rehabilitation needs of patients with head and neck cancer.

6.2 Provision of Services by Dietitians

6.2.1 Current Provision

The role of specialist dietitians within MDTs is well-established. Preliminary feedback on the first 28 responses to the Cancer Services Collaborative Improvement Partnership Questionnaire [1] suggests around 70% of MDTs currently has a dietitian as a fully active member of the team. However in some Cancer Networks dietitians are insufficiently resourced to allow regular attendance at these meeting. Although some patients currently receive pre-treatment assessment, early responses to the CSC questionnaire suggest that in many Centres the resources are not currently adequate to provide this service to all patients who would benefit. The level of dietetic support in radiotherapy support clinics varies between hospital and the increasing use of chemoradiotherapy is putting increasing demands on the support required from dietitians. The level of support available for the long term rehabilitation of patients will need to increase significantly to allow dietitians to play a full role in the long term rehabilitation of patients as part of the local support teams.

No formal audits of the current numbers of dietitians providing services to head and neck patients have been identified. Discussions with dietitians around the country have confirmed that current levels of input vary considerably between hospitals. Resources are often over-stretched with dietitians unable to meet the needs of all patients. Based on these discussions it is assumed that on average there is currently to 1 to 1.5 WTE funded dedicated head and neck dietitian posts at Cancer Centres and approximately 0.2 WTE at Units

[AWAITING FURTHER FEEDBACK – TO BE UPDATED FOR FINAL REPORT]

[CHECK AVAILABILITY OF RESPONSE TO RECENT DAHNO QUESTIONNAIRE FOR POTENTIAL INCLUSION IN FINAL REPORT]

6.2.2 Future Provision

The guidance will impact on the demand for dietitians and additional posts or part-time posts will be required to allow the duties of existing specialist dietitians to be expanded to a greater volume of patients and to fulfil all the roles outlined in the guidance. The centralisation of surgery to the Cancer Centres will increase the demand on the time of dietitians at the Cancer Centres.

Discussions with a number of leading dietitians suggest that, as a minimum, Cancer Centres should have between 3 to 4 WTE dedicated dietitians, implying a typical increase of 2.25 WTE per Centre and that Cancer Units should have 0.5 to 1 WTE to provide community support implying an increase of up to 0.8 WTE per Unit. This exact level of input required will be dependent on the number of head and neck patients seen by the Cancer Units.

[FURTHER FEEDBACK REQUIRED PARTICUALRLY ON LEVEL OF INPUT REQUIRED FOR LONG TERM REHABILIATION ROLE. MORE DETAILED ANALYSIS REQUIRED ON NUMBE R OF PATIENTS TREATED PER NETWORK and IMPLICATIONS FOR WTE POSTS REQUIRED]

It is assumed that there is one Cancer Centre per Network, and that each Network has 4 or 5 Cancer Units. Based on the preliminary feedback it is estimated that an additional 2.25 WTE specialist dietitians will be needed at the Cancer Centre and that between 0.5 and 1WTE posts are needed at the Units, particularly to provide long term support. This corresponds to an estimated increase of between 167 and 250 WTE posts for dietitians nationally. The actual allocation of resources between the Centres and the Units will be dependent on the structure of service provision within the Network. The role of dietitians within local support teams is discussed further in Chapter 10.

6.3 Costs

For the purposes of this analysis it is assumed that dietitians at the Cancer Centre are employed as Senior 1 PL16 Point 3 at a cost of £28,398 including on costs.

[OBTAIN FEEDBACK ON APPROPRIATE GRADES FOR DIETITIANS WITHIN

6.4 Cost Impact

Based on the assumption that between 167 and 250 additional dietitian posts are required, at a cost of £28,398 per post, the total cost of providing additional dietitians for head and neck cancers in England and Wales is estimated to be between £4.7 and £7.1 million. This corresponds to an additional 5.8 WTE posts per Cancer Network of 1.5 million, at an estimated cost of approximately £166, 000 per Network. This is a preliminary estimate only.

Cost savings will results from improved patient care, including a reduction in dehydration-related hospital admissions, fewer complications resulting in shorter hospital admissions and improved long term health outcomes. There is insufficient evidence to quantify these cost savings and therefore they have not been taken into account.

[FURTHER WORK IS BEING UNDERTAKEN TO PROVIDE A MORE ROBUST ESTIMATE OF THIS COST AND WILL BE PRESENTED IN THE FINAL REPORT]

7. Nurse Practitioners

7.1 Background

According to the guidance *"an ENT / maxillofacial nurse practitioner, based in ENT and maxillofacial outpatient departments, can provide advanced skills for the management of stomas (tracheotomies and gastrostomies), nasogastric tubes and tracheo-oesophageal valves. The nurse practitioner should work alongside the CNS and SLT, and help to teach local hospital and community and nursing teams, thus creating a sustainable and robust seven-day service for patients who require help"*.

7.2 Current Provision

Based on consultations with senior nursing staff, it is estimated that only 10% of Cancer Centres currently have a dedicated head and neck nurse practitioner, equivalent to four across the whole of England and Wales. It is currently assumed that no Unit currently has a nurse practitioner. These assumptions are reinforced by the preliminary results from the results of the Cancer Services Collaborative Improvement Partnership Questionnaire , which aimed to determine the current provision of head and neck cancer services across England. Initial results showed

that very few hospitals even have access to a nurse practitioner. This can be explained in part by the fact that the work may be carried out by someone in a different role e.g. a clinical skills facilitator, who may work across ENT / Maxfax / head and neck. As part of such a role, these staff are sometimes required to carry out the role of the nurse practitioner.

[TO BE UPDATED BASED ON FINAL RESULTS FROM CSC QUESTIONAAIRE]

In many head and neck teams, the nurse practitioner would therefore be a newly-created role, their job being to support the CNS in some of the more practical aspects of patient support, and assuming a development role towards a CNS. Much of the work which would be carried out by nurse practitioners is currently carried out by CNSs, and it is acknowledged that in some hospitals, the provision of a nurse practitioner may not in effect involve the creation of a new post. It has, however, been assumed that the nurse practitioner posts required are all newly-created.

7.3 Future Provision

The increasingly diverse role of the nurse practitioner under the recommendations of the guidance would increase the numbers required to include duties such as:-

- Working more closely with the CNS and SLT in ENT departments;
- Providing input to the local support teams (see Chapter 10).

It is anticipated that diversifying the role of the nurse practitioner would reduce turnover of staff and enable further training to be offered to aid development towards a CNS role.

It has been assumed that, in order to provide the services given above, one nurse practitioner would be required at each Cancer Unit, and two at each Centre i.e. a total of 241 across England and Wales.

[ADDITIONAL FEEDBACK ON ROLE and NUMBER OF NURSE PRACTITIONERS IS BEING OBTAINED FOR INCLUSIONIN FINAL REPORT]

This analysis covers both areas of the nurse practitioner's work (it was assumed in the analysis of the staffing implications for the local support teams that 1 WTE nurse

practitioner would be required for every support team i.e. 204 for the whole of England and Wales).

7.4 Costs

The estimated salary of a Grade F nurse practitioner is £24,374 per annum, including on-costs. [7]

7.5 Cost Impact

Based on the assumption that there are currently only four dedicated head and neck nurse practitioners in England and Wales, this equates to an annual cost of just under £100,000. In order to provide the necessary 241 full-time nurse practitioners, this would incur annual costs to £5.9 million across England and Wales, an increase of £5.8 million.

8. Centralisation of Surgery

8.1 Background

The guidance recommends that "It is anticipated that all surgery for head and neck cancer will be centralised within the next decade. Patients requiring radical surgery should be managed by the MDT in a cancer centre, with surgery being carried out by surgeons who are members of the MDT. Care for these patients should, if possible, be provided in a specialised head and neck cancer ward. Minor surgery to remove early tumours may be carried out by nominated surgical specialists in District General Hospitals with the agreement of the MDT. This is only appropriate if these surgeons are active members of the head and neck cancer MDT and can provide adequate post-operative support, aftercare and rehabilitation for their patients. There should be 24-hour access to emergency surgery to reverse flap failure."

The current incidence of head and neck cancer is around 8,000 cases per year, or 240 cases per Cancer Network (based on each Network serving a population of 1.5 million people). For upper aero-digestive tract (UAT) cancer (head and neck cancers excluding cancers of the thyroid), the annual incidence is approximately 190 cases per Network. The guidance recommends that Head and Neck MDTs should deal with a minimum of 100 news cases of UAT cancer per annum (excluding glandular cancer),

which implies a population base of over a million. For Networks in sparsely populated areas, it may more practical to develop teams for smaller numbers of cases.

Treatment by Surgery

Most head and neck cancers are treated with surgery or radiotherapy or a combination of the two. Table 4 shows the incidence (Office of National Statistics [8]) of cancers in various head and neck sites in a typical Network, the proportion of patients treated with surgery (based on data from the SWAHN II audit [5]), and the expected number of patients to which this corresponds.

Table 4: Incidence and surgery numbers in a typical Network

Cancer Site	**Annual incidence**	**Proportion of patients receiving surgery**	**Number of patients receiving surgery**
Oral	67	66.4%	44
Pharyngeal	39	31.7%	12
Laryngeal	55	17.9%	10
Salivary gland	13	85.7%	11
Other	10	55.7%	6
Thyroid	32	N/A*	N/A*
Total	**216**	**46.5%**	**83**

* The SWAHNII audit does not include thyroid cancers

Based on these figures, a typical Cancer Network of 1.5 million could expect to operate on 1.6 UAT patients per week (assuming 37 Networks).

8.2 Activity

8.2.1 Current Activity

Cancers of the Upper Aerodigestive Tract (UAT)

Hospital Episode Statistics (HES) data have been obtained for patients with a diagnosis of head and neck cancer [9]. Data from 2000 to 2001 has been used in the analysis, as this is the most recent data available which provides a breakdown of all surgical procedures. Problems exist with the use of HES data to identify current activity: not only are the data somewhat out of date, but coding problems mean that there are some inaccuracies. We have been unable to fully validate the HES data in any one Network / hospital because of a lack of adequate data from any other source. However via discussions with surgeons within 3 different Cancer Networks, we have informally validated the data and identified specific problems with their local data.

Data was also collected from Health Solutions Wales on the level of surgical activity in the three Welsh Cancer Networks. Of these, only the South Wales Network covers a population comparable with many English Networks, with a similar number of radical procedures being carried out as in the North Trent region. The Mid-Wales Network covers a much smaller population, and hence the volume of head and neck surgery is considerably lower. The North Wales Network is thought to be relatively well centralised, with relatively low surgery figures owing to the small population.

Table 5 shows the proportion of radical procedures which were carried out in the Cancer Centre for head and neck cancer patients. "Radical" surgery covers the more complex major procedures (including procedures such as laryngectomies, pharyngectomies, resections and skull-base surgery), for which patients would benefit from being operated on by an experienced surgeon who performs such operations on a regular basis, A list of procedures classed as "radical" for the purposes of this analysis is given in Box 1.

Box 1: **List of "radical" surgical procedures**

Category 3 procedures	Microtherapeutic endoscopic extirpation of lesion of larynx; Microtherapeutic endoscopic resection of lesion of larynx.
Category 4 procedures	Excision of pharynx (other specified) Excision of pharynx (unspecified)
Category 5 procedures	Open excision of lesion of pharynx Partial glossectomy Total excision of parotid gland Excision of lesion of larynx using thyrotomy as approach Excision of lesion of larynx using lateral pharyngotomy as approach.
Category 6 procedures	Total pharyngectomy Partial pharyngectomy Total laryngectomy Partial vertical laryngectomy Partial horizontal laryngectomy Laryngectomy nec Total glossectomy
Thyroid procedures	Total thyroidectomy Sub-total thyroidectomy

Table 5: Proportion of radical surgery carried out in Cancer Centre by Network, assuming one Centre per Cancer Network

Cancer Network	**Proportion of radical surgery carried out in Centre (Head and Neck cancer patients)**
North Trent	49.25%
Four Counties	59.29%
Yorkshire	71.07%
Pan-Birmingham	29.67%

This data shows the variability in the degree to which centralisation already exists. The majority of surgery in the North Trent Network is split between Sheffield and Doncaster, which together make up 78% of all radical surgery in the Network.. A similar pattern is seen in the Pan-Birmingham Network, where 77% of all radical surgery takes place at either the University Hospitals or at Sandwell Hospital.

Neck Dissections

Neck dissections are perhaps the most common procedure for patients with head and neck cancer, but despite an OPCS4 code existing for this group of procedures, they

are not recorded in the HES data. The number of these operations carried out per year has therefore been estimated through consultations with head and neck surgeons.

This absence of neck dissection data has a knock-on effect on post-treatment services, because such primary surgery can require an in-patient stay of several days. Based on discussions with a number of ENT / head and neck surgeons, it has been assumed that a typical Cancer Network would perform 60 neck dissections per annum. It is assumed that the neck dissection would be the primary surgical procedure in 50% of these cases, while in the remaining 50% of cases the neck dissection has been assumed to be performed in conjunction with another procedure. The distribution of these between the Cancer Centres and Units has been assumed to be equivalent to other "radical" procedures, equating to 15 neck dissections being carried out at the Centre with the remaining 15 being carried out in the Units.

Thyroid Cancer

The guidance recommends that all patients with thyroid cancer, including those whose cancer is discovered during surgery for apparently benign disease, should be referred for management by thyroid cancer MDTs. These MDTs will also only be required in large Centres (those which serve populations in excess of a million). Thyroid cancer MDTs may manage patients with both malignant and non-malignant disease. Because of the relatively low incidence of thyroid cancer, it is anticipated that specialist thyroid cancer MDTs would only be required in large Centres (those serving a population in excess of one million).

Around 80% of patients with thyroid cancer require a total thyroidectomy, a procedure which requires expertise in thyroid surgery to prevent problems such as voice change and hypoparathyroidism. In the past, thyroid surgery has often been carried out by general surgeons; however, there has been a trend towards more specialist treatment by ENT surgeons in recent years [10]. Such surgery may be carried out in Cancer Units, providing the referring surgeon has sufficient expertise and with the agreement of the MDT. Alternatively, the referring surgeon may work with the specialist surgeon in the MDT, with the surgery taking place in the Cancer Centre. However, further treatment, such as ablation of residual thyroid tissue, is likely to require expertise and facilities only available at Cancer Centres. From the HES data,

it is currently estimated that only around half of all total thyroidectomies for patients with head and neck cancer take place at the Cancer Centres.

Hormone and calcium supplements are required by patients for life, and long-term monitoring by members of the MDT should be made available (this necessitates annual visits to see a member of the thyroid cancer MDT, and for the maintenance of appropriate levels of thyroid hormones). Long-term supportive care for thyroid cancer patients is already recommended, and so the guidance is expected to act as a means of reinforcing this recommendation, and is not expected to incur significant additional costs. The specialist level of support required by UAT cancer patients is not expected to be required for thyroid patients in addition to the supportive care already mentioned.

8.2.2 Future Activity

The implication from the guidance is that a significant proportion of surgery will move to the Cancer Centres, with the exception of some minor procedures to remove early tumours, which would be carried out by nominated surgical specialists in District General Hospitals.

For the purposes of the economic analysis, we consider two Scenarios relating to surgical activity. Firstly that only radical surgery is centralised and secondly that all surgery is centralised.

8.3 Costs

The costs involved in centralisation of surgery fall into several categories: -

- Cost of the surgical procedure itself;
- In-patient costs (specialised head and neck wards);
- Cost of rehabilitation and other support services.

The cost of transferring the surgery to the Cancer Centre will include the costs of providing extra medical, nursing support staff in the Centres to cope with additional patients. In some cases the costs of building extra facilities to cope with the extra caseload will be required, but these costs will vary by Network and have been excluded form the analysis.

Costs have been obtained from a number of different sources. Reference Costs from 2003 [11] have been used, which group surgical procedures into categories depending on their site and complexity, and assign a standard cost to each group of procedures (Box 2 shows the point estimates used for these groups). Reference Costs include the cost of surgery, plus any in-patient stay required by the patient.

Box 2: Reference Costs 2003

HRG Category	Reference Cost
Category 1 Ear Procedures	£820
Category 1 Nose Procedures	£863
Category 1 Mouth and Throat Procedures	£1,003
Category 2 Ear Procedures	£1,121
Category 2 Nose Procedures	£1,061
Category 2 Mouth and Throat Procedures	£1,008
Category 3 Ear Procedures	£1,227
Category 3 Nose Procedures	£979
Category 3 Mouth and Throat Procedures	£889
Category 4 Ear Procedures	£1,562
Category 4 Nose Procedures	£1,293
Category 4 Mouth and Throat Procedures	£1,396
Category 5 Ear Procedures	£2,031
Category 5 Nose Procedures	£1,545
Category 5 Mouth and Throat Procedures	£2,933
Category 6 Mouth and Throat Procedures	£6,778
Thyroid Procedures	£1,962
Parathyroid Procedures	£1,831

Reference Cost data has also been used to estimate costs of neck dissections. The 2003 data gives an average cost of a neck dissection of £2,002. The costs of neck dissections which are carried out as part of more radical procedures are assumed to be absorbed into the costs of the primary operation.

Data from an audit by Corbridge and Cox [12] has also been used in the analysis, which estimated that the average cost of treating a head and neck in-patient to be £11,450.

This cost includes the cost of the inpatient stay, cost of surgery , cost of rehabilitation (physiotherapy, dietetics, SLT and liaison nurse) and overheads. However the costs of pre-operative assessment and post-discharge care or re-admissions are not included and therefore these costs are considered to be a minimum total cost. This figure has been scaled up by an annual factor of 1.5% [8] to reflect current costs. The figure used in subsequent calculations is £12,335.

In addition to these cost estimates, data has been sought from a major costing study carried out in Liverpool , which suggest that the cost per major head and neck case is higher than the figures quoted so far. This data is not yet available, but will be incorporated into the final report if it becomes available before the publication date.

8.4 Cost Impact

The costs of surgery for patients with a diagnosis of head and neck cancer have been estimated in two Cancer Networks: North Trent and Four Counties. The cost impact has been estimated based on the HES data for 2000 to 2001, in addition to the estimates of volumes of neck dissection surgery mentioned earlier.

8.4.1 North Trent Cancer Network

Table 6 summarises the breakdown of surgical procedures in the North Trent Network, according to HealthCare Resource Group (HRG) categories. This system categorises procedures according to their complexity (Category 1 being the simplest and Category 6 being the most complex): -

Table 6: Activity in North Trent Cancer Network- Surgical Procedures 2000 to 2001

Hospital Trust	**Number of Procedures per category.**						**Total no. of procedures**
	Cat 1	Cat 2	Cat 3	Cat 4	Cat 5	Cat 6	
Sheffield	0	5	22	4	16	19	66
Doncaster	0	7	13	0	7	8	35
Chesterfield	0	3	6	4	9	2	24
Rotherham	0	5	6	0	2	0	13
Barnsley	0	2	4	0	2	0	8
Total	**0**	**22**	**51**	**8**	**36**	**29**	**146**

The various cost data discussed in the previous Chapter have been applied, to give estimates of costs to the Cancer Centre (Sheffield) of this surgery pattern. Using the NHS Reference Cost data from 2003, the current cost of surgery in Sheffield is

estimated at £205,000. Using the Corbridge and Cox cost data gives an estimated cost of £800,000.

Scenario A: only radical surgery is centralised

Under the guidance, it is assumed that radical surgery would move to the Cancer Centre. For simplicity, it has been assumed that "radical" surgery covers operations in HRG categories 5 and 6, plus any neck dissections.

Two examples are considered for North Trent: firstly that all radical surgery is centralised on one site (assumed to be Sheffield as this currently has largest volume of procedures) and secondly that surgery is centralised at 2 locations: Sheffield and Doncaster (both of which currently undertake a significant volume of surgery). The impact of the first scenario on surgery volumes is shown in Table 7: -

Table 7: Impact of centralisation of radical surgery within the North Trent Cancer Network (Assuming all surgery moves to Sheffield)

Hospital Trust	Current			Future			Change		
	Cat 5	Cat 6	Total	Cat 5	Cat 6	Total	Cat 5	Cat 6	Total
Sheffield	16	19	35	36	29	65	20	10	30
Doncaster	7	8	15	0	0	0	-7	-8	-15
Chesterfield	9	2	11	0	0	0	-9	-2	-11
Rotherham	2	0	2	0	0	0	-2	0	-2
Barnsley	2	0	2	0	0	0	-2	0	-2
Total	**36**	**29**	**65**	**36**	**29**	**65**	**0**	**0**	**0**

In the first instance, using the 2003 NHS Reference Costs, the estimated costs to Sheffield would be £330,000 per annum, an increase of £125,000 on the current surgery pattern (from Table 7). Using the Corbridge and Cox data would create a corresponding cost to Sheffield of £1.6m, representing an increase of £370,000 per annum. It is expected that the cost savings at the remaining hospitals would be minimal, given that the associated fixed costs would not be released from these hospitals.

In the second instance it is assumed that surgery is undertaken on two sites. The North Trent Network covers a relatively large population (approximately 1.8 million), and there are currently two hospitals at which large volumes of surgery are undertaken (Sheffield and Doncaster), each operating with its own MDT. In this example it is assumed that patients from Chesterfield and Barnsley are transferred to Sheffield, and

those from Rotherham to Doncaster. As before, the impact of moving only patients requiring either HRG Category 5 or 6 surgery has been considered. This would imply that 27 Category 5 procedures and 21 category 6 procedures would be carried out at Sheffield, and 9 Category 5 and 8 Category 6 procedures at Doncaster. Using Reference Cost data, this would increase costs at Sheffield by £46,000 per annum, and £6,000 per annum at Doncaster. Using the Corbridge and Cox data, the corresponding additional costs would be £160,000 (Sheffield) and £25,000 (Doncaster).

If it is assumed that of the 30 neck dissections carried out per year, 15 of these would be split equally between Sheffield and Doncaster (the other 15 would be carried out at hospitals in the periphery); the total cost to each hospital would therefore be £15,000, also based on Reference Cost data.

Scenario B: all surgery is centralised

In Scenario B it is assumed that *all* surgery is centralised at the Cancer Centres. In the North Trent Network, this would increase the volume of surgery in Sheffield from 66 cases per annum to 146 per annum. The anticipated total cost of performing all surgery at Sheffield would be £380,000 per annum (using the NHS Reference Cost data), an increase of £175,000 per annum. Centralisation of all neck dissections at Sheffield would increase the costs by £30,000 at the Centre. The Corbridge and Cox cost data is not used in this example on the basis that it is likely overestimate the cost of more minor surgery.

If **all** surgery were to move to either centralise at Sheffield or Doncaster, the costs at Sheffield would increase to £270,000, an increase of £64,000 per annum compared to current costs, while those at Doncaster would increase by £16,000 to £110,000 (using Reference Cost data). Assuming that the neck dissections which are currently done in the periphery would be move to Sheffield and Doncaster in equal proportions, this would increase costs by a further £15,000 at both locations.

8.4.2 Four Counties Network

Similar calculations have been carried out for the Four Counties Network, which has a Cancer Centre at Oxford, and whose population base is around 2.75 million people.

Table 8 shows the breakdown of surgery volume by hospital trust and HRG Category for the 2000 to 2001 data.

Table 8: Activity in Four Counties Cancer Network - Surgical Procedures in 2000 to 2001

Hospital Trust	Number of Procedures per category.						Total no. of procedures
	Cat 1	Cat 2	Cat 3	Cat 4	Cat 5	Cat 6	
Oxford	2	12	38	6	18	32	137
Northampton	0	5	6	7	5	6	18
Kettering	0	2	2	1	1	4	5
Berkshire and Battle	0	2	4	3	4	3	9
Milton Keynes	0	0	4	0	1	4	4
Stoke Mandeville	0	1	2	0	1	0	3
Total	**2**	**22**	**56**	**17**	**30**	**49**	**176**

As with the North Trent data, the costs have been assessed using the two different cost assumptions. The current cost to the Cancer Centre at Oxford are estimated to be £325,000 per annum (using Reference Costs), compared with £1.7m (using Corbridge and Cox).

Scenario A: only radical surgery is centralised

Under the assumption that all Category 5 and 6 procedures would move to the Centre at Oxford under the new guidance, the impact on surgery volume in the different hospitals is shown in Table 9: -

Table 9: Impact of centralisation of radical surgery within the Four Counties Cancer Network

Hospital Trust	Current			Future			Change		
	Cat 5	Cat 6	Total	Cat 5	Cat 6	Total	Cat 5	Cat 6	Total
Oxford	18	32	50	30	49	79	12	17	29
Northampton	5	6	11	0	0	0	-5	-6	-11
Kettering	1	4	5	0	0	0	-1	-4	-5
Berkshire and Battle	4	3	7	0	0	0	-4	-3	-7
Milton Keynes	1	4	5	0	0	0	-1	-4	-5
Stoke Mandeville	1	0	1	0	0	0	-1	0	-1
Total	**30**	**49**	**79**	**0**	**0**	**0**	**0**	**0**	**0**

Applying the Reference Costs to this data would indicate a total cost to Oxford of £475,000, representing an increase of £150,000. Using the Corbridge and Cox cost data would give a total cost to Oxford of just over £2m, an increase of £360,000.

As with the North Trent Network, the distribution of neck dissections between the hospitals in the Four Counties Network is unknown, and so it has been assumed that there would be 15 per year, at an additional cost of £30,000 to the Centre at Oxford.

Scenario B: all surgery is centralised

An assessment has also been made of the impact of centralising all surgery at the Cancer Centre. This would increase the number of procedures being carried out at Oxford from 137 to 262, giving a total cost of £520,000, representing an increase of £195,000 (using HRG Reference Costs). The costs associated with neck dissections would be £60,000 per annum, as above. The Corbridge and Cox cost data is not used on the basis that it is likely overestimate the cost of more minor surgery.

8.5 Cost Impact (thyroid cancers)

As with UAT cancers, the costings are based upon the centralisation of surgery in the North Trent and Four Counties Cancer Networks. It has been assumed that radical surgery relates to total thyroidectomies and sub-total thyroidectomies in the case of thyroid cancers.

8.5.1 North Trent Cancer Network

Table 10 summarises the distribution of thyroid surgery in the North Trent Network, in addition to the estimated costs: -

Table 10: Thyroid surgery volume in the North Trent Cancer Network 2000-01

Hospital Trust	Total number of thyroid procedures (including radical)	Number of radical thyroid procedures	Cost (Reference Cost data)
Sheffield	34	6	£66,708
Doncaster	8	3	£15,696
Chesterfield	3	2	£5,886
Rotherham	1	0	£1,962
Barnsley	3	0	£5,886
Total	**49**	**11**	**£96,138**

Assuming that "radical" thyroid surgery all moved to the Centre, this would involve the transfer of 5 procedures per year to Sheffield (4 total thyroidectomies and 1 sub-

total thyroidectomy). This would increase the total cost to Sheffield to £76,500 per annum, an increase of £10,000 per annum (based on Reference Cost data).

If all thyroid surgery was centralised, the total cost at Sheffield would be £96,000 based on HRG Reference Costs, an increase of approximately £30,000 per annum compared to the current Scenario.

8.5.2 Four Counties Network

Table 11 summarises the current distribution of thyroid surgery in the Four Counties Network, along with cost estimates.

Table 11: Thyroid surgery volume in the Four Counties Cancer Network 2000-01

Hospital Trust	Total Number of thyroid procedures (including radical)	Number of radical thyroid procedures	Cost (Reference Cost data)
Oxford	44	8	£86,328
Northampton	16	2	£31,392
Kettering	14	8	£27,468
Berkshire and Battle	7	4	£13,734
Milton Keynes	3	1	£5,886
Stoke Mandeville	2	0	£3,924
Total	**86**	**23**	**£168,732**

If all radical thyroid surgery was centralised at Oxford, this would mean an extra 15 thyroid procedures would be carried out at the Centre (all total thyroidectomies). This would increase the total cost at Oxford to £116,000 per annum, an increase of £30,000 per annum (based on Reference Costs).

Centralising all thyroid surgery at Oxford would almost double the number of thyroid procedures carried out in the Centre from 44 to 86 per annum. This would increase the cost of thyroid surgery at Oxford to £168,700, based on Reference Costs.

8.6 Summary of Results

Based on the results presented, the total costs associated with the centralisation of radical surgery in any Cancer Network are made up of the following components: -

- UAT surgery
- Neck dissections
- Thyroid surgery

The estimated additional costs (based on Reference Cost data and data from Corbridge and Cox) of the centralisation of radical surgery (Scenario A) in the North Trent Network at Sheffield are as follows: -

Table 12: Total annual costs of centralisation of radical surgery in Sheffield (Scenario A)

Cost component	Current volume (all procedures)	Future volume (all procedures)	Additional costs (Reference Costs)	Additional Costs (Corbridge and Cox data)
UAT surgery	66	96	£125,000	£370,000
Neck dissections	15	30	£30,000	£185,000
Thyroid surgery	49	54	£10,000	£60,000
Total	**164**	**214**	**£165,000**	**£615,000**

The additional annual cost to Sheffield is estimated to be £165,000. Using the two-Centre scenario, whereby radical surgery is centralised at Sheffield and Doncaster, the total additional costs would be £72,000 and £13,000 at the two sites respectively compared with current costs, using Reference Cost data. Applying the Corbridge and Cox data would result in corresponding increases of £325,000 and £130,000 respectively (including surgery on UAT and thyroid cancers, plus neck dissections).

Under the Scenario of all surgery being centralised at Sheffield, the costs are expected to be as follows (using Reference Costs): -

Table 13: Total costs of complete centralisation of all surgery in Sheffield (Scenario B)

Cost component	Estimated current annual cost	Estimated future annual cost	Additional cost (Reference Costs)
UAT surgery	£205,000	£380,000	£175,000
Neck dissections	£30,000	£60,000	£30,000
Thyroid surgery	£67,000	£96,000	£29,000
Total	**£302,000**	**£536,000**	**£234,000**

The centralisation of all head and neck surgery in Sheffield is therefore expected to cost an additional £234,000 per annum.

By comparison, the cost estimates for the Four Counties Network, assuming centralisation of radical surgery (Scenario A) at the Centre in Oxford, would be as follows: -

Table 14: Total costs of centralisation of radical surgery in Oxford (Scenario A)

Cost component	Current volume (all procedures)	Future volume (all procedures)	Additional costs (Reference Costs)	Additional Costs (Corbridge and Cox data)
UAT surgery	137	166	£150,000	£360,000
Neck dissections	15	30	£30,000	£185,000
Thyroid surgery	44	59	£30,000	£185,000
Total	**196**	**255**	**£210,000**	**£730,000**

The figure of £210,000, representing the additional annual cost of the centralisation of radical surgery is higher than the equivalent figure for the North Trent Network given in Table 12 – this can be explained in part by the difference in population between the two Networks. Under the assumption that all head and neck surgery in the Four Counties Network would be centralised at Oxford, the estimated costs (based on Reference Cost data) would be as below: -

Table 15: Total costs of centralisation of all surgery in Oxford (Scenario B)

Cost component	Estimated current annual cost	Estimated future annual cost	Cost Increase
UAT surgery	£325,000	£520,000	£195,000
Neck dissections	£30,000	£60,000	£30,000
Thyroid surgery	£86,000	£169,000	£83,000
Total	**£441,000**	**£749,000**	**£308,000**

The centralisation of all surgery would increase the costs at Oxford by over £300,000 compared to current practice, based on Reference Cost data.

Since both of the Networks considered in this analysis have population bases in excess of the average of 1.5 million (North Trent covers around 1.8 million and Four Counties covers around 2.75 million), the costs have been adjusted to demonstrate the potential cost implications for a typical Cancer network of 1.5 million. allow a model of the total cost impact across England and Wales to be developed. The results of this are shows in Table 16, based on both the Reference Cost data and data from Corbridge and Cox: -

Table 16: Estimated additional costs to the Cancer Centre in a typical Network

Network	NHS Reference Costs		Corbridge and Cox data
	Estimated additional costs (radical surgery centralised)	**Estimated additional costs (all surgery centralised)**	**Estimated additional costs (radical surgery centralised)**
Estimated from North Trent costs	£137,500	£195,000	£510,000
Estimated from Four Counties costs	£140,000	£205,000	£485,000

In order to estimate nationwide costs, these figures from the two Networks have been averaged, to give an additional cost per Network of £138,750 per annum if all radical surgery is centralised (£498,500 if Corbridge and Cox data are used), compared with an additional cost of £200,000 per annum if all surgery is centralised.

Based on these figures, the cost impact of centralising all radical surgery at the Cancer Centres would be £4.7 million per annum (based on Reference Costs), compared with £6.7 million if all surgery was centralised. The Corbridge and Cox costs are likely to include an element of double counting given that they include the costs of support services provided by clinical nurse specialists, dietitians etc which are reported separately in this report.

The costs could be expected to vary greatly between Networks because of the differences in population coverage and incidence of head and neck cancers within different Networks.

8.7 Discussion of Centralisation Issues

Centralisation of surgery has already taken place in some Cancer Networks. For example, the Merseyside and Cheshire Network has recently transferred the majority of surgery to the Cancer Centre at Aintree. This has however resulted in increased waiting times for patients and increased workload for surgeons and nurses at Aintree, due to a lack of resources both in terms of the number of surgeons and the space available. [13] The SWAHN II audit indicates that centralisation had occurred by default in the South Coast Network, but that little move towards centralisation has occurred in the other Cancer Networks covered by the audit. No additional resources were made available to the South Coast Network resulting in a significant increase in workload and stress to existing staff at the Cancer Centre in Southampton, accompanied by increased waiting times for patients.

The case for centralising surgery in one location will not always be straightforward. For instance in the North Trent Cancer Network, two hospitals, Royal Hallamshire Hospital, Sheffield and the Doncaster Royal Infirmary, both have their own independent MDTs and receive patients referred from other DGHs in the Network. Currently both hospitals perform high volumes of surgery. Neither hospital has the facilities to accommodate all the surgical cases for the entire Network.

Centralisation of surgery can cause problems too in Networks which cover a large geographical area. For example, in the Peninsula Network, which covers Devon and Cornwall, the centralisation of the service at the Cancer Centre in Exeter would involve lengthy journeys for some patients. Patel et al [14] estimated that such a process would involve patients travelling on average 840 miles further during the course of their treatment, compared to them being treated at their local DGH. In such Networks, it may therefore be inappropriate to centralise the service, given that members of the MDT would also be required to travel long distances to attend MDT meetings.

In some of the larger Cancer Networks, the sheer volume of surgery moving under Scenario B (where all surgery is centralised) could have staffing implications at the Cancer Centres. This could lead to escalating waiting times, and increased pressure on staff and resources.

The impact at Network level will depend primarily on the size of the Network, and the degree to which centralisation has already taken place. For example, a large Network such as the Four Counties Network, could expect to carry out roughly 1 additional radical procedure per week under Scenario A (all radical surgery centralised), or 2 per week under Scenario B. By contrast, a small Network such as North West Midlands (and in which 75% of head and neck cancer surgery is carried out at the Centre) would see a relatively small change, with the movement of around 25 procedures per year under Scenario B.

9. Radiotherapy

9.1 Background

Radiotherapy is one of the major treatment indications for patients with head and neck cancer, with around 70% of all patients receiving this type of treatment. The discussion of the provision of radiotherapy services within the guidance manual is not extensive, mentioning the need to avoid gaps in treatment, the extended use of chemoradiotherapy and the need for greater support for patients who undergo radiotherapy (e.g. for problems with swallowing, eating and speech). A number of other issues have been identified through conversations with clinical oncologists, and these are discussed in the following sections..

There are currently 48 radiotherapy facilities in England and Wales, not all of which are based at specialist Cancer Centres. Some of the smaller centres do not currently deal with a large number of patients and are therefore being closed down, with large, new centres being developed to relieve the pressure on centres which are currently overwhelmed with patients. The guidance is not however expected to lead directly to an increase in the need for new radiotherapy centres.

9.2 Chemoradiotherapy and altered fractionation regimens

The guidance manual states that *"synchronous chemoradiation or altered fraction regimens should be available for selected patients. These more intensive forms of treatment are appropriate for patients with advanced disease who are fit enough to deal with their adverse effects"*. Chemoradiotherapy has been used increasingly over the past few years as a means of supplementing the use of conventional radiotherapy with the addition of chemotherapy. It is considered suitable only for patients with

locally advanced disease (Stage III or IV) and who are physically fit. However, since fitness is a matter of opinion, the proportion of patients being treated with chemoradiotherapy varies greatly between centres.

Currently, it is estimated that around 70% of patients with a diagnosis of head and neck cancer receive radiotherapy at some point in their treatment programme, of which roughly 20% receive chemoradiotherapy (i.e. 14% of all patients). The service is not currently offered by all radiotherapy centres in the United Kingdom; those which do not are being encouraged to do so, whilst those which only use it sparingly are also being encouraged to use it more extensively. It is expected that chemoradiotherapy as a treatment indication will be discussed more routinely in individual patient discussions at the MDT meeting.

Through consultations with clinical oncologists, it has become clear that, although many radiotherapy centres have the capacity and facilities to offer altered fractionation regimens, only a minority of patients are treated in this way because of the high cost associated with changing the fractionation. The guidance does not imply that a significant number of additional patients would be treated in this way in the future, and hence no economic analysis has been performed.

9.3 Current Activity

A number of clinical oncologists have been consulted in determining the current levels of radiotherapy use and specifically the use of chemoradiotherapy. The following assumptions regarding current provision are based on these consultations and have been applied in the cost calculations: -

- 70% of head and neck cancer patients currently receive radiotherapy;
- 20% of these patients currently get chemoradiotherapy.

9.4 Future Activity

It is anticipated that under the guidance, the proportion of head and neck cancer patients receiving radiotherapy who would receive chemoradiotherapy would increase from 20% to 30%. Based on an annual incidence of head and neck cancer of 7,500 cases, this would equate to roughly 1,050 patients currently receiving chemoradiotherapy, compared to a figure of 1,575 under the guidance.

9.5 Costs

Chemoradiotherapy usually consists of a period of 4 to 6 weeks' radiotherapy treatment, including two or three chemotherapy sessions. The way in which chemoradiotherapy is administered varies between centres; for example, some centres treat patients on an in-patient basis, typically requiring a number of separate overnight stays for the patient, whilst others treat patients on a day-case basis. The additional cost of treating a patient with chemoradiotherapy as opposed to standard radiotherapy depends on whether or not the patient is treated on a day-case or in-patient basis. This additional cost would typically be made up of a drug cost, an administration cost, and the cost of supportive care (e.g. dietetic support).

Assuming that patients treated on an in-patient basis would require 3 separate overnight stays at a cost of £946 per stay (this cost is fixed irrespective of the length of each stay), the cost of a course of chemoradiotherapy could be expected to be around £2,838, in addition to the drug and pharmacy costs for chemotherapy (around £210) to give a total of £3,048 per patient, plus the cost of the radiotherapy itself. If patients were treated on a day-case basis, the cost would be considerably lower, with each day-case session estimated to cost £78; a typical course would require 6 such sessions, which when combined with the drug and pharmacy costs would give a cost per patient of £678, plus the cost of radiotherapy. [15]

9.6 Cost impact

It is estimated that an additional 525 head and neck cancer patients would be treated with chemoradiotherapy per year (1,575 compared with 1,050 currently); this equates to an additional 14 patients per Cancer Network. If all such patients were treated on a day-case basis, the annual cost per Network of providing chemoradiotherapy would currently be estimated to be around £19,000, compared with around £29,000 under the guidance i.e. an additional cost of around £10,000 per annum per Network. If this

result is scaled up to encompass all 37 Cancer Networks in England and Wales, the estimated additional cost is expected to be around £355,000 per annum.

By contrast, if all patients were treated on an in-patient basis, this would currently cost £86,000 per year per Network, compared with £130,000 under the guidance (an additional cost of £44,000 per Network per annum). Across the whole of England and Wales, the additional cost is expected to be around £1.6 million.

Assuming that half of patients receive chemotherapy as an inpatient and the other half receive it as a day case the total cost implications are £79,000 for the Cancer Network and £2.93 million for England and Wales as a whole (an increase of around £1 million on current costs).

9.7 Other Radiotherapy Issues

The guidance highlights a number of other issues which relate to the provision of radiotherapy care. These issues have not been costed either because the cost impact is expected to be minimal, or because the issue is not a direct outcome of the guidance, and is being dealt with by other means.

9.7.1 Treatment interruptions

The guidance states that "radiotherapy departments should make every effort to ensure that each patient receives a complete and unbroken course of the prescribed treatment; gaps in treatment must be avoided if at all possible".

These recommendations re-enforce existing recommendations on minimising the incidence of treatment interruptions. Treatment interruptions are sometimes unavoidable – some patients will have gaps in their treatment, the vast majority of these being due to clinical reasons. Delays can also be caused by a lack of machinery or qualified staff.

Radiotherapy centres should have a systematic protocol in place to avoid delays in treatment (e.g. if a machine breaks down). The guidance is not however expected to have a significant impact on the level of treatment interruptions. The radiotherapy service would clearly benefit from the purchase of new, high-precision equipment in order to minimise interruptions in treatment. However, the guidance does not explicitly state that this should be done, and so this has not been costed.

9.7.2 Brachytherapy

The guidance manual states that *"each Network should make arrangements for provision of brachytherapy for selected patients. Brachytherapy need not be provided in every Network, but where it is not available, there should be specific agreements for referral between Networks"*.

Brachytherapy is not a widely used treatment indication, having been largely replaced by surgery. Few centres offer brachytherapy, and many of these only treat a handful of patients in this way each year. Given the small volume of patients involved brachytherapy is not considered to be a major cost issue.

9.7.3 Waiting Times and Equipment

The guidance states that "the interval between surgery and radiotherapy should be as short as possible, ideally less than six weeks."

The length of time which patients wait between a treatment plan being drawn up and commencing radiotherapy treatment is currently one of the main issues in the radiotherapy service. This average waiting time varies greatly between radiotherapy centres in the country and is caused by the increasing incidence of cancer, an ageing population, the increasing diversity of treatment indications involving radiotherapy. These problems are exacerbated by the difficulties involved in recruiting radiographers and physicists and a lack of modern equipment (particularly linear accelerators). The situation is serious enough in some Networks that some patients waiting for radiotherapy are given chemotherapy initially as an alternative treatment.

There is a serious shortage of modern equipment throughout the country, as highlighted in a recent publication by the Royal College of Radiologists (2003). These problems are being addressed through the 2003 to 2006 Government spending plans and the NHS Cancer Plan, which include an equipment replacement programme of around 60 linear accelerators throughout the UK. However, the radiotherapy service also needs further investment in CT simulators and new planning computers to allow the replacement linear accelerators to be used to their optimum. This extra provision is not expected to meet demand in 2006 because it was based on the demand in 1997 and not on predicted demand for 2006. Staffing for radiotherapy centres can only be increased through sustained significant increases in training places for clinical oncologists, radiographers and medical physicists. [16]

The new guidance is not expected to exacerbate the problems relating to either waiting times or new equipment needs. Consequently, the cost implications of these issues are not assessed here, as they are being dealt with through other initiatives e.g. the Cancer Plan.

9.7.4 Radiotherapy Support Clinics

The guidance states that "Patients treated with radiotherapy need access to support over a protracted period, both in their homes and in the radiotherapy centre. Radiotherapy departments should have radiotherapy support clinics, staffed by cancer nurses and/or therapy radiographers who receive education and support from head and

neck cancer CNSs. Patients should have access to a specialist oncology dietitian and speech therapist within the radiotherapy centre, who should liaise with local support teams".

This service may require input from radiologists, and patients would need access to a specialist oncology dietitian and speech therapist within the radiotherapy centre, who should liaise with local support teams. It is anticipated that an additional local support team within the Cancer Centre could cover this extra support.

10. Local Support Teams

10.1 Background

Patients treated for head and neck cancer generally need a high level of post-treatment supportive care; the particular needs of this group of patients are not covered in the Supportive and Palliative Care guidance. The guidance recommends a new model of provision of support and rehabilitation service: *"every Cancer Unit and Cancer Centre which deals with patients with head and neck cancer should establish a flexible local support team, providing services to a defined geographical area. Each such team should work closely with the Cancer Centre staff and primary care teams and provide access to the expertise required to manage the rehabilitation needs of its patients".*

Current provision of post-treatment supportive care is poor, and hence the cost implications are likely to be significant.

Local support team members

The guidance recommends that a typical local support team should consist of the following members: -

- a clinical nurse specialist (CNS) in head and neck cancer;
- a speech and language therapist (SLT);
- a dietitian;
- an ENT/maxillofacial nurse practitioner;
- an occupational therapist;

- a social worker;
- a physiotherapist;
- a psycho-oncology, liaison psychiatry or clinical psychology services;
- a dental hygienist;
- local patients (not costed within this report).

Not all members of each team would be required full-time: this is discussed later.

One member of each team (any of the above roles) should work in conjunction with the MDT members and the patient to draw up a written rehabilitation plan, and take formal responsibility for co-ordinating the care provided by the team for that patient. Each patient should have a written rehabilitation plan (drawn up by the MDT members and the patient).

The cost implications for CNSs, SLTs and dietitians have been considered separately in chapters 4, 5 and 6. The costs described within this chapter are part of the total costs outlined in those chapters and are not additional costs.

10.2 Current position regarding local support teams

A number of Cancer Centres and Units have been consulted in order to estimate the current level of provision of support teams in England and Wales. The level of activity is generally low, with significant differences between provision in different Networks. For example, teams at the Centres in Aintree and Preston are well established and patients have dedicated access to the majority of the team members given above. However in many other Cancer Networks little dedicated input is available from the majority of team members. The provision also varies in terms of the availability of team members to head and neck cancer patients.

Cancer Centres

Based on these consultations, a number of assumptions about the current provision of support teams in Cancer Centres have been made, as follows: -

- 10% of Centres have a full support team. Of the remaining 90%: -
    - All have a CNS;

- 75% have a SLT;
- 50% have a dietitian.

In addition, it has been assumed in the current provision estimates given above that each member is dedicated full-time to head and neck cancer patients (i.e. 1 WTE). It is assumed that the current support teams do not contain input from any of the other roles mentioned earlier.

The cost of providing this level of service in a Cancer Centre is estimated to be around £92,000, which equates to a total of £3.4 million over the 37 Cancer Networks in England and Wales. Clearly, the cost per Centre would vary greatly between Centres depending on the level of care provided and the number of patients being seen, but this figure is given as an estimate of a "typical" Network.

Cancer Units

The provision of support teams in Cancer Units is even more patchy. Again, there is a degree of variability in the availability of staff, with many having responsibilities across a variety of therapeutic areas, and so not being solely dedicated to head and neck cancer patients. The following assumptions have been made about the provision in Cancer Units: -

- 25% of units have a CNS;
- 10% of units have a speech and language therapist;
- 10% of units have a dietitian.

It is assumed that none of the other support team members mentioned earlier are currently involved. Based on these assumptions, the cost of providing this level of service in a Cancer Unit is estimated to be around £14,380 which equates to a total of £2.4 million over the 37 Cancer Networks in England and Wales.

Combining the costs from Centres and Units gives a total cost of around £5.8 million for the whole of England and Wales, or £157,000 per Network. This makes the additional assumption that every Unit in England and Wales deals with a sufficiently large number of patients to warrant having a full team.

Alternative assumptions for current provision

Since the number of support team staff across England and Wales is unknown and has therefore been estimated, conservative estimates of the proportions of Centres and Units which currently have support team staff have been used thus far. An alternative scenario (see Chapter 10.6) assumes slightly higher estimates of current provision of support team staff, based on preliminary results from the Cancer Services Collaborative Questionnaire [1]. [TO BE UPDATED IN FINAL REPORT BASED ON ALL COMPLETED RESPONSES] The following assumptions have been made in this scenario concerning the provision in the Centres:-

- 20% of Centres have a full support team (previously 10%). Of the remaining 80%:-
    - All have a CNS
    - 90% have a SLT (previously 75%)
    - 75% have a dietitian (previously 50%).

The following assumptions have been made with regard to the current provision in the Units: -

- 50% of units have a CNS (previously 25%)
- 20% of units have a SLT (previously 10%)
- 20% of units have a dietitian (previously 10%).

The costs associated with providing this level of care are estimated to be £9.5 million per annum, or approximately £250,000 per Network.

10.3 Future Provision

For the purposes of the economic analysis, a number of assumptions have been made regarding the likely provision of these teams. A cost has been derived for the provision of support teams within a typical Cancer Network, based on the assumption that a Network covers a population of 1.5 million people. Within each such Network, it has been assumed that there is one specialist head and neck cancer centre (covering a population of 400,000 and providing tertiary care for the whole 1.5 million population), and four or five units (DGHs) covering the remaining 1.1 million (this was calculated by dividing the total number of Cancer Units by the number of Networks). It has been assumed that one team will be required in each Cancer Unit and two teams in each Cancer Centre, to reflect the greater volume of patients dealt with in the Centre i.e. an average of 6.5 teams per Network.

10.4 Cost Data

The calculations on the costs of providing a comprehensive patient support service are based on data on the salaries of the support team members as in Table 17. The data have been collected from a variety of published sources, and relevant expert opinion has been sought in order to determine the typical grade of each role on their particular pay scale.

Table 17: Support team members

Role	Annual salary (including on-costs)	Whole time equivalent	Salary source / assumptions
Clinical Nurse Specialist	£31,525	1	2002 *Grade H* NP57 spine 3.
Speech and Language Therapist	£41,834	1	The Royal College of Speech and Language Therapists
Dietitian	£28,398	1	2002 Senior I dietitian PL16 point 3

Nurse Practitioner	£24,374	1	2002 *Grade F* NP36 spine 3 *
Physiotherapist	£28,398	0.5	2002 Senior I PT PC16 point 3
Occupational Therapist	£28,398	0.5	2002 Senior I OT PB16 point 3
Social Worker	£25,419	0.25	Personal Social Sciences Research Unit (2003)
Clinical psychologist	£37,891	0.25	Personal Social Sciences Research Unit (2003)
Dental hygienist	£29,916	0.25	British Dental Hygienist's Association recommended remuneration pay scales (2003)

** It is acknowledged that some nurse practitioners are at nursing grade G as opposed to F, but the costings have been calculated using the salary of a grade F nurse.*

Applying these numbers to a typical Network of 1.5 million people, this would be equivalent to having 6 or 7 CNSs, SLTs, dietitians and nurse practitioners, 3 to 3.5 physiotherapists and occupational therapists, and 1.5 to 1.75 social workers, psychiatrists and dental hygienists per Network.

[ADDITIONAL FEEDBACK IS BEING OBTAINED ON THE POTENTIAL ROLE OF SLTs WITH THE LOCAL SUPPORT TEAMS – IN THE CURRENT REPORT IT IS ASSUMED THAT THE LOCAL SUPPORT TEAM TAKES ON A SIGNIFICANT ROLE IN THE LONG TERM REHABILITATION OF PATIENTS. HOWEVER THIS MAY NOT BE FEASIBLE GIVEN THE COMPLEXITY OF MANY OF THE CASES AND IT MAY BE NECESSARY FOR SPECIALIST SLTs AT THE CENTRE TO PLAY A GREATER ROLE THAN CURRENTLY ASSUMED]

Based on these salaries and whole time equivalents, one support team could be expected to cost £178,000 per annum.

In larger Cancer Networks, such as the Yorkshire Cancer Network with a population of 2.5 million,, the number of patients may be large enough to warrant full-time posts for the four key support team posts (CNS, SLT, dietitian and nurse practitioner). In

smaller Networks, or in areas with lower incidence of head and neck cancer, part-time posts at Units, or full-time posts shared between more than one Unit may be sufficient. An additional scenario has been assessed (see Chapter 10.6), in which for smaller Networks, it has been assumed that the level of input required at the Units is half of that at the Centre for all support team roles (i.e. 0.5 WTE CNS, 0.5 WTE SLT etc). This is equivalent to halving the number of support teams required in the periphery, giving an average of 4.25 teams per typical Network (compared with 6.5 previously). As an example of the staffing implications, this would mean that an additional 78 CNSs would be required, compared with an additional 162 under the previous set of assumptions.

10.5 Cost Impact

Each local support team is assumed to consist of the members listed above, with the clinical nurse specialist, the speech and language therapist, the dietitian and the nurse practitioner required full-time in each team, and the remaining members required part-time (see Table 17 for whole time equivalents).Table 18 shows the estimates of the additional number of staff (whole time equivalent) required in order to implement these changes in England and Wales: -

Table 18: Future staff requirements and associated annual costs

Team member	Current Number (WTE)	Current Cost	Future Number (WTE)	Future Cost	Additional Number (WTE)	Additional Cost
Clinical nurse specialist	79	£2,490,452	241	£7,597,455	162	£5,107,003
Speech and language therapist	46	£1,924,335	241	£10,081,947	195	£8,157,592
Dietitian	38	£1,079,128	241	£6,843,945	203	£5,764,816
Nurse practitioner	4	£97,496	241	£5,874,148	237	£5,776,652
Physiotherapist	4	£113,592	120	£3,407,773	116	£3,294,180
Occupational therapist	4	£113,592	120	£3,407,773	116	£3,294,180
Social worker	4	£101,674	60	£1,525,115	56	£1,423,440
Clinical psychologist	4	£151,566	60	£2,273,484	56	£2,121,918
Dental hygienist	4	£119,663	60	£1,794,940	56	£1,675,277
Total Cost		**£6,191,519**		**£42,806,580**		**£36,615,061**

Based on these assumptions the additional cost of providing local support teams over and above current levels is over £36 million per annum. This is equivalent to an

additional cost of nearly £1 million per annum per Cancer Network, though this will of course vary, depending on the current level of provision in each particular Network. The main costs come from the provision of the four full-time posts required within each team: the clinical nurse specialist, the speech and language therapist, the dietitian and the nurse practitioner. These costs reflect the cost of paying staff salaries, and do not take into consideration other costs such as travel and administration costs.

10.6 Alternative scenario

An alternative scenario have been carried out as discussed previously, through varying the assumptions made about current provision of staff and future requirements. This scenario makes the following assumptions: -

1. Support teams in the Units only require half as much input as those in the centres.
2. Current provision of staff is higher.

These two scenarios have been considered in conjunction with one another to estimate a possible upper and lower bound on the cost impact of the provision of local support teams. The results of these analyses are discussed below.

Table 19: Future staff requirements and associated annual costs (alternative scenario)

Team member	Current Number (WTE)	Current Cost	Future Number (WTE)	Future Cost	Additional Number (WTE)	Additional Cost
Clinical nurse specialist	120	£3,782,965	157	£4,949,379	37	£1,166,414
Speech and language therapist	67	£2,802,865	157	£6,567,907	90	£3,765,042
Dietitian	62	£1,760,683	157	£4,458,503	95	£2,697,820
Nurse practitioner	7	£170,618	157	£3,826,727	150	£3,656,109
Physiotherapist	7	£198,787	79	£2,243,451	72	£2,044,664
Occupational therapist	7	£198,787	79	£2,243,451	72	£2,044,664
Social worker	7	£177,930	39	£991,324	32	£813,394
Psychologist	7	£265,240	39	£1,477,764	32	£1,212,524
Dental hygienist	7	£209,410	39	£1,166,711	32	£957,301
Total Cost		**£9,567,284**		**£27,925,219**		**£18,357,934**

The total expected additional costs across the whole of England and Wales are therefore around £18 million per annum, or £500,000 per Network. The results of the base case analysis are compared with those from the alternative scenario analysis in Table20.

Table 20 Comparison of Scenarios

Scenario	Total Current Costs	Total Future Costs	Cost Increase
Base case	£6.2 million	£42.8 million	£36.6 million
Alternative	£9.6 million	£27.9 million	£18.3 million

It is clear from these results that the effect of changing the assumptions on current and future provision has a substantial impact on the estimates of future costs. The costs for a particular Network will depend on the population covered by the Network and the incidence of head and neck cancers within the Network.

[FURTHER, MORE DETAILED ANALYSIS IS CURRENTLY BEING UNDERTAKEN TO PROVIDE A CENTRAL ESTIMATE OF THE LIKELY SCALE OF THE IMPLICATIONS FOR A TYPICAL CANCER NETWORK and FOR ENGALND AND WALES AS A WHOLE. THE RESULTS WILL BE REPORTED IN THE FINAL VERSION OF THIS REPORT.]

10.7 Other Cost issues

A number of other potential cost implications arising from the rehabilitation and follow-up Chapter of the manual have been identified as follows: -

- Clinical follow-up e.g. to check for disease recurrence, late side-effects etc. – this is already standard practice and so will not be affected significantly by the guidance;
- Life-long surveillance for thyroid patients – it is already standard practice for thyroid cancer patients to be followed up for the rest of their lives, and hence the guidance identifies this as a means of re-enforcing previous recommendations.

11. Other Potential Cost Implications

11.1 Pre Treatment Assessment

The guidance recommends a number of assessments be made prior to patients receiving treatment, In order to inform appropriate treatment planning, a careful

assessment of each patient's medical, nutritional and psychological state is necessary.

Imaging

The guidance recommends that all patients with cancers of the UAT should have chest x-rays, in addition to other forms of imaging such as specialist ultrasound, CT and MRI imaging, which are required to assess the stage and the extent of the spread of the tumour. PET imaging should be used, where available, when it is important to distinguish between benign and malignant lung nodules. Imaging assessments of this nature are routinely carried out at present and as such the guidance on this issue is not expected to have any significant cost impact.

Dental Assessment

Patients whose treatment will affect the mouth or jaw should have a pre-treatment dental assessment. Many patients will require dental work prior to treatment to correct any existing dental problems. Patients who undergo radiotherapy (primarily those requiring treatment for cancers of the salivary glands and the jaw, constituting around 50% of all head and neck cancer patients receiving radiotherapy) often require pre-treatment dental care (since many patients have very poorly maintained teeth); such treatment should be carried out well in advance of the patient commencing radiotherapy, to allow time for healing and to reduce the risk of complications and infections during radiotherapy. It is also recommended that a dental hygienist should work with these patients to achieve a high standard of oral hygiene, in order to minimise dental problems post-treatment.

It is likely that the availability of a pre-treatment dental assessment for patients will depends upon whether the Centre / Unit has a restorative dentist as part of their MDT. Given that this is not always the case at present, many patients slip through the net. Some Centres / Units currently see such patients through a separate oncology support clinic, but this has not been implemented in many Units, resulting in a poor level of service. Shortages of NHS dentists are causing problems in some area. Hygienists work to a prescription from a dental practitioner and therefore need to work in tandem with the restorative dentist in the MDT.

Assessment by Speech and Language Therapist

Patients whose treatment will affect their speech or ability to swallow should be referred to a speech and language therapist prior to treatment. The speech and language therapist should explain rehabilitation strategies and describe the process of helping to restore the patient's speech.

Around 90% of all head and neck cancer patients should have an assessment of this kind. However, many of these patients do not currently receive such an assessment, partly due to a lack of hospital-based speech and language therapists, but also because their services are required more urgently post-treatment, meaning that the time spent with patients pre-treatment is often minimal or non-existent. Of the 75 patients included in the SWAHN II audit, only 48 (64%) of these had a pre-treatment assessment by a speech and language therapist.[5] The additional time required for carrying out additional pre-treatment assessments is taken into account in the overall role of speech and language therapists in Chapter 5.

Assessment by Dietitian

Patients whose treatment is likely to affect their ability to swallow should be given the opportunity to discuss nutritional problems with a specialist dietitian prior to treatment. The dietitian should discuss the likely effects of treatment on swallowing, and prepare the patient for any interventions which might be required e.g. feeding through a nasogastric tube or by percutaneous gastrostomy (PEG). The dietitian should also advise the patient and carers on modifications to food preparation and diet to maintain adequate nutrition during outpatient treatment. The additional time required for carrying out additional pre-treatment assessments is taken into account in the overall role of dietitians in Chapter 6.

Assessment by Anaesthetist

The guidance recommends that any patient requiring surgery involving the airways should be assessed by a specialist anaesthetist who leases with surgeons in the MDT. This is often done on the ward when the patient is admitted for surgery. All patients are routinely assessed by an anaesthetist prior to surgery, and so there are not expected to be any additional costs arising from this recommendation.

Assessment by Clinical Nurse Specialist

One of the roles of the clinical nurse specialist (CNS) is to provide support to each patient throughout the course of the disease, and all patients should be seen the appropriate clinical nurse specialist (CNS) prior to a treatment decision being made. Ideally, this would be done at the time of diagnosis, but this is not always possible due to logistical difficulties. Because of the nature of their relationship with patients, the CNSs can contribute significantly to the treatment decision through their knowledge of the patient's preferences and social situation. The role of the CNS is discussed in Chapter 4.

12. Conclusions

Implementation of the guidance is likely to have significant cost implications. It is estimated that the total additional cost per year for managing patients with head and neck cancers following implementation of the guidance will have a range of £43.2 to £60.1 million per annum. The level of uncertainty surrounding the estimates is high and there will be significant variability between Cancer Networks.

The most significant resource implication is likely to be the additional staff required to allow development of local support teams and to allow ensure patients are receiving high quality care, including pre-treatment assessment and support following radical therapy. Additional Clinical Nurse Specialists, speech and language therapists, dietitians and nurse practitioners are required to provide the optimal service for these patients. Further analysis is being undertaken but preliminary estimates suggest that this cost will lie in the range £33.2 million to 47.2 million per annum, depending on assumptions about the current provision of staff in the Centres and Units, the level of input required from each team member, and the number of Units per Network which offer such post-treatment support. Of these costs, it is estimated that between £18.3 million and £36.6 million would be attributable to the local support teams roles.

Centralisation of radical surgery is recommended by the guidance. This has already occurred in a limited number of areas around the country but in many Cancer Networks significant re-structuring of services will be required, at an estimated cost of £4.7 million per annum. It is anticipated that, in the long-term, all head and neck cancer surgery will be centralised, and so the volumes and costs presented under the second scenario in Chapter 8 may be more representative of future activity and costs.

Re-structuring of services into large head and neck multi-disciplinary teams (MDTs) and thyroid MDTs (each typically covering a population base of over 1 million) is also required and in many cases this recommendation constitutes a significant change to current practice. An estimated annual cost of £3.5 million arises from ensuring that MDTs are properly resourced. In addition a continuing rise in the proportion of patients receiving chemo-radiotherapy will require additional funding estimated to be £1 million per annum.

Cost savings will be derived from the effective implementation of the guidance. High quality care is likely to result in improved long term outcomes, reduced complications, reduced anxiety, and is likely to reduce post treatment hospital admissions by ensuring that any problems are dealt with promptly and appropriately. There is however insufficient evidence on which to quantify these savings.

It will not be possible to address all recommendations in the short term and prioritisation will therefore be necessary. All Cancer Networks will need to assess their current levels of service against the guidance recommendations and prioritise according to that assessment. This assessment should take note of all local variables that may impact on the manner in which services are configured and delivered. The prioritisation process will affect the timeframe of implementation for different services within different Networks.

One of the main resource implications of the guidance is the staffing levels required to implement the recommended models of care. The workforce planning implications are enormous and a significant time period will be required to gradually build up to the required staffing levels.

As a result of the guidance, some cost savings may be seen at the Units, through the movement of surgery to the Centres; however, this is expected to be offset by the costs of providing long-term local patient support.

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Appendix III – Composition of Research Review and Critical Appraisal Teams

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Members of the Editorial Board (see the Manual for the list of members)