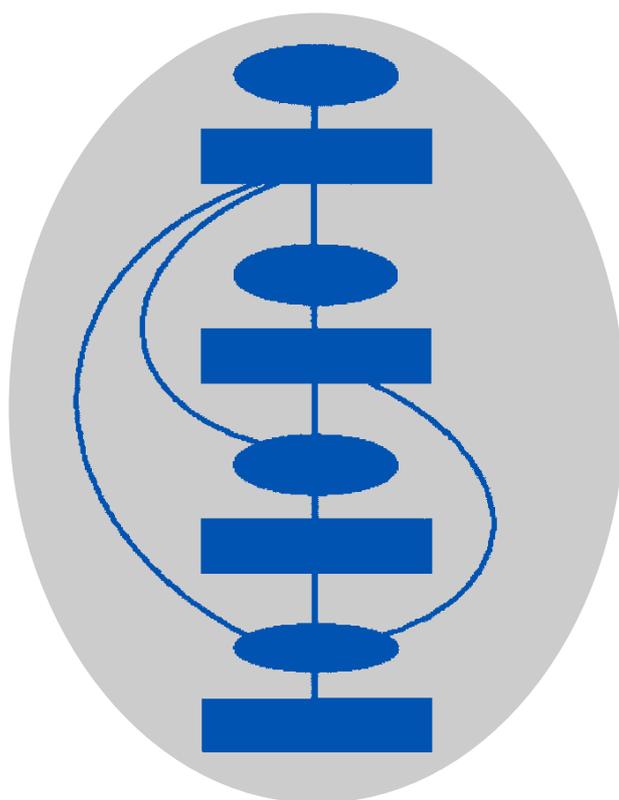


Guidance on Commissioning Cancer Services

Improving Outcomes in Upper Gastro-intestinal Cancers

The Manual



January 2001

Purpose of this document

This guidance is intended to help Cancer Networks – NHS Trusts, Health Authorities and Primary Care Groups/Trusts working with the voluntary sector – to review and identify ways to improve services for patients with upper gastro intestinal cancers.

GOOD PRACTICE

Examples of and advice on good practice

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Foreword

A great deal of effort has been expended in recent years to help both public and professionals appreciate that for many patients, a diagnosis of cancer may increasingly be approached with cautious optimism. 5-year survival for some cancers (e.g. breast) is good and improving. The three cancers covered in this document, oesophageal, gastric and pancreatic, may seem at first sight to be “stuck” in an old paradigm in which cancer is seen as almost always fatal, and care as predominantly palliative. Does it matter, then, how services for upper gastrointestinal cancers are organised?

Together, the three cancers that are the subject of this guidance manual comprise about 7.5% of cancers in women and nearly 10% in men. Although none of the individual cancers is common, together they represent a sizeable group of patients (more than colon cancer, but less than breast cancer).

For all three, there are real grounds for believing that current low expectations can change. The historical provision of care for these patients in most parts of the country has been fragmented, poorly organised, and with important deficiencies in many aspects of care. All aspects of care are therefore open to significant improvement, and some outcomes should be much better than at present. Such improvements are feasible based on existing knowledge about outcomes from modern well-organised health care.

This patient group has very diverse, usually complex, clinical needs. Hence the primary treatment of these patients is inevitably a very selective process, requiring high levels of expertise and skill in all areas, from diagnostic and staging procedures through to the relief of problematic symptoms and potentially life-threatening situations. The key to improving outcomes lies in ensuring that careful assessment of these patients allows these clinical needs to be identified and acted on by specialists in the various forms of management. Achieving this state of affairs will require change at all levels, including Cancer Centres.

The prime therapeutic modality for successful treatment of these diseases has been surgery. Such surgery is technically complex. Despite this, surgical management of these patients has in the past been thinly spread across the UK, with individual surgeons operating on very few patients each year. In contrast to the best international figures, prevailing rates of morbidity and mortality from surgery are high in Britain, arguably the highest of any elective surgical procedures. For example, typical 30 day post-operative mortality rates from pancreatic cancer surgery are eight times those for coronary artery by-pass grafts (national audit data 1997/8), and 50% worse than the highest mortality rates in elective cardiac surgery. As a consequence, an important priority in developing surgical services for these cancers is to ensure that surgery, when appropriate, takes place in skilled and experienced hands in hospitals which are geared up to support these patients in the difficult post-operative phase.

Although these diseases have not historically been perceived to be particularly amenable to radiotherapy or chemotherapy, this view is now inaccurate and both modalities have important roles in defined groups of patients. The majority of patients have advanced disease at the time of first presentation that is not amenable to potentially curative surgical treatment. Further improvements in outcome are increasingly likely to flow from multi-modality treatments carried out in Centres with all relevant expertise within the clinical teams concerned, and which are active in clinical trials.

This guidance manual recommends a specific service model in which specialist care is available to all requiring it, based on full assessment of individual needs. The model defines the nature and location of separate specialist teams for the treatment of oesophageal/gastric and pancreatic cancers. A worthwhile clinical role in assessment, diagnosis and some aspects of treatment is defined for those Cancer Units able to perform at the required level. For some patients the optimum arrangements are not clear-cut and local arrangements will need to be determined; this will require decisions about the balance between care at Units and Centres. As in *Improving Outcomes in Gynaecological Cancers*, we have laid the responsibility for deciding such issues (agreeing the necessary ground rules and preparing documented clinical policies), on Cancer Networks. We are aware that this may be a difficult task in some places, for genuine organisational and logistical reasons or because of individual or institutional anxiety about change.

The historical fragmentation of these services urgently needs to be replaced by a carefully thought out clinical model, based on the recommendations in this guidance manual, with some aspects negotiated amongst those involved in each area. It is crucial to the effective delivery of the right “package” for each part of the country that key issues are addressed and resolved in the interests of patients, rather than in response to vested interests amongst individual clinicians, groups of clinicians, hospitals or trusts.

Implementing these recommendations will involve changes in the location of care, with new lines of referral for some patients. It is important that the transition from the existing to the new pattern of service is carefully co-ordinated. Changes in referral patterns should follow, rather than precede, any necessary ‘gearing up’ of specialist services and their supporting facilities to handle additional workloads.

There will also be significant costs, which will build up over a period of some years. The estimated total, if all the recommendations are fully implemented across the country, is £87.5 million. However, the level of uncertainty is high. This cost impact is an unavoidable consequence of both reversing the current level of fragmentation of the service, and making optimum treatment available to patients with upper gastro-intestinal cancer. Whilst re-organisation could reduce pressure on some local hospital facilities, this will not usually result in quantifiable savings which can be released for planned re-investment in new services in other locations.

The resulting arrangements will need to be carefully monitored and the clinical results audited across the Network as a whole. Because of the large populations envisaged for delivering specialised services, particularly for pancreatic cancer, it is important that there is at least regional, and ideally some national, review of the intended service models which are to be put in place around the country. It is important to check that decisions on service configuration do reflect the thrust of this guidance and that compromises are justifiable in the light of geography or local

circumstance, and not a failure to grasp the issues. It was always envisaged in Calman/Hine¹ that patient flows should be managed to ensure appropriate care, involving all levels of the service relating efficiently together. This remains a fundamental goal of cancer policy.

Professor R A Haward

Chairman, National Cancer Guidance Steering Group.

¹ Calman, K and Hine, D. *A Policy Framework for Commissioning Cancer Services*.
Department of Health, 1995.

Key Recommendations

- All hospitals which intend to provide services for patients with upper gastro-intestinal cancer should be fully involved in appropriate Cancer Networks which include inter-linked Cancer Centres and Cancer Units. Each region should review proposals for these services, to ensure that proposed local arrangements reflect the recommendations in this guidance manual accurately.
- There should be documented local referral policies for diagnostic services for suspected upper gastro-intestinal cancer. These should be jointly agreed between General Practitioners (GPs) in Primary Care Groups and Trusts, and appropriate specialists in local hospitals and Cancer Units and Centres in each Network.
- Specialist treatment teams should be established at appropriate Cancer Centres or Units. Oesophago-gastric Cancer Teams should aim to draw patients from populations of more than one million; Pancreatic Cancer Teams should aim to draw patients from populations of two to four million.
- There should be clear documented policies for referral of patients between hospitals, and for processes by which clinicians in local hospitals seek advice from specialist treatment teams about the management of individual patients for whom referral may not be appropriate.
- Palliative support and specialist care should be available to all who need it. This will require effective co-ordination and communication between primary care, social and voluntary services, local palliative care teams, hospital services and those who provide specialist advice and interventions.
- Monitoring systems using common data-sets should be established throughout each Cancer Network to audit patient management, key communications, referral processes, and key outcomes of treatment.

Background

Cancers of the oesophagus, stomach, and pancreas – referred to collectively as upper gastro-intestinal cancers - led to 18,250 deaths in England and Wales in 1997, or 13.5% of all cancer deaths. These cancers are rarely diagnosed until they reach an advanced stage; the symptoms of early tumours are very common and are not specific to cancer. Consequently, the prognosis for most patients is very poor and more than three quarters die within a year of diagnosis.

Table 1. Upper gastro-intestinal cancers: registrations, incidence,¹ and deaths,² England and Wales.

Cancer site	ICD 10 code	Number of registrations, 1994	Incidence rate per 100,000, 1994		Deaths, 1997	Mortality rate per 100,000, 1997	
			Men	Women		Men	Women
Oesophagus	C15	5,960	14.0	9.2	5,855	13.6	8.4
Stomach	C16	9,780	24.3	13.8	6,613	15.1	9.5
Pancreas	C25	5,970	11.7	12.0	5,782	10.5	11.2

The incidence of upper gastro-intestinal cancers is shown in Table 1. These figures imply that the average GP, with a list of 2,000 patients, is unlikely to see more than one new patient with any of these cancers per year, whilst a notional average District General Hospital, serving a population of 200,000, could expect to deal with fewer than 25 people with oesophageal cancer, 40 with gastric (or stomach) cancer, and 25 with pancreatic cancer each year, although there are local variations in incidence. Some of these patients would benefit from radical treatment (usually surgery), which may offer the hope of cure; most will require palliative interventions to minimise the impact of their symptoms and improve their quality of life.

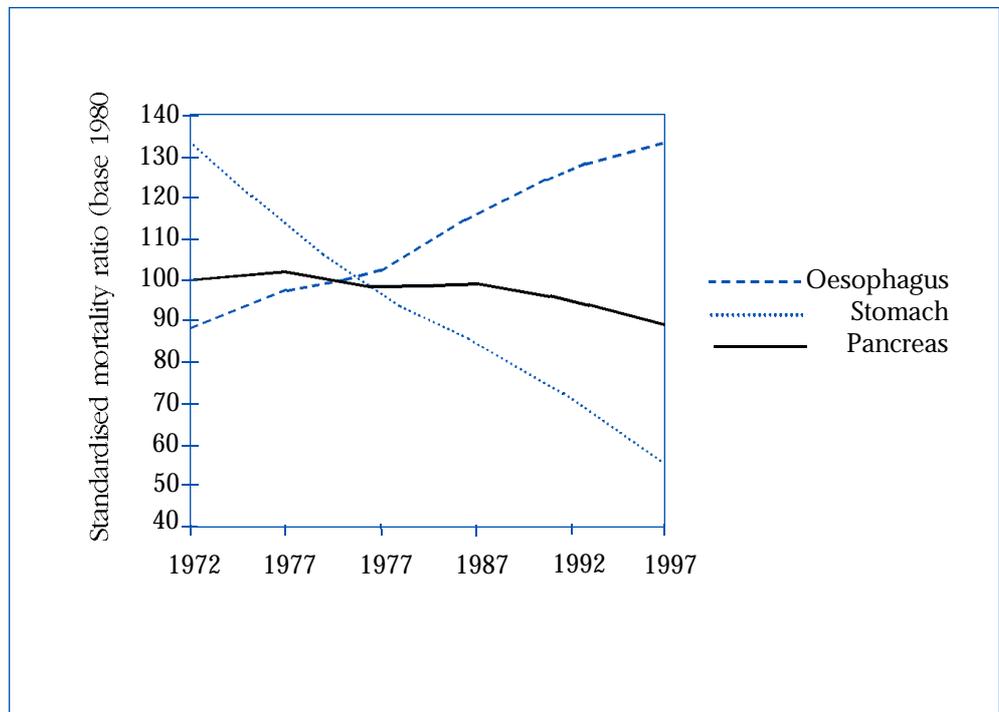
These numbers are too small for staff in most hospitals to develop and maintain expertise, and probably too small to justify setting up specialised facilities – yet the nature of the disease is such that expert management is crucial. Surgical resection of these tumours is associated with death-rates of between 10 and 20% within 30 days in

¹ Office for National Statistics, Registrations of cancer diagnosed in 1993-1996, England and Wales. *Health Statistics Quarterly* 1999;4:59-70.

² Office for National Statistics, *Mortality Statistics, Cause*. London, ONS, 1999.

most hospitals,^{3,4} an operative mortality rate much greater than for other cancers, or indeed for other types of major surgery. Targeting effective treatment and reducing treatment-related mortality are among the issues addressed by this guidance manual.

Figure 1. Trends in upper gastro-intestinal cancer mortality, England and Wales.⁵



Mortality rates for gastric and oesophageal cancers have been changing dramatically over recent years (Figure 1). Incidence and mortality rates for gastric (stomach) cancer have been declining for more than half a century. By contrast, oesophageal cancer is becoming more common. Tumours at the junction between the stomach and the oesophagus are increasing particularly rapidly. All these cancers are more common among men than women (Table 1). Pancreatic cancer, however, shows a different pattern; both sexes are equally likely to develop it (Table 1), and mortality rates are fairly stable (Figure 1).

The survival rate at one year for all upper gastro-intestinal cancers combined is just over 20%, though it is improving gradually (Table 2). Whilst the poor survival figures can be attributed mainly to the late stage at which the disease usually becomes apparent, it may also be due to poor management in some NHS hospitals. Reported survival rates among patients in England and Scotland are worse than the European average (Table 3), and considerably poorer than rates achieved in Japan

³ Bachmann M, Alderson D, Peters T, *et al.* Survival, clinical practice and costs in patients with pancreatic, oesophageal and gastric cancers: influences of doctor and hospital volumes. Report to NHS National Cancer Research and Development Programme, 1999.

⁴ Northern and Yorkshire Cancer Registry and Information Service, *Cancer treatment policies and their effects on survival*. Leeds: NYCRIS/University of Leeds, 1999.

⁵ Office for National Statistics, information provided on request.

and the USA.^{6,7} International comparisons may not be entirely reliable, but these figures support the contention that British services could be improved. This is particularly apparent for patients with gastric cancer, among whom the European average 5-year survival rate is 21%, compared with 12% in England.

Table 2. Survival rates among patients with upper gastro-intestinal cancers (England and Wales, age-standardised).⁸

Cancer site	1-year survival, % of patients diagnosed in 1986-90		Average increase in 1-year survival rate every 5 years from 1971		5-year survival, % of patients diagnosed in 1986-90		Average increase in 5-year survival rate every 5 years from 1971	
	Men	Women	Men	Women	Men	Women	Men	Women
Oesophagus	21	25	3.1	3.2	5	8	0.8	1.1
Stomach	23	26	3.6	3.5	9	11	1.6	2.0
Pancreas	9	10	1.1	0.9	2	2	0.3	0.2

Table 3. 1-year and 5-year survival rates, with 95% confidence intervals (CI), among patients with upper gastro-intestinal cancers in England and Europe.⁵

Cancer site	1-year survival rate, England	1-year survival rate, European average	5-year survival rate, England	5-year survival rate, European average
Oesophagus	27 (26-28)	33 (30-36)	9 (8-10)	10 (7-14)
Stomach	28 (27-29)	40 (39-41)	12 (11-12)	21 (20-22)
Pancreas	12 (11-13)	15 (14-17)	3 (2-4)	4 (3-5)

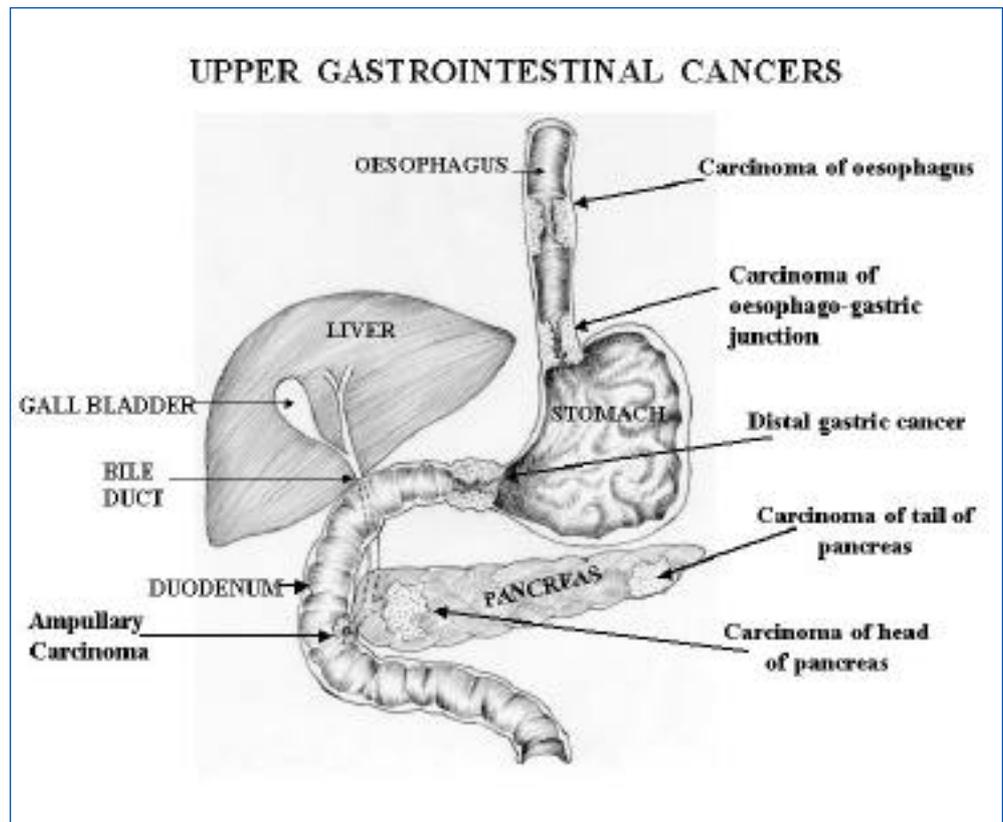
⁶ Faivre J, Forman D, Esteve J, *et al*, The Eurocare Working Group. Survival of patients with primary liver cancer, pancreatic cancer and biliary tract cancer in Europe. *European Journal of Cancer* 1998;**34**:2184-2190.

⁷ Faivre J, Forman D, Esteve J, *et al*, The Eurocare Working Group. Survival of patients with oesophageal and gastric cancers in Europe. *European Journal of Cancer* 1998;**34**:2167-2175.

⁸ Office for National Statistics, *Cancer Survival Trends*. London, ONS, 1999.

The anatomy of the upper gastro-intestinal tract, with the sites of the cancers discussed here, is shown in Figure 2.

Figure 2. Upper gastro-intestinal cancers.



Oesophageal cancer

Oesophageal cancer shows greater geographical variation in world-wide incidence than any other cancer.⁹ Striking differences are found both between local areas of the same region, and between different ethnic groups within regions. These differences suggest that environmental and lifestyle factors play crucial parts in the aetiology of these cancers.^{10,11}

There are two types of oesophageal cancer, squamous cell and adenocarcinoma. They tend to develop in different parts of the oesophagus, respond differently to treatment, show different incidence trends, and probably have different causes.

⁹ Blot W, Esophageal cancer trends and risk factors. *Seminars in Oncology* 1994;**21**:403-410.

¹⁰ Boyle P, Maisonneuve P, Audisio R, *Epidemiology*. In: McCulloch P, Kingsnorth A. (eds), *Management of Gastrointestinal Cancer*. BMJ Publishing Group, London, 1996.

¹¹ Thomas R, Lade S, Giles G, *et al*. Incidence trends in oesophageal and proximal gastric carcinoma in Victoria. *Australia and New Zealand Journal of Surgery* 1996;**66**:271-275.

Squamous cell cancer, which usually develops in the upper or middle part of the oesophagus, used to be the predominant form in developed countries. This is no longer the case in many places because the incidence of adenocarcinoma has increased dramatically; however, incidence trends vary from country to country.^{12,13,14}

Squamous cell cancer of the oesophagus is strongly associated with alcohol and tobacco consumption, which both increase risk independently and act synergistically. The results of a French case-control study illustrate the interaction between drinking and smoking. This found a relative risk (RR) among non-smokers in the highest category of alcohol use of 5.1, compared with non-smokers who drank least; for those in the highest category of tobacco use the RR was 18.0; but among those in the highest category for both alcohol and tobacco use, the RR was 44.4 (Table 4).

Table 4. Relative risks of oesophageal cancer associated with use of alcohol and tobacco.¹⁵

Tobacco consumption (gms per day; 1 gm \cong 1 cigarette)	Alcohol consumption (units per week; 1 unit \cong 10g pure alcohol)		
	0-28	29-56	>57
0-9	1.0	3.4	5.1
10-19	7.3	8.4	12.3
20	18.0	19.9	44.4

¹² McKinney P, Sharp L, MacFarlane G, *et al.* Oesophageal and gastric cancer in Scotland, 1960-1990. *British Journal of Cancer* 1995;**71**:411-415.

¹³ Hansson L, Sparen P, Nyren O, Increasing incidence of both major histological types of esophageal carcinomas among men in Sweden. *International Journal of Cancer* 1993;**54**:402-407.

¹⁴ Devesa S, Blot W, Fraumeni J, Changing patterns in the incidence of esophageal and gastric carcinoma in the United States. *Cancer* 1998;**83**:2049-2053.

¹⁵ Figures calculated from data reported by Tuyns *et al.* from cases registered 1972-3, in: Tuyns A, Pequignot G, Jensen O, Le cancer de l'oesophage en Ille-et-Vilaine en fonction des niveaux de consommation d'alcool et de tabac: des risques qui multiplient. *Bulletin du Cancer* 1977;**64**:45-60. Most of these are likely to be squamous cell cancers rather than adenocarcinoma, but the authors do not differentiate between histological types.

The incidence of adenocarcinoma is increasing rapidly in many places.^{16,17,18} In the USA, these tumours increased faster than almost any other cancer throughout the 1980s, at a rate of around 5% to 10% per year;¹⁹ in Norway, the rise was even more dramatic – about 15% per year.²⁰ Incidence rates for squamous cell cancer and adenocarcinoma were approaching parity in the USA at the beginning of the last decade; now, adenocarcinoma seems to be the more common form, both in the UK and the USA.

Relationships have been reported between oesophageal cancer risk and diet, but these reports do not discriminate between the two types of cancer. Diets high in fruit and vegetables reduce risk; a review of 22 case-control studies (most of which controlled for smoking) found that 18 reported significantly lower risks with higher fruit and vegetable consumption.²¹

Adenocarcinomas mainly occur in the lower third of the oesophagus and at the oesophago-gastric junction, where they can be particularly difficult to treat. It has been suggested that most of these cancers develop from malignant changes in a condition known as Barrett's oesophagus, a distinctive morphological form of the lining of the lower end of the oesophagus. About 2% of people examined by endoscopy are found to have Barrett's oesophagus. In these individuals, the risk of developing oesophageal cancer can be 30 to 125 times the average for their age-group.²²

Although the precise nature of the link between Barrett's oesophagus and adenocarcinoma is uncertain, both appear to follow recurrent gastro-oesophageal reflux. Reflux is an important risk factor for oesophageal adenocarcinoma; indeed, it is likely that it can cause this type of cancer.²³ A Swedish case-control study revealed that people who had suffered from recurrent reflux five years earlier were nearly eight times as likely to develop adenocarcinoma of the oesophagus, and twice as likely to develop adenocarcinoma of the gastric cardia, as those who did not have these symptoms (odds ratios 7.7, 95% CI: 5.3 to 11.4, and 2.0, 95% CI: 1.4 to 2.9, respectively). More severe symptoms were associated with greater risk.

¹⁶ Devesa S, Blot W, Fraumeni J, Changing patterns in the incidence of esophageal and gastric carcinoma in the United States. *Cancer* 1998;**83**:2049-2053.

¹⁷ Hansson L, Sparen P, Nyren O, Increasing incidence of both major histological types of esophageal carcinomas among men in Sweden. *International Journal of Cancer* 1993;**54**:402-407.

¹⁸ Thomas R, Lade S, Giles G, *et al.* Incidence trends in oesophageal and proximal gastric carcinoma in Victoria. *Australia and New Zealand Journal of Surgery* 1996;**66**:271-275.

¹⁹ Blot W. Esophageal cancer trends and risk factors. *Seminars in Oncology* 1994;**21**:403-410.

²⁰ Hansen S, Wiig J, Giercksky K, *et al.* Esophageal and gastric carcinoma in Norway 1958-1992: incidence time trend variability according to morphological subsites and organ subsites. *International Journal of Cancer* 1997;**71**:340-344.

²¹ World Cancer Research Fund. *Food, Nutrition and the Prevention of Cancer: a Global Perspective*. Washington DC: American Institute for Cancer Research, 1997.

²² Cameron A, Lomboy C, Pera M, *et al.* Adenocarcinoma of the esophagogastric junction and Barrett's Esophagus. *Gastroenterology* 1995;**109**:1541-1546.

²³ Lagergren J, Reinhold B, Lindgren A, *et al.* Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma. *New England Journal of Medicine* 1999;**340**:825-831.

Oesophageal tumours are uncommon (about 2 per million population) in people under 40 years old, but incidence rises steeply with increasing age.²⁴ The main presenting symptoms are difficulty with swallowing (dysphagia) and pain.

Surgery offers the chance of long-term survival for some patients with early stage tumours of either type. Surgery and chemo-radiotherapy seem to be equally effective for patients with squamous cell tumours, and the use of multi-modality treatment is increasing. A variety of palliative interventions may be used to relieve oesophageal obstruction, including chemotherapy, radiotherapy, laser treatment, and stenting.

Gastric cancer

60 years ago, gastric cancer was the leading cause of cancer death in Britain; by 1997, it was responsible for just 5% of cancer deaths. Its incidence has been falling throughout the world, probably because of improved methods of food preservation and declining prevalence of *Helicobacter pylori* (*H. pylori*), the bacterium associated with stomach and duodenal ulcers. Nevertheless, it remains the second most common cause of cancer death in the world, with particularly high incidence rates in Japan and South America.²⁵

Like oesophageal cancer, gastric cancer is uncommon in people under 40 years old but its incidence rises steeply after the sixth decade, reaching a peak rate of 200 per 100,000 among men over 80 years. It is relatively more common among poorer people.²⁶

There are wide variations in prevalence patterns between populations and evidence of associations between gastric cancer and diet. In a review of 32 case-control studies, 27 found significantly reduced risk with higher consumption of fruit and vegetables; and the three largest of six cohort studies also reported that fruit and vegetables were protective.²⁷ A high dietary intake of vitamin C seems to be particularly beneficial. However, vitamin supplementation is not effective unless initial intakes are very low.

Most patients with gastric cancer suffer from dyspepsia, but there is no clear symptom pattern that is peculiar to this disease and very few people with dyspepsia have cancer.

More advanced tumours close to the stomach exit (pylorus) tend to cause nausea and vomiting, whilst tumours near the entrance (cardia) cause problems with swallowing (dysphagia). Loss of appetite, a sense of fullness, and nausea are other common symptoms, and anaemia and blood in stools are frequent laboratory findings. More extensive disease causes anorexia, pain and weight loss. The diagnosis can be confirmed by endoscopy and biopsy.

²⁴ Office for National Statistics, information provided on request.

²⁵ Pisani P, Parkin DM, Bray F, Ferlay J. Estimates of the worldwide mortality from 25 cancers in 1990. *International Journal of Cancer* 1999;**83**:18-29.

²⁶ McKinney P, Sharp L, MacFarlane G, *et al.* Oesophageal and gastric cancer in Scotland, 1960-1990. *British Journal of Cancer* 1995;**71**:411-415.

²⁷ World Cancer Research Fund, *Food, Nutrition and the Prevention of Cancer: a Global Perspective*. Washington DC: American Institute for Cancer Research, 1997.

Surgery is the most important intervention for gastric cancer and up to half of all patients undergo resection. Potentially curative resection is possible for perhaps 25% of patients, who have early-stage disease; in the majority, the cancer is too far advanced to be removed in its entirety, but surgery may be used to relieve symptoms. Other forms of palliative treatment, such as chemotherapy, are also available.

Pancreatic cancer

Pancreatic cancer is predominantly a disease of the elderly; three-quarters of deaths are in people over 65 years old. This is a particularly lethal cancer, with rarely more than a few months between diagnosis and death.

Smoking is the most important known risk factor, with an attributable risk of 20-40% for men and 10-20% for women.²⁸ As with other types of cancer, higher consumption of fruit and vegetables appears to be protective; nine out of ten case-control studies have found significant effects, although three cohort studies have failed to demonstrate significant benefit.²⁹

Pancreatic cancer causes jaundice, nausea, weight loss, loss of appetite, and severe pain; it may also cause diabetes, diarrhoea and profound depression. Surgical resection offers the possibility of cure for a small minority of patients, particularly those with unusual types of tumour. Effective palliation of symptoms is often possible but may require specialist interventions.

Prevention

The evidence on risk factors, summarised above, suggests that it might be possible to prevent a substantial proportion of upper gastro-intestinal cancers. Appropriate interventions are likely to include the following:

- Action against smoking;
- Interventions to reduce excessive consumption of alcohol;
- Promotion of fruit and vegetable consumption.

Recommendations on interventions to reduce smoking were made in the document on lung cancer in this series.³⁰

Although *H. pylori* is believed to have a causative role in gastric cancer, it is not clear whether increasing use of treatment to eradicate *H. pylori* infection will affect cancer rates.

²⁸ Working Group on Diet and Cancer, Committee on Medical Aspects of Food and Nutrition Policy, *Nutritional aspects of the development of cancer*. Report 48, London: Department of Health, 1998.

²⁹ World Cancer Research Fund, *Food, Nutrition and the Prevention of Cancer: a Global Perspective*. Washington DC: American Institute for Cancer Research, 1997.

³⁰ National Cancer Guidance Group, *Improving Outcomes in Lung Cancer: The Manual*. NHS Executive, Department of Health, 1998. This document may be obtained through the NHS Response Line (0541 555 455).

Services for upper gastro-intestinal cancers

The context of services for upper gastro-intestinal cancers has changed considerably in recent years. Until relatively recently, quite large numbers of people were treated by surgery for benign conditions, notably peptic ulcers. Now medical treatment has replaced surgery for these ulcers, the upper gastro-intestinal surgical work-load has declined dramatically. This means that few surgeons in District General Hospitals can develop and maintain the expertise necessary for this type of work, and this has inevitable repercussions for cancer services.

The service model advocated in this guidance manual reflects this new situation. It takes into account the numbers of patients who present with symptoms that could be due to each type of cancer, the numbers likely to have cancer, and the level of expertise necessary to treat them.

Symptoms that could be due to early-stage upper gastro-intestinal cancers – particularly early gastric cancer - are very common. Initial diagnosis therefore requires investigation of symptoms in a relatively large group of patients, most of whom do not have malignant disease. Such investigations are likely to be carried out in gastro-intestinal out-patient clinics in District General Hospitals, but responsibility for the patient may remain with the GP at this stage.

Patients become the responsibility of specialised treatment teams when a probable or definite diagnosis of cancer has been established and further assessment is necessary to select appropriate interventions. Two types of specialist team are required, one to deal with cancers of the oesophagus and stomach, the other with pancreatic cancer.

Radical treatment (notably surgical resection) improves survival prospects for patients with early cancers, but the number of patients for whom this is appropriate is relatively small. This is because most patients have cancers too advanced for such interventions to be effective, and also because many, being elderly, have a variety of other health problems and are not sufficiently fit to benefit from radical treatment.

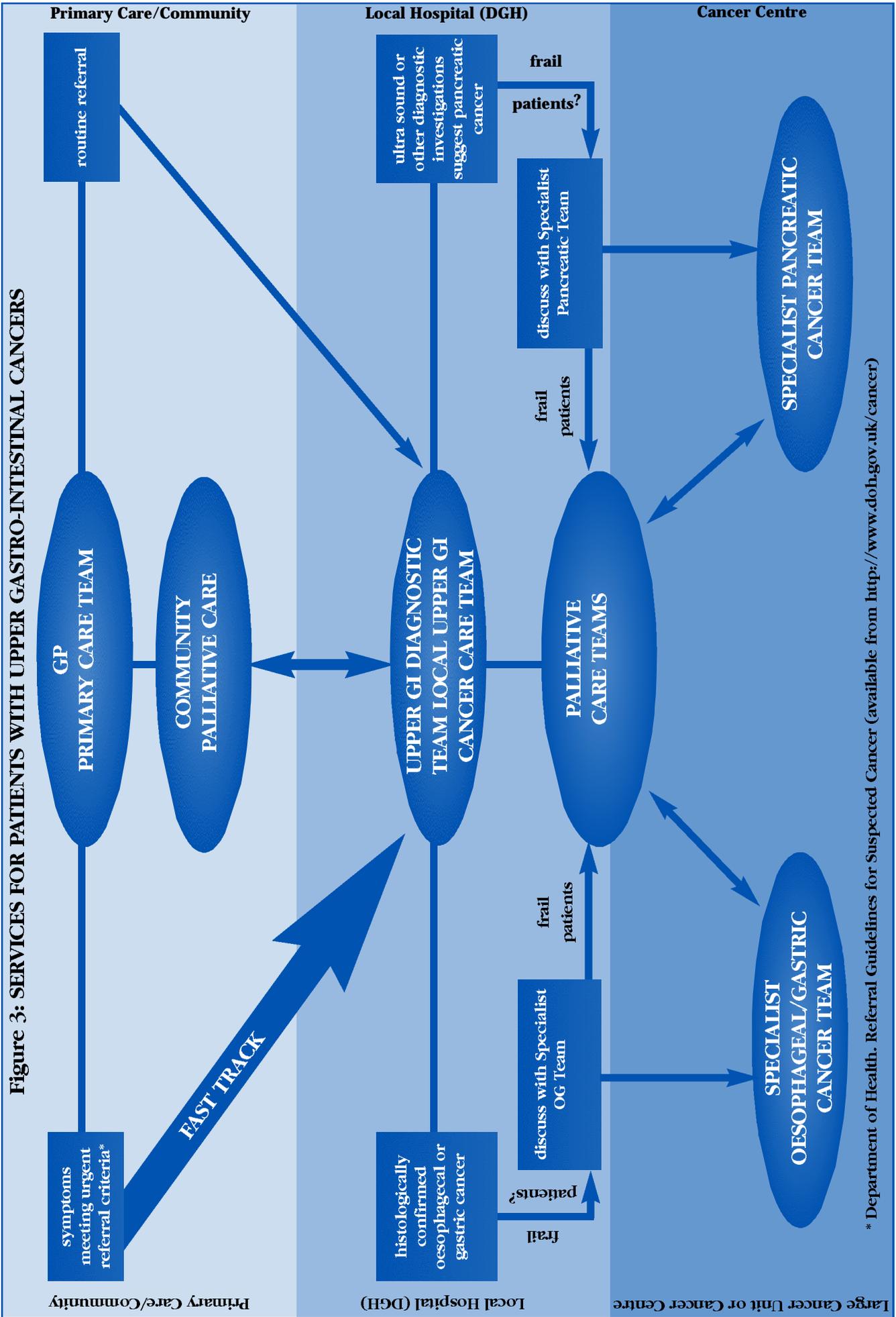
The majority of these patients need palliative interventions and care to minimise suffering during their final months of life. Such interventions often require the specialist expertise available at Cancer Centres, for example chemotherapy, radiotherapy, palliative surgery, relief of obstruction caused by tumour, and nerve blocks. Teams based at local hospitals would deal with patients who are too ill or too frail for referral to a Cancer Centre to be appropriate. Emergency intervention is rarely required; treatment is generally elective and can be planned.

The service diagram below (Figure 3) is a diagrammatic illustration of this model, which is described in Topic 3, *Specialist Services and Multiprofessional Teams*.

Cost implications of the guidance

As part of the guidance process (see Appendix 2), the potential cost implications of the recommendations of the guidance have been examined. A summary of this work is given in Appendix 1, and specific results are given in Part E, Resource Implications, at the end of relevant sections of the guidance manual.

Figure 3: SERVICES FOR PATIENTS WITH UPPER GASTRO-INTESTINAL CANCERS



* Department of Health. Referral Guidelines for Suspected Cancer (available from <http://www.doh.gov.uk/cancer>)

Primary Care in Diagnosis and Referral

In total, the incidence of upper gastro-intestinal cancer is roughly 1 person per 2,500 population per year. The symptom pattern in patients with early tumours is not distinctive, so diagnosis is rarely possible on the basis of symptoms alone. People with oesophageal or gastric cancer may present with any of a variety of common symptoms such as indigestion, heartburn, reflux, and pain or discomfort in the area of the stomach, chest or upper abdomen; these symptoms will be generically described as dyspepsia in this guidance manual. Dyspepsia prompts a substantial proportion of primary care consultations, but fewer than 2% of patients with dyspepsia will have cancer. Oesophageal cancer or cancer of the oesophago-gastric junction and pancreatic cancer may also cause more specific symptoms: dysphagia (food sticking when swallowed, difficulty with swallowing) and jaundice, respectively. Any upper gastro-intestinal cancer may cause weight loss (60% of patients), anaemia (50%) and vomiting (25%).

A. Recommendations

Patients with symptoms that could be due to upper gastro-intestinal cancer should either be referred for endoscopy,¹ or for investigation by a designated Upper Gastro-intestinal Diagnostic Team at a local District General Hospital. (See Topic 3, *Specialist Services and Multiprofessional Teams*.) Symptoms of uncomplicated dyspepsia in patients under the age of 55 should be managed empirically.

Fast-track endoscopy services (which may be provided within primary care) should be established. Those who carry out endoscopy should meet Joint Advisory Group on Gastro intestinal Endoscopy (JAG) training criteria.² GPs should be encouraged to refer selected patients directly to these services. If endoscopy reveals or suggests the presence of a tumour, the patient should be assessed by the designated Upper Gastro intestinal Diagnostic Team.

Patients with any of the following symptoms or characteristics should be referred to the Upper Gastro-intestinal Diagnostic Team for investigation within two weeks:³

- Dysphagia - food sticking on swallowing (any age).

¹ Whenever the term “endoscopy” is used in this Manual, it refers to oesophagogastroduodenoscopy (OGD).

² Joint Advisory Group on Gastrointestinal Endoscopy. *Recommendations for training in gastrointestinal endoscopy*. JCHMT, 1999.

³ Department of Health. *Referral Guidelines for Suspected Cancer* (available on <http://www.doh.gov.uk/cancer>).

- Dyspepsia combined with one or more of the following 'alarm' symptoms:
 - weight loss;
 - proven anaemia;
 - vomiting.
- Dyspepsia in a patient aged 55 years⁴ or more with at least one of the following 'high risk' features:
 - onset of dyspepsia less than one year ago;
 - continuous symptoms since onset.
- Dyspepsia combined with at least one of the following known risk factors:
 - family history of upper gastro-intestinal cancer in more than two first-degree relatives;
 - Barrett's oesophagus;
 - pernicious anaemia;
 - peptic ulcer surgery over 20 years ago;
 - known dysplasia, atrophic gastritis, intestinal metaplasia.
- Jaundice.
- Upper abdominal mass.

Other symptoms which should alert GPs to the possibility of upper gastro-intestinal cancer, particularly in older patients, include persistent nausea and/or vomiting, recurrent reflux or regurgitation of food or fluid from the stomach, a sensation of fullness in the stomach, or early satiety.

B. Anticipated Benefits

Prompt identification of patients whose symptoms are likely to be due to upper gastro-intestinal cancer, and rapid referral to appropriate diagnostic services, will minimise delays in diagnosis. This is likely to reduce patients' anxiety and may improve the chance of long-term survival.

C. Evidence

Upper gastro-intestinal cancers are very unusual (1 per 100,000 population) in people under the age of 40. The incidence rises steeply in middle to old age,

⁴ Age 55 years is considered to be the maximum age threshold. Local Cancer Networks may elect to set a lower age threshold (e.g. 50 years or 45 years).

almost doubling with every five years in age-groups from 40 to 70. In people aged between 45 and 54, the combined incidence of cancers of the oesophagus, stomach, and pancreas is 20 per 100,000 (1 per 5,000); amongst those over 55, it is 155 per 100,000 (about 1 per 650).⁵ Symptoms are more likely to be due to causes other than cancer in patients aged under 55.

At least two thirds of patients with oesophageal or gastric cancer suffer from dyspepsia. However, dyspepsia is not uncommon; in an average year, this symptom will provoke 3% of patients over the age of 55 to consult a GP. A GP with 2,000 patients could expect to see one or more patients with dyspepsia every week, but only one patient per year is likely to have upper gastro-intestinal cancer (around four or five patients per year in an average group practice). This relatively low incidence rate justifies selection for other features that suggest the possibility of cancer. The list of symptoms which should prompt early referral was derived from the consensus of the Working Party on Upper Gastro-intestinal Referral Guidelines.(C)

A large retrospective review of case notes of patients with cancer suggested that only one person per million population under the age of 55 presenting with uncomplicated dyspepsia and no sinister symptoms (in particular, persistent vomiting, dysphagia or weight loss) is likely to have cancer.(B)

Recurrent symptoms of reflux are linked with increased risk of oesophageal and gastric adenocarcinomas. A nation-wide case-control study in Sweden found that, compared with people who had no such symptoms, the odds ratios for people with recurrent reflux were 7.7 (95% CI: 5.3 to 11.4) for oesophageal adenocarcinoma, and 2.0 (95% CI: 1.4 to 2.9) for adenocarcinoma of the gastric cardia. The more frequent, severe, and long-lasting the symptoms, the greater the risk.(B)

Reflux is also associated with the development of Barrett's oesophagus, but a recent Development and Evaluation Committee Report concluded that there is no reliable evidence to show that patients with Barrett's oesophagus benefit from surveillance, or that such surveillance can reduce morbidity or mortality from oesophageal adenocarcinoma.(B)

Evidence from prospective case-series reports reveals that GPs will use open-access endoscopy services effectively. Comparative studies suggest that this can avoid a large number of unnecessary out-patient clinic visits.(B) A Danish trial which compared prompt endoscopy for patients with dyspepsia (average age 44 years) with attempted symptom control with an H₂ blocker, found that prompt endoscopy was associated with reduced treatment costs and increased patient satisfaction.(A)

In reported case-series, the proportion of patients with malignancies is generally as high among patients referred by GPs as among patients referred by specialists.(B) Overall, between 1 and 2% of patients referred for endoscopy are likely to have cancer; the rate is higher in older patient groups.(B) Diagnosis of potentially resectable gastric cancer is usually achieved at endoscopy.(B)

Although several studies suggest that earlier diagnosis and the availability of open-access endoscopy could be associated with improved survival, there is as yet no evidence that demonstrates this unequivocally. There are two reasons for this. First, there have been no randomised controlled studies, and reports from case-

⁵ Figures calculated from 1992 incidence figures by ONS (data provided on request).

series and other uncontrolled studies tend to produce biased impressions. Second, no study has related survival time to diagnostic delay.

Nevertheless, it does appear that a higher proportion of the tumours found are at an early stage when there is less delay. For example, one study found that the median time to diagnosis for patients with stage I and II oesophageal cancer was less than seven weeks, whilst for those with stage III or IV disease it was 21 weeks.(B) Other studies have reported that the proportion of early gastric cancers detected is significantly higher when rapid access to endoscopy is available for patients with dyspepsia.(B)

At present, delays in diagnosis can be substantial. A 1997 UK study found that the median delay from onset of symptoms was four months (17 weeks). For a quarter of patients, the median delay was nine months. The largest component of this (32%) was delay in establishing a diagnosis at the hospital.(B)

An earlier (1990) study reported that the most common reason for a delay of more than three months by doctors was a false negative result from a barium meal and radiological assessment.(B) This practice is likely to be less efficient than prompt endoscopy because patients with radiological signs of tumour will require endoscopy to confirm the diagnosis, as will those whose radiological investigation fails to reveal the cause of persistent symptoms. (See Topic 4, *Oesophageal and Gastric Cancers: Diagnosis and Assessment*.)

Pancreatic cancer usually presents late, with pain, when only palliative treatment is possible. It can be diagnosed at an early (painless) stage if the tumour presses on the bile duct, causing jaundice. The two most common causes of jaundice, gallstones and cancer, can be distinguished by imaging (see Topic 5, *Pancreatic Cancer: Diagnosis and Assessment*).

D. Measurement

Structure

- Availability of upper gastro-intestinal diagnostic facilities with ultrasound.
- Availability of fast-track or open-access endoscopy facilities with staff trained in accordance with JAG criteria, to which GPs can refer patients with minimal delay.

Process

- Time between first GP consultation with symptoms of upper gastro-intestinal cancer and histological confirmation of diagnosis.
- Stage of cancer at diagnosis.

E. Resource Implications

- Resources will be required to establish and staff fast-track upper gastro-intestinal diagnostic clinics in areas where these are not already provided, or to provide alternative fast-track referral services.
- Increased demand for endoscopy could increase annual costs for England by £9.5 million (low estimate £2.3 million, high estimate £14.6 million; see Appendix 1).

Patient-centred Care

A. Recommendations

(i) Communication and information

Patients should be given as much information as they wish to have, in language they are likely to understand, and in both verbal and written forms. This should include realistic information about the disease, and about the aims and likely effects of diagnostic procedures and treatment options (including known risks and potential adverse effects). A clear explanation should be also given when interventions which patients might anticipate are not offered – for example, when histological confirmation of cancer is not sought. Patients should receive both individual support and guidance, and well-produced information leaflets.

Providers should ask patients if they want additional information and seek to discover how much they wish to be involved in discussions about treatment. If patients want support from relatives or carers during consultations, this should be encouraged.

Providers must be sensitive to potential problems with communication, and those who provide direct patient care should have training in communication and counselling skills. They need to be aware that patients often find it difficult to take in information given during the consultation, especially just after receiving bad news.

All health professionals involved should know what information has been given to each patient. A record of this, along with the patient's preferences for information and involvement in decision making, should be included in the notes and given to the patient's GP, together with a comprehensive summary of the management plan.

Many patients with upper gastro-intestinal cancers do not survive for more than a few months after diagnosis. Time is often short, so communication needs to be effective, with fast and efficient links between hospitals and primary care teams.

(ii) Dietary advice and nutritional support

Since these are disorders that directly affect patients' ability to eat and drink, help with nutrition can be vital. All patients should be given practical information about appropriate diets and advice on minimising problems with eating.

Specialist advice should be available from a dietitian. This should focus on helping patients to achieve adequate nutrition despite nausea, vomiting, difficulties with swallowing, and/or problems with digestion. Nutritional supplements are likely to be appropriate, both for patients who have undergone surgery, and for poorly nourished patients. Appropriately trained nurses will be required to assist patients who need any form of tube feeding.

Patients who have undergone surgery for oesophageal or gastric cancer should be given guidance to help them deal with post-surgical syndromes which can cause problems with eating. Patients with pancreatic cancer, or who have undergone pancreatic resection, may require specific help to cope with diabetes. Research is required both into the nutritional needs of these patients, and effective methods of improving nutrition.

(iii) Practical and social support

The majority of patients are over 70 years of age. Many will require both practical and social support. Additional support may also be necessary for carers who look after patients at home. The primary and palliative care teams have particularly important roles in ensuring that the needs of both patients and carers are identified and met.

Patients should be given information about sources of help, such as local and national support groups⁶ and disability and benefits helplines, both verbally and in writing.

(iv) Psychological (behavioural, counselling and educational) interventions

Psychological interventions designed to help patients to come to terms with their cancer, its consequences and treatment, should be offered to those who may be expected to benefit. This group is likely to include those who show high levels of anxiety or depression, or who have particular difficulty in coping with their disease, but whose cognitive abilities are not significantly impaired.

B. Anticipated Benefits

Provision of clear and timely information can help patients to cope with their disease, to enhance satisfaction with services, and to reduce criticism and complaints. Information has a variety of benefits for cancer patients, particularly anxiety reduction, improved ability to cope with treatment and better self-care. Effective communication will tend to heighten awareness of the various needs - whether practical, psychological, dietary or social - of patients and carers, and increase the probability that these needs can be met.

C. Evidence

(i) Communication and information

No studies were identified which specifically addressed communication and information needs of patients with cancers of the oesophagus, stomach, or pancreas. The following conclusions were drawn from studies which included patients with a variety of cancers.

⁶ The Oesophageal Patients Association (0121 704 9860) offers leaflets, advice and support for people with oesophageal cancer, or who have undergone oesophageal surgery. Leaflets for patients with various types of cancer, and their carers, are available from CancerBACUP (0207 696 9003).

There is considerable evidence of problems with communication between both doctors and patients, and doctors and nurses, which can cause unintended distress.(B) Although some patients may not wish to take an active part in decision making, there is strong evidence that they value accurate information, and that many feel they are not given sufficient information.(B)

The following strategies have been found to be beneficial:

- Doctors asking patients directly, in a structured way, whether they would like to know about particular issues.(A)
- A taped or written record of the consultation.(A) However, although most patients find audiotapes helpful, they can increase distress in those whose prognosis is poor.(A) This group will include the majority of patients with upper gastro-intestinal cancers.
- Patient-held shared-care records giving details of appointments, medication, strategies for symptom control, contact addresses and telephone numbers, and a diary of significant events.(B)
- Provision, usually by a nurse, of specific information about management of symptoms and adverse effects of treatment. This can reduce anxiety and lead to more effective symptom control and self-care.(B)
- Cancer information booklets, videos, tapes and telephone help-lines. Whether these provide specific information, for example on pain management or anti-cancer treatments, or more general information on cancer, they are appreciated by patients and carers alike.(B)

Training in communication skills can change the attitudes of health professionals, improve their methods of eliciting and offering information, and increase their confidence in their ability to deal with terminally ill patients.(B) The benefits appear to be greatest for people who hold particularly negative attitudes before training.(B) Improvements may be maintained for several years.(B)

Although there appears to be little direct research evidence to show how changes resulting from communication training for professionals affect patients with whom they deal, studies designed to assess the effects of enhanced communication generally suggest higher levels of satisfaction and reduced symptom intensity.(B)

(ii) Dietary advice and nutritional support

Patients who have undergone surgery for cancer of the oesophagus or stomach are likely to suffer from a variety of post-surgical syndromes which can lead to nausea, reflux, abdominal discomfort and diarrhoea. The impact of these problems can often be reduced by appropriate dietary adjustments. Supplementary pancreatic enzymes are necessary to aid digestion after pancreatic resection.(C)

(iii) Practical and social support

Patients with cancer and their carers particularly value support from others with similar experience, and local initiatives which facilitate social contact are appreciated. A study of a monthly discussion group which included patients, carers/relatives, and oncology professionals reported that over 80% of patients and their 'significant others' received some or all of the information they sought in the

group. Most felt happier or more relaxed and over half felt clearer about ways of coping.(B)

Initiatives of this type are more likely to be successful if they involve a range of health service professionals who work alongside patients and carers.(C)

(iv) Psychological (behavioural, counselling and educational) interventions

Psychological interventions can improve the quality of life of patients with cancer.(A) Effective interventions are likely to include guidance on positive coping strategies, which can reduce anxiety, depression and fatigue.(A) These are more effective than interventions which do not offer specific help with coping with the consequences of their illness.(A) One trial which included patients with upper gastro-intestinal cancers reported that sessions with a counsellor trained in dealing with the dying reduced depression and increased life-satisfaction, and that these benefits could be maintained for a year. Counselling is more likely to be effective when it is provided early in the course of the illness.(B)

Cognitive interventions, distraction, music and relaxation training can all reduce treatment-related problems such as anticipatory nausea and anxiety associated with chemotherapy.(B)

Psychological and educational interventions can also be beneficial for carers.(A) Counselling can improve the carer's ability to cope with the problems of looking after a patient with cancer, and may be associated with reduced depression among patients.(A)

D. Measurement

Structure

- Providers should be able to demonstrate that patients are given appropriate and adequate verbal and written information about their cancer, proposed treatments and options, and sources of practical help.
- Training courses in communication skills should be available for clinical and other staff.

Process

- There should be evidence that patients receive information and support from suitably trained staff.
- The proportion of staff involved in direct patient care who have had specific training in communication and counselling skills should be monitored.

Outcome

- Providers should carry out surveys of patients to assess the adequacy of each component of patient-centred care, for example patient knowledge about available resources, and patient satisfaction with the quantity of information and the manner in which it was given.

E. Resource Implications

- Additional resources may be necessary for the provision of information and educational material for patients with upper gastro-intestinal cancers. Much of this information is available from organisations such as CancerBACUP.
- Resources will be required to allow sufficient staff time for provision of help and support for patients.
- Adequate training in communication skills for nurses and other clinical staff may require additional resources.

Specialist Services and Multiprofessional Teams

A. Recommendations

The incidence and management requirements of the three cancer sites considered here demand a more complex model than has been proposed in previous documents, although the structure of the service should again be based on Cancer Units and Cancer Centres, as described by Calman and Hine.⁷ All the levels of service should work closely together to form an integrated Cancer Network which offers efficient and consistent delivery of high standards of care.

The specific recommendations below are discussed in terms of patient throughput, but potential overlap between the levels of throughput handled by Units and Centres is likely to lead to local variations in the form of service established. Two examples may clarify this point: whilst surgery for oesophageal and gastric cancers will usually be restricted to Cancer Centres, the catchment areas of some larger Cancer Units may generate sufficient patient numbers for them to establish specialist teams to treat these cancers. Likewise, the patient base of some Cancer Centres will be too small to meet the criteria required to provide treatment for pancreatic cancer; so these Centres, and any hospitals which normally refer patients to them, will have to establish links with other Centres.

Most of the diagnostic and palliative functions of specialist teams, Cancer Units and Cancer Centres may be carried out in more than one geographical location. However, teams which provide surgery should carry out surgical procedures and provide appropriate post-operative care at a specifically designated location. Within each trust, there should not be more than one treatment team of each of the types described below.

The optimum management of upper gastro-intestinal cancers requires that different levels of service within the Network, which draw patients from populations of disparate sizes, function in a co-ordinated way. Protocols for referral and treatment need to be agreed both locally and across the Network, as do systems to ensure effective co-ordination and communication between all those involved. Audit should also be co-ordinated across the Network, using common data-sets to permit comparative audit.

Diagnostic Services

Diagnostic services should be established at local District General Hospitals (DGHs). These must permit rapid access for relatively large numbers of patients, but fewer than 5% of these patients are likely to have cancer. Patients with cancer must then

⁷ Calman, K and Hine, D. *A Policy Framework for Commissioning Cancer Services*. Department of Health, 1995

be assessed promptly, both to select those who could benefit from further assessment and treatment in specialist hospitals experienced in managing such patients, and to determine care plans for those who require palliative interventions.

Two types of service are required: fast-track endoscopy, and one-stop gastro-intestinal diagnostic clinics with facilities for both endoscopy and ultrasound imaging. Both should have rapid referral systems for patients who are thought to be at high risk (as defined in Topic 1, *Primary Care in Diagnosis and Referral*). Gastro-intestinal diagnostic clinics should be staffed by designated Upper Gastro-intestinal Diagnostic Teams.

Members of the Upper Gastro-intestinal Diagnostic Team

All members of the Upper Gastro-intestinal Diagnostic Team should have a special interest in upper gastro-intestinal cancers.

- A designated lead clinician (normally a physician or surgeon) who will take responsibility for the service.
- One or more designated clinicians specialising in gastroenterology.
- Endoscopists.
- Histopathologist(s).
- Radiologist(s). The team should include a radiologist who has expertise in cross-sectional imaging (US, CT, MR).
- A clinical nurse specialist with knowledge of endoscopy (see Local Upper Gastro-intestinal Cancer Care Team for a fuller description of this nurse's role).

The role of the Upper Gastro-intestinal Diagnostic Team

- Rapid diagnostic service for patients with possible, or suspected, upper gastro-intestinal cancer.
- Referral service for patients found to have cancer.
- Liaison with primary care teams and specialist teams.
- Data collection and audit.

The Upper Gastro-intestinal Diagnostic Team should aim to achieve histological confirmation of cancers of the oesophagus or stomach. Tissue diagnosis may be inappropriate for pancreatic cancer, but a highly probable diagnosis can usually be achieved with a combination of physical examination and ultrasound imaging. Patients with confirmed oesophageal or gastric cancer should normally be referred to a Specialist Oesophago-gastric Cancer Team for (see below) assessment and treatment. Those who are believed to have, or might have, pancreatic cancer should normally be referred to the Specialist Pancreatic Cancer Team (see below). This includes patients with distal bile duct stricture.

Referral for specialist assessment may not be appropriate for patients who are frail and have serious co-existing disease or advanced metastatic disease, especially if the Cancer Centre is a long distance from the patient's home. In this situation, a clinician member of the Upper Gastro-intestinal Diagnostic Team should discuss the patient with a member of the Specialist Oesophago-gastric or Pancreatic Cancer Team, as appropriate. If it is agreed that the patient should not be referred for direct assessment, the reasons for the decision should be recorded in the patient's notes and the patient should be managed by the Local Upper Gastro-intestinal Cancer Care Team (see below). The proportion of patients managed in this way must be audited.

Explicit referral protocols should be agreed between all the hospitals and specialist teams in the Network. When patients do not precisely fit protocol criteria, or there is any uncertainty about referral, a clinician member of the Upper Gastro-intestinal Diagnostic Team should discuss the case with a clinician from the appropriate specialist team.

Specialist Teams (Assessment and Treatment)

Two types of multiprofessional specialist teams are required for assessment and treatment of patients with upper gastro-intestinal cancer: Specialist Oesophago-gastric Cancer Teams and Specialist Pancreatic Cancer Teams. These teams should be involved in the management of all patients. Each team should meet weekly to discuss individual patients.

Minimum figures for the population base to be served by each team are specified below. These take the diverse geography of the different regions of Britain into account. Where possible, commissioners should work together to achieve numbers at the higher end of the ranges given, since the evidence shows that higher patient throughput is associated with better outcomes.

There should be more than one individual member for each key role in the team. Larger teams are likely to offer more consistent care, and duplication of roles - particularly that of the surgeon - is important to ensure that all patients receive adequate care. Where workloads permit, some individuals (such as histopathologists and radiologists) may be members of both types of team.

Decisions about management and standards for therapy should follow documented clinical policy which has been agreed throughout the Cancer Network. This policy should be demonstrably evidence-based and should be produced jointly by members of all the teams in the Network which deal with patients with upper gastro-intestinal cancer, i.e. those working in local hospitals, Cancer Units and Cancer Centres. All teams should participate fully in the local upper gastro-intestinal Cancer Network, and all members of teams should be involved in discussions on local policy decisions and auditing adherence to them.

Audit of outcomes, and action such as training needs which may be stimulated by audit findings, should be discussed in team meetings. Teams should be jointly responsible for Network-wide audit and participation in clinical trials. Data collection systems should be compatible throughout the Network, to facilitate common audit.

Close co-ordination is required between the primary care teams, the diagnostic and treatment teams at local hospital, Cancer Unit and Cancer Centre levels, palliative care teams, and patients and their families. There should be a designated individual

in each team with responsibility for communication and information provision, and adequate support must be provided to ensure that all decisions about patient management are recorded. There should be defined arrangements to ensure that appropriate information (including the name of the clinician who is directly responsible for each patient) is communicated promptly to patients and others such as GPs who may require, or may benefit from, information about decisions concerning particular patients. Sufficient information should also be provided to GPs about each patient's cancer and its management to enable them to advise and support patients and their carers.

The Specialist Oesophago-gastric Cancer Team

It is anticipated that most Specialist Oesophago-gastric Cancer Teams will be based at Cancer Centres, although some will work in larger hospitals with designated Cancer Units. In the latter case, the Unit team must have strong links with an associated Cancer Centre team. Each team should appoint a lead clinician who will take an active role in the co-ordination of oesophageal and gastric cancer services provided by the Network as a whole.

Each team should aim to draw patients from a catchment area with a population of one to two million. (The minimum acceptable population size, for sparsely populated areas only, is 500,000.) A team with a population base of one million could expect to manage at least 100 patients with oesophageal cancer and 150 with gastric cancer who might require specialist treatment each year. Resections would be appropriate for about 100 of these patients. Adequate intensive care, high-dependency facilities and specialist post-operative care (including out-of-hours consultant cover) must be provided to minimise peri-operative mortality.

Members of the Specialist Oesophago-gastric Cancer Team

All members of the team should be specialists in oesophageal and gastric cancer. The number of people required to fulfil each role will depend on the team's workload.

- A designated lead clinician (physician or surgeon) who will take responsibility for assessment and treatment of patients with oesophageal or gastric cancer.
- Specialist oesophago-gastric surgeons. Requirements for these surgeons have been defined in a recent document.⁸ They should not normally be specialist hepato-pancreato-biliary (HPB) surgeons.
- Some teams may include thoracic surgeons with expertise in oesophageal resection.
- Gastroenterologist.
- Anaesthetist/intensivist.
- Radiotherapy specialist (clinical oncologist). If radiotherapy is not available at the hospital at which the team is based, close links must be established with the radiotherapy service to which patients may be referred.

⁸ Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland. *Upper Gastrointestinal Surgical Service Provision*. London, 1999.

- Chemotherapy specialist with expertise in the treatment of upper gastrointestinal cancers (medical oncologist or clinical oncologist).
- Radiologist with a gastro-intestinal sub-speciality interest and expertise in interventions.
- Histopathologist.
- Cytopathologist.
- Dietitian.
- Clinical nurse specialist.
- Palliative care specialist.

At least one member of the team (surgeon, physician or radiologist) should be trained in endoscopic ultrasonography.

The Specialist Pancreatic Cancer Team

Specialist assessment and interventions for patients with pancreatic cancer should be provided by multiprofessional teams based at Cancer Centres which draw patients from catchment areas with populations of two to four million. (The minimum acceptable population size is one million, but this figure is only appropriate for sparsely populated areas.) A team with a population base of two million could expect to discuss at least 200 new patients who might require specialist treatment each year.

Management of pancreatic cancer requires particularly high input from consultant surgeons, and larger numbers would allow more specialists to work together. Resections might be appropriate for about 15% of these patients, and at least 60% are likely to require biliary stents. Life-threatening complications are common after surgery, so adequate intensive care, high-dependency facilities and specialist post-operative care (including out-of-hours consultant cover) must be provided to minimise mortality.

Members of the Specialist Pancreatic Cancer Team

All members of the team should be specialists in the management of pancreatic cancer. The number of people required to fulfil each role will depend on the team's workload.

- A designated lead clinician (physician or surgeon) who will take overall responsibility for assessment and treatment of patients with pancreatic cancer.
- Specialist HPB surgeons. These surgeons will also operate on patients with non-malignant disease, since malignancy may not be confirmed until after resection.
- Gastroenterologist.
- Anaesthetist/intensivist.
- Radiotherapy specialist (clinical oncologist).

- Chemotherapy specialist with expertise in the treatment of upper gastro-intestinal cancers (medical oncologist or clinical oncologist).
- Radiologist with a gastro-intestinal sub-speciality interest and expertise in interventions.
- Histopathologist.
- Cytopathologist.
- Dietitian.
- Clinical nurse specialist.
- Palliative care specialist.

One or more members of the team (surgeon, physician or radiologist) should be trained in endoscopic ultrasonography.

Local Services

The Local Upper Gastro-intestinal Cancer Care Team

The function of the Local Upper Gastro-intestinal Cancer Care Team is to provide local care and palliative interventions for patients for whom specialist treatment is not appropriate, in accordance with locally agreed Network policy. This team should maintain an ongoing dialogue with the specialist teams to which patients are normally referred, and should also liaise with primary care teams and hospices.

Members of the Local Upper Gastro-intestinal Cancer Care Team

- Gastroenterologist (physician or surgeon) with a special interest in upper gastro-intestinal cancer.
- Clinical nurse specialist with knowledge of upper gastro-intestinal cancer.
- Endoscopist(s) with expertise in stenting (oesophago-gastric and biliary).
- Interventional radiologist.
- Dietitian.
- Palliative care specialist.

Where there is overlap between this team and the Upper Gastro-intestinal Diagnostic Team described earlier, the same individuals should be members of both. Palliative procedures such as stenting, which may be carried out by members of Local Upper Gastro-intestinal Cancer Care Teams, must be provided in the context of facilities which can demonstrate expertise in the use of the technology, and where outcomes are rigorously audited. Surgery (including palliative surgery) should not be carried out by these local teams, but only by designated members of specialist teams.

The clinical nurse specialist should act as the central contact point, both for the team and for patients. This is a multi-faceted role which includes not only nursing care, but also continuing support and provision of information for patients, ensuring continuity and co-ordination of care, and liaison between patients, clinicians, and primary care.

Palliative care

Palliative care services and specialist palliative care teams are discussed in Topic 9, *Palliative Interventions and Care*.

Patient-centred Care

At any one time, there should be a named clinician to whom the patient principally relates. Initially, this is likely to be a gastroenterologist or lead clinician responsible for diagnosis at the local hospital; responsibility for this role should be passed on at the time of referral to a member of the appropriate specialist team. Such arrangements should be explicit and clearly understood by patients and health care professionals, including the primary care team. Patients should be given written information about members of the team directly involved in their management.

From the time of assessment, each patient should have access to a named clinical nurse specialist who can offer support and continuity of care. This nurse should have had training in communication skills, should know about the patient's cancer and treatment, and should work closely with those who provide palliative care. A clinical nurse specialist should play a central co-ordinating role in each treatment team in the Network.

B. Anticipated Benefits

A co-ordinated Cancer Network will be capable of delivering consistent, efficient and effective care to all patients within the region. Within each level of the service, team working will facilitate co-ordinated care. Patients managed by teams are more likely to be offered appropriate treatments and to receive continuity of care through all stages of the disease. Treatment by doctors who manage larger numbers of patients with these types of cancer, in hospitals which have appropriate specialist facilities, can be expected to improve survival rates. Increasing specialisation offers valuable opportunities for enhancing specialist clinical training, improves potential research opportunities, and facilitates recruitment into clinical trials.

C. Evidence

Specialist treatment, patient throughput and survival

The research evidence summarised below reveals a consistent pattern of association between specialisation or higher patient throughput and better outcomes. However, because of the nature of the questions in this area, controlled trials are unlikely to be undertaken and none have been identified. Neither have there been any studies of the effectiveness of the particular service model recommended.

Oesophageal cancer

A large prospective study, carried out in 23 hospital trusts in south-west England between June 1996 and May 1997, examined relationships between specialisation, clinical practice, and patient survival. 781 patients with oesophageal cancer were followed for between 16 and 34 months from the time they first arrived at hospital. The discussion below refers to the period covered by the study.

31% of patients were managed by doctors who were responsible for six or fewer patients with oesophageal cancer. These patients were less likely to undergo resection, more likely to receive no active treatment, and had higher mortality rates, than patients managed by doctors who were responsible for larger numbers. The calculated mortality rate for patients managed by consultants who dealt with one new case per week was 31% lower than that for patients whose consultants managed one new case a month (after adjustment for case-mix, numbers treated at the hospital, and types of treatment provided).(B)

Overall, the peri-operative mortality rate (death within 30 days of surgery) was 11%. However, clinicians who dealt with larger numbers again achieved better outcomes. Mortality was about 30% lower among patients whose surgeons did 10 resections, than amongst those whose surgeons performed this operation only once. (Adjusted odds ratio of peri-operative death for patients treated by surgeons who carried out one resection 0.97, 95% CI: 0.94 to 1.00, compared with 0.68, 95% CI: 0.52 to 0.96 for patients treated by surgeons who carried out ten resections.)(B)

There is also evidence from the USA of an association between patient throughput and peri-operative mortality after oesophageal resection. A well-adjusted study found a clear advantage for surgery carried out in hospitals which dealt with larger numbers of patients. Mortality among patients over the age of 65 was 17.3% (95% CI: 13.3% to 22.0%) in hospitals which carried out fewer than five procedures per year and 3.4% (95% CI: 0.7% to 9.6%) in hospitals where the corresponding figure was over 11.(B)

Gastric cancer

The 23-hospital prospective study described above included 731 patients with gastric cancer. The outcomes discussed below refer to a period of 16 to 34 months beginning in 1996-7, from the time these patients first arrived at hospital until the end of the study.

Better outcomes were achieved in hospitals which treated larger numbers of patients with gastric cancer. The risk of death was 23% lower for patients treated in hospitals which admitted one case per week, compared with hospitals which dealt with one per month, even after adjustment for prognostic factors and types of treatment provided.(B) This suggests that aspects of hospital care which were not measured in the study - for example, nursing and nutrition - might be better in specialist hospitals and may have contributed to better outcomes.

35% of patients were managed by doctors who dealt with four or fewer new cases of gastric cancer per year. Patients treated by doctors who managed larger numbers were more likely to undergo surgery, particularly resection (adjusted odds ratio for an increase in volume of one patient 1.11; 95% CI: 1.07 to 1.14), and less likely to have no active treatment (adjusted odds ratio 0.94, 95% CI: 0.11 to 0.97). However, after adjustment for case-mix, hospital throughput and treatment, no independent relationship was found between numbers treated and survival rates.(B)

Studies which show variations in outcomes according to hospital type are difficult to generalise to the UK context but they tend to support the view that treating larger numbers of patients is associated with better outcomes. A Norwegian study reported 5-year survival rates in larger hospitals of 42-46%, compared with 34% in small local hospitals.(B) In Japan, patients treated in teaching hospitals survive longer.(B)

One study reveals how post-operative morbidity falls as the surgeon's level of experience increases. Outcomes achieved by an individual surgeon after intensive specialist training improved continuously over two years, or 15 to 25 procedures, before a plateau was reached.(B)

Pancreatic cancer

The prospective study described above included 782 patients with pancreatic cancer. In order to achieve patient numbers for pancreatic cancer comparable with those for other types of upper gastro-intestinal cancer, 6 hospitals in South Wales were studied in addition to 23 in England. As before, the outcomes discussed refer to a period of 16 to 34 months beginning in 1996-7.

The results for pancreatic cancer were broadly similar to those reported for oesophageal and gastric cancers. Higher-volume hospitals achieved better outcomes, reflected in a 36% lower risk of death (after adjustment for case-mix and treatments) among patients treated in hospitals which treated one new case a week, compared with hospitals which treated one new case a month. Clinicians who managed larger numbers were more likely to offer active treatments, in particular resection or a stent; however, after case-mix and hospital volume had been taken into account, there was no independent relationship between survival time and doctor volume.(B)

Surgery for pancreatic cancer is difficult and peri-operative mortality rates can be high, particularly in hospitals which treat few patients and are therefore unlikely to employ specialist surgeons. Seven studies, with varying levels of case-mix adjustment, all report that mortality after surgery is significantly lower in hospitals which treat larger numbers of patients.(B) Numbers ranged from 1 to 49 resections per year; in each study, the best outcomes reported were achieved by hospitals in the highest volume category. Mortality rates in hospitals which carried out fewest resections were as much as four times greater than those in high-volume hospitals, some of which achieved peri-operative mortality rates below 5%.(B)

Results from Yorkshire show similar associations between hospital volume and mortality. In 8 of 16 trusts, fewer than one resection was carried out per year for pancreatic cancer between 1986 and 1994. Overall, the peri-operative mortality rate was 17.7%.(B)

No studies were identified linking volume or specialisation with long-term outcomes, nor does there seem to be reliable evidence of an independent association between consultant workload and survival.

Multiprofessional teams

No evidence has been identified on the effectiveness of team working in the treatment of upper gastro-intestinal cancers, but it appears that the particular investigations and treatments given to patients may be largely determined by doctors' specialisation.(B) This suggests that patients who are managed by multiprofessional teams could get more appropriate treatment.

Non-surgical approaches to treatment have not played major roles in previous models and patterns of care. As evidence accumulates that such treatments can benefit patients, and in some cases offer alternatives to surgery, it is important that treatment teams should include specialists who can deliver the full range of treatment modalities appropriately, and to high quality standards. With the involvement of increasing numbers and types of clinicians and interventions, the need for effective communication, co-ordination and continuity of care will also grow.

No research evidence was identified on the level of specialisation required for team members, but evidence on training needs and expertise necessary to carry out specific diagnostic procedures is discussed in later sections of this guidance manual. (See topic 4, *Oesophageal and Gastric Cancers: Diagnosis and Assessment* and topic 5, *Pancreatic Cancer: Diagnosis and Assessment*.)

In palliative care, multidisciplinary teams caring for patients with a variety of cancers consistently achieve better symptom control and higher levels of patient and carer satisfaction than any individuals with whom they have been compared. (B) The contributions of specialist nurses and nurse co-ordinators appear to be crucial (see Topic 9, *Palliative Interventions and Care*).

How the teams function

There is strong general evidence that the use of clinical guidelines can improve the process and outcome of care. Local adoption of guidelines of good quality, incorporating the best up-to-date evidence and addressing relevant aspects of care, can lead to better outcomes for patients. (A)

Costs

Clinicians and hospitals which deal with larger numbers of patients with upper gastro-intestinal cancers tend to offer more active treatments (see above). This leads to higher costs per patient. (B) However, when case-mix and types of treatment are taken into account, the lowest doctor volumes are associated with higher than average costs for both oesophageal and pancreatic cancers, presumably due to long in-patient stays. (B) Care by such doctors may therefore be both unsatisfactory for patients and an inefficient use of NHS resources.

D. Measurement

Structure

- A Cancer Network in which the roles of hospitals which offer services for patients with upper gastro-intestinal cancer are specified.
- Systems to link and co-ordinate the activities of hospitals within the Network.
- Appropriate teams in place in each hospital in the Network.
- Adequate systems and support for rapid communication between teams within the Network.
- Evidence-based assessment, treatment and referral guidelines, agreed by specialist teams throughout the Network.
- Systems for Network-wide audit of procedures and outcomes.
- Provision of adequate and appropriate facilities for surgery and post-operative care.

Process

- Evidence of regular team meetings at both Cancer Units and Centres.
- Use of locally agreed clinical policies and guidelines.
- Number of patients managed annually by each team.

Outcome

- Peri-operative mortality rates for each team and type of cancer.
- 1-, 2- and 5-year survival rates for each type of cancer, adjusted for case-mix.
- Audit of outcomes of treatment, including detailed information on case-mix.

E. Resource Implications

- It is estimated that increased surgical referrals to Cancer Centres would increase annual costs for England by £14.4 million (see Appendix 1).
- Cost per patient is likely to rise when services are concentrated in more specialised facilities, because more active treatment is likely to be given. (See topic 6, *Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction*, topic 7, *Treatment for Gastric Cancer* and topic 8, *Treatment for Pancreatic Cancer*.)
- Increased provision of intensive care and high dependency facilities at Centres will require funding (see Appendix 1).
- Increased audit, monitoring and measurement will also require funding.

Oesophageal and Gastric Cancers: Diagnosis and Assessment

A. Recommendations

The lead clinicians of Upper Gastro-intestinal Diagnostic Teams and Specialist Oesophago-gastric Cancer Teams in each Network should produce agreed assessment and referral guidelines which specify the nature and sequence of diagnostic procedures to be used throughout the Network.

Patients suspected of having oesophageal or gastric cancer should be examined initially by endoscopy. Histological and cytological confirmation of the diagnosis should be sought by brushing and biopsy of suspect lesions. Patients with cancer should normally be referred to a Specialist Oesophago-gastric Cancer Team at a designated Cancer Unit or Cancer Centre for assessment. (See Topic 3, *Specialist Services and Multiprofessional Teams*.)

The stage and spread of the cancer should then be assessed using computed tomography (CT) or magnetic resonance (MR) scanning. If this reveals inoperable or metastatic disease, there may be no advantage in further assessment of the primary tumour. Further research is required to clarify the role of positron emission tomography (PET) scanning in the assessment of upper gastro-intestinal cancer.

The responsibility for the scan, its interpretation, and any decisions informed by it, will normally lie with the Specialist Oesophago-gastric Cancer Team. In exceptional cases, patients who are very frail need not be referred for direct assessment and it may be appropriate for CT scanning of such patients to be carried out by Upper Gastro-intestinal Diagnostic Teams working in local hospitals. The management of such patients should be agreed with the appropriate specialist treatment team. (See Topic 3, *Specialist Services and Multiprofessional Teams*.)

If the patient is sufficiently fit to undergo radical treatment and imaging produces no evidence of widespread or metastatic disease, endoscopic ultrasound (EUS) should be used to estimate the depth of tumour penetration.⁹ If this also suggests that radical treatment could be successful, patients whose tumours could involve the peritoneal cavity (i.e. those which extend below the diaphragm) should proceed to laparoscopy.

⁹ Units procuring EUS equipment should consider specific pieces of equipment for diagnosis and biopsy, since these functions require different tools.

Radical treatment for cancer of the oesophagus, oesophago-gastric junction or stomach should normally be carried out only after careful selection of patients and prior assessment of tumour stage and spread by EUS and laparoscopy when appropriate.

B. Anticipated Benefits

A co-ordinated approach to diagnosis and assessment, based on research evidence and agreed throughout the Cancer Network, would prevent duplication of testing and minimise delay in diagnosis. Adequate pre-treatment assessment is essential to avoid subjecting patients to radical treatment if it is not likely to be beneficial, and to ensure that appropriate treatment is offered to all those who are likely to benefit from it.

Collection and reporting of full diagnostic and staging data for all patients will provide better information for audit and routine monitoring by cancer registries.

C. Evidence

Endoscopy and radiology (barium meal or barium swallow) have both been used as initial diagnostic procedures for patients with symptoms which suggest the possibility of oesophageal or gastric cancer.

The methods have been directly compared in two studies of diagnosis; in both, all cases of oesophageal cancer were identified by both methods.(A) However, a retrospective review reported a positive predictive value of 42% for barium studies; in other words, more than half of those who had a positive or suspicious test result did not, in fact, have cancer.(B)

A variety of studies of endoscopy have reported that some patients found to have cancer had already undergone diagnostic imaging, but no abnormality had been apparent.(B) Also, studies of delay in diagnosis report that cancer may be missed when patients are assessed by radiology rather than endoscopy.(B) No research report was found which described cases where radiology had revealed cancer previously missed by endoscopy.

Endoscopic diagnosis has the additional advantage that it allows samples of suspect lesions to be collected for pathological examination without the need for a second diagnostic procedure. A series of prospective studies report that the accuracy of such sampling (by brushing and biopsy or fine needle aspiration) can be between 90% and 100% in oesophageal cancer. Endoscopic diagnosis of gastric cancer appears to offer similar levels of accuracy, particularly when brushing is followed by multiple biopsies.(B)

Patients do not appear to have strong preferences for either method.(A)

Achieving competence in endoscopy requires considerable practice. A study of gastroenterology fellows and fourth year surgical residents concluded that experience of over 100 procedures was necessary before success was achieved in 90% of attempts to pass an endoscope through the oesophagus.(B)

Although diagnostic endoscopy is not risk-free, the risks are not large; most adverse effects are mild and transient. The perforation rate reported in studies published since 1960 is around 1 in 2,000, and the overall death-rate around 1 in 10,000.(B) The majority of procedure-related complications are caused by sedation and analgesia, rather than perforation.

Studies in which results from pre-operative CT scanning have been compared with surgical findings show a consistent pattern in both oesophageal and gastric cancer. The sensitivity of CT for staging the tumour and assessing the extent of its spread is very variable and often poor, but its specificity is high.(B) This means that CT is a fairly reliable means of identifying patients whose cancer is so far advanced that radical surgery is unlikely to be effective. However, perhaps half of those who appear from CT results to have localised tumours will actually have more widespread disease. MRI produces similar results to CT scanning.(B)

A large Health Technology Assessment review has examined the role of EUS in gastric and oesophageal cancer. This concluded that:

- EUS is highly effective for discriminating between oesophageal or stomach cancers of stages T1/T2 and T3/T4. It can, therefore, be used to distinguish between tumours that are likely to be operable and those that are not.
- EUS is less effective for assessing cancer in the cardia (the upper opening of the stomach) than for cancers in other locations.
- It is not clear whether the risk involved in dilating the oesophagus to allow the passage of an ultrasound probe is justified.
- EUS is less accurate for assessing lymph node status than for tumour staging, and is not adequate for assessing metastatic spread.

The combination of CT scanning and EUS offers considerably higher levels of accuracy for staging of gastric tumours than CT alone.(B)

Laparoscopy can be highly effective for identifying patients with metastatic disease.(B) In oesophageal cancer, it has been found to be considerably more sensitive for assessing the extent of the disease than the combination of CT scanning and ultrasound.(B) Laparoscopy appears to be the only accurate method of detecting nodal metastases and peritoneal disease.(B)

Results of studies of PET imaging suggest that this could be a non-invasive yet sensitive method of assessing tumour stage, lymph node involvement, and distant metastases.(B) However, all these studies are small (25 to 58 patients) and further research is required.

D. Measurement

Structure

- Guidelines for diagnosis, assessment and referral of patients with suspected oesophageal or gastric cancer, agreed by all specialist treatment teams in the Cancer Network.
- Availability of EUS at Cancer Centres.

Process

- Audit to assess whether locally agreed guidelines are followed.
- Audit of use of endoscopy by suitably trained staff, with brushing and biopsy of suspect lesions, at Cancer Units.
- Audit of use of other methods in addition to CT (EUS, laparoscopy, and/or PET) for assessment of tumour spread before radical surgery for oesophageal cancer.

Outcome

- Audit of adverse effects of diagnostic procedures, including endoscopy.
- Proportion of surgical procedures during which anticipated resection is abandoned because of metastatic spread.

E. Resource Implications

- Acquisition of additional EUS equipment could cost £3.0 million for the whole of England (see Appendix 1).
- The increase in the number of assessments (CT, EUS and laparoscopy) could increase annual costs by up to £6.6 million (see Appendix 1).
- Increased expenditure on pre-surgical assessment could reduce resources consumed by inappropriate surgery by an estimated £0.7 million (see Appendix 1).
- Increased audit and improved monitoring of both process and outcomes will require funding.

Pancreatic Cancer: Diagnosis and Assessment

A. Recommendations

The lead clinicians of Upper Gastro-intestinal Diagnostic Teams in each Network should collaborate with the Specialist Pancreatic Cancer Team to produce agreed assessment and referral guidelines which specify the nature and sequence of diagnostic procedures to be used throughout the Network for patients with suspected cancer of the pancreas.

Patients with jaundice should have fast-track access to the Upper Gastro-intestinal Diagnostic Team for initial assessment by abdominal ultrasound. Patients over the age of 55 who have pain or other symptoms which could be due to pancreatic cancer should also be assessed using abdominal ultrasound in a gastro-intestinal diagnostic clinic. Patients with dilated bile ducts and no evidence of gallstones, and any other patients considered likely to have pancreatic cancer on the basis of symptoms and ultrasound findings, should normally be referred immediately to the Specialist Pancreatic Cancer Team at the Cancer Centre.

It may not be appropriate for frail patients with advanced disease to be referred to the Cancer Centre for direct assessment; the management of such patients should be discussed with the Specialist Pancreatic Cancer Team. (See Topic 3, *Specialist Services and Multiprofessional Teams*.) Further investigations such as CT scanning and endoscopic retrograde cholangiopancreatography (ERCP) should not be carried out by the Local Upper Gastro-intestinal Diagnostic Team, except in these specific cases after consultation with the Specialist Pancreatic Cancer Team. Patients with jaundice should only be given biliary stents by, or with the specific agreement of, the Specialist Pancreatic Cancer Team. (See Topic 8, *Treatment for Pancreatic Cancer*.)

Further assessment of the tumour may involve spiral CT scanning, EUS, magnetic resonance cholangiopancreatography (MRCP), and/or ERCP. All these diagnostic modalities should be available at Cancer Centres which offer assessment services for patients with pancreatic cancer. If radical surgery seems appropriate, tumour stage and spread should be assessed by laparoscopy.

When symptoms or imaging clearly show that the disease is metastatic or inoperable, or the patient is not sufficiently fit to undergo radical treatment, there may be no advantage in further assessment of the primary tumour. Such patients should be offered appropriate palliative treatment.

Further investigations to achieve a tissue diagnosis should only be considered if the findings are expected to influence management (for example, by informing choice of palliative therapy), since every method involves significant risk and discomfort to patients. Histological confirmation of tumour is, however, required before treatment with chemotherapy or radiotherapy.

B. Anticipated Benefits

The use of locally agreed and documented clinical policies which define diagnostic and referral pathways will improve access to effective management. This will permit earlier symptom control and increase the probability that those patients who could benefit from each form of treatment will be identified.

C. Evidence

Abdominal ultrasound is an effective method of detecting pancreatic abnormalities, and allows a correct diagnosis to be made in over 80% of patients with symptoms of pancreatic cancer.(B) Ultrasound is not reliable for determining whether the disease is resectable.(B)

In patients with jaundice, ERCP may permit a diagnosis of pancreatic cancer when imaging shows no abnormality or is inconclusive.(B) In general, ERCP is less accurate than CT for identifying the presence of cancer and technical failure is common, but ERCP with bile cytology and brushing can provide tumour cells for tissue diagnosis.(B) This is an invasive procedure with two major drawbacks. First, it can have serious adverse effects. Second, it necessitates the insertion of a biliary stent, which can reduce the accuracy of imaging and may cause inflammation. This may reduce the probability of success of subsequent treatment.(C)

ERCP can have both diagnostic and therapeutic uses. It is a valuable palliative procedure, providing a means by which a stent may be placed in the bile duct to relieve jaundice. (See Topic 8, *Treatment for Pancreatic Cancer*, and Topic 9, *Palliative Interventions and Care*.) Achieving technical competence may require experience of 180-200 procedures.(B) The Joint Advisory Group on Gastro-intestinal Endoscopy (JAG) states that, "Trainees should have completed training in diagnostic upper gastro-intestinal endoscopy before starting ERCP," and that, "Trainees should carry out at least 100 procedures under supervision and be achieving a high percentage of success before performing the procedure independently."¹⁰

MRCP is a new technique. Small prospective studies suggested that it might offer a higher level of accuracy than other diagnostic methods, with the additional advantage that contrast media are not required. A recent study, in which MRCP was compared with ERCP in 124 patients, suggests that MRCP may be more effective for discriminating between cancer and other causes of pancreatic disease. The comparison between sensitivity figures for the two modalities was not quite statistically significant ($p=0.059$), but this did not include data for 16 patients for whom ERCP failed. MRCP was impossible for only one patient, who had claustrophobia. In addition, MRCP was free from complications, whereas ERCP was associated with a morbidity rate of 7%.(B)

¹⁰ Joint Advisory Group on Gastrointestinal Endoscopy. *Recommendations for training in gastrointestinal endoscopy*. JCHMT, 1999.

The results of studies assessing the effectiveness of non-invasive imaging procedures (abdominal ultrasound, CT and MRI) for the diagnosis of pancreatic cancer vary widely, but the overall accuracy of these techniques appears similar. No studies were identified which report direct comparisons between different types of CT. None of these methods, used alone, is reliable for establishing whether the disease is resectable.(B)

To establish whether radical surgery is possible, it is important to know how far the tumour has invaded blood vessels. The accuracy of abdominal ultrasound seems particularly poor for this, but it is not clear which technique is most reliable because there is wide variability between studies. Consistently excellent results are not achieved with any single method.(B)

Studies of the accuracy of imaging for detection of tumour in lymph nodes and metastatic disease show a similar pattern. Laparoscopy seems to be more accurate than imaging for identification of metastases, but these methods have not been directly compared in a randomised study.(B)

Laparoscopy with ultrasound appears to be more effective than EUS, CT or both, or laparoscopy alone, for detecting metastatic spread to lymph nodes, veins, the liver, and the peritoneum.(B) Information from laparoscopy may change treatment strategy in a substantial number of cases, since radical surgery is normally impossible when such spread has occurred.(B)

Transperitoneal needle biopsy can be used to obtain histological confirmation of cancer. This has two drawbacks: first, it has been suggested that it may spread tumour cells into the abdomen (peritoneal seeding); and second, it has a significant false negative rate.(C)

D. Measurement

Structure

- Guidelines for diagnosis, assessment and referral of patients with suspected pancreatic cancer, agreed by all specialist treatment teams in the Network.
- Availability of EUS, spiral CT facilities, MRCP and ERCP at Cancer Centres.

Process

- Audit to assess whether locally agreed guidelines are followed.
- Audit of use of ERCP by suitably trained staff, including success rates in diagnosis and stent placement.
- Use of laparoscopy for assessment of tumour spread before surgical resection for pancreatic cancer.

Outcome

- Audit of adverse effects of endoscopy, ERCP and biopsy.
- Proportion of surgical procedures during which anticipated resection is abandoned because of metastatic spread.

E. Resource Implications

- Acquisition of additional EUS and MRCP equipment could cost £4.0 million for the whole of England (see Appendix 1).
- The increase in the number of assessments (spiral CT, MRCP, EUS and laparoscopy) could increase annual costs by up to £1.9 million (see Appendix 1).
- Increased audit and improved monitoring of both process and outcomes will require funding.

Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction

A. Recommendations

Treatment for patients with oesophageal cancer¹¹ should be the responsibility of Specialist Oesophago-gastric Cancer Teams based in Cancer Units or Cancer Centres which would normally serve populations of at least one million. (See Topic 3, *Specialist Services and Multiprofessional Teams*.) Patients for whom radical interventions would not be appropriate may be treated in local Cancer Units which offer palliative care, but the Specialist Oesophago-gastric Cancer Team should be informed of every case and should normally be involved in working out an appropriate care plan. Referral guidelines, clearly specifying which types of patient should be referred to a specialist team, should be agreed and documented by all the specialist teams involved in the care of these patients throughout the Network.

The interventions described below should be provided by Specialist Oesophago-gastric Cancer Teams. Radical interventions (surgery or chemo-radiotherapy) should be offered to patients with localised tumours who are sufficiently fit to tolerate these forms of treatment. Neo-adjuvant chemotherapy should be considered, but adjuvant radiotherapy should not be used outside the context of multi-centre randomised trials. Chemotherapy alone is not appropriate for first-line radical treatment and should be considered for palliation only.

Radical interventions

The most appropriate treatment for individual patients should be discussed by surgeons and oncologists in Specialist Oesophago-gastric Cancer Team meetings.

Surgery

Surgical resection offers the chance of long-term survival for carefully selected patients with early stage cancer. Pre-operative (neo-adjuvant) chemotherapy, using two cycles of cisplatin/5-Fluorouracil (5-FU), should be considered.

These operations should be undertaken only by specialist surgeons who carry out a sufficiently high volume of such procedures for meaningful audit of outcomes (likely to be at least 10 per year). A high level of consultant out-of-hours commitment is required to manage post-operative complications.

¹¹ Tumours of the oesophago-gastric junction are considered here as a subset of adenocarcinoma of the oesophagus.

Patients should be selected so that only those who are judged to have a reasonable chance of long-term survival undergo resection; surgery is not appropriate for palliation of oesophageal stricture. Selection should take account both of the stage and spread of the tumour, and the patient's general level of fitness. Patients should be offered realistic information about adverse effects of surgery and the probability of long-term success.

Chemo-radiotherapy

Definitive chemo-radiotherapy (normally using chemotherapy based on platinum/5-FU) may be considered as an alternative to surgery for selected patients with early stage tumours. Multi-modality treatment, involving chemo-radiotherapy followed by surgery, may also be considered.

Patients should be offered realistic information about potential adverse effects of these forms of treatment and encouraged to participate in decision-making. The level of uncertainty about individual responses to treatment should be acknowledged.

Further research evidence is required to establish the effectiveness of chemo-radiotherapy as first-line treatment for oesophageal cancer.

Palliative interventions

About two thirds of patients have inoperable disease at the time of diagnosis and most will need treatment for dysphagia. The methods outlined below are complementary and may be used singly or together, as required. These interventions should be carried out by members of Specialist Oesophago-gastric Cancer Teams.

Stents

A range of stents may be used for patients with oesophageal strictures or fistulae; the choice of type (metal or polythene) will depend on the features of the individual case. A stent should not usually be inserted before the patient has been discussed with a specialist oncologist.

Chemotherapy

Palliative chemotherapy should be available for patients with advanced oesophageal cancer. Epirubicin/cisplatin/fluorouracil (ECF) is likely to be appropriate.

Radiotherapy

Intra-luminal radiotherapy (brachytherapy) should be considered for patients for whom definitive chemo-radiotherapy is not appropriate.

Other endoscopic methods

A range of methods, including laser treatment, may be used to re-open the oesophagus and relieve symptoms. No evidence was identified to assess the relative effectiveness or appropriateness of these methods.

B. Anticipated Benefits

Radical treatment offers the possibility of long-term survival for the minority of patients who have early cancers. Results of recent trials suggest that survival rates after surgery and chemo-radiotherapy may be similar. Currently, only about 15% of patients who undergo surgery are still alive five years later. Surgery by specialists, combined with improved selection of patients, would reduce the proportion whose survival time is short and who suffer deterioration in quality of life after surgery.

Palliative interventions can allow patients to live near-normal lives by reducing problems with swallowing, often for most of their remaining life.

C. Evidence

Radical interventions

Surgery

Surgery is widely regarded as the only type of intervention that offers the hope of cure and about a third of patients with oesophageal cancer undergo surgery. However, success rates are poor and operative mortality and morbidity can be high. In Yorkshire, the 5-year survival rate after surgery in 1991-1993 was 13.9% (95% CI: 10.3% to 17.6%). This is clearly better than the 3.9% (95% CI: 1.8% to 6.0%) survival rate among patients who did not receive surgery, but the difference could be largely due to the fact that patients selected for surgery have less advanced tumours and are likely to be fitter.(B)

In south west England, the overall peri-operative mortality rate in 1996-7 was 11%, but the probability that patients would survive was significantly higher when surgeons carried out these operations more frequently. An increase of 10 in the number of patients treated over the period of the study was associated with a 32% fall in the risk of peri-operative death (odds ratio, adjusted for case-mix 0.68, 95% CI: 0.52 to 0.96).(B)

A variety of surgical procedures may be used. Transthoracic surgery has been compared with transhiatal surgery in five small RCTs; no significant survival differences were found but the transthoracic operation took longer.(A) Studies comparing different reconstruction techniques have also failed to demonstrate substantial differences in outcome.(A)

Four studies show that oesophageal resection leads to impaired quality of life for some months after surgery. In patients who survive for more than two years, quality of life returns to baseline levels after about six months and may continue to improve. However, among those who do not go on to become long-term survivors, quality of life continues to deteriorate, despite improved ability to swallow. Whilst the deterioration after six months is likely to be due to disease progression, the overall effect of surgery appears to be beneficial only when the operation is curative. Relief of dysphagia seems to have considerably less overall impact on quality of life during the post-operative period than the trauma of major surgery.(B)

In one study, a single pre-operative measure, appetite loss, discriminated clearly between patients who survived for two years or more and those who did not. No survivors reported loss of appetite before surgery, compared with over 60% of those who died within two years.(B)

Neo-adjuvant and adjuvant chemotherapy

Randomised studies of chemotherapy for patients with resectable oesophageal cancer do not provide consistent evidence of effectiveness. Meta-analyses of studies published before 1999 show no significant advantage for either neo-adjuvant or adjuvant chemotherapy.(A) However, early results from an MRC trial (OEO2) involving 802 patients suggest that two cycles of neo-adjuvant chemotherapy using cisplatin/5-FU may improve survival rates.(A)

In this trial, chemotherapy was associated with a 10% (95% CI: 3% to 16%) improvement in survival at two years. Two thirds of the patients had adenocarcinoma, but information on the relative effectiveness of chemotherapy for patients with different types of tumour is not yet available. About 40% of patients in both groups had post-operative complications but levels of physical activity, dysphagia, and general well-being after treatment did not differ significantly between the groups.

This trial is the largest so far conducted and it provides persuasive evidence that chemotherapy can be effective for these patients. More specific information will become available when more complete and detailed analyses can be carried out.

Chemo-radiotherapy

At present, the place of chemo-radiotherapy in the primary treatment of operable oesophageal cancer is uncertain. Seven trials have compared neo-adjuvant chemo-radiotherapy with surgery alone. Although these trials have been combined by meta-analysis, the differences between them are such that the results are difficult to interpret.

Meta-analysis of the four trials that included only patients with squamous cell cancers (n=540) did not demonstrate better results for multi-modality treatment than surgery alone (odds ratio for 3-year survival 1.22, 95% CI: 0.83 to 1.80).(A) Pooling the results of two trials which included mainly patients with adenocarcinomas suggests that pre-operative chemo-radiotherapy can lead to improved 3-year survival rates in these patients, compared with surgery alone (odds ratio 3.63, 95% CI: 1.90 to 6.97).(A) However, this result is heavily influenced by the results of one particular trial in which the two patient groups do not appear to have been comparable at baseline, and which may therefore be unreliable.

No trial yet identified includes a comparison between chemo-radiotherapy alone and chemo-radiotherapy followed by surgery. It is therefore not clear that surgery confers any additional benefit for patients who show a complete response to chemo-radiotherapy. More RCTs are necessary to clarify the optimum treatments for both squamous cell cancer and adenocarcinoma.

In advanced disease, chemo-radiotherapy appears to extend survival time more than radiotherapy alone, despite local failure rates of 40-50%.(A)

Neo-adjuvant and adjuvant radiotherapy

A meta-analysis of individual patient data from trials which compared pre-operative radiotherapy with surgery alone found that radiotherapy improved survival rates at two years from 30% to 34% despite increased surgical mortality, but this result fell short of statistical significance (p=0.06).(A) This possible survival benefit is offset by greater morbidity and increased duration of treatment.

Radiotherapy after surgery impairs quality of life without improving survival. (Odds ratio for survival at three years, combined treatment versus surgery alone 0.86, 95% CI: 0.54 to 1.37).(A)

Palliative interventions

Most patients require palliative interventions to relieve dysphagia. A range of techniques are available, including removal of tumour in the oesophagus by laser and other methods, and chemotherapy and/or radiotherapy to shrink the tumour. There is no evidence that any one of these techniques should be used routinely in preference to others.

Stents

Stents permit swallowing by keeping the oesophagus open and sealing fistulae; they can be used on their own or in combination with other types of palliative treatment. Currently, about 40% of patients receive them.(B) Compared with other types, expanding metal stents (Wallstents) are associated with fewer complications, better quality of life for patients, less need for re-intervention, and less time spent in hospital.(A)

Small studies comparing stenting with laser treatment or gastric bypass suggest that stenting may produce slightly better outcomes.(A) In practice, these methods may be used in combination.

Oesophageal stents placed before chemotherapy or radiotherapy may cause problems. They may interfere with defining the target for radiotherapy and can become dislodged when treatment causes the tumour to shrink.(C)

Chemotherapy

A French trial comparing palliative chemotherapy (cisplatin and 5-FU) with no treatment found no evidence of improved survival with chemotherapy; median survival times for the two groups were 13 months and 14 months, respectively.(A) However, many patients in this trial had undergone surgical resection and the results may not be applicable to previously untreated patients.

The results of two UK RCTs which included patients with advanced or metastatic tumours of the oesophagus, stomach, or the junction between them, suggest that chemotherapy can increase survival time and palliate symptoms.(A) 51 of 256 patients in one trial had oesophageal cancer; the 1-year survival rate for those treated with ECF was 37.0%, compared with 12.5% for patients treated with adriamycin, 5-FU and methotrexate (FAMTX) ($p=0.032$). Overall survival rates at one year were 36.5% with ECF, compared with 21.5% with FAMTX.(A)

Radiotherapy

External beam radiotherapy has been compared with surgery in patients with operable squamous cell tumours. Those who had surgery survived significantly longer ($p=0.002$) and had less dysphagia.(A)

Intra-luminal radiotherapy (brachytherapy) may increase survival time and can relieve dysphagia.(A) In one study, 10%, 22% and 35% of patients who received 12Gy, 16Gy (two fractions) or 18Gy (three fractions), respectively, were alive one year later.

D. Measurement

Structure

- Documented local clinical policies describing types of patients to be treated and forms of treatment to be offered by each specialist team dealing with patients with oesophageal cancer.
- Locally agreed guidelines specifying which patients should be referred to Specialist Oesophago-gastric Cancer Teams.
- Availability of brachytherapy at specified facilities.

Process

- Number of resections carried out annually by each surgeon.
- Proportion of patients who receive specified interventions to palliate dysphagia.
- The histopathological report after oesophageal resection should comply with the Royal College of Pathologists' Minimum Data Set for Oesophageal Carcinoma.¹²

Outcome

- 30-day, 1-year and 5-year survival rates of patients who undergo radical surgery, with information on cancer stage, co-morbidity, age and other features of case-mix. These data should be recorded for each surgeon.
- Short-term, 1-year and 5-year survival rates of patients who undergo other types of radical treatment, with information on case-mix.
- Audit of quality of life and degree of dysphagia among patients.
- Audit of short-term and long-term adverse effects of treatment.

E. Resource Implications

- Increased use of chemotherapy and chemo-radiotherapy is estimated to increase annual costs by £12.9 million (see Appendix 1).

¹² Available on <http://www.rcpath.org/activities/publications/oesophageal.html>.

Treatment for Gastric Cancer

A. Recommendations

Treatment for patients with gastric cancer should be the responsibility of Specialist Oesophago-gastric Cancer Teams based in Cancer Units or Cancer Centres which would normally serve populations of more than a million. (See Topic 3, *Specialist Services and Multiprofessional Teams*.) Patients for whom radical interventions would not be appropriate may be treated in local Cancer Units which offer palliative care, but the Specialist Oesophago-gastric Cancer Team should be informed of every case and should normally be involved in working out an appropriate care plan. Referral guidelines, clearly specifying which types of patient should be referred to a specialist team, should be agreed and documented by all the specialist teams involved in the care of these patients throughout the Network.

Surgery

Surgical resection, carried out by specialist oesophago-gastric surgeons, should be considered for all patients with localised tumours who are sufficiently fit to tolerate the procedure. Radical surgery which involves extensive removal of regional lymph nodes (D2 or “Japanese” surgery) cannot be justified on the basis of current evidence. This procedure should not, therefore, normally be used except in the context of large, well-designed RCTs. The spleen should not be removed, nor should the pancreas, if this is avoidable. Sub-total gastrectomy should be used in preference to total gastrectomy whenever possible.

Palliative operations (including bypass when appropriate) should be considered for selected patients whose cancer is too far advanced to be removed completely.

Chemotherapy

Adjuvant chemotherapy should be discussed with selected patients in whom the risk of recurrence is relatively high. Palliative chemotherapy based on fluorouracil (5-FU) (fluorouracil) should be considered for patients with advanced gastric cancer.

Adjuvant radiotherapy or chemo-radiotherapy

Adjuvant radiotherapy, with or without chemotherapy, should not be considered outside the context of large, well-designed, multi-centre RCTs.

B. Anticipated Benefits

Surgery can eradicate the cancer and lead to long-term survival for patients whose tumours are not too advanced. When this is not possible, resection may help to relieve symptoms. The results are likely to improve if surgery is carried out by specialised surgeons. Palliative chemotherapy can enhance quality of life and increase survival time in patients whose cancer is more advanced.

C. Evidence

Surgery

Radical surgery offers the possibility of long-term survival for a minority of patients with gastric cancer. Although some surgeons achieve peri-operative mortality rates of 5% or below, a prospective study found that the peri-operative mortality rate in south west England was 14%. An increase of 10 in the number of patients treated by individual surgeons over the period of the study was associated with a reduction in mortality of 40% (odds ratio for peri-operative death, adjusted for case-mix 0.60, 95% CI: 0.39 to 1.00).(B)

One third of patients with gastric cancer were managed by doctors who dealt with four or fewer such patients per year. These low-volume doctors were less likely to record cancer stage and less likely to carry out any form of surgery. Nevertheless, the cost per day of survival time among their patients was relatively high. This was because these patients spent a greater proportion of their remaining lives in hospital.(B)

In the UK generally, 5-year survival rates after surgery are about 20%. Long-term survival rates reported from Japan are considerably higher, around 50%. These results have been attributed by some to the use of a more extended operation known as a D2 resection, in which 30 or more lymph nodes are removed, along with the spleen and part of the pancreas in some cases. There have been no RCTs in Japan comparing this procedure with less radical operations; all the evidence for its alleged superiority has been based on retrospective reports.

Results similar to those achieved in Japan have been reported from non-randomised trials in the UK, leading to a widespread belief that D2 resections would lead to higher long-term survival rates than the D1 operation which had been used by western surgeons. This belief has now been tested in four RCTs, two of which were quite large (998 and 400 patients).

None of these four RCTs found any evidence that D2 (Japanese-style) resection was associated with better survival or improvements in other outcomes than D1 (western) surgery.(A) Indeed, if anything, the reverse appears to be true. More extended operations lead to significantly higher rates of complications, greater use of blood transfusion, more post-operative deaths, longer hospitalisation and higher costs, with no benefits for patients.(A)

The worst survival rates were among patients whose spleens were removed. This was associated with more than double the risk of death (relative risk (RR) 2.13, 95% CI: 1.44 to 3.16). Removal of the pancreas, which was part of the D2 protocol for some patients, increased the risk of major complications (RR 3.03, 95% CI: 1.98 to 4.65). On the basis of these results, it has been suggested that some aspects of the more extended operation might be beneficial, but that these were obscured by the harm caused by removing the spleen and pancreas. This possibility has not been tested in an RCT.

These trials have been criticised on a variety of points. One suggestion was that the skill of the surgeons is lower in the west than in Japan. However, the results achieved by an experienced Japanese surgeon working in the Netherlands were similar to those of European surgeons, which suggests that unspecified differences between European and Japanese patient groups could be responsible for the different patterns of outcomes.

Other problems include non-compliance with the protocol in the largest trial, which could have reduced the distinction between the procedures. Despite considerable non-compliance, the results did show significant differences in outcomes between the trial arms: specifically, that the D2 procedure led to higher rates of adverse effects. This criticism therefore seems to be based on the dubious supposition that non-compliance could have obscured evidence of putative benefits without affecting evidence of hazards.

Different types of gastrectomy (stomach resection) have been compared in 10 comparative trials. These show that resection can relieve the symptoms of gastric cancer even when potentially curative surgery is impossible. Some report that sub-total gastrectomy is associated with fewer symptoms and better quality of life after surgery; none report any advantage for total gastrectomy when either operation is possible.(A) These trials suggest that there are no differences between types of gastrectomy in survival rates or post-operative mortality.(A)

Chemotherapy

Over 250 RCTs and three meta-analyses of chemotherapy have been identified. More recent trials have been of various combinations, usually including 5-FU and often also adriamycin, leucovorin or cisplatin. Whilst some trials suggest that 5-FU alone can offer minimum toxicity with survival equivalent to that associated with more complex regimens, most show improved survival with combination chemotherapy.(A)

The most recent meta-analysis shows that adjuvant chemotherapy can increase survival rates after curative resection for gastric cancer. The combined hazard ratio was 0.82 (95% CI: 0.75 to 0.89) in favour of chemotherapy, reflecting an absolute survival benefit at five years of 4% for patients with stage II or stage III disease and 2% with stage I.(A)

Western trials of intra-peritoneal chemotherapy report increased complication rates with no improvements in survival rates.(A) Japanese trials, by contrast, report that intra-peritoneal chemotherapy improves survival.(A) The reasons for this difference are not apparent.

Palliative chemotherapy can improve quality of life and may extend survival time in patients with advanced gastric cancer by about six months, compared with best supportive care.(A) A particularly effective regime for fitter patients is ECF.(A)

Adjuvant radiotherapy

There is some evidence suggesting that pre-operative (neo-adjuvant) radiotherapy may improve survival rates.(A) There is no reliable evidence to suggest that either intra-operative or post-operative (adjuvant) radiotherapy is beneficial.(A)

Adjuvant chemo-radiotherapy

The largest trial to compare surgery followed by chemo-radiotherapy with surgery alone has reported that adjuvant treatment for high-risk patients with adenocarcinoma of the stomach or oesophago-gastric junction is associated with improved survival rates at three years (52% versus 41%, $p=0.03$). (A) At the time of writing, the median follow-up in this trial was 3.3 years and the results had been published in abstract only, so few details are available and the data are not sufficiently mature to provide a reliable guide to practice. Previous studies of adjuvant chemo-radiotherapy had not demonstrated any significant survival benefits.(A) Patients who undergo multi-modality treatment are likely to experience severe toxic effects.

D. Measurement

Structure

- Documented arrangements to ensure that surgery for patients with gastric cancer is the responsibility of designated specialists, each of whom does a sufficiently large number of resections per year for meaningful audit of outcome.

Process

- Number of patients treated at each hospital.
- Number of patients managed by specialist teams.
- Proportion of patients who undergo surgery.
- Number of resections carried out annually by each surgeon.
- Proportion of patients who receive palliative chemotherapy.

Outcome

- 30-day, 1-year and 5-year survival rates of patients who undergo radical treatment, with information on cancer stage, co-morbidity, age and other features of case-mix.
- Audit of short-term and long-term adverse effects of treatment.

E. Resource Implications

- Over the whole of England, increased use of resection for gastric cancer could increase annual costs by £9.7 million, whilst increased use of chemotherapy is estimated to increase annual costs by £15.8 million (see Appendix 1).
- Restricting surgery to specialised and experienced surgeons could reduce the average time patients spend in hospital.

Treatment for Pancreatic Cancer

A. Recommendations

Treatment for patients with pancreatic cancer should be the responsibility of Specialist Pancreatic Cancer Teams. These should be based in Cancer Centres and should serve populations of two to four million (minimum one million, in sparsely populated areas). (See Topic 3, *Specialist Services and Multiprofessional Teams*.) Patients for whom radical interventions would not be appropriate may be treated in local hospitals with Cancer Units which offer palliative care, but the Specialist Pancreatic Cancer Team should be informed of every case and should normally be involved in working out an appropriate care plan. There should be arrangements to allow for members of Specialist Pancreatic Cancer Teams to see patients in local hospitals.

Referral guidelines, clearly specifying which types of patient should be referred to a specialist team, should be agreed and documented by all the specialist teams involved in the care of these patients throughout the Network.

The majority of patients with pancreatic cancer have advanced disease, for which radical treatment is not appropriate. Palliative interventions are frequently required to relieve the major symptoms: jaundice due to bile duct obstruction, and severe pain.

Surgery

Pancreatic resection may be appropriate for about 10-15% of patients. Surgery for patients with pancreatic cancer should only be carried out by specialist for Hepato-pancreato-biliary (HPB) surgeons working in multiprofessional Specialist Pancreatic Cancer Teams. This type of surgery, whether palliative or carried out with curative intent, often has a stormy post-operative course. A high level of out-of-hours commitment is required for surgical and anaesthetic consultants to monitor patients, manage post-operative complications, and minimise mortality. Cancer Centres should aim to achieve peri-operative (30 day) mortality rates for both radical and palliative surgery of less than 5%.

Octreotide, a drug which reduces pancreatic secretions, should be given after surgery to reduce the risk of complications.

Adjuvant therapy

Post-operative (adjuvant) chemotherapy using 5-FU may be beneficial, but adjuvant radiotherapy (with or without chemotherapy) is not recommended.

Relief of bile duct obstruction

The staging sequence (see Topic 5, *Pancreatic Cancer: Diagnosis and Assessment*) should be complete before ERCP and biliary stenting is carried out. Expanding metal stents (Wallstents) should be available for patients with jaundice or other

symptoms caused by bile duct obstruction who are expected to survive for several months. Polythene stents may be appropriate for patients with shorter life-expectancy.

Clinicians who carry out ERCP should have been trained in accordance with criteria defined in JAG Recommendations.¹³

Chemotherapy

Palliative treatment with chemotherapy should be considered. 5-FU is probably as effective as other drug regimens but there is no clear evidence to guide the choice of therapy. Hormone treatment should not normally be used in the primary treatment of patients with pancreatic cancer.

Chemo-radiotherapy and Radiotherapy

Chemo-radiotherapy may be considered for fitter patients with inoperable localised disease, but the risk of adverse effects must be carefully balanced against potential benefits. Radiotherapy alone is not recommended.

B. Anticipated Benefits

Although long-term survival after surgery for pancreatic cancer is unusual, resection for carefully selected patients can increase life-expectancy and may improve quality of life. Ensuring that patients are treated by clinicians with specialist expertise is likely to reduce mortality rates. Efficient delivery of appropriate palliative interventions is important to minimise the impact of symptoms on patients' quality of life.

C. Evidence

Surgery

Surgery for pancreatic cancer is difficult and hazardous. Outside specialist centres, it is associated with high levels of mortality. In Yorkshire between 1986 and 1994, the death-rate within 30 days after surgery was 17.7%.(B) Palliative and curative operations carried equal risk of peri-operative death.

Radical surgery for pancreatic cancer (pancreaticoduodenectomy, or the Whipple procedure) can lead to long-term survival when the tumour is at a sufficiently early stage to be entirely removed. However, curative resection is rarely possible, and only about 4% of patients in England survive for five years after surgery. Such poor results are not universal; some published case-series from institutions with a specialist interest in pancreatic surgery report 5-year survival rates as high as 20%.(B)

When curative surgery is not possible, resection can reduce symptoms and may improve life-expectancy. A randomised study which compared the palliative effects of radical surgery with bypass surgery, laparotomy alone or no surgery reported that patients who had radical operations suffered less pain, nausea and vomiting than those in other groups.(A)

¹³ Joint Advisory Group on Gastrointestinal Endoscopy. *Recommendations for training in gastrointestinal endoscopy*. JCHMT, 1999.

A variety of studies, carried out in the UK and other countries, have shown that peri-operative mortality rates tend to be lower when individual surgeons manage larger numbers of patients with pancreatic cancer. (B) The survival of patients with pancreatic cancer generally is greater when consultants treat larger numbers of these patients, whatever treatment is given and after adjustment for case-mix. (B)

In most parts of Britain, treatment of patients with pancreatic cancer is fragmented and few patients are treated by specialist HPB surgeons. In Yorkshire between 1986 and 1994, about 90% of patients were treated by consultants who dealt with five or fewer such cases a year; and in south-west England and south Wales in 1996-7, 31% of patients were the responsibility of doctors who managed fewer than three new cases per year. Surgeons who managed larger numbers of patients with cancer of the pancreas were more likely to carry out resections.

A well-designed prospective study in south west England and Wales found that 77% of patients died within a year of first presentation to hospital. Survival rates throughout the period of the study (up to 34 months) were significantly higher for patients cared for by hospitals which dealt with larger numbers. The risk of death among patients managed by hospitals that dealt with one new case each week was 36% lower than for those treated in hospitals that managed one new case a month. This risk was independent of both case-mix and the nature of the treatment provided, which suggests that it could be due to variables which were not measured, such as better nutrition and nursing care in more specialised hospitals. (B)

The results of four RCTs which examined the effectiveness of octreotide, a drug which reduces pancreatic secretions after surgery, show that it can substantially reduce the risk of surgical complications. (A)

Adjuvant therapy

A major study (ESPAC-1) is assessing the effectiveness of different forms of post-operative treatment for patients with pancreatic cancer. Adjuvant 5-FU plus folinic acid (5-FU/FA) or chemo-radiotherapy (40Gy plus 5-FU, then weekly 5-FU) have been compared with no adjuvant treatment. Preliminary results for 530 patients suggest that chemotherapy is beneficial (median survival 19.5 months with 5-FU, versus 13.5 months without; $p=0.003$) but radiotherapy is not (median survival 14 months with chemo-radiotherapy, versus 15.7 months without). No information is yet available on adverse effects. (A)

In July 1999, the Independent Data Monitoring Committee recommended that patients should no longer be recruited for radiotherapy, but the trial continues to randomise between adjuvant chemotherapy and surgery alone. It will roll into ESPAC-3, which will compare surgery alone with surgery followed by 5-FU/FA or gemcitabine.

Relief of bile duct obstruction

Pancreatic cancer frequently causes obstruction of the bile ducts and jaundice. Trials comparing interventions to relieve biliary obstruction show that self-expanding metal stents (Wallstents) are superior to polythene stents. Patients who receive metal stents are less likely to suffer from pain and inflammation of the gall bladder; they are less likely to have complications and require less time in hospital, and their quality of life is better. (A)

Studies comparing stents with bypass surgery show that both types of procedure are effective for relief of jaundice but the balance of associated risks and costs differs. Stenting requires shorter initial hospitalisation and costs significantly less than surgery, but stents can become blocked, leading to recurrent jaundice.(A) Palliative surgery is more risky (see above).

Acquisition of expertise in stent placement using ERCP requires considerable practice; see Topic 5, *Pancreatic Cancer: Diagnosis and Assessment*.

Chemotherapy for advanced disease

A variety of chemotherapy regimens have been used in attempts to extend survival time and palliate symptoms. The trials have, in general, been small and are often inconclusive. Three of the seven RCTs which compared chemotherapy with best supportive care found that chemotherapy increased median survival by a few weeks or months; the others reported no significant difference.(A) Quality of life may improve, but this has not been unequivocally demonstrated and it is often not clear whether reported benefits outweigh toxicity.

Hormone therapy involving tamoxifen offers no clear benefits for these patients.(A) One small trial of flutamide (n=49) reported dramatic improvements in survival, but only 35% of the patients had histologically confirmed pancreatic cancer. This result requires replication before it can be considered reliable.

Chemo-radiotherapy for advanced disease

Small studies suggest that radiotherapy plus chemotherapy based on 5-FU may increase survival time by a few weeks compared with single-modality treatment, but combined treatment causes greater toxicity.(A) Studies comparing different combinations of radiotherapy and chemotherapy do not show a clear advantage for any particular type of treatment.

D. Measurement

Structure

- Availability of specialist HPB surgeons.

Process

- Proportion of patients who undergo surgery.
- Proportion of patients who receive chemo-radiotherapy.

Outcome

- 30-day, 1-year and 5-year survival rates of patients who undergo surgery, with information on cancer stage, co-morbidity, age and other features of case-mix.
- Audit of short-term and long-term adverse effects of treatment.

E. Resource Implications

- Over the whole of England, changing patterns of surgery for pancreatic cancer could increase annual costs by £3 million. This figure is based on the assumption that the resection rate will increase three-fold, from 5% to 15% of patients (see Appendix 1).
- Increased use of chemotherapy and chemo-radiotherapy is estimated to increase annual costs by £6.9 million (see Appendix 1).

Palliative Interventions and Care

The majority of people with diagnoses of upper gastro-intestinal cancer have advanced disease and do not survive for more than a few months. Quality of life is therefore of paramount importance. Since symptom control is crucial to quality of life, there must be local arrangements to ensure that patients receive palliative interventions when required. Attention should be given to patients' comfort and to the psychological and social well-being of both patients and their carers throughout the course of the illness.

A. Recommendations

(i) Structure and organisation of palliative care

Palliative care should be an integral part of patient management. Specialist multiprofessional palliative care teams should be available to arrange the provision both of relief from symptoms and social and psychological support for patients and their carers when these needs cannot be met by primary care teams.

Patients with advanced upper gastro-intestinal cancers may require care from specialist cancer treatment teams, specialist palliative care teams and primary care teams. Specialist palliative care services should work closely with primary care teams and hospital services, particularly specialist palliative care teams; rapid and effective communication and information-sharing between teams is essential.

Criteria for referral for specialist care should be agreed and documented for the whole Cancer Network by palliative care specialists and representatives from primary care and specialist treatment teams. Primary care teams should assess patients' needs regularly and accurately, to ensure that patients who require specialist palliative care or interventions (see below) are referred quickly and appropriately.

The Specialist Palliative Care Team

Palliative care is essentially a local service, and Specialist Palliative Care Teams should be based both in all hospitals that manage patients with upper gastro-intestinal cancer, and in the community. The role of the Specialist Palliative Care Team includes both direct care for patients and families with complex problems, and the provision of advice, support and education for other health professionals. One member of the team should be responsible for ensuring co-ordination of palliative care services and rapid communication, both between professionals and with patients and their families.

The Specialist Palliative Care Team should be multiprofessional, and should, as a minimum, include the following members:

- Palliative care physician.
- Palliative care nurse specialists.

The team should have close links with the following:

- Staff and facilities to support tube feeding for patients at home.
- Physiotherapist.
- Psychologist/psychiatrist.
- Social worker.
- Chaplain/pastoral care worker who can offer counselling and spiritual guidance for patients with advanced incurable illness and their carers.
- Bereavement care worker.
- The Primary Care Team.

Patients, their carers, GPs and hospital staff who care for these patients should have access to a member of the Specialist Palliative Care Team at any time of the day or night. A named member of the team should be responsible for ensuring effective co-ordination of palliative care services, continuity of care, and rapid communication, both between professionals and with patients and their families.

The team should endeavour to make it possible for patients to spend their remaining life in the place they prefer, whether this is home, hospital or hospice, but should be alert to the possibility that this preference may change as death approaches.

(ii) Symptom management

A substantial minority of patients are likely to require specialist interventions to control their symptoms. The main symptoms of each type of cancer, and palliative interventions used, are shown in Table 5, below. Specific interventions for each type of cancer are discussed in more detail earlier in this document (see Topic 6, *Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction*, Topic 7, *Treatment for Gastric Cancer* and Topic 8, *Treatment for Pancreatic Cancer*).

Table 5. Palliative interventions for upper gastro-intestinal cancers

Cancer site	Symptoms of advanced disease	Main specialist palliative interventions
Oesophagus	Difficulty with swallowing (dysphagia) due to oesophageal obstruction.	Insertion of a stent or polythene tube to keep the oesophagus open, chemotherapy or radiotherapy to shrink tumour, interventions (e.g. laser treatment) to remove obstruction.
Stomach	Nausea and vomiting; Dysphagia.	Surgical resection, bypass, stent. Stent.
Pancreas	Severe pain. Biliary obstruction, jaundice, nausea and vomiting.	Coeliac plexus or other nerve block. Stent; surgical resection and/or bypass.
Any	Pain, nausea, eating problems, fatigue, weight loss, depression. Poor nutrition and dehydration when food and drink cannot be taken by mouth.	Management of pain and other symptoms should follow evidence-based guidelines. Insertion of feeding tube into the digestive tract (by gastrostomy - PEG feeding - or enterostomy).

Oesophageal cancer

About 40% of patients require stents to open the oesophagus and seal fistulae. Stenting and other techniques for the management of oesophageal stricture are discussed in Topic 6, *Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction*.

Gastric cancer

While most symptoms can be managed medically, some patients will need help from specialist teams. A stent, surgical resection or palliative bypass should be available for fitter patients for palliation of symptoms of advanced gastric cancer. Palliative chemotherapy may also be appropriate. These issues are discussed in Topic 7, *Treatment for Gastric Cancer*.

Pancreatic cancer

Patients for whom palliative surgery might be appropriate should be referred to the Specialist Pancreatic Cancer Team. Suitable stents to keep bile ducts open should be provided for patients with jaundice, but these should not be inserted until it is clearly established that surgical resection is not appropriate. These interventions, and anti-cancer treatments including chemotherapy, are discussed in Topic 8, *Treatment for Pancreatic Cancer*.

Pain control

All patients should be asked regularly if they have pain, so that prompt action may be taken to relieve it. Cancer pain should normally be controlled with oral or parenteral analgesics, usually opiates, in accordance with the World Health Organisation (WHO) 3-step method for control of cancer pain.¹⁴ This requires assessment and frequent reassessment of the pain, with titration of the dose of analgesia against pain severity.

Advanced pancreatic cancer, in particular, may cause intractable pain which cannot be controlled by conventional forms of analgesia. Patients with such pain should be promptly referred to a specialist in pain control. Relief may be achieved by destruction or blockade of the coeliac plexus, or by infusion of analgesics into epidural or intrathecal space. All these options should be available.

Radiotherapy may be useful for palliation of pain due to pancreatic or oesophageal cancer, and should be considered for suitable patients.

B. Anticipated Benefits

Prompt treatment of symptoms is crucial to reduce patients' distress and disability and diminish strain on carers. High quality co-ordinated palliative care services can improve quality of life for people with advanced cancer, and effective home care can usually keep symptoms sufficiently well controlled to allow patients to stay at home for as long as they wish. This is preferred by most patients and may be the least expensive option for the NHS.

C. Evidence

(i) Structure and organisation of palliative care

Patients with advanced disease can receive high quality care in a variety of settings, including hospitals, hospices, and their own homes, so long as there is adequate input from specialists who can offer pain and symptom control when required. However, retrospective studies, based on interviews with cancer patients or carers, report that the needs of patients may not be identified or adequately met if they are managed by GPs alone, or in general hospital wards without specialist palliative care. Such patients may suffer both psychological and physical distress.(B)

Most patients prefer to remain at home and wish to die at home. However, many of these patients actually die in hospital.(B) Hospital care has often been criticised, particularly for the difficulty of obtaining information, the perception that hospital staff are too busy to talk, and lack of peace and privacy.(B)

A systematic review of studies which compared "standard home care" with interventions based in hospitals, hospices or the community, suggests that standard care alone may not be sufficient. Additional interventions may be required for patients who remain at home, to control physical symptoms and reduce the need for re-admission. Favourable results were reported in studies in which multiprofessional palliative home care team members visited patients at home, and when these teams held regular meetings.(B)

¹⁴ World Health Organisation. *Cancer Pain Relief*. Geneva: World Health Organisation, 1996.

Almost all patients with cancer referred to a palliative care team in the UK were experiencing psychological distress, and many were also suffering from pain and anorexia at the time of referral. The palliative care team was able to reduce the intensity of most of their symptoms.(B) An Italian study which reported similar findings suggested that improvements were greatest for the most distressed patients.(B)

A Dutch study demonstrates the importance for patients' quality of life of effective co-ordination and communication between hospital-based care providers and home care teams. In this study, excellent results were obtained combining the following elements: a specialist nurse co-ordinator, a 24-hour telephone service based in the hospital ward where the patient had undergone assessment or treatment, a home-care team linked with the hospital, a collaborative case file designed to improve communication, and the use of protocols for specific interventions developed by a multiprofessional team.(B)

Improved co-ordination and co-operation among providers can lead to improvements in patients' physical functioning, and may reduce the need for re-hospitalisation after discharge from an oncology ward.(B) It may also reduce costs by reducing duplication of effort.(A)

(ii) Symptom management

Evidence on specialist palliative interventions for upper gastro-intestinal cancers is discussed in the context of treatment for these cancers (see Topic 6, *Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction*, Topic 7, *Treatment for Gastric Cancer* and Topic 8, *Treatment for Pancreatic Cancer*).

Pain control

Severe pain is particularly common in pancreatic cancer. 90% of patients report good to excellent pain relief after coeliac plexus block, and some benefit persists for three months or until death.(B) This method is more likely to be effective when it is used within two months of onset of pain than if it is delayed. Adverse effects such as local pain and diarrhoea are common but generally transient and mild; overall, the adverse effects of coeliac plexus block appear to be less severe than those of analgesics.

D. Measurement

Structure

- Documented local clinical policies to guide referral and treatment.
- Evidence that appropriate palliative care services are available in hospitals, hospices and the community, and that their resource and staff levels are adequate.
- Systems to permit 24-hour access to specialist advice on palliative care.
- Arrangements to facilitate prompt access to specialist interventions, including specialist pain control.
- Evidence of effective communication systems for information-sharing between all levels of the service and all those involved in individual patient management.

Process

- Use of the WHO 3-step analgesic ladder for pain control.
- Audit of palliative interventions provided.

Outcome

- Audit of time to provision of specialist palliative interventions.
- Audit of symptom control.

E. Resource Implications

- Increase use of palliative chemotherapy will have the most significant cost impact (see topic 6, *Treatment for Oesophageal Cancer and Cancer of the Oesophago-gastric Junction*, topic 7, *Treatment for Gastric Cancer* and topic 8, *Treatment for Pancreatic Cancer*).
- Improved co-ordination of care could reduce costs per patient, but improving access to specialist palliative care services is likely to require increased resources in some areas.
- Increased audit and improved monitoring of both process and outcomes will require funding.

Appendix 1

Economic Implications of the Guidance

An economic modelling exercise was carried out to estimate the cost implications for England of implementation of the main recommendations of this guidance. The major impacts on costs fall in four broad areas (summarised in Table 6):

- increased demand for endoscopy for diagnosis of oesophageal and gastric cancer;
- centralisation of surgical services;
- the use of new technologies for tumour assessment;
- increased use of chemotherapy and radiotherapy.

In the text that follows, overall costs are given for all three Upper GI cancers. Figures quoted in the Resource Implications sections of the Manual may refer only to one or two cancer sites, and sometimes, therefore, do not appear to match those given in this appendix.

Table 6. Cost impact of implementing the guidance in England¹

	Cost impact (£m)	% of total
Endoscopy	9.5	11
(Low scenario)	2.3	
(High scenario)	14.6	
Specialist services – additional referrals	14.4	16
Specialist services – additional resections	12.5	14
Assessment – additional equipment	7.0	8
Assessment – additional volume	8.5	10
(Low scenario)	3.5	
Chemotherapy and radiotherapy	35.6	41
Total	87.5	100

¹ All costs are estimated annual costs with the exception of additional equipment for assessment, which is a one off cost.

Endoscopy

Three scenarios for the potential growth in the number of endoscopies (urgent and non-urgent) have been considered. The intermediate scenario assumes that the number of endoscopies will increase by an average of 40,000 per annum between 2000/1 and 2003/4. (10,000 and 60,000 for low and high scenarios respectively.) The estimated cost impact of the intermediate scenario is £9.5 million per annum but the low and high scenario figures of £2.3 million and £14.6 million reflect the level of uncertainty.

Impact of Centralisation

Centralisation of Surgical Referrals

Approximately 60% of the oesophageal and gastric cancer workload currently handled by Cancer Units is expected to shift to nominated Cancer Centres. This assumes that 40 Centres are nominated. The annual cost of additional surgical referrals to Centres is estimated to be around £14.4 million, assuming no release of marginal costs. Releasing marginal costs from Units may be difficult. Because the volumes are small, transfer of work to Cancer Centres will not permit reductions in medical staff or hospital ward provision in local Units.

Cost changes will depend on local geography. Current resection activity moved to a typical Oesophago-gastric Centre would increase costs by 237%, an average increase of £290,000. The variation between Centres is substantial and the largest increase is estimated to be up to £590,000.

For Pancreatic Centres, approximately 60% of the resection workload and 80% of the bypass workload is estimated to shift from Cancer Units to the nominated Centres. Assuming that 24 Centres are nominated, costs for resection surgery at a typical Pancreatic Centre would rise by an estimated 233%, an average rise of just under £40,000. The variation between Centres is substantial and the largest increase is estimated to be up to £80,000. Costs for bypass surgery would rise by an estimated 450%, an average rise of around £150,000. The largest increase is almost £200,000. These costs could be underestimates because they assume that existing post-surgical admissions will remain at Cancer Units.

Increased Surgical Activity

There is also likely to be an absolute increase in surgical workload resulting from an increase in the proportion of patients receiving resection for all three cancers. This will be offset by a small reduction in the proportion of patients receiving pancreatic bypass. The net cost increase of additional surgical activity is estimated at £12.5 million.

The estimated increase in pancreatic resection rates from 5% to 15% will have a significant impact on the resection workload of the Centres. The resection cost will rise by an additional £131,000 for the average Centre, resulting in an overall increase in resection costs of 700% at Pancreatic Centres.

The key elements of the Cancer Centre team structure are likely to be in place in many of the Oesophago-gastric Centres. The development of integrated teams to achieve the proposed changes is not expected to incur significant additional costs beyond those shown above. However the centralisation of treatment for pancreatic cancer will require changes to the existing manpower structure.

Increased provision of intensive care and high dependency care will need funding. These costs are included within the cost of increased referrals and increased resection activity. Typically Oesophago-gastric Centres will need to accommodate 130 additional nights in ICU and 130 nights in HDU, Pancreatic Centres will need to accommodate 100 additional nights in ICU and 90 nights in HDU.

Assessment

Acquisition of Endoscopic Ultrasound (EUS) equipment will be required for Oesophago-gastric and Pancreatic Centres. The total cost of provision of new EUS equipment (diagnosis only) is estimated to be £2.8 million. If it is assumed that biopsy facilities are also required, this will rise to around £4.2 million. The additional cost impact of ensuring MR scanners of adequate specification to allow MRCP to be undertaken is likely to be in the order of £2.9 million.

Aside from equipment costs it is also expected that the absolute volume of assessment will increase by up to £6.6 million for oesophageal and gastric cancer and up to £1.9 million for pancreatic cancer. Increases in the volume of EUS and laparoscopy contributes to over 85% of these costs (Centres will have to run additional clinics to accommodate extra demand and additional staff may be required).

An alternative “low case” scenario has been considered, in which it is assumed that the increases in demand can be accommodated within existing clinics. The marginal cost for CT scans, EUS and MRCP are therefore based on the costs of consumables only, assumed to be £30 for each procedure. This reduces the cost of assessment from £6.6 million to £2.7 million for oesophageal and gastric cancer and from £1.9 million to £0.9 million for pancreatic cancer.

Increased expenditure on pre-surgical assessment could reduce resources consumed by inappropriate surgery. If the level of abandoned resections is reduced by 10% (from 20% to 10% of oesophageal and gastric resections) the cost saving could be around £0.7 million.

Chemotherapy and radiotherapy

Increased use of chemotherapy and radiotherapy is likely to produce the largest impact on costs, estimated at around £35.6 million. The cost impact for oesophageal, gastric and pancreatic cancer is estimated at £12.9 million, £15.8 million and £6.9 million respectively. These figures are likely to be an upper ceiling, based on leading clinical opinion of best practice. They represent a significant change to current practice and may not be translated into standard practice across all palliative care providers, particularly in the short term. Approximately £28.2 million of the total is the estimated impact of increased use of palliative chemotherapy for oesophageal (£10.3 million), gastric (£13.0 million) and pancreatic (£5.0 million) cancer. The remaining £7.4 million is the estimated impact of additional use of double or triple modality treatment – chemo-radiotherapy alone or in combination with surgery, and adjuvant chemotherapy.

Other Cost Implications

A number of other treatment issues raised in the guidance have been considered. These include the increased use of metal stents for oesophageal cancer patients and self-expanding metal stents for pancreatic cancer patients; changes in the proportion of D2 surgery and the proportion of sub-total gastrectomy for gastric cancer patients; and the use of octreotide after pancreatic surgery. The impact of these changes is expected to be small.

Survival

Centralisation of surgery will result in improvements in peri-operative survival and 1-year survival. The cost impact of this is not known. If patients have been successfully treated, there will be a reduction in hospital resource use. However, if patients' lives are only extended for a short period of time, costs will be briefly postponed.

Palliative Care

The use of palliative procedures such as surgery and stenting are not expected to change significantly under the new guidance. The use of palliative chemotherapy will have the most significant cost impact; this has been discussed above. Improving access to specialist palliative care services may have some cost consequences, but these are expected to be small.

Appendix 2

How this Guidance Manual was Produced

The manuals in this series are intended to guide health authorities, commissioners, trust managers and lead clinicians in improving the effectiveness and efficiency of services for patients with cancer. The information and recommendations in the manual are based on systematic reviews of the best available evidence on diagnosis, treatment and service delivery. This evidence is assessed by experts and the recommendations are the product of extensive discussion with leading clinical specialists. The production process is described briefly below; more detail is available in earlier guidance manuals in the series.

The production process begins with a two-day residential event where proposals for improving services for patients with cancer of a specific site are generated. A large group of relevant health care professionals, people with personal experience of the particular type of cancer being considered, health care commissioners and academics from around the country, meet to put forward structured proposals based on their experience and knowledge of the research literature. These are then sent to referees, including clinicians, academics, representatives of health authorities, the Department of Health, patient organisations, and relevant charities, many of whom make detailed comments and suggestions. Systematic reviews of the research literature, designed to evaluate the proposals, are then carried out or commissioned by the NHS Centre for Reviews and Dissemination (CRD) at the University of York.

This process culminates in the production of two large sources of information, one with a practical or operational focus, and the other containing detailed research evidence on effectiveness. The guidance draws on both these sources, with added input from commissioners, patients, and experts in the particular fields. The writing of the guidance manual is overseen by an editorial group chaired by Professor Bob Haward, accountable to the National Cancer Guidance Steering Group. The writing is undertaken by Dr Arabella Melville, in conjunction with CRD.

Complementary research, designed to quantify the potential cost of major changes in services, is carried out by the School of Health and Related Research at the University of Sheffield. This work involves literature searching, interviews with clinicians and managers, and analyses of costs.

The production of this guidance was funded by the Department of Health and the NHS Executive.

Evidence grading

The reliability and quality of evidence which supports the recommendations in the guidance manual is graded throughout the document. The grades are as follows:

- A. Evidence derived from randomised controlled trials or systematic reviews of randomised trials.
- B. Evidence from non-randomised controlled trials or observational studies.
- C. Professional consensus.

The quality of research evidence forms a continuum and there is overlap between these categories. Most of the published research on cancer focuses on clinical evaluations of treatment; little direct research has been carried out on the organisation and delivery of services, issues on which randomised controlled trials (categorised here as the highest quality evidence) may not be feasible. Research designs which might be regarded as of relatively poor quality for evaluating a clinical intervention may therefore be the most reliable available for assessing the organisational issues.

Linked documents

This Manual is one of four linked documents. The other three are:

- *Improving Outcomes in Upper Gastro-intestinal Cancers: The Research Evidence.* This is an exposition of the systematic reviews used to inform the Manual; it includes details of all the studies to which the Manual refers.
- *Improving Outcomes in Upper Gastro-intestinal Cancers: Guidance for General Practitioners and Primary Care Teams.* A four-page summary of the Manual.
- *Management of Upper Gastro-intestinal Cancers. Effective Health Care, Vol.6 No.4* (<http://www.york.ac.uk/inst/crd/ehc64.htm>). Effective Health Care is a regular publication produced by CRD to inform health care decision makers. This issue summarises information given in *The Research Evidence*.

Appendix 3

People and Organisations Involved in Production of the Guidance

3.1 National Cancer Guidance Steering Group/Cancer Guidance Group

3.2 Members of the Proposal Generating Event

3.3 People/organisations invited to comment on original proposals

3.4 Researchers carrying out literature and economic reviews

3.5 Members of focus groups

Guidance synthesis and writing

Dr A Melville, Independent Consultant

Ms A Eastwood, Senior Research Fellow

Professor J Kleijnen, Director

NHS Centre for Reviews and Dissemination, University of York

assisted by members of the National Cancer Guidance Steering Group, together with:

Mr R M Charnley, Consultant Surgeon in Gastroenterology, Freeman Hospital, Newcastle upon Tyne

Dr D Cunningham, Consultant Physician, The Royal Marsden Hospital, Sutton

Dr A Crellin, Consultant Clinical Oncologist, Cookridge Hospital, Leeds

Professor M J G Farthing, Professor of Gastroenterology, St.Bartholomew's and the Royal London School of Medicine and Dentistry, London

Mr J Fielding, Consultant Surgeon, The Queen Elizabeth Hospital, Birmingham

Professor P Hungin, Professor of General Practice, Stockton on Tees

Dr D F Martin, Consultant Radiologist, Withington Hospital

People/organisations invited to comment on drafts of the guidance

National Cancer Guidance Steering Group

Focus Groups

Various professional organisations

Department of Health

Economic Reviews

School of Health and Related Research, University of Sheffield

Project support

The Northern and Yorkshire Cancer Registry and Information Service

Appendix 3.1

Membership of the National Cancer Guidance Steering Group

Note: The original Cancer Guidance Group set up to oversee the development and production of the first guidance documents was superseded by a smaller National Cancer Guidance Steering Group in November 1998. The membership of the new and original Groups is given below. The continued interest and involvement of members from the wider Group is gratefully acknowledged.

Chairman

Professor R A Haward Professor of Cancer Studies, University of Leeds

Vice Chairman

Professor M Richards Sainsbury Professor of Palliative Medicine, St Thomas' Hospital, London and National Cancer Director

Members

Dr J Barrett	Consultant in Clinical Oncology, Royal Berkshire Hospital
Mr A Brennan	Director of Operational Research, School of Health and Related Research, University of Sheffield
Ms A Eastwood	Senior Research Fellow, NHS Centre for Reviews & Dissemination, York
Dr A Hibble	GP, Stamford
Professor P Littlejohns	Clinical director, National Institute for Clinical Excellence
Professor R E Mansel	Chairman, Division of Surgery, University of Wales College of Medicine, Cardiff
Ms T Norman	Cancer Strategy Co-ordinator, Department of Health, Wellington House
Dame G Oliver	Director of Service Development, Macmillan Cancer Relief
Mrs V Saunders	Manager, Northern and Yorkshire Cancer Registry and Information Service
Dr J Verne	Consultant in Public Health Medicine, NHS Executive - South and West

Membership of the Cancer Guidance Group

Chairman

Professor R A Haward Professor of Cancer Studies, University of Leeds

Vice Chairman

Professor M Richards Sainsbury Professor of Palliative Medicine, St Thomas' Hospital, London

Members

Dr S Atkinson Regional Director of Public Health, NHS Executive London
Dr J Austoker Director, Cancer Research Campaign Primary Care Education Group, University of Oxford
Professor C C Bailey Regional Director of R&D, NHS Executive Northern & Yorkshire
Dr J Barrett Consultant in Clinical Oncology, Royal Berkshire Hospital
Mr M Bellamy Chief Executive, Ealing, Hammersmith and Hounslow Health Authority
Professor J Carmichael CRC Professor of Clinical Oncology, Nottingham City Hospital
Professor J Hardcastle Chair, Royal College of Surgeons Cancer Committee
Mrs S Hawkett Nursing Officer, Department of Health, Wellington House
Professor J Kleijnen Director, NHS Centre for Reviews & Dissemination, University of York
Dr A Kostick GP, Aylesbury
Ms J McKessack Assistant Secretary, Department of Health, Wellington House
Professor R E Mansel Chairman, Division of Surgery, University of Wales College of Medicine, Cardiff
Mrs R Miles Regional Cancer Adviser, NHS Executive - West Midlands; Chair, National Cancer Alliance
Dame G Oliver Director of Service Development, Macmillan Cancer Relief
Professor P Quirke Professor of Pathology, University of Leeds
Professor I Williams Professor of General Practice, University of Nottingham
Dr E Wilson Senior Medical Officer, Department of Health, Wellington House

Appendix 3.2

Participants in the Upper Gastro-intestinal Cancers Proposal Generating Event

Professor D Alderson	Professor of Gastrointestinal Surgery, Bristol Royal Infirmary
Mrs M Allen	Patient, Otley, West Yorkshire
Mr K Baldwin	Patient, Leeds
Mr J Bancewicz	Consultant Surgeon, Hope Hospital, Salford
Dr D Beckly	Consultant Radiologist, Derriford Hospital, Plymouth
Dr P Bevan	Deputy Director of Public Health, NHS Executive - London
Mr M C A Brett	Consultant Surgeon, Warrington Hospital
Dr E A Charlesworth	Consultant in Public Health Medicine, North Derbyshire Health Authority (now retired)
Dr I G Cox	Macmillan GP Adviser in Cancer and Palliative Care, Laurie Pike Health Centre, Birmingham
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Mrs C Duddle	Macmillan Palliative Care Nurse Specialist, Fazakerley Hospital, Liverpool
Professor J B Elder	Professor of Surgery, North Staffordshire Hospital
Dr S Ford	GP, Nottingham
Dr R A Frost	Consultant Radiologist, Salisbury District Hospital
Dr J Gildersleve	Consultant in Clinical Oncology, Royal Berkshire Hospital
Mr S M Griffin	Consultant Surgeon, The Royal Victoria Infirmary, Newcastle upon Tyne
Mrs S Griffiths	Head of Therapy Radiography, Cookridge Hospital, Leeds
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Dr K M Harris	Consultant Radiologist, The General Infirmary at Leeds
Ms S Hunton	Director, Bradford Cancer Support Centre
Dr R D James	Consultant in Clinical Oncology, Maidstone Hospital, Kent
Dr M Jefferson	Consultant in Palliative Medicine, University Hospital of Wales, Cardiff
Mr D Kirby	Chairman, Oesophageal Patients Association
Miss J Lees	Cancer Services Manager, Greenwich District Hospital, London
Dr S F Levy	GP, Stockport

Mr R C Mason	Consultant Surgeon, Guy's Hospital, London
Professor J P Neoptolemos	Professor of Surgery, Royal Liverpool University Hospital
Dr F A Pitt	Consultant in Public Health Medicine, Sheffield Health Authority
Dr E Pugh	Medical Director, Butterwick Hospice, Stockton-on-Tees
Professor J V Reynolds	Professor of Surgery, St James' Hospital, Dublin
Professor B J Rowlands	Professor of Surgery, Queen's Medical Centre, Nottingham
Dr M T Seymour	Consultant in Medical Oncology, Leeds Teaching Hospitals NHS Trust
Dr M B Sheridan	Consultant Radiologist, St James's University Hospital, Leeds
Ms R Sitamvaram	Ward Manager, The Royal Marsden Hospital, Sutton
Dr J M Sloan	Consultant Pathologist, The Royal Victoria Hospital, Belfast
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Dr P M Smith	Consultant Gastroenterologist, Llandough Hospital, Penarth
Dr R Stout	Consultant in Clinical Oncology, Christie Hospital, Manchester
Dr D M Tait	Consultant in Clinical Oncology, The Royal Marsden Hospital, Sutton
Mr A M Thompson	Consultant Surgeon, Ninewells Hospital and Medical School, Dundee
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Dr B Walker	GP, Seascale, Cumbria
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Dr C Wolfe	Reader in Public Health Medicine, Guy's, King's and St Thomas' Medical School, London

Facilitated by:

Mr J W L Fielding	Consultant Surgeon, The Queen Elizabeth Hospital, Birmingham
Professor R A Haward	Professor of Cancer Studies, University of Leeds
Professor M Richards	Sainsbury Professor of Palliative Medicine, St Thomas' Hospital, London and National Cancer Director

Appendix 3.3

Referees of the Upper Gastro-intestinal Cancers Proposals

Invited to comment:

Professor A Adam	Professor of Interventional Radiology, Guy's Hospital, London
Professor D Alderson	Professor of Gastrointestinal Surgery, Bristol Royal Infirmary
Mr W H Allum	Honorary Secretary, The Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
Dr C M Anderson	GP, Stockport
Mr R W Anderson	Economic Adviser, Department of Health
Professor P Armstrong	President, The Royal College of Radiologists
Professor Sir W Asscher	Chairman, United Kingdom Co-ordinating Committee on Cancer Research
Dr D V Ash	Dean and Vice-President, Faculty of Clinical Oncology, The Royal College of Radiologists
Dr S Atkinson	Director of Public Health, NHS Executive - London
Professor A T R Axon	Professor of Gastroenterology, The General Infirmary at Leeds
Professor M R Baker	Medical Director, North Yorkshire Health Authority
Dr M Baker	GP, Lincoln
Mr J Bancewicz	Consultant Surgeon, Hope Hospital, Salford
Dr C Bartram	Consultant Radiologist, Northwick Park Hospital, Middlesex
Professor J Baxter	Professor of Surgery, Morriston Hospital, Swansea
Mr M Bellamy	Chief Executive, Ealing, Hammersmith and Hounslow Health Authority
Professor I S Benjamin	Professor of Surgery, King's College Hospital, London
Mr G Bennett	Director of Finance, Birmingham Health Authority
Mr A E Berry	Director of Operations, Macmillan Cancer Relief
Dr A Birchall	GP, Nottingham
Professor R Blamey	President, British Association of Surgical Oncology
Professor S G Bown	Professor of Laser Medicine and Surgery, Royal Free and University College Medical School, London
Dr S A Bridgman	Consultant in Public Health Medicine, North Staffordshire Health Authority
Mr J A C Buckels	Consultant Hepatobiliary and Transplant Surgeon, The Queen Elizabeth Hospital, Birmingham
Dr J Bull	Consultant Physician, Worthing Hospital, West Sussex
Dr J Bullimore	Member of the National Cancer Forum

Ms M Butler	Gastroenterology Specialist Nurse, Royal Liverpool University Hospital
Mr D Campbell	Director of Finance, Liverpool Health Authority
Mr P D Carey	Consultant Surgeon, Belfast City Hospital
Professor Y H Carter	Professor of General Practice, St Bartholomew's and The Royal London School of Medicine and Dentistry
Professor J Cassidy	Professor of Oncology, University of Aberdeen
Dr A G Chalmers	Consultant Radiologist, The General Infirmary at Leeds
Dr A H Chapman	Consultant Radiologist, St James's University Hospital, Leeds
Mr E M Chisholm	Consultant Surgeon, St Peter's Hospital, Surrey
Dr J L Christie	Consultant Histopathologist, Russells Hall Hospital, Dudley
Dr H J Close	Consultant in Clinical Oncology, Cookridge Hospital, Leeds
Dr S Closs	Consultant in Palliative Medicine, Morriston Hospital, Swansea
Dr R Cockel	Consultant Physician, Selly Oak Hospital, Birmingham
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Ms P Cook	Assistant Chief Executive, NHS Executive - North West
Professor R C Coombes	Professor of Medical Oncology, Charing Cross Hospital, London
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Mr W J Crisp	Consultant Surgeon, Staffordshire General Hospital
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Mr J G R Cumming	Member of the National Cancer Forum
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Professor Sir A Cuschieri	Professor of Surgery, Ninewells Hospital and Medical School, Dundee
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Dr D W Day	Consultant Histopathologist, Torbay Hospital, Torquay
Mr M Deakin	Consultant Surgeon, North Staffordshire Hospital
Mr T C B Dehn	Consultant Surgeon, Royal Berkshire Hospital
Dr N D J Derbyshire	Consultant Radiologist, Royal Berkshire Hospital
Ms R Devlin	Practice Development Nurse, Derriford Hospital, Plymouth
Professor M F Dixon	Professor of Gastrointestinal Pathology, University of Leeds

Mr I A Donovan	Consultant Surgeon, City Hospital, Birmingham
Dr F Dudley	GP, London
Dr A M Dunbar	GP, Keighley
Dr R Dunlop	Medical Director, St Christopher's Hospice, London
Mr J E Dussek	Consultant Thoracic Surgeon, Guy's Hospital, London
Mr S R Ebbs	Consultant Surgeon, Mayday University Hospital, Surrey
Dr C Edmundson	Consultant Anaesthetist, Wrexham Maelor Hospital
Mr S Edwards	Macmillan Clinical Radiographer, Cookridge Hospital, Leeds
Dr J E Ellershaw	Medical Director, Liverpool Marie Curie Centre
Mr S Evans	Chief Executive, The College of Radiographers
Mr I Eyre-Brook	Consultant Surgeon, Taunton & Somerset Hospital
Dr M Fallon	Consultant in Palliative Medicine, Western Infirmary, Glasgow
Dr L Fallowfield	Professor of Psycho-oncology, University College London Medical School
Professor A Faulkner	Professor of Communication in Health Care, Trent Palliative Care Centre
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Mr P J Finan	Consultant General and Colorectal Surgeon, The General Infirmary at Leeds
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Dr A H Freeman	Consultant Radiologist, Addenbrooke's Hospital, Cambridge
Dr R A Frost	Consultant Radiologist, Salisbury District Hospital
Dr J M Galloway	GP, King's Lynn
Professor O J Garden	Professor of Hepatobiliary Surgery, The Royal Infirmary of Edinburgh
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Dr N Gent	Director of Public Health, Morecambe Bay Health Authority
Mr W Gillison	Research Associate, City Hospital, Birmingham
Dr H M Gilmour	Senior Lecturer in Pathology, University Medical School, Edinburgh
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Dr R Glynn-Jones	Consultant in Clinical Oncology, Mount Vernon Hospital, Middlesex
Mr R Gompertz	Consultant Gastroenterological Surgeon, Burton Hospital, Burton on Trent
Professor E Gordon-Smith	Professor of Haematology, St George's Hospital, London
Dr J Gough	Consultant Histopathologist, Llandough Hospital, Penarth
Mr D Gourevitch	Consultant Gastrointestinal Surgeon, Sandwell District General Hospital, West Bromwich
Mrs K Gowland	Gastroenterology Nurse Specialist, Royal Liverpool University Hospital
Ms S Greavy	Ward Sister, The Queen Elizabeth Hospital, Birmingham
Dr S Green	Director of Commissioning and Information, Solihull Health Authority

Mr S M Griffin	Consultant Surgeon, The Royal Victoria Infirmary, Newcastle upon Tyne
Mrs S Griffiths	Head of Therapy Radiography, Cookridge Hospital, Leeds
Mr R Grimley	Consultant Surgeon, Russells Hall Hospital, Dudley
Ms C Gritzner	General Manager, The Patients' Association
Professor P J Guillou	Professor of Surgery, St James's University Hospital, Leeds
Mr P Hale	Consultant Surgeon, The Royal Sussex County Hospital
Mr M Hallissey	Senior Lecturer in Surgery, The Queen Elizabeth Hospital, Birmingham
Dr J Halpin	Consultant in Public Health Medicine, East and North Hertfordshire Health Authority
Professor G W Hanks	Macmillan Professor of Palliative Medicine, Bristol Oncology Centre
Dr J Hanson	Cancer Services Project Co-ordinator, Welsh Office
Professor J Hardcastle	Professor of Surgery, University of Nottingham
Mr T Harris	Director, Association of Community Health Councils for England and Wales
Mr J D Harrison	Consultant Surgeon, Scarborough Hospital
Dr P Harvey	Consultant Clinical Psychologist, The Queen Elizabeth Hospital, Birmingham
Ms A Hayes	Director of Counselling, Cancerlink
Dr V Hemsall	Deputy Director of Public Health, Dorset Health Authority
Dr A G Hibble	GP, Stamford
Dr F Hicks	Consultant in Palliative Medicine, St James's University Hospital, Leeds
Dr N J Hicks	Consultant in Public Health Medicine, Portsmouth and South East Hampshire Health Authority
Professor I Higginson	Professor of Palliative Care and Policy, Guy's, King's and St Thomas' School of Medicine, London
Professor R Hobbs	Professor of General Practice, University of Birmingham
Dr N J Hodson	Consultant in Clinical Oncology, The Royal Sussex County Hospital
Dr P G Houghton	Clinical Director, Birmingham Medical Audit Advisory Group
Dr A J Howat	Consultant Pathologist, Royal Preston Hospital
Dr T R J Hughes	GP, Kirbymoorside
Ms S Hunton	Director, Bradford Cancer Support Centre
Mr S Y Iftikhar	Consultant Surgeon, Derbyshire Royal Infirmary
Dr A M Jackson	Consultant Histopathologist, Scarborough Hospital
Mr B Jackson	President, The Royal College of Surgeons of England
Mr C Jackson	Regional Cancer Co-ordinator, NHS Executive - West Midlands
Dr P James	GP, Birmingham
Dr R D James	Consultant in Clinical Oncology, Maidstone Hospital, Kent
Dr M Jefferson	Consultant in Palliative Medicine, University Hospital of Wales, Cardiff
Mr T G John	Upper Gastrointestinal and Cancer Specialist Surgeon, North Hampshire Hospital, Basingstoke
Dr D M Justins	Consultant in Pain Management and Anaesthesia, St Thomas' Hospital, London
Dr S A Kelly	Consultant Histopathologist, Whiston Hospital, Merseyside
Dr S Kelly	GP, Chichester
Dr T Kennedy	Lecturer in General Practice, Guy's, King's and St Thomas' School of Medicine

Professor D J Kerr	Professor of Clinical Oncology, The University of Birmingham Medical School
Mr J F Khalil-Marzouk	Consultant Thoracic Surgeon, Birmingham Heartlands Hospital
Mr T H Khawaja	Consultant Gastrointestinal and Pancreatobiliary Surgeon, Queen Mary's Hospital, Sidcup, Kent
Professor A N Kingsnorth	Professor of Surgery, Derriford Hospital, Plymouth
Mr D Kirby	Chairman, Oesophageal Patients Association
Dr N Kirkham	Consultant Histopathologist, The Royal Sussex County Hospital
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Professor F D Lee	Professor of Pathology, Glasgow Royal Infirmary
Miss J Lees	Cancer Services Manager, Greenwich District Hospital, London
Professor W Lees	Professor of Medical Imaging, The Middlesex Hospital, London
Dr M Leslie	Consultant in Clinical Oncology, St Thomas' Hospital, London
Professor D A Levison	Professor of Pathology, Ninewells Hospital and Medical School, Dundee
Miss J Linsell	Consultant Surgeon, University Hospital Lewisham
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Dr F J Lofts	Consultant in Medical Oncology, St George's Hospital, London
Professor D London	Registrar, Royal College of Physicians
Mr J C Lotz	Consultant Surgeon, Staffordshire General Hospital
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Dr A Mairs	Member of the National Cancer Forum
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Mr R C Mason	Consultant Surgeon, Guy's Hospital, London
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Dr D G Maxton	Consultant Physician and Gastroenterologist, Royal Shrewsbury Hospital
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Ms K Money	Director of Commissioning & Primary Care for East Sussex, Brighton and Hove Health Authority
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Dr A I Morris	Consultant Physician and Gastroenterologist, Royal Liverpool University Hospital
Ms J Mossman	Chief Executive, CancerBACUP
Mrs J Murray	Regional Cancer Co-ordinator, NHS Executive - Northern & Yorkshire
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Dr M C Nicolson	Consultant in Medical Oncology, Aberdeen Royal Infirmary
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Dr P Norris	GP, Kingston upon Thames
Mr R Norton	Consultant Cardiothoracic Surgeon, Walsgrave Hospital, Coventry
Dr J Oldham	GP, Glossop
Dame G Oliver	Director of Service Development, Macmillan Cancer Relief
Dr R Orchard	Consultant Physician, St Helier Hospital, Surrey
Mr W J Owen	Consultant Surgeon, Guy's Hospital, London
Dr G Park	GP, Stokesley
Mr M C Parker	Consultant Surgeon, Joyce Green Hospital, Kent
Dr D R Peake	Consultant in Clinical Oncology, The Queen Elizabeth Hospital, Birmingham
Dr S Pearson	Director of Public Health, Gloucestershire Health Authority
Professor Sir D Pereira Gray	President, The Royal College of General Practitioners
Dr J Piris	Senior Lecturer in Pathology, University Medical School, Edinburgh
Ms J Pitkeathley	Chief Executive, Carers National Association
Dr M Pitman	Regional Cancer Co-ordinator, NHS Executive - South and West
Mr G J Poston	Consultant Surgeon, Royal Liverpool University Hospital
Dr A B Price	Consultant Histopathologist, Northwick Park Hospital, Harrow
Dr P Price	Reader in Clinical Oncology, The Hammersmith Hospital, London

Mr R J Priestley	Chief Executive, North Staffordshire Health Authority
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Dr J Pritchard	Member of the National Cancer Forum
Mr M C A Puntis	Consultant Surgeon, University Hospital of Wales, Cardiff
Mr J Pye	Consultant Surgeon, Wrexham Maelor Hospital
Professor P Quirke	Professor of Pathology, University of Leeds
Ms H Rees	Nursing Sister, Morriston Hospital, Swansea
Mr M Rees	Consultant Surgeon, The North Hampshire Hospital, Basingstoke
Dr D Richards	Consultant Radiologist, Morriston Hospital, Swansea
Ms M Rigge	Director, College of Health, London
Dr S Riley	Consultant Gastroenterologist, Northern General Hospital, Sheffield
Dr P F Roberts	Consultant Histopathologist, Norfolk and Norwich Hospital
Dr A J Robertson	Clinical Director of Pathology, Ninewells Hospital and Medical School, Dundee
Mr C Robertson	Consultant General and Gastrointestinal Surgeon, Worcester Royal Infirmary
Professor B J Rowlands	Professor of Surgery, Queen's Medical Centre, Nottingham
Dr G P Rubin	GP, Yarm
Mr R C G Russell	Consultant Surgeon, The Middlesex Hospital, London
Dr I Rutter	GP, Shipley
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Dr J D Sanderson	Consultant Gastroenterologist, Guy's Hospital, London
Mr R E Sayer	Consultant Thoracic Surgeon, St George's Hospital, London
Dr N Scott	Consultant Histopathologist, Central Pathology Laboratory, Stoke on Trent
Professor P J Selby	Member of the National Cancer Forum
Dr N A Shepherd	Consultant Histopathologist, Gloucestershire Royal Hospital
Dr P J Shorvon	Consultant Radiologist, Central Middlesex Hospital, London
Professor K Sikora	Member of the National Cancer Forum
Dr K H Simpson	Consultant Anaesthetist, St James's University Hospital, Leeds
Dr R H W Simpson	Consultant Histopathologist, Royal Devon and Exeter Hospital
Dr C Sinnott	Consultant in Palliative Medicine, St Thomas' Hospital, London
Dr D N Slater	Consultant Histopathologist, Rotherham District Hospital
Dr M L Slevin	Consultant Physician and Medical Oncologist, St Bartholomew's Hospital, London
Professor J Sloane	Professor of Pathology, University of Liverpool
Mr C Smee	Chief Economic Adviser, Department of Health
Dr D Smith	Regional Cancer Co-ordinator, NHS Executive - Trent
Dr D B Smith	Consultant in Medical Oncology, Clatterbridge Centre for Oncology
Dr P M Smith	Consultant Gastroenterologist, Llandough Hospital, Penarth
Dr J Spiby	Director of Public Health, Bromley Health Authority
Mr R T Spychal	Consultant Surgeon, City Hospital, Birmingham
Mr A Steger	Consultant Surgeon, University Hospital, Lewisham

Mr M Stewart	Consultant Surgeon, Joyce Green Hospital, Kent
Mr H M Sue-Ling	Consultant Surgeon, The General Infirmary at Leeds
Dr P Sutton	GP, Brigg
Dr S K Suvarna	Consultant Histopathologist, Northern General Hospital, Sheffield
Dr N Sykes	Consultant in Palliative Medicine, St Christopher's Hospice, London
Dr D M Tait	Consultant in Clinical Oncology, The Royal Marsden Hospital, Sutton
Professor I C Talbot	Professor of Histopathology, St Mark's Hospital, Middlesex
Ms C Teague	Cancer Information Nurse Specialist, CancerBACUP
Dr A Theobald	GP, Aylesbury
Dr J Thomas	Director of Public Health, Sunderland Health Authority
Mr A M Thompson	Consultant Surgeon, Ninewells Hospital and Medical School, Dundee
Mrs H Thornton	Chairman, Consumers' Advisory Group for Clinical Trials
Dr A R Timothy	Consultant in Clinical Oncology, St Thomas' Hospital, London
Dr A Tookman	Medical Director, Edenhall Marie Curie Centre, London
Dr C Topham	Consultant in Clinical Oncology, Royal Surrey County Hospital
Professor Sir L A Turnberg	President, British Society of Gastroenterology
Dr P Twentyman	Secretary, United Kingdom Co-ordinating Committee on Cancer Research
Dr J Verne	Consultant in Public Health Medicine, NHS Executive - South and West
Dr M von Fragstein	Lecturer in General Practice, University of Nottingham
Dr C Waine	Director of Health Programmes and Primary Care Development, Sunderland Health Authority
Dr B F Warren	Consultant Gastrointestinal Pathologist, The John Radcliffe Hospital, Oxford
Dr M Watson	Consultant Clinical Psychologist, The Royal Marsden Hospital, Sutton
Dr P Watson	Director of Health Policy and Public Health, North Essex Health Authority
Dr B Wee	Consultant in Palliative Medicine, Countess Mountbatten House, Southampton
Professor J Weir	Dean, Faculty of Clinical Radiology, The Royal College of Radiologists
Mr N T Welch	Consultant Upper Gastrointestinal and General Surgeon, Queen's Medical Centre, Nottingham
Mrs K Westbrook	Therapeutic Radiographer, Bristol Royal Infirmary
Dr W H Whitehead	GP, Barmouth
Dr C Wilkinson	Senior Lecturer in General Practice, University of Wales College of Medicine
Dr J Wilkinson	Deputy Director of Public Health, North Yorkshire Health Authority
Dr M L Wilkinson	Consultant Physician/Senior Lecturer in Gastroenterology, Guy's Hospital, London
Dr S Will	Consultant in Public Health Medicine, Bury and Rochdale Health Authority
Professor G T Williams	Professor of Pathology, University of Wales College of Medicine, Cardiff

Professor R C N Williamson	Professor of Surgery, Hammersmith Hospital, London
Dr E Wilson	Senior Medical Officer, Department of Health
Professor N A Wright	Professor of Histopathology, The Hammersmith Hospital, London
Ms J Young	Director of Services, Lynda Jackson Macmillan Centre for Cancer Support and Information, Mount Vernon Hospital, Middlesex
Mr N Young	Member of the National Cancer Forum
Ms T Younger	Policy Development and Implementation Manager, NHS Executive - London
Department of Health/NHS Executive representatives	

283 people were asked to act as referees, of whom 34% responded.

Appendix 3.4

Researchers carrying out literature reviews

Overall Co-ordinators

Ms A Eastwood and
Professor J Kleijnen NHS Centre for Reviews and Dissemination, University of
York

Dr A Melville Independent Consultant

i) Literature Reviews

Professor D Forman Cochrane Collaborative Review Group in Upper GI and
and Ms E Morris Pancreatic Diseases, Academic Unit of Epidemiology and
Health Services Research, School of Medicine, University
of Leeds

Contributed reviews which were used to inform guidance on all Topics.

Professor I Higginson Department of Palliative Care and Policy, King's College
and Ms C Copp School of Medicine and Dentistry, London

Contributed reviews which were used to inform guidance on Topics 2, 3 and 9.

ii) Economic Review

Mr A Brennan,
Ms E Clayton, School of Health and Related Research, University
of Sheffield

Mr C Knight

Ms S Ward

Ms E Warren

Appendix 3.5

Focus Groups: Membership

Professor M R Baker	Medical Director, North Yorkshire Health Authority
Mr M Bellamy	Chief Executive, Ealing, Hammersmith and Hounslow Health Authority
Dr A Benghiat	Cancer Lead Clinician, Leicester Royal Infirmary
Dr P Bevan	Deputy Director of Public Health, NHS Executive - London
Mr D Campbell	Director of Finance, Liverpool Health Authority
Dr I G Cox	Macmillan GP Adviser in Cancer and Palliative Care, Laurie Pike Health Centre, Birmingham
Miss C Edwards	Assistant Director of Commissioning, North Derbyshire Health Authority
Mrs S Ellis	Assistant Director of Strategic Development, Wakefield Health Authority
Mr J Grimes	Director of Finance, North Yorkshire Health Authority
Dr J Halpin	Consultant/Senior Lecturer in Public Health Medicine, East & North Hertfordshire Health Authority
Dr V Hemsall	Deputy Director of Public Health, Dorset Health Authority
Dr A W Lee	GP, Scunthorpe
Dr S Munday	Deputy Director of Public Health, Birmingham Health Authority
Dame G Oliver	Director of Service Development, Macmillan Cancer Relief
Dr S Pearson	Director of Public Health, Gloucestershire Health Authority
Dr F A Pitt	Consultant in Public Health Medicine, Sheffield Health Authority
Mr R J Priestley	Chief Executive, North Staffordshire Health Authority
Dr E A Scott	Director of Public Health, Leeds Health Authority
Dr J Spiby	Director of Public Health, Bromley Health Authority
Dr J Thomas	Director of Public Health, Sunderland Health Authority
Dr J Verne	Consultant in Public Health Medicine, NHS Executive - South and West
Dr P Watson	Director of Health Policy and Public Health, North Essex Health Authority
Ms T Younger	Policy Development and Implementation Manager, NHS Executive - London

Facilitated by:

Ms S O'Toole Consultant in Health Policy and Management

Supported by:

Mrs V Saunders Manager, Northern and Yorkshire Cancer Registry and Information Service

Glossary of Terms

Adenocarcinoma

Adenocarcinomas are malignant growths of glandular tissue. They can develop in the lower part of the oesophagus at the junction between the oesophagus and the stomach and in the stomach. These tumours may be associated with *Barrett's oesophagus*.

Adjuvant treatment

Treatment used in addition to main treatment, usually radiotherapy or chemotherapy given after surgery.

Aetiology

The origins or causes of disease.

Ampullary carcinoma

A tumour which develops at the junction between the common bile duct and the duodenum.

Analgesia

Pain relief. In oral analgesia, drugs are given by mouth, whilst parenteral analgesia is given by injection. Titration of analgesia means gradually increasing the dose and/or using more powerful drugs until the pain is controlled.

Anastomosis (plural, anastomoses)

Connection of tissues after surgical resection; the point at which the cut ends of a tube such as the oesophagus are re-joined after a section has been removed.

Angiography

Imaging to reveal blood vessels. This normally involves injection of a dye which can be seen on X-ray photographs.

Anorexia

Loss of appetite; inability or refusal to eat.

Atrophic gastritis

Inflammation and shrinkage of the stomach lining.

Audit

A method by which those involved in providing services assess the quality of care. Results of a process or intervention are assessed, compared with a pre-existing standard, changed where necessary, and then reassessed.

Barium meal/barium swallow

A technique used to produce images of the upper part of the digestive system. The patient swallows barium sulphate, which then coats the lining of the oesophagus and stomach. The shape outlined by barium can be seen in X-ray photographs.

Barrett's oesophagus

A condition in which the normal lining of the lower oesophagus is replaced by a characteristic columnar tissue. It results from damage due to chronic reflux of stomach acid, and is associated with a greatly increased risk of oesophageal cancer.

Bile duct

A tube which carries bile from the gallbladder to the intestine (duodenum). Feeding into the common bile duct are branches leading from the liver and from the pancreas.

Biliary

Of the bile duct.

Biopsy

Removal of a sample of tissue or cells from the body to assist in diagnosis of a disease.

Brachytherapy

Radiotherapy delivered within an organ such as the oesophagus.

Cardia

The upper (proximal) part of the stomach, close to the junction with the oesophagus.

Chemotherapy

The use of drugs that kill cancer cells, or prevent or slow their growth.

Clinical Oncologist

A doctor who specialises in the treatment of cancer patients, particularly through the use of *radiotherapy*, but who may also use *chemotherapy*.

Coeliac plexus

A network of nerves located in the peritoneal cavity. These nerves transmit sensation from the area around the pancreas.

Cognitive and behavioural interventions

Types of therapy, often delivered by psychologists, usually based on talking and practising specific types of voluntary activity. This group of interventions can include, for example, relaxation training, counselling, and psychological approaches to pain control.

Cohort studies

Research studies in which groups of patients with a particular condition or specific characteristic are compared with matched groups who do not have it.

Computed tomography (CT)

An X-ray imaging technique.

Contrast media

Substances, usually dyes, used to enhance X-ray images.

Cytology

The study of the appearance of individual cells under a microscope.

Cytopathologist

A person who specialises in diagnosis through detecting and identifying disease in individual cells.

Cytotoxic

Toxic to cells. This term is used to describe drugs which kill cancer cells or slow their growth.

Diabetes

A condition in which blood glucose levels rise above normal. This can be due to problems with the pancreas, which secretes a hormone (insulin) that is crucial to normal glucose metabolism.

Distal bile duct stricture

Constriction of the lower end of the tube that takes bile from the gallbladder to the intestine.

Dumping

A syndrome that may develop after surgery on the oesophagus or stomach. It causes abdominal discomfort and diarrhoea after meals.

Dyspepsia

A general term for a group of common symptoms originating in the upper digestive system. It includes indigestion, heartburn, reflux, and pain or discomfort in the area of the stomach, chest or upper abdomen.

Dysphagia

Difficulty with swallowing.

Dysplasia

Abnormal changes in the morphology (form, appearance or nature) of tissues.

ECF

Epirubicin, cisplatin and 5-FU, a combination of drugs often used for *chemotherapy*.

Endoscope

A tubular device with a light at the end that transmits images to aid diagnosis or therapy. Specialised endoscopes may be threaded down the oesophagus to the stomach or beyond, or through an incision in the abdomen. They may also be used to take samples of tissues (*biopsy*) or to carry out therapeutic functions such as inserting *stents*.

Endoscopic retrograde cholangiopancreatography (ERCP)

A method by which the bile and pancreatic ducts may be accessed using an endoscope.

Endoscopic ultrasound (EUS)

Imaging using high-frequency sound waves, carried out inside the body using an *endoscope*.

Endoscopy

In this manual endoscopy refers only to examination of the upper gastro-intestinal tract (oesophagogastroduodenoscopy).

First-degree relatives

Parents, siblings, sons and daughters.

Fistula (plural: fistulae)

A hole in tissue where such a hole would not normally exist.

Gallstones

Solid masses like small pebbles that can form spontaneously in the gallbladder and that may sometimes block bile ducts.

Gastrectomy

Surgical removal of the stomach (total gastrectomy) or a substantial part of it (partial gastrectomy).

Gastric bypass

A surgical manoeuvre whereby the intestine is attached directly to the stomach, so that food no longer passes through the duodenum.

Gastroenterology

The branch of medicine that deals with the digestive system.

Gastroenterologist

A doctor who specialises in diseases of the digestive system.

Gastroesophageal reflux

A condition in which stomach acid rises into the oesophagus.

Gastrostomy

A surgical procedure to create a hole (fistula) through the body wall, leading into the stomach. Patients can be fed via a tube through this hole when the digestive tract is blocked higher up (*PEG feeding*).

H₂ blocker

A drug which suppresses production of stomach acid.

Helicobacter pylori

A bacterium that lives in the stomach and may cause ulcers.

Hepato-pancreato-biliary (HPB) surgeons

Surgeons who specialise in operations on the liver, pancreas, and gallbladder.

Heterogeneous

Of differing origins, or different types.

Hiatus hernia

A condition in which part of the stomach protrudes through the diaphragm.

Histological grade

Degree of malignancy of a neoplasm, usually judged from its histological features.

Histological type

The type of tissue found in a tumour.

Histology

Examination of the microscopic structure of tissue.

Histopathologist

A person who specialises in the diagnosis of disease through study of the microscopic structure of tissue.

Interventional radiologist

A doctor who specialises in imaging and the use of imaging techniques to guide the placement of therapeutic devices like *stents* inside the body.

Intestinal metaplasia

A type of abnormal tissue in the stomach.

Intra-luminal radiotherapy

See *brachytherapy*.

Intra-peritoneal chemotherapy

Chemotherapy delivered inside the abdomen (peritoneum).

Japanese (D2) surgery

A type of radical surgery for stomach cancer that involves removal of larger amounts of tissue, and crucially, larger numbers of lymph nodes, than have traditionally been removed by most Western surgeons.

Jaundice

A condition in which abnormally large quantities of bile pigments circulate in the blood, giving a characteristic yellow tinge to the skin. Causes of jaundice include liver disease and a blockage in the *biliary* tract.

Laparoscopy

Visualisation of the interior of the abdomen using a special type of *endoscope*, inserted through a small incision in the abdominal wall.

Laparotomy

Surgical opening into the abdomen.

Laser treatment

Removal of tissue using a laser. Laser treatment may be used for patients with oesophageal cancer to re-open the oesophagus when it has become blocked by tumour.

Localised disease

Tumour confined to a small part of an organ.

Lymph node status

The presence or absence of tumour in a *lymph node*.

Lymph nodes

Small organs which act as filters in the lymphatic system. Lymph nodes close to the primary tumour are often the first sites to which cancer spreads.

Magnetic resonance cholangiopancreatography (MRCP)

An imaging method which can be used to assess bile and pancreatic ducts.

Magnetic resonance imaging (MRI)

A non-invasive method of imaging which allows the form and metabolism of tissues and organs to be visualised (also known as nuclear magnetic resonance).

Medical Oncologist

A doctor who specialises in the treatment of cancer by *chemotherapy*.

Meta-analysis

A form of statistical analysis used to synthesise results from a collection of individual studies.

Metastases/metastatic disease

Spread of cancer away from the primary site.

Neo-adjuvant treatment

Treatment given before the main treatment; usually *chemotherapy* or *radiotherapy* given before surgery.

Nerve block

A method of producing analgesia in a limited area of the body by injection of a suitable drug close to a selected nerve or nerve root.

Nerve plexus (ablation of)

Destruction of a network of nerves to produce analgesia in a selected area of the body.

Neurolytic coeliac plexus block

Chemical over-stimulation intended to damage the network of nerves that transmits sensation from the area of the pancreas, and thus produce analgesia.

Octreotide

A drug that reduces production of pancreatic secretions.

Oesophageal obstruction/stricture

Narrowing of the oesophagus. Obstruction is most often due to tumour, but stricture may also result from physical damage (including surgery) or radiotherapy.

Oesophagectomy

Removal of part of the oesophagus.

Oesophago-gastric junction

The junction where the oesophagus opens into the stomach.

Oncologist

A doctor who specialises in treating cancer.

Oncology

The study of the biology and physical and chemical features of cancers. Also the study of the cause and treatment of cancers.

Palliative

Anything which serves to alleviate symptoms due to the underlying cancer but is not expected to cure it. Hence palliative care, palliative *chemotherapy*.

Pancreaticoduodenectomy

Surgical removal of most of the pancreas, the encircling loop of duodenum, the common bile duct and the *pylorus*.

PEG feeding

Feeding by a tube which leads directly into the stomach. See *gastrostomy*.

Peptic ulcers

Ulcers in the lining of the stomach; stomach ulcers.

Peritoneal disease

Disease (in this context, tumour) that develops on the inner surface of the abdominal cavity or on the outer surface of abdominal organs.

Peritoneal seeding

Spread of tumour cells into the abdominal wall; it is believed that this can occur along the track of a needle used for biopsy (see *Transperitoneal needle biopsy*).

Peritoneum

The delicate membrane that lines the abdominal cavity and covers the abdominal organs.

Pernicious anaemia

A type of anaemia caused by abnormalities in the stomach lining.

Positron emission tomography (PET)

An imaging method which reveals the level of metabolic activity of different tissues. PET scans are used in diagnosis.

Post-gastrectomy syndromes

Problems with digestion that develop after surgical removal of the stomach or a major part of it.

Protocol

A policy or strategy which defines appropriate action.

Psychological interventions

Interventions directed at altering mental processes which do not involve the use of drugs or any physical or invasive procedure. These include a large group of therapeutic approaches including counselling, cognitive therapy, and relaxation.

Pylorus

The lower part of the stomach, from which the small intestine (duodenum) extends.

Quality of life

The individual's overall appraisal of her situation and subjective sense of well-being.

Randomised controlled trial

A type of experiment which is used to compare the effectiveness of different treatments. The crucial feature of this form of trial is that patients are assigned at random to groups which receive the interventions being assessed or control treatments. *RCTs* offer the most reliable (i.e. least biased) form of evidence on effectiveness.

Radiotherapy

The use of radiation, usually X-rays or gamma rays, to kill tumour cells.

Radical radiotherapy

Radiotherapy given with curative, rather than *palliative*, intent.

RCT

See *Randomised controlled trial*.

Remission

A period when cancer has responded to treatment and there are no signs of tumour or tumour-related symptoms.

Resection

The surgical removal of all or part of an organ.

Squamous cell carcinoma

A common type of cancer which originates in superficial layers of tissue (squamous epithelium).

Staging

The allocation of categories (Stage I to IV) to tumours defined by internationally agreed criteria. Stage I tumours are localised, whilst stages II to IV refer to increasing degrees of spread through the body from the primary site.

Stent

A tubular device made of metal or polythene designed to hold open a tube or opening in the body, such as the oesophagus (oesophageal stent) or bile duct (biliary stent).

Stenting

Putting a *stent* in place.

Titration of analgesia

See *analgesia*.

Transhiatal surgery

Surgery carried out through an incision in the diaphragm.

Transperitoneal needle biopsy

A method of taking cells from an organ such as the pancreas, using a needle inserted through the abdominal wall.

Transthoracic surgery

Surgery carried out through an incision in the chest.

Tube feeding

Feeding through a tube leading directly into the stomach.

Tumour penetration

The depth of extension of tumour into tissue.

Ultrasound

High-frequency sound waves used to create images of structures and organs within the body.

Whipple procedure

See *pancreaticoduodenectomy*.

